ESTP comment to ECHA proposal applying REACH to tattoo inks. February 10, 2019

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Preface

We acknowledge the attempt to establish EU wide measures to increase tattoo and permanent make-up inks by the European Commission.

This comment includes a lot of point's that should have been stated in previous consultations. However, we and a few small manufacturers are the only stake holders of this small industry. The fact, that me missed essential points until now reflects that this industry is not used to chemical regulatory measures since they are used to comply with national legislations that adapted the ResAP(2008)1 incl. the cosmetic annexes including the link to the biocides regulation.

Therefore, the restriction under REACH bares the risk of further points that today's compliance with regulations will be lowered in future. An important point is that preservatives will automatically fall under the biocide regulation that cannot be seen directly from the REACH restriction dossier. Even now, we are not sure that we found all potential pitfalls of this restriction due to the enormous amount of substances that are covered. Hence, unknown socio-economic and health consequences in addition to those raised below seem likely.

ECHA and regulations of tattoo inks is simply the wrong way because many problems will stay unsolved and new problems will arise by its implementation.

2. Remarks on the amended and modified RO1

We acknowledge that the dossier submitter amended the proposed restriction options RO1 and RO2.

Positive amendments in our opinion are:

a. improved readability
b. the phrases for nickel and chromium for labelling (paragraph 6e, f).
c. the derogation list of pigments is still part of the restriction options
d. the amendments of the element limits in table A, but we still propose other limits (see **section 10** below)

Negative amendments in our opinion are:

e. the derogation of volatile compounds (see **section 7** below)
f. the wording “used” in paragraph 3 concerning the labelling of inks (see **section 11** below)
g. it should be written more clearly that the paragraphs in the right column of the restriction option only apply to the substances included in points a) to d) in the right column (e.g. put a heading in the left column)

Positive points in the amended RO1 of RAC/SEAC are:

h. exact concentration limits on harmonized substances in paragraph 1 a), d), e), f)

Negative points in the amended RO1 of RAC/SEAC are:

i. removal of the derogation for Table B (colorants) (see **section 5** below)
j. specific concentration limits for pigments (see **section 11** below)

3. Comment on the scope of the restriction

The scope of the restriction is not sufficient due to the following points:

a. The substances covered **do not include preservatives** (unless harmonized classified in the scope of the restriction) since this is not possible in a REACH restriction dossier and they would fall under the EU biocide regulation (EU 528/2012). Since no biocides are yet listed for use in tattoo inks, this will produce a ban of all biocides since a manufacturer will need to make an application for approval. The expensive experiments necessary for safety dossiers to achieve an authorization will not be economically feasible for an ink manufacturer.Bbiocidal substance **and** the biocidal product has to be approved (see article 3 and 58). A very expensive process, could be more than 1 mill. Euros per application which displays an impossible economic burden to tattoo ink manufacturers. Since tattoo inks are injected into the body, we also feel that the authorization authorities will not know how to handle tattoo inks and will also ask for information from physical properties to long term carcinogenic studies and therefore reach a six-figure sum on safety testing required. Infections are one of the most common side effects from tattooing. Therefore, this restriction will significantly increase risk of tattoo related side effects if the products cannot be protected against microbial growth. Costs for medical treatment of skin and skin structure infections range from $6618 to $14,391 per person according to Keylound et al., 2016

(https://academic.oup.com/ofid/article/3/suppl_1/1145/2637397). Additionally, even if an application for biocide approval for the new product category tattoo inks would be submitted, the approval will take much longer than the time until the tattoo ink restriction will entry into force (details see **section 8**).8

b. The scope of the current restriction does not include a complete list of ingredients and this is also not possible within a REACH restriction. Consumers and physicians that may treat patients with allergic tattoo reactions cannot judge which components of risks with non-harmonized substances might be in the ink bottle. Especially pigments are non-harmonized substances and pose the highest risk of releasing potential allergens (see also **section 4**).
c. Concentration limits of substances (impurities) listed in Table A of the restriction are not technically achievable for certain pigments (see **section 10**). Ink manufacturers depend on pure pigments on the market, e.g. sold for cosmetic applications. They have no facilities or expertise for pigment synthesis. Costs for additional purification are not known since this will need future research and development on purification steps, e.g. for solvent extractions.
d. Derogation of colorants as present in the submitter's dossier is favoured by us. RAC/SEAC removed them in the modified version. We propose to keep the derogation due to socio-economical and risk-based reasons (see **section 5**).
e. The restriction would not allow an EU wide positive list for all pigments and other ingredients (see **section 4**).

4. Comment on the justification that the restriction is the most appropriate EU wide measure

In general, we would prefer a tattoo specific regulation on tattoo inks on the European level and still oppose this REACH restriction on tattoo inks for the following reasons:

a. A positive list is the only regulatory measure to ensure safety of pigments used in tattoo inks. The RAC states non-harmonized substances may still be regulated on national level incl. positive lists (see RAC opinion page 65). However, it is unclear if this would also be possible for pigments in Annex II and IV that would be covered by the restriction but are not harmonized classified. The most urgently ingredients that need a positive list are pigments and preservatives. If this is not possible due to inclusion of Annex II and IV and the EU Biocides Regulation (BPR) 528/2012, sufficient safe tattoo inks can never be achieved with a REACH restriction.
b. The restriction dossier is linked to annexes of the Cosmetics Directive which are excluded by Article 67 of REACH (cosmetics exclusion from the scope of restrictions). An Annex XV dossier under REACH needs to justify a restriction based on an assessment of the hazards and risks of the covered substances. This is not the case for the substances covered in the Annexes II and IV which are only linked to the restriction without scientific justification. In the RAC opinion it is also admitted "*many of the pigments prohibited in hair colours were included in Annex II of the CPR on the basis of the cosmetic industry not providing relevant information to justify continued use in the hair dyes application.*" –hence listing is not necessarily based on risks of the listed substances. In the RAC opinion on page 45 it is also 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*"- so no data on risks or hazards are available for these substances anymore. It is

therefore **questionable if the Annexes II and IV can be legally included into a REACH restriction dossier**.

c. No full labelling of ingredients can be implemented via a REACH restriction. This will dramatically reduce the transparency for the consumer since no label may actually be present anymore (see examples **section 14**). Physicians depend on a full list of ingredients as necessary for cosmetic products to conclude the potential allergens causing an allergic reaction. Additionally, monitoring of compliance in terms of pigments used will be immediately over since most national laboratories lack methods for pigment identification and by now use the labelling to identify non-compliant inks (currently the case in Germany). This will pose a not yet quantifiable health costs since used pigments cannot be controlled.
d. Preservatives cannot be regulated specifically for this application since in REACH they can only be addressed through EU Biocides Regulation (BPR) 528/2012 (see **section 8**).
e. The inclusion of skin and eye irritants as well as corrosives will make tattoo ink production unfeasible (see **sections 9** and **14**). A restriction approach that would lead to a legal ban of most tattoo inks on the market would result in a prohibition and a non-controllable black-market of tattoo inks. In terms the effectiveness in health risk reduction, the current state of the restriction would therefore lower the consumer safety.
f. The SEAC argues that "*it would be difficult and time consuming to negotiate such legislation EU-wide as the hygiene and certification aspects are normally within the jurisdiction of local and regional authorities, although the existence and the nature of these requirements varies substantially among Member States*". This is not true in our opinion. Points like certification aspects for tattoo artists and hygiene may not need to be included in the first version of a European regulation. In terms for hygiene, stakeholders just agreed on a CEN/TC 435 standard for tattoo hygiene that can be implemented on regional, national or EU level. In our opinion, even an **EU wide regulation on tattoo inks may be composed of the amended RO1 with our additional suggestions for labelling and other points raised in this comment**. The instant addition of a true labelling and the option for further amendments will give a higher degree of consumer safety right now and leaves the option to increase consumer safety in the future by a true positive list and thereby give the option to further improve the safety to an acceptable level and still maintain the industry which is not the case with the current restriction (see especially **sections 9** and **14**).
g. The decision on the restriction via REACH of the European Commission did not include the regulatory management option analysis (RMOA) and therefore seems forced onto consumers, manufacturers and the ECHA. The SEAC also states on page 12 of its opinion "*SEAC was not provided with this previous assessment and therefore could not verify the rationale for this conclusion.*".
h. Instead of a limited list of pigments, it would be more effective and monitorable to choose an approach that will ban pigments able to cleave the list of harmonized carcinogenic aromatic amines (see **section 13**). The potential of synthesis of new pigments with just a new side chain or group is endless. Today, already >10,000 pigments and dyes are listed in the colour index (C.I.). Our proposal would display a more holistic approach.

5. Derogation of list of colorants, especially pigment B15:3 (C.I. 74160) and pigment G7 (C.I. 74260)

We want to point out that tattoo inks shall be controlled under a REACH restriction where substances that pose an unacceptable risk to health or environment identified by risk or hazard assessment are included (see **section 4b**) compared to an authorization process were data on safety must be provided. Thus, it is questionable that stakeholders need to provide safety data as demanded in the RAC and SEAC statements (SEAC opinion page 19 "*health benefits are correspondingly uncertain and therefore no clear recommendation on an exemption is currently possible.*" ; RAC opinion page 50 *"[..] exemption of these 21 colourants cannot be based on their non-hazardous profile, primarily due to lack of adequate information on their hazard properties and risk for human health.*") instead of the dossier submitter to give data hazard and risks to human health by these pigments. There are no data on hazards deriving from these colorants in tattoo inks so far.

The ECHA dossier contains a derogation of Pigment Blue 15 and Pigment Green 7 and other pigments that were deleted in the RAC/SEAC option. The major argument of RAC are limited data on genotoxicity, reprotoxicity, carcinogenicity (RAC opinion page 49). As stated in **section 4b**, both Pigment Blue 15 and Pigment Green 7 as well as the majority of substances taken from the Cosmetics Directive are non-harmonized substances. Banning these pigments would force the use of other pigments with even less data on health hazards and thus even a higher risk of costs to the health system. Due to this reason, Pigment Blue 15 is not banned at the moment in Switzerland.

The consequences of a ban would be the loss of classic blue and green colours including colours generated out of mixing the blue or green pigment with each other or white, yellow and/or red pigments.

The industry and therefore the tattoo artists will loose classic colours like:

- True blue
- Medium blue
- Light blue
- True green
- Dark green
- Medium green
- Light green

Additionally, the restriction of the two classic pigments results also in the loss of:

- Aquamarine (dark, medium, light)
- Turquoise (dark, medium, light)
- Lime green (different shades
- Coloured grey tones

The next table is showing the total assortment of relevant market players and the affected colours containing blue and/or green pigment. In this questionnaire we asked for colours of different brands containing CI 74160, CI 74260 and CI 74265 and compared it with the total amount of each colour range.

Table 1: Percentage of Cu-Phthalocyanine containing inks in the colour palette of different manufacturers.

	Intenze:	WorldFam:	Fusion:	Eternal:	Bullets:
Whole assortment colours	282	240	171	143	53

CI74265:	0	0	47	24	11
CI74260:	0	9	0	0	0
CI74160:	129	157	34	22	11
in %	45.7	69.2	47.4	32.2	41.5

The minimum loss would be 32.2 % of a colour range the maximum would be 69.2 % of a whole assortment.

The existing blue or green alternatives – regardless if allowed or not according to the EU Cosmetic Directive – are insufficient due to the following reasons:

- Good fastness properties but insufficient tinting strength what would lead to an extensive use of the colouring pigment to create dark, medium or light shades.
- Good fastness properties and good tinting strength but unstable against polar solvent or reactive in environmental conditions like pH < 7 (producing toxic gases H_2S)
- Good fastness properties but dull shades of colours if combined with white or another organic pigment
- Dyestuffs instead of pigments would lead to a very fast fading (not useful for permanent tattoos) due to biodistribution through blood and lymph fluid which includes passage of liver with unknown metabolism and therefore unknown toxicity

The following illustration shows the evaluation of a test series of blue pigments in the mixture with titanium dioxide. Therefore, we used a very simple formulation of 60 % w/w water, 0.5 % w/w of a non-ionic triblock copolymer, 9.5 % w/w of an homopolymer and 5 % w/w of a polyvalent alcohol, titanium dioxide and different blue pigments. The total amount of pigment

is 25 % w/w.

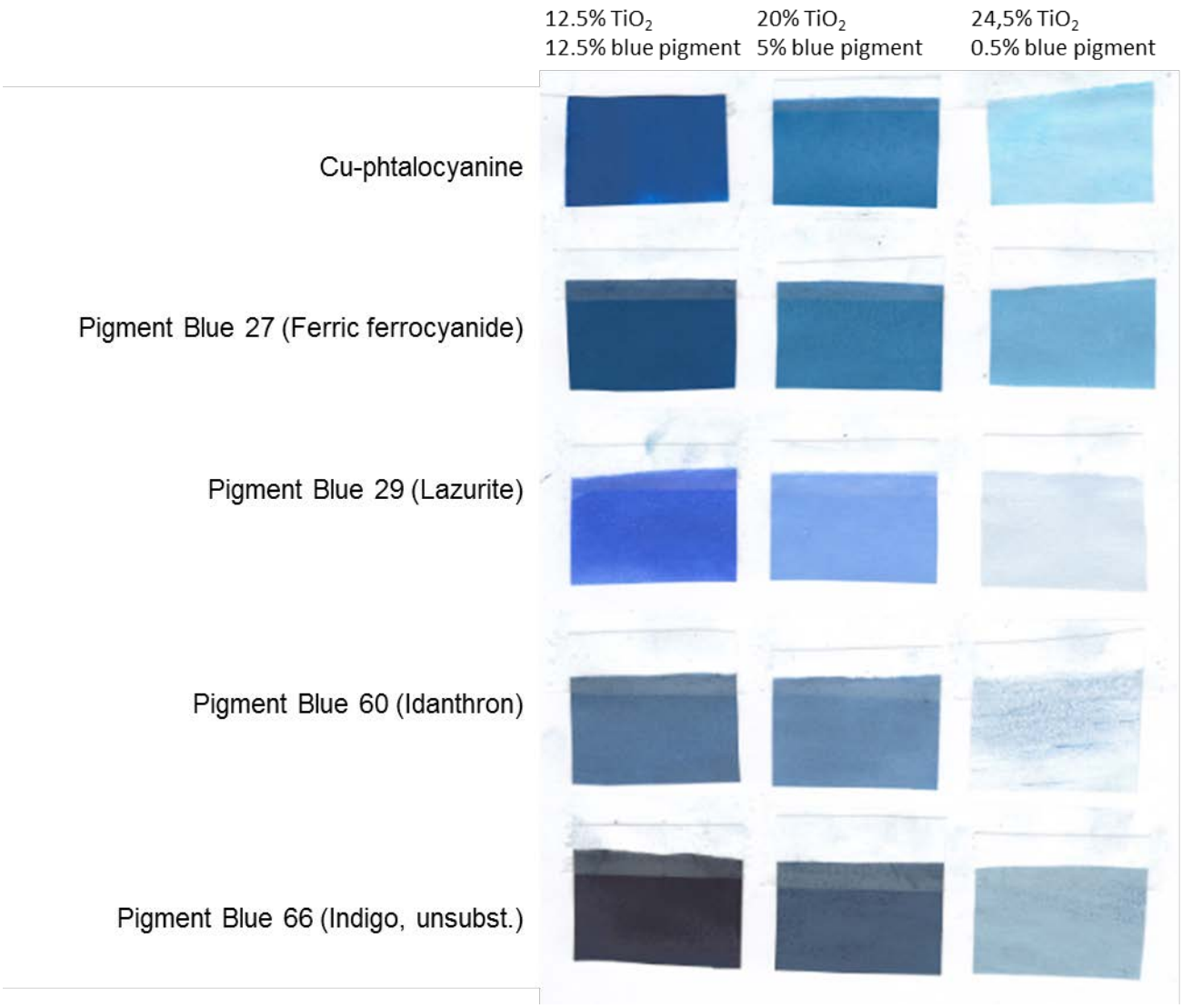

Figure 1: Different blue pigments in the mix with titanium dioxide (TiO_2).

The procedure of ink making can be described as:

- Dissolving all ingredients except of the pigments in the water and stirring it, till complete homogeneity.
- put the weighted pigments in the solution while stirring with 2500 RPM for 10 minutes.

Immediately after the mixing we used a film applicator and applicated a wet film of 60 micron. As we haven't used as much binder as you would use in conventional coatings, we faced a problematic called rub-out, what makes the visual evaluation a little difficult. But to explain the problem of substitution of phthalocyanine blue it is still enough. The first row from up is the classic pigment blue 15. It is obvious that pigment Blue 60 and 66 are not able to substitute the classic pigment blue 15. Blending the two greyish blues with a green or yellow pigment to achieve green will not result in the desired colour tone.

Pigment blue 29 was immediately releasing a terrible smell from the moment we began dissolving it in the liquid phase. We know that pigment blue 29 can release H_2S but we were not expecting it this fast. Pigment blue 27 is the tested pigment that results in the most similar colour tone compared to pigment blue 15 but if you are going to compare the fastness properties you will not find a pigment what is able to substitute pigment blue 15. Next reason

why Pigment blue 27 is not suitable for substitution is the fact that it is a ferrocyanide. When it comes to laser removal of a blue tattoo (when it is not already faded away from alone) it is able to release cyanides.

Table 2: Alternative blue pigments and dyes with the latter not relevant for tattooing due to quick biodistribution and thus fading of the tattoo. Abbreviations: P.B. = Pigment Blue; Cu-Pht. = Copper-Phthalocyanine; C.I. = Colour Index.

C.I. Name	**C.I.-Nr.**	**CAS-Nr.**	**Pigment Class**	
P.B.1	42595:2	1325-87-7	Triarylcarbonium	Common feature of this class is the triaryl carbonium structure, in which at least two of the aryl radicals contain electron donors in the form of amino groups as substituents. Pigments of this class are characterized by an unusual hue purity and brilliance. Their durability/fastness level does not meet any higher requirements. Against polar solvents, for example against alcohols, they are very unstable. Even alkalis decompose the complexes. The pigments are often added according to their colour index name, the heteropolyacids in the form of abbreviations. It means: PMA for Phosphomolybdic Acid, PTA for Phosphotungistic Acid, PTMA for Phosphotungstic molybdenum Acid, SMA for Silicomolybdic Acid and CF for Copper-1-hexacyano iron-II-oic acid.
P.B.2	44045:2	1325-94-6		
P.B.9	42025:1	596-42-9		
P.B.10	44040:2	1325-93-5		
P.B.14	42600:1	1325-88-8		
P.B.18	42770	1324-77-2		
P.B.19	42750	58569-23-6		
P.B.56	42800	6417-46-5		
P.B.61	42765:1	1324-76-1		
P.B.62	44084	57485-98-0		
P.B.15	74160	147-14-8	Cu-Pht., not stabilized	Copper phthalocyanine blue is without exception the most significant of any synthetic organic pigment produced today, with its excellent colour strength and durability. It has a high molar absorption coefficient (ca. 105), and its light fastness and weather fastness are generally superior to all other organic pigments. Phthalocyanine blue is known to exist in several crystal modifications, with the three more important crystal forms, α, β and ε, all industrially available. This pigment has been used for decades for tattooing
P.B.15:1	74160	147-14-8	Cu-Pht., α-mod.	
P.B.15:2	74160	147-14-8	Cu-Pht., α -mod.	
P.B.15:3	74160	147-14-8	Cu-Pht., β-mod.	
P.B.15:4	74160	147-14-8	Cu-Pht., β-mod.	
P.B.15:6	74160	147-14-8	Cu-Pht., ε-mod.	
P.B.16	74100	574-93-6	metal free Phthalocyanine	Rinse-off products
P.B.24:1	42090:1	6548-12-5	Triphenylmethan, Ba	The pigment has a trisulfonated triphenylmethane dye as a base. The

P.B.24:x	42090:2	15792-67-3	Triphenylmethan, Al	dissolved dye is converted in a suspension of aluminium hydroxide with aluminium chloride or barium chloride solution in the corresponding salt. The greenish blue pigment (24:x) is approved as FD & C Blue 1 for food, pharmaceuticals and cosmetics, subject to certain purity criteria in the United States. The light fastness is bad. Also, colour strength and resistance to organic solvents differ only slightly from P.B 24: 1. The pigment gives brilliant, greenish blue shades. It is very strong in colour. Its importance has fallen sharply in favour of copper phthalocyanine blue. It's not stable against acid, alkaline and soap.
P.B.25	21180	10127-03-4	Dianisidine /Naphthol AS	The pigment is produced only to a limited extent in Europe, Japan and the USA. The colour can be described as a little reddish navy blue. The light fastness does not meet higher standards. Azo-Pigment (Naphthol AS-Pigment).
P.B.60	69800	81-77-6	Indanthron	Indathron blue is characterized by high weather fastness and stability against temperature and chemicals but Its colour is noticeably redder and duller than that of phthalocyanine blue. The pigment shows average colour (tinting) strength. To adjust dyeing in 1/3 ST (1% TiO2), 0.15% pigment is required; for comparison: in the case of copper phthalocyanine blue, this is about 0.08% pigment.
P.B.63	73015:x	16521-38-3	Indigo.sulfonic acid, Al	Purity criteria as set out in Commission Directive 95/45/EC (E 132).The basic structure is indigo, which is converted by sulfonation into indigo-5,5'-disulfonic acid. By reaction with aluminum trichloride, the insoluble pigment is obtained. The aluminum lake is approved in the EC as E 132 if certain purity requirements are met. Its colour is bluish red. The resistance to chemicals is moderate. The light fastness is bad. The pigment is poor in colour (low tinting strength).
P.B.64	69825	130-20-1	Indanthron	Chlorine derivative of P.B.60
P.B.66	73000	482-89-3	Indigo, unsubst.	
Acid Blue 1	42045			Not to be used in products applied on mucous membranes
Acid Blue 3	42051	3536-49-0		Purity criteria as set out in Commission Directive 95/45/EC (E 131), soluble dye
	42080	3486-30-4		Rinse-off products

Acid Blue 9	42090	3844-45-9		Purity criteria as set out in Commission Directive 95/45/EC (E 133), soluble dye
	42735	6505-30-2		Not to be used in products applied on mucous membranes
	44045	2580-56-5		Not to be used in products applied on mucous membranes
	61585	4474-24-2		Rinse-off products
Acid Blue 62	62045	4368-56-3		Rinse-off products
	74180	1330-38-7 / 1328-51-4		Rinse-off products
P.B.29	77007	12769-96-9 / 1302-83-6 / 57455-37-5	Lazurite	The pigment is stable in alkaline environment, but it reacts with acids, releasing hydrogen sulphide (H_2S) which is toxic
P.B.27	77510	14038-43-8 / 12240-15-2 / 25869-00-5	Ferric ferrocyanide	free from cyanide ions. It is weak in alkaline environment. Possible release of cyanides due to laser removal

Table 1: Blue pigments and dyes. Note: Dyes are not relevant for tattooing!

The same situation exists regarding green pigments with even less candidates for discussing a possible substitute available.

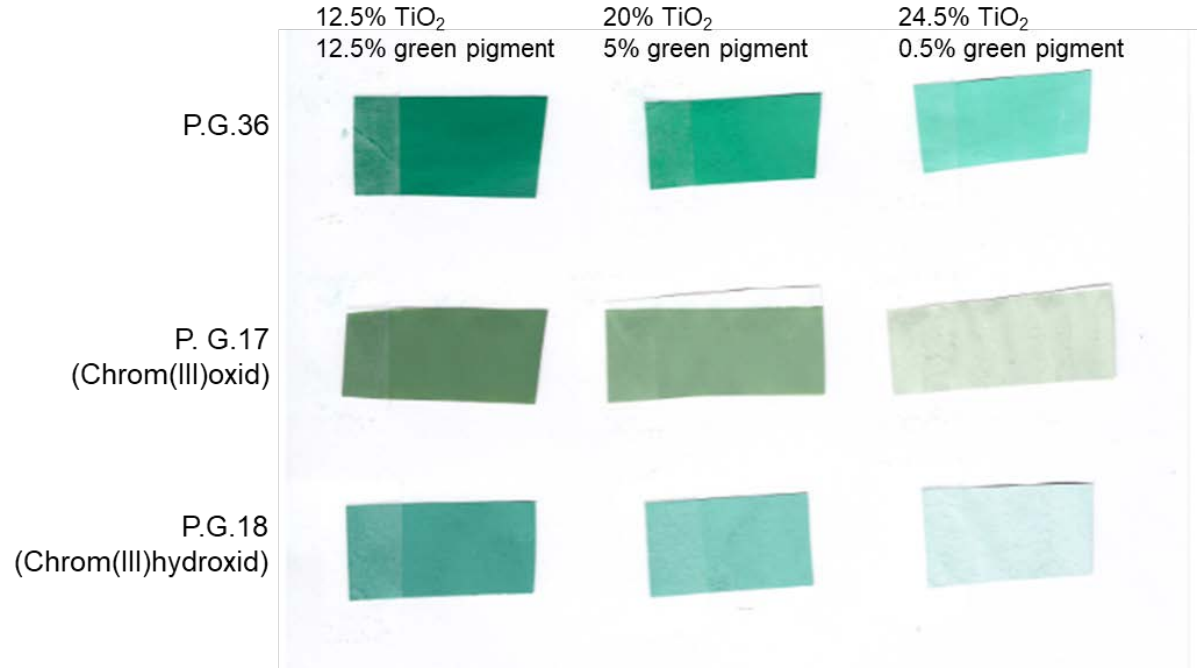

Figure 2: Different green pigments in the mix with titanium dioxide (TiO_2). Abreviations: P.G. = pigment green.

We refrained from the display of Pigment Green 7 since the result is similar to those of Pigment Green 36. The only difference is not the colour intensity but the yellow to red switch in the shading of the pigment with increasing bromination. However, we still feel that the

chlorine-bromine alternative green 36 is not a good replacement since less experience and data in terms of toxicity exists.

The chromium-based pigments are not suitable to create a classic green colour tone. Especially in the mixture with only 0.5% green pigment the chromium pigments show only little colour intensities. Mixing the chromium pigments with organic colour pigments will lead to a colour separation upon tattooing since the heavier chromium pigments will enter the skin more easy and thus would lead to a different colour after healing compared to the ink bottle which makes them less suitable.

Table 3: Alternative green pigments and dyes with the latter not relevant for tattooing due to quick biodistribution. Abbreviations: P.G. = Pigment Green; Cu-Pht. = Copper-Phthalocyanine; C.I. = Colour Index.

C.I. Name	**C.I.-Nr.**	**CAS-Nr.**	**Pigment Class**	
P.G.1	42040:1	1325-75-3	Triarylcar-bonium	Compared to the other triaryl carbonium pigments, P.G.1 lacks brilliance. The light fastness is comparable to the blue Triaryl carboniums P.G.4 is mostly produced in the USA and has only a low market importance. The colour range is in between P.G. and P.G.2.
P.G.2	42040:1	1325-75-3		
P.G.4	42000:2			
P.G.45	-			
P.G.7	74260		Cu-Pht.	Not to be used in eye products. Has been used for decades of tattooing
P.G.8	10006		Metal complex	Rinse-off products
P.G.10	12775		Metal complex	Metallised azo pigment with excellent fastness properties consisting of the nickel complex of the azo compound p-chloroaniline
P.G.36	74265		Cu-Pht.	Alternative to P.G.7
Acid Green 1	10020	19381-50-1	Metal complex	Not to be used in products applied on mucous membranes
E143	42053	2353-45-9		Soluble dye. This substance has been found to have tumorigenic effects in experimental animals, as well as mutagenic effects in both experimental animals and humans. It furthermore risks irritation of eyes, skin, digestive tract, and respiratory tract in its undiluted form.
Acid green 9	42100	4857-81-2		Rinse-off products
Acid Green 22	42170	5863-51-4		Rinse-off products
Acid Green 50	44090	221-409-2		Purity criteria as set out in Commission Directive 95/45/EC (E 142). Water soluble dye
Solvent Green 7	59040	6358-69-6		Not to be used in products applied on the mucous membranes
Solvent Green 3	61565	128-80-3		This dye is an anthraquinone derivative. It is a black powder that is soluble in polar organic solvents, but insoluble in water.

Acid Green 25	61570	4403-90-1		Water solubility 0.903 g/L. Not practicable in tattoo inks
E140	75810			Purity criteria as set out in Commission Directive 95/45/EC (E 140, E 141) water soluble dye. Not stable in light and heat
P.G.17	77288	1308-38-9	Chrom(III)oxid green	free from chromate ion. Stable pigment but not comparable (chroma, hue) to P.G.7
P.G.18	77289	1308-14-1 / 12001-99-9	Chrom(III)hydroxid green	free from chromate ion. Stable pigment but not comparable (chroma, hue, tinting strength) to P.G.7
P.B.28	77346	1345-16-0	Cobalt Aluminium oxide	Possible source of H_2S (toxic)

The little existing alternative green pigments are not a good substitution either due to fastness and stability properties or due to health reasons. The phthalocyanines are the most stable and safest green pigments existing.

If the EU Commission votes against derogation of these pigments less stable and therefore putatively pigments with increased risk to health must be used. This is, since for no other blue pigment compared to pigment Blue 15 as many toxicity studies are available to our knowledge. To replace 32.2-69.2 % percent of all colour tones of the manufacturers stated above- with the less suitable blue and green pigments- a transition period of 2 years will be necessary at least.

The replacement will therefore increase socio-economic costs and potential risks without any justification of health benefits of their ban.

6. Derogation of magenta pigments in Annex IV of the CPR

In its opinion, the RAC/SEAC concluded that no other pigments from Annex IV of the CPR are of value for tattoo inks since no other derogation was demanded by any stake holder. We apologize that we missed to ask for the derogation of quinacridone pigments. The basic magenta quinacridone (C.I. 73900) is limited in its application for short term skin contact in Annex IV- the same accounts for the more violet C.I.73915 methylated quinacridone. Therefore, both are banned from use in tattoo inks.

Magenta is a primary colour and cannot be mixed from other colour pigments. The yet only allowed quinacridone is chlorinated pigment Red 202 (C.I. 73907) and is therefore often contaminated with the carcinogen (4-)chloroaniline. We therefore **propose a derogation of C.I.73900 and C.I.73915** since they are more suitable to mixe a true magenta colour and are less likely contaminated with putative carcinogens.

Also dioxazine violet C.I. 51319 falls under this ban.The dioxazine pigment (available with cosmetical purity) can be substituted with others but these often only have industrial quality. Violet cannot be mixed from blue and red since it will result in aubergine colour tones. Manganese violet is not able to substitute this colour tone since it is quickly vanishing from the skin.

7. Derogation of volatiles

We were very surprised to see volatile compounds been derogated in the new RO1 of the dossier submitter. The explanation in the RAC opinion (page 43) was the following:

"*During the opinion-development process, the following changes to the proposed restriction wording were introduced by the Dossier Submitter as a result of Forum advice:*

- *Proposed derogation for gaseous substances: as substances that are gaseous (at temperature of 20°C and standard pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50°C) are excluded from the scope as they are not expected to be in tattoo inks. A definition of gaseous substances is included in the wording of the restriction*."

It is not true that substances that have physico-chemical properties as stated above are not present in tattoo inks.
A warning example would be formaldehyde which is gaseous at room temperature. Gases can and are always soluble to a certain extent in solvents. This already accounts for oxygen and other air components.
Free formaldehyde was found in tattoo ink analysis:

- Lim & Shin, 2016 (doi: 10.1093/chromsci/bmw163)
- Report of the cantonal laboratory 2014 and others (0.005 -0.035%)

The found formaldehyde values are above the limits for carcinogens and sensitizers in the proposed restriction dossier.
Currently the derogation is also written as "*paragraph 1 [concentration limits or ban of carcinogens/sensitizers] does not apply to substances that are gases at standard temperature and pressure.]*"
This actually means: there is no concentration limit at all for these!
We therefore state that **it is absolutely necessary to delete the derogation of volatiles**.

8. Preservatives and the Biocidal Products Regulation (BPR)

We notice that an inclusion of preservatives into the REACH restriction is not possible since they automatically fall under the EU Biocidal Products Regulation with REACH. In the SEAC opinion it is stated that this issue can be addressed by adding tattoo inks to the allowed lists of biocides and by that generate a positive list on national levels. However, it is unclear if tattoo inks belong to any of the already existing product types. Also, this stays in contrast of controlling tattoo ink ingredients on European wide uniform way to ease free distribution which is another important argument for a European regulation. Each single company has to apply for authorization. This is a waste of resources compared to a positive list as proposed below.

We especially see a problem in health protection concerning isothiazolinones. A recent review stated that in some European countries up to 20 % of population is already sensitized for these substances (Herman et al., *Dermatol Venereol.*, 2018). The limit of 0.1% for harmonized sensitizers in the dossier's submitter RO1 will be an invitation to use these substances. With the modified limit of 0.01% it is also still possible to use methylisothiazolinone (MIT), benzisothiazolinone and octylisothiazolinone. Also, this limit is 7 times higher for C(chloro)MIT/MIT than the limit of leave-on cosmetical products.

From the RAC/SEAC comment «*Further, MIT/CMIT and BIT have specific classification limit of 0.0015% and 0.05%, respectively, under the CLP regulation. A specific concentration limit of 0.0015% will also be applicable for MIT once the recently adopted harmonized classification enters into force. Thus, independently of the BPR, tattoo inks containing these substances in concentrations exceeding the specific concentration limits would have to be labelled as skin sensitizers. It is assumed unlikely that the producers would select a preservative that would require this type of labelling on a tattoo ink.»* we take the following information: even if limits for these biocides apply under the BPR, and apply by the restriction, the consequences would be that they just have to be labelled as skin sensitizers. For the reasons stated above, this is no preventive measure to increase human health which is stated to be the reasoning behind some other parts of the REACH restriction. Together with a BPR product type 6 (in-can-products) this would be an invitation to use these substances that caused a major increase in sensitization with cosmetics in the last years.

The SEAC states in its opinion that "*only a small fraction of the preservatives listed in the CPR or actually found in tattoo inks during surveys, would be under the scope of the proposed restriction.*" This is actually a negative point since especially not all of the isothiozolinones which bare a high sensitization potential are banned. Benzisothiazolinone or octylisothiazolinone are harmonized classified as skin sensitizers and may therefore be forbidden/unsuficiently limited in concentration but methylchloroisothiazolinone is not (see **section 9**).

We propose at least **to include the preservatives listed in Annex VI of the EU Cosmetics Directive allowed for leave on products** in the REACH tattoo restriction. This is, since the products need some kind of protection against microbial growth and these preservatives underwent at least basic risk assessment for skin application. The biocide list is generated for "in-can-products" and will in no way be safer than the ones approved for application on the skin.

It also needs to be said that the manufacturers are not aware of the problem that all biocides will be regulated automatically by the BPR, since they are not used to the REACH process. It reads much more complicated than the cosmetics regulation which poses a problem to ensure compliance. This includes, that with the BPR additional labelling requirements are needed- hence there are a multitude of legislation documents that need to be followed when it comes to labelling that are not yet clear to the industry. At the other hand, the concentration limits of the BPR are not sufficient for prolonged skin applications: e.g. peracetic acid is allowed in concentrations up to 15 % in product type 1 in the BPR. The positive list is very short, and many decisions are still pending.

Another crucial point is the solvent isopropanol that may also have preserving functions in tattoo inks. It is crucial to the industry that this main ingredient will still be allowed in tattoo inks but since it is listed as eye irritant it will be banned with the current version of the REACH tattoo restriction (see **section 9**) and therefore ban tattoo inks as sold on the market without health effects today (see **section 14**). Also, the use of isopropanol as preservative (in-can-products) was denied and still is.

9. Concentration limits for eye and skin irritants and skin corrosive substances will prevent tattoo ink production

In the first commenting phase we pointed out that the inclusion of skin/eye irritants is not possible in the given concentration limits since surfactants and dispersing agents needed for tattooing are often classified as such.

The RAC asked in its opinion on page 61: "*which are the most commonly used chemicals as surfactants/dispersing agents in tattoo inks and a concentration needed to ensure their function, availability of potential alternatives*."

A tattoo ink is made out of pigments, binders/film formers, solvents and auxiliary ingredients/additives:

- Auxiliary ingredients/additives are substances with a concentration < 5%, mostly surfactants, preservatives and thickening agents
- Solvents used for tattoo inks are water in a mix with simple or polyvalent alcohols
- The practical usage concentration of binders is on average 10-15 % w/w
- Binders/film formers are used to bind pigment particles to each other and to the tattooing needles for easier injection of the ink into the skin

In the following we provide a list of possible ingredients and their use with regard to their current classification:

Table 4: List of possible tattoo ink ingredients besides pigments.

Application	**Name**	**CAS**	**CLP**	**EU harmonized**	**Specific Conc. Limits, M-factors**
Preservatives	benzoic acid	65-85-0	STOT RE 1 **Skin Irrit. 2** **Eye Dam. 1**	yes	
Preservatives	methylchloroisothiazolinone	26172-55-4		no	
Preservatives	methylisothiazolinone	2682-20-4	fatal if inhaled, is toxic if swallowed, is toxic in contact with skin, causes **severe skin burns and eye damage**, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an **allergic skin reaction**	No (but will be soon)	
Preservatives	benzisothiazolinone	2634-33-5	Acute Tox. 4 * **Skin Irrit. 2** **Eye Dam. 1** **Skin Sens. 1** Aquatic Acute 1	yes	

Preservatives	octylisothiazolinone	26530-20-1	toxic in contact with skin, causes **severe skin burns and eye damage**, is toxic if inhaled, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is harmful if swallowed and may cause **an allergic skin reaction**	yes	
Preservatives	2-phenoxyethanol	122-99-6	Acute Tox. 4 * **Eye Irrit. 2**	yes	
Preservatives	3-phenylpropan-1-ol	122-97-4	causes severe **skin burns and eye damage and causes serious eye damage**	no	
Preservatives	3-Methyl-2-benzothiazolinone hydrazone hydrochloride monohydrate, 99%	38894-11-0	toxic if swallowed, causes **serious eye irritation, is suspected of causing cancer and causes skin irritation**	no	
Preservatives	Butyl 4-hydroxybenzoat / butyl paraben	94-26-8	causes **serious eye damage**, is harmful to aquatic life with long lasting effects and **causes skin irritation**	no	
Preservatives	formaldehyde	50-00-0	toxic if swallowed, is toxic in contact with skin, causes severe skin burns and eye damage, is toxic if inhaled, may cause cancer, is suspected of	yes	

			causing genetic defects and may cause an **allergic skin reaction**		
pH / Preservatives	acetic acid … %	64-19-7	Flam. Liq. 3 Skin Corr. 1A	yes	Skin Corr. 1A; H314: C ≥ 90 % Skin Corr. 1B; H314: 25 % ≤ C < 90 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %
Preservatives /other	edetic acid; (EDTA)	334-48-5	Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 3	yes	
Preservatives	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	55965-84-9	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	yes	Skin Corr. 1B; H314: C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 % Skin Sens. 1; H317: C ≥ 0,0015 %
pH	hydrochloric acid ... %		STOT SE 3 Skin Corr. 1B	yes	Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3; H335: C ≥ 10 %
surfactants/thickening	Beta-Naphthol Ethoxylate (2-(2-Naphthoxy)ethanol)	93-20-9	toxic to aquatic life with long lasting effects and causes **serious eye irritation**	no	

surfactants/thickening	Octylphenol Ethoxylate (Octoxynol; e.g. Triton X-100)	9002-93-1	toxic to aquatic life with long lasting effects, causes **serious eye damage**, is harmful if swallowed and **causes skin irritation**	no	
surfactants/thickening	Nonylphenol Ethoxylate (Nonoxynol)	26571-11-9	toxic to aquatic life with long lasting effects, causes s**erious eye damage**, is harmful if swallowed and **causes skin irritation**	no	
surfactants/thickening	Poloxamer 407	-	harmful if inhaled	no	
surfactants/thickening	Poloxamer 188	-	-	-	
surfactants/thickening	Ethylenoxid Propylenoxid Copolymer = Poloxamer	-	-	-	
surfactants/thickening	PEG	s.u.	no	-	
surfactants/thickening	PEG-8	s.u.	no	-	
surfactants/thickening	PEG-200	s.u.	no	-	
surfactants/thickening/preservative	Ethylhexylglycerin	70445-33-9	**serious eye damage** and is harmful to aquatic life with long lasting effects	yes	
surfactants/thickening	Tetramethyldecinediol	1333-17-1	preregistration process, no data yet	no	
surfactants/thickening	Polysorbate 20 (Tween 20)	9005-64-5	few companies **notified skin sensitizer, eye irritant**	no	
surfactants/thickening	Polysorbate 80	9005-65-6	no	no	

surfactants/thickening	C9-11 PARETH-6	68439-46-3	toxic to aquatic life, causes serious **eye damage**, is harmful if swallowed and **causes skin irritation**	no	
surfactants/thickening	Lecithin	8002-43-5 / 8030-76-0 (soybean)	no	no	
surfactants/thickening	Disodium Cocoyl Glutamate	68187-30-4	**serious eye irritation**	no	
surfactants/thickening	Sodium Cocoyl Glutamate	68187-32-6	causes **serious eye irritation**	no	
surfactants/thickening	Polyglycol esters	EC / List no.: 933-692-6	very toxic to aquatic life and is harmful if swallowed	no	
surfactants/thickening	Caprylyl Glycol	1117-86-8	**serious eye irritation**	no	
surfactants/thickening	Poly(ethylene glykol)	25322-68-3	no	-	
surfactants/thickening	Propylene glycol	57-55-6	no	no	
surfactants/thickening	Ethylene Glycol	107-21-1	harmful if swallowed, cause damage to organs through prolonged or repeated exposure	yes (harmful if swallowed)	
surfactants/thickening	Polyoxyethylenl aurylether	9002-92-0	very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is harmful if swallowed and causes **serious eye irritation**	no	
surfactants/thickening	Poly(ethylen glycol)-block-poly(propylen glycol)-block-poly(ethylen glycol)	9003-11-6	harmful to aquatic life with long lasting effects and causes **serious eye irritation**	no	

surfactants/thickening	Natriumdodecylsulfat SDS	151-21-3	harmful if swallowed, causes **serious eye damage**, is harmful to aquatic life with long lasting effects, is a flammable solid, is harmful if inhaled, **causes skin irritation** and may cause respiratory irritation	no	
surfactants/thickening	Tris(hydroxymethyl)-aminomethan TRIS	77-86-1 / 1185-53-1 (Hydrochlorid)	no (some notified skin irritation, and eye irritant for the hydrochloride)	no	
surfactants/thickening	Polyoxyethylenlaurylether	9002-92-0	very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is harmful if swallowed and **causes serious eye irritation, some notified skin irritation**	no	
surfactants/thickening	IGEPAL® CA-630 octylphenoxypolyethoxyethanol	9036-19-5	toxic to aquatic life with long lasting effects, causes serious eye damage and is harmful if swallowed	no	
binders	Shellac	9000-59-3	serious **eye irritation**, is harmful if swallowed, **causes skin irritation** and may cause respiratory irritation	no	

binders	Ammonium Acrylate Copolymer	?	?	?	
binders	Trimethylolpropan Triisostearate	68541-50-4	no	no	
binders	PVP	9003-39-8	no (some skin/eye irritant, eventually due to impurities)	no	
binders	Hydroxypropylmethylcellulose	9004-64-2	no	no	
binders	VP/VA (Vinylpyrrolidon und Vinylacetat) Copolymer	25086-89-9	ong lasting harmful effects to aquatic life, **causes serious eye irritation** and is harmful if swallowed	no	
binders	Simethicone	8050-81-5	causes **serious eye irritation** and is harmful to aquatic life with long lasting effects	no	
binders	Modified organo polysiloxanes				
Binders/preservative	Caprylyl Glycol /Octane-1,2-diol	1117-86-8	causes **serious eye irritation**	no	
binders	2-Methyl-2-propenoic acid polymer				
binders	Baysilon oil (Polydimethylsiloxane)	42557-10-8	pregistration process	no	
solvents	ethanol	64-17-5	Flam. Liq. 2	yes	
solvents	isopropanol	67-63-0	Flam. Liq. 2 STOT SE 3 Eye Irrit. 2	yes	
Solvents	Methanol	67-56-1	Flam. Liq. 2 Acute Tox. 3 STOT SE 1	yes	STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %

As can be seen in the table, in the current situation for most substances no problem exists for surfactants/thickening agents since they are not yet harmonized classified and therefore

outside the scope of this regulation. However, if this will happen in future and include the eye/skin irritant classification as already appearing in the C&L inventory, no legal measure would exist to still allow these substances up to certain concentration in tattoo inks with the current REACH restriction.

The inclusion of eye/skin irritants is problematic with preservatives (biocide “in-can list” is not taken into consideration here as already discussed above):

2-Phenoxyethanol used as a preservative and limited by annex V CPR to 1% is listed as **Eye Irrit. 2** in the CLP and therefore a proposed concentration limit of 0.01% in the tattoo ink modified RO1 restriction would apply. At this concentration it will have no preserving properties anymore. Compared to other preservatives it has much less toxicity and most of all no sensitizing properties!

Isopropanol is also listed as **Eye Irrit. 2** but is currently used as a solvent in the majority of tattoo inks (as seen in declaration and analytics) without any noticeable health effect.

We therefore **propose to delete the category eye irritant** from the REACH restriction for tattoo inks since this endpoint is of no value for a skin application.

The inclusion of **skin irritant** substances is also not understandable. The irritating properties are only coming into action for prolonged usage of most of these substances. The inclusion would ban **EDTA** which is used for medical treatments in intra venous applications! Also, **benzoic acid** which is a commonly used cosmetic preservative would be banned since it is classified as **skin irritant**. Benzoic acid is allowed in concentrations of 0.5 % in leave on cosmetics according to Annex V of the EU Cosmetic Directive (http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20V_v2.pdf). We therefore **propose to set the limit of the category skin irritant to 1%** in the REACH restriction for tattoo inks to allow the use of such preservatives. Also, due to the BPR, which not lists benzoic acid for type 6 products, the use of the non-sensitizing benzoic acid will not be possible anymore. **This is another argument that the REACH restriction and accompanying restrictive measures are not the right decision to control tattoo ink ingredients**.

Other substances like acetic acid and hydrochloric acid are listed as skin corrosives but with Specific Conc. Limits (M-factors) in the REACH Annex of harmonized substances. They are sometimes added to achieve a certain pH and corrosive properties are just coming into action at the given concentration by the ECHA. We therefore **propose to add the sentence “exceeding the specific concentration limits” in paragraph 1B** of the tattoo restriction and increase the restriction concentration of substances with no concentration limit given.

The limits for eye/skin irritants and corrosives currently present in the restriction are not based on risk assessment which takes the strength and potency of individual compounds into consideration.

If the ECHA wants to stay with the ban of skin corrosive and eye damaging, it should at least define higher limits that are not related to the skin sensitizers. E.g. natrium hydroxide is of no concern if diluted but only in high concentration may also damage skin.

The current state would mean that most relevant ingredients would be restricted to a limit with no practical relevance and therefore ban tattoo inks as present today (see **section 14**).

Comment on classified **PAAs and Table A**:
PAAs that are harmonized sensitizers (95-70-5, 2,5-toluenediamine) have a limit of 0.000 5% and other non-PAA sensitizers only 0.1% (RO1) or 0.01% (modified RO1). This means, that sensitizing substances like the isothiazolinones CMIT/MIT will be allowed at concentrations

of 0.1%/0.01% but more than 0.0005% sulfanilic acid will be tolerated. This is incoherency in this regulation.

10. Concentration limits for cobalt, antimony, organometallic tin, BaP and other PAH

In their opinions SEAC/RAC requested comments on new concentration limits stated in Table A.

It has to be clarified, that technical feasible limits may only be defined for a specific ink colour/pigment. It is of no use to say that in market surveys of inks (covering white, black and all shades of colours and intensities) there are those that are below the limits and therefore it must be feasible to keep these limits.
Also, since no validated method for total PAH yet exists (if ever possible) the extraction strength of the method used will define the amount of PAHs detected in inks.
Therefore, in the following some limits are displayed and suggest by colour tone for white, black, blue/green and iron oxide pigments.

In our opinion, the limits of Benzo[a]pyrene (BaP) and other PAH can be achieved with black pigments and inks currently on the market.
Still, it is unclear why BaP is handled differently, since other PAHs like dibenzo[*a,h*]anthracene have a higher potency and for all other carcinogens potency is not taken into account at all. We **propose to include all EFSA-PAHs** into the restriction.

CARBON BLACK CERTIFICATE OF ANALYSIS

Sales Order Number 032114547128SO / 3
Customer P.O.Nu
Grade 14929a
ASTM Code
Customer Grade
Quantity Shipped
Vehicle ID
Lot Number
Shipping Date
Manufacturing Plant

PHYSICAL AND CHEMICAL PROPERTIES

Production and Packing Lot Individual Data

Property Description	Unit	Ref	Specification Min	Individual Values			Specification Max
					Individual		
Benzo[a]Pyrene	ppb	12 42	0.0		1.0	✓	5.0 ✓
OAN	ml/100g	D-2414	112.0		120.0		132.0
RES-325	ppm	D-1514	0		0		200
TOTAL-PAH	ppm	CAL 00015	0.00		0.11	✓	0.50 ✓

Production and Packing Lot Average Data

Property Description	Unit	Ref	Specification Min	Average Values			Specification Max
				Min	Average	Max	
I2NO	g/Kg	D-1510	238.0	255.7	260.6	263.7	278.0
MOISTURE	%	D-1509	0.0	1.9	2.4	3.0	3.0

Figure 3: Certificate of analysis for carbon black in terms of PAHs.

Limits of elements in **black inks / carbon black**:

Analysis	Minimum Value	Maximum Value	Test Method
Appearance	POWDER	POWDER	10-010
Odour	NONE	NONE	10-022
Water solubility	INSOLUBLE	INSOLUBLE	10-046
Full shade (delta E < 1,2)	Passed	Passed	10-125
Müller blasting (delta E<1,2)	Passed	Passed	10-126
Antimony (ppm)	0	10 ✗	10-210
Arsenic (ppm)	0	3.0 ✗	10-213
Lead (ppm)	0	10 ✗	10-210
Mercury (ppm)	0	1.0 ✓	10-213
Barium (ppm)	0	50 ✓	10-214
Cadmium (ppm)	0	1.0 ✓	10-210
Chromium (ppm)	0	50	10-210
Cobalt (ppm)	0	30 ✗	10-210
Copper (ppm)	0	50 ✓	10-210
Nickel (ppm)	0	30 ✗	10-210
Zinc (ppm)	0	100 ✓	10-210
Selenium (ppm)	0	10.0 ✗	10-210

Figure 4: Specification of a cosmetic carbon black.

As shown in figure 3 and 4, available cosmetic carbon black pigments achieve the limits of PAH but manufacturers of pigments only guarantee relatively high levels of elemental impurities.

Pigment concentrations in carbon black inks are:
Carbon black for linings x ≧ 8 ≦ 10 % pigment in tattoo ink
Carbon black for filling x ≧ 9 ≦ 15/20 % pigment in tattoo ink

Table 5: Specification of a cosmetic carbon black and technical achievable limits.

	Max. Value in cosmetic carbon black specification [ppm]	Max. proposed allowed value RO1	Max. possible pigment conc. in ink	Needed limit max. conc. for 20% pigm. conc.
Antimony	10	0.5 ppm	5%	2 ppm
Arsenic	3	0.5 ppm	17 %	0.6 ppm
Lead	10	0.7 ppm	7 %	2 ppm
Mercury	1	0.5 ppm	Current limit ok	Current limit ok

Barium	50	500 ppm	Current limit ok	Current limit ok
Cadmium	1	0.5 ppm	Current limit ok	Current limit ok
Chromium	50 (unknown if Cr(VI))	0.5 ppm (Cr(IV))	n.a.	n.a.
Cobalt	30	0.5 ppm	1.7 %	6 ppm
Copper	50	250 ppm	Current limit ok	Current limit ok
Nickel	30	5 ppm	17 %	6 ppm
Zinc	100	2000 ppm	Current limit ok	Current limit ok
Selenium	10	2 ppm	Current limit ok	Current limit ok

Limits of elements in **white inks / titanium dioxide**:

Analysis	Minimum Value	Maximum Value	Result	Test Method
Appearance	POWDER	POWDER	POWDER	10-010
Color	WHITE	WHITE	WHITE	10-021
Odour	NONE	NONE	NONE	10-022
Water solubility	INSOLUBLE	INSOLUBLE	INSOLUBLE	10-046
Volatile matter - 105°C (%)	0	.5	.1	10-102
Water soluble matter (%)	0	.5	.3	NFT 30-033
Full shade (delta E < 1,2)	Passed	Passed	Passed	10-125
Müller blasting (delta E<1,2)	Passed	Passed	Passed	10-126
Antimony (ppm)	0	2.0 ✗	0 ✓	10-210
Arsenic (ppm)	0	1.0 ✓	.8 ✓	10-213
Barium (ppm)	0	50 ✓	3 ✓	10-210
Cadmium (ppm)	0	1.0 ✓	0 ✓	10-210
Chromium (ppm)	0	50 ?	5 ✗	10-210
Cobalt (ppm)	0	30 ✗	0 ✓	10-210
Copper (ppm)	0	50 ✓	0 ✓	10-210
Lead (ppm)	0	10 ✗	0 ✓	10-210
Mercury (ppm)	0	1.0 ✓	0 ✓	10-213
Nickel (ppm)	0	10 ✓	1 ✓	10-210
Selenium (ppm)	0	10.0 ✗	0 ✓	10-210
Zinc (ppm)	0	50 ✓	0 ✓	10-210

Figure 5:Certificate of analysis for titanium dioxide.

Analysis	Minimum Value	Maximum Value	Result	Test Method
Appearance	POWDER	POWDER	POWDER	10-010
Color	WHITE	WHITE	WHITE	10-021
Odour	NONE	NONE	NONE	10-022
Water solubility	INSOLUBLE	INSOLUBLE	INSOLUBLE	10-046
Volatile matter - 105°C (%)	0	.5	.4	10-102
Water soluble matter (%)	0	.5	.4	NFT 30-033
Full shade (delta E < 1,2)	Passed	Passed	Passed	10-125
Müller blasting (delta E<1,2)	Passed	Passed	Passed	10-126
Antimony (ppm)	0	2.0	0 ✓	10-210
Arsenic (ppm)	0	1.0 ✓	.1 ✓	10-213
Barium (ppm)	0	50 ✓	2 ✓	10-210
Cadmium (ppm)	0	1.0 ✓	0 ✓	10-210
Chromium (ppm)	0	50 ?	0 ✓	10-210
Cobalt (ppm)	0	30 ✗	0 ✓	10-210
Copper (ppm)	0	50 ✓	0 ✓	10-210
Lead (ppm)	0	10 ✗	0 ✓	10-210
Mercury (ppm)	0	1.0 ✓	.1 ✓	10-213
Nickel (ppm)	0	10 ✓	0 ✓	10-210
Selenium (ppm)	0	10.0 ✗	0 ✓	10-210
Zinc (ppm)	0	50 ✓	0 ✓	10-210

Figure 6:Certificate of analysis for titanium dioxide.

Analysis	Minimum Value	Maximum Value	Result	Test Method
Appearance	POWDER	POWDER	POWDER	10-010
Color	WHITE	WHITE	WHITE	10-021
Odour	NONE	NONE	NONE	10-022
Water solubility	INSOLUBLE	INSOLUBLE	INSOLUBLE	10-046
Volatile matter - 105°C (%)	0	.5	.4	10-102
Water soluble matter (%)	0	.5	.4	NFT 30-033
Full shade (delta E < 1,2)	Passed	Passed	Passed	10-125
Müller blasting (delta E<1,2)	Passed	Passed	Passed	10-126
Antimony (ppm)	0	2.0	0 ✓	10-210
Arsenic (ppm)	0	1.0 ✓	.1 ✓	10-213
Barium (ppm)	0	50 ✓	2 ✓	10-210
Cadmium (ppm)	0	1.0 ✓	0 ✓	10-210
Chromium (ppm)	0	50 ?	0 ✓	10-210
Cobalt (ppm)	0	30 ✗	0 ✓	10-210
Copper (ppm)	0	50 ✓	0 ✓	10-210
Lead (ppm)	0	10 ✗	0 ✓	10-210
Mercury (ppm)	0	1.0 ✓	.1 ✓	10-213
Nickel (ppm)	0	10 ✓	0 ✓	10-210
Selenium (ppm)	0	10.0 ✗	0 ✓	10-210
Zinc (ppm)	0	50 ✓	0 ✓	10-210

Figure 7:Certificates of analysis for titanium dioxide.

Pigment concentrations in white inks are:
titanium dioxide for mixing with other colours x ≧ 20 ≦ 35 %
titanium dioxide for highlights x ≧ 30≦ 50 %
We used 35 % for our calculation.

The only problems concerning with inks in is regard to arsenic. The technical achievable limits are listed in table 6. Not all values can be met without changing the characteristics of the white tattoo ink with impure pigment batches which will result in less quality tattoo inks by reducing pigment concentrations.

Table 6: Specification of a titanium dioxide and technical achievable limits.

	[ppm]	Max. proposed allowed value RO1	Max. possible pigment conc. in ink	Needed limit max. conc. for 35 % pigm. conc.
Arsenic (max. manufacturer)	2	0.5 ppm	25 %	0.7 ppm
Arsenic (max. manufacturer analysis)	8	0.5 ppm	6.25 %	2.8 ppm

Limits of elements in **blue and green inks/cu-phthalocyanines**:

Analysis	Minimum Value	Maximum Value	Test Method
Appearance	POWDER	POWDER	10-010
Odour	NONE	NONE	10-022
Water solubility	INSOLUBLE	INSOLUBLE	10-046
Volatile matter - 105℃ (%)	0	12.0	10-102
Full shade	Passed	Passed	10-125
Müller blasting	Passed	Passed	10-126
Antimony (ppm)	0	10 ✗	10-210
Arsenic (ppm)	0	3.0 ✗	10-213
Barium (ppm)	0	50 ✓	10-214
Cadmium (ppm)	0	1.0 ✓	10-210
Chromium (ppm)	0	100 ?	10-210
Lead (ppm)	0	10 ✗	10-210
Mercury (ppm)	0	1.0 ✓	10-213
Zinc (ppm)	0	100 ✓	10-210

Figure 8:Certificates of analysis for Cu-Phthalocyanine green pigment CI 74260 and blue CI 74160.

Pigment concentrations in blue and green inks are:
blue x ≧ 12 ≦ 30 % (but 30% not necessary)
green x ≧ 20≦ 35 %
We used 20 % for our calculation.

Table 7: Specification of a Cu-Phthalocyanine pigments and technical achievable limits.

	Max. Value in cosmetic carbon black [ppm]	Max. proposed allowed value RO1	Max. possible pigment conc. in ink	Needed limit max. conc. for 20% pigm. conc.
Antimony	10	0.5 ppm	5%	2 ppm
Arsenic	3	0.5 ppm	17 %	0.6 ppm
Lead	10	0.7 ppm	7 %	2 ppm
Mercury	1	0.5 ppm	Current limit ok	Current limit ok
Barium	50	500 ppm	Current limit ok	Current limit ok
Cadmium	1	0.5 ppm	Current limit ok	Current limit ok
Chromium	100 (unknown if Cr(VI))	0.5 ppm (Cr(IV))	n.a.	n.a.

Limits of elements in **iron oxide pigments**:

Analysis	Minimum Value	Maximum Value	Test Method
Appearance	POWDER	POWDER	10-010
Odour	NONE	NONE	10-022
Water solubility	INSOLUBLE	INSOLUBLE	10-046
Full shade (delta E < 1,2)	Passed	Passed	10-125
Müller blasting (delta E<1,2)	Passed	Passed	10-126
Antimony (ppm)	0	10 ✗	10-210
Arsenic (ppm)	0	1.0 ✓	10-213
Barium (ppm)	0	5 ✓	10-214
Cadmium (ppm)	0	1.0 ✓	10-210
Chromium (ppm)	0	25	10-210
Cobalt (ppm)	0	15 ✗	10-210
Copper (ppm)	0	10 ✓	10-210
Iron (%)	68.0	100.0	10-139
Lead (ppm)	0	3 ~	10-210
Mercury (ppm)	0	.5 ✓	10-213
Nickel (ppm)	0	10 ✓	10-210
Selenium (ppm)	0	10.0 ✗	10-210
Zinc (ppm)	0	20 ✓	10-210

Figure 9: Certificates of analysis for cosmetical iron oxide pigment.

Pigment concentrations in iron oxide inks are:
Iron oxide x ≦ 35 %
We used 30 % for our calculation.

Table 8: Specification of a cosmetic iron oxide and technical achievable limits.

	Max. Value in cosmetic carbon black [ppm]	Max. proposed allowed value RO1	Max. possible pigment conc. in ink	Needed max. conc. for 30% pigm. conc.
Antimony	10	0.5 ppm	5%	2 ppm
Arsenic	1	0.5 ppm	Current limit ok	Current limit ok
Lead	3	0.7 ppm	23.3 %	0.9 ppm
Mercury	0.5	0.5 ppm	Current limit ok	Current limit ok
Barium	5	500 ppm	Current limit ok	Current limit ok
Cadmium	1	0.5 ppm	Current limit ok	Current limit ok
Chromium	25 (unknown if Cr(VI))	0.5 ppm (Cr(IV))	n.a.	n.a.
Cobalt	15	0.5 ppm	3.3 %	4.5 ppm
Copper	10	250 ppm	Current limit ok	Current limit ok
Nickel	10	5 ppm	Current limit ok	Current limit ok

Zinc	20	2000 ppm	Current limit ok	Current limit ok
Selenium	10	2 ppm	Current limit ok	Current limit ok

Iron oxide pigments are of special interest to the permanent make-up industry. E.g. to replace iron oxide brown and ink must be mixed from titanium dioxide, carbon black, orange and violet. The results are not satisfying to the tattoo artists and costumers since the different particle sizes lead to a pigment separation and discrimination during healing in the skin. Therefore, the colour tone varies from the initial mixture after application and produces unforeseeable colour tones.

Another problematic elemental impurity and hence concentration limit is zirconium. Zirconium and its compounds are listed in Annex II of the cosmetic regulation. With the current ECHA restriction option RO1, no concentration limits are given and hence it should not be present. With the modified SEAC/RAC RO1 a limit of 0.000 05% (5 ppm) is given.
In this case, we propose to implement this maximum concentration of 5 ppm instead of not beeing allowed since some good alternative red and orange pigments sometimes contain trace amounts of zirconium (see Table 9). This would still allow to use this pigments in concentrations of 25%.

Table 9: Specification of a red and orange pigments (non-azo pigments).

Probe	**Cr** **mg/kg**	**Co** **mg/kg**	**Ni** **mg/kg**	**Cu** **mg/kg**	**Zn** **mg/kg**	**As** **mg/kg**	**Zr** **semiquant.** **mg/kg**
Red SR2P	<1	<2	<1	<1	<1	<1	2
Red SR1C	<1	<2	<1	<1	<1	<1	4
Rubine SR5H	<1	<1	<2	5,3 ± 0,3	<1	<1	8
Rubine SR6T	8,3 ± 3,5	<1	2,8 ± 1,4	19,6 ± 1,5	2,0 ± 0,2	<1	7
Orange SJ1C	<1	<1	1,7 ± 0,6	7,0 ± 0,6	2,9 ± 1,2	<1	9

11. Concentration limits of pigments problematic in analysis, only qualitative methods at hand- no enforcement possible

The modified RO1 of RAC/SEAC give a concentration limit of 0.0005% w/w for substances in annex IV of the Cosmetics Directive (paragraph 1c), paragraph 2 (Table A with colorant limit of 0.1% w/w and paragraph 4 (includes some specific concentration limits).
A limit of concentrations for pigments is very problematic since no quantitative analytical methods exist at the moment and in the discussion on analytical methods to come no method is currently at hand that can quantify all the pigments covered by the restriction. Therefore, no law enforcement is possible, and the manufacturers can argument that no quantification is possible if products are accused to be non-compliant. Also, since standard substances for most of these pigments are missing, quantification cannot be carried out.
We therefore **propose to state for all pigments that they "should not be present"** since qualitative methods do exist and would therefore allow law enforcement by state laboratories in Europe. In the qualitative methods, the limit of detection for most pigments is already that high (e.g. 1-20% percent depending on the ink composition and pigment, Niederer et al., 2018, https://doi.org/10.12688/f1000research.13035.2) that trace impurities will not be detected but intended use of banned pigments can be enforced.

12. Dynamic vs. static link to the EU Cosmetic Directive

It is still under discussion whether the link should be static or dynamic.
A major argument also pointed out by SEAC is that "updates will be targeted to tattoo use and will enable scrutiny on risks, concentration limits and alternatives" with a static link.
The current restriction is not based on risk assessment but at least gave the chance of discussing values with tattoo related stake holders.
As seen by the vast amount of critical points included in this comment, a tattoo related proof of amendments is highly necessary. Also, a static link would give more time for adaption not only for ink manufacturers but also law enforcement if new or modified analytical methods would be necessary. Therefore, we **propose a static link to the Annexes** of the EU Cosmetic Directive.
Additionally it has to be taken into account, that also an amendment to the list of harmonized substances may impair tattoo ink production in the future if eye/skin irritant, corrosives are added and thereby eventually ban the majority of surfactants or other ingredients with the current version of the restriction (cf. section 9).

13. List of cleaved aromatic amines instead of azo pigments

In the original dossier the list of banned pigments in Table A is derived from their potential to cleave carcinogenic aromatic amines from their structure either during sun light exposure but also during laser removal (with the latter only relevant for a subpopulation).
However, the potential of synthesis of new pigments with just a new side chain or group is endless. Today, already >10,000 pigments and dyes are listed in the colour index (C.I.).
Hence, updating the list of hazardous pigments will always delay the enforcement of pigments newly appearing in tattoo inks and can never be complete. The negative list can therefore easily be avoided.
Thus, instead **we propose a list of aromatic amines to be banned when cleavable from pigments** as taken from its structure.

There are at least three examples for such a group ban without naming the single colorants in the REACH regulation: CLP annex VI:

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
611-024-00-1	Benzidine based azo dyes; 4,4'-diarylazobiphenyl dyes, with the exception of those specified elsewhere in this Annex			Carc. 1B	H350	GHS08 Dgr	H350			A
611-029-00-9	o-dianisidine based azo dyes; 4,4'-diarylazo-3,3'-dimethoxybiphenyl dyes with the exception of those mentioned elsewhere in this Annex			Carc. 1B	H350	GHS08 Dgr	H350			A

611-030-00-4	o-toluidine based dyes; 4,4'-diarylazo-3,3'-dimethylbiphenyl dyes, with the exception of those mentioned elsewhere in this Annex			Carc. 1B	H350	GHS08 Dgr	H350			A

Hence, a similar ban can be used in Table A or by stating all harmonized classified PAAs that are either carcinogens or skin sensitizers and can be released by azo or amide bond cleavage (both of which have been shown to occur after UV irradiation) should be banned from tattoo inks.

It is obvious that ECHA wants to ban PAAs of annex A, therefore our proposed approach displays a more holistic way to do so.

This would also be more monitorable since either free amines can be analysed in the finished products after cleavage conditions like adapted reductive cleavage, UV irradiation or using pyrolysis to release potential PAAs from the pigments. By this, the difficulties in monitoring the pigments used (it is impossible to obtain standard substances for all thousands of pigments eventually existing and those not yet invented) but a method including the targeted PAAs is possible by little adaption of existing methods. Hence, this approach will certainly increase the health benefits and enforceability of any restriction or EU wide regulation.

14. Examples of tattoo inks before and after REACH restriction

Complete list of ink ingredients	**Labelling if RO1 comes into action**	**Allowed with modified RO1**	**Explanation for allowance/ban in modified RO1**
Blue Ink: Water, Isopropanol (30%), C.I. 74160 (Cu-Phthalocyanine), C.I. 77891 (Titanium dioxide), Phenoxyethanol (1%), Triton X 100, Propylene glycol, Shellac Impurities: none above threshold	Isopropanol (Flam. Liq. 2, STOT SE 3, Eye Irrit. 2) Due to biocide regulation: Contains 1% phenoxyethanol (hazard statement)	No	C.I. 74160 banned due to CPR Annex II, Phenoxyethanol and Isopropanol banned due to their listing as eye/skin irritant when present >0.01%
Red Ink: Water, methanol (11%), C.I. 12475 (Pigment Red 170), methylchloroisothiazolinone (0.0014%), methylisothiazolinone (0.0014%), Acrylate-Block-Copolymer, Impurities: Formaldehyde (0.6%), Naphthol AS (0.2%)	methanol (Flam. Liq. 2, Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT SE 1)	yes	Azo-Pigment R170 is not listed in Table A and together with methylchloroisothiazolinone and Naphthol AS not harmonized classified. The latter two are known sensitizers and according to the BPR only have to be labelled if present >0.0015 %). Formaldehyde, a carcinogen and sensitizer, is not banned due to the

			derogation of volatiles. Both formaldehyde and Naphthol AS are unintentionally added and thus don’t have to be declared even if present below given limits and even if both were harmonized classified.

The imaginary inks stated above illustrate perfectly the misery of the current REACH restriction. The blue ink would be perfectly suitable for tattooing and inks with similar composition are on the market at the moment without health complaints.

The red ink contains several substances of major concern which are neither banned nor have to be declared so that tattoo artists aware of putative dangers of red azo pigments which are thought to cause tattoo allergies can avoid these kinds of inks. Even some costumers want to avoid azo pigments since they already appear in the media as putative harmful pigments. But without labelling, they cannot control which ink and thus which pigment they use. For the current RO1, the isothiazolinones may even be used up to a concentration of 0.1% and would then require a statement on the label. We do not think that this would keep tattooists from using their favourite ink producers.