**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction on

**Substances used in tattoo inks and permanent make-up**

**Non-confidential**

ECHA/RAC/ RES-O-0000001412-86-240/F

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| **Substance name** | **EC number** | **CAS number** |
| Substances used in tattoo inks and permanent make-up | - | - |

29 November 2018

General Comments and answers to specific information requests

## Specific information requests:

1. The proposed restriction limits the use of a range of chemicals with severe human health hazardous properties in tattoo and permanent make-up inks. For some impurities that are known to be regularly detected in these inks, such as heavy metals, PAHs and methanol, there is a need to carefully consider the feasibility of newly proposed limit values. Will you face difficulties finding or formulating tattoo and permanent make-up inks on the EU market meeting the concentration limits listed in the table below? If you expect to face difficulties, please clarify for which impurity (ies) and what concentration limit(s) would be achievable and what time would be needed to be able to formulate compliant inks.

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| **Substance name** | **EC#** | **CAS#** | **Proposed concentration limit (% w/w)** |
| Mercury | 231-106-7 | 7439-97-6 | 0.00002 |
| Nickel | 231-111-4 | 7440-02-0 | 0.001 |
| Tin | 231-141-8 | 7440-31-5 | 0.005 |
| Antimony | 231-146-5 | 7440-36-0 | 0.0002 |
| Arsenic | 231-148-6 | 7440-38-2 | 0.0000008 |
| Barium\* | 231-149-1 | 7440-39-3 | 0.84 |
| Cadmium | 231-152-8 | 7440-43-9 | 0.00002 |
| Chromium\*\* | 231-157-5 | 7440-47-3 | 0.00002 |
| Cobalt | 231-158-0 | 7440-48-4 | 0.0025 |
| Copper\* | 231-159-6 | 7440-50-8 | 0.05 |
| Zinc | 231-175-3 | 7440-66-6 | 0.23 |
| Lead | 231-100-4 | 7439-92-1 | 0.00007 |
| Selenium | 231-957-4 | 7782-49-2 | 0.0002 |
| Methanol | 200-659-6 | 67-56-1 | 10.9 |
| Individual polycyclic aromatic hydrocarbons (PAH) with harmonised classification as carcinogenic or mutagenic |  |  | 0.0002 |

Notes: \*Soluble. \*\*Chromium (VI).

1. Previous consultations have indicated that there are no technically feasible and safe alternatives for two specific pigments which are covered by the scope of the proposed restriction: Pigment Green 7 (CI 74260, EC 215-524-7, CAS 1328-53-6) and Pigment Blue15:3 (CI 74160, EC 205-685-1, CAS 147-14-8). Would you agree with this? How long will it take to develop alternatives to these two pigments?
2. The colourants listed below are banned in hair dyes (Annex II Cosmetics Regulation). Are they used in tattoo inks or permanent make-up? If so, can these colourants be substituted by safe alternatives available at similar market prices?

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| **Substance name** | **Substance market name** | **EC #** | **CAS #** |
| 1,4-bis(p-tolylamino)anthraquinone | Solvent Green 3, CI 61565 | 204-909-5 | 128-80-3 |
| Dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)amino]  (4-hydroxy-2-sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]  (3-sulphonatobenzyl)ammonium, disodium salt | Fast Green FCF, CI 42053 | 219-091-5 | 2353-45-9 |
| 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)  -4-methylbenzo[b]thiophene-3(2H)-one | VAT Red 1, CI 73360 | 219-163-6 | 2379-74-0 |
| Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]  -4-hydroxynaphthalene-1-sulphonate | Red, CI 14700 | 224-909-9 | 4548-53-2 |
| N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]  -2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide | Pigment Red 5, CI 12490 | 229-107-2 | 6410-41-9 |
| Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate | Pigment Red 63:1, CI 15880 | 229-142-3 | 6417-83-0 |
| 1,2-dihydroxyanthraquinone | Pigment Red 83, CI 58000 | 200-782-5 | 72-48-0 |
| 1-hydroxy-4-(p-toluidino)anthraquinone | Solvent Violet 16, CI 60725 | 201-353-5 | 81-48-1 |
| Sodium 4-(2,4-dihydroxyphenylazo)benzenesulphonate | Acid Orange 16, CI 14270 | 208-924-8 | 547-57-9 |
| 4-(phenylazo)resorcinol | Solvent Orange 1, CI 11920 | 218-131-9 | 2051-85-6 |
| Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]  -1-naphthyl]azo]naphthalene-2,7-disulphonate | Food Black 2, CI 27755 | 218-326-9 | 2118-39-0 |
| 1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085)  and its salts when used as a substance in hair dye products,  1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol and its insoluble barium,  strontium and zirconium lakes, salts and pigments, Pigment red 4 | CI 12085/Red | 220-562-2, | 2814-77-9 |
| Trisodium 3-hydroxy-4-(4′-sulphonatonaphthylazo)naphthalene-2,7  -disulphonate (Acid Red 27; CI 16185) when used as a substance in hair dye products,  Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate | CI 16185 / ACID RED 27 | 213-022-2 | 915-67-3 |
| Ethanaminium, N-(4-((4-diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)  -2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1)  (Acid Blue 3; CI 42051) when used as a substance in hair dye products,  Ethanaminium, N-(4-((4-(diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)  -2,5-cyclohexadien-1-ylidene)-N-ethylhydroxide, inner salt, calcium salt (2:1)  and its insoluble barium, strontium and zirconium lakes, salts and pigments | CI 42051 / ACID BLUE 3 | 222-573-8 | 3536-49-0 |
| 2-(6-Hydroxy-3-oxo-(3H)xanthen-9-yl)benzoic acid; Fluorescein  and its disodium salt (Acid Yellow 73 sodium salt; CI 45350)  when used as a substance in hair dye products,  Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate | CI 45350/ Yellow | 208-253-0 | 518-47-8 |
| CI 45350/ Yellow | 219-031-8 | 2321-07-5 |
| 4′,5′-Dibromo-3′,6′-dihydroxyspiro[isobenzofuran-1(3H),9′-[9H]xanthene]  -3-one; 4′,5′-Dibromofluorescein; (Solvent Red 72) and its disodium salt (CI 45370)  when used as a substance in hair dye products,  4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),  9'-[9H]xanthene]-3-one and its insoluble barium,  strontium and zirconium lakes, salts and pigments | CI 45370 / SOLVENT RED 72/ Orange | 209-876-0 | 596-03-2 |
|  | 224-468-2 | 4372-02-5 |
| 2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)benzoic acid;  Fluorescein, 2′,4′,5′,7′-tetrabromo-; (Solvent Red 43),  its disodium salt (Acid Red 87; CI 45380) and its aluminium salt  (Pigment Red 90:1 Aluminium lake) when used as a substance  in hair dye products, Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)  benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments | CI 45380/ Red | 239-138-3 | 15086-94-9 |
| CI 45380 / PIGMENT RED 90:1 ALUMINUM LAKE | 240-005-7 | 15876-39-8 |
| CI 45380 / ACID RED 87 | 241-409-6 | 17372-87-1 |
| 2′,4′,5′,7′-Tetraiodofluorescein, its disodium salt (Acid Red 51; CI 45430)  and its aluminium salt (Pigment Red 172 Aluminium lake)  when used as a substance in hair dye products,  Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthen-9-yl)  benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments | CI 45430 / PIGMENT RED 172 ALUMINUM LAKE | 235-440-4 | 12227-78-0 |
| CI 45430 / ACID RED 51 | 240-474-8 | 16423-68-0 |

1. Are the following colourants used in tattoo inks or permanent make-up? Do they have substitutes at similar market prices? How long will it take to identify substitutes? Is it possible for industry to comply with the proposed concentration limits for these pigments?

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| **Substance name** | **Other regulatory process names** | **EC#** | **CAS#** | **Proposed concentration limit** |
| Acid Green 16 | sodium 4-{[4-(diethylamino)phenyl][4-(diethyliminio)cyclohexa-2,5-dien-1-ylidene]methyl}naphthalene-2,7-disulfonate | 603-214-8 | 12768-78-4 | 0.1% w/w |
| Acid Red 26 | Disodium 1-(2,4-dimethylphenylazo)-2-hydroxynaphthalene-3,6-disulphonate | 223-178-3 | 3761-53-3 | 0.1% w/w |
| Acid Violet 17 | Hydrogen [4-[[4-(diethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt | 223-942-6 | 4129-84-4 | 0.1% w/w |
| Basic Red 1 , Basic red 1 | 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis (ethylamino)-2,7-dimethylxanthylium chloride | 213-584-9 | 989-38-8 | 0.1% w/w |
| Disperse Blue 106 | Ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]- | 602-285-2 | 12223-01-7 | 0.1% w/w |
| Disperse Blue 124 | Disperse Blue 124 | 612-788-9 | 61951-51-7 | 0.1% w/w |
| Disperse Blue 35 | C.I. Disperse Blue 35 | 602-260-6 | 12222-75-2 | 0.1% w/w |
| Disperse Orange 37 | Propanenitrile, 3-[[4-[2-(2,6-dichloro-4-nitrophenyl)diazenyl]phenyl]ethylamino]- | 602-312-8 | 12223-33-5 | 0.1% w/w |
| Disperse Red 1 | 2-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]ethanol | 220-704-3 | 2872-52-8 | 0.1% w/w |
| Disperse Red 17 | 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol | 221-665-5 | 3179-89-3 | 0.1% w/w |
| Disperse Yellow 9 | N-(2,4-dinitrophenyl)benzene-1,4-diamine | 228-919-4 | 6373-73-5 | 0.1% w/w |
| Pigment Violet 3 | 4-[(4-Aminophenyl)-(4-methyliminocyclohexa-2,5-dien-1-ylidene)methyl]aniline | 603-635-7 | 1325-82-2 | 0.1% w/w |
| Pigment Violet 39 | Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, molybdatephosphate | 264-654-0 | 64070-98-0 | 0.1% w/w |
| Solvent Yellow 2 | 4-dimethylaminoazobenzene | 200-455-7 | 60-11-7 | 0.1% w/w |

1. Do you have information on the percentage of tattoo inks that are already compliant with the proposed restriction, national legislation already in place or the Council of Europe resolution ResAP(2008)1?

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1882** | **Date:** 2018/01/02 10:47  **Content:**  Scope or restriction option analysis  **Type:** Individual  **Country:**  Netherlands | **Comment:**  In the "auxiliary ingredients" in the "definitions used in the proposal" section, dilutantys are not mentionend. Dilutants are added to the product before use, but can to my best knowing also be part of the manufactered product.  comment: suggest adding "dilutants"  question: would the restriction apply when ingrediants are added by a tattooist before using the product? |
| **Dossier submitter response:**  Thank you for your comments. We agree that the definition for auxiliary ingredients could be modified so as to show that other ingredients, such as dilutants also are included. We propose to change the wording of the definition of auxiliary ingredients in the Background Document, by including "amongst others" in the definition to make this clearer.  The restriction applies to tattoo artists who mix their own tattoo inks, as is specified in the restriction dossier in section 2.2 e, ii. Additional conditions, Restriction on the use of tattoo inks not meeting the requirements by tattoo artists. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC supports the Dossier Submitter’s response. |
| **SEAC Rapporteurs comments:**  Thank you for the comment, we recognise the Dossier does not document dilutants and that there is no information whether hazardous dilutants that can be used in tattoo inks have been classified as such. Therefore, the effectiveness of the proposed restriction to reduce risk has to rely on the effectiveness of the EU classification system. |
| **1883** | **Date:** 2018/01/10 19:40  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline;  Description of analytical methods;  Information on alternatives;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transit  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential:** Yes  **Privacy comment:** Protections of commercial interests | **Comment:**  As a representative of ,<redacted>, I would like to thank the ECHA for allowing myself to contribute any useful input. I hope that the input that I am providing can be used to establish a fair and realistic proposal that can allow for some flexibility in order to allow <redacted> and other ink manufacturers to continue to conduct business within the regions affected by this piece of legislation. |
| **Answer to specific info request 1:**  Changing the limits for heavy metals would become a challenge, with difficulties to follow in order to properly adjust our formulations around this. Considering where the raw sources of our products are provided from, these limits may fluctuate frequently making it a challenge to pinpoint a target level to measure against. We would require an extended amount of time to research and develop a method that would be able to land us within most of the limits that have been proposed in this annex. |
| **Answer to specific info request 2:**  I would agree that Pigment Green 7 and Blue Blend 15:3 are two of the best options available to the tattoo industry that cover this spectrum of color. Through our own testing, we have not found any issues that would show Green 7 to conflict with the current Resap 2008(1) testing methods. These are both very durable products that show very little issues with performance in the body or in tattoos. To find better alternatives to these would pose a huge challenge as there are few alternatives available that would be able to pass the required limits set by the ReSap 2008(1) or the newly proposed limits set for this annex. |
| **Answer to specific info request 3:**  None of these listed products have ever been used for <redacted> products. |
| **Answer to specific info request 4:**  None of these listed products have ever been used for <redacted> products. |
| **Dossier submitter response:**  Thank you for your comments and information. It will be considered in the further work with the restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comments. They were considered in the development of RAC opinion.  Regarding derogation of Pigment Blue 15:3 and Pigment Green 7 proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. |
| **SEAC Rapporteurs comments:**  Thank you for the comment, it will be taken into account in the opinion of SEAC on derogations. Regarding Pigment Green 7 and Blue 15:3, SEAC notes the need for the derogation of Pigment Green 7 and Pigment Blue 15:3 but regards the information provided too limited to currently justify it. SEAC will use the public consultation on its final draft opinion to gather further justification on a the need for derogation and the consequences of no derogation. |
| **1890** | **Date:** 2018/02/16 12:08  **Content:**  Scope or restriction option analysis  **Type:** MemberState  **Country:**  Sweden | **Comment:**  The Swedish Medical Products Agency controls tattoo inks on the Swedish market. We believe that the proposed requirements regarding labeling of substances, see section 6 (RO1) and 7 (RO2), is not suitable for products which is intended to be injected in skin like tattoo inks. Instead we suggest that “a list of ingredients” should be stated in the labeling like what is required in section 3.3 of ResAP 2008(1), and like the list of ingredients required for cosmetic products, see article 19.1 g in regulation (EU) nr 1223/2009 on cosmetics. In the Swedish national legislation on tattoo inks a list of all ingredients is required. We see the following advantages listing all the ingredients in the labeling of tattoo inks:  • The consumer is able read the list of ingredients before the tattooing and will see the names of all the ingredients which have been added to the ink. People may be sensitive for certain substances (for example preservatives). With the RO1- and RO2-proposal the consumer will, what we can see, not get information of all ingredients. This might lead to that the consumers are injected with substances they want to avoid.  • The authorities will get information about all the ingredients which will make market surveillance easier/possible. If all ingredients are not listed it will be harder/impossible for the authorities to follow up for example unwanted effects. A consumer might have reacted to an ingredient which is not listed. It would also be difficult for researchers wanting to study health effects of tattoo inks on human health, if they are not able to identify all ingredients in a tattoo ink.  If “a list of ingredients” would be required in RO1 and RO2, we suggest that it is also stated what is not seen as an ingredient. Note for example that contaminants is not seen as ingredients in cosmetics, see article 19.1 g) regulation (EU) nr 1223/2009 on cosmetics, and therefore do not have to be declared on such cosmetic products. Section 6 (RO1) and 7 (RO2) seems to require that contaminants like lead should be declared in the labeling. We think that it is important that the tattoo inks do not contain higher levels of such contaminants than stated in the RO1/RO2-appendices, but that a list of ingredients/substances would be too long if all the substances covered by the proposal should have to be declared.  The Swedish Medical Products Agency also suggests that the presence of traces of chromium (VI) in products for tattoos and PMU should be mentioned on the package together with a warning (for example, “Contains chromium. Can cause allergic reactions.”), and that the presence of traces of nickel in products for tattoos and PMU should be mentioned on the package together with a warning (for example, “Contains nickel. Can cause allergic reactions.”). Such warnings are found in table 3, references 6 and 8, in ResAP 2008(1) and also in the Swedish national legislation on tattoo inks. Such warnings would help the consumers better understanding the risks with nickel and chromium (VI).  Our experience when controlling tattoo inks on the Swedish market, is that the majority of the tattoo inks have lists of ingredients in their labeling. This is probably because tattoo ink companies follow ResAP 2008(1) or national member state legislations based on ResAP. We also have not experienced that tattoo ink manufacturers or distributors have complained about listing all the ingredients in the labeling. |
| **Answer to specific info request 5:**  In market surveilance project the year 2014/2015 including chemical analysis, about 51% of the tattoo inks on the Swedish market contained forbidden substances or too high levels of contaminants, see report <https://lakemedelsverket.se/upload/om-lakemedelsverket/rapporter/rapport_och_analyser_av_tatueringsfarger_permanent_makeup.pdf>  We are about to publish a report about our control of tattoo inks on the Swedish market year 2017, inluding chemical analysis. We estimate that the report will be published in March at latest |
| **Dossier submitter response:**  Thank you for the comments and the information on the market surveys. The results have been included in the Background Document.  In relation to the labelling requirements, these have been developed to the extent possible under REACH; in a restriction, a condition must be underpinned by its ability to reduce a risk. Therefore, in the proposal made by the Dossier Submitter, all hazardous substances (classified in CLP) used (i.e. intentionally added) in tattoo inks must be cited on the label (this does not include impurities). The Dossier Submitter chose not to include self-classified substances in this requirement as this could cause differences in labelling depending on the source of the ingredients (i.e. whether the supplier self-classified or not). It is our understanding that additional labelling measures are possible to introduce by Member States under national consumer protection legislation. The Dossier Submitter agrees to include the labelling suggestions on Cr (VI) and Ni and has amended the Background Document.  On preservatives, these are subject to the Biocidal Products Regulation and the legislative requirements under that legislation. In addition, those preservatives with a relevant harmonised legislation will also have to comply with the proposed restriction (see comment #1904 for further detail).  Regarding RO2, the proposed practical limits are higher than in RO1 as they were selected to discourage intentional use in tattoo inks and with regard to effectiveness and practicality. However, we understand your concerns and the Dossier Submitter is working with RAC and SEAC to identify other practical limits, where necessary to effectively discourage the use of hazardous substances in tattoo inks, taking into account the submitted comments during the Public Consultation. However, with regard to the concentration limit for skin sensitisers the Dossier Submitter is proposing to reduce the concentration limit in RO2 to ≥ 0.01% see response 1921 for details. |
| **RAC Rapporteurs comments:**  Thank you for your comments and provided information. They were considered in the development of RAC opinion. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. We agree with the response provided by the Dossier Submitter. The level of compliance is in line with the information in the Dossier and is reflected in the opinion. |
| **1891** | **Date:** 2018/02/16 13:28  **Content:**  Scope or restriction option analysis;  Hazard or exposure  **Type:** MemberState  **Country:**  Finland | **Comment:**  1. In the Annex to the restriction report it is mentioned that according to measurements conducted by Kemi (2010) strontium was found in 10 samples out of 31. Table 11 of the restriction report lists limit concentrations for different impurities, including metals from cadmium to tin. However, strontium is not mentioned.  Is there a reason for this exclusion?  2. In the report section 1.1.5 Scope of the restriction it is stated inks that are classified as carcinogenic but only via inhalation are out of scope of the restriction because they are “not inhaled by the recipient of the tattoo.”. The restriction does not seem to address the potential exposure by the tattoo artists during the tattooing process via possible aerosols from the tattoo gun or preparing the ink from the dry powder form product. According to the footnote 15 on page 27 “Some Tattoo inks may be provided in powder form and made up by tattoo artists into the final mixture.” You can also find instructions in the internet on how to prepare your own inks using a blender. One piece of advice found on an internet page was “Although pigments normally are not toxic, you need a mask because breathing pigment particles can cause permanent lung damage.”  Is there a reason for the exclusion of workers in this restriction? |
| **Dossier submitter response:**  Thank you for your comments.   1. Seven Member States already have national legislation on tattoos based on a Council of Europe (CoE) resolution (ResAP(2003)2 and ResAP(2008)1) and have several years of experience of enforcing this legislation. This restriction proposal has built on these existing laws.   Table 11 of the restriction report lists the proposed concentration limits for the substances in the scope of the restriction, including those for impurities listed in Table 3 in the Council of Europe Resolution ResAP(2008)1 (CoE ResAP(2008)1). Strontium is not listed on the CoE ResAP(2008)1 Table 3.  Strontium as such does not fulfil the other criteria to be included in the scope of the restriction either (i.e., relevant harmonised classification or prohibition under the Cosmetic Products Regulation) and therefore no specific concentration limit is proposed.  We can however add that many strontium-containing pigments are covered by the restriction since they are on Annex IV to the CPR (the positive list of colourants allowed in cosmetic products) because their conditions in columns g-i of Annex IV (specific use restriction, maximum allowed concentration limits, purity requirements, etc.) mean that if the substances are used in tattoo inks they may represent a risk to the consumer. (See Annex B.5.12 for more detail.)   1. The aim of this restriction is to protect consumers. In section 1.1.5 of the report "Scope of the restriction" the following text is written: The intention of this restriction is to minimise the risk to consumers from chemicals used in tattoo inks. Therefore, workers exposure has not been considered in this restriction proposal. The Directive 89/391 - OSH "Framework Directive" with its amendments still applies to protect workers from exposure to chemical agents and ensure chemical safety. In addition, the restriction will reduce the risk to workers due to the reduction of hazardous substances in the inks they work with.   In addition, the Dossier Submitter has information that the great majority of tattoo inks available on the market are in liquid form.  The Dossier Submitter has considered the comments and concluded that it was not necessary to change the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for your comments and the provided information.  RAC supports the Dossier Submitter’s response, and would just add that some strontium salts (i.e. strontium lactate, strontium nitrate, strontium polycarboxylate) are prohibited by the CPR (listed in Annex II). |
| **SEAC Rapporteurs comments:**  Thank you for the comment. No action needed on behalf of SEAC. |
| **1893** | **Date:** 2018/02/16 16:45  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  Our Association did not have the time to review the whole document, but below you find our comments to your questions. We will provide detailed comments later in the public consultation. |
| **Answer to specific info request 1:**  Most concentrations are realistic to achieve in the final product except of two positions:  Chromium can be difficult for some pigments. 0,2 ppm are as well difficult to detect and a higher value is desirable for the industry. We propose 2 ppm.  Lead is difficult with the proposed concentrations for pigment black CI 77266. As it is manufactured of oil, the concentration of lead varies between 2,6 and 6,5 ppm in the pure pigment (Based on 8 analysed batches). Regarding a maximum pigment concentration of 25% the industry suggest a limit of 2 ppm that is technically achievable. It is not always possible to get pigment with low concentration of lead ( less 2,8 ppm). |
| **Answer to specific info request 2:**  Both pigments are needed to formulate tattoo inks and all substitutes are worse or not suitable. The industry is searching for a long time already to replace those pigments, but as for now there are no better alternatives. There is no realistic chance to replace those pigments in the future. |
| **Answer to specific info request 3:**  Some pigments are still used. For example Pigment Red 5 (CI 12490), but can be replaced without bigger problems. |
| **Answer to specific info request 4:**  Yes it is possible to comply with the proposed limits as these pigments are not used in tattoo and permanent make up inks or can be replaced by other pigments. |
| **Dossier submitter response:**  Thank you for the information on the substitutes and other pigments in tattoo inks.  Regarding the concentration limits on chromium and lead, firstly on Chromium, the concentration limit proposed in both RO1 and RO2 are the same as in the CoE resolution. We assume companies have been complying with the Member States legislation based on that measure. In addition related to lead pigments, the responses do not specify what would be the impacts, for example, if pigment black CI 77266 cannot be used. Therefore the Dossier Submitter does not agree with these proposals to change the relevant concentration limits. |
| **RAC Rapporteurs comments:**  Thank you for your comments and the provided information.  RAC supports the Dossier Submitter’s response. Regarding lead in carbon black pigments RAC also notes that in Swedish Medical Products Agency report (Kontroll av tatueringsfärger för tatuering och permanent makeup; 2018-04-23) less than 0.0001% lead (LoQ for the method applied) was found in a sample of black ink IC 77266.  Regarding derogation of Pigment Blue 15:3 and Pigment Green 7 proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. |
| **SEAC Rapporteurs comments:**  Thank you for the comments. We agree with the response provided by the Dossier Submitter. Information on pigments PG7 and PB15 confirm information in the submitted dossier; please see comment 1883 for further details. |
| **1894** | **Date:** 2018/02/16 16:50  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Request for exemption  **Type:** MemberState  **Country:**  Belgium  **Attachment:** | **Comment:**  - |
| **Dossier submitter response:**  Thank you for your comments. The answers below are organised per PowerPoint slide.  1. We appreciate your support for a dynamic link with CLP to include additional substances in the future which receive relevant harmonised classification. The Dossier Submitter has also proposed a number of provisions (e.g., labelling requirements) which will enable investigation of exposure and risks in the future. Both RO1 and RO2 have a (semi-)quantitative approach to substances where this was possible, e.g., for those with threshold effects. Both restriction options include all CMR substances except those which are classified as CMRs only via the inhalation route (see answer to slide 2) or gaseous only substances, as the latter are not expected to be present in tattoo inks.  2. The CLP criteria for carcinogenicity (CLP guidance, section 3.6.4.1.), says that "state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard". This means if there is any evidence that a substance can cause the hazard through more than one route (e.g. inhalation exposure causes tumours in other organs) then a route of exposure should not be given. A good example of this is the recent discussion of TiO2. In the RAC opinion for TiO2, this was discussed in the following way: "Generally, classification for carcinogenicity does not specify a route of exposure. However, the profile of lung carcinogenicity described for TiO2 is specifically linked to the inhalation route of application. Currently, there is no experimental evidence for TiO2 carcinogenicity for the oral or dermal route of application. TiO2 lung carcinogenicity is associated with inhalation of respirable TiO2 particles. Based on the data available today RAC considers it conclusively proven that no other route of exposure causes the carcinogenicity hazard. Correspondingly, RAC proposes to classify TiO2 as a Category 2 carcinogen, with the hazard statement H351 (inhalation)". The Dossier Submitter has not been able to find any studies with intradermal injection of TiO2. Therefore, inclusion in the restriction of substances that are carcinogenic only via inhalation would only be based upon the precautionary principle. The Dossier Submitter has considered the comment and concludes that there is no need to change the Background Document.  Regarding the concentration limits for RO2, please see comment 1890. We agree that the generic concentration limits in CLP have not been set based on the risk for intradermal exposure. However, for the major impurities either a risk assessment based concentration limit has been set or the concentration limits in the CoE resolution have been adopted.  3. For each reprotoxic substance, individual DNELs were derived. Justifications for Assessment Factors (AFs) are provided in Appendix B3 of Annex A. The AF of 30 relates only to warfarin (CAS 5543-58-8/5543-57-7) which is the substance with the lowest DNEL (except for tributyltin chloride). For warfarin, an AF of 30 was used since toxicity data are derived from human studies (AF=10 for intraspecies differences, and AF=3 as PoD is a LOAEL). See also Table 74 in Appendix B3 of Annex A.  4. Please see reply below to comment #1898 on the same issue.  5. The colourants on Annex IV of the CPR that remain outside the scope of the proposed restriction do not have relevant classification, the majority are not registered and sufficient information for risk assessment is not available. The Dossier Submitter welcomes future assessment of the exposure and risk of the substances outside the scope of the current restriction via proposals for their harmonised classification or other risk management measures including future possible restriction under REACH Annex XVII.  6. RO1 and RO2 propose concentration limits for many impurities listed on Table 3 of the Council of Europe ResAP(2008)1 similar to those in ResAP(2008)1. Notable deviations are proposed where results of quantitative derivation of their limits suggested that different limits are justifiable or when assessments under similar measures have concluded on higher limits (i.e., PAHs).  7.The Dossier Submitter considers the limit effective as colourants have to be used in larger quantities than 0.1 % to provide a colour to the ink, thus the 0.1 % is a practical limit would prevent deliberate use of the colourants. The avoidance of PAAs in relation to azo-colourants are a major concern and the low limit of 5 ppm is also intended to prevent the deliberate use of azo-colourants that have not been listed specifically in the restriction proposal but which could cause PAAs to be present in the ink.  8. According to WHO, endocrine disruption implies both an endocrine mode of action and an adverse effect. In the case of this restriction proposal, the adverse effects potentially caused by phthalates are characterised by reproductive toxicity and thresholds protective for these effects have been established. In addition, on the level of the adverse effect, a distinction between “simple” and “endocrine” reprotoxicants does not appear meaningful and it is unclear on which grounds such a distinction should be made. Moreover, the thresholds for the phthalates have been established and accepted in the restriction proposals (for the phthalates). The phthalates restriction acknowledged the Member State Committee (MSC) has confirmed that these four phthalates are endocrine disruptors related to human health and therefore the risk may be underestimated. However, the Dossier Submitter still assessed reproductive toxicity as a threshold endpoint in this restriction proposal as this will indicate a minimum level of risk where the concern may be higher if there was no threshold due to any ED effects.  9. Thank you for noting an error in the PAH concentration limit in tables 2 and 3 in the restriction report. The typos were corrected as per the proposed limit in sections 1.2.6 and Table 11 in the restriction report and B.10.2 in Annex B, i.e., 0.00005% w/w. The limit for PAHs in this restriction applies to each individual PAHs with harmonised classification as carcinogenic or mutagenic, in the same way as for the eight PAH substances in REACH Annex XVII, entry #50(6), for toys and childcare articles, as written in section 1.2.6.1. This approach is taken to be consistent with previous regulatory decisions. The Dossier Submitter is aware that entry 50 is currently being reviewed and any changes to this limit should be reflected in this restriction.  Many of the tattoo ink impurities are due to the manufacturing process and some can be unavoidable. While the intentional use of these substances is prohibited, this restriction proposes concentration limits for the non-intended presence of small quantities (traces) of prohibited substances stemming from, for example, impurities, the manufacturing process, storage and migration from packaging. This is the same principle used in other existing legislations, such as the CPR.  10. Thank you for the comment but these exemptions are proposed on a number of criteria, not just potential risk, including availability of substitutes. With regard to the dynamic link of the restriction to the CPR, these have been added to demonstrate the positives and negatives of the option. The positives and negatives are explained in section 2.2 of the report (specifically sections 2.2.2 and 2.2.4). However, if it is assessed that the positives outweigh the negatives then it can be applied to the final option chosen by the Commission.  11. Thank you for providing information on the recent publication from European Directorate for the Quality of Medicines and Healthcare (EDQM). An earlier version of the document was taken into account during the dossier development work. |
| **RAC Rapporteurs comments:**  Thank you for your comments and the provided information. They were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response to the comments, and also notes the following:   * RAC agrees with your comment that RO2 (and some RO1) concentration limits seem not to be protective enough, and therefore proposed to modify RO1, for the substances for which both RO1 nor RO2 was considered by RAC as not adequately protective. In proposing RAC modified RO1 concentration limits, practicality issues were also taken into account (including those raised by the Forum), while minimising the risk for human health. * RAC is not mandated to recommend a review clause, but regular updates of the restriction are proposed in the opinion. The updates are expected to allow risk assessment of substances used in tattoo inks for which information on exposure, hazards and risks are inadequate at the present moment (including substances present in internet-purchased tattoo inks, which were not identified in the market surveys considered in this restriction proposal). * Uncertainties related to intradermal route of exposure (compared to oral, dermal or inhalation routes used in standard toxicological studies) are highlighted in RAC opinion, as well as a need for assessing any new information on health risks of intradermally applied chemicals, which are generally lacking at the present moment. Where possible the intradermal route was considered in RAC’s evaluation of risk assessment performed by the Dossier Submitter (i.e. for skin corrosives/irritants and eye damaging/irritative substances) and in the case where data from oral exposure were used for risk assessment, a correction factor for oral absorption was considered and used where relevant (e.g. for copper and barium). * Regarding your comment on CMR substances, RAC agrees that tattoo inks should not contain these substances. This is reflected by risk-based concentration limit proposed for these substances (please see Table 6 *Concentration limits proposed by the Dossier Submitter and RAC*, in RAC opinion). Nevertheless, taking into account the Forum advice (regarding difficulties in enforcement of substances regulated at the limit of detection) and other practicality issues, RAC proposed for these (and some other substances), practical concentration limits (for definition please see RAC opinion), while minimising the risk for human health. * The same approach as above was applied for skin sensitising substances, for which practical concentration limit of 0.001% was proposed by RAC, based on 95th percentile level of protection for strong human skin sensitisers. * Regarding impurities listed on Table 3 of the Council of Europe ResAP(2008)1, deviations from the CLs set in CoE Resap(2008)1 or from those proposed by the Dossier Submitter are justified in RAC opinion (please see Appendix 4 of the opinion, *Derivation of concentration limits*). |
| **SEAC Rapporteurs comments:**  Thank you for the comment. No action is needed on behalf of SEAC as no SEA information is provided. |
| **1898** | **Date:** 2018/03/15 14:25  **Content:**  Scope or restriction option analysis;  Hazard or exposure  **Type:** MemberState  **Country:**  Sweden | **Comment:**  The Swedish Chemicals Agency would like to thank ECHA and the contributing competent authorities for developing this restriction proposal. Although it is a very complex proposal, we find the dossier transparent and easy to read.  We do agree with the prerequisites for the development of the dossier. If a substance is either  1) not permitted in cosmetic products because it is not considered safe to apply on human skin,  2) classified as CMR (cat 1A and 1B), or  3) having a hazard profile that suggests it may lead to skin sensitisation, irritation or corrosion of the skin or eye damage or irritation,  it is reasonable to assume that it is not safe to inject that substance under the skin (or into the eye). We thus agree with restriction proposal and with the finding that a restriction is required on an EU level.  We have the following comments and questions on the dossier:  • We appreciate the dynamic relationship with the Cosmetic Product Regulation (CPR) of RO1, which will ensure that any future changes in Annexes II and IV of the regulation will be taken up in the proposed restriction automatically. We also appreciate the dynamic relationship to the CLP Regulation of both RO1 and RO2 as regards the inclusion of harmonized classification of substances in the restriction. This means that when a substance is harmonized classified for CMR, skin sensitisation, skin corrosion/irritation or eye damage/irritation, it will be covered also by this restriction.  • Regarding RO2, our major concerns relate to the proposed concentration limits for the substances included in the scope:  o In paragraph 1 of RO2, the proposed concentration limits for harmonized classified substances are the generic (or specific) concentration limits specified in the CLP Regulation. As regards substances that are classified for skin corrosion/irritation and skin sensitisation, this proposal may cause problems. For these effects, the concentration limits of the CLP Regulation are, as far as we understand, established in order to prevent from skin reactions following dermal exposure to a substance after direct skin contact for a period of time. Substances in tattoo inks are injected directly into the skin, and thus the protective barrier of the outer skin layer is bypassed. The substances will also remain in the skin for very long times, which may result in (life-) long exposure times. We are therefore concerned that the generic (and specific) concentration limits of CLP, may not be relevant, and that the intended level of protection of the restriction may not be reached. If it is assumed that the generic concentration limits of the CLP Regulation are relevant for substances that are injected intradermally, would it then also be reasonable to argue that the concentration limits for substances in contact with skin should be higher than they are today? Perhaps it would for RO2 be more relevant to propose concentration limits that are for instance 10-fold lower than the concentration limits in the CLP Regulation (assuming a 10 % passage of substances over the outer skin layer)?  o We see a similar problem with the proposed concentration limit of 0.1 % (w/w) for substances included in Annex II to CPR (see paragraph 3 of RO2). A prerequisite for the development of this restriction proposal is that substances that are not permitted in cosmetic skin products are also not safe to inject under the skin. It is therefore unlucky that higher concentration limits are proposed for substances in tattoo inks than in cosmetic products (no concentration limits are given in Annex II of the CPR). May the concentration limits proposed in RO2 have implications on the achievements made so far as regards substitution of substances of concern in cosmetic products? May it be assumed that risks related to the use of substances in cosmetic skin products are overrated since the substances are allowed at higher concentrations in tattoo inks (which are injected under the skin)?  o It is not clear from the scope of RO2 whether the rules of addition, which according to CPL Regulation can be used for corrosive/irritant substances in mixtures, should apply in this restriction.  • In paragraph 1b of RO1, a practical concentration limit of 0.1 % is proposed for substances that are classified for skin sensitisation, skin corrosion/irritation or eye damage/irritation. The reasoning behind the choice of this value is not clearly described in the dossier and could be further clarified.  • Paragraph 2 of RO1 indicates that “tattoo inks and permanent make-up shall not be placed on the market…”. We propose that “permanent make-up” is removed from the sentence since, as we understand from the definition denoted in paragraph 7, a tattoo ink is the mixture used for making a permanent make-up. Thus, a permanent make-up cannot be placed on the market.  • According to the dossier, preservatives are not further examined in the dossier since they are under the scope of the Biocidal Products Regulation (BPR) and subjected to the authorisation regime of the BPR. We would like to point out that the typical assessment of use of preservatives under BPR does not include any risk assessment after injection into the skin. |
| **Dossier submitter response:**  Thank you for your comments and for your support to the general approach of the argumentation for risk, as well as the proposed dynamic link to CLP and the CPR.  Concerning the proposed concentration limits for skin sensitising substances, the Dossier Submitter considered the argument that small concentrations of skin sensitisers would be harmful when injected to the skin. The value of 0.1% w/w in RO1 and the generic or specific concentration limit for classification and labelling for skin sensitisers in RO2 was proposed to prevent deliberate use of the substances.  The concentration limits for elicitation of skin sensitisers in a mixture are given in Table 3.4.6 of the CLP regulation. If a mixture contains a skin sensitiser above the threshold for elicitation it triggers a requirement to label the mixture. The concentration limits for elicitation of skin sensitisers in a mixture are ≥ 0.1% for category 1/1B sensitisers and ≥ 0.01% for category 1A sensitisers. This concentration limit for elicitation is used for the application of the special labelling requirements of section 2.8 of Annex II in the CLP regulation to protect already sensitised individuals. A SDS is required for the mixture containing a component at or above this concentration. Information on the contents of skin sensitizers in mixtures above these concentration limits are thus assumed to be readily available and communicated in the supply chain on a regular basis. For sensitising substances with specific concentration limit lower than 0.1 % or 0.01% for the specific categories respectively, the concentration limit for elicitation should be set at one tenth of the specific concentration limit. These concentration limits are thus be applied in RO2 to assure a better protection without imposing any additional administrative burden on the producers as the information is assumed already to be available and communicated in the supply chain.  The skin sensitisers used in tattoo inks are typically used for preservation (which are regulated under the Biocidal Products Regulation) or as colorants. (<https://www2.mst.dk/Udgiv/publications/2017/06/978-87-93614-06-2.pdf>) For the substances to function as a colourant relative large amounts of the substances are required. The same argument applies to the limit values for skin sensitising substances under RO2. Considering the large amount of substances the producer need to control, a limit value corresponding to the classification limit value would ensure a low cost implementation with respect to compliance control by the producers, because the producer can rely on the SDS. See also our response to comment #1890 related to the use of CLP generic concentration limits as it applied to CPR and I/C substances. The proposed restriction also imposes limits to the use of preservatives with hazardous properties of relevance for exposure via tattoos (in addition to the BPR). See also comment #1913.  The Dossier Submitter also deleted the erroneous reference to permanent make-up in the wording of the restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comments and the provided information, which were considered in the development of RAC opinion. RAC supports the Dossier Submitter’s response to the comments.  Regarding the CL for skin sensitisers, please see also the fifth bullet in RAC response to comment #1894 and RAC opinion. For the substances listed in Annex II to the CPR, the lowest CL set for groups of substances with harmonised classification included in the Annex II is proposed (i.e. the practical limit set for CMs of 0.00005%). Namely, RAC considered RO1 unfavourable regarding enforceability and RO2 inadequately protective. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. No action is needed on behalf of SEAC as no SEA information is provided. |
| **1903** | **Date:** 2018/05/01 10:22  **Content:**  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** Tattoo and piercing education/ SRT  **Org. country:** Sweden | **Comment:**  I think in a general that the work done to greatly improve resap 2008 is benefitial for the practitioner and the consumer. However i see a great gap in the way the law an legistration is applied in the EU zone when import of colourants and ink still is avalible for the general public. Nothing has been done to stop the home market and tattooing in non registred enviroments, and its still not illigal to acctually give someone for example HEP C Or B by tattooing in a home enviroment. So i think That provides for the resistance that the legistration is meeting from the tattoo community.  Even if you forbid the content of colourants, unfortunately many tattooers will be able to buy these and use it any way, they will just be sold as "artist material" rather then listed as tattoo inks. I also think that ECHA has a huge responsibility to use the data where it makes the most sence.  Ive been a part of this work for a long time now and im very disturbed over the fact that you put so much energy in to trying prove that tattooing is dangerous, well it was alot more dangerous 50 years ago. In fact, shouldnt Lasertreatment be adressed as the more dangerous practice? Why are not the public warned about laser? if tattooing and getting this pigment inserted in the body is as dangerous as the data says, why isnt Laser considered to be 10 times as dangerous? With a laser treatment a 100% of the ink is supposevly transported thru the body system, should not that be considered a much greater risc of cancer or allergy?  The legislation is a great tool, but it should be taken in to grave consideration to use it in the right way. Right now its used only in few prespectives, it should apply for Laser treatment as well. And the fact that there is a high nr of people getting reactions from tattoo ink also more show that the typical human is getting more and more sensitive in a generall, probably from for example the textile industry, more exposure for chemichals in food, beauty products and other type of exposure. The tattoo industry needs a better tool for education, as well as the PMU industry and other similar trades.  The practitioner needs to have knowledge on how allergys work, how the skin works and how bacteria works.  Forbidding inks will not help the fact that EU is allowing anybody to be a practitioner regardless of skills or knowledge. The legislation it self will not stop the fact that EU is promoting free market, and allowing dangerous substances to flow over the boarder via internet.  These reflections is based on the fact that i meet a lot of practitioners in a educational situation. We get a lot of god intel when we do the Hygiene courses and my experience is that education is the most effective tool to reach the practitioners and also effect their consumer behaviour, wich is the key to get them to use the better alternative for inks and other material.  Sweden is the first country in the world to launge a journey mans certificate with a possiblity to reach master level. This is the first trade certificate for tattooers. This is our way to try to meke a positive change. We hope that within 10 years it will be customary to have this certificate, that also forces the practitioner to keep a certain standard, follow legislations and provide a safe way to practice. |
| **Dossier submitter response:**  Thank you for your comments.  The Dossier Submitter recognises that the safety of tattoo practices depend on a number of factors, in addition to the regulation of the chemical composition of tattoo inks that can be addressed under REACH. Notably, the Dossier Submitter considered:   * the reflections on the improvement of ResAP 2008(1) and agree that to some extent improvement was required, * the reflections about professional and private tattoo artists. However, this issue cannot be regulated within the scope of REACH. The individual Member States have the competence to regulate this if they may wish to do so, * the reflection on microbiological risks, communicable diseases and hygiene. While these issues are of paramount importance for safe tattoo practices, these must be considered under national or other EU-wide legislation, as REACH is not the appropriate legal instrument for addressing these risks, * the reflection on compliance. The information provided is seen as a request from the tattoo community to the MS to make sure the regulation is enforced. It should be noted that trade via the internet is also subject to surveillance, * the reflection on risk due to tattooing and the development of the risk over time. From the JRC reports, the Dossier Submitter also got the impression that colourants based on hazardous heavy metals have been substituted, if that is what the comment is referring to. In general the hazard assessments of the chemicals considered are based on animal testing results and not epidemiological observation. Since tattooing is becoming more and more popular, the idea of applying the results of animal testing is to avoid future widespread hazardous effects due to tattooing. The dossier does not claim that tattooing is dangerous, only that adverse effects have been observed from tattooing as such and from specific chemicals observed in tattoo inks. Further, the dossier aims to provide the same protection for the consumer as is provided in respect to cosmetic products, * the reflections on laser treatment. The Dossier Submitter agrees that laser treatment may be problematic. Prohibition or recommendations for the use of laser instrument is outside the scope of the restriction, * the reflection on sources of exposure to sensitising substances. However, the information provided does not give rise to a re-examination of tattoo inks being of minor importance when it comes to being exposed to sensitising substances, * the reflection of the role of education. The Dossier Submitter agrees that education will have a positive effect on compliance. However, the Dossier Submitter considers that it can be better addressed at national level, similar to the regulation of other professions. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC supports the Dossier Submitter’s response to the comments, and also notes that uncertainties related to health risks of chemicals and their degradation products during laser removal are highlighted in RAC opinion. Namely, although the Dossier Submitter has taken into account laser decomposition of azo colourants, toxicological data for risk assessment of chemicals related to tattoo’s laser removal are generally very limited. This aspect is expected to be assessed in updates of the restriction, when more data become available. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. We agree with the response provided by the Dossier Submitter. |
| **1904** | **Date:** 2018/05/25 21:44  **Content:**  Scope or restriction option analysis;#Hazard or exposure;#Information on alternatives;#Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** Health and Environment Alliance (HEAL) + European Environmental Bureau (EEB)  **Org. country:** Belgium  **Company name confidential:** False  **Attachment:** | **Comment:**  Scope - Components covered by the restriction proposal  The Health and Environment Alliance (HEAL) and the European Environmental Bureau (EEB) would welcome clarifications about the scope of the restriction. According to the tattoo industry, a typical tattoo ink comprises of:  • up to 3 preservatives (which at present also include those not on the positive list of preservatives allowed in cosmetics);  • 1 astringent;  • up to 3 viscosity regulators;  • up to 3 solvents;  • water, and up to 6 pigments (added as powder).  [See Council of Europe EDQM’s 2017 report: “Tattoo inks should be safe for consumers and have no adverse effects on human health@, p. 25 available for download here: https://www.edqm.eu/en/tattoos-and-permanent-make ]  Whether all these components are in the scope of the restriction is unclear, nor is it clear whether labeling requirements apply to these. Preservatives appear to be excluded, for example, even though that category can include formaldehyde [public consultation, comment 1894].  Scope - Workers and inhalation  Workers (tattoo artists and permanent make up applicators) are excluded from the scope of the restriction, since the exposure of concern is intradermal. Similarly, substances identified as carcinogenic or mutagenic by inhalation only -- e.g., TiO2 -- are excluded from the restriction, since (a) inhalation is expected to be a minor route for tattoo recepients, and (b) tattoo artists, for whom inhalation might contribute a significant exposure, are excluded from the scope.  HEAL and the EEB concur with the comments made by Belgium (in response to the public consultation) that intradermal exposure is very poorly understood and has direct and obvious exposure, and that ingestion isn’t necessarily or obviously predictive of CM outcomes from intradermal exposure, and thus it is unscientific and unwise to exclude data from inhalation.  HEAL and the EEB support the inclusion of workers (tattoo artists, and possibly manufacturers) in the scope. There is so much overlap in evaluation of substances between tatto artists and tattoo recipients that it would be shortsighted to exclude workers who use these same chemicals literally every day.  • At a mínimum, exposures of and risks for workers need to be evaluated. Whether zero/de minimus risk is found or whether the risk is uncontrolled, then the restriction options can be adjusted appropriately.  • Estimating workers’ exposure is a DRAMATICALLY simpler a problem than estimating tattoo recipients’ exposure, since this is a straightforward risk assessment problem involving inhalation and dermal exposures.  • The proposed restriction should largely eliminate risks to all nonthreshold compounds for all intents and purposes, and workers’ exposures are presumably much lower (although of a very different route).  • The only major change in including workers is that those substances that are “CMR by inhalation only” would not be excluded from the scope. Not excluding this subset would help protecting workers from known/identified hazards, and also offer more protection for tattoo recepients in any cases where inhalation toxicity is predictive of intradermal toxicity.  Scope - General focus of the restriction on local effects -  HEAL and the EEB do not understand the proposed focus on local effects. The assumption seems to be that the main effects of tattoo inks are local, acute, and skin-related - driven mostly by the fact that most reporting is for local, acute, and skin-related effects. Almost no data is available for later or systemic problems, whereas we know there is exposure via tattoo/permanent make up (T/PMU) inks to substances that we expect would cause such problems.  Reprotoxicants – Hazard or exposure  HEAL and the EEB are concerned about the proposed approach to reproductive and developmental toxicants in this restriction proposal, which assumes that all reprotox are threshold chemicals: “quantitative risk assessments were made for a number of threshold substances, such as substances toxic to reproduction...” [RP p3].  We would welcome proper justification for this logic. Any use of a nonthreshold substance carries some risk by definition. The risks on the population level may be “acceptable”, but that does not justify labeling as “safe” a compound that carries individual risk.  Endocrine disruption – Hazard or exposure  Considering that no specific classification is given for endocrine disrupting substances (EDCs) under the proposed options, HEAL and the EEB are concerned that EDCs would most would probably be considered in the reprotoxicants’ category.  The RP treats the “reprotoxicants only” category as a group, using the lowest derived DNEL in the risk assessment of the group of reprotoxic substances. However, the lowest DNEL, for tributyltin, was considered to be “exceptionally low” and “highly uncertain”, and was ignored as an outlier when setting the DNEL for the reprotoxicant group. The RP admits that “underestimation may have occurred for potent reprotoxic substances” falling below the DNEL adopted for the reprotox group, “as for example for tributyltin chloride”. [RP p 84] This appears to be a deliberate choice to underestimate the possible effects of tributyltin, and an illustrative example of the problems arising from the approach of using one DNEL or risk assessment for a group. Further research on specific reprotoxicant substances would be helpful in understanding the RP.  Finally, the RP does not consider additive effects, which are particularly likely with EDCs that may act through one pathway or by crosstalk between pathways. A single substance in a T/PMU ink at the allowable concentration would in principle be at or below the appropriate DNEL, contributing a zero risk. However, if several substances are present at the allowable concentration, and depending on their mode of action, either the total concentration of similar-acting substances or the total risk could easily exceed thresholds. The RP briefly acknowledges this problem [RP p 85], as well as the related problem of non-tattoo sources of reprotoxicants that might contributed to combined effects, but does not offer a solution. HEAL and the EEB would welcomed further elaboration on these points.  Request for exemptions  HEAL and the EEB are concerned that the proposal includes many derogations for substances with no alternative (e.g., Pigment Green 7 and Pigment Blue15:3). ECHA’s public consultation requests information on these and other pigments; the industry responses (in public comments) are predictable, asserting that no alternatives are available. However, better information on alternatives may be available from the tattooing community and does not seem to be included so far.  The RP’s “main concern” with RO1 is that the presence of unintentional impurities would mean that some existing inks could no longer be used. [RP p59] However, according to HEAL and the EEB, the point of the restriction should be the following: any product that poses a health risk to the consumer, intentionally or otherwise, should be withdrawn or reformulated.  Moreover, in the case of tattooing, the non-use scenario is always a plausible alternative. When manufacturers applied for authorisation to use certain pigments for road paints, they were able to cite legal requirements for those specific colors when arguing that there were no alternatives. There is no equivalent requirement in tattooing for any specific pigment or ingredient.  Lack of information on presence or absence of alternatives is the major data gap.  Since manufacturers will have little incentive to identify these, this may require research at the user level (i.e., experienced and knowledgable tattoo artists).  General responses  According to HEAL and the EEB, the goal for this restriction should follow from the Council of Europe EDQM’s 2017 report: “Tattoo inks should be safe for consumers and have no adverse effects on human health”. [EDQM p29, available for download here: https://www.edqm.eu/en/tattoos-and-permanent-make ]  In this regard, we support the comments made by Belgium that “the submitted dossier fails to capture the entire CoE ResAP(2003) (and CoE ResAP(2008)1) instrument that is in force into numerous MSs (and other countries) and, in particular, we identified substances classified CMRs that are not captured in the list of banned substances in the present Restriction dossier.” [public consultation, comment 1894]  HEAL and the EEB support a precautionary aproach to this restriction, especially when considering the following points:  • the wide range of substances included;  • the complex nature of tattoo inks;  • the fact that these substances can be assumed to be 100% bioavailable;  • the known migration of tattoo inks from the tattoo site;  • The very high prevalence of hazardous substances in tattoo inks: An analysis in 2014/2015 found that “about 51% of the tattoo inks on the Swedish market contained forbidden substances or too high levels of contaminants” . [public consultation, comment 1890]  • the very poor level of toxicity data on very many of these substances;  • and especially the very poor data available on the intradermal route;  • the very widespread use of tattooing (the RP estimates that 81 million people in EEA31 will have at least one tattoo by 2021 [RP 47]  • the extremely high prevalence (68%) of skin problems among tattooed people [Klugl et al, in ECHA’s information note]  • the unknown but apparently very high (6.6%) occurance of systemic reactions in tattooed people [Klugl et al, in ECHA’s Info Note]  Concentrations: HEAL and the EEB support Belgium’s comments that “the (OECD) test basis for deriving these [CLP concentration] limits are not adequate for intradermal use of these substances”, and, more specifically, that the uncertainty factors used in the analysis must be much larger in order to account for the lack of data on the intradermal route. [public consultation, comment 1894]  According to HEAL and the EEB, the restriction should not give a stamp of approval for safety of inks when not demonstrably safe. However we know that T/PMU inks that meet the terms of the restriction will be thought to be “safe”, and we can’t justify labeling them as “safe” if they carry a risk to that individual. Especially because substances are literally injected into the body and that compliance will be very difficult to monitor, applying the “no data, no market” principle will be very important. In this regard, we are puzzled by the grouping approaches laid out in the RP [p30]:  • non-threshold substances were evaluated qualitatively;  • threshold substances were evaluated quantitatively by deriving a DNEL;  • some non-threshold substances were evaluated semi-quantitatively with a DMEL (derived mimimal effect level).  In particular, the last category is the most troubling. Non-threshold substances should be limited to zero (or below LOD) only. Threshold substances should be permitted only in concentrations set by rigorously supported DNELs. Moreover, threshold substances where no reliable DNEL can be derived should not be permitted.  Comments on the 2 restriction options:  About RO2:  The relatively high concentration limits -- including for SVHCs -- laid out by RO2 make that restriction option unacceptable according to HEAL and the EEB. RO2 would simplify testing requirements and enforcement, but is simply not protective enough.  About RO1: According to HEAL and the EEB, RO1 looks better in comparison to RO2 but is still not a strong regulation. In this regard, we fully support the comments made by Belgium that RO1 “lacks of ambition and should be subject to supplemental provisions”. [public consultation, comment 1894]  According to HEAL and the EEB, RO1 would only be aceptable if it is strengthened, despite the expected high enforcement costs.  Comments on labelling approach proposed in the RP:  According to HEAL and the EEB, the labeling approach outlined in the RP is a good start in order to increase the information available to consumers, but could be strengthened. For example,  • Labels should specifically and clearly indicate intended use as T/PMU.  • Products that do not meet the restriction, but which might reasonably be used in T/PMU, should bear a specific label indicating that they should not be used in T/PMU. For example, any cosmetics inks/dyes not meeting the restriction should bear a clear label.  • There should be separate annotations, including use of standard CLP/GHS symbols and text, for any substances with any harmonised classification.  • There should be separate annotations for any substance within the scope of the restriction that is below the concentration thresholds.8  • In some cases -- e.g., with an allowable amount of a nonthreshold substance -- an intermediate label could be used as a warning (e.g., “intended for tattoo use, but safety not assured”). |
| **Dossier submitter response:**  Thank you for your comments.  *Scope*: Components covered by the restriction proposal: The type of ingredients included in tattoo inks are discussed in section D.2.1 of Annex D. We agree that the definitions could be modified so as to show that other ingredients, such as viscosity regulators and others also are included in the definition of auxiliary ingredients. We propose to change the wording of the definition of auxiliary ingredients in the Background Document, by including "amongst others" in the definition to make this clearer. However, although preservatives are added to tattoo inks, and as such are auxiliary ingredients, they are under the scope of the Biocidal Products Regulation (BPR). This category of substances is therefore not further examined in the restriction proposal as the continuing use of these substances is subject to the authorisation regime of the BPR. However, it should be noted that certain preservatives would be restricted for use in tattoo inks due to their harmonised classification (e.g., formaldehyde, 2-phenoxyethanol, triclosan, 3-iodo-2-propynyl butylcarbamate).  The labelling requirements apply to all substances in the tattoo inks, regardless of function.  *Scope – Workers and inhalation:* Please see answer to comment #1894.  *Scope - General focus of the restriction on local effects:* The restriction proposal clearly covers substances other than those causing local effects, as all classified CMRs are included, for example, as well as substances included in CPR Annex II. If you mean that the health impact assessment only considers local effects then you are correct. This focus was because this was where the information on benefits was available. However, the Dossier also explains there may also be other benefits from reducing systemic exposure to tattoo inks. See section D.6 of the Annex to the Background Document.  *Reprotoxicants – Hazard or exposure:* The concern regarding additive effects is acknowledged. One possible solution could consist of applying a concentration limit to the sum of all reprotoxic substances in a given ink rather than to each substance alone. Nevertheless, the “group DNEL” derived for all reproductive toxicants was based on the lowest DNEL of the group (excluding the value for tributyltin chloride) assuming that the individual DNELs for most reprotoxicants will be considerably higher, which provides an additional margin of safety.  *Endocrine disruption – Hazard or exposure*: Please see answer to comment #1894.  Regarding tri-n-butyltin, the DNEL is based on findings in one particular and rarely used mouse strain (Kun Ming). The resulting DNEL is orders of magnitude lower than in other studies on rats or different mouse strains. In addition, the studies in Kun Ming mice did not follow guidelines and used a low number of animals. In addition, enforcement at such a low level could be a problem (the current Annex XVII entry 20 foresees a 0.1% concentration limit (w/w of tin) in articles.  *Request for exemptions:* The proposed exemptions were evaluated on the basis of effectiveness, practicality and monitorability, similar to the evaluation of the proposed restriction options. This included considerations such as risk, alternatives and other socio-economic considerations. A number of pigments were proposed for derogations first and foremost on the basis of inability to demonstrate risk to human health on the basis of currently available information. The lack of alternatives to Pigment Blue15 and (a less risky alternative) to Pigment Green 7 have been identified in previous discussions with stakeholder, including in the framework of consultations for the preparation of the JRC reports (see JRC 2015a, JRC 2015b, JRC 2016a, JRC 2016b), the ECHA call for evidence, surveys and interviews conducted in preparation of the restriction proposal. These conclusions were expressly tested again during the PC (questions 2, 3, and 5). The submissions in response to these questions can be seen in this document.  A “non-use” scenario (i.e., an effective a ban on tattooing as we understand you are implying) may be a valid scenario in the event of complete ban of the substances in the scope of this proposal. In this case the benefits for human health would be higher, the cost for industry would also be higher as well as the negative effects on individuals who find tattooing an important expression of their personality and an important contributor to improved self-image and confidence.  *Information on alternatives:* Information on alternatives was gathered during extensive consultation with stakeholders including tattoo artists was undertaken by the JRC (see JRC 2015a, JRC 2015b, JRC 2016a, JRC 2016b), the ECHA call for evidence, surveys (of tattoo artist and formulators) and interviews (of tattoo artists and formulators). See Annex F for further information on consultations conducted in preparation of the restriction proposal.  *General responses:* Thank you for your support for the precautionary approach and for the bullet points outlined in your comment which are also key findings and assumptions employed in the submitted dossier. For the points raised in comment #1894, please see the response to that comment.  *Concentrations:* See response 1898 related to the concentration limits  *Comments on the 2 restriction options:* See response 1898  *Comments on labelling approach:* See response 1890 related to the labelling requirements. In addition, related to your first bullet point this is already required by the proposal; for the 2nd bullet point, the SDS which accompanies the substances used in tattoo inks should contain the uses advised against; for the 3rd bullet point, CLP applies in addition to the requirements in the restriction proposal, the supplementary information (such as the requirement for all hazardous substances, regardless of concentration, be shown on the label) is to increase the level of protection; for bullet point 4, as stated, all hazardous substances are required on the label, the reference to annotations is not explained in detail and therefore is not addressed; on bullet point 5: Regarding RO2, please see response #1890. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC supports the Dossier Submitter’s response to the comments.  Regarding pigments proposed by the Dossier Submitter to be exempted (21 colourants banned for use in hair dyes but allowed for all other cosmetic products), RAC does not support derogation for 19 non-phthalocyanine pigments, since in available literature and other information sources there is a lack of adequate information on their hazard properties and risk for human health, and during the Call for Evidence and Public Consultation no concern was raised regarding non-derogation of these 19 colourants.  On the other hand, RAC acknowledges that during the Call for Evidence and the Public Consultation a major concern was raised that two phthalocyanine pigments, Pigment Blue 15:3 and Pigment Green 7, are essential for tattooing, without technically adequate alternatives. RAC is also aware that alternatives with more concerning hazard profile are presently used in blue and green inks (please see Appendix B.12 in the Background Document). Taking into account these considerations, and since the data on health hazard and risk profile of these two pigments, as well as data on health hazards and risks and technical feasibility of potential alternatives, are too deficient (please see RAC opinion, section B.3.1.3, and Appendix B.12 in the Background Document), RAC remains neutral, i.e. RAC cannot conclude on derogation of these two phthalocyanine pigments. |
| **SEAC Rapporteurs comments:**  We agree with the response provided by the Dossier Submitter. Regarding Pigment Green 7 and Blue 15:3; please see comment 1883 for further details. |
| **1905** | **Date:** 2018/05/30 22:27  **Content:**  Scope or restriction option analysis  **Type:** Individual  **Country:**  Austria | **Comment:**  In generally it is a good idea to regulate tattoo and PMU inks but it has to be feasible. |
| **Answer to specific info request 1:**  The limit of arsenic with 0,0000008 % w/w is not realistic as you show in the table 4.39 "Metals present in tattoo and PMU inks". The ResAp2008\_1 limit of arsenic was 0,0002 % w/w and the range of detected arsenic is in between 0,00002 and 0,006 %. I have been searching for a titanium dioxide pigment with low impurity profile and the lowest concentration of arsenic was 0.000013 %. I think this is one of the lowest values ever detected for a CI 77891. That means in case of setting the limit for arsenic as low as you want to it will have a total ban of white inks or the use of titanium dioxide in inks as we would not be able to produce any white color. I think in generally that the limit for arsenic will hit a lot of possible inorganic pigments. The titanium dioxide I was testing is proposed to be a high purity rutile pigment for cosmetics. |
| **Answer to specific info request 2:**  Pigment Blue15:3 and Pigment Green 7 are the best pigments for tattooing. There is no alternative existing and there will be no alternativ to this pigments developed as there is no R&D for new pigments in the conventional industry. |
| **Dossier submitter response:**  Thank you for your comment and the information in response to question 2. In response to question 1, the limit for arsenic was set on the basis of risk, taking into account the detection limits related to various monitoring methods (see table 113 in Appendix B.6 to Annex B). However, we understand your concerns and the Dossier Submitter is working with RAC and SEAC to identify relevant limits taking into account the submitted comments during the Public Consultation. |
| **RAC Rapporteurs comments:**  Thank you for your comments and provided information, which were considered in the development of RAC opinion.  Taking into account your comment, in addition to risk-based CL for arsenic (“should not contain”), RAC proposed a practical limit of 0.00005%, i.e. the same CL that is proposed by RAC for other carcinogenic/mutagenic substances. This value is supported by the range of concentration limits of 0.00002% to 0.00003% set for rice for adult EU population (Regulation EU 2015/1006).  Regarding derogation of Pigment Blue 15:3 and Pigment Green 7 proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. |
| **SEAC Rapporteurs comments:**  We agree with the response provided by the Dossier Submitter. SEAC will reflect on the feasibility of the proposed limits as appropriate. Regarding Pigment Green 7 and Blue 15:3; please see comment 1883 for further details. |
| **1910** | **Date:** 2018/06/11 11:47  **Content:**  Hazard or exposure;Baseline;Information on alternatives;Information on costs  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** ANSES  **Org. country:** France  **Attachment:** | **Comment:**  please see attached xls document |
| **Dossier submitter response:**  Thank you for your comments.  *Hazard or exposure:* The proposed concentration limit for PAH substances with carcinogenic or mutagenic harmonised classification is 0.00005% w/w. See section 1.2.6.1. Only 2,6-xylidine has been included in the scope of the restriction proposal since 2,4-xylidine does not have a harmonised classification (e.g., as carcinogenic or skin sensitiser).  *Hazard or exposure 1.2.6.2:* The concentration limit for reprotoxic substances of 0.0014% w/w was calculated based on the lowest DNEL of all “reprotoxic only” substances (the most potent of which is warfarin which is taken as a representative of a potent reprotoxic substance) as described in table 24 on page 70.  *Regarding your comment on RO2 please see table 3 in BD:* “Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than the relevant generic concentration limit…”  *Scope or restriction options:* Thank you for your support for RO1. Paragraph 5 is included to highlight the obligation for tattooist to ensure compliance of the inks used in tattoo procedures. In both RO1 and RO2 substances in Table A are not allowed if “exceeding specified the concentration limits”.  *Baseline:* Annex C discusses the uncertainty related to the estimation of the number of people with PMU and that the amount of PMU ink on the market is estimated on the basis of information from stakeholders such as manufacturers and JRC 2015b, therefore, the volume of PMU ink on the market. The main scenario presented in Table 17 assumes that the same number of people who get tattoos today will continue to get tattooed annually during the study period. This assumption is also made for the number of people who get tattooed for the first time, i.e., there total number is assumed to be similar every year, therefore, the overall prevalence (the total number of people with tattoos in the population) would increase.  *Alternatives:* The Dossier Submitter supports your view that regrettable substitution should be avoided. Therefore, a grouped approach is proposed for this restriction, where all substances with similar hazard and risk are proposed to be restricted. Editorial change was made in section D.2.3.1 to reflect your comment.  *Costs:* The section on enforcement costs for enforcement authorities assumes that the authorities will be able to allocate similar budgets for both restriction options. Compliance costs for industry (including testing and analytical costs) are estimated separately. There, the Dossier Submitter anticipated that the compliance costs for RO2 will be somewhat lower, also for the reasons you point out.  *Benefits:* The section on the social costs of adverse tattoo reactions recognises that productivity related costs (absences or efficiency loss) are not included in the estimates.  *Other:* The Dossier Submitter evaluated a number of (hazard and risk, availability of alternatives, socio-economic impacts, enforceability, practicality, monitorablity and other) elements. As a result two restriction options were proposed. The analysis and the evaluation of the effectiveness, practicality and monitorability of RO1 and RO2 are detailed in the dossier. Regarding RO2, please see response #1890.  *Submitted French Data:* The Dossier Submitter also welcomes the French surveillance and biomonitoring data submitted. The risk assessment in this proposal has addressed the exposure via tattooing only. As shown by the data submitted by ANSES here and e.g. the DK/ECHA restriction proposal on phthalates (including biomonitoring data) there are other potential sources of exposure of the general population for the four phthalates and this can be assumed for the majority of the compounds in this proposal. It should be noted, however, that under RO1 the proposed concentration limit for Repr. Cat 1A and 1B substances is lower than it would be for DBP (as the phthalate with the lowest DNEL) and in RO2 the proposed limits for the two phthalates DBP and DEHP are lower than for other reprotoxic substances covered by the 0.3% limit.  *Baseline B.9.3.2.1:* Regarding the comment on potentially smaller size of PMU in comparison to tattoos the Dossier Submitter considers this assumption by ANSES as plausible but has no data to substantiate or quantify this. Since the scope of the proposal shall cover both tattoos and PMU the more conservative assumption (larger covered skin area) should be considered for the restriction of substances in tattoos and permanent make up. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC supports the Dossier Submitter’s response to the comments.  Regarding your question “How can it be acceptable to propose concentration limits that are higher than those already enforced by member state national legislation?”, RAC also notes that deviations from the CLs set in CoE Resap(2008)1 or from those proposed by the Dossier Submitter are justified in RAC opinion, and, as the Dossier Submitter already stated in their response, they include both risk-based and practical considerations (please see Table 6 *Concentration limits proposed by the Dossier Submitter and RAC*, and Appendix 4: Derivation of concentration limits in RAC opinion). |
| **SEAC Rapporteurs comments:**  We agree with the response provided by the Dossier Submitter. As regards enforcement costs SEAC will take into account the arguments provided. |
| **1911** | **Date:** 2018/06/12 16:42  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Regional or local authority  **Org. name:** Bayerisches Staatsministerium für Umwelt und Verbraucherschutz  **Org. country:** Germany | **Comment:**  RESTRICTION REPORT  Proposed restriction  RO1:  rechte Spalte  zu 1.a.i.:  CM-Stoffe 1A, 1B und 2, insbesondere genotoxische Stoffe:  Es fehlt eine Anforderung, dass genotoxische Stoffe wie z.B. Nitrosamine nur in Spuren geduldet werden, die technisch unvermeidbar und gesundheitlich unbedenklich sind, da für genotoxische Substanzen kein sicherer Grenzwert festgesetzt werden kann (vgl. Vorgaben der VO (EG)  Nr. 1223/2009).  zu 1.a.ii.:  Liste der für kosmetische Mittel verbotenen Stoffe; wir verweisen hierzu auf die Anmerkungen zu den CM-Stoffen im Hinblick auf die Ergänzung von technisch unvermeidbaren und gesundheitlich unbedenklichen Spuren, die geduldet werden.  zu 1.a.iii.:  Farbstoffe mit eingeschränktem Anwendungsbereich für kosmetische Mittel - Für die Praxis ergibt sich bei der Formulierung „shall not contain“ („sollen nicht enthalten sein“) das Problem, dass der einzufordernde Grenzwert von der Nachweisgrenze des eingesetzten Analysenverfahrens abhängt.  zu 1. b.:  Ein genereller Grenzwert von 0,1 % für sensibilisierende Stoffe der Kategorie 1, 1A und 1B ist nach unserer Auffassung nicht akzeptabel. Als Vergleich können die Regulierungen für Isothiazolinone in kosmetischen Mitteln herangezogen werden. Hier ist die Verwendung von Chlormethyl- und Methylisothiazolinonen in kosmetischen Mitteln, die auf der Haut verbleiben, nicht mehr erlaubt (früherer Grenzwert: 0,0015 %). Benzisothiazolinon mit der Einstufung „Skin Sens. 1“ wurde als Konservierungsstoff in kosmetischen Mitteln mit einem vorgeschlagenen Grenzwert von 0,01 % aufgrund seiner sensibilisierenden Eigenschaft nicht zugelassen. Ein Grenzwert von 0,1 % (= 1000 mg/ kg) würde deutlich über dem für kosmetische Mittel abgelehnten Grenzwert liegen.  zu 1.c.:  Hier werden generelle Grenzwerte für reproduktionstoxische Stoffe festgelegt. Wir verweisen in diesem Zusammenhang auf die Vorgaben für die beiden als „Repr. 1B“ eingestuften und in Tabelle A explizit genannten Phthalate „Bis(2-  ethylhexyl) phthalate“ und „Dibutyl phthalate“ mit den Grenzwerten von 0,009 und 0,07 % w/w, die deutlich höher liegen als die hier getroffene Festlegung. Diese Sonderregelung ist nicht nachvollziehbar.  zu 2.:  Hier an dieser Stelle wird die Produktkategorie “permanent make-up” zusätzlich aufgeführt. An den meisten anderen Stellen wird immer nur von “tattoo inks” gesprochen. Es wäre empfehlenswert aus Gründen der Konsistenz diese Produktkategorie immer in Verbindung mit den Tätowierfarben anzuführen. Alternativ könnte im Vorwort ein Hinweis aufgenommen werden, dass der Begriff „Tattoo inks“ auch die Permanent-Make-up-Farben mit einschließt.  Der für die polyzyklischen aromatischen Kohlenwasserstoffe (PAK) aufgeführte Grenzwert von 0,0005 % w/w (= 5 mg/kg) scheint falsch zu sein. An anderer Stelle des Dokuments wird ein Grenzwert von 0.00005% w/w (= 0,5 mg/kg)gefordert (siehe Seite 37: „For the PAHs, under both RO1 and RO2, the Dossier Submitter proposes the same concentration limit for all PAHs with harmonised classification as CM as for the eight PAH substances in REACH Annex XVII, entry #50 (6), for toys and childcare articles, namely: 0.00005% w/w).  Der Vorschlag für die Regulierung von PAKs bezieht sich nur mehr auf die folgenden Stoffe:  (a) Benzo[a]pyrene (BaP) (CAS No 50-32-8)  (b) Benzo[e]pyrene (BeP) (CAS No 192-97-2)  (c) Benzo[a]anthracene (BaA) (CAS No 56-55-3)  (d) Chrysen (CHR) (CAS No 218-01-9)  (e) Benzo[b]fluoranthene (BbFA) (CAS No 205-99-2)  (f) Benzo[j]fluoranthene (BjFA) (CAS No 205-82-3)  (g) Benzo[k]fluoranthene (BkFA) (CAS No 207-08-9)  (h) Dibenzo[a,h]anthracene (DBAhA) (CAS No 53-70-3)  Die in der Europarats-Resolution genannten Grenzwerte für die Summe an PAKs von 0,5 mg/kg und für Benz(a)pyren von 5 μg/kg wurden damit nicht übernommen. Für den Summenwert für PAKs aus der Europarats-Resolution wurde (ungeachtet der Klassifizierung) vom Bundesinstitut für Risikobewertung  (BfR) eine Stellungnahme abgegeben, dass höhere Summengehalte als 0,5 mg/kg in Tätowierfarben geeignet sind, die menschliche Gesundheit zu schädigen (siehe http://www.bfr.bund.de/cm/343/taetowiermittel-koennen-krebserregendepak-enthalten.pdf „Tätowiermittel können krebserregende PAK enthalten“; Stellungnahme Nr. 044/2011 des BfR vom 1. Juli 2011).  Hier gibt es nur noch eine Erfassung der als „karzinogen“ oder „mutagen“ mit den Klassen 1A, 1B und 2 eingestuften PAKs, für die im Einzelnen ein Grenzwert von 0,5 mg/kg festgelegt werden soll (sofern diese Vorgabe entsprechend korrigiert wird). Damit wurde das Stoffspektrum deutlich reduziert und die Grenzwerte deutlich angehoben. Für Benz(a)pyren bedeutet dies eine Erhöhung des Wertes von 5 μg/kg auf 500 μg/kg (unter der Voraussetzung, dass der Angabefehler in der Restriktion korrigiert wird; ansonsten wäre es Faktor 1000).  zu 3.:  Diese Regulierung wird begrüßt, da sie die Farbstoffe, die nach Anhang II der VO (EG) Nr. 1223/2009 zur Verwendung als Haarfarbstoffe verboten, jedoch zur Verwendung als Farbstoffe in kosmetischen Mitteln uneingeschränkt erlaubt sind, vom Verwendungsverbot ausnimmt und daher Rechtssicherheit schafft (bisherige Doppelregulierung als verboten und gleichzeitig nicht verboten). Diese  Doppelregulierung hat dazu geführt, dass viele Farbenhersteller zu toxikologisch bedenklicheren, aber nicht regulierten Pigmenten ausgewichen sind.  zu 4.:  Hier empfehlen wir die Einfügung eines Hinweises, dass sich die Vorgaben immer auf den jeweils aktuellen Stand der VO (EG) Nr. 1223/2009 beziehen. Dieser Hinweis könnte jedoch auch grundsätzlich an einer anderen, allgemeinen Stelle  erfolgen.  zu 5.:  Die bisher genannten Restriktionen haben sich nur auf die Bereitstellung der Farben auf dem Markt bezogen; hier wird das Verbot auch auf die Verwendung zum Tätowieren ausgedehnt.  zu 6.:  Diese Kennzeichnungsvorgaben beinhalten keine Volldeklaration mehr. Dieser Vorschlag zur Deklaration bedeutet, dass viele in Tätowierfarben eingesetzte  Stoffe wie z.B. Pigmente oder Konservierungsstoffe nicht deklariert werden müssten, wenn sie offiziell nicht als Gefahrstoffe eingestuft sind oder die Einstufung nach Chemikalienrecht so niedrig ist, dass eine Deklaration nicht  notwendig wäre.  Dies ist nicht nur intransparent für alle beteiligten Kreise wie Kunden (Tätowierer)und die amtliche Überwachung, sondern auch problematisch bei medizinischen Behandlungen im Falle von Hautreaktionen nach Tätowierungen oder im Falle  von Laser-Entfernungen von Tattoos (Entstehung von gefährlichen Spaltprodukten).  Es ist aus Verbraucherschutzgründen nicht nachvollziehbar, weshalb hier für Tätowierfarben andere Vorgaben gelten sollten als für kosmetische Mittel, die auf der Haut angewendet werden. Die Ausprägung einer Allergie unter der Haut ist wesentlich kritischer zu sehen als auf der Haut, bei der das Allergen leichter wieder entfernt werden kann.  Hinzu kommt, dass nach unserer Erfahrung die Hersteller und Importeure von Tätowierfarben und Permanent-Make-up-Farben keine Kenntnis über die Anwesenheit von kritischen Inhaltsstoffen wie beispielsweise Spuren von Nickel  oder Chrom(VI)-Ionen oder von Phthalaten haben. Die Kenntlichmachung dieser Stoffe würde für jede einzelne Charge eine Vollanalyse voraussetzen.  RO2:  Rechte Spalte  zu 1.:  Bei RO2 werden keine spezifischen Grenzwerte genannt, sondern diese beziehen sich auf die Vorgaben zur Einstufung der Gefahrstoffe in der VO (EG) Nr. 1272/2008, die z.T. deutlich höher liegen.  zu 2.:  Bei dieser Passage fehlt die Ergänzung “exceeding the specified concentration limits” nach “listed in Table A”. Dieser Zusatz ist jedoch essentiell und ist zu ergänzen.  Auch hier wurde für die PAKs ein vermutlich falscher Grenzwert genannt, der auch hier entsprechend korrigiert werden müsste.  Im Übrigen ist hier auf unsere Ausführungen zur RO1 zu verweisen.  zu 3.:  Hier wird im Gegensatz zur RO1 ein allgemeiner Grenzwert von 0,1 % w/w (= 1000 mg/kg) für die in Tabelle C (verbotene Stoffe nach Anhang II der VO (EG)Nr. 1223/2009) und Tabelle D (Anhang IV der VO (EG) Nr. 1223/2009) genannten Stoffe aufgeführt.  Dieser allgemeine Grenzwert für alle Stoffe kann nicht toxikologisch begründet sein und erscheint insgesamt für Stoffe, die nur in toxikologisch unbedenklichen und technisch unvermeidbaren Spuren vorhanden sein sollten, zu hoch.  zu 5.:  Dieser Paragraph entspricht den Vorgaben aus der RO1. Wir verweisen auf unsere entsprechenden Ausführungen.  zu 6.:  Dieser Paragraph entspricht den Vorgaben aus der RO1. Wir verweisen auf unsere entsprechenden Ausführungen.  zu 7.:  Dieser Paragraph entspricht den Vorgaben aus der RO1. Wir verweisen auf unsere entsprechenden Ausführungen.  zu 9.:  Eine gleichlautende Formulierung fehlt in der RO1 und sollte auch dort aufgenommen werden.  Kommentierung der für beide Restriktionsoptionen geltenden stofflichen Vorgaben in Tabelle A (siehe Tabelle 4 auf Seite 10 des Restriktionsreport):  Grenzwerte für verschiedene aromatische Amine:  Das hier aufgeführte Stoffspektrum an aromatischen Aminen (AA) deckt sich weitgehend mit den Vorgaben in Table 1 der Europarats-Resolution (sowie in der deutschen TätowiermittelV). Diese stofflichen Regelungen sind bis auf zwei AA, die in Tabelle A nicht aufgeführt sind (6-Amino-2-ethoxynaphthalin und 2,4- Xylidin) und vier weitere AA (Anilin, p-Toluidin, 2-methyl-p-phenylenediamin und  Sulfanilsäure), die zusätzlich enthalten sind, identisch.  Für alle AA gleich welcher toxikologischer Einstufung gilt der gleiche Grenzwert von 0,0005 % w/w (= 5 mg/kg). Es ist daher fraglich, nach welcher Einschätzung dieser Grenzwert abgeleitet worden ist.  Grenzwerte für verschiedene Azopigmente:  Die Freisetzung von AA aus Azopigmenten wird nun über ein Verbot der Azopigmente selbst geregelt. Statt einem generellen Verwendungsverbot von Azopigmenten, welche kanzerogene oder sensibilisierende AA abspalten können,  wurde diese Negativliste aufgenommen, die allerdings nicht vollständig ist. Es gibt noch viele weitere Azopigmente, die entsprechende AA abspalten können. Die aufgeführten Azopigmente wurden mit einem Grenzwert von 0,1 % w/w (=  1000 mg/kg) belegt. Problematisch ist hier, dass es aufgrund der Unlöslichkeit der Pigmente nur eingeschränkte Analysenverfahren gibt. So ist die Identifizierung und Quantifizierung z.B. über „MALDI-TOF Massenspektrometrie“ (Matrix–Assistierte Laser–Desorption–Ionisierung mit Flugzeitanalyse) umsetzbar. Diese Methodik steht jedoch nicht uneingeschränkt zur Verfügung. Ein weiteres Problem  ist, dass nur sehr eingeschränkt Referenzmaterialien (vor allem für verbotene Stoffe) zur Verfügung stehen. Daher ist nach unserer Einschätzung dieses Verbot in der Praxis analytisch kaum überprüfbar.  Zu den neu aufgenommenen Stoffen „Methanol“ mit einem Grenzwert von 10,9 % w/w und den beiden Phthalaten „Dibutylphthalat“ (Grenzwert: 0,009 % w/w) und  Bis(2-ethylhexyl)phthalat (Grenzwert: 0,007 % w/w) liegen am LGL keine Erkenntnisse vor. Auf die relativ hohen Grenzwerte der beiden Phthalate im Vergleich zur sonstigen Regelung von reproduktionstoxischen Stoffen der Kategorie 1 haben wir bereits an anderer Stelle hingewiesen.  Fazit:  Der Vergleich der beiden vorgestellten Restriktionsoptionen zeigt, dass RO2 deutlich niedrigere Anforderungen enthält, weshalb grundsätzlich der RO1 der Vorzug zu geben ist.  U.E. besitzt die RO1 ein der Europarats-Resolution  weitgehend vergleichbares Schutzniveau, das von den beteiligten Kreisen in der Vergangenheit bereits als Basis akzeptiert und überwiegend befolgt worden ist. Auch wird der direkte Bezug zur VO (EG) Nr. 1223/2009 und VO (EG) Nr.  1272/2008 befürwortet.  Allerdings besteht nach unserem Ermessen auch bei RO1 noch dringender Verbesserungsbedarf. Insbesondere sollte der Absatz über die erforderlichen Kennzeichnungselemente im Sinne einer Volldeklaration ergänzt werden und der  falsche Grenzwert für die PAKs muss korrigiert werden. |
| **Answer to specific info request 1:**  Der Grenzwert für Arsen wurde auf 0,008 mg/kg (0,0000008 % w/w) festgelegt. Nach Aussage der für die Schwermetall-Analytik zuständigen Sachverständigen am Bayerischen Landesamt für Gesundheit und Lebensmittelsicherheit(LGL) ist die Überprüfung der Einhaltung dieses Grenzwertes mit den zur Verfügung stehenden analytischen Verfahren nicht möglich.Die Bestimmungsgrenze von Arsen in Tätowiermitteln liegt bei 0,1 mg/kg.  Auch der Grenzwert für Blei von ursprünglich 2 mg/kg wurde erniedrigt; der Wert von 0,7 mg/kg kann jedoch analytisch noch erfasst werden. |
| **Dossier submitter response:**  Thank you for your comments.  Proposed restriction: RO1:  1. It is not possible to include the wording ‘technically unavoidable’ in the REACH restriction related to the CMs and CPR Annex II substances. This would not be practicable and lead to different standards in different MS depending on enforcement practices.  Preservatives are impacted by this proposed restriction if they have relevant classification (see comment #1904 for further details) in addition to the provisions of the BRP. Concerning the specific preservatives referred to, MIT/CMIT, BIT and MIT, they are already regulated under the BPR. For MIT/CMIT the substance has already been evaluated and approved as an active ingredient for in-can preservation and product applications have been submitted for various applications. MIT and BIT are currently under evaluation as active ingredients.  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 sensitisers. It is assumed unlikely that the producers would select a preservative that would require this type of labelling on a tattoo ink.  In RO1 a limit value of 0.1 % for skin sensitisers with a harmonised classification was proposed in order to prevent intended use of the substances in general. According to the analysis performed by the Danish EPA, the skin sensitisers reported by JRC with a harmonised classification applied or found in tattoo inks (apart from the ones addressed specifically, such as the PAAs) are not impurities, but functional substances (<https://www2.mst.dk/Udgiv/publications/2017/06/978-87-93614-06-2.pdf>).  Note, that in RO2 the limit value of 0.0015% would apply for MIT/CMIT and MIT substances. A limit value of 0.05% would apply for BIT (i.e., the limit set in the CLP)  2. The reference to PMU and the PAH concentration limit has been corrected. In the restriction report under RO1 it is proposed that no substance included in Part 3 of Annex VI of the CLP Regulation with a classification as Repr. Cat. 1A or Cat. 1B should be present in tattoo inks or PMU at a concentration higher than 0.0014 %. This will also apply to the phthalates „Bis(2-ethylhexyl) phthalate“ and „Dibutyl phthalate“. Under RO2 for substances with a harmonised classification under CLP as Repr. Cat. 1A or Cat. 1B the generic concentration limits of the CLP Regulation (0.3 %) are proposed as concentration limits. In addition to „Bis(2-ethylhexyl) phthalate“ and „Dibutyl phthalate“ the limits of 0.009 % and 0.07 % (derived from their individual DNELs) will apply (paragraph 2. of RO2). Therefore, in the present proposal the phthalates will have a concentration limit equal (RO1) or lower (RO2) than the other substances with a harmonized classification under CLP as Repr. Cat. 1A or Cat. 1B  3-5. Thank you for your support for the proposed approach for pigments banned for use in hair dyes but allowed for use in all cosmetic products (Annex IV of CPR), as well as your other two comments. They have been reflected in the Background Document.  6. Please refer to response 1890 and 1904 regarding the labelling requirement.  RO2:  For comments 2, 5-7, please see above answers for RO1.  1 & 3. Regarding RO2, please see response # 1890.  9. Please see above our comments regarding concentration limits for reprotoxicants.  Concerning explanations for the aromatic amines and azo-colourants please consult appendix B.2. p. 81-109 in the Background Document. The aromatic amines have been selected based on their classifications. This is explained on p.82-88. The identified PAAs have a harmonised classification as carcinogenic or as skin sensitising, and:   * have been found in tattoo inks on the market (13 PAAs); * may be present in tattoo inks due to either cleavage of azo bond or amide hydrolysis of an azo colourant used in tattoo inks or originate from the production of the azocolourants used in tattoo inks (10 PAAs); * may be present in tattoo inks due to reductive cleavage of azo bond of one of the azo colourants listed in the CoE ResAP(2008)1 (3 PAAs ); or * may be present in tattoo inks either due to reductive cleavage of azo bond or due to Amide hydrolysis of one of the azo colourants restricted in Annex XVII entry 43 of REACH in various textiles (22 PAAs). * may be present in tattoo inks due to the listing in the CoE ResAP(2008)1 (25 PAA)   After the identification of the relevant aromatic amines the limit value was derived.  Concerning the limit values for the selected aromatic amines please consult appendix B.2. p. 96-104 in the Background Document. The carcinogenic effect was considered as the critical effect in relation to tattooing for the ten selected PAAs that frequently have been identified in tattoo inks. For the evaluated PAAs it is considered that there is no threshold for the carcinogenic effects and, therefore, a DNEL cannot be established. Instead, DMELs might be derived. For two of the PAAs (aniline and o-Anisidine), a DMEL could be established. For the remaining 8 PAAs a DMEL could not be established based on the available data. The DMEL for aniline is set at approximately 2 x 10-5 mg/kg bw per day for the carcinogenic effects. The DMEL for o-anisidine is set at approximately 4 x 10-5 mg/kg bw per day. Since all the PAAs with a harmonised classification as carcinogenic are very similar, a grouping approach is applied and the lowest DMEL value of 2 x 10-5 mg/kg bw per day is applied for all members of the group as a conservative assumption. In general there may be large variations among the cancer potency in a group of similar carcinogenic substances. However, this is considered a conservative approach.  For the derivation of limit values for the PAAs, 4 308 mg ink/tattoo session, a body weight (bw) of 60 kg, and a DMEL value of 2 x 10-5 mg/kg bw per day are applied. This gives a risk based limit value for the concentration of PAAs in the ink of 0.28 ppm for each individual PAA. This figure is rounded to 0.3 ppm.  The limit of detection of the test method applied in Italy is 1 ppm. However, in Denmark (DEPA, 2012) for some of the PAAs a limit value of up to 10 ppm is found. Therefore, assuming a limit value of 0.3 ppm for the PAAs is not considered practical. Further, it might also not be economically feasible (please see appendix B.2. p. 96-104 for further explanation). Thus in order to assure a practical limit value, which is reasonably consistent with the current regulation in some Member States, a limit value of 5 ppm for PAAs is proposed.  Concerning the list of azo-colourants, being incomplete, please consult appendix B.2. p. 81-109. The selected azo-colourants have been chosen from the list of azo-colourants in use identified by the JRC (for references please consult appendix B.2. p. 96-104). The azo-colourants are proposed to be restricted in tattoo inks due to either:   * decomposition by amide hydrolysis * photodecomposition forming 3,3’-dichlorobenzidine * scientific evaluation by the SCCP * listed in the CoE ResAP(2008)1 and harmonised classification as skin sensitiser, category 1 or as carcinogenic, category 1B   In general it is considered economically disproportionate to simply restrict all azo-colorants irrespective of their use in tattoo inks. The Italian Authorities are currently developing an analytical method for measuring azo-colourants.  Your overall support for RO1 (with improvements) is noted.  Specific info request 1: In the Background Document, Annex B, Appendix 6, Table 113, a review of available detection methods for arsenic are given, including EPA method 1669 for arsenic in water with a detection limit of 0.000003 mg/kg. This table seems to indicate the concentration limit will not prove difficult to enforce. However, we understand your concerns and the Dossier Submitter is working with RAC and SEAC to identify relevant limits taking into account the submitted comments during the Public Consultation. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC, in general, supports the Dossier Submitter’s response to the comments.  Nevertheless, regarding skin sensitising substances, RAC points out that some non-CMR skin sensitisers could be present both as a functional substance and as an impurity in tattoo inks (e.g. methenamine is used as a preservative in tattoo inks (DEPA, 2017a), but it has been also found as an impurity in black tattoo inks in concentrations 0.000008% – 0.0022% (Lehner et al., 2011)). Regarding the CL for skin sensitisers, please see the fifth bullet in RAC response to comment #1894 and the RAC opinion.  Concerning your comment of the list of azo-colourants being incomplete, please note that in RAC opinion this uncertainty has been highlighted (including the relevance of azo bond cleavage), and that regular updates of the restriction have been recommended, which are expected to enable risk assessment of colourants (and other chemicals used in tattoo inks) for which information on hazards and risks are inadequate at the present moment.  RAC acknowledges that very sensitive analytical determination of arsenic in tattoo inks (at LoD <0.000001%) could be challenging for routine laboratory practice. However, practical CL for arsenic proposed by RAC is 0.00005% (for justification please see RAC response to comment #1905 and RAC opinion). This value is expected to be both technically and analytically achievable. |
| **SEAC Rapporteurs comments:**  We agree with the response provided by the Dossier Submitter. |
| **1912** | **Date:** 2018/06/13 23:36  **Content:**  Hazard or exposure;Description of analytical methods;Information on benefits  **Type:** Individual  **Country:**  Norway  **Attachment:**    **Privacy comment:** I have no such reasons | **Comment:**  In an attached explanatory paper I firstly expresses the proposed regulation is clearly insufficient in that it does not say only ink constituents found safe in use are allowed – all other chemicals are banned. The Council of Europe resolution (CoE) recommended such a “positive list regulation”.  You propose a majority of the CoE recommendations for heavy metal maximum limits be converted into regulation having the power of law. This without being aware of the health reasoning behind them. This I think a serious insufficiency. Since I took part in the CoE work leading up to these recommendations, I would like to assist in removing that insufficiency – see paper about Chromium in the first place. I will be back with more on this later. Besides, I recommend you rethink about the proposal for the regulation of copper – see paper. |
| **Answer to specific info request 1:**  This concerns copper for which I in the paper argue should not be allowed in a higher concentration than 10 mg/Kg (I come back a deepened assessment later |
| **Answer to specific info request 2:**  There are alternatives that I will inform about before the hearing time limit expires |
| **Answer to specific info request 3:**  The following to my knowledge find use in tattooing inks (overview produced 2017 by the CoE): CI 12085 (PR4), CI 12490 (PR5), CI 15880 (PR63:1), CI 73360 (PR 181). An answer as to whether there are safer alternatives for use in tattooing inks requires specific safety assessments of some other red pigments. To my knowledge no pigments finding use in tattooing inks has this far been subjected to traditional risk evaluations. The plan of the former DG SANCO was to ask the SCCS undertake such assessments. All these pigments are currently allowed in all types of cosmetic products except for the hair colouring products. PR4 tested positive in the Ames test and may spit off 2-chloro-4-nitroaniline that may possess genotoxic properties. PR5 may split off a sulphanilamide and are not allowed in the US and Japan. |
| **Answer to specific info request 4:**  Basic Red 1 (CI 45160) has been detected in a tattooing ink. It is mentioned in the Table 2 of the CoE resolution and so accordingly forbidden. The other questions I cannot answer. |
| **Dossier submitter response:**  Thank you for your comments. We begin with answers to your comments in the attachment:  Precautionary-based regulation, positive list: The European Commission requested ECHA to investigate and prepare a REACH restriction dossier addressing the risk from substances in tattoo inks. As you point out, it is difficult to establish a positive list within the framework of REACH.As far as we are aware there is no intention to return to this issue if a REACH restriction is adopted. Your support for a positive list of substances to be allowed in tattoo inks has been reflected in the Background Document.  Justification for concentration limits on impurities: Thank you for the comments and information.  Copper: The Dossier Submitter has proposed a concentration limit (CL) for soluble copper of 0.05% w/w (500 ppm). In your comments in the attachment there is a proposal for a substantially lower CL for soluble copper of 10 mg/kg (10 ppm). The Dossier Submitter has based the proposed CL for soluble copper on the WHO Guidelines for Drinking-water Quality (2004) where WHO concludes with a guideline value of 2 mg/l to be protective against the adverse gastrointestinal effects of copper and to provide an adequate margin of safety in populations with normal copper homeostasis. The comment submitter argues that GI effects will never occur from tattooing and that the copper homeostasis will be bypassed when tattooing is performed. The Dossier Submitter agrees that GI irritation is not likely to occur after a subcutaneous injection with tattoo inks. However, this is the first effect to arise after oral copper intake and to base a CL on this will probably protect against systemic effects occurring at higher levels of intake. We consider the WHO document to be the most relevant and reliable source, especially as it contains human data.  A lengthy discussion of arguments for lowering the CL follows your comment in the attachment. No new toxicity studies are presented in this comment. Several arguments concerning a more precautionary approach are presented, such as the total copper intake also from other sources, GI absorption of 45%, i.e. lower than the bioavailability from tattooing, the use of additional safety factors e.g. based on teratogenic effects at higher doses in rodents and the content of soluble copper in tattoo inks on market. A study by Ferm and Hanlon (1974)\* is mentioned in public consultation comment no. 1916 below from the same comment submitter. In this study hamsters received an intravenous injection of copper compounds on day 8 of gestation and teratogenicity was observed as well as maternal toxicity. The Dossier Submitter recognises that none of the scientific bodies/committees that have evaluated the toxicity of copper compounds has based their assessments on reproductive effects based on the administration route in this study. We question the findings in this old, non GLP study.  The Dossier Submitter agrees that the CL should be adjusted on lower intake via the GI tract than via intradermal injection. We propose to lower the CL to 0.025% w/w (250 ppm) based on ca 50% GI absorption and 100% bioavailability from tattoo inks. The BD should be amended accordingly.  \*Ferm V.H.; Hanlon D.P. (1974) Toxicity of Copper Salts in Hamster Embryonic Development. Biology of Reproduction 11:97-101; Not GLP; Published  Chromium VI: Thank you for the information on the concentration limit for chromium, we have adapted the background document to reflect your information.  Specific info request 1: Please see response above for Copper, which also integrates comment #1916.  Specific info request 2: We await your additional contribution.  Specific info request 3 & 4: Your comments have been reflected in the BD. |
| **RAC Rapporteurs comments:**  Thank you for your comments. They were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response to the comments.  Following your comments and the information provided by the Dossier Submitter, RAC agrees with the Dossier Submitter to propose new CL for copper, 0.025%, which accounts for 50% gastrointestinal absorption from diets containing adequate levels of copper.  In addition to the Dossier Submitter’s response, RAC points out that gastrointestinal effects were observed in animals and humans after parenteral copper exposure as well (ATSDR 2004, Poisindex 2018). Studies in monkeys, dogs, and ferrets indicated that copper-induced emesis results from stimulation of the vagus nerve, since abdominal vagotomy or administration of compounds that block 5-HT3 receptors resulted in a decrease in emesis following oral or intravenous administration of copper sulphate.  Regarding other effects discussed in your comment, i.e. genotoxicity *in vivo* and reproductive toxicity, RAC considers that available data show that they were observed at relatively high doses at which homeostatic mechanisms cannot anymore prevent copper toxicity. CL proposed by RAC, on the other hand, implicates exposure to copper at the level at which efficient copper homeostasis is expected.  Regarding a “positive list” of substances allowed in tattoo inks, RAC is aware that there is no possibility to have such a list in a REACH restriction. Nevertheless, a positive list could be introduced in EU Member States at a national level, as already done in Spain and Norway. Spain, under the national legislation on cosmetics, has a positive list of tattoo inks that can be placed on the market, and Norway has a positive list of 26 preservatives with low sensitisation potential. In its opinion, RAC suggests evaluating the efficiency of these examples, and taking the results of the evaluation into account in any future review of the restriction.  Agency for Toxic Substances and Disease Registry (ATSDR). 2004. Toxicological profile for copper. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. POISINDEX(R) MANAGEMENTS. Truven Health Analytics LLC MICROMEDEX(R) Healthcare Series Vol. 175, March 2018 |
| **SEAC Rapporteurs comments:**  The statement on banning pigments PG7 and PB15:3 is noted; please see comment 1883 for further details. No further action is required by SEAC. |
| **1913** | **Date:** 2018/06/14 10:34  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Federal Food Safety and Veterinary Office FSVO  **Org. country:** Switzerland | **Comment:**  Comments on Annex XV Restriction Report (Proposal for a Restriction Version No. 1.2 Oct. 2017)  We thank you for giving us the opportunity, as official authority in Switzerland for the legislation on tattoos, to comment on Annex XV Restriction report.  Based on the experience of an official control authority, specialized in analyzing tattoo inks and in enforcing corresponding legal restrictions, the following comments are added:  Three General Remarks  1. To our knowledge, no compounds used in tattoo inks have ever been tested yet to ensure their health safety when injected into the human skin.  2. The proposal for restriction only considers compounds with a harmonized classification. Unclassified compounds are not included, even if evidence shows them to be carcinogenic, genotoxic or sensitizing.  3. The line of argumentation that a general ban on compounds would ban tattooing as such is unfounded: cosmetic regulations include limitless bans on more than a thousand ingredients and contaminants without them having any major impact on the market.  Comments on the Summary (Pages 1 - 19)  The two restriction options RO1 and RO2 presented by the dossier submitter are both only based on quantitative limits. The reasoning behind this is that a total ban would not be realistic, as this would ban tattooing as such. We do not agree with this line of argumentation:  - A ban on certain compounds of major concern does not mean a ban on all compounds used for tattooing. Why should this lead to a ban on tattooing? (Please refer on our general remarks.)  - A general obligation to quantitate any given compound of a tattoo ink could pose an unnecessary major obstacle for authorities entrusted with market controls. The following example shall explain problems that might arise with this demand: insoluble pigments are major constituents of tattoo inks that can reach almost 60% by weight (JRC –Tattoo-Final Report). Methods for the identification of organic pigments in tattoo inks have recently been published in peer reviewed scientific journals (e.g.: F1000 Research 2018, 6:2034). Analysis of 150 pigment samples and 450 tattoo ink and PMU samples from market surveys proved that the validated in-house method used (LDI-TOF-MS) is fit for purpose and can be used for enforcing legal restrictions. With a limit of detection in inks of between 1 and 20% depending on the pigment and proposed limits generally being 0.1% for restricted pigments, the present qualitative method could still be applied if pigments have been added as ingredients. However, should mandatory quantitation mean more than comparing a limit at 0.1% with the limit of detection, then market surveys on pigments would no longer be possible. No method is yet capable of performing pigment quantitation for a given content range. With no quantitative references for pigments available, the situation is unlikely to change in the future.  Nevertheless, for compounds of concern, which are soluble in inks, we regard legal limits as indispensable, which require quantitative determination.  - The report also mentions, that especially colourants which would be hard to substitute by the industry, and taking into account possible risks and hazards, derogations are proposed.  Referring to our general remarks, what would be the basis for this from a consumer safety standpoint?  Comments on RO1  Preservatives are not mentioned at all, as they will be included in the biocides regulation. What does this signify? Are there no restrictions that must be observed? Can a preservative of major concern such as Methylisothiazolinone /Methylchloroisothiazolinone be added at will to tattoo inks? Does the proposal regard the safety level of preservative use in tattoo inks to be the same as for in can preservation of e.g. wall paints? This issue must be clarified.  Table 2  1a. CMR Compounds  In contrast to regulations on cosmetics, there is no requirement, that genotoxic compounds, such as nitrosamines, may only be tolerated in technically unavoidable contents.  1b. Limit for sensitizers  The limit for sensitizers is set as a general limit of 0.1%. This is unacceptable e.g. for Methylisothiazolinone/Methylchloroisothiazolinone, benzothiazolinone or methylisothiazolinone:  MCI/MI is not allowed anymore in leave-on cosmetics because the limit of 0.0015% wasn’t safe. The same applies to Methylisothiazolinone at a limit of 0.01%. BIT never was permitted in cosmetics, as the proposed limit of 0.01% did not prove to be safe. On the other hand, a sensitizer such as 2,5-diaminotoluene, because being also a primary aromatic amine (nota bene not carcinogenic), would have a stricter limit of 0.0005%. This demonstrates that the proposal measures safety with unequal standards.  2. Limits for PAH  The proposed limit of 0.0005% for every carcinogenic congener is not in line with existing limits in utensils of daily use (e.g. handles of gulf clubs or hammers) being 1 mg/kg. Compared to Res(AP) this would also mean a 1000 times higher limit for benzo(a)pyrene. The limits for individual CMR congeners would even be higher than the existing limit for total PAH content. Furthermore, restricting limits to classified congeners is not reasonable, as the European Union (e.g. 15 EFSA PAHs) has not yet classified many PAHs with undoubted evidence of being carcinogenic (Refer to our general remarks).  6. Non-requirement of comprehensive declaration  The relinquishment of a mandatory declaration of all ingredients is unacceptable. This would relate to most pigments, due to them either not being classified as hazardous compounds or being in a class of minor concern. On the one hand, it is hard to understand why regulations for tattoo inks would be less strict than those for cosmetics, on the other hand medical staff would lack vital information in cases of skin disorders or laser treatments. Furthermore, incomplete declaration would be intransparent towards consumers.  Supplimentary Table A  Aromatic amines  It is hard to understand why all aromatic amines, regardless of their CMR classification, would have the same limit of 5 mg/kg. As examples the same limit would refer to benzidine (C 1A), 3,3‘-benzidine (C 1B) as well as aniline (C 2 et M 2). Furthermore, our general remark (3) also applies to amines: e.g. 2,4-xylidine, 4-chloro-2,5-dimethoxyaniline, or naphthol AS plus is derivatives, all known to be of special concern, are left out because of a missing harmonized classification.  All aromatic amine entries are marked with \*\* describing them to be soluble. What does soluble mean? Is the soluble portion of a given compound meant? This would require definition of the solvent. Or does it mean „not azo-bound“, respectively amines present as impurities? In this case, limits would not refer to a specific solvent. The term soluble should therefore better be omitted or replaced by a better term.  Azo colorants  Instead of establishing a general ban on those azo colorants, which, according to their structure could degrade into carcinogenic or sensibilizing aromatic amines, an incomplete negative list is proposed with limits of 0.1%, which in many cases could barely be verified. Even assuming that methods do exist, quantitation would be doomed to fail as crucial reference standards would hardly be available.  Furthermore, establishing an incomplete list naming only certain pigments of concern and their corresponding limits, invites manufacturers to replace listed pigments by unlisted related ones having similar toxicological profiles (e.g. replace C.I.12315 with C.I.12325, or replace C.I.21108 with C.I.21100 or C.I.21105). Therefore, only a ban on azo colorants containing problematic structure elements would be feasible and at the same time effective.  Missing limits  Market surveys of tattoo inks, which included the determination of nitrosamines, have been reported (e.g. JRC Tattoo Final Report). Products have been banned due to these tests. What are the reasons why limits for these compounds group are missing?  This also applies to phenol, a mutagenic compound of class 2, which often has been found in tattoo inks.  Comments on RO2  The limits proposed for CMR substances as well as sensitizers are not acceptable.  This also applies to the limit of 0.1% for forbidden substances in cosmetics (Annex II of the Cosmetics Regulation).  Bern, 13.06.2018  Roger Meuwly, Dr Phil II  Scientific collaborator  Federal Department of Home Affairs FDHA  Federal Food Safety and Veterinary Office FSVO  Foods and Nutrition  Schwarzenburgstrasse 155  3003 Bern, Switzerland  Phone +41 58 462 95 77  roger.meuwly@blv.admin.ch  www.fsvo.admin.ch |
| **Dossier submitter response:**  Thank you for your comments. Please see responses 1911 and 1890 as they deal with some of your issues. To clarify regarding preservatives, they are regulated under the Biocidal Products Regulation (BPR) but if they meet the criteria for the restriction (i.e. because they are skin sensitisers) they are in any case restricted in tattoo inks. The preservatives that are classified as skin sensitisers are examples of this.  Regarding classified vs non-classified substances to be included in the scope, this was on the clear advice of the Commission and as substances with data are subject to harmonised classification, then they will also become subject to this restriction. Appendix D.1. gives further details on this.  Concerning the reference to aromatic amine being soluble, the term "soluble" should be seen in contrast to aromatic amines released from the pigments because of reductive cleavage. The term "soluble" is written in the restriction proposal and is linked to the analytical method. See also response to comment #1918 with respect to the discussion of analytical methods. |
| **RAC Rapporteurs comments:**  Thank you for your comments. They were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response to the comments.  Regarding the proposed derogations, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904.  With respect to your comment “A ban on certain compounds of major concern does not mean a ban on all compounds used for tattooing. Why should this lead to a ban on tattooing?”, RAC reflects to the Dossier Submitter’s explanation that the pigments used in tattoo inks are not specifically produced for such purposes, so they may contain levels of hazardous substances that are not appropriate for injecting into the human skin. While the CPR allows in technically unavoidable traces of prohibited substances (according to Article 17 of the CPR), this is not possible under REACH. “Should not contain” requirement for some impurities in this restriction proposal are, therefore, expected to mean a total ban for some colourants (please see comment #1905 regarding arsenic in titanium dioxide pigment, as well as RAC’s reply to that comment).  Concerning skin sensitisers, please see RAC response to comment #1894, and concerning azo colourants, RAC response to comment #1911. |
| **SEAC Rapporteurs comments:**  We agree with the response provided by the Dossier Submitter. SEAC notes a repeated request for a list of all ingredients on the label of tattoo inks as required by ResAP. Ingredients that do not meet the criteria for classification as hazardous according to CLP and that are not in the scope of the restriction cannot be included on the label. SEAC will reflect this issue in its opinion. |
| **1915** | **Date:** 2018/06/15 13:35  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:** ANEC  **Org. country:** Belgium  **Attachment:**  See comment **#1921** | **Comment:**  See document attached below in Section IV. |
| **Dossier submitter response:**  Please see response to comment #1921. |
| **RAC Rapporteurs comments:**  Please see response to comment #1921. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. |
| **1916** | **Date:** 2018/06/18 00:08  **Content:**  Scope or restriction option analysis;Hazard or exposure  **Type:** Individual  **Country:**  Norway  **Attachment:**    **Privacy comment:** I have no such reasons | **Comment:**  I herewith come back with a second submission providing arguments for lowering the proposed soluble copper regulation from 500 to 10 mg /Kg ink – see attached paper |
| **Answer to specific info request 1:**  I herewith come back with a second submission providing arguments for lowering the proposed soluble copper regulation from 500 to 10 mg /Kg ink – see attached paper |
| **Answer to specific info request 2:**  Like I said in my fist submission 13 June there are alernatives which I will show in a Third submission soon to be posted |
| **Answer to specific info request 3:**  The following pigments to my knowledge find use in tattooing inks (overview produced 2017 by the CoE): CI 12085 (PR4), CI 12490 (PR5), CI 15880 (PR63:1), CI 73360 (PR 181). An answer as to whether there are safer alternatives for use in tattooing inks require specific safety assessments of some other red pigments. To my knowledge no pigments fining use in tattooing inks has this far been subjected to traditional risk evaluations. The plan of the former DG SANCO was to ask the SCCS undertake such assessments. All of these pigments are allowed in all types of cosmetic products except for the hair colouring products. So there is no need for substituting them |
| **Answer to specific info request 4:**  I provided information on this in my first submission |
| **Dossier submitter response:**  Thank you for your comments.  Specific info request 1 & attachment: Please see the response to comment #1912.  Specific info request 2: Please see the response to comment #1934  Specific info request 3: Please see the response to comment #1912. |
| **RAC Rapporteurs comments:**  Thank you for your comments. Please see RAC response to comments #1904 and #1912. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. |
| **1918** | **Date:** 2018/06/18 19:32  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** CTL-Bielefeld  **Org. country:** Germany  **Country:**  Germany | **Comment:**  CTL GmbH is one of the leading analytical labs that test tattoo inks and PMUs with clients all across the world. We appreciate the common effort to harmonise national law in this field and welcome the interest into the safety of tattoos and PMU inks.  A harmonisation would allow everyone working in the field of tattoo and PMU a greater certainty as to their rights and obligations concerning the testing and the allowed substances.  The current draft is strongly aligned with the 1223/2009 cosmetics regulation. Yet, there is certainly a distinction that needs to be made between PMUs and tattoo inks compared to cosmetics. The proposal has to reflect the distinct usage and application of the different products. Tattoo inks and PMUs are products which are designed to last for several years and are not, like cosmetics applied on a daily basis. The cosmetics regulation does not allow any exceptions for single cosmetics pigments. The ROs seems to indicate that this might be different for tattoo inks and PMUs with the new regulation. If such a separate list of possible derogations is established it would have to be exhaustive and checked whether it is up-to-date on a regular basis.  As to the proposed changes we strongly advise to differentiate between free and bonded concentrations of substances in the ink. For example heavy metals in free form are relevant when applying a tattoo or PMU. Safely bonded heavy metals on the other hand are more of concern in the long term or when removing a tattoo or PMU. In the ROs Copper and Barium are to be measured in soluble concentrations (giving the free concentrations) the other metals are to be measured in total concentrations (giving the sum of bonded and free concentrations). We advise to implement a standard when to measure soluble concentrations and when to measure total concentrations and apply it to all substances. This would create the possibility to better reflect practical usage and minimise necessary tests while guaranteeing the safety of the consumer.  However, our major concern is the lack of standardisation in terms of analytical methods. The question how a sample is analysed and how it is assessed is just as important as a common list of forbidden pigments. If the analytical methods are not harmonised one can also not expect comparable data when examining the same product as a different testing method leads to different results in the analysis. These concerns are picked up in the ROs and the Restriction Report ANNEX XV. Yet, this harmonisation is left to national authorities and will therefore not create an EU-wide common system. |
| **Dossier submitter response:**  Thank you for your comments. As you point out, the Dossier Submitter recognises the need for harmonisation of analytical methods to ensure consistent enforcement in all Member States in the EU. This need was also highlighted by the Forum on exchange of information on enforcement.  With respect to differentiation between free and bonded concentrations of substances, in the proposal the Dossier Submitter generally refers to the total content of the corresponding metal (or other compounds). It is our understanding that the analytical method should be adapted if necessary to measure this total concentration. This is also suitable in terms of its relationship with the risk as once the substance is injected under the skin the free and bonded concentrations will be in equilibrium, meaning eventually all the substance may be available to exert its effects. In particular for barium and copper we have related the effects to the soluble fraction for copper because 1) evidence from animal studies that ("insoluble") Cu-Phthalocyanines have a lower toxicity than "soluble" Cu-salts like Cu-Chloride 2) the Resap also refers to soluble Cu and 3) one of the very few blue Pigments would be restricted without clear necessity. In the case of Barium because "insoluble" BaSO4 is a common ingredient in tattoo inks and, according to our assumption, does not dissolve (or at least very slowly) and would therefore not lead to the same toxic effects as Ba2+ ions. |
| **RAC Rapporteurs comments:**  Thank you for your comments. They were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response to the comments.  RAC also notes that according to the Dossier Submitter’s information, there is an ongoing multi-country project, involving Denmark, Germany, Switzerland and Italy, on developing analytical methods for the regulated substances in tattoo inks. This project is expected to assist with the enforcement of the proposed restriction as well as with the compendium of analytical methods, in line with Forum’s advice.  Regarding a need for regular updates of derogated colourants, please see RAC response to comment #1921.  Considering a differentiation of soluble and insoluble barium, copper and zinc salts, RAC considers that at the CLs proposed by RAC (i.e. 0.025%) it is possible to find (technically not too demanding) analytical method for identification of a soluble metal salt or other compound, after dissolution in water or dilute acid. An example is a simple limit test for soluble barium salts (allowed concentration limit of 0.001%), according to US Pharmacopoeia (USP, Chemical Tests / <191> Identification Tests – General; described also on <http://www.pharmacopeia.cn/v29240/usp29nf24s0_m7110.html>). |
| **SEAC Rapporteurs comments:** |
| **1919** | **Date:** 2018/06/19 13:31  **Content:**  Information on costs;Information on benefits;Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** Wirtschaftskammer Österreich (WKÖ)  **Org. country:** Austria  **Attachment:** | **Comment:**  See document attached. |
| **Dossier submitter response:**  Thank you for your comments. The scope of RO1 and RO2 is very similar to ResAP(2008)1, with minor differences, e.g., derogation of about 22 pigments banned in hair dyes in Annex II while allowed in Annex IV of the EU Cosmetics Products Regulation, small deviation in concentration limits (and slightly higher under RO2), derogation for substances with harmonised classification via the inhalation route. The need for harmonisation methods is recognised by the Dossier Submitter as important for the consistent enforcement in all Member States, although the availability of such methods is not a prerequisite for proposing a restriction and is outside the scope of restriction dossier development. In addition, to facilitate enforcement, the Dossier Submitter has provided information on the substances for which there is information that can be found in tattoo inks. One of the reasons for proposing RO2 was to minimise the need for material testing, as substances with harmonised classification would have to be included in the label/the safety data sheet if present in concentrations exceeding their general or specific concentration limits under the Classification, Labelling and Packaging (CLP) Regulation. |
| **RAC Rapporteurs comments:**  Thank you for your comments. RAC supports the Dossier Submitter’s response.  Regarding a harmonisation of analytical methods, please see RAC response to comment #1918. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. |
| **1921** | **Date:** 2018/06/19 14:54  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** ANEC  **Org. country:** Belgium  Belgium  **Attachment:** | **Comment:**  Please find acomments in section IV |
| **Dossier submitter response:**  Thank you for your comments. We’ve organised our response to your comments and proposals as presented in separate sections, omitting the summary and concluding sections where summaries of these issues are presented.  Summary: See responses below.  1. Background: no specific comments and proposals are outlined  2. The Restriction Proposals  2.1. RO1:  - A practical concentration limit for C and M substances of 10 ppm (0.001%) for cat. 1A, 1B and 100 ppm (0.01 %) for cat. 2. The limits set in RMO1 are to ensure the substances are not present in tattoo inks. A practical limit is set in RMO2 to prevent intentional use of these substances.   * Considerations for CPR substances. Thank you for the comments and indeed there is no possibility to have a positive list in a REACH restriction. As far as we are aware there is no intention to return to this issue if a REACH restriction is adopted. Your support for positive list of substances to be allowed in tattoo inks has been reflected in the Background Document. Related to the suggestion for a practical limit of 10 ppm this is also addressed in RMO2 where a practical limit is set. * Suggestion to include in scope substances without harmonised classification whose the majority of notifiers (> 50%) have self-classified the substance in the classifications already included in the scope – please see comment #1890 for further clarifications. * PAH limits: Thank you for noting an error in the PAH concentration limit in tables 2 and 3 in the restriction report. The typos were corrected as per the proposed limit in sections 1.2.6 and Table 11 in the restriction report and B.10.2 in Annex B, i.e., 0.00005% w/w. The limit for PAHs in this restriction applies to each individual PAHs with harmonised classification as carcinogenic or mutagenic, in the same way as for the eight PAH substances in REACH Annex XVII, entry #50(6), for toys and childcare articles, as written in section 1.2.6.1. This approach is taken to be consistent with previous regulatory decisions. The Dossier Submitter is aware that entry 50 is currently being reviewed and any changes to this limit should be reflected in this restriction. * Derogation for substances in Supplementary Table B: The Dossier Submitter has proposed a derogation for these pigments primarily as sufficient information to demonstrate risks currently is not available and for some of these pigments (Pigment Blue15 and Green 7), consultations have revealed that (less risky) alternatives are not available. These conclusions were tested during this public consultation and any comments in response to questions 2 and 3 will be taken into account. While the Dossier Submitter is open to considering time limiting the derogation, information to set this time period is not provided in your submission, e.g., on how long it would take to identify and transition to alternatives to these pigments. * Annex IV conditions in columns h to i: The Dossier Submitter has consulted enforcement experts to ensure the restriction wording reflects the intent of the proposal: to adopt the conditions laid out in columns h to I of Annex IV of the CPR. However, the final wording of the decision on the Annex XVII entry in REACH is determined by the European Commission. * Definition for tattoo procedure: The word procedure is used in the wording of the proposed restriction; therefore, a definition is proposed. The final wording of the decision on the Annex XVII entry in REACH is determined by the European Commission. * Support for addressing tattoo inks risks via the CPR or separate positive list of pigments to be used – Your support is noted in the Background Document, section D.1.3. Other Union-wide risk management options than restriction in Annex D. * Concerning the threshold of 0.1% w/w for skin sensitising substances please consult the reply to 1890 and 1898. * Concerning the comments on the limits in Table A (given in Table 4 of the restriction dossier) for certain colourants classified as carcinogenic category 2 (Disperse Yellow 3) or category 1B (Solvent Yellow 1 and 3), the deliberate use of pigments would imply that the concentration of these colourants would need to be significantly higher than 0.1% in order to be able to colour the ink.   2.2. RO2:   * PAH limits, colourants with carcinogenic harmonised classification in Table A, time limited derogations for pigments in Supplementary Table B, additional labelling requirements, definition of tattoo procedure, inclusion of substances with relevant self-classifications, addressing tattoo inks risks via the CPR or separate positive list of pigments: Please see our response to your similar comments for RO1 above. * Practical limits for carcinogenic and mutagenic substances, and for CPR substances: Your comments have been taken into account. Please see the response to comment #1890. * Concerning the comments on the threshold for skin sensitising substances being the classification limit. In Annex I Part 3 of the CLP Regulation it states that allergic responses in individuals who are already sensitised may be elicited in quantities below the generic concentration limits (see 3.4.3.3.2 and Table 3.4.6) and special labelling requirements for substances in mixtures which are 10 times lower compared to the generic concentration limits for triggering classification, i.e. 0.01% for Skin Sens. 1A and 0.1% for Skin Sens. 1 and 1B (see special labelling requirements of Annex II section 2.8) to protect already sensitised individuals. Therefore, the Dossier Submitter supports similar limits for substances with this harmonised classification in RO2.   3. Missing provisions:   * Preservatives: The Dossier Submitter has proposed that a number of preservatives (with CMR, skin sensitising, irritant, corrosive, damaging properties or those prohibited for applications on the skin) are not used in tattoo inks. We also recognise that the BPR would add additional provisions. We agree with your observations on the deficiencies of the BPR in this respect and include your recommendations in the Background Document, section D.1.3. Other Union-wide risk management options than restriction in Annex D on: adding additional product code and development of specific assessment guidelines or the establishment of a positive list of preservatives to be allowed for use in tattoo inks either under the CPR or a separate legislation. * Suggestion to include substances with relevant self-classifications: Please see our response to your similar comment for RO1 above.   4. Is REACH the appropriate legislative framework? – The Dossier Submitter welcomes your opinion. As mentioned above, it has been reflected in the Background Document  5. Concluding remarks: Please see preceding responses to the similar points you raise already in sections 2-4. |
| **RAC Rapporteurs comments:**  Thank you for your comments. They were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response to the comments.  Regarding CMR and skin sensitising substances, please see justification for CLs proposed by RAC in RAC opinion, as well as RAC response to comment #1894. Concerning CLs for CPR substances, please also see RAC reply to comment #1898.  RAC considers that any legislative gaps related to a dynamic link with the CPR, pointed out also by the Dossier Submitter in the BD, should be solved in regular updates of the restriction, which are recommended in RAC opinion.  Regarding derogations of pigments proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. In case the derogations are granted, the updates are also recommended to provide re-assessment of available, less hazardous alternatives for derogated colourants (without a notion on time limits, due to the reason pointed out by the Dossier Submitter).  With respect to a “positive list” of substances allowed in tattoo inks, please see RAC response to comment #1912. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. Regarding Pigment Green 7 and Blue 15:3; please see comment 1883. |
| **1924** | **Date:** 2018/06/20 12:48  **Content:**  Scope or restriction option analysis;#Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Regional or local authority  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  Proposal for a Restriction – Substances in tattoo inks and permanent make-Up  - Public Consultation der European Chemicals Agency (ECHA)  Zu dem o. g. Entwurf im Hinblick auf eine Regulierung von Tätowiermitteln und Permanent Make-Up haben wir folgende Anmerkungen:  Im o. g. Dokument werden zwei Optionen (Restriction Option 1 – RO 1 und Restricion Option 2- RO 2) für eine mögliche Regelung vorgeschlagen.  Anmerkungen zu Restriction Option 1 (RO1):  - Unter Punkt 1 Buchst. a werden kanzerogene oder mutagene Stoffe, sowie Stoffe, die in Anhang II der VO (EG) Nr. 1223/2009 aufgeführt sind, und einige bestimmte Farbstoffe, die in Anhang IV der VO (EG) Nr. 1223/2009 aufgeführt sind, verboten. In der Praxis führen derartige Formulierungen oft zu unterschiedlicher Rechtsauslegung, da nicht genau klar ist, ab welcher Konzentration es sich um einen verbotenen Stoff und nicht mehr um „technisch unvermeidbare Verunreinigungen“ handelt. Um für alle Beteiligten Rechtssicherheit zu schaffen wäre es daher wünschenswert, wenn eine zusätzliche Formulierung im Hinblick auf die zulässige Konzentration geschaffen wird. Dabei wäre es u. E. zielführend analog zu Art. 17 der VO (EG) Nr. 1223/2009 vorzugehen und den Hersteller zu verpflichten, schlüssig darzulegen, dass die Anwesenheit von Spuren verbotener Stoffe die Sicherheit des Verbrauchers bei der Anwendung des Tätowiermittels nicht beeinträchtigt.  - Unter Punkt 1 Buchst. b werden Stoffe, die nach der VO (EG) Nr. 1272/2008 als Hautsensibilisierend, Hautätzend oder –reizend und/oder Augenschädigend oder –reizend eingestuft sind, verboten, wenn sie in Tätowierfarben in einer Konzentration von mehr als 0,1 % enthalten sind. Den Höchstwert von 0,1 % sehen wir im Hinblick auf einen vorbeugenden Verbraucherschutz als kritisch an. Die Einstufung nach der VO (EG) Nr. 1272/2008 wird im Hinblick auf eine intakte Hautbarriere durchgeführt. Durch die intradermale Applikation von Tätowierfarben wird jedoch das Risiko einer Hautreaktion noch erhöht. In diesem Zusammenhang möchten wir darauf hinweisen, dass beispielsweise für kosmetische Mittel bekannt ist, dass zahlreiche Substanzen auch in Konzentrationen von deutlich weniger als 0,1 % allergische Reaktionen auslösen können (z. B. Methyl-isothiazolinone, allergene Duftstoffe…). Insbesondere im Hinblick auf die Gefahr einer Sensibilisierung ist eine zulässige Konzentration von 0,1 % u. E. deutlich zu hoch.  Anmerkungen zu Restriction Option 2 (RO 2):  - Unter Punkt 1 werden Stoffe, die nach der VO (EG) Nr. 1272/2008 als Hautsensibilisierend, Hautätzend oder –reizend und/oder Augenschädigend oder –reizend und/oder als CMR-Stoffe eingestuft sind, verboten. Als Höchstgrenze werden dabei die allgemeinen Berücksichtigungsgrenzwerte aus der VO (EG) Nr. 1272/2008 herangezogen, sofern es keine spezifischen Konzentrationsgrenzwerte gibt. Die allgemeinen Berücksichtigungs-grenzwerte in der VO (EG) Nr. 1272/2008 liegen teilweise bei 1 % und sind daher sehr hoch angesetzt. Diese Regelung ist aus Sicht des vorbeugenden Verbraucherschutzes u. E. äußerst kritisch zu betrachten, da es somit möglich wird, dass kritische Stoffe in Konzentrationen im Prozentbereich enthalten sind. Da auch nur einzelne Stoffe geregelt werden, werden zudem mögliche additive Effekte völlig unberücksichtigt gelassen. In diesem Zusammenhang möchten wir auch auf die o. g. Hinweise zu Punkt 1 Buchst. b der RO 1 verweisen.  - Unter Punkt 3 wird auf Tabelle C und D verwiesen. In Tabelle C werden die in Kosmetika verbotenen Stoffe nach der VO (EG) Nr. 1223/2009 (Stand: Juli 2017) aufgeführt. In Tabelle D werden Farbstoffe aus Anhang IV der VO (EG) Nr. 1223/2009 (Stand: Juli 2017) aufgeführt.  Ein Verweis auf die europäische Kosmetikverordnung mit Stand vom Juli 2017 halten wir für nicht sinnvoll. Im Zuge des wissenschaftlichen Fortschritts wird die VO (EG) Nr. 1223/2009 in regelmäßigen Abständen aktualisiert und diese Änderungen sollten u. E. auch direkt für Tätowierfarben gelten. Mit der hier vorgeschlagenen Formulierung in RO 2 muss nach einer Änderung der VO (EG) Nr. 1223/2009 auch die hier vorliegende Regelung ständig aktualisiert werden. Das erachten wir für unnötigen Verwaltungsaufwand und ein viel zu langwieriges Verfahren.  Weiterhin wird als Konzentrationsgrenze sowohl für Tabelle C als auf für Tabelle D ein Wert von 0,1 % festgelegt. Insbesondere für die Stoffe in Tabelle C ist dieser Wert u. E. nach viel zu hoch. Die Stoffe in Tabelle C sind in kosmetischen Mitteln verboten und sollten daher u. E. in so niedrigen Konzentrationen enthalten sein wie irgendwie möglich. Bei Gehalten von 0,1 % handelt es sich bei den meisten Stoffen nicht mehr um technisch unvermeidbare Spuren. U. E. wäre es hier zielführender eine Formulierung analog zu Art. 17 der VO (EG) Nr. 1223/2009 zu wählen (vgl. Ausführungen zu Punkt 1 Buchst. a der RO 1).  - Unter Punkt 4 wird auf Tabelle E verwiesen. Hier handelt es sich ebenfalls um eine Tabelle, die auf Anhang IV der VO (EG) Nr. 1223/2009 (Stand: Juli 2017) verweist. Einen Verweis auf die europäische Kosmetikverordnung mit Stand vom Juli 2017 halten wir auch hier für nicht sinnvoll. Dazu möchten wir auf die Anmerkungen im Hinblick auf Tabelle C und D verweisen.  Anmerkungen betreffend beide Vorschläge (RO 1 und RO 2):  - Unter RO 1 Punkt 2 wird aufgeführt „Tattoo inks or permanent make-up shall not be placed on the market…“. In allen weiteren Regelungen heißt es immer nur „Tattoo inks…“.  Sofern die Definition unter Punkt 7 Buchst. a (RO 1) bzw. Punkt 8 Buchst. a (RO 2) hier richtig verstanden wird, wird vom Begriff „Tattoo ink“ jedoch sowohl der Begriff „Tätowierfarbe“ als auch „Permanent Make-Up“ abgedeckt. Es heißt „… whereby a permanent skin marking or design (a „tattoo“ or „permanent make-up“) is made.“. Es sind also sowohl Produkte, die für ein Permanent Make-Up verwendet werden, als auch Produkte, mit denen ein klassisches Tattoo gestochen wird, durch den Begriff „Tattoo ink“ abgedeckt. Im Widerspruch dazu steht jedoch die Definition unter Punkt 7 Buchst. b (RO 1) bzw. Punkt 8 Buchst. b (RO 2). Dort heißt es „intradermal injection of tattoo ink (or permanent make-up)“.  Es sollte daher die Begriffsbestimmung unter Punkt 7 (RO 1) bzw. Punkt 8 (RO 2) geprüft werden. Falls der Begriff „Tattoo ink“ beide Produktarten abdeckt, so muss unter RO 1 Pkt. 2 der Teil „… or permanent make-up…“ gestrichen werden.  Andernfalls müsste der Begriff „permanent make-up“ in alle anderen Punkte eingefügt werden.  - Unter Punkt 6 (RO 1) bzw. Punkt 7 (RO 2) wird eine Kennzeichnungspflicht für Tätowiermittel vorgeschlagen. Dabei müssen jedoch nur die Substanzen deklariert werden, die die Kriterien für eine Einstufung nach der VO (EG) 1272/2008 erfüllen. Wie bereits oben erläutert, beziehen sich die Einstufungskriterien der VO (EG) 1272/2008 nicht auf eine intradermale Applikation. Derzeit ist es, ähnlich wie bei Kosmetika, üblich, dass auf Tätowierfarben und Permanent Make-Up alle Inhaltsstoffe deklariert werden. U. E. muss es dem Verbraucher ermöglicht werden, bestimmte Stoffe meiden zu können. Dafür ist es dringend notwendig, dass eine vollständige Bestandteilliste auf Tätowierfarben angegeben ist. Auch im Hinblick auf die Diagnose und Behandlung von möglichen Hautreaktionen ist es u. E. notwendig, dass die Zusammensetzung des Produktes vollständig angegeben wird. Eine teilweise Deklaration nach den Kriterien der VO (EG) 1272/2008 halten wir aus Sicht des vorbeugenden Verbraucherschutzes für nicht zielführend.  - In Tabelle A werden Stoffe aufgeführt, die sowohl nach RO 1 als auch nach RO 2 nur bis zu bestimmten Konzentrationen in Tätowierfarben enthalten sein dürfen. Zu Tabelle A haben wir folgende Anmerkungen:  1. Es wird ein Arsenwert von 0,0000008 % vorgeschlagen. Dieser Wert ist u. E. nach nicht realistisch. Aufgrund der sehr schwierigen Matrix ist es u. E. nicht möglich, derart geringe Gehalte an Arsen in Tätowierfarben zu quantifizieren.  2. Für Barium, Kupfer und die gelisteten primären, aromatischen Amine wurde die Anmerkung „Soluble“ hinzugefügt. Es ist hier nicht ganz klar, wie genau diese „Löslichkeit“ definiert ist. In der Praxis macht eine derartige Regelung nur Sinn, wenn alle Beteiligten eine einheitliche Definition von „löslich“ nutzen. Es sollte daher genau definiert werden, was unter löslich zu verstehen ist und wie die Analytik dieser Stoffe stattfinden soll.  3. Für Methanol wird ein Wert von 10,9 % vorgeschlagen. Hier ist nicht ganz klar, warum ein derart hoher Methanolgehalt in Tätowiermitteln toleriert werden soll. Da es sich nach den hier vorliegenden Informationen nicht um einen Stoff handelt, der bestimmte Funktionen in Tätowiermitteln erfüllt, kann Methanol u. E. leicht reduziert werden. Eine Höchstmenge von 10,9 % ist für den Stoff Methanol u. E. nach zu hoch angesetzt.  - Unter der Rubrik „Scope and general information“ wird unter Punkt 1.1.4 aufgeführt, dass Konservierungsmittel in Tätowierfarben dem Biozidrecht unterliegen und daher nicht Bestandteil des Gesetzesentwurfes sind. Wir möchten in diesem Zusammenhang darauf hinweisen, dass das Biozidrecht nicht für Substanzen konzipiert wurde, die unter die Haut gespritzt werden. Aufgrund der intradermalen Applikation ist es u. E. dringend notwendig, dass auch Konservierungsstoffe in Tätowierfarben gesondert geregelt werden. Eine alleinige Regelung über die biozidrechtlichen Bestimmungen ist u. E. nicht zielführend. Derzeit werden in Tätowierfarben sehr kritische Konservierungsstoffe wie z. B. Benzisothiazolinone, Methylisothiazolinone oder Formaldehyd eingesetzt. Diese Substanzen sind zum Teil für Kosmetika nicht zugelassen bzw. streng reguliert und sollten aufgrund des sehr hohen allergenen Potentials auch in Tätowiermitteln gesondert reguliert werden. |
| **Dossier submitter response:**  Thank you for your comments.  RO1:   * Limits for CMR substances: For carcinogenic and mutagenic substances, please see responses to comments #1911 and #1890. * Limits for SS substances: Please see reply to comments #1890 and 1898   RO2:   * SS, irritant and corrosive substances and additive effects: please see comment #1998 * Dynamic link to the CPR: thank you for your support for updating the scope of the proposed restriction with future changes to the CPR. * Limits for CPR substances in scope: The proposed practical limits in RO2 were selected to discourage intentional use in tattoo inks and with regard to effectiveness and practicality. The Dossier Submitter considers that the limit for CPR substances in Annex II and Annex IV should be the lowest limit set for other hazardous properties in RO2. The Dossier Submitter is working with RAC and SEAC to identify other practical limits, where necessary to effectively discourage the use of hazardous substances in tattoo inks, taking into account the submitted comments during the Public Consultation. * Limits for SS substances: Please see reply to comments #1890, 1898 and 1921.   RO1 and RO2:   * Reference to permanent make-up (PMU): The proposed restriction wording was amended to avoid differentiating between PMU and tattoo ink. * Labelling: please see responses to comments 1890. * Concentration limits for substances in Table A:   + Arsenic: Please see the response to comment 1905.   + Soluble barium and copper: please see answer to comment #1918?   + Methanol: The Dossier Submitter is aware that methanol is just one of the denaturing agents that can be used. However data from the JRC report (2015b) actually show that methanol is currently already present in the products used by tattoo artists. Methanol is used as denaturing agent of ethanol up to a concentration of 5% and, as worst case, ethanol is reported to be used in tattoo ink in percentage up to 48% (JRC, 2015b). Within this scenarios we could assume that a maximum concentration of 2.4% of methanol could be reached in the formulation of ink (see annex III of Cosmetic Regulation). However the concentration limit for methanol in the ink corresponding to an RCR  = 1 has been calculated according to the following formula: Concentration Limit (CL) = maximum acceptable dose (DNEL x body weight)/amount of ink in (mg) x 100   CL = [(8 mg / kg bw / day x 60 kg)/ 4308 mg (amount of ink in a single session)] x  100 =  0.11 corresponding to an RCR = 1 in the worst case scenario. Thus, 10.9% is the concentration limit derived for an RCR < 1 (for both RO1 and RO2).   * Preservatives: The Dossier Submitter has proposed that a number of preservatives (with CMR, skin sensitising, irritant, corrosive, damaging properties or those prohibited for applications on the skin) are not used in tattoo inks. We also recognise that the BPR would add additional provisions. We agree with your observations on the deficiencies of the BPR in this respect and include your recommendations in the Background Document, section D.1.3. Other Union-wide risk management options than restriction in Annex D. * Concerning the comment on solubility, please see answer to comment #1918. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion. RAC supports the Dossier Submitter’s response.  Concerning carcinogenic/mutagenic and skin sensitising substances, please see justification for CLs proposed by RAC in RAC opinion, as well as RAC response to comment #1894. Concerning CLs for CPR substances, please also see RAC reply to comment #1898.  Regarding analytical determination of arsenic at CL proposed by the Dossier Submitter, please see RAC response to comment #1911. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. |
| **1927** | **Date:** 2018/06/20 15:08  **Content:**  Scope or restriction option analysis;#Hazard or exposure;#Baseline;#Description of analytical methods;#Information on costs  **Type:** MemberState  **Country:**  Netherlands  **Attachment:** | **Comment:**  NL in general prefers Restriction Option 1 (RO1) because this is more restrictive and thus more adequately fulfills the mandate for the restriction.  Restriction Option 2 (RO2) proposes to use the general concentration limits (or specific concentration limits if derived) from the CLP-regulation for Carc, Muta, Repro and sensitization. NL considers these limits as being unacceptably high for tattoo inks for substances known to be hazardous for these endpoints given the fact that tattoo inks are inserted into the skin.  Although overall NL prefers RO1, we still have objections to RO1 on several points:  • the proposed limit for skin sensitizers of 0.1% is too high for this important category of substances (most health complaints reported for tattoos consist of sensitization reactions);  • the proposed limit for substances classified for reproductive toxicity is arbitrary because it is based on risk calculations for a very low number of substances (only 4 relevant for tattoos). “Shall not contain” would be a better alternative in our view;  • azo dyes in the restriction should also include those azo dyes known to be used in tattoo inks, which are degradable to aromatic amines via azobond cleavage;  • the basis for the derogation for 23 colourants from Annex II to the cosmetics regulation which are banned from use in hair dyes but which are allowed in Annex IV, is unclear. This should be amended.  For more detailed comments see attachment. |
| **Answer to specific info request 5:**  See attachment with references to our yearly enforcement campaigns (in Dutch) |
| **Dossier submitter response:**  Thank you for your comments. Your support for RO1 and concerns with RO2 are noted. The answers below are organised in the same general topics as included in the submitted attachment:  General:   * *Reprotoxic substances:* The proposal “shall not contain” for reproductive compounds would be more protective than setting a concentration limit. However, Forum in its advice recommended to set concentration limits because they are easier to enforce than a total ban. * *Aromatic amines:* The release of aromatic amines from the azo-colourants is addressed in the uncertainty assessment. Since the exposure scenario is based on lifelong daily injections this can be seen as comparable to a daily release of aromatic amines from colourants captured in the skin. This approach would also hold had any colourant been risk assessed.   RO1:   * *Exemption of substances with harmonised classification via the inhalation route only:* Please see the responses to comments #1891 and #1894 for our response on this issue. * *Concentration limits for:*    + *skin sensitisers:* Please see the response to comment #1898   + *reprotoxic substances:* Your remark that the DNEL was based only on four substances cannot be supported as there are no data on the occurrence of other reprotoxic substances. The proposal of a concentration limit of 0.0014% was not based on the four reprotoxic substances found in tattoo inks, instead the concentration limit was based on a range of DNELs derived from 27 classified reprotoxicants as a surrogate for the level of potential DNELs in general.   + *PAHs:* Thank you for noting an error in the PAH concentration limit in tables 2 and 3 in the restriction report. The typos were corrected as per the proposed limit in sections 1.2.6 and Table 11 in the restriction report and B.10.2 in Annex B, i.e., 0.00005% w/w.   + *Barium:* The lower value of 0.2 mg/kg bw/day proposed by SCHER in 2012 is already discussed in Appendix B7 "Risk assessment of barium (Ba)". There is no need for a modifying factor of 3 to account for the lack of an adequate developmental toxicity study any longer as there now is a negative OECD 414 developmental study from 2014 available.   + *Chromium:* Thank you for the support for the proposed limit.   + *Remaining impurities from Table 3 of the Council of Europe ResAP(2008)1:* thank you for your support for the proposed limits   + *Aromatic amines and azo-colourants:* Thank you for the support of the proposed approach concerning the aromatic amines. Concerning cleavage of the azo-bond it is assumed that it does not occur as the decomposition products are not detected in tattoo inks (DEPA 2017b). It is further assumed that the amide hydrolysis may be biological mediated. Thus the strength of the chemical bond is not indicative for the decomposition pathway. With respect to the limit value in entry 43 of REACH Annex XVII, the low value was chosen in order to keep the concentration of the aromatic amines low as there are no limit values for the aromatic amines. As there are limit values for the aromatic amines in this proposal, no strict limit values for the azo-colourants are deemed necessary. * *Derogation for colourants:* The Dossier Submitter has proposed a derogation for these pigments primarily as sufficient information to demonstrate risks currently is not available and for some of these pigments (Pigment Blue15 and Green 7), consultations have revealed that (less risky) alternatives are not available. These conclusions were tested during this public consultation and any comments in response to questions 2 and 3 will be taken into account. These arguments for derogation were strengthened in the Background Document as you suggested. * *Labelling:* please see our responses to comment #1904 and #1890 on this issue. * *Remaining substances in scope of RO1:* Your agreement with the Dossier Submitter’s proposal is noted.   RO2:   * *Concentration limits:* Regarding RO2 please see the response to comment #1890. * *Dynamic link to CPR:* Thank you for stating your arguments in favour of dynamic link with the CPR. Your comments have been reflected in the Background Document.   Further remarks:   * *Definitions:* the definition of tattoo procedure was expanded to include microblading among other tattooing techniques. * *Impurities:* The proposed restriction does not differentiate whether the substance is intentionally added or present in tattoo inks as an impurity. * *Surveillance results:* Thank you for providing us with detailed information (including costs) on your surveillance projects on tattoo inks. The information has been reflected in the Background Document. * *Exposure assessment:* Please see General above. * *Preservatives:* Please refer to comments #1904, #1890 and #1921. * *Other comments:* The Dossier Submitter notes your support for the development of harmonised analytical methods, harmonised diagnostic codes to support of epidemiological evaluation, future updates and investigation of other substances that may pose risk to human health if contained in tattoo inks. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion. RAC supports the Dossier Submitter’s response.  Concerning skin sensitising substances, please see RAC response to comment #1894. Concerning CLs for CPR substances, please also see RAC reply to comment #1898. Also, please note that CL for soluble barium compounds proposed by the Dossier Submitter was corrected for oral absorption, leading to a value of 0.056% (for details, please see RAC opinion).  Concerning your comment on the relevance of azo bond cleavage, please note that in RAC opinion this uncertainty has been highlighted, and that regular updates of the restriction have been recommended, which are expected to enable risk assessment of colourants (and other chemicals used in tattoo inks) for which information on hazards and risks are inadequate at the present moment, including azo colourants decomposing by azo bond cleavage.  Regarding derogated colourants , please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. |
| **SEAC Rapporteurs comments:**  Thanks for the comments. SEAC takes note of the request for labelling all ingredients. The information on enforcement costs will be taken into account in the opinion in addition to information available in the background document. Regarding Pigment Green 7 and Blue 15:3; please see comment 1883 for further details. |
| **1928** | **Date:** 2018/06/20 15:32  **Content:**  Scope or restriction option analysis;#Hazard or exposure;#Baseline;#Description of analytical methods;#Information on alternatives;#Information on costs;#Information on benefits;#Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Academic institution  **Org. name:** European Society of Tattoo and Pigment Research (ESTP)  **Org. country:** Denmark  **Attachment:**      **Privacy comment:** There are three documents and they all are non-confidential and submitted as such, but I could not check all three were in and therefore submitted as confidential as well.  BUT ALL ARE NON-CONFIDENTIAL. Thus, if found in the non-confidenetial folder as three separate documents do not consider it confidential. | **Comment:**  All submitted material is non-confidential |
| **Answer to specific info request 1:**  See submitted reviews |
| **Answer to specific info request 2:**  See submitted reviews |
| **Answer to specific info request 5:**  See submitted synopsis and reviews  Percentage is surely very low, under 5%, difficult to determine sinde analytical standards are missing and analyses in practice chaotic! |
| **Dossier submitter response:**  Thank you for the comments of your membership. The Dossier Submitter’s response is organised to address the points you raise by general topic as outlined in the attached File 1 and by Review number as outlined in your attached File 2.  File 1: Synopsis of comments of ESTP members   * *The size, format, content and readability of the ECHA draft proposal relative to the industrial practitioners:* ECHA submitted the proposed restriction in cooperation with Denmark, Italy, and Norway. Germany also contributed significantly to the work. The restriction report follows prescribed format guided by REACH Annex XV, which refers to Annex I for risk assessment. While the report is extensive, it communicates clearly in the summary that the final proposal is very similar to the Council of Europe ResAP(2008)1. Norway and Germany already have national legislation on tattoo inks which is based on the predecessor of this resolution. Notable differences are the higher concentration limits for some groups of substances (in RO1: azo colourants, PAAs, PAHs, copper, methanol, barium, zinc and RO2: those plus CMRs and CPR Annex II and IV substances). Industry is already familiar with the requirements of ResAP as seven EU Member States and three EFTA members have national legislation based on ResAP. * *The risk that the ECHA proposal based regulation may criminalize the tattoo industry and open for a chaotic situation:* As stated above, RO1 is very similar to ResAp, while RO2 proposes higher limits and therefore, less strict requirements than in ResAP/national legislation. As national legislation has not criminalised the tattoo industry, or at least there is no such evidence on the basis of continued tattoo practice after the introduction of national legislation, it is difficult to assume that the proposed restriction, which proposes similar or less strict concentration limits, would lead to such criminalisation. The proposed restriction is on placing of the market and use of tattoo inks not meeting the requirements and not on the manufacturing or formulation of tattoo inks. The assumed price increase for tattoo inks for analytical purposes is 15% (main scenario) and up to 30% (sensitivity) and not 8% as included in your comment. * *ECHA proposal is not concordant with recent EU reports from the Joint Research Center, Ispra, Italy and a recent report from the European Council and neglects the many limitations delineated in these reports:* The Dossier Submitter has referenced extensively the work of the JRC and the Council of Europe in the restriction proposal. The four points you make on analytical methods, exposure assessment, epidemiological evidence for cancer and need for further knowledge of biokinetics are also acknowledged in the restriction report. Other relevant information in addition to the findings of JRC and the Council of Europe was also taken into account. * *ECHA proposal, cost-effectiveness in relation to the health condition end-point:* The Dossier Submitter acknowledges that the safety of tattoo practices depends also on factors that are outside of the remit of REACH, such as hygiene, training, licensing, etc. Thank you for acknowledging that “lack of clinical observation of association between tattoos and clinical cancer,” “cannot rule out that there is an association manifested as rare events or otherwise overlooked” and that “a large epidemiologic study has not been conducted” and that “such study may not be realistic since a huge sample and a control group will be required with measurement of a spectrum of events over many years.” Concerning the red tattoo inks and increased occurrence of skin complication, this has been reflection in the background document. * *The ECHA proposal is hazard based, not risk based:* All substance groups have been subject to a risk assessment according to Annex I of REACH and the relevant ECHA guidance, either qualitative or quantitative, that takes into account that these substances have been introduced into the dermis (in one or several tattooing session) and are available to exert their effects. * *Erroneous risk assessment in the ECHA report:* The approach is a pragmatic one in the absence of biokinetic data. We do not think that the majority of released substance from tattoo pigments is chemically different from the pigment, since the majority of pigments pigments are not chemically reactive. On the other hand, transport of pigment to the lymph nodes is well documented and probably accounts for the bulk of release or migration from the site of injection. * *Chemical ingredients, particles and analysis; RO1 and RO2:* The Dossier Submitter acknowledges the need for harmonisation of analytical methods. The availability of such methods is not a prerequisite for proposing a restriction. * *Labelling:* please see responses to comment #1890 and #1904. * *Tattoo ink production, industrial production line and the raw material supplies, missing link in the ECHA proposal:* The Dossier Submitter recognises that the tattoo ink industry is a small market segment for large pigment manufacturers and that some formulators have challenges acquiring pigments. It is possible that as a result of the more transparent requirements for tattoo inks introduced by the restriction proposal, more pigment manufacturers may increase their sales to the tattoo industry. * *Countries, national authorities and inspectors – can they practice the ECHA proposal?:* The restriction proposal is very similar to existing national legislation in seven EU Member States and three EFTA members, with some of these countries having experience enforcing this legislation for more than 10 years. It is anticipated that the remaining EU Member States will be able to build on this experience. * *Tattoo field is under-researched with an urgent need for research programs that can argue future regulation, “positive list”:* The need for further research was identified in the submitted dossier. . While difficult to introduce under REACH, your support for positive list of substances to be allowed in tattoo inks has been reflected in the Background Document.   File 2: Section 1: Reviews 5-8 from academic ESTP members independent of the industry:   * *Review 5:* For comments on hazard vs risk based restriction, harmonised analytical methods, microbial contamination (issues with tattoo safety outside of REACH remit), labelling, please see answers provided to the same points raised in File 1. Concerning the comment on detergents and surfactants having harmonised classifications as skin sensitisers, corrosive or irritants: no specific information is provided in the consultation but, in the event substances with these harmonised classifications are used, the proposed restriction will be effective in limiting any future use. * *Review 6:* Thank you for the information on tattoo reactions and complications. The information has been reflected in the Background Document. Concerning your comment on the production of pigments this has been addressed in the background document. * *Review 7:* The Background Document, section D.2.3.1 of Annex D, contains information on studies which support the assumption that about 50% of tattoo inks currently on the market meet the requirements of current national legislation (main scenario, 30% and 70% in sensitivity analysis). This information was enhanced with additional studies submitted during the public consultation; however, the Dossier Submitter does not find this additional information is pointing towards different assumptions related to the share of compliant tattoo inks. Your point of business size in terms of revenues is welcomed. The Dossier Submitter has no information on industry revenues as most formulators are privately owned. Thank you for your opinion that cancer effects are the most serious. We would like to highlight that the restriction dossier does not claim that infectious effects will be addressed as they are not impacted by the chemical composition of the inks. Your support for a positive list is noted. (An answer to this point in response to File 1.) Concerning the remark that RO1 and RO2 do not take into account the hazardous degradation products originating from colourants, which are the moment used in tattoo inks: Please see reply to comment #1911 (9), since this analysis is based on the list of colourants used in tattoo inks established by the JRC (se references in the background document). * *Review 8:* The preparation of this restriction proposal was initiated on the request of the Commission from 3 December 2015.[[1]](#footnote-1) The proposal sets specific concentration limits on substances in tattoo inks and does not differentiate between intentional presence or impurities of these substances. Similar to ResAP, the proposed restriction bans (RO1) or sets concentration limits to discourage use of pigments on Annex IV of the CPR restricted for use on cosmetic products in the vicinity of the eye, mucus membranes or allowed only in rinse off products. All other pigments (that meet the remaining proposed concentration limits) are not restricted. The proposal does not establish positive list. As stated above in more detail, the restriction report recognises the need for further work on analytical methods. The availability of such methods is not a prerequisite for a restriction proposal.   For comments related to the readability of the report, impacts on the tattoo industry, and analytical methods, please see answers to similar comments in File 1. There is no separate application for derogations. Derogation means that the restriction proposal does not apply to the derogated substances. Concerning the comments on azo colourants please see comment to #1911 (9). Concerning the comment on detergents and surfactants having harmonised classifications as skin sensitizers, corrosive or irritants: See comment to Review 5.  File 2: Section 2: Reviews 9-12 (12 includes 6 comments) from the tattoo industry:   * *Review 9:* For comments related to the readability of the report, impacts on the tattoo industry, and analytical methods, please see answers to similar comments in File 1. * *Review 10:* Please see answers to comments #1893, #1882 and #1883. * Review 11: With respect to impurities, the Dossier Submitter would appreciate detailed information on the feasibility of the proposed concentration limits. It is unfortunate that the provided submission is not sent in its entirety but we see that your comments are also incorporated in Review 12. Concerning the remark on azo-colourants and aromatic amine and diazonium salts, it should be noted that based on the list of azo-colourants that was provided by JRC, not all red, yellow and orange azo-colourants is included in the restriction proposal. * *Review 12:* The Dossier Submitter notes your opinion that RO2 “are much more feasible to implement and to adhere to from the industries perspective”. The submitted restriction report already recognised that RO2 “will minimize cost of testing” as you point out. Your arguments for a longer transitional period (of 5 years) are reflected in the Background Document.   The proposed restriction sets concentration limits that are similar to ResAP(2008)1 or higher. Notable exceptions are lead and arsenic. The information on potential sources of impurities is contained in Annex A. Please see Review 8 for derogations. Once in force, the scope of the restriction can only be amended with a new restriction proposal similar to this one.  Pigment Violet 23 and Pigment Red 122 have also been tested for the purpose of their use in cosmetic products: Pigment Violet 23 is prohibited in hair dyes (Annex II) and allowed in only rinse-off cosmetic products (Annex IV) but prohibited in any other cosmetic products by the CPR. Pigment Red 122 is also allowed in rinse-off cosmetic products only (Annex IV) by the CPR. According to the CPR *rinse-off product* means a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes. The Dossier Submitter has found that the nature of the exposure to tattoo inks can be equated to leave-on cosmetics products, at a minimum. Therefore, similar measures for tattoo inks are proposed as those for leave-on cosmetic products. The proposed restriction is proposing to exempting Pigment Green 7 as information to demonstrate risk is not sufficient and there are no less-risky alternatives.  Please see answers to similar points in File 1 regarding hygiene requirements and impacts on the tattoo industry.  Your request for five-year transitional period has been noted. The Dossier Submitter has included all documentation used for the assessment in the restriction report published here: <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/18114/term>. For answers to your comments on funding, similarity with ResAP(2008)1 and other considerations in addition to those within the remit of REACH, please see answers to similar points in File 1.  Concerning the data on the size of tattoo and other issues related to the tattoo practice, this has been developed and supported by the Danish Tattoo associations.  Due to lack of data and information, the removal of tattoos has been addressed in the current restriction proposal under uncertainties.  Concerning the remark on azo colourants and aromatic amines please consult comments to #1911 (9). Also no additional information has been provided.   * *Appendix, Review 1:* Both RO1 and RO2 state that in the event a substance is subject to more than one of the conditions, the stricter condition applies, except when specific concentration is set in Table A. Concerning the comment on detergents and surfactants having harmonised classifications as skin sensitizers, corrosive or irritants: See comment to Review 5. * *Appendix, Review 2:* Please see answers to submission #1913. * *Appendix, Review 3:* Please see answers to Review 7. * *Appendix, Review 4:* There is no tonnage limit for restriction under Annex XVII of REACH. Regarding comments on similarities between the restriction proposal and ResAP(2008)1, impacts on businesses, analytical methods, cancer effects, please see answers to similar points above. Your comment for the need of a registry for clinical complications of tattooing has been reflected in the Background Document. “P16.B.5.1 intro rightly recognizes the scarce knowledge on toxicokinetics…” Your concerns are noted, despite the uncertainties the proposal intends to use the best approach that is feasible with the available data on qualitative or if possible quantitative risk assessment. Page 59:The realistic worst scenario has been developed and supported by the tattoo associations in Denmark. Please consult the Background Documents for more details. Page 376: Both skin sensitising aromatic amines, metals and other substances with a harmonised classification as skin sensitisers have been addressed in the dossier. Thus, even though there is not yet established a one to one relationship in the skin reactions observed so far, the restriction proposal is most likely going to have an impact on the skin reaction in the red inks. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response, and notes, in addition:   * *File 1, Synopsis* - Regarding the comment that there is a risk “that the ECHA proposal based regulation may criminalise the tattoo industry and open for a chaotic situation” RAC also notes that the proposed restriction would maybe give an initiative for industry to develop a new branch of colourants intended to be specifically injected into the skin. This would change the present situation in which the colourants used in tattoo inks are often manufactured for other purposes (e.g., industrial applications such as printer inks or car paints) so they may contain levels of hazardous substances that are not appropriate for injecting into the human skin, while at same time, as correctly stated in your comment “the tattoo industry grew up over several decades from people’s wish to decorate their skin and grew into a huge and global industry with many millions tattooed all over the world”. * *Review 5* RAC noted your concern that too low CL for surfactants, which are often irritants, would make a good ink dispersion nearly impossible. However, since no further information on this group of substances (e.g. 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) were provided during the Public Consultation, RAC could not further evaluate this concern. This issue, nevertheless, could be further assessed during the Public Consultation on the SEAC draft final opinion. * *Review 6* – Uncertainties related to allergic reaction (and other adverse reactions) to not yet identified decomposition products of injected tattoo pigments are highlighted in RAC opinion (e.g. please see Section B.3.2). * *Review 7* – Regarding harmonisation (and standardisation) of analytical methods please RAC response to comment #1918. * *Review 10* – Concerning CL for arsenic, please note that a practical CL proposed by RAC (0.00005%, please see RAC response to comment #1905) is at the level that you proposed (0.00004%). Regarding arsenic level in iron oxides, no comment was received during the Public Consultation. * *Appendix, Review 2* – Please see RAC response to comment #1913. * *Appendix, Review 3* – Please see RAC response to Review 7. * *Appendix, Review 4* – Uncertainties related to allergic reaction (and other adverse reactions) to not yet identified decomposition products of injected tattoo pigments are highlighted in RAC opinion (e.g. please see Section B.3.2).   Regarding derogation of Pigment Blue 15:3 and Pigment Green 7 proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904.  With respect to a “positive list” of substances allowed in tattoo inks, please see RAC response to comment #1912. |
| **SEAC Rapporteurs comments:**  SEAC takes note of the information and statements regarding derogation of PG7 and PB15 (please see comment 1883 for further details), the transitional period, the concentration limits, effectiveness, labelling and practicality. This will be reflected on in the opinion. |
| **1929** | **Date:** 2018/06/20 16:05  **Content:**  Scope or restriction option analysis;#Hazard or exposure;#Baseline;#Description of analytical methods;#Information on costs;#Information on benefits;#Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Academic institution  **Org. name:** Euroepan Society of Tattoo and Pigment Research (ESTP)  **Org. country:** Denmark  **Company name confidential:** False  **Attachment:**    **Privacy comment:** All submitted ESTP material is non-confidential | **Comment:**  This submission of the ESTP final conclusion is the third submission (earlier today submission of synopsis and reviews as two separate documents) |
| **Answer to specific info request 1:**  See package of three ESTP documents |
| **Answer to specific info request 2:**  See package of three ESTP documents |
| **Answer to specific info request 3:**  See package of three ESTP documents |
| **Answer to specific info request 4:**  See package of three ESTP documents |
| **Answer to specific info request 5:**  See previously submitted note by ESTP |
| **Dossier submitter response:**  Thank you for your comments. The Dossier Submitter notes your earlier submission with detailed comments synthesised in the attached file of this submission. Please see detailed responses to comment #1928 for the issues you raise again in the attached file.  Your support for a stand-alone regulation and a positive list of substances to be allowed in tattoo inks is reflected in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response. Please, also see RAC response to comments #1912 and #1928. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. |
| **1930** | **Date:** 2018/06/20 17:53  **Content:**  Scope or restriction option analysis;#Hazard or exposure;#Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** Health and Environment Alliance (HEAL) + European Environmental Bureau (EEB)  **Org. country:** Belgium | **Comment:**  These comments complement comments filed by the Health and Environment Alliance (HEAL) and the European Environment Bureau (EEB) on 25th May 2018.  Comments about proposed approach to reprotoxic chemicals  HEAL and the EEB are surprised at the assumption made in the restriction proposal that reprotoxic substances have thresholds. This is not justified, in particular with respect to those that are endocrine disrupting substances (EDCs). As the proposal itself points out, "Some of the substances that were assessed are known to have endocrine disrupting properties, e.g., phthalates". It is well-known that EDCs can be effective at extremely low concentrations. However, the proposal dismisses this concern, by stating that "The Dossier Submitter still assessed reproductive toxicity as a threshold endpoint in this restriction proposal as this will indicate a minimum level of risk where the concern may be higher if there was no threshold due to any ED effects." This appears to be an admission that the threshold assumption indicates the \*minimum\*, not the maximum, estimate of risk. According to HEAL and the EEB, this is the opposite of a health protective approach and should be changed.  Whether or not EDCs can be expected to have a threshold is a complex question. Perhaps the primary argument against a threshold is that a single molecule of a ligand can bind a receptor, possibly triggering a downstream effect. A 2013 review commissioned by KEMI found evidence on both sides of this question, concluding that, "it seems that the decision on whether or not to accept a non-threshold model for EDCs has to be based on considerations of mechanism of action," and that "the decision on whether or not to accept a non-threshold model for EDCs has to be based on considerations of mechanism of action” (KEMI 2013a).  If EDCs act by binding and activating (or antagonising) receptors, there is also a great potential for joint action. In particular, it is clear that "similarly-acting" compounds that trigger the same receptor can in some cases produce greatly elevated, apparently "synergistic" effects. For example, an early paper by Silva et al. (2002) showed that mixtures of xenoestrogens provoked strong responses, even though each individual compound was in the mixture at a level below the NOAEL (or NOEC).  Although the definition of "similar action" is still debated, simple mathematical models of ligands acting on receptors can effectively predict their joint effects. Mixtures with similar action at the molecular level -- for example, different ligands of a particular receptor -- can in principle be modelled. This approach has been used successfully for both estrogenic (Brinkmann et al. 2018) and anti-androgenic (Kortenkamp et al. 2010) modes of action.  Thus, it is very plausible that EDCs do not have a threshold, and that any EDC acts jointly (or additively) with both the endogenous hormones and the other EDCS to which a person might be exposed. The threshold assumption for EDCs will almost always be an underestimate of the risk, as even the restriction proposal admits.  Therefore,EDCs should be considered as non-threshold substances by default.  Comments about the DNEL approach  The "lowest DNEL" risk characterization of the reprotoxic substances would appear to be a precautionary approach to assessing risks for this group of chemicals, \*only if\* all have thresholds. However, in the case of this restriction, the approach is overextended.  The proposal omits the dose descriptor for tributyltin compounds as an "outlier", without justification. The "lowest" DNEL will therefore underestimate the risk for tributyltin compounds, and any other compounds that might have similarly low dose descriptors.  Considering the size of this restriction, which may be in place for many years, HEAL and the EEB are concerned that this "lowest DNEL" approach might be applied to many more possible reprotoxic compounds. In addition to the reprotoxic substances category 1a/1b, the restriction proposal also applies the "lowest DNEL" to all reprotoxic substances category under CLP. There are even less data available about reprotoxic category 2 substances, so it is unclear what other approach would be available. It should be noted that the reprotoxic categories (1a/1b vs 2) have nothing to do with potency, but only with the amount of data and the weight of evidence available. We have no reason to assume that a CLP category 2 reprotoxic substance has a higher DNEL than a reprotoxic category 1a/1b substance; so the "lowest DNEL" is being applied very broadly with little justification.  Finally, while the "lowest DNEL" approach seems reasonable, it appears to be an overextension of the read-across process. The reprotoxic group is defined based only on a very general endpoint or set of endpoints (reprotoxic), but the application of "lowest DNEL" approach means that the read-across is used to predict potency (NOAEL/LOAEL or DNEL) of very different molecules. Read-across is usually used for comparison of substances with very similar structure, activity, and mode of action. The "lowest DNEL" approach is therefore making a lot of assumptions about the potency of reprotoxic substances in general without proper justification.  The "no data, no market" principle is a core principle of REACH. The "lowest DNEL" approach would only be reasonable if all reprotoxic substances worked similarly. If this was the case, we could assume that the DNEL of one might apply to the others. In this case however, it appears that the lowest DNEL approach is based on the assumption that limited data available can be applied to a broad and nearly unrelated category of substances in order to allow them on the market.  Other comments  • We support the comments made by Sweden, in particular the note of caution about the specific concerns relating to the intradermal route of tattoo inks through injection. We have highlighted this issue in the previous comments that we filed.  • As we have also pointed in our earlier comments, in its current form and under the proposed options, the restriction proposal would weaken the existing regulations of some Member States. This is clearly unacceptable and we fail to understand the rationale for the proposed approach.  • The restriction proposal explicitly emphasizes skin sensitization over other endpoints. Skin sensitization is clearly an important endpoint for T/PMU, but we should not be ignoring other, more chronic and subtle endpoints.  • When it comes to labelling, it is important to keep in mind that most tattoo artists are independent and very small businesses, with little or no resources or expertise to evaluate the chemicals they use. In this context, the regulatory emphasis should be placed on the producers of tattoo inks (and other cosmetic inks which should be labelled as not suitable for T/PMU). Since there are presumably many fewer ink producers than tattoo artists, labelling will be easier to monitor and enforce than ink use. Finally, effective labels would allow consumers (tattoo recipients) to participate in enforcement as well, since they can simply request to see the label on the ink tube or bottle used by the artist. ECHA should make a concerted effort to engage the relevant constituents – tattoo artists, ink producers and tattoo recipients - to ensure that the regulation is most appropriate and effective in the long-term. |
|  |  | **Dossier submitter response:**  Thank you for your comments. The Dossier Submitter has organised the answers to the comments by the general topics outlined in your submission:  Proposed approach to reprotoxic chemicals: Please see the answers to comments #1894 and #1904  DNEL approach: Please see the answers to comments #1894 and #1904. Your concern about assuming that a CLP category 2 reprotoxic substance has a higher DNEL than a category 1 reprotoxic substance is noted.  Other comments:   * Please see answers to comments #1890 and 1898. * As explained previously, the proposed RO1 is very similar to ResAP(2008)1 and the national legislation based on it and its predecessor. With small exceptions (for barium, copper and zinc), the originally proposed concentration limits are lower than those enforced under some national legislation. Regarding RO2, the proposed practical limits are higher than in RO1 as they were selected to discourage intentional use in tattoo inks and with regard to effectiveness and practicality. However, we understand your concerns and the Dossier Submitter is working with RAC and SEAC to identify other practical limits, where necessary to effectively discourage the use of hazardous substances in tattoo inks, taking into account the submitted comments during the Public Consultation. * *The restriction proposal explicitly emphasizes skin sensitisation over other endpoints:* See response to comment #1904. * Labelling: please see response to comment #1890 and #1904. Your support for clear labelling is noted and is the intention of the restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response. |
| **SEAC Rapporteurs comments:**  No further action required by SEAC. |
| **1931** | **Date:** 2018/06/20 18:17  **Content:**  Scope or restriction option analysis;#Baseline;#Information on alternatives;#Transitional period;#Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** TIME - Tattoo Ink Manufacturer of Europe  **Org. country:** Germany  **Attachment:** | **Comment:**  please see attachment |
| **Answer to specific info request 1:**  not achievable for Arsenic and Lead, difficulties with chromium |
| **Answer to specific info request 2:**  There are no alternatives for these pigments |
| **Answer to specific info request 3:**  can be replaced by alternatives |
| **Answer to specific info request 4:**  It is possible to comply with the limits |
| **Answer to specific info request 5:**  less than 50% are compliant |
| **Dossier submitter response:**  Thank you for your comments. The Dossier Submitter has organised the answers to the comments by the general topics outlined in your submission:  Applicability of REACH: For microbiological risks, applicability of REACH resriction to tattoo inks and analytical methods, please see response to comment #1928. Your support for a stand-alone legislation is noted.  Preference for RO2: Your support for RO2 is noted and reflected in the Background Document.  Transitional period: Your request for five year transitional period is reflected in the Background Document.  *Concentration limits for selected heavy metals and Specific info request 1:*   * *Arsenic:* Please see response to comment #1905. * *Lead:* Please see comment #1893 – the same considerations apply. * *Chromium:* Thank you for the comments. Insufficient information has been submitted for assessing the proposed concentration limit as this is also the current limit in ResAp. The Dossier Submitter’s understanding is the current ResAp limit of 0.2 ppm is measurable.   Derogated pigments: Thank you for your comments. They have been reflected in the Background Document.  Final comments: Please see response to comment #1928.  Thank you for your comments to specific info request 2-4. They have been noted. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response.  Concerning CL for arsenic, please see RAC response to comment #1905, and regarding your comment on missing harmonised and validated analytical methods, please see RAC response to comment #1918.  Regarding derogation of Pigment Blue 15:3 and Pigment Green 7 proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. |
| **SEAC Rapporteurs comments:**  SEAC takes note of the information and statements regarding derogation of PG7 and PB15 (please see comment #1883 for further details), the transitional period and the concentration limits. This will be reflected on in the opinion. |
| **1934** | **Date:** 2018/06/20 21:13  **Content:**  Hazard or exposure;#Information on alternatives  **Type:** Individual  **Country:**  Norway  **Attachment:**    **Privacy comment:** No info on this | **Comment:**  In this third submission I argue against the derogation of the colorants PB15 and PG7 also mentioning possible alternative colorants. |
| **Answer to specific info request 1:**  See my secondary submission about soluble copper |
| **Answer to specific info request 2:**  I do not agree - see Attached paper |
| **Answer to specific info request 3:**  See previous submission |
| **Answer to specific info request 4:**  See previous submission |
| **Answer to specific info request 5:**  No information |
| **Dossier submitter response:**  Thank you for your comments on the proposed derogation for Pigment Blue15 and Pigment Green 7 and possible alternatives.  Derogation for Pigment Blue15 and Pigment Green 7:  The Dossier Submitter has on the basis of technical feasibility and hazard and risk considerations proposed a derogation for Pigment Blue15:3, Pigment Green 7 and other pigments prohibited for use in hair dyes under Annex II of the CPR (see section 2.2 c and Annex D in the restriction proposal). In the ECHA Call For Evidence in 2016, Pigment Blue15:3 and Green 7 were named by industry as the only two pigments which could not be replaced with suitable alternatives (technically feasible and leading to lower risks) in the short to medium term. Both are phthalocyanines and as such their crystalline structure leads to low solubility in organic solvents. They are insoluble in water, and stable in neutral, acidic or alkaline solutions. As shown in Appendix B.9, the Dossier Submitter cannot demonstrate risk from phthalocyanines (e.g., Pigment Blue15 or Green 7) with the currently available information.  While there are a number of pigments on the global market, according to stakeholders, whether a pigment is suitable for tattoo purposes can only be determined via tattoo tests. Some of the main technical characteristics sought in a tattoo ink and a PMU are: colour hue, brilliance, permanence, good workability, healing properties, particle size, etc.  Pigment Blue15:3 is reportedly the best blue colourant on the market for tattoo inks and to date, there is no information for a possible substitute of this pigment. No other information on technically feasible alternatives was received during the public consultation. Although there are other blue pigments, these have been found to lead to higher risks (due to degradation products) or lead to colour change when blended with white pigment (a desirable quality as colourants are often mixed to obtain different colour shades).  Pigment Green 7 is also considered the best green pigment on the market from a technical standpoint. Although Pigment Green 36 has been identified by some as a technical equivalent to Pigment Green 7, industry has expressed that on the basis of available hazard information on both green 7 and 36, it can be concluded that Pigment Green 7 has better hazard and risk profile for human health. No other technically feasible alternatives to Pigment Green 7 have been identified to date. No other information on alternatives was received during the public consultation.  Both Pigment Blue15:3 and Pigment Green 7 are examples of colourants restricted in hair dyes under Annex II of the CPR on the basis of the cosmetic industry not providing relevant information to justify continued use for this application. Under Annex IV of the CPR both colourants are allowed in all other cosmetic products, although there is a restriction for Pigment Green 7 for use in products in the vicinity of the eye.  According to information gathered by JRC (JRC, 2015b), 13 blue and green pigments have been reportedly used in tattoo inks. Of those, ResAP(2008)1 recommends that the three colourants Pigment Blue15:3, Direct Blue 86 and Pigment Green 7 are not used in tattoo inks. However, it should be noted that consultation with Forum has revealed that Pigment Blue15:3 is not consistently enforced in all Member States with national legislation as it is banned under Annex II but allowed under Annex IV of the CPR.  Therefore, to your question on whether Pigment Blue15:3 and Pigment Green 7 should be allowed or not, the Dossier submitter is of the opinion that the two pigments should be derogated on the basis of technical feasibility and hazard and risk considerations.  Possible alternatives:  Thank you for your additional information on the use of blue and green pigments in tattoo inks, which is based on the market surveillance data included in the recent CoE EDQM report. The continued use of blue and green pigments under the proposed restriction options are already described in section D.2.3.1 "Availability of alternatives" of the restriction proposal. The additional use information for blue and green pigments in tattoo inks will be included in the BD to supplement the already existing information taken from the JRC report (JRC 2015b).  Comments on other pigments:  In your comment you also raise some concerns related to the use of some other blue and green pigments in tattoo inks. Neither of these pigments fall into the harmonised classification groups included in the scope of the two restriction options and Acid Blue 9 (CAS no. 3844-45-9), Acid Blue 74 (CAS no. 860-22-0) and Pigment Green 17 (CAS no. 1308-38-9) will be allowed to use in tattoo inks based on similar conditions as specified for these pigments in CPR Annex IV. Concerns related to the risk profile of Pigment Green 36 (in comparison to Pigment Green 7) were expressed on several occasions during consultations with stakeholders for the preparation of the restriction dossier (see section Appendix D.1 "Substances for future assessment"). Pigment Green 36 (CAS 14302-13-7) is registered under REACH, it has no harmonised classification and no relevant self-classifications have been submitted to ECHA. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response.  Regarding derogation of Pigment Blue 15:3 and Pigment Green 7 proposed by the Dossier Submitter, please see RAC opinion (section B.3.1.3) and Appendix B.12 in the Background Document, as well as RAC response to comment #1904. |
| **SEAC Rapporteurs comments:**  SEAC takes note of the information and statements regarding derogation of PG7 and PB15 and the availability of alternatives for these two pigments; please see comment 1883 for further details. |
| **1935** | **Date:** 2018/06/20 23:55  **Content:**  Hazard or exposure;Description of analytical methods;Information on alternatives;Information on costs;Information on benefits  **Type:** MemberState  **Country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:** As the comments in the present submission might correlate to the proceeding of ongoing work of ECHA Committees we decided to submit these as confidendial to prevent any disturbing effect. However if ECHA considers these comments are safe to be released, we allow (and encourage) ECHA to declassify these comments and release them for public access. | **Dossier submitter response:**  Thank you for your comments. The The Dossier Submitter has organised the answers to the comments by the general topics outlined in your submission:  1. *RAC mandate with respect to setting concentration limits:* Thank you for the comment. Unfortunately this is not a comment on the Annex XV restriction report, so the Dossier Submitter will not comment further.  2. *Update of list of classified substances:* Thank you for the comment. Unfortunately this is not a comment on the Annex XV restriction report, so the Dossier Submitter will not comment further.  3. *CLP concentration levels:* Regarding RO2, the proposed practical limits are higher than in RO1 as they were selected to discourage intentional use in tattoo inks and with regard to effectiveness and practicality. However, we understand your concerns and the Dossier Submitter is working with RAC and SEAC to identify other practical limits, where necessary to effectively discourage the use of hazardous substances in tattoo inks, taking into account the submitted comments during the Public Consultation.  4. *Skin sensitisers:* Please see answer to comment #1898  5. *Labelling:* Please see response to comment #1890.  6. *Reprotoxic substances:* Please see the answers to comments #1894 and #1904.  7. *Methanol:* Please see answer to comment #1924.  8. *PAHs:* Please see the answer to comment #1894  9. *Arsenic, barium and lead:* Thank you for the comment and the support for the risk based limits for these substances. The soluble barium impurities that may be present in insoluble pigments are not added intentionally to produce a colour. The concentration are set to limit the amount of impurities. Switching to alternative inks to e.g. BaSO4 (white pigment) is not seen as a realistic option. However, to limit the content of impurities will minimise the risk.  10. *Azo colourants* and aromatic amines: Concerning aromatic amine and azo colourants in general please see the answer to 1911 (9). Concerning the methods for measuring aromatic amines even when applying the standardised methods as you have mentioned not all laboratories could obtain a detection limits of 5 ppm for all aromatic amines in the proposal.  11. *Cumulative effects:* Thank you for the comment. The issue of cumulative effects is not possible to consider for all the individual substances included in the restriction scope. The Dossier Submitter suggests this is dealt with in the uncertainties section of the Background Document related to the risk assessment.  12. *Training requirements:* Please response to comment #1928 on this issue. |
| **RAC Rapporteurs comments:**  Thank you for your comments, which were considered in the development of RAC opinion.  RAC supports the Dossier Submitter’s response. In addition, RAC notes the following:  *1st comment* – RAC agrees with you that RAC’s recommendation of CLs cannot be based on availability of analytical methods, for the reasons you pointed put. On the other hand, RAC acknowledges that some practical considerations have to be taken into account. RAC, therefore, proposed for some substances, in addition to risk-based (e.g. “should not contain”, please see Table 6 *Concentration limits proposed by the Dossier Submitter and RAC* in RAC opinion), practical concentration limits (for definition please see RAC opinion), while minimising the risk for human health. Practicality considerations which RAC primarily took into account were Forum advice on enforceability (please see RAC response to comment #1894), as well as technical achievability, taking into account justifications provided by the Dossier Submitter and comments received during the Public Consultation. An example is a practical concentration limit for arsenic (for details, please see comment #1905 regarding arsenic in titanium dioxide pigment, as well as RAC’s reply to that comment). Another case are PAAs, for which RAC supported the Dossier Submitter’s proposal for a practical CL (in addition to a risk-based), primarily based on technical achievability and availability of alternatives. In this case LoDs of available analytical methods were discussed, but were not decisive for RAC proposal.  *2nd comment* – Thank you for your considerations, including your support for a seamless connection to the Cosmetic Regulation annexes, where applicable. Namely, a dynamic link with the CPR is a preferred option by RAC as well (please see RAC opinion, section B.3.1.3).  *3rd comment* – Please see RAC response to comment #1894.  *4th comment* – In addition, please see RAC response to comment #1894.  *6th comment* – Regarding non-threshold substances, please see RAC response to your 1st comment.  *8th comment* – Unfortunately, data that would enable risk assessment of PAHs via intradermal exposure route are not available at the present moment, as well as for a great majority of other substances in the scope. Until new data become available, RAC agrees with the Dossier Submitter’s proposal to apply CL set for PAHs in children’s toys, but proposes to set a lower CL for BaP, based on higher carcinogenicity potency of this compound compared to other regulated PAHs (which is also in line with CoE ResAP(2008)1). PAHs are not intentionally added to tattoo inks, but depending on the production process they can be present as impurities in carbon black pigments. |
| **SEAC Rapporteurs comments:**  Thank you for the comments. Regarding your support for a dynamic link to the CPR, SEAC’s preference is for a static link, so that information on substitutes, costs etc. of including additional substance in the restriction can be assessed. However, the need to add such substances are likely to be limited due to the dynamic link with CLP that SEAC supports. |

1. <https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf/ed07424a-328d-88e0-b7c6-412251426582> [↑](#footnote-ref-1)