Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. Please provide details on individual substances whose limits outlined below are not technically feasible. Do these individual substances have alternatives in tattoo inks that are technically and economically feasible and leading to lower risk? Where the substance is an impurity in a pigment (or another substance) for example, is the pigment available with impurity levels meeting these concentration limits or does the pigment have technically and economically feasible alternatives? What would be the consequences for the tattoo industry if tattoo inks are not allowed to be sold and used in the European Economic Area (EEA) if they contain these individual substances in concentrations above these limits? Please justify your answers.

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| **Substance group** | **RAC modified concentration limits (% w/w):** |
| CPR Annex II | 0.00005 |
| CLP Carcinogenic categories 1a/b, 2 | 0.00005 |
| CLP Mutagenic categories 1/ab, 2 | 0.00005 |
| CLP Reprotoxic categories 1a/b, 2 | 0.001 |
| CPR Annex IV (column g) | 0.00005 |
| CPR Annex IV (column h-i) | CPR, Annex IV requirements in columns h-i |
| PAH with harmonised classifications as CM | 0.00005 (for each PAH except for BaP: 0.0000005%) |
| PAAs of concern (dissolved fraction) | 0.0005 |
| Azo colourants with relevant classification (CMR, SS), or which could decompose to PAAs of concern | 0.1 |
| CLP Skin sensitisers categories 1, 1a/b | 0.001 |
| CLP Skin irritant & corrosive categories 1a/b/c, 2 | 0.01 |
| CLP Eye irritant & damaging categories 1, 2 | 0.01 |
| Methanol | 11 |
| Impurities in ResAP(2008)1 Table 3: | |
| -Cadmium | 0.00005 |
| -Chromium(VI) | 0.00005 |
| -Mercury | 0.00005 |
| -Copper\* | 0.025 |
| -Zinc\* | 0.2 |
| -Barium\* | 0.05 |
| -Nickel | 0.0005 |
| -Selenium | 0.0002 |
| -Antimony | 0.00005 |
| -Lead | 0.00007 |
| -Cobalt | 0.00005 |
| -Arsenic | 0.00005 |
| -Organometallic tin | 0.00005 |

1. What will be the consequences if tattoo inks are not allowed to be sold or used in the EEA if they contain Pigment Blue 15:3 and Pigment Green 7 in concentrations above 0.00005% w/w? (Please note that the other crystalline modifications of Pigment Blue 15 are proposed to have the same concentration limit.) Are there other technically and economically feasible blue and green pigments leading to lower risk in comparison to Pigment Blue 15:3 and Pigment Green 7? Please provide justification for your answers.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 403 | **Date/Time:** 2019/01/22 09:30  **Type:** MemberState  **Country:**  France  **Attachment:** | **Comments on the SEAC draft opinion:**  It seems that the comments of the ANSM could not be taken into account last June, that is why at the request of your services, we will address them, hoping this time that these comments are well taken into account. |
| **SEAC Rapporteurs response:**  Thanks for resending the ANSM comments.  We take note of your concerns regarding the alignment of the proposed restriction with the current French regulatory requirements. It is not in SEACs remit to provide an opinion on Member State national regulatory changes needed following a REACH restriction.  We note your request to ascertain in the restriction that the tattoo ink/PMU marketing authorisation holder is responsible for assessing safety of use of all ingredients, i.e. including those ingredients that are not included in any of the lists of covered by the restriction and for which limit values are proposed. SEAC rapporteurs note that it is not the intention of the Dossier Submitted to introduce a system of market Authorisation of tattoo and PMU products. The restriction proposed aims to control the unacceptable risks of all chemicals for which based on current knowledge and evidence action needs to be taken at EU-wide level. The restriction does not prevent national authorities to take additional measures that are not addressed via the proposed REACH restriction. This comment does not affect SEACs opinion on the proposed restriction.  SEAC notes your lack of support for RO2 based on too high concentration limits. We note your support for RO1 limit and request for inclusion Cat 1A/B reproductive toxicants without a limit value. SEAC supports RAC modified concentration limits, which take into consideration risks and feasibility and are set at 0.001% (w/w) for Reprotoxic Cat 1A/B/2 substances. We see no need to amend the final SEAC opinion.  We note your request for the restriction to cover all CMR substances based on the CLP 1272/2008 regulation (Annex VI of CLP entry) and not only once these substance are covered in Annex II of CPR. SEAC sees this in line with the proposal by the dossier submitter. There is no need to refer to this remark in the final SEAC opinion.  We note your lack of support with exempting Carcinogenic substances classified for the inhalation route only as people may become exposed e.g. through nano-sized droplets formed during the tattoo procedure. SEAC notes RAC concluded risks associated with the inhalation route only are not relevant for those getting a tattoo and furthermore stated that such substances might create a risk for tattoo artists, but health hazards related to occupational exposure are out of the scope of this proposal. This remark does not affect the final SEAC opinion.  Regarding the pigments in Table D and E you request a clarification why these are included. Please compare by Annex IV entry number. CI77015 and CI77489 (in Annex IV entries 121 and 134 respectively) are matched based on automatic CAS or EC matching with entries 135 and 137, which have conditions. The proposed restriction will be referring to the current text of the Annexes II and IV of the Cosmetics Products Legislation (CPR).  We note your lack of support for exempting colourants that are banned in Annex II but allowed in Annex IV based on the fact that their use has not been assessed for the dermal route. SEAC does not support derogations of 19 colourants listed in supplementary Table B of the Background Document since the Public Consultation on the submitted dossier revealed only some of the pigments are used and for all of them alternatives are available. Based on all comments received, Several comments were received on the issue of derogation. Based on all comments received SEAC proposed a time-limited derogation for Pigment Blue 15 and Pigment Green 7 on the basis of other submissions and RAC’s conclusions on the proposed pigment derogations.  We note your lack of support for the generic 0.1% (w/w) concentration limit for sensitising substances in RO1. SEAC supports RAC modified concentration limits for all sensitisers set at 0.001% (w/w). This remark does not affect the final SEAC opinion. |
| 404 | **Date/Time:** 2019/02/02 22:45  **Type:** Individual  **Country:**  United States  **Attachment:** | **Comments on the SEAC draft opinion:**  To Whom It May Concern,  I am writing my comment on the approach of banding C.I.P.G7 (Cyanine Green)& C.I.P.B15 (4352 Fast Blue B); in which I think is very unfair to the tattoo industry & pigment producers on the steps that are being taken to try and bring us down. All of the name brand tattoo ink producers that have been around for many years have taken every precautionary action possible by having our colors tested, gamma ray treated, having clean rooms, etc., so that we can have our pigments as pure, clean, & safe as possiblebut yet we’re getting organizations that no nothing about the tattoo industry to try and tear this business down. We have been making pigments safer& saferfor many years and still continuing to do so and yet you guys are still not satisfied and want to make it impossible for us to make safe pigments by making regulations unrealistic, unfair, unaffordable and impossible to meet. You are not helping the tattoo industry by doing this you are making it worse and artists will fall of the face of the earth doing them illegally and hidden. Looking back on how unsanitary tattooing used to be to how sanitary it has become now is just amazing and such a huge relief for us as pigment manufactures. I speak for myself but I think all of us would not put tattoo ink into your skin if we would not put it in our own. Also, why have you all not done these decades ago when the tattoo industry was very unsafe& unsanitary but yet even then there has been no fatalities or severe health illnesses known of. This makes me believe the only reason that these groups are formed to try and bring us down is pure greed and discriminating because there has never been a fatality ever and most of the bad reactions that are severe come from untrained and unprofessional artists. What is being done is going to drive this business back underground in which it has already started because we are all being frowned upon once again by people that are against tattoos. You need to understand that tattoos have become a way of life and people get them to express who they are and to help them get through the best and worst times of their lives. Stop trying to take that away from all of us.  That being said by abandoning C.I.P.G7 (Cyanine Green); C.I.P.B15 (4352 Fast Blue B) will be devastating to our business because you will now have taken over half of our colors away from us since we mix a lot of them with greens and blues. These colors have never been a problem nor have we ever had any complaints about them causing any problems. I do not understand where and how you are making the assumptions to get rid of some of these colors especially the basics for they have been around for decades with no harm done. By doing this you will also make it harder on tattoo artists to give their clients the best color work they can give them by taking this out of their color palette. These are some of our most popular colors and again we use them for over half of our StarBrite brand that is distributed worldwide so by doing this you will hurt our brand that we have worked so hard for many years to get our customers a massive color option to make their jobs easier, consistent and more efficient. We ask you with our deepest concerns not to allow this to happen for it will destroy half of our colors that took us a long time to perfect and mix them as you see it today. This will not be good for anyone so again please stop trying to hurt this business; guidance is one thing but destroying it is another. Most important you are messing with people’s livelihoods, their passions, and jobs.  Sincerely  Tom Ringwalt  Owner Of StarBrite Colors  01/28/2019 |
| **SEAC Rapporteurs response:**  Thanks you for your comment not supporting a restriction on use of Pigment Blue 15:3 and Pigment Green 7. SEAC notes you have not provided detailed justifications supporting the claim of serious effect on your business as a result of a restriction on the use of Pigment Blue 15:3 and Pigment Green 7 and you have not provided any information on other technically and economically feasible blue and green pigments leading to lower risk in comparison to Pigment Blue 15:3 and Pigment Green 7 that you might use for re-formulating your products. Based on all comments received SEAC proposed a time-limited derogation for Pigment Blue 15 and Pigment Green 7 on the basis of other submissions and RAC’s conclusions on the proposed pigment derogations. |
| 405 | **Date/Time:** 2019/02/04 14:54  **Type:** Individual  **Country:**  United Kingdom | **Comments on the SEAC draft opinion:**  From a tattooists perspective the inks we use should be made to be as safe as possible.  An argument that there is no alternative to certain chemicals for the inks or there is no R&D for new pigments in the industry seems to suggest that the manufacturers of these inks have not had the foresight to change or to spend funds on making the inks safer with continued R&D even though they have profited greatly from the popularity of tattooing.  Is it feasible to have an EU wide 'Safety Index' on specific colours per manufacturer?  Once proposed limits of chemicals/metals are agreed upon, then the composition of each colour should be known. If it's not possible to have a complete list of ingredients on the bottles of ink (no matter how small the quantity of ingredient) then is it possible to have a 'Safety Index' that has a range showing how safe the colour is based on its ingredients and what allergies and underlying health implications could arise from the ingredients?  Certain colours which require specific levels of ingredients may have a higher or lower (depending on how you rate the scale) 'Safety Index'.  With supporting literature the tattooist and the client can make a more informed decision on what they will allow in their bodies or as a tattooist that they are ethically willing to purchase based on how safe the colour is expected to be. This puts the onus of the manufacturers to work towards safer ingredients to have colours with better safety ratings. One would hope tattooists would move to brands that had better safety ratings and this would help drive market competitiveness for safer inks.  Ratings seem to be a better way to communicate with consumers and make it easier to understand than a list of ingredients to which very few actually know what impact they can have and it seems the list of ingredients and warnings they may have is too large to fit onto a label on a bottle. |
| **SEAC Rapporteurs response:**  Thank you for your comments. SEAC rapporteurs note it is the primary intention of the proposal by the Dossier Submitter to prevent risks as a result of chemical composition of tattoo products. The idea of a Safety Index for tattoo products is not assessed by the dossier submitter as the proposal includes already a range of extensive additional labelling requirements informing transparently about any not-prohibited hazardous ingredient that is in the ink. SEAC has no information based on which it could assess the feasibility and risk communication efficacy of such index. SEAC in its opinion has taken note of the Forum support for the suggestion in the Background Document of the introduction of an EU wide registry of tattoo inks, which, among other information, will gather data on the chemical composition of the mixtures. Such database would facilitate the identification of substances that are considered most problematic. SEAC rapporteurs consider this database may be used to trigger further regulatory action on specific ingredients that are not yet covered in the proposal. |
| 406 | **Date/Time:** 2019/02/07 16:18  **Type:** BehalfOfAnOrganisation  **Org. type:**  Regional or local authority  **Org. name:**  Bayerisches Staatsministerium für Umwelt und Verbraucherschutz  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  Es wird begrüßt, dass für alle beschränkten Stoffklassen nun analytisch überprüfbare Höchstmengen festgelegt worden sind.  Analyseverfahren mit denen Azofarbstoffe nachgewiesen werden bzw. mit denen die Einhaltung der Höchstmenge von 0,1 % überprüft werden kann, stehen jedoch nur spezialisierten Laboren zur Verfügung. Über die Schaffung von Schwerpunktlaboren sollte nachgedacht werden.  Auf nachfolgenden Widerspruch im „Draft opinion of SEAC“ weisen wir hin:  A.Opinion of RAC and SEAC - Table 1 Restriction option 1 (RO 1):  Nach der Vorgabe unter 1.a.ii. (Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/20092) ist die Verwendung von Farbstoffen, die im Anhang II der EU-KosmetikV aufgeführt sind, verboten. Einige der in Anhang II der EU-KosmetikV gelisteten Farbstoffe wie z.B. der Farbstoff unter Nr. 1365 Cl 73360 im Anhang II oder der Farbstoff unter Nr. 1367 Cl 74160 im Anhang II sind auch im Anhang IV der KosmetikV gelistet, nämlich unter der Nr. 100 sowie der Nr. 105 jeweils ohne Eintrag in der Spalte g und damit nach Vorgabe unter 1.a.iii. (Substances in Annex IV of Regulation (EC) 1223/2009 with the following conditions in column g of that Annex: - Rinse-off products - Not to be used in products applied on mucous membranes - Not to be used in eye products) wieder zulässig!  U.E. ist es problematisch, dass bei den Tätowierfarben keine vollständige Deklaration der verwendeten Inhaltsstoffe gefordert wird. Dies bedeutet Intransparenz für alle beteiligten Kreise wie z. B. Tätowierer, Überwachungsbehörden, aber auch Ärzte, die im Falle einer notwendigen Behandlung von Hautreaktionen nach Tätowierungen/Laserentfernungen von Tattoos Informationen über die genaue Zusammensetzung benötigen. Aus Verbraucherschutzgründen sollten für Tätowierfarben die gleichen Vorgaben gelten wie für kosmetische Mittel, die auf der Haut angewandt werden. Die Ausprägung einer Allergie unter der Haut ist wesentlich kritischer zu sehen als auf der Haut (Allergen auf der Haut kann entfernt werden). |
| **SEAC Rapporteurs response:**  Thank you for your comments  SEAC rapporteurs take note of your claim for development of key laboratories specialised in chemical analysis of low levels of ingredients in tattoo ink formulations. We have no further indications from the Forum or other stakeholders there is a compelling need for such key laboratories, although several EU Member States have experience with implementing the Council of Europe Resolutions.  The Dossier Submitter is proposing that only ingredients that are not classified as hazardous are not included on the label. SEAC supports the labelling as proposed. |
| 407 | **Date/Time:** 2019/02/10 17:30  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  TIME - Tattoo Ink Manufacturer of Europe  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  1. Transition time:  1 year transition time is too short. Testing and reformulation of tattoo inks needs more time, as the best supplier for pigments need to be found and new pigments used in the inks needs extensive testing, as well in human skin. This affects as well manufacturers that comply with ResAP 2008, as for example yellow 97 (CI 11767) is possible to use as it does not split aniline by amide hydrolysis, only by laser decomposition.  As ink manufacturers mostly work with a supply chain we need to take into account the whole supply chain. Inks are not manufactured on demand, the manufacturer have in general a stock of ink to sell for 6 – 12 months. The reseller in the supply chain keep as well a stock of inks for about 6 – 12 months and those inks can than be used in the tattoo studio for about 12 months after opening. So we suggest below the transition period along the supply chain.  Manufacturer:  a. Stop of production for non-compliant products: 24 months  b. Stop of sale of non-compliant products: 30 months  Reseller and Distributor:  a. Stop of sale for non-compliant products: 36 months  Tattoo artist and cosmeticians:  a. Stop of use of non-compliant products: 48 months  Final comments:  Based on our experience with ResAP 2008 on tattoos and permanent make-up we believe:  a. The amended proposal is more clear to understand, especially that add of concentration limits  b. A regulation only based on chemical properties is not sufficient and a step back compared with ResAP 2008.  c. Harmonised and validated analytical standards for quantitative chemical analysis are missing, but they are essential for a regulation.  d. Problems and reactions on inks will raise, as microbiological unsafe inks can be sold all over Europe.  e. Tattoo artists and cosmeticians will finally have to carry the burden to work with unsafe and non-compliant inks |
| **Specific information 1:**  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) |
| **Specific information 2:**  Pigment Blue 15:3 is essential für the industry and there is no possibility to replace this pigment. Pigment Green 7 can only be replaced by Pigment Green 36 and should be allowed for the use in tattoo inks. If Pigment blue is not allowed in tattoo inks, this will create big damage to the European tattoo business. Ink manufacturer will not be able to offer good blue and green-blue inks and tattoo artist will be forced to work illegal with inks manufactured outside Europe. |
| **SEAC Rapporteurs response:**  Thank you for your comments. We take note of your request for longer transitional periods for manufacturers, distributors and tattoo artists. You have however not provided justifications underpinning the need for much longer transitional periods. Therefore, it is difficult to amend SEACs final opinion based on the information you provide.  Specific information request 1.  The RAC modified concentration limit for lead of 0.00007 % (w/w) is based on risk assessment and takes into account technical feasibility. SEAC supports this proposed concentration limit, which at 25% maximum pigment concentration in your product formulation would mean that 2.8 ppm would be allowed in the pure pigment, or you would have to reformulate using a lower concentration of the lead-containing pigment in your final product formulation.  Specific information request 2.  SEAC takes note of your request to exempt PG7 and PB15:3. We note your claim is not supported with justifications of the impact it will have on the manufacture of “good” blue and green inks for the EU market. Based on all comments received SEAC proposed a time-limited derogation for Pigment Blue 15 and Pigment Green 7 on the basis of other submissions and RAC’s conclusions on the proposed pigment derogations.  SEAC takes note of your final comments.   1. SEAC shares your view that the amended proposal is more clear than the original one 2. SEAC takes note of your policy statement. It is not in the remit of SEAC to discuss risk management options that are beyond those proposed by the Dossier Submitter 3. SEAC takes note of your request for harmonised analytical methods, which is consistent with advice provided by Forum. SEAC’s final opinion reaffirms the importance for harmonised standards for consistent EU-wide compliance testing 4. SEAC notes microbiological safety is outside the scope of REACH and the proposed restriction 5. The proposed restriction aims at preventing the use of unsafe inks. Any use of non-compliant inks is an issue that can effectively be enforced once an EU-wide restriction is in place. |
| 408 | **Date/Time:** 2019/02/10 23:00  **Type:** BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  European Society of Tattoo and Pigment Research  **Org. country:**  Denmark  **Attachment:** | **Comments on the SEAC draft opinion:**  All comments to the SEAC Committee are included in the attached document. |
| **Specific information 1:**  All comments to the SEAC Committee are included in the attached document. |
| **Specific information 2:**  All comments to the SEAC Committee are included in the attached document. |
| **SEAC Rapporteurs response:**  Comments on scope  We note your lack of support for excluding preservatives from the scope of the tattoo ink restriction as substances with a biocidal preservative function fall under the scope of the Biocidal Products Regulation (BPR). You state that ‘*Infections are one of the most common side effects from tattooing. Therefore, this restriction will significantly increase risk of tattoo related side effects if the products cannot be protected against microbial growth’*. SEAC does not agree with these statements, as the proposed restriction does not change the existing legal situation that is currently in place for biocides applied as preservatives in tattoo inks. Therefore, it is not justified to state that the restriction will increase the risk of microbial infection, as the products cannot be anymore protected against microbial growth. As explained, the restriction does not change the legal situation as regards protection against microbial growth in tattoo inks. Furthermore, prevention against risk of infection also covers hygiene measures taken by tattoo shops, which is in the remit of Member State authorities to regulate. We note you propose ‘*at least to include the preservatives listed in Annex VI of the EU Cosmetics Directive allowed for leave on products in the REACH tattoo restriction*’. With this we think you mean at least the preservatives on Annex V of the CPR (List of preservatives allowed in cosmetics products) should be allowed. We again remind you that the restriction is not aimed at providing a positive list of any kind. Preservatives in Annex V of CPR are not covered by the restriction (unless they have relevant harmonised classification, i.e., only 21 out of the 148 preservatives on Annex V currently have such classification). Hence, in principle, the majority of preservatives on Annex V would be allowed under REACH (in the event the restriction is adopted) but for biocidal use, the rules of BPR apply.  We note your request for a complete list of ingredients to be made available for consumers and physicians instead of labelling as currently proposed. The Dossier Submitter proposes listing all hazardous components on the label and all substances covered by the restriction present at levels below the concentration limits. SEAC in its opinion has taken note of the Forum support for the suggestion in the Background Document of the introduction of an EU wide registry of tattoo inks, which, among other information, will gather data on the chemical composition of the mixtures. Such database would facilitate the identification of substances that are considered most problematic. SEAC rapporteurs consider this database may be used to trigger further regulatory action on specific ingredients that are not yet covered in the proposal.  We note your lack of support for the concentration limits for (metal) impurities present in black inks based on the fact that it is not feasible for you to synthesise highly purified pigments and your dependence on pure inks available on the (cosmetics) market. SEAC supports RAC modified concentration limit which are risk-based and for which feasibility information insofar available has been considered. Based on all information available SEAC has not arguments to challenge technical feasibility of RAC modified concentration limits for antimony, arsenic, lead, cobalt and nickel in black tattoo inks.  We note your request for an EU-wide positive list for all pigments and other ingredients. The Dossier Submitter did not consider a positive list approach. In its opinion, SEAC noted some stakeholders requested a positive list. SEAC states that the elements to justify such a list were not provided and SEAC notes that the resources needed to define such a list could be substantial. SEAC concurs with RACs statement that non-harmonised substances may still be regulated at national level which may include positive lists. SEAC will reflect on this in the final opinion and will also address the stakeholder request for positive listing of pigments and preservatives.  You state it is ‘*questionable if the Annexes II and IV can be legally included into a REACH restriction dossier*’ as for the substances covered in the Annexes II and IV which are only linked to the restriction without scientific justification based on hazards and risks. As this concerns the hazard and risk discussion in RACs remit SEAC will not reply to it.  We note your concerns as regards the inclusion of skin and eye irritants (including isopropanol) and corrosives in the scope of the restriction as you claim this would make production of tattoo inks unfeasible leading to a transition to illegal practices and increase of risks as a result of the restriction. SEAC regards these claims unjustified as no you provide no justification as to why for all substances covered by these harmonised classifications no alternatives are available for use in tattoo inks.  Thank you for sharing with us information on the application percentages of PG7, PG36 and PB15:3 in tattoo ink formulations of five manufacturers. You furthermore state that existing blue or green alternatives are insufficient for a range of technical reasons. SEAC appreciates the examples you have provided of alternative pigments that could replace PG36 and PB15 and the technical difficulties involved. Based on the information provided SEAC will reflect in its opinion that a ban on PG36, PG7 and PB15 would according to you lead to a need to reformulate between 33% and 69% of manufacturers product ranges for which you claim at least 2 years would be needed. As regards PG36 SEAC notes it is not in the scope of the restriction, hence there is no discussion on exemption. Based on information provided on PG7 and PB15 it is clear that a restriction would lead to necessary reformulations by manufacturers, possibly using alternatives, which are not providing the same technical quality for which the hazard and risk profiles are likely to be more uncertain compared to PG7 and PB15. SEAC has taken note of your arguments, as well as others submitted and RAC’s conclusion on the proposed derogation. Based on all comments received SEAC proposed a time-limited derogation for Pigment Blue 15 and Pigment Green 7 on the basis of other submissions and RAC’s conclusions on the proposed pigment derogations.  You claim for additional derogation of quinacridone pigments with CI 73900 and CI 73915 as these are needed to substitute the carcinogen containing pigment with CI 73907 (Pigment Red 202). As only risk considerations are provided SEAC will not refer to this proposal in its opinion. We note that Pigment Red 202 is included in Appendix D.1 Substances for future assessment by the Dossier Submitter.  SEAC notes you request to not derogate volatiles as gaseous substances at room temperature can be dissolved aqueous mixtures or solvents. SEAC agrees that the proposed derogation for gaseous substances with harmonised classifications should be adapted so that the concentration limit for CMRs in tattoo inks applies to formaldehyde. |
| 409 | **Date/Time:** 2019/02/11 17:59  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  In case of the label we want to keep our company and brand name confidential.  In case of impurities we want to protect our commercial interest. | **Comments on the SEAC draft opinion:**  After extensive reading of the proposal, the labeling requirements especially regarding language requirements are not clear to us, respectively gives room for interpretation.  Our colors for permanent make-up are sold in small containers of 10 ml, 5 ml or less. Other competitors use containers of 15 ml, but still the containers are very small. Therefore, the space on the labels is very limited.  As a manufacturer of colors for permanent make-up available in different EU countries resp. worldwide, it is not possible to ensure that the labels are always in the local language. The situation is aggravated by cross-border commerce by distributors or internet commerce.  From our perspective, the labeling requirements should be harmonized with the cosmetic regulation EC No.1223/2009, Annex VII. It should be possible to use the symbols given in Annex VII for period after opening and date of minimum durability. See attached example of a generic label design  In the past, we had issues with the strict interpretation of labeling requirements from national authorities (especially in Germany), who did not accept this well-known symbols on the labels, even though this information had been specified in an enclosed manual in different languages.  Due to the limited space on the labels in combination with the diversity of languages in the EU, it would be recommendable that the use of these well-known symbols form Annex VII, EC No.1223/2009 is accepted from all national authorities in the EU.  To avoid conflicts in interpretation from different national authorities between the following labeling requirements:  a) "The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise (see Table 4: SEAC modified RO1).”  and:  b)“Where necessary because of the size of the package, the labelling information shall be included in the instructions for use"  a harmonization with the labeling requirements in Annex VII, EC No.1223/2009 should be included in the proposal.  We agree on the requirement that warning for hazards like nickel or chromium should be given, as we already do in our product manual in all required local languages.  In the proposal, it is stated that: "Where necessary because of the size of the package, the labelling information shall be included in the instructions for use."  The manual is not fixated on the product container and could be lost. Therefore, we are worrying on conflicts with the interpretation of national authorities.  1. It should be possible to include the required language variants of the warnings in a manual. The authorities must accept that it is not possible to include the warnings in all languages of sales on the product label.  2. If that does not apply it should be possible to use a foldout label. Here we have major concerns, that national authorities will not consider this as clearly visible. |
| **Specific information 2:**  We agree with the proposed restriction of 19 additional colorants, except for Pigment Blue 15 (PB 15), Pigment Green 7 (PG 7), and Pigment Green 36 (PG 36) (see Chapter C.3.4.5 b) Derogations).  We do not use any of these 19 colorants in our formulations. As a manufacturer, we support the proposed extended restriction of Azo-colorants because of the well-discussed hazards and the potential risk of discomposure of PAA.  As stated in the proposal, there is no alternative to Pigment Blue 15. In the past, we have been using this pigment in our formulations. After restriction, we terminated permanent make-up colors and tattoo inks containing this pigment, whereas comparable products from other brands containing this pigment were still available. For us it was a big competition drawback to be a manufacturer located in Germany. The restriction of Pigment Blue 15 is not reasonable in terms of safety concerns, and only will result in illegal and uncontrolled internet commerce. Since products from these sources have lower standards regarding impurities and do not comply with the proposed regulation or ResAP (2008)1), the total risk exposure for the consumer who wants to have a blue tattoo will increase due to the restriction of PB 15. Consequently, only manufacturers with high standards regarding impurities and hazards will suffer a significant competition drawback since they comply to ResAP(2008)1 or the new proposed regulations.   Sometimes the proposal refers to Pigment Blue 15, sometimes to Pigment Blue 15.3. As a manufacturer, we are using Pigment Blue 15.1. Could you please clarify in the proposal that the derogation of Pigment Blue 15 includes its derivates.  In the proposal on page 19, it is stated that Pigment Green 36 was not in the scope of this restriction, as it does not have relevant harmonized classification. PG 36 is very important for our formulations, and a restriction would lead to major economic losses. PG 36 must be included in the derogation as well, because it is only a derivate of the copper Phthalocyanine Pigment Green 7. As stated in the proposal there are no information available indicating that PG 36 is more hazardous than PG 7. Moreover, our extensive testing of our tattoo colors on volunteers before product launch or our long market experience does not indicate an elevated health risk for the consumer.  Therefore, PG 36 should be included in the derogation together with PG 7 and PB 15. |
| **SEAC Rapporteurs response:**  SEAC takes note of your concerns regarding the generic small size of the tattoo product packaging and limited space for information on a label. SEAC will reflect in its opinion your request for alignment of the labelling requirement with those included in Annex VII of CPR. SEAC recommends appropriate actions are taken to arrive to practical labelling requirements that can be consistently implemented across the EU.  Specific information request 2  SEAC takes note of your comments requesting to exempt Pigment Green 7 and 36 and Pigment Blue 15:3. As regards Pigment Blue 15:3 you state in the past you already stopped using it in your formulations based on restrictions. We understand this implied a competitive disadvantage as no EU harmonised legislation was in place. The proposed restriction will bring such EU harmonisation and there will be no competitive disadvantage for any supplier on the EU market. All have to comply with the restriction. A restriction on the use of chemicals in tattoo inks has no influence on illegal sales of products that are not compliant. This is an issue for enforcement. Based on all comments received SEAC proposed a time-limited derogation for Pigment Blue 15 and Pigment Green 7 on the basis of other submissions and RAC’s conclusions on the proposed pigment derogations.  Thank you for your clarifying question on Pigment Blue 15 or Pigment Blue 15:3. We will clarify in the opinion that the discussion on exemption regards Pigment Blue 15:3 specifically and not any other crystal modifications of Pigment Blue 15. |
| 410 | **Date/Time:** 2019/02/11 18:56  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  <redacted>    **Privacy comment:**  For protection of our commercial interest these test report are conficential. | **Comments on the SEAC draft opinion:**  Non. |
| **Specific information 1:**  Form our perspective we do not understand the reason for these significant reduction of the established impurity limits of the ResAP(2008)1.  In the first consultation process, a table of concentration limits was given to clarify the question if these limits would be achievable. In case of Nickel, a concentration of 0.001 ppm was proposed. The accepted limit in some E.U. member states was much higher (e.g. Netherlands). The above given limit for nickel is 5 ppm, which is hard to achieve with iron oxide pigments. This will lead to a greater use of organic or azo pigments in the E.U. having their specific hazards. The nickel limit should be 10 ppm as discussed in the first consultation process.  As a manufacturer we have tested all our raw pigments and PMU/ tattoo ink according to the limits of the ResAP(2008)1. The tested analytes ware within the specified limits. Therefore, we cannot asses if they will comply with the stricter limits. |
| **SEAC Rapporteurs response:**  Thank you for the additional information. It has been reviewed in the context of the proposed concentration limits. |
| 411 | **Date/Time:** 2019/02/11 21:34  **Type:** MemberState  **Country:**  Sweden | **Comments on the SEAC draft opinion:**  In the draft opinion SEAC expresses a slight preference for a static link to the CPR. SEAC notes that a dynamic link with the CPR would ensure immediate benefits for human health. Furthermore, SEAC states that a dynamic link will have disadvantages in that there will not be any assessment of the technical and economic feasibility of alternatives and that tattoo ink formulators will have very limited time to transition to potential alternatives.  Like RAC, the Swedish Chemicals Agency is of the opinion that a dynamic link with the CPR would be the better option. If a substance is listed in CPR Annex II (and IV), and thus not considered suitable to be applied on skin, it can be assumed that it is not suitable to be injected under skin, and should be restricted with shortest delay possible. In our view, this consideration should be emphasized more in the draft SEAC opinion.  With both static and dynamic links to the CPR there is a possibility to make later adjustments of the restriction as regards included substances or concentration limits, based on an assessment of specific substances. Also, if most additions to the CPR Annex II (and IV) are relevant to include in the restriction on tattoo inks, the dynamic link incurs less costs than the static link. Regarding the need for a transitional period for tattoo ink formulators when substances are added to the CPR annexes, the same transitional period as is indicated for the substances used in cosmetics would apply. This would give the time for industry to transition to the restriction by substitution/reformulation. |
| **SEAC Rapporteurs response:**  We thank Sweden for their comments on the link with CPR Annexes II and IV. However, we see no need for changing the opinion or putting more emphasis on the aspect of “time needed to regulate”, which in the opinion of SEAC is given appropriate attention in the discussion on the linkage. Based on arguments provided SEAC concurs with its slight preference for a static link. |