Annex 15 Restriction Report Proposal for a restriction

Substances in tattoo ink and permanent make-up

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PROPOSAL FOR A RESTRICTION

Definitions used in the proposal

The definitions adopted in this proposal are those used in the EU restriction on substances in tattoo inks and permanent make-up (PMU) except for the definition for tattooing.

Within the EU restriction, tattooing is defined as “injection or introduction of the mixture into a person’s skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body”. For consistency with existing legislation in Great Britain, the definition for tattooing that is being proposed for this restriction uses wording from the Tattooing of Minors Act 1969.[1]

Tattooing (tattoo procedure or permanent make-up) means the insertion into the skin, mucous membrane or eyeball, of any colouring material by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation) designed to leave a permanent mark.

Colourant is the commonly used denomination for pigments, lakes and dyes that are coloured molecules.

Pigments are in general very poorly soluble in water and application media, and unlike most dyes, they have low solubility in organic solvents. For this reason, they remain essentially in the solid state, including in live tissues.

Dyes are organic molecules that are soluble in general. Certain substances like titanium dioxide (TiO_2) or barium sulphate ($BaSO_4$) can be used as carriers for dyes used in tattoos, thereby forming “lakes” which are insoluble in water.

Auxiliary ingredients are necessary to obtain ready-to-use tattooing products. They include solvents, stabilisers, “wetting agents”, pH-regulators, emollients and thickeners.

Permanent make-up (PMU) is a mixture consisting of colourants and auxiliary ingredients administered by intentional insertion into the skin to enhance the contours of the face or to enhance or imitate other parts of the human body (e.g., nipple areola).

Tattoo ink is a mixture consisting of colourants and auxiliary ingredients, including

[1] https://www.legislation.gov.uk/ukpga/1969/24/section/3

possible impurities, that is ready to use and administered by intentional insertion into the skin whereby a permanent skin marking, or design (a “tattoo” or “permanent makeup”) is made.

Sterile in this context means the absence of viable organisms, including viruses.

Summary

On 29 April 2021, the Health and Safety Executive (HSE) as the Agency for UK REACH (referred to as the Agency hereafter) received a request under Article 69(1) of UK REACH from the Defra Secretary of State, with the consent of the Scottish Government and the Welsh Government, to prepare an Annex 15 restriction dossier assessing the risks to humans from substances in tattoo ink and permanent make up (PMU). As of 4 January 2022, the European Union (EU) has restricted the presence of over 4000 potentially harmful substances in these preparations[2]. This dossier examines whether a similar restriction should be introduced into Great Britain (GB)[3].

In the request, DEFRA asked the Agency to include in this dossier all substances listed in Council of Europe resolution ResAP(2008)1 (CoE, 2008)[4] and also the following substances:

- Carcinogenic or mutagenic substances
- Substances that are toxic to reproduction
- Skin sensitisers
- Skin corrosive or irritant substances
- Substances that cause serious eye damage/eye irritant substances
- Substances that are prohibited for use in cosmetic products under the Cosmetic Products Regulation (EUR 2009/1223)[5]

To prepare this dossier, the Agency has made extensive use of the information that was gathered for and presented in the European Union (EU) restriction dossier. Since the United Kingdom (UK) was a member of the EU at the time that this restriction was proposed and the technical documents to support the proposal were drafted, the information in the EU dossier includes data from the UK (and therefore GB). For this reason, where appropriate, when GB specific information is not

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[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R2081&from=EN

[3] UK REACH entered into force on 31st December 2020 at the end of the transition period. It regulates the access of chemicals to the GB market. Under the Northern Ireland Protocol, EU REACH continues to regulate the access of chemicals to the Northern Ireland market.

[4] The CoE resolution and an earlier Council of Europe resolution (CoE ResAp(2003)2) on the same topic were used as the basis for national legislation in certain EU and EEA member states but not in the UK or GB. Prior to this restriction proposal there has been no GB or UK legislation that specifically governs the chemical composition of tattoo inks and PMU. The text of CoE ResAP(2008)1 can be found here: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805d3dc4. The text of CoE ResAP(2003)2 can be found here: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805df8e5.

[5] https://www.legislation.gov.uk/eur/2009/1223/contents

available, we have assumed that the information in the background document prepared by the European Chemicals Agency (ECHA), and its appendices and annexes (ECHA, 2019a,b,c) applies to GB.

To supplement this information the Agency held a call for evidence to gather information on tattoo inks and PMU on the GB market (see Appendix 2 for more details). The Agency also conducted a literature search to identify any new publications that are relevant to this restriction proposal.

Given the popularity of tattooing and PMU and current lack of regulations in GB governing the chemical composition of inks used for tattoos and PMU, it is important to ensure the substances that are used in tattoo inks and PMU do not cause adverse health effects. Information gathered to support preparation of the EU restriction suggested that around 12% of European citizens are tattooed and that the prevalence in the younger generations (18 – 35-year-olds) may be double that (JRC, 2016b). This JRC report also estimated that 12% of UK citizens are tattooed.

Less information is available on the proportion of the population that has had one or more PMU treatments. Cosmetic tattoos, also known as PMU or semi-permanent makeup, are used to resemble make-up (JRC, 2016b). Based on information from 3 EU Member States, it has been estimated that up to 20% of the general EU population, may have PMU procedures carried out (JRC, 2016b). Specific data for GB for PMU procedures is not available.

There are reports in the literature linking tattoos and PMU to various adverse effects often collectively referred to as complications. While some of the reported complications are due to bacterial contamination of inks, others are due to substances that are present in the inks because they are intentionally present or because they are impurities. These include allergic and other skin reactions at the site of the tattoo or permanent make up. The evidence linking tattoos with adverse systemic effects is less clear, though there are reports in the literature that suggest that systemic complications may occur.

It is possible to link some complications to substances in the ink (particularly when the reaction is localised to the tattoo or PMU or to specific colours within a tattoo). While some complications emerge within weeks of getting a tattoo or PMU, it can take months or years before complications appear. Complications can also appear intermittently. Often it is not clear which of the many substances that may be found in tattoo inks is causing these complications.

Given the uncertainties about which substances are causing tattoo and PMU related compilations and uncertainties about how often complications arise, it is difficult to quantify the level of risk that is associated with tattoo ink and PMU. This restriction is therefore being proposed on the hypothesis that certain hazardous substances when

used in tattoo ink or PMU have the potential to trigger complications. Since it is possible for anyone in GB who is over 18 years old to get a tattoo or PMU[6], this potential risk applies to any member of the adult population in GB that chooses to get a tattoo or PMU. This action is therefore a precautionary measure to limit the impacts of this potential risk.

Currently, unlike the situation in the EU, there is no legislation in GB which addresses this risk. The Agency has therefore developed three restriction options that have the potential to manage this risk, referred to in this dossier as RO1, RO2 and RO3.

The Agency examined the other options that had been considered by ECHA but not taken forward such as other REACH regulatory measures than restriction, existing legislation, and other possible actions, including voluntary action by industry (see Appendix 4 for details). Of these options, the Agency identifies the option to introduce standalone legislation covering all aspects of tattooing and PMU treatments as worthy of further consideration. A detailed analysis of this option cannot be a part of this REACH restriction proposal dossier.

Proposed restriction

The proposed restriction options apply to mixtures supplied for decorative tattooing, traditional tattooing, PMU treatments and to mixtures supplied for medical tattooing where the ink is not exclusively used as a medical device or an accessory to a medical device within the meaning of The Medical Devices Regulations 2002 (MDR)[7].

The restriction will apply to the following substances and substance categories if they are present in tattoo ink or PMU:

- Substances that are classified in the GB MCL list as:
    - Carcinogens or mutagens
    - Toxic to reproduction
    - Skin sensitisers
    - Skin corrosive or skin irritants

[6] It is illegal to tattoo someone under the age of 18 in GB under the Tattooing of Minors act 1969: https://www.legislation.gov.uk/ukpga/1969/24/contents . Within this act "Tattoo" shall mean the insertion into the skin of any colouring material designed to leave a permanent mark.
[7] https://www.legislation.gov.uk/uksi/2002/618/contents/made

    - Substances that cause serious eye damage/eye irritant substances

- Substances that are prohibited for use in cosmetic products under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (hereafter referred to as the Cosmetic Products Regulation or CPR).

- Additional substances listed in resolution ResAP(2008)1 of the Council of Europe that are not covered by one or more of the above categories.

Three restriction options are presented in this dossier. Restriction option 1 (RO1) and restriction option 2 (RO2) largely replicate the options that ECHA proposed for the EU restriction but also take account of the revisions described in Annex D, section D.1.1h of the EU background document that were introduced during the opinion forming process (ECHA, 2019c).

RO1 proposes that tattoo inks shall not contain substances that are prohibited for use in cosmetic products according to Annexes II or IV of the CPR. The rationale for linking the use of substances in tattoo inks to provisions in the CPR is that if a substance is restricted for use in cosmetics that are applied onto the skin, that substance should also be restricted for use in products that are inserted into the skin. RO1 also proposes that tattoo inks shall not contain substances classified as carcinogens, mutagens or toxic to reproduction. For other substances and substance categories, concentration limits are proposed. It is proposed that there should be dynamic links between the GB MCL list, these Annexes of the CPR, and this restriction. This means that when updates are made to the GB MCL list or to these Annexes of the CPR, these changes will automatically take effect under this restriction.

Instead of the ‘shall not contain’ approach, RO2 proposes concentration limits for all substances and substance categories. RO2 retains the proposed dynamic link with the GB MCL list but proposes that where changes are made to Annexes of the CPR, a further assessment should be carried out to decide if the change should also be implemented within this restriction.

RO1 and RO2 retain ECHA’s proposal to derogate 21 colourants that are prohibited for use in hair dyes in Annex II of the CPR but are permitted for use as colourants in cosmetics in Annex IV of the CPR. RO1 and RO2 also include a clarification to indicate that inks that are placed on the market for use exclusively as a medical device or an accessory to a medical device are exempted from the scope of the restriction.

Restriction option (RO3) reflects the implemented EU restriction. Like RO2, RO3 proposes concentration limits for all substances and substance categories but these

are typically lower than the concentration limits proposed under RO2 and may be lower than the concentration limits proposed in some cases under RO1. RO3 retains the dynamic links with the GB MCL list and the CPR proposed under RO1. Whereas the EU granted a time limited derogation for Pigment Blue 15:3 and Pigment Green 7 until 4 January 2023, given the continuing concerns from the tattoo industry about the consequences if they lose Pigment Blue 15:3 and Pigment Green 7, the Agency is proposing to retain the derogation proposed by ECHA for these and 19 other pigments and that this derogation should remain in place until such a time that changes would be introduced within the Annexes of the CPR that would bring the colourant into scope of the general provisions of this restriction (further information about this proposed derogation is available in section 3.3.1c).

The scope of this derogation can be reviewed in the light of information obtained during the public consultation about the use of these 21 pigments in tattoo inks and PMU supplied to the GB market.

Further information and a list of the proposed concentration limits is available in section 1.2.6. The wording of the proposed restriction options is presented in table 2 (RO1), table 3 (RO2) and table 4 (RO3). Supplementary information for these options is presented in Appendix 1.

Each option restricts tattoo inks or permanent make-up from being:

a) placed on the market if they contain any of the substances in scope of the restriction above the specified concentration limit;

b) used if they contain any substance above the specified limit.

Several definitions for tattoo ink, tattoo or PMU procedures are introduced. In addition, a labelling requirement is also proposed to:

- list ingredients that would not be identified on the label under REGULATION (EC) No 1272/2008 as retained and amended for GB (hereafter referred to as GB CLP)[8];
- identify the intended use of the mixture as ink for tattooing or PMU procedures;
- highlight the presence of nickel and/or chromium VI in inks where relevant;
- include a manufacturer's reference number for the ink to uniquely identify

[8] The amendments are set out in The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 No. 720 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020.

each batch; and

- provide instructions for use.

A transitional period of one year after its entry into force is proposed. This is the same transitional period that was allowed for EU industry. It is expected that work to develop inks for the EU market that comply with the EU restriction will reduce the time needed to develop inks which will comply with a similar restriction if this is introduced into GB, hence a one-year transitional period could be achievable.

The proposed restriction options take account of the following:

- If a substance is restricted for use in cosmetic products because it is not considered safe to apply onto human skin (in general or under specific conditions listed in the CPR), it is logical to assume that it is also not safe to be inserted into the skin, i.e., in a tattoo or permanent make-up where the skin is damaged, and the substance remains in the skin for a prolonged period of time.

- Substances classified as carcinogens (C) mutagens (M) and/or reproductive toxicants (R) in category 1A or 1B, and thereby not permitted to be placed on the market or used for supply to the general public as substances on their own or as constituents of other substances or in mixtures (by virtue of entries 28 to 30 of Annex 17 to REACH), should not be used in tattoo inks that will be inserted into the skin of members of the public.

- Substances classified as skin sensitisers, skin irritants, corrosive, eye irritants or eye damaging should not be inserted into the skin (or in the eye), i.e., in a tattoo or permanent make-up where the skin is damaged, and the substance remains in the skin or in the eye for a prolonged period of time.

- The hazard and risk assessments carried out by the EU for certain hazardous substances and groups of substances (ECHA, 2019a,c).

- The concerns reported by industry that suitable alternatives are not available for certain widely used substances. Given these concerns, derogations are proposed for key pigments.

- The possibility for tattoo artists to stockpile powder pigments and use these to mix ink themselves. The restriction therefore puts the onus on tattoo artists and PMU practitioners to use only compliant inks by proposing that any tattoo ink and PMU that does not meet the requirements is not used for tattoo or PMU procedures.

This restriction is being proposed to manage a potential risk that applies to any adult

in GB seeking to get a tattoo or PMU. As described in section 3.5.3, it is difficult to identify which substances in tattoo inks and PMU are causing the greatest number of complications. Given this uncertainty, the Agency has taken a precautionary approach and included in the scope of these restriction options substances that meet one or more criteria which indicate that the substance has the potential to cause adverse effects if inserted into the skin.

These three restriction options are being proposed so that each of the options considered within the EU process can be assessed in depth for their suitability for GB. This does not preclude the development of additional options during the restrictions process if evidence is available to demonstrate that these provide a better approach.

Justifications

In order to propose a restriction under Article 69(1) of UK REACH, the Agency must demonstrate that there is risk that is not adequately controlled and that the proposed restriction is the most appropriate measure to manage that risk. The appropriateness of the proposed restriction is assessed on these criteria:

- Effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk.
- Practicality: the restriction must be implementable, enforceable, and manageable.
- Monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

Identified hazard and risk

Over 4,000 substances meet one of more of the criteria that bring them into scope of this proposed restriction. These criteria aim to identify substances which have the potential to cause adverse effects when inserted into the skin, as is the case during tattooing and the application of PMU.

There are reports in the literature linking substances in tattoo ink and PMU to various adverse effects often collectively referred to as complications. These include allergic and other skin reactions at the site of the tattoo or permanent make up. The evidence linking substances in tattoo ink and PMU with adverse systemic effects is less clear, though there are reports in the literature that suggest that systemic complications can occur. Further details of the complications that have been

reported is available in section 3.5.3.

Complications can take weeks, months or years to develop or may appear intermittently. In many cases, complications are mild but sometimes it is necessary for those affected to seek medical assistance and even have their tattoo removed because of the severity of the adverse effect.

It is possible to link some complications to substances in the ink (particularly when the complication is localised to the tattoo or PMU or to specific colours within a tattoo). Often it is not clear which of the many substances that may be found in tattoo inks is causing a complication. This is due to the limited number of investigations and the challenges of identifying causal agents when exposures occurred months or years before any adverse effects were apparent.

Given these uncertainties this restriction is being proposed on the hypothesis that certain hazardous substances when used in tattoo ink or PMU have the potential to trigger complications. Since it is possible for anyone in GB who is over 18 years old to get a tattoo or PMU, this potential risk applies to any member of the adult population in GB that chooses to get a tattoo or PMU. This action is therefore a precautionary measure to limit the impacts of this potential risk.

Currently, unlike the situation in the EU where a REACH restriction has been introduced to manage this risk, there is no legislation in GB that regulates which substances may be present in tattoo ink or PMU. It is therefore appropriate to consider if a REACH restriction is an appropriate route to manage this risk for GB. Three restriction options are proposed, referred to in this dossier as RO1, RO2 and RO3. These restriction options are broad in scope and target substances that meet one or more criteria that suggest they could potentially cause a complication.

On the assumption that reducing the levels of these hazardous substances in tattoo inks will reduce the number and severity of complications, each restriction option proposes concentration limits for substances that are in scope of the restriction. These concentration limits do not necessarily reflect a level of exposure that is guaranteed to prevent ill health because it is not always possible to identify such levels from the available data. The concentration limits do indicate levels of exposure that represent a low level of risk and provide a tool for compliance monitoring.

Effectiveness

The restriction targets the effects or exposures that cause the risks identified, is capable of reducing these risks to an acceptable level within a reasonable period of time and is proportionate to the risk for the following reasons:

- The proposed restriction targets substances that meet one or more criteria which indicate a potential risk for adverse health effects if the substance is

inserted into the skin. The restriction proposes to limit exposure by setting concentration limits to minimise the presence of those substances in tattoo inks and PMU. Concentration limits have been used for other restrictions in Annex 17 of REACH which apply to broad groups of substances. This approach can therefore be an effective approach to reduce risks to an acceptable level.

- Different concentration limits are proposed under RO1, RO2 and RO3. RO1 includes a shall not contain approach for certain substances categories and concentration limits for other substances and substance categories and potentially will have the greatest risk reduction capacity. RO3 proposes concentration limits for all substance categories and substances that are in scope. In some cases, these concentration limits are lower than the limits proposed under RO1. The least stringent limits are proposed under RO2 therefore, this potentially will offer the lowest risk reduction capacity.

- It is not clear if any of the proposed restriction options will fully eliminate substance related tattoo/PMU complications. This is because the scientific community does not know the agents responsible for many of the tattoo and PMU complications that are reported or in some cases the biological mechanisms that underlie reported complications. Also, it is possible that reformulation of tattoo inks and PMU could result in substances with poorly understood hazard profiles being used as alternatives. These alternatives may have adverse health effects that have not yet been identified. For these reasons, it is not clear if any of the proposed restriction options will capture all causes of substance related tattoo and PMU complications and it is not possible to quantify the risk reduction capacity that any of these options will provide. This restriction therefore aims to take a precautionary approach by capturing any substance that, based on its known hazards, could potentially lead to complications if it is present in tattoo inks or PMU and is inserted into the skin.

- In relation to the time required to reformulate inks, information presented in the EU restriction dossier indicates that inks have been supplied to the EU market which will comply with the concentration limits specified in RO1 and RO2 (ECHA, 2019a,c). Although these inks may not comply with the current EU restriction, there is no legal reason why manufacturers based outside of the EU cannot continue to produce these inks for supply to GB. In the case of RO3, since this option reflects the implemented EU restriction, inks that are being reformulated to comply with this legislation can be available for the GB market. These factors imply that reformulation can be achieved within a reasonable time.

- Where there is a need to choose alternative substances, the EU restriction dossier indicates that for most substances in scope, technically feasible alternatives with similar or better hazard and risk profiles exist (ECHA, 2019a,c). For specific colourants where alternatives have not been identified, derogations are proposed (see table B in Appendix 1 and section 3.3.1c).

- Within the EU, the inclusion of Pigment Blue 15:3 and Pigment Green 7 in the scope of the restriction has raised concerns among stakeholders that a significant proportion of the colour palette available for tattooing will be lost because good alternatives are not available. This dossier includes a proposal under all three restriction options to derogate these and 19 other pigments that fall into scope because they are prohibited for use in hair dyes in Annex II of the Cosmetic Products Regulation (CPR). The list of pigments is given in Appendix 1, Table B. The derogation is proposed because these 21 pigments are permitted for use as colourants in cosmetics in Annex IV of the CPR and because these pigments are currently not included in the GB MCL list and therefore do not meet any of the classification criteria which would bring these substances into scope. Allowing the use of key pigments to continue when there is no clear evidence that these pigments present an unacceptable risk to human health when used in tattoo inks increases the proportionality of the restriction.

- The estimated substitution costs in GB under RO1 are approximately £789,000 in 2021/22. It is difficult to monetise substitution costs for RO2 and RO3. However, as RO2 and RO3 impose less strict requirements than RO1, it is anticipated that more tattoo inks and PMU on the market are already compliant with RO2 and RO3. Therefore, RO2 and RO3 substitution costs are likely to be lower.

  In its opinion, ECHA's Socioeconomic Assessment Committee (SEAC) (ECHA, 2019d) writes that it is difficult to quantify the differences in substitution costs between RO3 and RO1 or RO2. Overall, RO3 has lower limits in comparison to RO2, therefore, it can be expected that it would lead to the reformulation of more tattoo inks in comparison to RO2. RO3 has some higher concentration limits (e.g., for CMRs) but lower for other (e.g., nickel, cobalt) in comparison to RO1 with the overall effect on costs being unclear. The difference in the mechanism to update the future scope of the proposed restriction has unpredictable effects in terms of substitution costs difference between RO1, RO2 and RO3. The assumptions made by ECHA (2019d) around the difficulty in quantifying differences between restriction options can also be applied to this analysis for GB. Further information on substitution costs is included in section 3.5.1.1.

- The estimated enforcement costs for GB under RO1 are approximately £36,000 in 2021/22. As with ECHA's (2019c) assumptions, enforcement costs are expected to reduce across the appraisal period[9] with industry compliance. This is not demonstrated in the cost estimates as it is unknown how much costs will diminish over the appraisal period; therefore, costs carry a degree of uncertainty so should be seen as illustrative as they are likely to be an overestimate. Further information on the relationship between enforcement costs and compliance is provided in section 3.5.1.2.

  SEAC (ECHA, 2019d) notes that the available information does not allow for a quantitative differentiation of enforcement costs (calculated by ECHA for the EU) between RO1, RO2 and RO3. Further information is provided in section 3.5.1.2.

- The familiarisation costs for GB under RO1 are approximately £69,000 - £2,551,000 with a central estimate of £867,000. This is a one-off cost presented in 2021/22 prices, but it is expected to be incurred in the year that the restriction is implemented. The familiarisation costs in this analysis have been estimated for RO1 however, RO2 and RO3 will also require industry to understand the proposed restriction, therefore it is expected that familiarisation costs under RO2 and RO3 would be similar to RO1. It is difficult to provide a quantitative differentiation between options.

- The restriction is expected to provide benefits relating to avoided cases of complications and any associated need to seek tattoo removals, also avoided cases of adverse effects arising as a result of tattoo removal procedures.

Table 1: Annual compliance costs and cost-effectiveness of the proposed restriction options (Adapted from ECHA 2019a)[10]

2021 prices, GBP £, annual	**RO1**	**RO2**	**RO3**
Total compliance costs	£1,692,000	Lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2

[9] Appraisal period refers to the timeframe that costs and benefits are assessed as part of the socioeconomic analysis. The appraisal period in this restriction dossier is 20 years (2021/22 – 2040/41).

[10] Figures in this table have been rounded and totals may not add up precisely.

2021 prices, GBP £, annual	RO1	RO2	RO3
Substitution	£789,000	Lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2
Enforcement	£36,000	Similar to RO1 and RO3	Possibly similar or lower than RO1 but higher than RO2
Familiarisation	£867,000 (one-off cost in year 1)[11]	Similar to RO1 and RO3	Similar to RO1 and RO2
Social and distributional impacts[12]	This is non-monetised but RO1 is expected to have moderate impacts.	Similar to RO1 and RO3	Similar to RO1 and RO2
Wider economic impacts[13]	This is non-monetised but RO1 is expected to have minimal impacts.	Similar to RO1 and RO3	Similar to RO1 and RO2
Cost-effectiveness[14]	£83/litre of non-compliant tattoo inks removed from the market	Higher than RO1 and RO3	Higher than RO1 but lower than RO2
Risk reduction capacity	It would reduce risks but not fully eliminate them	Possibly lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2

[11] To note, this is a one-off cost which will be incurred the year that the restriction is implemented. To apportion this cost across the 20-year appraisal period, annual familiarisation costs would be approximately £43,000 (in 2021/22 PV).
[12] This refers to the impact to businesses in the tattoo and PMU industry, specifically tattoo and PMU formulators, tattoo artists and pigment manufacturers as a result of the proposed restriction.
[13] This refers to the availability of inks and trade impacts as a result of the proposed restriction.
[14] Cost-effectiveness examines the costs and health outcomes (benefits) of the proposed restriction by estimating how much it costs to gain a unit of the health outcome (CDC, 2021).

2021 prices, GBP £, annual	RO1	RO2	RO3
Benefits	Equivalent to the avoided cases of tattoo adverse effects (cutaneous, systemic, potential reproductive, developmental, malignant)[15]	Possibly lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2
Break-even[16]	Approximately 62 – 205 avoided cases of tattoo removal due to non-infectious inflammatory complications	Possibly fewer cases required for breakeven than RO1 and RO3	Similar to RO1 and more cases required for break-even than RO2
Affordability	Affordable	Likely more affordable than RO1 and RO3	Similar to RO1 but less affordable than RO2

Practicality

The proposed restriction options are practical (i.e., implementable, enforceable and manageable) for the following reasons:

Implementability

- RO1 proposes similar and RO2, slightly less strict measures than the measures that were recommended in CoE (2008) and the earlier Council of Europe resolution ResAP(2003)2 (CoE, 2003) relating to the composition of tattoo inks and PMU. These resolutions were used as the basis for national legislation which was implemented in several EU and EEA Member States. This demonstrates that it will be possible to implement legislation based on these options in GB.

[15] It is not possible to assess the magnitude of the number of cases avoided as the necessary data is unavailable.

[16] Break-even in economics describes the point at which costs, and benefits are equal. For this analysis, the total cost of the restriction is approximately £1.7 million, and this equates to between 62-205 cases of avoided tattoo removals (benefit), see section 3.5.5.3 for further information.

- RO3 proposes measures that are closely related to the implemented EU restriction with the key difference that derogations are proposed for the colourants listed in table B. The proposed derogation removes a major concern that industry has reported with the implementation of the EU restriction.

- Surveillance results from EU enforcement bodies have shown that the majority of tattoo inks and PMU on the EU market before the introduction of the EU restriction were in compliance with existing national legislation in EU Member States which had implemented legislation based on CoE (2003) or CoE (2008), suggesting that products are available that will comply with RO1 and RO2. Since tattoo and PMU inks are manufactured outside the EU, these non-EU inks should still be available for the GB market even if they may not comply with the implemented EU restriction.

- The Agency is aware that stakeholders have expressed concerns about aspects of the implementation of the EU restriction, on which RO3 is based. This includes comments made during the call for evidence that it is difficult to track which substances are in scope and difficulties relating to the loss of key pigments. The proposed derogation of the colourants listed in Table B should avoid the greatest of these difficulties.

- The transitional period of 1 year that is proposed for RO1, RO2 and RO3 reflects the growing awareness that exists in industry about this restriction and its requirements and the expectation that work to reformulate inks to meet the requirements of the EU restriction will speed up the time required to reformulate inks for the GB market.

Enforceability

- Although no specific legislation governing the composition of tattoo inks and PMU exists in GB, local authorities regulate other aspects of the operation of tattoo parlours and PMU practitioners. It is therefore feasible that these officers could take on the enforcement role for this restriction. These enforcement activities are covered as part of the enforcement costs presented in section 3.5.1.2.

- Within the EU, the Rapid Exchange of Information System (RAPEX) could be used to assist enforcement of the EU restriction. RAPEX is a tool developed within the context of the General Product Safety Directive (GPSD) to provide enforcement bodies with alerts about dangerous products. The UK no longer has access to RAPEX or the EU Information and Communication System on Market Surveillance (ICSMS); these have been replaced by the UK's Product Safety Database (PSD). Alerts to this database can be used by enforcers to

highlight particular products of concern.

- This dossier and information in the EU restriction dossier (ECHA 2019a,c) provides information on the substances found in tattoo inks that present risk to human health and highlights groups of substances that are considered most problematic. This information may help to develop targeted surveillance approaches which focus on those substances that present the greatest level of risk. Such targeted approaches have the potential to reduce the costs to monitor compliance. Targeted surveillance approaches have been used to check compliance with national legislation on the composition of tattoo inks and PMU where this exists in EU/EEA Member States.

- Analytical methods are used to determine the concentration of various substances in tattoo inks and PMU and can be used by industry and enforcers to confirm if the composition of an ink complies with the requirements of this proposed restriction. Methods are available for some groups of substances in the scope of the proposed restriction options. Appendix D.2 in ECHA (2019c) provides information on methods available for the following groups of substances:

    - primary aromatic amines (PAA);
    - colourants;
    - elements;
    - polycyclic aromatic hydrocarbons (PAHs);
    - phthalates;
    - nitrosamines.

    These groups were selected because they represent substances that are listed in CoE (2008). The lists in Appendix D.2 include methods that have been used by EU enforcement authorities in Member States with national legislation on the composition of tattoo inks and PMU to identify inks that contain unacceptably high levels of specific substances. Where analytical methods are available, information on the limits of detection of commonly used methods has been taken into account in setting the concentration limits for individual and groups of substances.

    The restriction options described in this dossier cover a much broader range of substances than those listed here. Work is being done by EU Member States to develop and validate analytical methods for use to confirm compliance with the EU restriction. Further work needs to be done to

understand whether it is necessary for enforcers to be able to quantify every restricted substance that may be present in tattoo ink and PMU or whether alternative targeted strategies will be sufficient (see section 3.3.1b for further information).

Manageability

- The provisions outlined in RO1 and RO2 are similar to legislation on substances in tattoo inks and PMU that had been implemented in several EU and EEA Member States before the EU restriction was proposed. Compliance rates reported in the EU restriction dossier (ECHA 2019a,c) for these Member States suggest that RO1 and RO2 will be manageable for industry.

- Given the short time that the implemented EU restriction has been in place, the Agency has no information about compliance rates for RO3. However, the proposed derogation of the 21 pigments listed in Table B which is applied to all options proposed by the Agency will remove one of the major difficulties that industry reports it will face with the implemented EU restriction. This will improve the manageability of RO3.

- Since the EU has recently implemented legislation with broadly the same scope as the options that are proposed for GB, industry awareness will be raised about the EU restriction. To ensure the EU restriction is successful, work will be underway to develop solutions for aspects of the EU restriction that are proving difficult to achieve. This raised awareness and the results of work to solve problems for the EU restriction will help GB industry manage a restriction with a similar scope to the EU restriction if it is implemented in GB.

- The provisions in each option are linked to previous recommendations on substances that should not be present in tattoo inks and PMU (CoE, 2008) and existing legislation (the GB MCL list and Annexes of the CPR). This has the potential to simplify the identification of which substances are in scope of the restriction. This does introduce a burden on industry to regularly check the GB MCL list and the Annexes of the CPR to confirm which substances are in scope.

- The dynamic link that is proposed under RO1, RO2 and RO3 between the way substances are classified in the GB MCL list and the restriction will reduce the administrative burdens to update lists of substances that are in scope when substances are newly classified. Manufacturers can use the GB MCL list to periodically check which substances are in scope.

- The dynamic link that is proposed under RO1 and RO3 (but not RO2) between Annexes II and IV of the CPR and the restriction will reduce the

administrative burdens to update lists of substances that are in scope when substances are added to or removed from these Annexes. Manufacturers can periodically check these Annexes to identify which substances are in scope.

- In the case of RO2, it is proposed that when substances are added to Annexes II or IV of the CPR, a separate assessment is performed to determine if those substances should fall into scope of this restriction. This will increase the administrative burden of this option.

Monitorability

The implementation of the proposed restriction options can be monitored by:

- Numbers of alerts to the UK's PSD made by enforcement officers where they deem it necessary to highlight particular tattoo ink and PMU products that are on the GB market.

- It is not known how easy it will be to use reductions in numbers of tattoo and PMU complications as a measure of the success of this restriction owing to the lack of robust data to understand the baseline situation.

Scope of the proposed restriction options

Three restriction options are proposed by the Agency.

Restriction option 1 (RO1) and restriction option 2 (RO2) largely replicate the options that ECHA proposed for the EU restriction but also take account of the revisions proposed by ECHA's Enforcement Forum during the EU opinion forming process as described by ECHA in section D1.1.h of the attached ECHA document (ECHA, 2019c). In addition, a clarification has been added to indicate that inks that are placed on the market for use exclusively as a medical device or an accessory to a medical device are exempted from the scope of the restriction.

Restriction option (RO3) reflects the implemented EU restriction with one key difference. Whereas the EU granted a derogation for Pigment Blue 15:3 and Pigment Green 7 until 4 January 2023, the Agency is proposing that these and 19 other pigments which are prohibited for use in hair dyes in Annex II of the Cosmetic Products Regulation (CPR) but are permitted for use as colourants in cosmetics in Annex IV of the CPR are derogated.

For all three restriction options, if the proposed derogation is accepted, it is proposed that the derogation should remain in place until such a time that changes would be introduced within the Annexes of the CPR that would bring the colourant into scope of the general provisions of this restriction.

The scope of the three restriction options is presented in tables 2 (RO1), 3 (RO2) and 4 (RO3). Appendix 1 provides supplementary lists of substances (tables A, B and F) or links to the relevant Annexes of the CPR.

Table 2. Restriction option 1 (RO1) – proposed scope

a) Substances included in the GB MCL list with a classification as: • carcinogenic, mutagenic, or toxic to reproduction category 1A, 1B, or 2 • skin sensitising, category 1, 1A or 1B • skin irritant or corrosive, category 1A, 1B, 1C, or 2 • eye damaging and irritant, category 1 or 2 b) Substances prohibited for use in cosmetic products as listed in Annex II of the Cosmetic Products Regulation (EUR 2009/1223) c) Substances on Annex IV of Cosmetic Products Regulation (EUR 2009/1223) that are subject to conditions in columns "g", "h" and "i" of that Annex	1. Tattoo inks shall not be placed on the market if they contain the substances specified in subparagraphs (a) to (c) below, unless a concentration limit is specified under paragraph 2 in which case, paragraph 2 applies for that substance. In the event a substance is subject to more than one of the conditions in subparagraphs (a) to (c), the stricter condition applies: a. Tattoo inks shall not be placed on the market if they contain the following substances: i. Carcinogenic or mutagenic substances, category 1A, 1B or 2 excluding those substances classified only with the hazard statements H350 (inhalation) (May cause cancer by inhalation), H351 (inhalation) (Suspected of causing cancer by inhalation), H340 (inhalation) (May cause genetic defects via inhalation) and H341 (inhalation) (Suspected of causing genetic defects by inhalation) ii. Substances prohibited for use in cosmetic products as listed in Annex II of the Cosmetic Products Regulation (EUR 2009/1223)[18] iii. Substances in Annex IV of the Cosmetic Products Regulation (EUR 2009/1223) with the following conditions in column g of that Annex: • Rinse-off products • Not to be used in products applied on mucous membranes

[18] This provision is recommended to apply one year after the substance is listed on Annex II.

d) Substances in Table A[17]	• Not to be used in eye products b. Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than 0.1% w/w: i. Skin sensitising substances, category 1, 1A and 1B ii. Skin irritant or corrosive substances, category 1A, 1B, 1C, and 2 [19] iii. Eye damaging and irritant substances, category 1 and 2 [10] c. Tattoo inks shall not be placed on the market if they contain substances toxic to reproduction: i. Category 1A and 1B in concentrations greater than 0.0014 % w/w ii. Category 2 in concentrations greater than 0.014% w/w 2. Tattoo inks shall not be placed on the market if they contain substances listed in Table A [8], exceeding the concentration limits specified in Table A, or Polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.00005% w/w. 3. By way of derogation: a. paragraph 1.a.ii) and 1.a.iii) does not apply to substances (colourants) listed in Table B [20] and

[17] Table A is presented in Appendix 1 and contains a list of substances for which specific concentration limits are being proposed under RO1 and RO2. These substances are methanol, impurities listed in Table 3 of CoE (2008), certain primary aromatic amines, certain azo dyes, DEHP and DBP.
[19] The concentration limit applies to each individual substance.
[20] Table B is presented in Appendix 1 and lists 21 colourants that are prohibited for use as hair dyes under Annex II of the CPR but permitted for use as colorants in cosmetics without conditions under Annex IV of the CPR.

	b. paragraph 1 does not apply to substances that are gases at standard temperature and pressure (with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).[21] 4. In the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV of the Cosmetic Products Regulation (EUR 2009/1223), tattoo inks shall not be placed on the market if the substance is present in the tattoo ink in a concentration, or in some other way, that does not accord with the condition specified in that column. If paragraphs 1 and 2 specify stricter conditions for that substance, then those stricter conditions apply. 5. Mixtures which do not meet the requirements specified in paragraphs 1 to 4 shall not be used for tattooing purposes. 6. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that the mixture is marked with the following information: (a) the statement “Mixture for use in tattoos or permanent make-up”; (b) a reference number to uniquely identify the batch; (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names that has been established in accordance with Article 33 of the Cosmetic Products Regulation (EUR 2009/1223), or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. “Ingredient”

[21] I.e., substances which are gaseous at temperature of 20°C and standard pressure of 101.3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50°C.

	means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with the GB CLP Regulation, that ingredient does not need to be marked in accordance with this Regulation; (d) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Table F; (e) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Table F; (f) safety instructions for use insofar as they are not already required to be stated on the label by the GB CLP Regulation. The information shall be clearly visible, easily legible and marked in a way that is indelible. Where necessary because of the size of the package, the information listed in paragraph 6(b) – (f) shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 7. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes. 8. Definitions for the purpose of this restriction entry a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional insertion into the skin, mucous membrane or eyeball, whereby a permanent skin marking, or

	design (“tattoo” or “permanent make-up”) is made. b. For the purposes of this entry use of a mixture “for tattooing purposes” means the insertion into the skin, mucous membrane or eyeball, of any colouring material by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation) designed to leave a permanent mark. 9. The restriction shall apply one year after its entry into force. 10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when the mixture is placed on the market or used exclusively as a medical device or an accessory to a medical device, within the meaning of The Medical Devices Regulations 2002 [22]. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of The Medical Devices Regulations 2002 and of this Regulation shall apply cumulatively.

Note: Supplementary tables A and B are presented in Appendix 1 to this report.

Table 3. Restriction option 2 (RO2) – proposed scope

a) Substances included in the GB MCL list with a classification as: • carcinogenic, mutagenic, or toxic to reproduction category 1A, 1B, or 2	1. Tattoo inks shall not be placed on the market if they contain: a. the following substances in concentrations greater than the relevant generic concentration limit in Part 3 of Annex 1 the GB CLP Regulation, unless a specific concentration limit is listed in the GB MCL list in which case the specific concentration limit applies: i. Carcinogenic and mutagenic substances,

[22] https://www.legislation.gov.uk/uksi/2002/618/contents

• skin sensitising, category 1, 1A or 1B • skin irritant or corrosive, category 1A, 1B, 1C, or 2 • eye damaging and irritant, category 1 or 2 b) Substances in Table A [6] c) Substances in Table C[23] d) Substances in Table D e) Substances in Table E	category 1A, 1B, or 2, excluding those substances classified only with the hazard statements H350 (inhalation) (May cause cancer by inhalation), H351 (inhalation) (Suspected of causing cancer by inhalation), H340 (inhalation) (May cause genetic defects via inhalation) and H341 (inhalation) (Suspected of causing genetic defects by inhalation) ii. Substances toxic to reproduction, category 1A, 1B and 2 iii. Skin irritant and corrosive substances, category 1A, 1B, 1C, and 2 [24] iv. Eye damaging and irritant substances, category 1 and 2 [16] b. skin sensitising substances in excess of 0.01% w/w for category 1A and 0.1% for category 1 or 1B. These provisions shall apply unless the substances are included in paragraph 2. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) and 1.b), the stricter condition applies. 2. Tattoo inks shall not be placed on the market if they contain the substances listed in Table A [6], exceeding the exceeding the concentration limits specified in Table A, or polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.00005% w/w. 3. Unless already covered by paragraphs 1 or 2, tattoo inks shall not be placed on the market if they contain the substances in: a. Table C [11] in concentrations exceeding 0.1% w/w and

[23] See Appendix 1 for further information about tables C, D and E.
[24] The concentration limit applies to each individual substance.

	b. Table D [12] in concentrations exceeding 0.1% w/w. 4. Unless already covered by paragraphs 1 to 3, tattoo inks shall not be placed on the market if they do not meet the conditions for the substances in Table E [13]. 5. By way of derogation: a) paragraph 3 shall not apply to substances (colourants) listed in Table B [9] and b) paragraph 1 shall not apply to substances that are gases at standard temperature and pressure (with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).[25] 6. Tattoo inks not meeting the requirements specified in paragraphs 1 to 4 shall not be used in tattoo procedures. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that the mixture is marked with the following information: (a) the statement “Mixture for use in tattoos or permanent make-up”; (b) a reference number to uniquely identify the batch; (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names that has been established in accordance with Article 33 of the Cosmetic Products Regulation (EUR 2009/1223), or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. “Ingredient” means any substance added during the process of

[25] I.e., substances which are gaseous at temperature of 20°C and standard pressure of 101.3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50°C.

	formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with the GB CLP Regulation, that ingredient does not need to be marked in accordance with this Regulation; (d) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Table F; (e) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Table F; (f) safety instructions for use insofar as they are not already required to be stated on the label by the GB CLP Regulation. The information shall be clearly visible, easily legible and marked in a way that is indelible. Where necessary because of the size of the package, the information listed in paragraph 7(b) – (f), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes. 9. Definitions for the purpose of this restriction entry a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional insertion into the skin, mucous membrane or eyeball, whereby a permanent skin marking, or design (a “tattoo” or “permanent make-up”) is made.

	b. For the purposes of this entry use of a mixture "for tattooing purposes" means the insertion into the skin, mucous membrane or eyeball, of any colouring material by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation) designed to leave a permanent mark. 10. The restriction shall apply one year after its entry into force. 11. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when the mixture is placed on the market or used exclusively as a medical device or an accessory to a medical device, within the meaning of The Medical Devices Regulations 2002 [26]. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of The Medical Devices Regulations 2002 and of this Regulation shall apply cumulatively.

Note: Information about supplementary tables A – E can be found in Appendix 1 of this report.

Table 4. Restriction option 3 (RO3) – proposed scope

Substances falling within one or more of the following points: (a) substances included in the GB MCL list with a classification as: • carcinogen category 1A, 1B or 2, or germ cell	1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, if the substance or substances in question is or are present in the following circumstances: (a) in the case of a substance classified in the GB MCL list as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or

[26] https://www.legislation.gov.uk/uksi/2002/618/contents

mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation, mutagenic, or toxic to reproduction category 1A, 1B, or 2 • reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation • skin sensitiser category 1, 1A or 1B sensitising, category 1, 1A or 1B • skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2 • serious eye damage category 1 or eye irritant category 2 (b) substances listed in Annex II of the Cosmetic Products Regulation (EUR 2009/1223). (c) substances listed in Annex IV of the Cosmetic Products Regulation (EUR 2009/1223) for which a condition is specified in at least one of the columns g, h and i of the table in that Annex	greater than 0.00005 % by weight; (b) in the case of a substance classified in the GB MCL list as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0.001 % by weight; (c) in the case of a substance classified in the GB MCL list as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0.001 % by weight; (d) in the case of a substance classified in the GB MCL list as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than: (i) 0.1 % by weight, if the substance is used solely as a pH regulator; (ii) 0.01 % by weight, in all other cases; (e) in the case of a substance listed in Annex II of the Cosmetic Products Regulation (EUR 2009/1223), the substance is present in the mixture in a concentration equal to or greater than 0.00005 % by weight; (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV of the Cosmetic Products Regulation (EUR 2009/1223), the substance is present in the mixture in a concentration equal to or greater than 0.00005 % by weight: (i) “Rinse-off products”; (ii) “Not to be used in products applied on mucous membranes”; (iii) “Not to be used in eye products”; (g) in the case of a substance for which a condition is

(d) substances listed in Table F [27]. The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry.	specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV of the Cosmetic Products Regulation (EUR 2009/1223), the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Table F, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Table F. 2. For the purposes of this entry use of a mixture "for tattooing purposes" means the insertion into the skin, mucous membrane or eyeball, of any colouring material by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation) designed to leave a permanent mark. 3. If a substance not listed Table F falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Table F also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance. 4. By way of derogation, paragraph 1 shall not apply to substances (colourants) listed in Table B [9]. 5. If the GB MCL list is amended to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of

[27] Table F is presented in Appendix 1 and lists substances for which specific concentration limits are proposed under RO3.

	application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification. 6. If Annex II or Annex IV of the Cosmetic Products Regulation (EUR 2009/1223) is amended to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that the mixture is marked with the following information: (a) the statement “Mixture for use in tattoos or permanent make-up”; (b) a reference number to uniquely identify the batch; (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names that has been established in accordance with Article 33 of the Cosmetic Products Regulation (EUR 2009/1223), or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. “Ingredient” means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded

	as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with the GB CLP Regulation, that ingredient does not need to be marked in accordance with this Regulation; (d) the additional statement “pH regulator” for substances falling under point (d)(i) of paragraph 1; (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Table F; (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Table F; (g) safety instructions for use insofar as they are not already required to be stated on the label by the GB CLP Regulation. The information shall be clearly visible, easily legible and marked in a way that is indelible. Where necessary because of the size of the package, the information listed in paragraph 7(b) to (g), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes. 9. This entry does not apply to substances that are gases at temperature of 20°C and pressure of 101.3 kPa or generate a vapour pressure of more than 300 kPa at temperature of 50°C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8). 10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when

	the mixture is placed on the market or used exclusively as a medical device or an accessory to a medical device, within the meaning of The Medical Devices Regulations 2002 [28]. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of The Medical Devices Regulations 2002 and of this Regulation shall apply cumulatively.

Note: Supplementary tables B and F are presented in Appendix 1 to this report.

[28] https://www.legislation.gov.uk/uksi/2002/618/contents

Report

1 The problem identified

1.1 Scope and general information

1.1.1 Introduction

The popularity of tattoos and permanent make-up (PMU) has been steadily increasing in the last few decades. A report published by the EU Joint Research Centre (JRC) in 2016 estimated that 12% of European citizens are tattooed and that the prevalence in younger people (18 – 35-year-olds) may be double that (JRC, 2016b). This report also estimated that around 12% of the UK population is tattooed. Percentages for GB are not available.

Less information is available on the proportion of the population that has had one or more PMU treatments. Cosmetic tattoos, also known as PMU or semi-permanent makeup, are used to resemble make-up (JRC, 2016b). Based on information from 3 EU Member States, it has been estimated that up to 20% of the general EU population, may have PMU procedures carried out (JRC, 2016b). Specific data for GB on PMU procedures is not available.

The need for tattoo inks and PMU, and the equipment used to apply these products, to be sterile is widely recognised. However, less attention has been paid to risks that could arise from the chemical ingredients used to make these inks and PMU. Currently, there is no legislation in GB that regulates which substances can and cannot be used in tattoo ink and PMU.

Tattoo inks and PMU are produced by mixing colourants with auxiliary ingredients that are used to improve the quality of the ink by controlling viscosity, drying properties, homogeneity in terms of particle sedimentation, and shelf life of the ink (Giulbudagian *et al.,* 2020). Since the tattoo and PMU ink market represents a small portion of the global production of colourants, the colourants that are available have not been manufactured for the purpose of tattooing or PMU. This means that colourants can contain, intentionally or as an impurity, hazardous substances.

JRC (2016b) states that more than 100 colourants and additives are in use in tattoo inks; numerous impurities have been found. Analyses of inks on the EU market have detected various hazardous substances including polycyclic aromatic hydrocarbons (PAH), primary aromatic amines (PAA) and heavy metals (JRC, 2016b).

A recent analysis of 78 tattoo inks and 7 PMU inks supplied to the Swiss market[29] found that 48 (61%) of the tattoo inks and 4 (57%) of the PMU products did not comply with legislative requirements (Hauri, 2021). This study included 2 tattoo inks stated to have originated from England, both were deemed non-compliant. Areas of non-compliance for inks tested in this study included:

- banned pigments found in 19 inks;
- n-nitrosodiethanolamine detected at levels of 97 and 1760 µg/kg in 2 inks;
- the primary aromatic amine o-toluidine was found in 18 inks at > 5 mg/kg (this is the maximum permitted concentration under the EU restriction);
- two further primary aromatic amines that could form as a result of reductive splitting of azo colourants (2,4-diaminotoluidine and 5-nitro-o-toluidine) were found in 2 red inks; and,
- excessive levels of total PAHs ranging from 22 – 52 mg/kg and BaP ranging from 0.038 – 0.23 mg/kg were found in 3 inks.

There were also problems with incorrect information on product labels, including the failure to list certain substances including pigments. The reasons for non-compliance for the two inks from England were not stated.

Similar mislabelling problems were found in another recent study of 73 inks on the Swedish market including inks purchased via the internet (Wang *et al.,* 2021). This study found only half of the tested inks had correctly described the ingredients in the ink compared with the substances that were detected in these analyses. Chemical analyses found only a few inks contained metal impurities exceeding the maximum concentrations that are permitted under the EU restriction that has now been implemented. Metals exceeding these limits included mercury (levels ranged from 0.004 – 1.6 µg/g ink) and lead (levels ranged from 0.023 – 5.35 µg/g). Total chromium (0.35 – 139 µg/g) and nickel (0.1 – 41 µg/g) were detected in almost all samples.

Information about the composition of inks supplied to the GB market is not available. Since the inks tested in these two studies included inks originating in England (Hauri, 2021) and brands available in GB (Wang *et al.,* 2021), it is reasonable to assume that these studies provide an insight into the GB situation.

[29] Switzerland has introduced legislation on substances in tattoo inks based on CoE (2008). SR 817.023.41: Verordnung des EDI über Gegenstände für den Schleimhaut-,Haut- und Haarkontakt sowie über Kerzen,Streichhölzer, Feuerzeuge und Scherzartikel (Verordnung über Gegenstände für den Humankontakt)1 vom 23. November 2005 (Stand am 20. April 2021)

The analyses that have been performed so far, may not have identified every substance that is currently used to produce tattoo inks and PMU, and may not have identified every hazardous impurity. It is also not known which substances might be used in future e.g., as alternatives for restricted substances, or what additional impurities may be found.

A further challenge to understanding the composition of inks is that whereas most inks used for tattooing are commercially produced, a minority of tattoo artists (though possibly not PMU practitioners) will formulate their own inks using pigments that they have purchased for this purpose. It is not known how widespread this practice is in GB. Several respondents to the call for evidence are concerned that this practice may increase if tattoo artists cannot purchase inks with the colour palette that they wish to use or that their clients may ask for.

In relation to commercially produced inks, tattoo inks and PMU manufacturers are typically micro and small businesses, often specialising in the manufacture of tattoo inks and PMU only. Some further specialise in formulating one of the two. Information received during the call for evidence suggested there may be 0 – 5 manufacturers of tattoo ink in GB. It is not known if any companies manufacture PMU in GB. There may be around 30 companies that import tattoo ink or PMU to GB, with the majority focussing on either tattoo ink or PMU. Several respondents to the call for evidence indicated that they source tattoo inks from US based manufacturers either directly or via UK based suppliers. One respondent indicated that they have purchased ink from China.

Information gathered for the EU restriction suggested that around 32% of tattoo inks on the UK market (specific information for GB was not presented) may be manufactured within the UK, with 40% imported from the US, 10% from Asia and 4% originating in the EU (JRC, 2015b). This information was obtained from questionnaire responses. The Agency does not know how reliable this information is for the situation in GB today. This JRC report listed 6 UK based companies that supply tattoo inks (about twice this number were named in the call for evidence). ECHA reports that the largest global manufacturer of tattoo inks is the US based Starlight Enterprises which supplies the Intenze line of tattoo inks (ECHA, 2019c).

Only one UK based supplier of PMU was identified in JRC (2015b) (two were named by respondents to in the Agency's call for evidence). Unlike tattoo inks a much greater proportion of PMU inks used in the EU are manufactured within the EU, with Germany dominating the market (JRC, 2015b). Michel (2015) estimated that whereas 70 – 80% of tattoo inks on the EU market originate outside the EU, about 70 – 80% of PMU is manufactured within the EU.

ECHA (2019c) estimates that more than 40,100 litres of tattoo inks and 11,000 litres of PMU inks were formulated within the EU in 2016 (ECHA, 2019c). Using this data,

it is estimated that around 18,800 litres of tattoo inks and 1,300 litres of PMU may have been placed on the market in GB in 2016 (see table 1.1.1a). These figures have been calculated based on the volume of ink on the EEA31 market in 2016 which is presented in ECHA's restriction dossier (ECHA, 2019c) (manufactured, exported and imported) and the GB population. The UK population as a proportion of the EEA31 population is calculated (~13%) and the GB population as a proportion of the UK population is calculated (~97%). These proportions are applied to the volume of ink of the EEA31 market to estimate the volume of ink on the GB market in 2016[30]. It is not possible to refine these estimates using the information obtained during the call for evidence due to the limited number of people that provided information.

Table 1.1.1a Tattoo inks and PMU on the GB and EEA31 market – 2016 estimates (litres)

	Tattoo ink[31]	**PMU[32]**	**Total**
EEA31 manufactured	40,100	11,300	51,400
Exported	2,100	2,100	4,200
Imported to EEA31	114,000	1,600	115,600
Total on EEA31 market	**152,000**	**10,800**	**162,800**
Total on the GB market	**18,800**	**1,300**	**20,100**

Note: Figures have been taken from ECHA (2019c) and adjusted for GB. ECHA's original estimates are based on interviews with selected manufacturers and JRC data (JRC, 2015b).

[30] Population has been used as a proxy as this data was readily available and most suitable (compared to GDP) when scaling down EU data for the volume of ink on the market.
[31] ECHA estimated the volume of tattoo inks on the EU market on the basis of information on the amount of tattoo ink used by tattoo artist on average annually: between 0.5 and 3 litres for full-time professional tattoo artist, with amateur artists 25-50% of this. (JRC, 2015b) (industry interviews). The number of tattoo artists was established by the JRC (JRC, 2015b) via questionnaires. The results were verified with industry representatives. Information from the same JRC report provided the share of EU manufactured (20-30% of ink volume), exported (about 5% of EU manufactured ink) and imported (70-80%) volumes for the EEA31 market. (JRC, 2015b) (Michel, 2015)
[32] ECHA estimated the volume of PMU on the EU market on the basis of information from the JRC report (JRC, 2015b), supplemented by interviews with industry. In contrast to tattoo inks, the majority of PMU placed on the EEA31 market is manufactured in the EU (80-90%). EU PMU manufacturers also export nearly 20% of their production internationally. Less than 5% of PMU on the EEA31 market is imported according to estimates, primarily from the US or China. (JRC, 2015b)

In addition to inks purchased from legitimate manufacturers, several people who responded to the call for evidence expressed concerns about the availability of counterfeit inks from online sellers including major online retailers. It is not known how much of the ink imported into GB is counterfeit. Such inks are cheaper than those supplied by reputable manufacturers and are likely to be of poorer quality.

There is evidence in the literature linking substances in tattoo ink and PMU to various adverse effects often collectively referred to as complications. These include allergic and other skin reactions at the site of the tattoo or permanent make up. The evidence linking substances in tattoo ink and PMU with adverse systemic effects is less clear though there have been reports in the literature that suggest systemic complications can occur. Adverse systemic effects/complications are adverse effects that occur in the body but away from the site of the tattoo or PMU. Further information is available in section 3.5.3.

Whereas some complications occur shortly after receiving the tattoo or PMU, other complications can take months or years to develop or may appear intermittently. In many cases, complications are mild but sometimes it is necessary for those affected to seek medical assistance and even have their tattoo removed due to the severity of the adverse effect.

Information on the proportion of those who get tattoos or PMU in GB that subsequently develop complications is mainly available from studies carried out in EU countries (see section 3.5.3 and Annex D.6.1 in ECHA (2019c) for details). No information is available for GB. It is not known if poor quality inks make a greater contribution to the incidence of tattoo complications compared with inks from reputable brands. This could happen for example if:

- the ink contains higher levels of impurities;
- the ink requires the tattoo artist to work over the tattooed area more times during the tattooing session increasing the likelihood that the physical damage caused by the tattooing process takes longer to heal or scarring occurs; and/or,
- the colourants fade more rapidly requiring the tattoo process to be repeated at a later date to return the image to good visibility incurring extra cost for the consumer and creating another opportunity for complications to arise.

When complications are localised to the tattoo or PMU or to specific colours within a tattoo it is easier to make links between substances in the tattoo or PMU. Often it is not clear which of the many substances that may be found in tattoo inks is causing a complication. This is due to the diverse range of substances that may be present in inks, the limited number of epidemiological investigations, the fact that people won't

automatically seek medical assistance when complications arise (and may not seek advice from their tattoo artist or PMU practitioner if the symptoms they experience appear to be trivial) and the challenges of identifying causal agents when adverse effects may only become apparent months or years after the initial exposure.

Given these uncertainties, it is difficult to quantify the level of risk that is associated with tattoo ink and PMU in general and the use of specific substances within those inks. This restriction is therefore being proposed on the hypothesis that certain hazardous substances when used in tattoo ink or PMU have the potential to trigger complications. Since it is possible for anyone in GB who is over 18 years old to get a tattoo or PMU, this potential risk applies to any member of the adult population in GB that chooses to get a tattoo or PMU. To limit the impacts of this potential risk, a precautionary action is being proposed.

Potentially anyone can offer tattooing and PMU services. Traditionally, professional tattoo artists learn their skills through “apprenticeships” with experienced tattooists. Although professional associations for tattoo artists exist (a list of associations for GB is presented in Appendix 3), there is no requirement for practicing tattoo artists to become members of an association or to undergo any formal accreditation.

In the case of PMU practitioners, courses are available in GB from private training providers. In some cases, these training providers may also supply PMU with the trainees going on to use that product on their clients. PMU professionals are often employed in laser surgery clinics, spas and other wellness centres, but may operate from independent premises.

There is no GB wide requirement for tattoo artists or PMU practitioners to operate from licenced or registered premises. It is the responsibility of local authorities to oversee the operation of tattoo parlours and PMU practitioners in their area. Due to regional differences in the legislation that governs local authority oversight, licensing and registration requirements differ between local authorities.

In England, local authorities can choose whether individuals carrying out tattooing and PMU procedures in their area need to be registered.

The situation is different in Wales. In this country, persons carrying out special procedures including tattooing and application of PMU must be licensed and must operate from approved premises. Licences are only valid for 3 years (or 7 days in the case of temporary licences granted for special events). Licenses can be revoked immediately if unsafe practices are identified.

Local authorities in Scotland also have powers to licence individuals who carry out tattooing activities as a business.

Local authorities across England, Scotland and Wales are focused on hygiene and

infection control, rather than the health risks associated with certain chemicals in tattoo inks (further details about the registration/licensing arrangements across GB are available in Appendix 4).

Given the variable registration/licensing requirements across GB, it is difficult to obtain accurate figures for the number of tattoo artists and PMU practitioners working in GB. For the purposes of this report, numbers have been estimated using available data and assumptions. Data is available on the number of licensed tattoo artists and PMU practitioners for some regions in Scotland suggesting at least 375 tattoo artists are working in that region. If this is extrapolated using the population of England and Wales, this suggests that there may be at least 4,495 tattoo artists working in GB.

Information from the Agency's call for evidence reported by three borough councils suggests this may be an underestimate. East Lindsay Borough Council reports 24 tattoo artists and 13 PMU practitioners. Ipswich reports 100 tattoo artists and PMU practitioners and Cheltenham reports 160 tattoo artists and PMU practitioners. Multiplying the figure from Cheltenham by the number of local authorities in GB (387) suggests up to 40,164 tattoo artists and 21,756 PMU practitioners may be working in GB. Comparing this number with the numbers reported by ECHA (2019c) for certain EU countries (see table 1.1.1b), this figure appears to be over 4 times higher than the highest estimate for any of the countries for which data is available. This may therefore substantially overestimate the number of registered/licenced tattoo artists and PMU practitioners in GB.

In addition to registered or licensed premises, there will be additional unregistered individuals offering tattooing or PMU services. Data presented by ECHA (2019c) for several EU countries (see table A2) suggests that the number of unregistered amateur or home tattooists (also referred to as "backyard tattooists" or "scratchers") could equal or in some cases substantially exceed the number of registered artists.

Table 1.1.1b. Number of professional and non-registered tattooists in various EU and EEA countries (ECHA, 2019c)

Country	Professional tattooists	Professional tattooists/inhabitants	Non-registered tattooists	Reference
Germany	6,000	1/13,000	6,000-20,000	*, ‡
Denmark	500	1/11,200	1,000-1,200	*, ‡
Spain	3,000-3,500		2,000-5,000	*, ‡

France	2,000-4,000	1/22,600		*, †
Iceland	8-10	1/30,000	16-70	*, †
Italy	1,200-10,000	1/20,000	4,000-30,000	*, †, ‡
Norway	400-650	1/10,000	3,000-5,000	*, ‡
Sweden	2,000-3,000	1/3,200	3,000-20,000	*, ‡
Switzerland	550-900	1/13,000	1,000	*, ‡

Extracted from: (JRC, 2015b)

Sources: * (Kluger, 2015a), † Questionnaire of Member States (JRC, 2015b), ‡ Questionnaire of Tattooist Associations (JRC, 2015b)

The numbers of non-registered tattooists reported in table 1.1.1b are highly uncertain and should be interpreted with extreme caution. ECHA (2019c) notes that the methods used to estimate numbers may vary by country. The number may be substantially overestimated if this is based on tattoo starter kits sold via the internet[33], as those kits may be purchased for personal use only.

Little information was obtained from the call for evidence about numbers of unregistered tattoo artists and PMU practitioners that may be operating in GB. One respondent suggested there may be at least 5,000 unregistered tattoo artists. Another suggested the number of unregistered artists could be at least twice the number of registered artists.

This rather unstructured nature of the tattooing and PMU professions presents challenges for gathering and disseminating information about risks and safe practices. It could also present challenges for enforcing any regulations governing the composition of tattoo inks if enforcement bodies cannot easily identify where tattoo artists and PMU practitioners are operating.

A further challenge relates to uncertainty about the availability of analytical methods that can identify each component in tattoo ink and PMU that will fall into scope of the restriction if this is required. This will be a challenge for both manufacturers/suppliers to confirm that the inks that they are supplying comply with the requirements of the restriction and for enforcement officers seeking to check that compliant inks are being used. It may be possible for enforcement bodies to develop strategies that focus on key substances. Approaches of this type have been used in EU Member

[33] A tattoo starter kit is defined by ECHA as a kit containing essentials for tattooing: needles, inks and a collection of designs.

States with national legislation on the composition of tattoo ink and PMU (ECHA, 2019c).

1.1.2 Request to the Agency

Currently, in GB there is no legislation that regulates which substances can be used in tattoo ink and PMU. To determine if it is necessary to introduce regulations, the Defra Secretary of State, with the consent of the Scottish Government and the Welsh Government made a request to the Agency under Article 69(1) of UK REACH to prepare an Annex 15 restriction dossier in respect of this risk and consider the need for such measures.

The Agency was requested to address all substances listed in CoE (2008) and also the following groups of substances:

- Carcinogenic or mutagenic substances
- Substances that are toxic to reproduction
- Skin sensitisers
- Skin corrosive or irritant substances
- Substances that cause serious eye damage/eye irritant substances
- Substances that are prohibited for use in cosmetic products under the Cosmetic Products Regulation (EUR 2009/1223).

CoE (2008)[34] and the earlier resolution CoE (2003)[35] set out criteria for the safety of tattoos and permanent make-up. They include provisions relating to the chemical composition of tattoo inks as well as guidance on best practices to ensure that tattoo and PMU products do not endanger the health and safety of humans. CoE (2008) makes the following recommendations in relation to the chemical composition of tattoo ink and PMU (this text reproduces the recommendations as written in CoE (2008) and the tables and appendices referred to in this text are those appearing in CoE (2008))[36]:

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[34] Adopted by the Committee of Ministers on 20 February 2008 at the 1018th meeting of the Ministers' Deputies of the CoE https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805d3dc4

[35] Adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies of the CoE https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805df8e5

[36] Table 2 of CoE (2008) is a non-exhaustive list of substances which have carcinogenic, mutagenic, reprotoxic and/or sensitising properties which should not be present in tattoo ink or PMU.

- they do not contain or release the aromatic amines listed in Table 1 of this appendix in concentrations that are technically avoidable according to good manufacturing procedures; the presence or release of these aromatic amines should be determined by using appropriate test methods which should be harmonised across the member states in order to ensure comparable health protection of the consumer and to avoid divergent enforcement, drawing on existing methods which can serve as models (see Tables 4.a-c);
- they do not contain the substances listed in Table 2 of this appendix;
- they do not contain substances listed in Directive 76/768/EEC (Annex II);
- they do not contain substances specified in Directive 76/768/EEC (Annex IV, columns 2 to 4);
- they do not contain carcinogenic, mutagenic and reprotoxic substances of categories 1, 2 or 3 which are classified under Directive 67/548/EEC;
- they comply with maximum allowed concentrations of impurities listed in Table 3 and the minimum requirements for further organic impurities for colorants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC;
- they are sterile and supplied in a container which maintains the sterility of the product until application, preferably in a packaging size appropriate for single use. In case multi-use containers are used, their design should ensure that the contents will not be contaminated during the period of use;
- preservatives should only be used to ensure the preservation of the product after opening and by no means as a correction of insufficient microbiologic purity in the course of manufacture and of inadequate hygiene in tattooing and PMU practice;
- preservatives should only be used after a safety assessment and in the lowest effective concentration.

1.1.3 General composition of tattoo inks and PMU

Information on the composition of tattoo inks and PMU is provided in ECHA (2019a, c). The summary from ECHA (2019a) is reproduced here since this information is applicable to inks supplied to the GB market.

Reproduced ECHA text

The substances in the scope of the proposed restriction belong to three distinct groups: colourants, impurities, and other auxiliary ingredients. Additional information

on the function of the substances and composition of tattoo inks is presented in a report by the JRC (JRC, 2015b). More extensive information is also contained in Annex A and D.

a) Colourants

“Colourant” is the commonly used term for coloured pigments, lakes and dyes (CoE, 2008). Pigments are mostly insoluble colourants (Olsen, 2015). They are the major ingredients of tattoo and PMU inks (up to 60% w/w but typically around 25%) and are responsible for the ink’s colour (Olsen, 2015); (JRC, 2015b). Pigments used in tattoo inks have high light fastness and low migration properties (Petersen & Lewe, 2015). These qualities differentiate them from dyes, which due to their solubility are generally not suitable for such use. However, dyes are used in PMU where they are used as insoluble lakes of dye and other substances (JRC, 2015b).

Pigments can be grouped in two distinct categories: inorganic or organic substances. Organic pigments are favoured for tattooing because of their high tinting strength, light fastness, enzymatic resistance, dispersion, and relatively inexpensive production costs (Olsen, 2015). Inorganic pigments are more frequently used for PMU than for tattoo applications, due to their dull and non-brilliant hue compared to organic ones (JRC, 2015b), which make them more compatible with the natural tones observed on the human body.

b) Impurities

Impurities have no function in tattoo inks. Their presence is usually the result of the manufacturing process or the degradation/reaction of the substances contained in the tattoo inks.

c) Auxiliary ingredients

According to (JRC, 2015b) additives are used to modify certain characteristics of the inks and are usually added in a concentration lower than 5% by weight. They can include surfactants, binding agents and fillers.

Another group of auxiliary ingredients are preservatives. They are a natural or synthetic ingredient that is added to products to prevent them from spoiling. In particular for tattoo inks, preservatives are used to avoid the growth of microorganisms in the product after opening.

Preservatives in tattoo inks are under the scope of the Biocidal Products Regulation (BPR), therefore this category of substances will not be further examined as the continuing use of these substances is subject to the authorisation regime of the BPR. However, it should be noted that certain preservatives may be restricted for use in tattoo inks due to their harmonised classification (e.g., formaldehyde, 2-

phenoxyethanol, triclosan, 3-iodo-2-propynyl butylcarbamate).

End of reproduced ECHA text

1.1.4 Scope of the restriction

The intention of this restriction is to minimise the risk to consumers from chemicals that may be used or are present in tattoo inks and PMU. The restriction proposed for GB targets the same substances and groups of substances that are targeted by the EU restriction which also applies in Northern Ireland (NI) due to the requirements of the Withdrawal Agreement including the Northern Ireland Protocol.

Even if GB adopted a restriction with an identical scope to that implemented in the EU, there is the potential for differences to arise between GB and the EU/NI in relation to which specific substances fall within scope of the restriction.

In particular, this could occur for substances that fall within scope owing to their hazard classification. Now that GB operates its own classification and labelling scheme, GB CLP, there may be differences between the harmonised classification adopted by the EU under the EU CLP Regulation and the mandatory classifications that apply in GB.

Divergence between GB and the EU/NI is also possible for substances that fall within scope because they are listed on Annexes II or IV of the Cosmetic Products Regulation (CPR). At the EU level, substances are periodically added in batches to Annexes II or IV of the EU CPR, unless industry demonstrates essential use in cosmetics. In GB, the Secretary of State has powers to amend the UK CPR on the basis of scientific evidence. Therefore, changes proposed by the EU may also be considered independently by the Scientific Advisory Group for Cosmetics (SAG-CS) and in turn the UK Government will make a decision on any necessary changes to the UK CPR. If different approaches are taken on which substances should be added to Annexes II and IV, this could lead to divergence.

Divergence due to the approach taken to classify substances or due to the approach taken to add substances to Annexes II or IV of the CPR could be permanent or, in the case of different timelines to classify or add substances, temporary.

Divergence is not expected for substances falling into scope only because they are listed in CoE (2008) because this list is not expected to be updated by the EU now that a REACH restriction is in place.

If the EU decided to revisit aspects of the scope of their restriction on substances in tattoo inks and PMU in future years, this would create a further opportunity for divergence.

Since this restriction proposal for GB targets the same substances and groups of substances that are targeted by the EU restriction, the explanation on which substances are in scope given in ECHA (2019a) section 1.1.5. including ECHA's footnotes, is reproduced here for consistency. This text contains references to EU processes. Where the text refers to harmonised classifications, in GB these are the classifications included in the GB MCL list. References to Annexes and Appendices in this reproduced EU text relate to sections of the EU document which is attached as Document 1 in the Annex to this Agency dossier (ECHA, 2019c). The numbers of substances reported for each category in table 6 reflect the situation that existed at the time ECHA published the initial restriction proposal in 2017 (ECHA, 2017). These numbers may have changed as substances are newly classified and substances are newly added to the Annexes of the CPR.

Reproduced ECHA text[37]

The intention of this restriction is to minimise the risk to consumers from chemicals used in tattoo inks. This restriction proposal only covers decorative, PMU, traditional and medical tattoos (see Annex A). Temporary tattoos applied on the surface of the skin (stickers) and traumatic (non-intentional) tattoos are not in the scope of this proposal.

However, the available data concerning which substances can be found in tattoo inks and PMU is not considered sufficiently reliable and comprehensive to base a restriction in terms of individual substances present in the majority of inks. There are a high number of substances used, many of which are unknown and of the ones known, there is often insufficient information on concentrations in tattoo inks and/or hazard information to allow a traditional quantitative assessment of their risks. Moreover, such an approach that would list and restrict individual substances would have the disadvantage of not capturing all hazardous substances (including the substantial number of substances that may act as replacements) and hence, it would not fulfil the objective. Therefore, an approach is chosen by which all substances with certain specific hazards will no longer be allowed to be used in tattoo inks, based on the argumentation that these hazards are severe enough to justify the proposal. This approach is largely in line with the approach adopted under the CoE ResAP Resolution.

To capture the largest number of substances of potential concern in inks, the Dossier

[37] The ECHA text that has been reproduced in this document refers to the tattooing and PMU process as injection under the skin. Tattooists report that this description of the tattooing process is not strictly accurate. The Agency text therefore refers to the tattooing and PMU process as insertion into the skin.

Submitter proposes to not only include substances that are identified as being present in inks, but also to assess all substances which are included in Annex VI CLP with relevant classifications and in ResAP(2008) to prevent them being used as substitutes. The substances in scope include:

1. Substances included based on their harmonised classification(s)[38]:

- Substances classified as carcinogenic and mutagenic (CM), categories 1A, 1B and 2 are included in the restriction based on their hazardous properties of very high concern. This inclusion is justified based on their normally non-threshold hazards. Azo colourants that are not classified as CM category 1 or 2 may undergo decomposition to, contain residual aromatic amines that are so classified or are in table 2 of ResAP 2008 but not covered elsewhere). These azo colourants are also included in this qualitative or semi-quantitative risk argumentation (see Annex B.5.7/8 for more detail).
    - Substances classified as carcinogens or mutagens in Categories 1A, 1B and 2 only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation) are not included in scope. These substances are classified as carcinogens and mutagens through the inhalation route only and are excluded from the scope of the restriction based on the current knowledge that their intrinsic carcinogenic and mutagenic properties will only be manifested as cancer and genetic defects after inhalation. This exclusion takes into account that most of the inks available on the market are liquid[39] and not inhaled by the recipient of the tattoo. In addition, the restriction does not cover the manufacture of the tattoo ink ingredients or formulation of the tattoo inks where inhalation may be a relevant exposure route.
- Substances classified for reproductive toxicity (repro), categories 1A and 1B and 2 are normally considered to have a toxicological threshold and are therefore proposed to be restricted based on a quantitative assessment. This quantitative approach was established using 34 substances with harmonised classifications as repro 1A and 1B based on their individual thresholds for reproductive toxicity (see Annex B.5.9 for more detail). Substances classified

[38] It has been proposed only to use harmonised classifications as using self-classifications may lead to a non-harmonised implementation of the measure due to differences in how companies assess the date for a substance. However, the Dossier Submitter has used the available notifications to propose priorities for future action on potential ingredients (see Appendix D.1).
[39] Some Tattoo inks may be provided in powder form and made up by tattoo artists into the final mixture.

for repro, category 2, are proposed to be restricted based on 'the principles used in the quantitative assessment of repro 1A and 1B substances.

- Substances classified as skin sensitisers (SS) are included in the restriction proposal based on a qualitative assessment of their hazardous properties. This inclusion is justified as no reliable dose descriptor (i.e., a DNEL) can be set for skin sensitisation (see Annex B.5.5 for more detail).
- Substances classified as skin corrosives, skin or eye irritants or as eye damaging are included in the restriction proposal based on a qualitative assessment of their hazardous properties (see Annex B.5.3/4 for more detail).
- Lead compounds are included in the proposed restriction based on their non-threshold reproductive toxicity effects (EFSA's CONTAM Panel (EFSA 2013). These were acknowledged by RAC in the lead in jewellery and consumer product restrictions, where it was concluded that there is no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity (including from in utero exposure), increases in systolic blood pressure and renal effects (e.g., changes in proteinuria, glomerular filtration rate (GFR) or creatinine levels and clearance)) (see Annex B.5.9 for more detail).

2. Substances included in the restriction based on their inclusion in the Cosmetic Products Regulation (CPR):

- Substances on Annex II of the CPR (the list of substances prohibited in cosmetic products) are included in this restriction proposal as they are in Annex II of CPR on the basis of their risk to human health (see Article 14 of CPR). Therefore, no further risk assessment is needed (as an assessment under the CPR has been carried out, Annex I para 0.5 of REACH applies here). This justification is further supported by a specific assessment that substances prohibited in cosmetic products applied to the skin should also be prohibited from injection under the skin due to the potentially increased risk through circumventing the dermal barrier (see Annex B.5.11 for more detail).
- A number of substances on Annex IV[40] of the CPR (the positive list of colourants allowed in cosmetic products) are included in this restriction proposal because their conditions in columns g-i of Annex IV (specific use restriction, maximum allowed concentration limits, purity requirements, etc.) mean if the substances are used in tattoo inks they may represent a risk to

[40] A positive list of colourants allowed in cosmetic products (with some use or concentration restrictions).

the consumer. (See Annex B.5.12 for more detail.)

3. Substances included in the restriction based on the CoE resolution (and national legislation):

- Substances on the CoE Resolution lists that are not considered in the previous categories, i.e.:
    - 5 substances in Table 3 of ResAP(2008)1 (see Annex B.5.13 for more detail).
    - 14 colourants in Table 2 of ResAP(2008)1 without harmonised classification and not included in point 1 above.

In total, more than four thousand substances fall within the scope of the restriction proposal (in the categories described above). Table 6 gives an overview of the number of these substances by category:

Table 6. Breakdown of substances in the restriction proposal

Total number of substances in scope	Approximately **4,130**
1. Substances with harmonised classification in the CLP Regulation (EC) No 1272/2008 as:	Approximately **2,390**
a. carcinogenic and mutagenic Cat. 1A, 1B, and 2	Only classified as Cat 1A and 1B: **862** Classified as Cat. 1A, 1B, and 2 (with other relevant classifications): **1,287**
b. reproductive toxicant Cat. 1A,1B, and 2	Only classified as Cat 1A and 1B: **74** Only classified as Cat 2: **36** Classified as Cat 1A, 1B and Cat 2 (with other relevant classifications): **368**
c. skin sensitisers Cat. 1, Cat. 1A, Cat. 1B	Only classified as skin sensitiser Cat 1, 1A and 1B: **415** Classified as skin sensitiser Cat 1, 1A and 1B (with other relevant classifications): **1,159**
d. skin irritant (Cat. 2), skin	Only classified as skin irritant (Cat. 2), skin

corrosive (Cat. 1, Cat. 1A, 1B, 1C), eye irritant (Cat. 2) or eye damaging (Cat. 1) Irritation, corrosive.	corrosive (Cat. 1, Cat. 1A, 1B, 1C), eye irritant (Cat. 2) or eye damaging (Cat. 1) Irritation, corrosive: **895** Classified as skin irritant (Cat. 2), skin corrosive (Cat. 1, Cat. 1A, 1B, 1C), eye irritant (Cat. 2) or eye damaging (Cat. 1) Irritation, corrosive (with other relevant classifications): **1,577**
2. Substances on CPR Annex II:	Total: **1,490** Classified as CMR Cat 1A, 1B and 2: **795** Classified as skin sensitiser Cat 1, 1A and 1B: **103**
3. Substances on CPR Annex IV: a. restricted due to conditions on use (in column g of Annex IV) b. allowed in tattoo inks under specific conditions	Total on Annex 4: **260** Restricted due to conditions on use: **74** Allowed under specific conditions: **119** Classified as CMR or skin sensitiser/irritant/corrosive or eye irritant/damaging: **1**
4. Substances on CoE ResAP(2008)1 (CoE, 2008)	Approximately in total: **4,130** Excluding those in points 1-3: **19**

A number of substances were not included in the proposal due to lack of information and available resources (see Appendix D.1) and these substances would need to be considered at a later stage either through a further request by the Commission, through a further restriction proposal from a Member State or through agreement of a harmonised classification proposal bringing a substance into the scope of the proposed restriction.

It should be noted that all the aspects not covered by the restriction proposal, such as general hygiene requirements or chemicals with no hazard classification, can therefore continue to be regulated at the Member State level provided that such national requirements comply with the Treaty provisions on free movement and provision of services.

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1.2 The hazard, exposure, and risk

The Agency has not replicated the work carried out by the EU to assess the hazards and risks created by different substances and substance groups if they are present in tattoo inks.

In preparing this dossier, the Agency makes the following observations about the EU approach:

- For substances classified as Repr 1A/B or 2 and certain impurities where thresholds of effect can be identified, the EU carried out quantitative risk assessments to derive concentration limits. In this process Derived No Effect Levels (DNELs) were compared with the estimated exposure level to derive a risk characterisation ratio (RCR). RCRs greater than 1 signify a potential risk. Concentration limits were identified that give rise to an RCR of 1 or less for these substances when they are present in tattoo ink or PMU.

- For certain other substances and impurities with so called “non-threshold” effects (e.g., carcinogens) data were available to calculate Derived Minimal Effect Levels (DMELs). Where DMELs were calculated, ECHA used a semi-quantitative approach to assess risk. For these substances, the concentration limits that were derived by the EU are claimed to equate to a risk level for adverse effects of 1×10^{-6}, i.e., one case of ill health due to the causal agent in every one million people exposed to that agent.

- Risks for the remaining substances in scope were assessed in a qualitative manner. These qualitative risk characterisations aim to determine the likelihood that adverse effects will be avoided when receiving a tattoo or PMU. In the case of tattooing and PMU, this translates to a risk management approach that aims to avoid or limit the presence of unwanted substances in tattoo ink and PMU. This qualitative approach was taken for substances classified for skin sensitisation/irritation/corrosion, eye damage/irritation, mutagenicity and/or carcinogenicity on the basis that the available hazard data for these substances is insufficient to identify a level of exposure that does not cause adverse health effects. For the large number of substances that are covered by this qualitative risk assessment approach, the assumption has been made by the EU that the effects when these substances are inserted into the skin will be more severe than when applied onto the skin.

The hazard and risk assessments underpinning this proposal will be reviewed by the Agency and its independent scientific expert panel (RISEP) during preparation of the Agency opinion on this proposal.

1.2.1 Identity of the substances, and physical and chemical properties

A description of the identity of the substances in scope is provided in section 1.1.4. Owing to the high number of substances that are in scope, information on the physical and chemical properties of these substances has been omitted.

1.2.2 Justification for targeting

The justification for targeting the substances in this restriction is explained under 1.1.1 introduction and 1.1.4 scope.

1.2.3 Classification and labelling

The classification and labelling of substances that are in scope of this restriction is given in the GB MCL list [41].

1.2.4 Hazard assessment

Section 1.2.4 of this document reproduces the summary of the EU work given in ECHA, 2019a. It should be noted that in the case of methanol, the EU exposure limit that was used as the starting point to derive a DNEL for this substance is the same as the Workplace Exposure Limit established within the Control of Substances Hazardous to Health Regulations (2002) as amended (COSHH).

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In this restriction proposal information was retrieved from published literature, databases and REACH registrations in accordance with ECHA guidance on information gathering (R3) (ECHA, 2011). For more details, see the respective appendices.

To efficiently and effectively deal with all the substances included in the scope of the restriction (see 1.1.5), the Dossier Submitter has addressed a number of substances through a qualitative approach and the remaining, in a (semi-)quantitative manner.

According to REACH Annex I para 1.1.2 and ECHA Guidance R.8 (ECHA, 2012), when no reliable dose descriptor can be set for a given endpoint, a qualitative approach (analysis) has to be taken. The relevant endpoints/hazard categories where a qualitative analysis is appropriate are: irritation/corrosion, sensitisation,

[41] https://www.hse.gov.uk/chemical-classification/assets/docs/mcl-list.xlsx

carcinogenicity and mutagenicity. For most of these, a threshold cannot be identified. For endpoints where a threshold could be defined and DNELs could be derived, this was done for a selection of substances. In addition, for certain substances DMELs were derived for the purposes of risk characterisation and proposing concentration limits.

In the case of this restriction, the Dossier Submitter has therefore performed the hazard assessment in the following way:

- Substances in the scope of the restriction due to their predominantly non-threshold intrinsic hazardous properties, were evaluated in a qualitative manner (see 1.2.4.1).
- Some substances in the scope of the restriction with non-threshold intrinsic hazardous properties were evaluated in a semi-quantitative way with derivation of DMELs (see 1.2.4.2).
- Some substances in the scope of the restriction due to their predominantly threshold intrinsic hazardous properties and where a DNEL could be derived, were evaluated quantitatively (see 1.2.4.2).

- Substances in the scope of the restriction due to their prohibition from use according to the Cosmetics regulation or subject to special conditions were evaluated in a qualitative manner (see 1.2.4.3).

1.2.4.1 Substances with predominantly non-threshold intrinsic properties and evaluated in a qualitative manner

The following groups of substances can best be assessed in a qualitative manner in the context of this restriction due to their predominantly non-threshold effects, and/or the difficulty to identify a reliable dose-descriptor:

- substances with inherent properties that may cause an effect with no threshold. This is the case for most substances with C and/or M classifications (Annex B.5.7/8), as well as for lead compounds[42] (EFSA CONTAM Panel, 2013) (Annex B.5.9).
- substances classified as skin sensitisers, based on the observation that when allergens are deposited into the dermis via an injection, stronger sensitisation/elicitation reactions may occur and with lower doses than when deposited on the skin (Annex B.5.5). In theory skin sensitisers have

[42] For the purposes of deriving a concentration limit for lead a (semi)quantitative assessment has been made.

thresholds, but data is very seldom available to set the threshold.

- substances classified as skin irritants / skin corrosive and eye irritants / eye damaging, based on the assumption that the effects will be more severe when these substances are injected into the skin rather than applied on the skin (Annex B.5.3/4). This assumption also applies to these substances when injected into the eyes.

For all substances with inherent properties that may cause an effect with no threshold, it is not possible to do a quantitative hazard assessment, i.e., to identify a threshold for the given effect.

1.2.4.2 Substances included based on intrinsic properties and evaluated in a (semi-)quantitative manner

For the following substances either DN(M)ELs have been derived, or the substances have been grouped with other substances for which DN(M)ELs have been derived.

- Methanol, due to its classification as STOT SE (Annex B.5.2).
- Primary aromatic amines (PAAs) and azo colourants (Annex B.5.7/8).
- Substances classified for reproductive toxicity in hazard category Repr. 1A/B and 2 (Annex B.5.9).
- Certain substances listed on table 3 of the CoE ResAP(2008)1 considered to be impurities in tattoo inks and PMU (Annex B.5.13).

Methanol

Methanol is classified for STOT SE 1 based on its effects on the optic nerve (nervus opticus) and central nervous system seen after a single exposure. Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values, specifies an OEL for methanol of 260 mg/m^3 or 200 ppm for an 8-hour exposure, giving an exposure of 2.6 g/person/day, equivalent to 40 mg/kg bw/day. This OEL is considered to be, in the majority of cases, also protective for very slight, sub-clinical Central Nervous System (CNS) effects of methanol inhalation, which are reported to start to appear at 270 mg/m3 (FIOH 2008). A NOAEL/LOAEL as basis for the OEL is not available. A DNEL of 8 mg/kg bw/day for the general population was calculated by the Dossier Submitter based on the exposure of 40 mg/kg bw/day and an assessment factor (AF) of 5.

Primary aromatic amines (PAAs) and azo colourants

PAAs are used in the production of azo colourants and may therefore be present in the final colourant as non-reacted impurities. Degradation of azo colourants can

generate PAAs. Azo colourants can be degraded by irradiation: sunlight or laser (JRC, 2015b). Enzymatic degradation or bacterial degradation has also been shown (Sudha, *et al.*, 2014) (Chacko & Subramaniam, 2011). In addition, the Dossier Submitter proposes to include 14 other azo colourants in the restriction as they are included in seven Member States current national legislation (based on Table 2 of CoE ResAP).

A hazard evaluation was performed for the ten PAAs found in a Danish survey of tattoo inks (DEPA, 2012) to determine a DMEL for the carcinogenic effects. DMELs could only be derived for two substances – aniline and o-anisidine, see Table 7. The lowest DMEL was carried forward in the risk assessment for PAAs (see 1.2.6.2). For more information on the assessments of the other PAAs, see B.5.14 and appendix B.2.

Table 7. DMELs for PAAs

Substance	**CAS No.**	**Classification**	**Point of Departure (POD), Dose descriptor**	**DMEL general population, carcinogenic effects**	**Remark**
Aniline	62-53-3	Carc 2 Muta 2 Acute tox 3 STOT RE1 Eye damage 1 Skin sens 1	HT25, 4.6 mg/kg bw/day	2×10^{-5} mg/kg bw/day	The DMEL was based on HT25 for carcinogenicity and application of an HtLF (high to low dose risk extrapolation factor) of 250 000 (the 'default' for the 10-6 lifetime risk when T25 is used as a PoD (ECHA Guidance chapter 8 appendix 8-6 and 8-7).
o-Anisidine	90-04-0	Carc 1B Muta 2 Acute tox 3	HT25 9.9 mg/kg bw/day	4×10^{-5} mg/kg bw/day	

Approximately 54% (67 in number) of the colourants used in tattoo inks and ink for permanent make-up (PMU) are azo colourants (JRC, 2015b). Thirty-two of these azo colourants have been identified to be able to decompose to PAAs by cleavage of the azo bond and by amide hydrolysis (DEPA, 2017b), see B.5.7/8. Two of the 32 azo colourants are however also primary aromatic amines and are restricted as such. One of these 32 azo colourants has a harmonised classification as carcinogenic.

Substances classified for reproductive toxicity

Substances classified for reproductive toxicity in hazard category repro 1A/B due to their effects on sexual function and fertility in adults and developmental toxicity in offspring may exert their adverse effects when tattoo inks containing them are injected into dermis or other parts of the body (e.g. submucosal, intraocular, or under the tongue) of consumers. To demonstrate a risk and to derive concentration limits for substances toxic to reproduction in tattoo inks and PMUs, a quantitative hazard assessment approach is used that considers the group of all currently known repro 1A/B-classified substances.

As a starting point all substances classified in CLP category repro 1A/B and not also classified as CM or SS were listed and named "reprotoxic only" substances. Traditionally, reprotoxic substances have been assumed to have an individual threshold level below which no adverse effect is expected, thus a quantitative hazard assessment approach was used to derive DNELs for the "reprotoxic only" substances. In line with this, dose descriptors (NOAEL/LOAEL) were identified from available studies and DNELs were derived in accordance with ECHA guidance R.8 (ECHA, 2012). Some of the substances that were assessed are known to have endocrine disrupting properties, e.g., phthalates. 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.

Thirty-four "reprotoxic only" substances were found and assessed individually based on available data. It is to be noted that only four of these substances have actually been found in tattoo ink (JRC, 2015b). The dose-descriptors (i.e. NOAELs, LOAELs for sexual function and fertility, or development) for the "reprotoxic only" substances were in the range of 0.04-200 mg/kg/d. In addition, an exceptionally low dose-descriptor for tributyltin compounds of 0.00017 - 0.001 mg/kg/d was considered to be highly uncertain and not carried forward in the risk assessment of reprotoxic substances. Overall, for 27 of the 34 substances $DNEL_{\text{general population, reproductive}}$ effects could be derived. For 96% of the substances DNEL values between 0.001 and 1 mg/kg bw/d were obtained (for a detailed description of AFs, see section B.5.14 and appendix B.3).

Based on all the different individually derived DNELs, the "reprotoxic only"

substances were considered as a group, and the lowest DNEL for this group (not including the outlier) was carried forward to the risk characterisation, i.e. the most sensitive DNEL identified among the known 34 members of reprotoxic "only" compounds were considered to be representative for reprotoxic substances classified as Repr. 1 A/B. The overall **$DNEL_{general\ population,\ reproductive\ effects}$ of 0.001 mg/kg bw/d** is proposed as the most sensitive DNEL for risk assessment of reprotoxic substances in tattoo inks and PMU. The DNEL was derived from the substance (R)- and (S)-4-hydroxy-3-(3-oxo-1-phenylbutyl)-2-benzopyrone based on a LOAEL of 0.04 mg/kg bw/d and an overall AF of 30. (See Appendix B.3. for details).

The substances classified as category repro 2 in Annex VI of CLP have not been assessed individually due to the lack of available information and thus, the difficulty to estimate any dose descriptors. However, the Dossier Submitter proposes that as a starting point the resulting group DNEL for the repro 1A/B substances is also applied to Repro 2 substances.

Substances in Table 3 in the CoE ResAP(2008)1, impurities in tattoo inks and PMU

Table 3 in the CoE ResAP(2008)1 is a list of maximum allowed concentrations of impurities in products for tattoos and PMU. The majority of these substances are on Annex II of the CPR or have relevant harmonised classification (e.g., cobalt, S Sens 1). Some of the substances on this list were assessed in a (semi-)quantitative way, and DN(M)ELs were derived for these: arsenic, barium, copper, lead and zinc. These substances were selected for more detailed assessment to reflect conclusions of recent risk assessments and due to their presence in some tattoo inks colours. These substances were selected to reflect conclusions of recent risk assessments and due to their presence in some tattoo inks colours. For the remaining substances, except PAHs and nickel, the limits in Table 3 are proposed by the restriction as technically achievable limits, as they are already enforced in seven Member State's national restrictions based on ResAP. See the section on Risk Characterisation below for more explanation (1.2.6).

Table 8. Point of Departure (POD) and DN(M)ELs derived for selected substances on the CoE ResAP(2008)1, Table 3

Substance	Point of departure, POD	Information on key study	DMEL, general population, carcinogenic effects or DNEL STOT-RE
Arsenic	Excess lifetime risk of lung	Based on the WHO/FAO risk estimates from the Taiwanese	DMEL 0.0005882 µg

(As)	tumours = 1.7 x 10^{-3} per µg As/kg bw/day (as a systemic exposure)	drinking water cohort, using data from the most recent publications of Chen *et al* (2010a, 2010b), and 10^{-6} as an indicative tolerable risk level.	As/kg bw/d
Barium (Ba)*	NOAEL 60 mg/kg bw/d	Nephrotoxicity in male rats at 60 mg/kg bw/d in NTP 13-week study, also supported by findings in female rats and in male/female mice (NTP 13-week study), as well as interim findings in female rats in the NTP 2 year study	DNEL 0.60 mg/kg bw/d
Copper (Cu)*	2 mg/L drinking water, equalling 2.2 mg Cu/day	Two mg/l equals a mean total copper intake of 2.2 mg/day (95th percentile would be 5.6 mg), if assuming a bw of 60 kg and a water intake of 1.1 l/d (or with the 95th percentile 2.8 l/d) to avoid GI irritation (WHO guidelines for drinking-water quality, 2004)	DNEL 0.037 mg/kg bw/d
Lead (Pb)	$BMDL_{01}$ 0.50 ug Pb/kg day	Effects on the developing nervous system including in utero (EFSA 2010/2013), applied by RAC (ECHA 2011; 2013).	DMEL 0.05 µg
Zinc (Zn)*	NOAEL 0.83 mg/kg bw/d	An EFSA report from 2006 (EFSA 2006) and supported by the SCCS opinion from 2017 (SCCS/1586/17) adopted a NOAEL of 50 mg/day or 0.83 mg Zn^{2}+/kg bw/day which is based on the absence of any adverse effects on a wide range of relevant indicators of copper-status as critical endpoint.	DNEL 0.166 mg/kg bw/d

* Soluble

1.2.4.3 Substances included based on prohibition from use in the Cosmetic Products Regulation or subject to special conditions

The Dossier Submitter has determined that the following groups of substances can best be assessed in a qualitative manner in the context of this restriction as no further assessment is necessary because such was performed under the CPR and paragraph 0.5 of Annex I of REACH applies:

- substances on Annex II of the Cosmetics regulation (list of substances prohibited in cosmetic products*).*
- substances on Annex IV to the Cosmetics regulation that are not *allowed to be used in contact with mucous membranes, eyes or in prolonged contact with the skin (column "g") or subject to other conditions specified in columns "h" to "i" of the Annex (e.g., purity requirements).*

The Dossier Submitter assumes that the intrinsic properties will manifest themselves to a higher degree when injected into the dermis in a tattoo than if applied on the body via cosmetic products.

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1.2.5 Exposure assessment

The exposures covered by this restriction proposal are those to the consumer that result from tattooing and the application of permanent (and semi-permanent) make-up (PMU). This exposure is likely to be highly variable and will depend on the area of skin that is covered, the amount of ink that is injected during the procedure, the concentration of various substances in the ink, the length of time that each substance in the ink remains at the site of the tattoo or PMU, also the distribution within the body and rate of elimination for substances that migrate away from the site of the tattoo.

For the EU restriction, a single worst-case scenario was assessed consisting of isolated single tattoo sessions on 300 cm^2 skin, repeated until most of the body is covered. This approach was adopted to ensure that the exposure scenario included people getting full body tattoos as well as those getting single or a few tattoos or having PMU applied. This exposure estimate was used in (semi-)quantitative risk calculations to determine if there is a risk from substances present in tattoo inks and PMU and derive proposals for concentration limits to control those risks.

The following text reproduces the summary of the EU exposure assessment:

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1.2.5.1. Use 1: Intra-dermal injection of tattoo inks

Tattoo ink and PMU is injected into the dermis where capillary action acts to draw the ink further into the dermis. This exposure route is so far unique in the scope of REACH risk assessments. The exposure assessment has been performed to address hazardous constituents, as well as unavoidable hazardous impurities in tattoo ink and PMU. The aim of the exposure assessment is to determine if there is a risk from those constituents and impurities and to derive proposals for concentration limits of the hazardous constituents and impurities to control the risk.

Only one exposure scenario has been developed, consisting of isolated single tattoo sessions on 300 cm^2 skin repeated until most of the body is covered. The typical maximum area of a full colour tattoo that can be made in one session (in one day) is estimated to be 300 cm^2 (Appendix F.1). This exposure scenario will be protective for both people getting full body tattoos and for others getting single or several tattoos.

Amount of ink injected

Very limited data on the amount of tattoo ink deposited in the skin during the tattooing process is available. Still an estimate of 14.36 mg tattoo ink/cm^2 tattooed skin has been determined. Due to lack of information, no difference could be made concerning the amount of ink used by professional tattoo artists as opposed to amateurs, or between experienced and unexperienced tattoo artists. A tattoo ink containing 25% pigment was considered to be realistic based on market information (JRC, 2015b).

In a study by Engel *et al.* (Engel, *et al.,* 2008), the amount of a pigment (Pigment Red 22) injected in tattoos on excised pigskin and human skin by both professional tattoo artists and researchers was reported to be within the range of 0.60-9.42 mg/cm^2 for ink containing 25% Pigment Red 22. The mean value was 3.2 mg pigment/cm^2 and the median was 2.6 mg pigment/cm^2. The Dossier Submitter carried the 75^{th} percentile of 3.59 mg pigment/cm^2 forward in the risk assessment. The 75^{th} percentile was chosen since the data was limited and assumed to reflect a worst-case situation, in accordance with ECHA guidance on exposure assessment (R.14 and 15) (ECHA, 2016a) (ECHA, 2016b). Assuming 25% pigment in tattoo ink, this results in an injected amount of ink of 14.36 mg/cm^2.

A few other sources of information about the amount of ink injected in tattoos have been retrieved (Laux, *et al.*, 2016) (DEPA, 2012) (Prior, 2015). However, the Engel study gives the highest confidence as the value was experimentally derived and is likely a realistic worse case situation:

Table 9. Summary of studies on the amount of ink injected.

Source	Value
(Laux, *et al.*, 2016)	Ink: 1 mg/cm^2
(Prior, 2015)	Ink: 0.4 mg/cm^2
(Engel, *et al.,* 2008)	Pigment: range – 0.60-9.42 mg/cm^2
	Mean: 3.2 mg/cm^2
	75th percentile: **3.59 mg/cm^2**
	95th percentile: 7.73 mg/cm^2
This proposal, assuming 25% pigment in tattoo ink	Ink: **14.36 mg/cm^2**

Tattooed Skin Area

Former studies and reports (JRC, 2015b) (JRC, 2016b), and references within, have focused on the size of the final tattoo. However, the Dossier Submitter considers it more appropriate to base the exposure assessment on the total amount of tattoo ink injected during a single tattoo session.

To make the tattoo permanent the colourant needs to be injected into the dermis (1-2mm). During tattooing there may be loss of a minor part of the ink due to subsequent bleeding of the injured epidermis. However, since the tattooing is an injury to the skin barrier the ink should be considered as instantly absorbed by the human body. Soluble constituents of the ink are considered to be distributed within hours or days; thus being quickly systemically available. The insoluble pigments are considered to (mostly) remain in the skin so the tattoo will remain visible. Cui *et al.* (Cui, *et al*., 2005) suggests that the mechanism of fading of the pigments could include: 1) dispersion through the skin; 2) phagocytosis and removal; 3) metabolism of the pigments in the skin or 4) photochemical decomposition of the pigments.

According to a recent Danish survey (see Appendix F.1), repeated tattooing (i.e. repeated exposure) is quite common. For some persons repeated tattooing results in a full body part tattoo and for some even in a full body tattoo. With reference to both JRC (JRC, 2016b) and DEPA (Appendix F.1), it is assumed that 300 cm^2 skin is covered in a single tattoo session, and that this is repeated until the whole body, except for the face and hands, is covered. In the exposure scenario, it is assumed that the area of 300 cm^2 is completely covered with tattoo ink, although noticing that

in many cases tattoos have a much simpler design, e.g. in many cases consisting only of written words and not covered 100% with ink.

This approach assumes 100 % systemic bioavailability and excretion of the substances between tattoo sessions due to the lack of route-specific toxicokinetic information for the constituents in tattoo ink and PMU, even though some of the pigment obviously remains in the skin and makes the tattoo visible.

Conclusion - The Realistic Worst Case Exposure Scenario

The exposure is assessed as the exposure from a single tattoo session in this dossier. The Dossier Submitter assumes that the typical maximum area of a full colour covered tattoo made in one session is 300 cm^2. The corresponding amount of ink containing 25% pigment injected in a single session is estimated to be 14.36 mg ink/cm^2, corresponding to exposure to 4 308 mg ink when the tattoo size is 300 cm^2.

This scenario is based on a realistic worst-case situation where the exposed person repeatedly gets the maximum size tattoo that is possible in one session (300 cm^2), until the person has a full coloured full body tattoo.

It normally takes several tattoo sessions over a period of time to get a full colour, full body tattoo. Only a small part of the full body tattoo is normally completed in each session. In this scenario, the person will (on average) go to the tattoo artist once a month, which according to the survey (Appendix F.1) can be considered a typical behaviour in relation to having full body parts tattooed.

Comparison of the exposure with the long-term DNEL

The Dossier Submitter assumes that the exposed person receives a new tattoo of 300 cm^2 every month, until he/she has a full colour, full body tattoo. Taking into account the recommendations on body surface area (18 440 cm^2 [43]) from the US EPA Exposure factors handbook (US EPA, 2011), and the assumption of monthly tattoo sessions, it is assumed that it would take more than 5 years to complete a full body tattoo.

The repeated exposure over a period of more than 5 years supports that, in the risk characterisation, the exposure with 4 308 mg ink should be compared with a DN(M)EL related to lifetime exposure (ECHA, 2016).

Further, according to ECHA CSA Guidance R15 "as a conservative approach, the risk for a consumer exposure scenario can be characterised by comparing the event

[43] For a woman aged 50-60 years with a skin size equal to the 95 percentile, the tattooed body surface can be calculated to be 18 440 cm^2 (23,800 cm^2 – 1 140 cm^2 – (2 x 890 cm^2) – (2 x 1 220 cm^2) = 18,440 cm^2). Data for women is used because the largest skin area per kg body weight is found in women in the 95th percentile of the age interval 50 – 60 years.

exposure over a day to this DNEL" (ECHA, 2016). Accordingly, in the risk characterisation the DN(M)EL related to lifetime exposure is still relevant even if the exposure event results from an “only one use”-event for a person receiving a single tattoo.

Exposure Scenario – Summary

In the table below the data for the scenario has been summarised.

Table 10. Parameters to be applied in the exposure calculation for tattoo inks.

Parameter	**Value**
Size of tattoo per session (cm^2)	300
Pigmentation covering (%)	100
Weight of tattooed person (kg)	60
Amount of ink used per cm^2 (mg)	14.36
Amount of ink used per session (mg)	4 308
Bioavailability of pigments – Percentage of pigment removed from tattoo area by body fluids	100%
Bioavailability of impurities – Percentage of ink-fluids and soluble substances including impurities removed from the tattoo area	100%
Excretion of pigments	100%
Excretion for soluble substances including impurities	100%

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The literature search conducted by the Agency did not identify new information that contradicts any of the information used by the EU. In reviewing the EU exposure assessment, the Agency made the following observations:

- The use of a single worst-case scenario means that for many people getting a tattoo or PMU, their exposure to substances in the ink and the level of risk that this creates will be overestimated.
- The EU has based its calculations on the amount of ink that will be inserted into the skin (referred to as injected in the EU documents) on worst case estimates. This will add to the precaution in the (semi-)quantitative risk

assessments making it more likely that the risks from substances in tattoo inks have been overestimated.

- In relation to the bioavailability of substances in inks, although bleeding during the application of the tattoo or PMU may result in some loss of ink, assuming 100% uptake into the skin is a reasonable worst-case approach. It is also reasonable to assume that 100% of soluble substances may potentially distribute to other sites in the body.

- In the case of colourants, these need to remain at the site of the tattoo/PMU for the tattoo or PMU to remain visible. However, tattoos and PMU fade over time. According to Lehner *et al.* (2011), only a small portion of the originally injected colourant (1.0-13.0%) remains at the tattoo site permanently. This percentage range was derived by comparing the average concentration of red pigments including Pigment Red 22 (PR 22) found in 5 samples of tattooed skin taken from cadavers (0.077 mg/cm^2, range 0.002 – 0.110 mg/cm^2) with the range of concentrations measured by Engel *et al.,* (2008) in a study in which PR 22 was tattooed into *ex vivo* samples of pig or human skin (0.6 – 9.2 mg/cm^2). Lehner and Engel both consider that the estimates for the initial amount of colourant in the skin used to calculate the amount of colourant that remains at the site of the tattoo are likely to be high, meaning that the percentages suggested by Lehner may underestimate the amount of colourant that is retained at the site of the tattoo.

- A separate study by Engel *et al.,* (2010) in which mice were tattooed with an ink containing PR 22 found that the amount of pigment in the skin was reduced by 32% over 6 weeks and by 60% after exposure to a sunlight simulator. Taking these results into account, it seems likely that at least two thirds of the injected colourant will be removed from the site of a tattoo within a couple of months either by degradation at the site of the tattoo or because the pigment has migrated away from the initial site of contact. It is not known how much colourant will remain at the site of the tattoo in the long-term. Given this uncertainty, for the purposes of assessing the risks for adverse systemic effects, it seems reasonable to assume 100% distribution of colourants, and other insoluble impurities that may be present in tattoo inks and PMU away from the site of the tattoo/PMU to other sites in the body.

- The EU background document has assumed that impurities released from colourants are completely excreted before a new tattooing session, and that the sustained contribution from new release of impurities does not exceed the initial concentration of the impurities in the ink when injected into the body. This approach has the potential to overestimate exposure to chemicals that are excreted within days or a few weeks of the tattoo/PMU being applied.

However, in cases where large tattoos are obtained, it could potentially underestimate exposure to substances with long half-lives which might not be fully eliminated between repeated treatments.

1.2.6 Risk characterisation and derivation of concentration limits

1.2.6.1 Introduction

The Agency is proposing three restriction options. Since RO1 and RO2 propose the same concentration limits as RO1 and RO2 proposed by ECHA (ECHA, 2019a,c), the justification provided in ECHA (2019a) for those limits is reproduced below. Further details are provided in the ECHA document which is document 1 in the Annex to this dossier.

RO3 proposes the same concentration limits that were adopted in the EU restriction. These are the limits that were proposed by ECHA's Risk Assessment Committee (RAC) and SEAC (ECHA, 2019d). These limits were proposed to resolve concerns about the practicality of the 'shall not contain' approach proposed under RO1 and the level of protection afforded by several of the concentration limits proposed in RO2. Where these limits deviate from the limits proposed in ECHA (2019a), the Agency has included text to explain the rationale for these limits. Further details are provided in the RAC/SEAC opinion (ECHA, 2019d) which is attached as Document 2 in the Annex to this dossier.

Table 1.2.6. summarises the concentration limits that are being proposed for GB under RO1, RO2 and RO3. The subsequent text in this section provides a general explanation of the approach taken by ECHA to derive the concentration limits for this restriction. This is followed by justifications for the concentration limits proposed under each restriction option for specific substances and categories of substances. To help the reader understand the differences between RO1, RO2 and RO3, explanations for RO3 have been added at relevant points in the EU text for RO1 and RO2.

Table 1.2.6 Concentration limits proposed in RO1, RO2 and RO3

Substance group	**Concentration limit (% w/w)**		
	RO1	**RO2**	**RO3**
CPR Annex II	Shall not contain	0.1	0.00005

Substance group	Concentration limit (% w/w)		
	RO1	RO2	RO3
CLP Carcinogenic 1A/B	Shall not contain	0.1	0.00005
CLP Carcinogenic 2	Shall not contain	1	0.00005
CLP Mutagenic 1A/B	Shall not contain	0.1	0.00005
CLP Mutagenic 2	Shall not contain	1	0.00005
CLP Reprotoxic 1A/B	0.0014	0.3¤	0.001
CLP Reprotoxic 2	0.014	3	0.001
CPR Annex VI (column g)	Shall not contain	0.1	0.00005
CPR Annex VI (columns h and i)	See information about supplementary Table E in Appendix 1	See information about supplementary Table E in Appendix 1	in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV of the CPR, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column

Substance group	Concentration limit (% w/w)		
	RO1	**RO2**	**RO3**
Polycyclic aromatic hydrocarbons (PAH) with harmonised classifications as CM	0.00005	0.00005	0.00005 (individual concentrations)
Benzo[a]pyrene[44]	Included with other PAH	Included with other PAH	0.0000005
Primary aromatic amines (PAA) (dissolved fraction)	0.0005#	0.0005#	0.0005
Azo dyes	0.1	0.1	0.1
CLP skin sensitisers 1A	0.1	0.1	0.001
CLP skin sensitisers 1, 1B	0.1	1	0.001
CLP skin irritant and corrosive 1A/B/C, 2	0.1	1, 3, 5 or 10	0.1 (pH regulator), 0.01 in all other cases
CLP eye irritant and damaging 1, 2	0.1	1, 3, 5 or 10	0.1 (pH regulator), 0.01 in all other cases
Methanol	11	11	11
Impurities (ResAP(2008)1 Table 3) - Cadmium	0.00002	0.00002	0.00005
- Chromium**	0.00002	0.00002	0.00005
- Mercury	0.00002	0.00002	0.00005
- Copper*	0.05	0.05	0.025
- Zinc*	0.23	0.23	0.2

[44] Benzo[a]pyrene is a member of the polycyclic aromatic hydrocarbons group. A specific concentration limit for this substance is proposed under RO3 because this is the concentration limit that was recommended in CoE (2008).

Substance group	Concentration limit (% w/w)		
	RO1	RO2	RO3
- Barium*	0.84	0.84	0.05
- Nickel	0.001	0.001	0.0005
- Selenium	0.0002	0.0002	0.0002
- Antimony	0.0002	0.0002	0.00005
- Lead	0.00007	0.00007	0.00007
- Cobalt	0.0025	0.0025	0.00005
- Arsenic	0.00000082	0.00000082	0.00005
- Tin	0.005	0.005	0.00005

*Soluble, **Chromium VI compounds, #A CL of 0.0005% is proposed due to socio-economic reasons (see Annex D), ¤For certain Repr 1A/B specific CL are proposed, see Supplementary Table A in Appendix 1.

1.2.6.2 General approach

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Quantitative risk assessments and derivation of DNELs were made for a number of threshold substances, such as substances toxic to the reproduction and selected impurities with other threshold effects. Some impurities and non-threshold substances were risk assessed in a semi-quantitative way with derivation of DMELs, primarily for the derivation of concentration limits but also for risk characterisation.

The remaining substances in the scope were assessed by a **qualitative** approach and the exposure assessment described in 1.2.5 and Annex B.9 was not applied numerically in the risk assessment.

According to ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012), a qualitative approach has to be chosen when no reliable dose descriptor (without identified thresholds) can be set for a given endpoint. In this proposal this applies to the effects skin irritation/corrosion, eye damage/eye irritation, sensitisation, and mutagenicity/carcinogenicity, with a few exceptions for substances for which a (semi-) quantitative approach was applied. The purpose of the qualitative risk assessment is to assess 'the likelihood that effects are avoided when implementing the exposure

scenario…' as expressed in REACH Annex 1, Section 6.5.

> "6.5. For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out."

The exposure assessment indicates that significant exposure can occur and since these are non-threshold substances it cannot be excluded that risks to consumers can occur.

There is no single, standardised methodology for performing a qualitative assessment. The purpose of this qualitative risk characterisation is to assess the likelihood that these effects are avoided when receiving a tattoo. However, traditional operational conditions (OC) and risk managements measures (RMM), such as a level of containment and use of personal protective equipment, do not have relevance to the intradermal injection of tattoo inks and PMU. This makes the hazard bands presented in ECHA Practical Guide 15 (ECHA, 2016b) and ECHA guidance Part E (ECHA, 2016) depending on the EU hazard classification unsuitable to apply as such. The only way to manage the risk in the case of receiving tattoos is to limit the presence of unwanted substances in tattoo inks.

This use of a qualitative approach is consistent with the approach taken in REACH Annex XVII entries 28, 29 and 30 (restriction of substances classified as CMRs category 1A and 1B to the general public, CL/SCL apply).

The Dossier Submitter therefore proposes that the substances should be restricted in tattoo inks based on the risk from exposure to substances classified with regard to skin irritation/corrosion, eye damage/ irritation, sensitisation, mutagenicity and carcinogenicity and with consideration to the exposure as described in 1.2.5 and Annex B.9, even if a quantitative risk assessment could not be performed. A total ban is not realistic, as this would ban tattooing as such, so the risk should be managed by setting concentration limits for the chemical substances in tattoo ink, as proposed in the chapter on risk management options (see 2.2).

The output of the quantitative assessment is a proposal for setting concentration limits for hazardous substances detected in tattoo ink.

The use of the approach in this dossier to base the restriction on classifications will ensure that substances classified in the future also will be restricted in tattoo inks and PMU.

For the substances assessed in a (semi-)quantitative manner, DN(M)ELs were derived and compared to the exposure assessment in the exposure scenario (see B.9) to identify a concentration limit where exposure would be controlled to a risk

level of low concern.

When the content of the substances in tattoo and PMU ink is limited to the proposed concentration limits described below, the risk from exposure described in the exposure scenario for tattoos is considered to be adequately controlled for threshold substances with a quantitative approach. For non-threshold substances, such as carcinogens, a cancer risk level of 10^{-6} could be seen as indicative tolerable risk level when setting DMELs for the general population and has been used by the Dossier Submitter to derive concentration limits ((ECHA, 2012) R. 8-14 Evaluating carcinogenicity risk levels).

The non-threshold critical effect of developmental neurotoxicity for lead is described in an opinion adopted by the ECHA Committee for Risk Assessment (RAC), as 0.05 µg Pb/kg bw per day as a maximum exposure value based on benchmark dose (BMD) approach (ECHA, 2011b). This value was used by the Dossier Submitter in the risk characterisation.

In the risk characterisation, the risk arising from current content in tattoo inks when applying the exposure scenario described in section 1.2.5 has been compared with the derived DNELs described in section 1.2.4 for selected substances. For non-threshold carcinogens, the risk arising from current content in tattoo inks when applying the exposure scenario has been compared with the cancer risk level of 10^{-6} (Table 13 and Table 14).

Related to the discussion on concentration limits, two different restriction options (RO1 and RO2) are included in this restriction proposal. The two options differ mainly in terms of the concentration limits proposed, with RO1 having stricter limits for some substances that RO2 (for more detailed information see 2.2 and Annex D). The restriction options and concentration limits are presented in Table 11).

It should be noted that the concentration limit values arise from various sources, such as limits in CPR, CLP, CoE ResAP and concentration limits derived specifically for this restriction proposal. For substances covered by more than one concentration limit, the lower limit applies.

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1.2.6.3 Derivation of concentration limits for substances assessed in a qualitative manner

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Based on the harmonised classification and the conclusion that intradermal exposure poses at least the same or higher risk as dermal exposure, following concentration limits are proposed.

Substances with harmonised classifications as eye irritant/damaging, skin irritant/corrosive, skin sensitisers, carcinogenic and mutagenic substances

For substances with harmonised classification as eye irritant/damaging, skin irritant/corrosive substances, skin sensitisers the Dossier Submitter proposes under RO1 a practical concentration limit of 0.1% w/w to discourage intentional use, and under RO2 the concentration limit for classification in a mixture as specified under CLP Regulation.[45]

Since carcinogenic and mutagenic substances eventually will be added to CPR Annex II, similar concentration limits (depending on the RO taken) should apply. Therefore, under RO1, the Dossier Submitter proposes that tattoo inks and PMU shall not contain these substances.

For RO2, the Dossier Submitter proposes that the generic concentration limits (GCL) as well as the specific concentration limits (SCL) under CLP will be followed for the carcinogenic and mutagenic substances. The CLP GCLs are: 0.1% w/w for category 1A/B and 1% w/w for category 2.

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.

[45] 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.

This approach is taken to be consistent with previous regulatory decisions. It should be noted that entry 50 is currently being reviewed and any changes to this limit should be reflected in this restriction.

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RO3 proposes different concentration limits according to the hazard class.

Substances classified as eye irritant/damaging and/or skin irritant/corrosive.

Under RO3 a concentration limit of 0.1% w/w is proposed where substances are used solely as a pH regulator. A concentration limit of 0.01% is proposed for all other cases. For the reasons outlined in Appendix 3 of ECHA (2019d), a concentration limit of 0.1% was not thought to be sufficiently protective. A concentration limit of 0.01% was therefore proposed for all eye irritant/damaging and skin irritant/corrosive substances.

Information received during the second public consultation (ECHA (2019e), highlighted that, for some acids and bases which are used as pH regulators in tattoo inks and PMU, a concentration of 0.01% or lower may not be sufficient to achieve their function of adjusting the pH of the mixture. Acids and bases exhibit their irritant or corrosive properties because of their extreme pH values. However, the irritancy or corrosivity of a mixture containing such acids and bases will depend mostly on the overall pH of the mixture itself, rather than on the pH and concentration level of individual substances within it. In the light of these factors, the implemented EU restriction specifies a concentration limit of 0.1% for irritant or corrosive substances when they are used as pH regulators. Under RO3 therefore, a concentration limit of 0.1% w/w is proposed where substances are used solely as a pH regulator and a concentration limit of 0.01% is proposed for all other cases.

Usually when classifying mixtures containing eye irritant/damaging and skin irritant/corrosive substances, rules of addition are applied to determine whether the mixture should be classified based on the total concentration of all substances with the relevant classification (see pages 290 and 316 of ECHA's Guidance on the Application of the CLP criteria). In the case of substances in tattoo inks and PMU, to simplify the restriction requirements for stakeholders it is proposed that these rules should not be applied. Therefore, the concentration limits proposed for eye irritant/damaging and skin irritant/corrosive substances apply to each individual substance. This is the case for RO1, RO2 and RO3.

Skin sensitisers

For skin sensitisers a concentration limit of 0.001% w/w is proposed to provide protection for people who may already be sensitised to specific substances. This concentration limit was proposed based on studies that attempted to define

elicitation doses[46] for certain skin sensitising substances including those such as isoeugenol that are considered to be strong skin sensitisers in humans (ECHA, 2019d). The concentration limit of 0.001% represents the lower 95th percentile of the elicitation doses reported in the literature reviewed in this ECHA document.

Under RO1, RO2 and RO3, the concentration limits for skin sensitisers apply individually to each substance.

Carcinogens and mutagens

Under RO3 a concentration limit of 0.00005% by weight (0.5 ppm) is proposed for all substances classified in the GB MCL list as a carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, including PAHs. This concentration limit is proposed to avoid the situation where the concentration of carcinogens and mutagens in tattoo ink and PMU is determined by the sensitivity of the analytical method that is used to confirm compliance. This limit should apply individually to each carcinogen or mutagen. As an exception, under RO3 it is proposed that a lower limit of 0.0000005% by weight (5 ppb) should apply to benzo[a]pyrene (BaP). This is the limit that was adopted for BaP in CoE (2008).

Under RO1, RO2 and RO3, the concentration limits for carcinogens and mutagens apply individually to each substance.

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Substances included based on prohibition from use in the Cosmetics Products Regulation or subject to special conditions

Substances on Annex II to the CPR are prohibited in cosmetic products; therefore, their intentional use is currently enforced at a limit of detection (LoD) by Member States with national legislation. As the justification for risk is based on conclusions that intradermal exposure is at least as risky as dermal exposure, the appropriate measure would be to restrict these substances in the same way as under the CPR, i.e. tattoo inks shall not contain substances on annex II to the CPR (RO1).

The Dossier Submitter has also proposed a second restriction option (RO2), which allows small amounts of impurities, i.e., less than 0.1% w/w, in tattoo inks and PMU. The 0.1% w/w concentration limit is proposed as a practical limit aiming to discourage intentional use.

Following the same rationale for substances on Annex II, under RO1 it is proposed

[46] The elicitation dose is the minimum concentration that is required to elicit a positive patch test reaction in an individual that is known to experience allergic skin reactions when exposed to that substance.

that those substances on Annex IV with specific use restriction (i.e., allowed in cosmetic products with restrictions on their use on mucous membranes or eye products, and allowed in rinse-off products only) are not allowed in tattoo inks and PMU.

Again, to give more flexibility regarding the enforcement of the unintentional presence of small traces of these substances, a second restriction option is proposed – RO2 – with a practical limit of 0.1% w/w. It is worth noting that Annex IV substances are colourants and therefore, more likely to be found in tattoo inks and PMU only if intentionally added, although some exceptions are possible.

For the remaining 119 substances with conditions on their use in columns h and i of annex IV, it is proposed, under both RO1 and RO2, that those substances are also allowed in tattoo inks and PMU if the specified requirements for their use in columns h to i are met (e.g., for purity, constituents, concentration limits, particle size, etc.) (see also B.10.2.1).

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RO3 represents the EU restriction.

Here a concentration limit of 0.00005% by weight (0.5 ppm) is proposed for each individual substance that is listed on Annex II of the CPR.

Although the CPR requires that cosmetics shall not contain substances listed in Annex II, Article 17 of the CPR[47] also permits traces of prohibited substances to be present providing they were not intentionally added. This provision was introduced in the CPR in recognition of the fact that it may not be technically possible to remove all traces of every prohibited substance. For this reason, rather than apply the “shall not contain” approach, a low concentration limit of 0.00005% by weight (0.5 ppm) was adopted in the EU restriction to limit the levels of substances listed on Annex II of the CPR to levels which are technically achievable.

For the same reason, a concentration limit of 0.00005% by weight (0.5 ppm) was adopted for all substances that are listed on Annex IV of the CPR with specific use restrictions in column “g”. For the remaining substances with conditions on their use in columns “h” and “i”, these substances are allowed in tattoo inks and PMU if the requirements for their use are met.

[47] Article 17 of the CPR states that: The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.

1.2.6.4 Derivation of concentration limits for substances assessed in a (semi-) quantitative manner

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General approach for derivation of risk-based concentration limits:

DN(M)ELs for the general population expressed as daily dose of the substance per kg bw were derived based on available information. The DN(M)ELs were compared to the exposure from receiving a tattoo and the maximum content of each substance corresponding to where exposure is controlled to a risk level of low concern:

The DN(M)EL expressed as mg/kg/d

Bodyweight 60 kg

Maximum Dose received in a tattoo session = DN(M)EL x 60 kg

For a single 300 cm^2 tattoo, 4 308 mg (14.36 mg ink/cm^2 x 300 cm^2) ink is injected.

The concentration limit (CL) becomes (maximum dose mg /4 308 mg) = X

X multiplied by 100% w/w = concentration limit in % w/w or by 10 000 ppm w/w = concentration limit in ppm w/w.

For a more detailed explanation of the general approach, see B.9 and B.10.2.1.

Methanol

The DNEL for the general population of 8 mg/kg bw/day was derived from the OEL for workers based on exposure of 40 mg/kg bw/day and an assessment factor of 5, as explained in 1.2.4.2.

The general approach for derivation of risk-based concentration limits described above was then used to derive a concentration limit of 10.9% w/w. This figure has been applied for both RO1 and RO2.

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For the EU restriction (RO3) this limit has been rounded up to 11%. For practical purposes the Agency proposes this concentration limit for all three options.

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Primary aromatic amines (PAAs) and azo colourants

For primary aromatic amines (PAAs), the $DMEL_{general\ population,\ carcinogenic\ effects}$ of 2×10^{-5} mg/kg bw/day for aniline (see Table 7 in 1.2.4.2) was the lowest of the

derived DMELs. This DMEL was carried forward to the risk characterisation as the most sensitive DMEL and used to establish a general concentration limit for all PAAs. This results in a risk-based concentration limit for PAAs in the ink of 0.00003% w/w (dissolved fraction) for each individual PAA. However, due to practicality and socio-economic reasons another concentration limit (5 ppm) is proposed in RO1 and RO2, see Annex D.

For the azo colourants a practical approach is chosen. A minimum concentration of azo colourants of 5-10 percent in the tattoo ink is normally required in order to be able to colour the skin. Thus, a practical limit of 0.1% will prevent the use of the azo colourants that are in the scope of the restriction, see B.5.7/8. This limit is proposed for both RO1 and RO2.

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The concentration limits for PAAs and azo dyes proposed by ECHA for RO1 and RO2 were adopted in the EU restriction. Hence there is no change for RO3.

In addition to the PAAs and azo colourants that are listed under RO1 and RO2 (see table A in Appendix 1), two further PAAs were added to the EU restriction (RO3). These are (6-amino-2-ethoxynaphthaline (CAS 293733-21-8) and 2,4-xylidine (CAS 95-68-1)). These substances were included in table 1 of CoE (2008). This table lists aromatic amines that should not be present in tattoo ink or PMU or released from azo colourants that are used in such ink. They were excluded from the scope of RO1 and RO2 by ECHA because they do not have relevant harmonised classifications, they lack sufficient data to allow a robust risk assessment to be performed, and it is not known why they were included in table 1 of CoE (2008) (ECHA 2019c). By March 2022, neither of these substances had been included in the GB MCL list.

In reviewing the restriction proposal, ECHA's committees preferred to take a more precautionary approach. In line with the general approach to include substances in this restriction that were listed in CoE (2008), these were brought into scope of the EU restriction and are in the list of substances for which specific concentration limits are proposed under RO3 (see table F in Appendix 1).

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Substances classified for reproductive toxicity

Reprotoxic substances classified as "reprotoxic only" (classified as Repr. 1 A/B without being simultaneously classified as carcinogen, mutagen or sensitiser), were considered as a group and the lowest DNEL for this group (0.001 mg/kg bw/d) was carried forward to the risk characterisation as being protective for all reprotoxic substances classified as repro 1 A/B. This DNEL is also assumed sufficiently conservative to protect against potential risks from all substances which will be

classified as repro 1 A/B in the future. The general approach for derivation of risk-based concentration limits described above was then used to derive a concentration limit. The proposed concentration limit for reprotoxic “only” substances under RO1 is 0.0014% w/w.

Under RO1 it is further proposed to extend the concept of ‘one concentration for all reprotoxic substances classified as category 1A/B to include also reprotoxic substances of category 2 assuming that the most sensitive DNEL of 0.001 mg/kg and the concentration limit of 13.9 ppm will be conservative enough to cover also the risks from category 2 reprotoxins. Based on the fact that the generic concentration limit for category 2 reprotoxic substances in mixtures is tenfold higher than for category 1A/B reprotoxic substances, a pragmatic approach to include category 2 substances and to consider the potentially lower/uncertain potency has been implemented by applying a factor of 10 to the concentration limit for category 1A/B. The proposed concentration limit for category 2 reprotoxicants under RO1 is therefore 0.014% w/w.

For RO2, the generic concentration limits (GCL) for the reprotoxic substances, unless a SCL is given under the CLP Regulation is proposed: i.e. 0.3% w/w for category 1A/B and 3% w/w for category 2. For the two reprotoxic substances Bis(2-ethylhexyl) phthalate and Dibutyl phthalate which have been found in tattoo inks an individual concentration limit (0.07% and 0.009%) has been proposed, as the risk was not adequately controlled for those substances using the generic concentration limit.

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RO3 proposes a concentration limit of 0.001% by weight (10 ppm) for all substances classified as a reproductive toxicant category 1A/B and 2. This concentration limit was proposed by RAC (ECHA 2019d) and was adopted into the EU restriction.

RAC preferred to use the $DNEL_{\text{general population, reproductive effects}}$ of 0.007 mg/kg bw/day calculated for DBP as its starting point because this substance is known to be present in tattoo inks. RAC noted work by Muller *et al.,* (2012) which demonstrated that the potency of developmental toxicants as expressed by their lowest observed adverse effect level (LOAEL) varies between 0.002 and 2,281 mg/kg bw/day indicating a potency range of up to 1,000,000. The potency of substances affecting fertility as expressed by their LOAEL differs by a factor of over 8,000. RAC therefore considered that an additional uncertainty factor of 10 should be applied to the DNEL for DBP to identify a surrogate DNEL which could be applied to all reproductive substances in tattoo inks. RAC therefore established a $DNEL_{repr}$ of 0.0007 mg/kg bw/day.

Using this DNEL, RAC calculated that the maximal dose of “reprotoxic only”

substances injected during one tattoo session to a 60 kg person should not be higher than (60 kg x 0.0007 mg/kg bw/d) = 0.042 mg/day.

For a single session of tattooing in which 4,308 mg of tattoo ink is inserted into the skin the maximum concentration of “reprotoxic only” substances should not exceed a value calculated with this formula:

0.042 mg_{subst}/4,308 mg_{ink} = 0.00000975 mg_{subst}/mg_{ink} = 9.75 mg_{subst}/kg_{ink} ≈ 10 mg_{subst}/kg_{ink} = 10 ppm

RAC considered that the major difference between substances classified as category 1 and category 2 reproductive toxicants is in the quality and weight of evidence indicating hazard. Potency is not taken into account. For this reason, RAC saw no scientific justification to apply a higher concentration limit to substances classified as Repr. Cat. 2**.**

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Substances on Table 3 in the CoE ResAP(2008)1, impurities in tattoo inks and PMU

The impurities on Table 3 in the CoE resolution (ResAP(2008)1) have recommended limits for maximum concentration in products for tattoo and PMU. In the absence of these limits, many of the substances (i.e., arsenic, cadmium, chromium, mercury, nickel, lead, selenium, antimony) would have technically unachievable limits due to their presence on Annex II of the CPR (i.e., “shall not contain” in RO1) or limits that would not address the risk (i.e., 0.1% w/w in RO2) – the latter also applies to cobalt (Skin Sens 1). The limits on Table 3 of ResAP are demonstrated to be technically achievable as a large share of tattoo inks and PMU currently on the market in Member States with national legislation are compliant with them. Therefore, in line with national legislation, the limits on Table 3 of ResAP are proposed in for RO1 and RO2 with small deviations:

- For barium, copper, and zinc, a more in-depth assessment was deemed necessary and the Dossier Submitter has performed a risk assessment and has derived DNELs that conclude the need for different concentration limits than those recommended by ResAP(2008)1 (see Annex B.5.13 and corresponding appendices B.7-11). These three substances were selected for a more in-depth assessment as they can be found in a large number of tattoo inks, i.e., copper in blue and green inks, zinc and barium in white inks which are also often blended with other tattoo colours to create various colour shades. The general approach for derivation of risk-based concentration limits described above was used to derive concentration limits for these substances.
- For lead, arsenic and PAHs, recent risk assessments needed to be incorporated: recent opinions on restrictions (lead and PAHs) and for

derivation of OEL for arsenic. Therefore, for lead and arsenic, the Dossier Submitter has performed a risk assessment and has derived DMELs that conclude the need for different concentration limits than those recommended by ResAP(2008)1 (see Annex B.5.13 and corresponding appendices B.6 and B.10). For PAHs and BaP the CL in Annex XVII entry 50(6) are used (see 1.2.6.3).

- For the remaining substances on Table 3, the Dossier Submitter proposes to carry forward the limits in the CoE, as there are no more recent assessments that suggest the need for deviation from ResAP limits. An exception is nickel (Ni), where a practical concentration limit of 0.001% w/w is proposed, based on surveillance/monitoring data, as the limit in ResAP is "as low as technically achievable". The establishment of harmonised analytical methods is particularly important for this group of substances as the public consultation revealed that some labs do not have the capabilities to detect the low limits for some substances, e.g., chromium VI of 0.2 ppm.

The concentration limits for substances on CoE Table 3 are the same for both RO1 and RO2.

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With the exception of the substances listed below, the concentration limits adopted in the EU restriction (RO3) for this group of substances are the same as those proposed in ECHA options RO1 and RO2.

Arsenic

During the EU public consultation, a comment was submitted stating that a concentration limit of 0.0000008% may not be technically achievable for some colourants (ECHA, 2019f). For a titanium dioxide pigment with low impurity profile (high purity rutile pigment for cosmetics) the lowest concentration of arsenic measured was 0.000013% (comment #1905).

For this reason, a higher practical concentration limit of 0.00005% was adopted for the EU restriction (RO3) which is consistent with the concentration limit proposed for substances classified as carcinogens.

Barium

During the opinion forming stage, RAC considered that a lower DNEL was more appropriate. Since tattoo inks are inserted into the skin, a route for which 100% absorption is proposed, RAC considered that the point of departure (PoD) of 60 mg Ba/kg bw/day for renal effects of barium in rats should be corrected for the percentage of oral uptake of barium chloride in rats (ECHA, 2019d). According to

ATSDR (ATSDR, 2007b; Taylor *et al.*, 1962), 7% of barium chloride was absorbed in adult, fed rats, after a single oral dose (by gavage). The corrected PoD value according to RAC is, therefore, approximately 4 mg Ba/kg bw/day, which leads to a DNEL of 0.04 mg Ba/kg bw/day.

This gives a concentration limit of:

2.4 mg Ba/day / 4,308 mg ink = 0.00056 ≈ 0.05% w/w soluble/dissolved Ba

The concentration limit for soluble barium in RO3 is therefore 0.05%.

RAC noted that this calculation is subject to uncertainty in relation to the rate of elimination of barium. In the exposure scenario, it is assumed that all the barium received from a tattoo or PMU will be eliminated before the next procedure. If this is not the case, the risks from soluble barium could be underestimated (ECHA, 2019d).

The concentration limit for barium in the EU restriction only applies to soluble barium.

Copper

The concentration limit for copper in the EU restriction (RO3) is 0.025%. This concentration limit applies to soluble copper only.

In its opinion, RAC noted that copper absorption in human subjects from diets containing adequate levels of copper (1-10 mg/day) ranges from 30-60% (EU RAR 2007). To take account of this, RAC divided ECHA's DNEL of 2.2 mg Cu/day by half, obtaining a DNEL value for copper where it is inserted into the skin of 1.1 mg Cu/day, or 0.019 mg Cu/kg bw/day.

Based on the derived DNEL of 1.1 mg Cu/day (or 0.019 mg Cu/kg bw/day for a 60 kg person), 100% uptake for the exposure via insertion into the skin, and proposed exposure scenario (in which an amount of 4,308 mg ink is inserted in a single tattooing session), RAC calculated the safe concentration level for copper in the ink to be:

1.1 mg Cu/day / 4,308 mg ink/day x 100% = 0.025% of soluble Cu in the ink (250 ppm)

The proposed concentration limit does not apply to insoluble copper compounds.

Zinc

The concentration limit of 0.23% is rounded down to 0.2% under RO3.

Cadmium, cobalt, chromium VI, mercury, antimony, and organotin compounds

For the EU restriction (RO3), a concentration limit of 0.00005% (0.5 ppm) was

adopted for these impurities because this is consistent with the concentration limits applied to substances classified as carcinogenic or mutagenic and also substances that are listed on Annex II of the CPR.

Nickel

A lower concentration limit of 0.0005% (5ppm) was adopted in the EU restriction (RO3) to better take account of the sensitising properties of nickel.

2 Justification for action

Tattoos and permanent make-up (PMU) have increasing popularity. It has been estimated that around 12% of the UK population has received at least 1 tattoo (numbers receiving PMU treatments are not available but based on EU data this may comprise of up to 20% of the population). This data is several years old so the proportion of the population of the UK (and by analogy GB) with tattoos or PMU may now be different.

The need for tattoo inks and PMU, and the equipment used to apply these products, to be sterile is widely recognised. However, less attention has been paid to risks that could arise from the chemical ingredients used to make these inks and PMU. The colourants used in tattoo inks are not necessarily specifically produced for tattooing, i.e., insertion into the skin. These colourants may be of low purity and can contain, intentionally or as an impurity, hazardous substances. Exposure to these hazardous substances could lead to adverse health effects.

There is evidence in the literature linking tattoos and PMU and the substances used to produce tattoo ink and PMU with allergic and other skin reactions at the site of the tattoo or PMU. These complications can appear shortly after receiving the tattoo or PMU or can take months or years to develop or may appear intermittently. In many cases, complications are mild but sometimes it is necessary for those affected to seek medical assistance and even have their tattoo removed due to the severity of the adverse effect. Where it is necessary to have tattoos and PMU removed, this procedure comes with its own risks. If laser removal techniques are used, this includes risks due to degradation products of substances in the ink that are generated and released during the treatment. It may also be useful to consider the risks to health from the removal process itself in cases where the only reason the tattoo is being removed is because of the severity of complications. Further information is available in section 3.5.3.

It is less clear whether substances in tattoo ink or PMU can cause systemic reactions. Although the hazard profiles of some substances that have been found in tattoo ink and PMU raise concerns for possible carcinogenicity or reproductive toxicity, links between tattoos and PMU and cancer or adverse reproductive effects have not been studied to any great extent. Links between cancer and adverse reproductive effects remain unproven.

Other systemic reactions that have been discussed in the literature include sarcoidosis and generalised urticarial or eczematous reactions. Sarcoidosis is an exaggerated immune response to an external stimulus. Although sarcoid reactions have been reported at the site of tattoos, it is not clear if substances in tattoo inks can trigger systemic sarcoidosis. Similarly, when someone with a tattoo or PMU develops a skin rash that spreads to body sites that have not been treated, it is not

clear what role has been played by the substances that are present in the inks.

The underlying socioeconomic rationale for risk management action is that a burden to society from the use of hazardous substances in tattoo inks and PMU exists, as the private (industry) costs of using these hazardous substances in tattoo inks and PMU do not fully reflect the cost to society (through damage [external costs] to human health – see Section 3.5.1.4. on non-monetised costs). Customers of tattoos and PMU are not well informed about the health impacts they may experience/that may arise from the insertion of hazardous substances that are contained in tattoo inks and PMU into the skin. Given the proportion of the GB population that is estimated to have tattoos and PMU, these adverse reactions represent both a risk to human health and an associated economic burden to society. In the face of such market failure, government action to reduce this risk and burden is thus justified.

Currently in GB, unlike cosmetics, tattoo inks and PMU are not subject to any specific regulations that control their composition. The two Council of Europe resolutions, CoE (2008) and CoE (2003), making recommendations about substances and substance categories that should not be present in tattoo inks were not implemented into national legislation in the UK (or GB).

As of 4 January 2022, the EU has implemented a restriction that limits the presence of certain harmful chemicals in tattoo inks and PMU [48]. The EU restriction aims to prevent the use of chemicals in tattoo inks and PMU that we know have specific hazardous properties which make it more likely that someone might experience harmful effects. This Agency proposal aims to minimise adverse reactions in GB citizens that may arise from exposure to substances in tattoo inks and PMU.

Since the Agency is proposing restriction options that are very similar to the options which were discussed during the development of the EU restriction, the Agency has relied on the hazard, exposure and risk assessments carried out by ECHA (ECHA, 2019a,c) and developed by RAC (ECHA, 2019d). Literature searches carried out by the Agency did not identify new information that challenged ECHA's statements on the hazards of and risks from exposure to substances in tattoo inks and PMU.

[48] Further information on EU action is available on the website of the European Chemical Agency (ECHA).

3. Impact Assessment

3.1 Introduction

To address the risks created by the use of certain hazardous substances in tattoo inks and PMU, the EU implemented a restriction under REACH. ECHA initially proposed two options for the scope of the restriction (ECHA, 2019a,c). During the opinion forming process, RAC and SEAC proposed modifications to ECHA's options to resolve concerns about the practicality of the shall not contain approach proposed under RO1 and the level of protection afforded by several of the concentration limits proposed in RO2. The EU restriction largely implements the modifications proposed by RAC and SEAC. Currently, unlike cosmetics, there is no legislation in GB that regulates which substances can and cannot be used in tattoo ink and PMU.

In deciding how to tackle this concern for GB, DEFRA and the Welsh and Scottish Governments asked the Agency to consider options to manage risks via a restriction under UK REACH. The Agency examined the two restriction options proposed by ECHA and the implemented EU restriction. These three options differ primarily in the concentration limits proposed for selected substance groups and how links with the CPR are managed, the scope and other conditions of the options are identical. These options are presented in tables 2, 3 and 4. Supplementary information for these restriction options is presented in Appendix 1.

To assess the impacts of the restriction options that the Agency is proposing for GB, the Agency has used the same methodology that was used by ECHA where this is applicable and appropriate. Where the Agency is using the same methodology as ECHA, we have taken ECHA's text as our starting point and updated this with GB data where necessary to ensure that this impact assessment is specific for GB. All text that is unchanged from ECHA's work is shaded. Any changes that have been made to update this text with GB specific information appear as unshaded text.

The three options proposed by the Agency are not identical to the options proposed by the EU. Restriction option 1 (RO1) and restriction option 2 (RO2) largely replicate the options that ECHA proposed for the EU restriction but also take account of the revisions described in section D1.1h of the EU background document that were introduced during the EU opinion forming process (ECHA, 2019a). These options retain ECHA's proposal to derogate 21 colourants that are prohibited for use in hair dyes in Annex II of the CPR but are permitted for use as colourants in cosmetics in Annex IV of the CPR. The rationale for linking the use of substances in tattoo inks to provisions in the CPR is that if a substance is restricted for use in cosmetics that are applied onto the skin, that substance should also be restricted for use in products that are inserted into the skin. RO1 and RO2 also include a clarification to indicate that inks that are placed on the market for use exclusively as a medical device or an accessory to a medical device are exempted from the scope of the restriction.

Restriction option (RO3) reflects the implemented EU restriction with one key difference. Whereas the EU granted a time limited derogation for Pigment Blue 15:3 and Pigment Green 7 until 4 January 2023, given the continuing concerns from the tattoo industry about the consequences if they lose Pigment Blue 15:3 and Pigment Green 7, the Agency is proposing to retain the derogation proposed by ECHA for these and 19 other pigments which are prohibited for use in hair dyes in Annex II of the Cosmetic Products Regulation (CPR) but are permitted for use as colourants in cosmetics in Annex IV of the CPR.

For all three restriction options, if the proposed derogation is accepted, it is proposed that the derogation should remain in place until such a time that changes would be introduced within the Annexes of the CPR that would bring the colourant into scope of the general provisions of this restriction (further information about this proposed derogation is available in section 3.3.1c).

The scope of this derogation can be reviewed in the light of information obtained during the public consultation about the use of these 21 pigments in tattoo inks and PMU supplied to the GB market.

3.2 Baseline

The “business as usual” scenario is defined as the current and predicted future use of the substances in scope in tattoo inks without the proposed restriction.

The geographical boundaries for ECHA’s (2019a,c) restriction dossier are the territories of Member States of the European Union (EU) and the European Economic Area (EEA).

The study period – entry into effect (assumed for analytical purposes to be 2021/22 - 2040/41) plus 20 years – is selected on the basis of the time anticipated for the costs and benefits of the proposed restriction options to fully develop, in particular those quantified and monetised.

The most critical aspects of the baseline are discussed below, i.e., the number of people exposed to tattoo inks and PMU as well as volume of tattoo and PMU ink on the market.

The geographical boundary for this restriction is GB and a 20-year appraisal period (2021/22 - 2040/41) is used throughout the socioeconomic analysis unless stated otherwise. ECHA’s restriction dossier was prepared in 2016/17 when the UK was part of the EU therefore, all impacts described by ECHA will cover EU member countries, including the UK.

It is important to note that under the baseline scenario, despite there being no GB restriction in place the EU restriction still exists, therefore compliance with the EU restriction will have impacts for GB (through EU-GB trade.)[49] There is uncertainty around the data, particularly in relation to the number of people with tattoos and PMU and the volume of ink on the GB market. Data specifically for GB is difficult to obtain so throughout this analysis, data for the EU and EEA[50] presented in ECHA (2019a,c,d) is adjusted appropriately to reflect the GB situation. For this reason, all estimates carry some degree of uncertainty and should be understood to be interim figures. This will be explored further at the public consultation stage to understand whether better data exists.

Number of people with tattoos and PMU

a. Tattoos

For the purpose of assessing the impacts of the proposed restriction options, an important component of the baseline is the number of people exposed to tattoo inks and PMU or the total number of people who are estimated to have a tattoo (excluding removals) over the study period. The future population with at least one tattoo is estimated based on the basis of incidence and current and anticipated trends of getting a tattoo.

Table 3.2.1 provides estimates for the total number of people in the UK and GB who have a tattoo (excluding removals) over the 20-year appraisal period.

The following estimates have been produced by adapting ECHA's (2019c) approach to fit the UK and GB. The estimates have been derived using total population data for the UK and GB from the ONS[51] and application of ECHA's incidence rate[52] to understand the prevalence[53] over the appraisal period. In the absence of better information, ECHA's incidence rate has been applied to population data for the UK

[49] Appendix 6.6. assesses alternative baseline scenarios as there is uncertainty around the proportion of GB industry that are currently compliant with the EU restriction.
[50] The EEA refers to the EU member states and three EFTA member states (Iceland, Liechtenstein and Norway)
[51] UK population data available at https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/overviewoftheukpopulation/january2021 and GB population data was provided separately by ONS from Nomis.
[52] ECHA's prevalence rate for 2014 has been taken from a JRC report which adapted existing information reported in a DG SANCO 2003 document.
[53] The prevalence rate for GB has been calculated based off the incidence and further detail is provided in appendix 6.1 on prevalence rate scenarios, assumptions, and calculations.

and GB and is assumed to be representative of GB. The average incidence from 2021-2040 has been calculated by taking data for the total GB population in 2021 and 2040, applying ECHA's incidence rate[54] for both years (under the central scenario) and then averaging the two figures. The final figures are presented in table 3.2.1 as the average incidence from 2021-2040.

Table 3.2.1: Estimated number of people with tattoos in the UK and GB, 2014-2040.

Geographic area	Prevalence over study period				Average incidence 2021-2040
	2014	2016	2021	2040	
UK	7,816,000	8,509,000	10,279,000	17,326,000	369,000
GB	7,594,000	8,267,000	9,986,000	16,836,000	359,000
Prevalence rate	12.1%	13.0%	15.2%	24.1%	

Table 3.2.1 shows that under the central scenario, approximately 360,000 would get a new tattoo between 2021-2040. It should be noted that this figure does not indicate the number of visits to a tattooist, number of obtained tattoos, number of tattoo sessions per year or the quantity of potentially hazardous substance exposures and should therefore not be seen as a proxy. These latter estimates are expected to be considerably higher as approximately half of the people with tattoos have more than one tattoo.

The projected prevalence and average incidence on the basis of projections over the study period are also presented in table 3.2.1 above. These projections are estimated on the basis of anticipated future trends of obtaining tattoos. These are associated with high uncertainty, but some indication can be obtained from:

- Trends in other countries: the US and Canada led the tattoo revival, and they have high prevalence rates of 20% and 21% respectively (JRC, 2015b).
- Fashion trends: The change in social perception of tattoos, and substantial growth in the number of people with tattoos and number of tattoos per person, was boosted by the embracing of tattoos by fashion setters (icons) such as performance artists and elite athletes. Similarly, the popularity of PMU has

[54] It is unclear whether ECHA's incidence rate is adjusted for the age profile of the population, therefore it should be treated with a degree of caution.

increased thanks to advancements in PMU techniques, plastic surgery and the fashion trend towards more visible (heavy) make-up.

- Other impacts: It is possible that the increased perception of the safety of the tattoos and PMU and the decline in the social stigma would encourage more people in the future to have similar body enhancements.

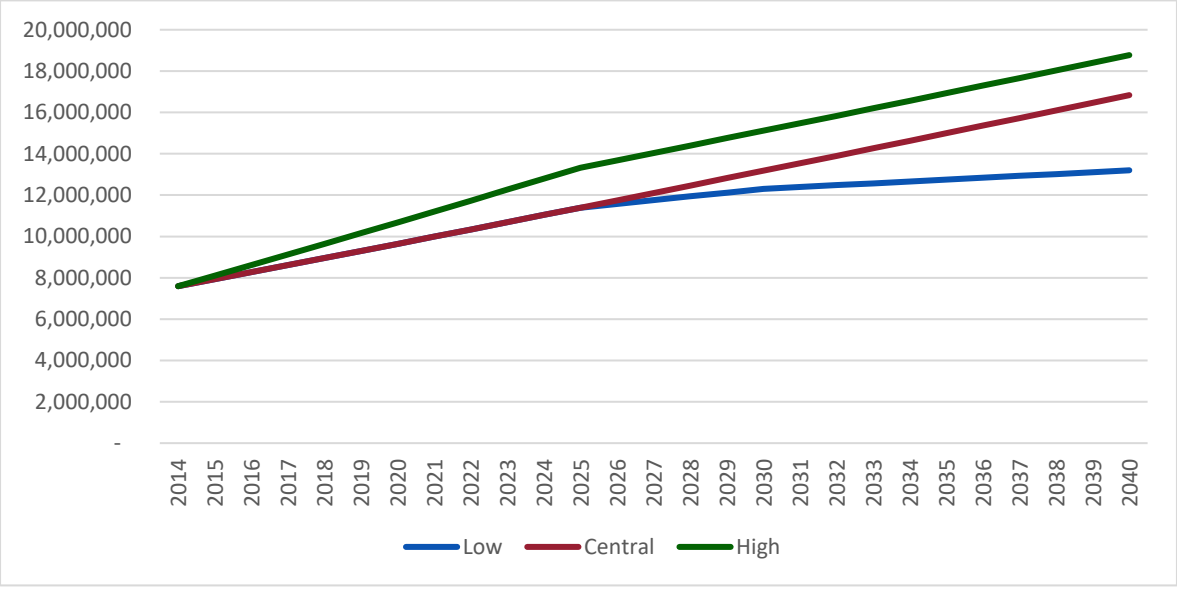
In addition to the central scenario, two other scenarios are presented to highlight this uncertainty:

- Low prevalence – this makes the assumption that in 2025 the current incidence rate will decline by 50% and again in 2030. The prevalence rate for this scenario is estimated at 15.2% in 2021 and 17.6% in 2040.
- High prevalence - this makes the assumption that in the short term, more people will get tattoos for the first time (50% higher incidence rate). Then the incidence rate will return to current levels by 2025. The prevalence rate for this scenario is estimated at 17.1% in 2021 and 26.9% in 2040.

Figure 3.2.1 displays the effects of these assumptions with further assessment of prevalence rate scenarios, incidence rate scenarios and incidence values provided in tables 6.1, 6.2 and 6.3 of Appendix 6.6.

Figure 3.2.1 uses the total GB population from the ONS and applies the incidence rate (this can be found in appendix 6.1). The graph shows the estimated tattooed population in GB from 2014-2040 rising steadily over time.

Figure 3.2.1: GB population with tattoos – projections for low, central, and high scenarios



Note: the figure above is based on GB population data from the ONS Nomis, and ECHA's incidence rate.

In the EU, two-thirds of Member States responding to a survey said that of those with tattoos, the group of people with between 2-5 tattoos was the largest (JRC, 2015b) and the total body surface tattooed for about 15% of men is greater than 20% (Høgsberg, *et al.*, 2013). These larger tattoos would require more visits to tattooists, sometimes over the course of a year or more, in particular if the tattoo design is complex (e.g., realistic style) and is comprised of several colours. Therefore, the number of sessions, the size and complexity of the tattoo, the amount of inks used, etc. – all important components for determining risks of exposure and the likelihood of developing an adverse effect – are discussed qualitatively in the analysis. Another important factor discussed qualitatively is tattoo removal.

See section 3.5.3 Human health and environmental impacts for further details.

Table 6.4 in Appendix 6.1 provides information from ECHA's restriction dossier (2019c) on tattoo size amongst men and women in Europe.

b. PMU

As part of ECHA's data collection from three EU Member States, it can be estimated that the PMU prevalence in EEA31 in the general population is between 3% and 20% (JRC, 2015b). Due to the limited information and the possibility that a person with a PMU could also have one or several tattoos, these estimates are not projected and estimates for the population with both tattoos and PMU are not included in this analysis. First PMU procedures are reported after 18 or 25 years of age (JRC, 2015b). PMUs tend to be more popular with women. Their popularity has increased due to advancements in PMU techniques, plastic surgery, and fashion trends. Industry expects that PMU would continue to replace traditional cosmetics and to be used as a technique for enhancing human features in the long term.

In GB, there is limited information on PMU prevalence. The assumptions used by ECHA (2019c) for PMU prevalence are applied to this analysis for GB in the absence of better estimates (see table 6.5 in Appendix 6.1). As with tattoo trends, this analysis assumes that PMU trends in Europe are likely to be seen across GB too.

Volume of tattoo inks and PMU on the GB market

The tattoo inks and PMU industry is relatively small therefore data for GB and international markets is not available. Section 1.1 of this restriction dossier and ECHA's (2019c) Annex A describe the industry, primarily composed of micro and small enterprises, which formulate the tattoo and PMU inks using ingredients

(colourants and auxiliary ingredients) manufactured by and for the purpose of other industries: industrial applications (such as paints, plastics, automotive, etc.) as well as cosmetics, food and medical sectors.

The estimated volume of tattoo ink and PMU on the GB market in 2016 has been presented below in table 3.2.2. This has been calculated based on the volume of ink on the EEA31 market in 2016 which is presented in ECHA's restriction dossier (2019a) (manufactured, exported and imported) and the GB population. The UK population as a proportion of the EEA31 population is calculated (~13%) and the GB population as a proportion of the UK population is calculated (~97%)[55]. These proportions are applied to the volume of ink of the EEA31 market (presented by ECHA 2019a) to estimate the volume of ink on the GB market in 2016.

Table 3.2.2 shows that in 2016, approximately 18,800 litres of tattoo ink and 1,400 litres of PMU are estimated to have been placed on the GB market. This takes the following into account:

- Tattoo inks: the volume of tattoo ink on the EEA31 market is derived on the basis of information on the amount of tattoo ink used by tattoo artist on average annually: between 0.5 and 3 litres for full-time professional tattoo artist, with amateur artists 25-50% of this. (JRC, 2015b) (industry interviews). The number of tattoo artists was established by the JRC (JRC, 2015b) via questionnaires in ECHA's restriction dossier and the results were verified with industry representatives from the ECHA dossier provided the share of manufactured (32% of ink volume) and imported (40% from the US, 10% from Asia and 4% from the EU) volumes of ink for the UK market[56] (NVWA, 2017) (JRC, 2015b).

  It is assumed that tattoo artists in GB; both professional and amateur, would use similar volumes of ink to tattoo artists in the EU. It is unclear which specific countries the JRC collected the above-mentioned data from and whether they have similar rates of tattooing compared to GB. It is also assumed that the volume of ink on the GB market is proportionate to the

[55] Population has been used as a proxy as this data was readily available and most suitable when scaling down EU data for the volume of ink on the market. Other measures such as GDP were an option, this data may have been more appropriate when scaling down enforcement costs (see section 3.5.1.2), but GDP data was more difficult to attain particularly for all EEA countries and enforcement costs are a small proportion of total costs, therefore this method is deemed proportionate for this analysis.

[56] This information has been extracted from ECHA (2019c) and appears to be incomplete as there is no mention of the remaining 14% of ink on the UK market nor any data or explanation for UK exports of ink.

volume of ink on the UK market (mentioned above) as this is the best available information.

- PMU: the volume of PMU placed on the EEA31 market was estimated on the basis of information from the ECHA dossier and JRC report (JRC, 2015b), supplemented by interviews with industry. The majority of PMU placed on the EEA31 market is manufactured in the EU (80-90%). EU PMU manufacturers also export nearly 20% of their production internationally. Less than 5% of PMU on the EEA31 market is imported according to estimates, primarily from the US or China. (JRC, 2015b).

  Due to data limitations, estimates for the proportion of manufactured, imported and exported PMU on the GB market is unavailable. This will be explored further as part of the public consultation.

Table 3.2.2: Tattoo inks and PMU on the GB market – 2016 estimates (litres)

Scenario	Tattoo ink	PMU	Total
GB manufactured	5,000	1,400	6,400
Exported	300	300	500
Imported	14,100	200	14,300
Total on the GB market	**18,800**	**1,300**	**20,100**

Note: as mentioned above, figures in this table have been taken from ECHA (2019a) and adjusted for GB. ECHA's original estimates are based on interviews with selected manufacturers and JRC data (JRC, 2015b). See Annex C: Baseline of ECHA (2019c) for further information.

Estimation of the tattoo ink and PMU volume on the basis of the projected incidence is hampered by lack of information and the numerous variables that impact the amount of ink used, e.g., style (realistic vs abstract), mono vs multicoloured, size, etc. Therefore, information about future volume can only be inferred on the basis of information available on the overall demand for tattoos and PMU in the future. For the purpose of the analysis of the impacts of the proposed restriction options, similarly to the projections of tattoo prevalence, it is assumed in the central scenario that the amount of tattoo ink and PMU on GB market is expected to remain at about current levels during the study period. For sensitivity purposes, two more scenarios, in line with the low and high prevalence scenarios, are prepared and the effects of these changes are assessed in section 4.2.

Table 3.2.3 shows the projected volume of tattoo inks and PMU on the GB market from 2016-2040. This has been calculated based information from ECHA (2019c) on the volume of ink on the EEA31 market from 2016-2040 (low, central and high) and the GB population. The UK population as a proportion of the EEA31 population is calculated (~13%) and the GB population as a proportion of the UK population is calculated (~97%). These proportions are applied to the volume of ink of the EEA31 market to estimate the volume of ink on the GB market from 2016-2040. The average from 2021-2040 is calculated by taking the average of the two stated years for each scenario (low, central and high). Three volume scenarios are presented due to the uncertainty around the figures. It should be noted that the approach used to estimate the volume of ink on the GB market is highly uncertain and figures should be seen as approximates.

Table 3.2.3: Tattoo inks and PMU on the GB market – projections (litres)

Scenario	2016	2021	2040	Average 2021-2040
Low	20,100	21,400	6,700	14,000
Central	20,100	21,400	22,800	22,100
High	20,100	31,500	22,900	27,200

Notes: Figures have been taken from ECHA (2019c) and adjusted for GB. ECHA's original estimates are based on interviews with selected manufacturers and JRC data (JRC, 2015b). See Annex C: Baseline of ECHA (2019c) for further information.

3.3 Risk management options

The three restriction options proposed (RO1, RO2 and RO3) differ primarily in terms of the proposed concentration limits for selected substance groups and how the links with the CPR are managed. Each option has advantages and disadvantages (discussed in detail in section 3.3.2) which makes it difficult to weigh each option against each other.

3.3.1 Aspects of the proposed restriction which are common to all three options (RO1, RO2 and RO3)

a) Rationale for the proposed restriction options

The proposed restriction options take account of the following:

- If a substance is not permitted in cosmetic products because it is not considered safe to apply on human skin (in general or under specific conditions listed in the CPR), it is logical to assume that it is also not safe to be inserted into the skin, i.e., in a tattoo or permanent make-up where the skin is damaged, and the substance remains in the skin for a prolonged period of time.

- Substances that are classified as CMR Cat 1A/B, and thereby not permitted to be placed on the market or used for supply to the general public as substances on their own or as constituents of other substances or in mixtures (by virtue of entries 28 to 30 of Annex XVII to REACH), should not be used in tattoo inks that will be inserted into the skin of members of the public.

- Substances whose hazard profile suggests that they lead to skin sensitisation, irritation or corrosion or eye irritation and damage, should not be inserted into the skin (or in the eye), i.e., in a tattoo or permanent make-up where the skin is damaged, and the substance remains in the skin or in the eye for a prolonged period of time.

- The hazard and risk assessments carried out by the EU for certain hazardous substances and groups of substances (ECHA, 2019a,c).

- The challenges that have been identified in relation to alternatives for some key substances, in particular selected colourants. Taking into account the hazards and risks of exposure to these pigments, derogations are proposed.

b) Concentration limits

The concentration limits proposed under each option have been derived by the EU on the basis of either the hazard classification for the substance, its listing in Annexes II or IV of the CPR or the risk assessments presented in Annex B10 of ECHA (2019c). In the case of RO1 and RO2, these concentration limits were proposed by ECHA and are described in the background document (ECHA 2019a) and its Annexes (ECHA 2019c). In the case of RO3, these are the concentration limits that were adopted within the implemented EU restriction.

The scientific justification for the numerical values for the concentration limits is presented in section 1.2.6. of this dossier. The rationale for the approach that has been taken in each restriction option is described in below in section 3.3.2.

Analytical methods are used to determine the concentration of various substances in tattoo inks and PMU and will be an important tool to check if particular tattoo and PMU inks comply with the restriction. Methods are available for some groups of

substances in the scope of the proposed restriction options. Appendix D.2 of the EU dossier provides information on the analytical methods that are available for the following groups of substances (ECHA, 2019c):

- primary aromatic amines (PAA);
- colourants;
- elements;
- polycyclic aromatic hydrocarbons (PAHs);
- phthalates;
- nitrosamines.

These groups represent groups of substances that are listed in CoE (2008). The lists in Appendix D.2 include methods that have been used by EU enforcement authorities in Member States with national legislation on the composition of tattoo inks and PMU to identify inks that contain unacceptably high levels of specific substances. Where analytical methods are available, information on the limits of detection of commonly used methods has been taken into account in setting the concentration limits for individual and groups of substances.

In the case of primary aromatic amines, the sensitivity of the available analytical methods is driving the concentration limit.

It has been stated that there are currently no analytical methods that will detect azo colourants that form PAAs via reductive cleavage of the azo bond. Instead, it is necessary to analyse inks for the PAAs that are generated as a result of this cleavage.

It has also been noted that the analytical methods for barium and copper will not differentiate between soluble and insoluble forms. However, the concentration limit that is proposed only applies to the soluble form. This is to avoid capturing insoluble compounds that do not meet any of the criteria that would bring those substances into scope of the restriction.

Finally, the restriction options described in this dossier cover a much broader range of substances than those for which analytical methods have been described by ECHA (ECHA, 2019c). In the call for evidence, one supplier of tattoo inks commented that the number of different substances that may need to be analysed for in tattoo ink and PMU means that it may be necessary for them to engage multiple analytical laboratories because one laboratory may not have the capabilities to analyse inks for the breadth of substances that are in scope.

Further work needs to be done to understand whether it is necessary for suppliers and enforcers to be able to quantify every restricted substance that may be present in tattoo ink and PMU or whether alternative targeted strategies will be sufficient. Work is underway in Italy and other EU Member States to develop and validate methods which could be included in the Enforcement Forum's compendium of analytical methods to control compliance with EU REACH restrictions[57]. The EU is also planning guidance on best practices to help EU enforcement authorities regulate the restriction in a consistent way. The Agency has no information on the timescales for this work to bear fruit but in its webinar, ECHA indicated that it can be a lengthy process to add methods to this compendium.

c) Derogations

i Selected colourants

A derogation is proposed for 21 pigments listed in Appendix 1, table B. This includes:

- two phthalocyanine pigments, Pigment Blue 15:3 and Pigment Green 7, which industry claim are essential for tattooing with no technically adequate alternatives;
- 19 other, non-phthalocyanine colourants.

These pigments fall into scope because they are listed in Annex II of the CPR with the condition "not to be used in hair colours. However, these pigments are also included in Annex IV of the CPR, the list of colourants permitted to be used in cosmetics without conditions of use or are permitted to be used where they meet certain purity criteria. In the case of Pigment Green 7 (CAS 1328-53-6) this substance is allowed in cosmetic products except when used in eye products (column g). ECHA reports that for these 21 substances the Annex II listing arose because the cosmetics industry chose not to provide relevant information to justify continued use in hair dye (ECHA, 2019a). ECHA's justification is reproduced here. The justification is also discussed in Annex D.1.1c of ECHA (2019c).

[57] ECHA publishes a compendium of analytical methods that its Enforcement Forum recommends for use to confirm compliance with EU REACH restrictions. As indicated in its work programme for 2019 – 2023, the Forum will review and update this compendium (see https://echa.europa.eu/documents/10162/17088/forum_work_programme_2019-2023_en.pdf/f8add1f0-f25e-abfc-fb0d-5ad66c717a6e?t=1545393518157. In a webinar to publicise the requirements of the implemented EU restriction, ECHA indicated that this work would include a review of the analytical methods that are available to confirm compliance of tattoo inks and PMU with the implemented EU restriction. The webinar is available to view here: https://www.youtube.com/watch?v=j181bw-D8Tc.

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The proposed restriction options have been designed taking into account the availability of alternatives for some substances, in particular colourants, which industry will find difficult to substitute. Also taking into account the hazards and risks of exposure to the pigments in Table B of RO1 (see Table 5), a derogation is proposed for these substances. For example, Pigment Blue 15:3 and Pigment Green 7 are two essential colourants in tattoo inks.

To date, there is no information for a possible substitute of Pigment Blue 15:3. No other information on alternatives was received during the public consultation on the submitted restriction proposal. Although there are other blue pigments, these have been found lacking in brilliance and change colour (e.g., turn grey) when mixed with white pigments – a common practice to achieve different colour tones. (ECHA CfE, 2016) Pigment blue 15:3, together with a number of other colourants were added to Annex II of the CPR with the condition 'not to be used in hair colours'. At the same time, Pigment Blue 15:3 and 20 other pigments are on the positive list for colourants allowed in cosmetic products (CPR, Annex IV) without conditions of use. Many of the pigments prohibited in hair colours were included in Annex II of the CPR on the basis of the cosmetic industry not providing relevant information to justify continued use in this application. As tattoo inks and PMU do not fall within the scope of the CPR, the tattoo industry was not able to participate in the process, even though the Annex II requirements applied to them via national legislation. Also considering that these pigments do not have relevant harmonised classification, many are not registered and lack detailed information on hazards, sufficient information is not available to conclude on the risks to human health from these substances due to their presence in tattoo inks. In addition, Appendix B.9 concluded that risk from phthalocyanines (e.g., Pigment Blue 15 or Green 7) also cannot be assessed with the current level of information. In addition, the consultation with Forum revealed that the ban of the pigments in hair dyes under Annex II of the CPR is not consistently translated into a ban of these pigments in all Member States in national legislation. These are allowed in Swedish legislation for example. In addition, the public consultation has revealed that this inconsistency creates an uncertain situation where some manufacturers may be turning to more toxic pigments in order to avoid these pigments. The public consultation also revealed that Pigment Red 4 (CI 12085), Pigment Red 5 (CI 12490), Pigment Red 63 :1 (CI 15880), and Pigment Red 181 (CI 73360) are used in tattoo inks. Another stakeholder commented that while Pigment Red 5 (CI 12490) is indeed used in tattoo inks, the substances can be replaced. Therefore, a derogation is proposed for Pigment Blue 15:3 and for the 20 other pigments prohibited in hair colours in Annex II but allowed in Annex IV of CPR (included Table B).

Pigment Green 7 was used in tattoo inks prior to the introduction of the national legislation based on ResAP, on the grounds that it is not allowed for use in hair

colours (Annex II of CPR) and eye products (Annex IV of CPR, column g). According to industry, this pigment has largely been replaced with pigment Green 36 which is a brominated version of Pigment Green 7 raising questions related to Green 36's hazard and risk. (ECHA CfE, 2016) 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 on the submitted restriction proposal. Furthermore, both Pigment Green 7 and Blue 15:3 are phthalocyanines, which are insoluble in water and stable in most solutions. As shown in Appendix B.9, risk for these substances cannot be demonstrated with the currently available information. Therefore, a derogation is also proposed for Pigment Green 7. (See Supplementary Table B marked as Table 5 in the report).

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The Agency notes that by 18 February 2022 none of these 21 pigments were included in the GB MCL list.

Initially, in the EU process ECHA proposed a derogation for these 21 colourants. RAC chose not to support the derogation (ECHA, 2019d). The reasoning given in the RAC opinion is quoted here:

Reproduced ECHA text

"Regarding the 21 colourants proposed by the Dossier Submitter to be excluded from the restriction on CPR Annex II substances, they were included in this Annex because of the concern that their use in hair dyes could be related to increased risk of cancer, primarily in the urinary bladder (e.g., Gago-Dominguez *et al.*, 2001; Miller and Bartsch, 2001; Harling *et al.*, 2010). Since epidemiological data underpinning this concern could not specifically indicate which colourants were responsible for the increased risk, the Commission proceeded with a ban on all permanent and non-permanent hair dyes for which the cosmetics industry did not submit any safety files and those hair dyes for which the SCCS had given a negative opinion (Ref. Ares(2015)4346889 - 16/10/2015). The colourants are proposed by the Dossier Submitter to be excluded from the restriction because they do not have harmonised classification and while they are banned in hair dyes (listed in Annex II of the CPR), at the same time they are allowed for use in all other cosmetic products (Annex IV of the CPR, some with conditions on use). The reasons why they are listed in Annex IV of the CPR are not available. This situation, however, creates inconsistency in their legal status in different EU Member States with national legislation, as stated in the Background Document.

After summarising the available toxicological data for the 21 colourants proposed by the Dossier Submitter to be excluded from the restriction on CPR Annex II substances (more detailed analysis was not possible due to unavailability of original

reports and lack of more extensive study descriptions), RAC considers that the risk of cancer indicated by epidemiological studies cannot be ruled out for the majority of these colourants.

As pointed out in the Background Document, experimental toxicological data on carcinogenicity of these colourants are deficient for 16 out of 21 colourants (see Appendix B.12 of the Background Document for further details). From the five colourants for which experimental data are of sufficient quality to draw conclusions (FD&C Red 4, Acid Red 27, Acid Blue 3, Fast Green FCF, Acid Red 51), three were negative (FD&C Red 4, Acid Red 27 and Acid Blue 3). An increased incidence of thyroid neoplasms observed in oral studies with Acid Red 51 was interpreted by EFSA as of limited human relevance (EFSA, 2011). For Fast Green FCF, although carcinogenicity was negative in oral studies, a high incidence of fibrosarcoma was reported in rats after long-term subcutaneous injections (Hansen *et al.*, 1966; Hesselbach and O'Gara, 1960). However, for three colourants for which experimental data did not indicate risk for carcinogenicity (i.e., FD&C Red 4, Acid Red 27 and Acid Blue 3), as well as for Acid Red 51, potential risk of other health hazards was noted. FD&C Red 4 is banned by the US FDA (in 1976) as a colour in food, ingested drugs and cosmetics, because of adverse effects observed in the urinary bladder (chronic follicular cystitis with haematomaous projections into the bladder), adrenals (atrophy of the zona glomerulosa) and liver (haemosiderotic focal lesions) in long-term oral study in dogs (Deshpande 2002; US FDA 21CFR81.10). Acid Red 27 (Amaranth) is permitted as a food additive in the EU under the restricted levels (0.003% to 0.01%), but embryotoxicity has been observed in some studies (Collins and McLaughlin, 1972, 1973; EFSA, 2010), and available data indicate it could trigger classification as eye irritant cat. 2. Acid Blue 3 is also approved as a food colourant (E 131) in the EU, and as a diagnostic tool in medicine. However, allergic reactions have been reported in patients after parenteral exposure, and an EFSA Panel (EFSA, 2013) noted that the application of this colourant in various fields (cosmetics, textiles, paints, inks) could potentially cause sensitisation. Acid Red 51 was non-mutagenic in oral in vivo studies, but it showed clastogenicity following i.p. administration (EFSA, 2011).

Non-carcinogenic hazards relevant for this restriction proposal cannot be ruled out for the following colourants as well: local (skin) or systemic allergic reactions for Solvent Violet 16 and Acid Yellow 73), and irritant or corrosive skin or eye effects for Pigment Red 83, Acid Yellow 73 and Acid Red 87. Fast Green FCF was mutagenic in in vitro bacterial and mammalian cell assays, and there are reports indicating possible risk of skin sensitisation in tattooed people.

RAC points out that carcinogenic potential for the majority of these chemicals was tested via the oral route (exceptions are FD&C Red 4 and Pigment Blue 15 for which long-term data with subcutaneous administration exists), which is of limited

relevance for risk assessment of the dermal exposure route related to hair dye exposure in human population or for intradermal application during tattooing procedure. Namely, for a majority of these colourants low or very low oral absorption was found (in toxicokinetic studies) or predicted (based on physico-chemical properties) (please see Table 132 in Appendix B.12 of the Background Document).

The uncertainty related to low oral absorption of these colourants also applies to Pigment Blue 15:3 (CI 74160; 29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper) and Pigment Green 7 (CI 74260; polychloro copper phthalocyanine), which are copper phthalocyanine colourants. Pigment Blue 15:3 represents the unmodified version of the molecule, while Pigment Green 7 is chlorinated 14- to 16-fold per phthalocyanine (SIAR, 2005). According to information provided in the Registration Dossiers, SIAR (2005) report and the Background Document, it could be concluded that both colourants are of low acute and repeated-dose toxicity, and apparently without irritant or sensitisation potential. However, regarding genotoxicity, carcinogenicity and reproductive toxicity, the toxicological data are too deficient to allow a reliable conclusion (for further details on toxicological information on these colourants please see Appendix B.12 of the Background Document). Briefly, genotoxicity testing did not include a standard battery of assays. In the case of Pigment Green 7, gene mutation assay in mammalian cells or in vivo assays are not available, and the potential for inducing aneuploidy was not tested. In the case of Pigment Blue 15, the testing was more extensive: negative results were obtained in an Ames test, in an in vitro test for chromosomal aberrations and in a mouse spot test (which can detect both somatic mutations and chromosomal aberrations). Nevertheless, the usefulness of the mouse spot test in toxicology is considered to be limited by restrictions in e.g., toxicokinetics (transplacental transfer of a substance is required) or sensitivity (small number of genes is tested) (Wahnschaffe *et al.*, 2005). Regarding reproductive toxicity, only a screening test (OECD 421) is available (and only for Pigment Blue 15), and, even more importantly, RAC points out that oral or dermal studies are of limited relevance for risk assessment of the intradermal application of these colourants since it is considered that copper phthalocyanine-based pigments are not absorbed after ingestion and after skin contact (Registration Dossiers for Pigment Blue 15:3 and Pigment Green 7). Carcinogenicity data for Pigment Blue 15 (for Pigment Green 7 no carcinogenicity study is available) were obtained following subcutaneous exposure route, but with significant limitations in study design (only one dose tested in 17 animals, short duration of the study, i.e., 34 weeks). As already discussed in section B.1.2.1.3, although these colourants have extremely low solubility in aqueous solutions, fate and bioavailability of phagocytosed phthalocyanine pigment particles is not known.

Therefore, RAC is of the opinion that the exemption of these 21 colourants cannot be based on their non-hazardous profile, primarily due to lack of adequate information on their hazard properties and risk for human health.

During the ECHA Call for Evidence (ECHA CfE, 2016a) and the Public Consultation, no concern was raised regarding the potential restriction of 19 non-phthalocyanine colourants. The reason could be a limited use of these colourants in tattoo inks or availability of alternatives for those which are used, as some answers during the Public Consultation indicated. Since in the available literature and other information sources there is a lack of adequate information on hazard properties and risk for human health for these 19 non-phthalocyanine colourants, and during the ECHA CfE and the Public Consultation no concern was raised regarding their restriction, RAC does not support their derogation.

On the other hand, RAC recognises that during the ECHA Call for Evidence and the Public Consultation a concern was raised by industry that two phthalocyanine pigments, Pigment Blue 15:3 and Pigment Green 7, are essential for tattooing and there are no, technically adequate alternatives. In addition to Pigment Blue 15:3 and Pigment Green 7, other blue and green pigments have been reported to be used in tattoo inks (see Appendix B.12 in the Background Document with a non-exhaustive list based on the information from the Background Document, open literature and internet sources, including technical data from producer/supplier Internet pages).

RAC concludes that although there are some blue pigments for which a low hazard profile could be expected, specific information on the hazardous properties and technical feasibility of these alternatives are not available or are very limited. Other pigments are either of higher concern for human health or their technical characteristics are reported inferior compared to Pigment Blue 15:3.

As for Pigment Green 7, it has been largely replaced with Pigment Green 36 (which is not in the scope of this restriction since it has no harmonised classification and it is not listed on Annex II or Annex IV of the CPR), a brominated version of Pigment Green 7. Not much data is available for Pigment Green 36. According to the Registration Dossier, this pigment was not genotoxic in bacterial gene mutation assay. For all other endpoints, read-across from Pigment Blue 15 was applied. Regarding bromide ion, it is known to be toxic to humans if taken in excessive amounts (e.g., in the range of 0.5-1 g/day orally, following chronic exposure, 2-4 weeks or longer). Although rapid and extensive release of bromide ion from phthalocyanine pigment is not expected, especially not in the extent to cause systemic toxicity, brominated Pigment Green 36 cannot be considered as a less hazardous alternative to chlorinated Pigment Green 7. Regarding other green pigments reported to be used in tattoo inks (see a non-exhaustive list in Appendix B.12 in the Background Document), RAC considers that limited information on their human health hazards and technical characteristics do not indicate less hazardous and, at the same time, technically feasible alternatives to Pigment Green 7.

In conclusion, since the data on health hazard and risk profile of the two

phthalocyanine colourants, Pigment Blue 15:3 and Pigment Green 7, are too limited, RAC cannot support their derogation.

Nevertheless, RAC is aware that a concern was raised by industry that these two colourants are essential for tattooing, without technically adequate alternatives, that alternatives with a more concerning hazard profile are presently used in blue and green inks, and that data on health hazards and risks and technical feasibility of potential alternatives are deficient."

End of reproduced ECHA text

After ECHA submitted its recommendation for the EU restriction to the European Commission, the German Federal Institute for Risk Assessment (BfR) conducted an independent assessment of Pigment Blue 15:3 and Pigment Green 7 (BfR, 2020). Both substances are registered in EU REACH at > 1,000 tonnes per year but with incomplete hazard data sets. Based on the information in these REACH registrations, BfR concluded that the currently available data suggest these pigments have a comparatively low level of toxicity. BfR noted other scientific committees that had also determined that these pigments exhibit a low level of toxicity (SCC, 1986[58]; OECD SIDS, 1997; BG-RCI, 1995[59]). These assessments resulted in these pigments being identified as a low priority for further regulatory work. Based on its assessment, BfR made the following recommendations:

- Any decision to exempt the two pigments from the restriction should consider the risk posed by potentially more harmful substitutes being used in their place.
- The ECHA should review the completeness of the REACH regulation data submitted for both pigments as part of the dossier evaluation and missing data should be requested.

The Agency has no information about whether any EU REACH actions will lead to the generation of additional hazard data for these pigments. The Agency shares the concerns expressed by BfR that alternatives for these pigments may not necessarily be safer, particularly if the alternatives fall outside the scope of this restriction because they lack robust hazard data sets. This is the case for an alternative for Pigment Green 7. This alternative is Pigment Green 36 which as discussed by RAC above is a brominated version of Pigment Green 7. Other colourants which currently

[58] Scientific Committee on Cosmetology: SCC, 1986: Reports of the Scientific Committee on Cosmetology (seventh series), pp. 127-128. published 1988. https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/scc_o_7.pdf (link broken)

[59] German Social Accident Insurance Institution for the raw materials and chemicals industry (in German: Berufsgenossenschaft Rohstoffe und chemische Industrie, (BG-RCI))

do not meet any of the criteria which would bring them into scope of this restriction but are potentially of concern if they are present in tattoo ink or PMU based on the hazard classifications notified to the EU C+L inventory are listed in Appendix D2 of EHCA (2019c).

Given the continuing concerns from the tattoo industry about the consequences if they lose Pigment Blue 15:3 and Pigment Green 7, the Agency considers that there is a need to decide if a derogation of these pigments is appropriate for inks supplied to the GB market. The Agency is therefore proposing a derogation for the 21 colourants that ECHA proposed should be derogated. The Agency is proposing that this derogation should remain in place until such a time that changes would be introduced within the Annexes of the CPR that would bring a colourant into scope of the general provisions of this restriction.

The scope of this derogation can be reviewed in the light of information obtained during the public consultation about the use of these 21 pigments in tattoo inks and PMU supplied to the GB market.

ii. Classified substances for inhalation exposure only

Since this restriction is intended to address risks to consumers who are receiving a tattoo or PMU treatment (i.e., risks from substances when they are inserted into the skin), risks that only apply to substances when inhaled are not relevant. For this reason, a derogation is proposed for substances that are classified as carcinogenic via the inhalation route only (e.g., titanium dioxide).

iii Substances that are gases at standard temperature and pressure

With one exception, a derogation is proposed for substances that are gaseous (at temperature of 20°C and standard pressure of 101,3 kPa or generate a vapour pressure of more than 300 kPa at temperature of 50°C) as they are not expected to be in tattoo inks. The only exception to this proposal is formaldehyde (CAS No 50-00-0, EC No 200-001-8). Free formaldehyde has been detected at concentrations of 0.005 – 0.035% in 7% of tattoo and PMU inks during compliance monitoring in Switzerland (Hauri, 2014). The sample of 206 tattoo inks and 23 PMU inks included 6 tattoo inks originating in the UK. Formaldehyde may be present in inks because it may be used as a preservative (ECHA, 2019d). It may also be formed in situ due to degradation of the preservative DMDM hydantoin or because it is an impurity in other components in the inks (Hauri, 2021). To prevent tattoo inks and PMU containing unacceptable levels of formaldehyde, this substance is included in the scope of the restriction.

d) Labelling requirements

Each restriction option proposes labelling requirements for tattoo inks and PMU. These include the following labelling recommendations from CoE (2008):

According to CoE (2008) “Tattoo and PMU products should contain the following information on the packaging:

- the name and address of the manufacturer or the person responsible for placing the product on the market;
- the date of minimum durability[60];
- the conditions of use and warnings;
- the batch number or other reference used by the manufacturer for batch identification;
- the list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Colour Index (CI) number;
- the guarantee of sterility of the contents.”

Some of these requirements may be necessary under the GB CLP Regulation. In addition, under this restriction is proposed that the person responsible for placing the tattoo ink or PMU on the market shall ensure that the label provides in addition to that required by the GB CLP Regulation the following information:

- The intended use of the mixture as a tattoo ink;
- A manufacturer’s reference number to uniquely identify the batch;
- The name of all substances used in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of the GB CLP Regulation but not covered by the current restriction proposal;
- The name of any additional substances covered by the restriction proposal that are used in the tattoo ink;
- Any relevant instructions for use.

[60] The date of minimum durability of a tattoo and PMU product should be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with the requirements that such products must not endanger the health or safety of people or the environment. The date of minimum durability should be indicated by the words: “To be used before the end of …”, followed by either the date itself (month and year) or details of where the date appears on the packaging. If necessary, this information should be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

- The phrase “Contains nickel. Can cause allergic reactions.” if the tattoo ink contains nickel below the concentration limit specified in Table A (RO1 an RO2) or Table F (RO3).
- The phrase “Contains chromium. Can cause allergic reactions.” if the tattoo ink contains chromium (VI) below the concentration limit specified in Table A (RO1 an RO2) or Table F (RO3).

The labelling shall be clearly visible, easily legible and appropriately durable.

Where necessary because of the size of the package, the information labelling shall be included on the instructions for use.

The information on the label shall be made available to any person who will undergo the tattooing procedure before the procedure is undertaken.

These requirements are included to ensure that substances that are not covered by the restriction proposal but may present a risk to human health will be listed to inform consumers who intend to undergo a tattoo or PMU procedure. This could be particularly useful for people who know they experience allergic skin reactions to specific substances to help them identify if those substances are present in the tattoo or PMU ink.

e) Additional conditions

The following additional conditions apply to the EU restriction and are proposed for the GB restriction:

Reproduced ECHA text[61]

i. Colourants in Annex 4 of CPR with conditions on their use

Some colourants used in cosmetic products have been shown to pose a risk to human health when applied to the skin in concentrations exceeding the maximum allowed concentrations specified in Annex 4 of the CPR or when not meeting the other conditions in columns “h” to “i” of the Annex (e.g., purity requirements). (See Supplementary Table E.) Therefore, given the similarities in exposure potential (not allowed if not complying with these conditions in cosmetic products which by definition (Article 2 of CPR) are applied, among other, on the external parts of the

[61] Supplementary Table E in this ECHA text refers to table E in the Appendix to the EU background document (ECHA, 2019b). This table lists substances in Annex IV of the CPR which are permitted to be used in cosmetic products subject to conditions in columns h and i. The Agency has not updated the table prepared by ECHA. More information is available in Appendix 1 of this Agency document.

human body, which include the epidermis), a comparable restriction for use of these colourants in tattoo inks and PMU is proposed.

ii. Restriction on the use of tattoo inks not meeting the requirements by tattoo artists

As it is possible for tattoo artists to stockpile pigments in powered form and mix tattoo inks, the restriction puts the onus on tattoo artists and PMU practitioners to ensure that non-compliant inks are not used for tattoo or PMU purposes by proposing that inks not meeting the restriction requirements are not used in tattoo and PMU procedures.

End of reproduced ECHA text

f) Transitional period

A transitional period of one year after its entry into force is proposed. This is the same transitional period that was allowed for EU industry. Respondents to the call for evidence suggested transitional periods ranging from 6 months to 10 years or more. The additional time was requested to provide more time to develop and test alternatives. Respondents noted that it can take several years to understand how durable colourants are when used for tattooing and PMU. It is expected that work to develop inks for the EU market that comply with the EU restriction will reduce the time needed to develop inks which will comply with a similar restriction if this is introduced into GB, hence a one-year transitional period could be achievable.

g) Definitions and other enforcement considerations

The proposed restriction text includes definitions of tattoo and PMU practices.

3.3.2 Aspects of the proposed restriction options which differ

3.3.3.1 Restriction options 1 and 2 (RO1 and RO2)

Since RO1 and RO2 propose the same concentration limits and interlinks with the CPR that were proposed by ECHA, the EU text explaining these restriction options is reproduced here:

Reproduced ECHA text[62]

2.2.1. Proposed restriction option: RO1

RO1 is formulated to follow to the extent possible and justifiable, existing national legislation in nine EEA Member States with national legislation on tattoo inks and PMU. Thus, the proposed concentration limits are set as follows:

a) Concentration limits

- Substances on Annex II and IV (column g) of the CPR

Article 14 of the CPR establishes that cosmetic products shall not contain substances listed in Annex II, restricted substances in Annex III and colourants not listed in Annex IV. Article 15(1) and (2) provide that CMRs are prohibited in cosmetic products (except under certain conditions). Under the CPR, the prohibition of Annex II substances is total in the sense that there are no concentration limits; however, Article 17 allows for "non-intended presence of a small amount of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3" [Safety]. Therefore, in practice, in Member States enforcing the CPR via national legislation, this is a prohibition at the level of detection/quantification of the available analytical methods, taking into account unavoidable impurities (or traces of prohibited substances). Guidance for these limits may be set in some Member States with national legislation on the basis of analytical methods used and best practices. Different Member States may apply different values for trace amounts.

Following the logic of the proposed restriction (i.e., what poses human health risk for application on the skin would also pose risks for injection in the dermis), tattoo inks should not contain prohibited substances in cosmetic products. Therefore, RO1 proposes to enforce Annex II substances under REACH similarly to the CPR.

Substances in Annex IV are also proposed to be enforced in a similar way to Annex II substances in RO1. They are prohibited for use in tattoo inks under national legislation based on ResAP on the premise that they are not allowed in high risk cosmetic applications (i.e., as per column g in Annex IV: in products applied on mucous membranes or in the vicinity of the eye, as well as leave-on products as they

[62] Supplementary Tables C and D in this ECHA text refer to tables C and D in the Appendix to the EU background document (ECHA, 2019b). Table C lists substances in Annex II of the CPR i.e. those prohibited for use in cosmetics. Table D lists substances in Annex IV of the CPR subject to conditions in column g. The Agency has not updated the tables prepared by ECHA. More information is available in Appendix 1 of this Agency document.

are allowed in rinse-off only). This is similar to the Member States enforcing national legislation.

- CMR substances

According to Article 15 of the CPR, CMR substances are periodically added in batches to Annex II, unless industry demonstrates essential use in cosmetics (see justification for inclusion of Annex II substances in Appendix B.4). As the majority of these substances will be included in Annex II (for category 1A and 1B, this is within 15 months but for category 2, there is no time limit), it would be appropriate to apply the same concentration limit as for Annex II substances, i.e., total prohibition, at least for carcinogenic and mutagenic substances, Categories 1A, 1B and 2.

As threshold effects can be demonstrated for many reprotoxic substances, a concentration limit derived on the basis of quantitative risk assessment is proposed under RO1 for these substances, Categories 1A, 1B and 2.

- Substances with harmonised classification as sensitisers, irritants and corrosives

A practical limit of 0.1% w/w is proposed for each individual substances with harmonised classification as skin sensitising, corrosive or irritant and eye irritant or damaging to discourage the use of these substances in tattoo inks. This will simplify the restriction requirements for stakeholders. (See respective appendixes to Annex B for further justification.) The CLP rules for additivity are not used for this proposal.

b) Interlinkages with the CPR

The proposed restriction scope would ideally be linked to Annex II of the CPR to ensure any future updates are reflected in the proposed RO1. This would ideally avoid frequent updating of an appendix to Annex XVII to REACH mirroring Annex II to the CPR. Therefore, the text of RO1 refers directly to CPR Annex II and Annex IV.

See introduction of section 2.2 for information on other conditions and elements of RO1 that are the same as RO2.

2.2.2. Justification for the selected scope of RO1

The proposed RO1 follows existing national legislation in Member States to the extent possible and equalises the level of protection of people in EEA31 who seek to get a tattoo.

The main advantages of RO1 are that it:

- follows national legislation to the extent possible and it will therefore, provide similar level of protection currently applied by national rules in seven EU

Member States (and two additional EEA members) that are based on the recommendations of the CoE ResAP;

- is easy to communicate as the proposed restriction scope follows to the extent possible existing current legislation based on the recommendations of ResAP. Tattoo ink manufacturers are already aware of these requirements (although some substances are added). This will facilitate compliance with the proposed restriction;
- will ideally be dynamically linked to Annex II and IV to the CPR and Annex IV of the CLP to ensure future changes to those annexes apply directly to the restriction;
- proposes concentration limits that are derived on the basis of the argumentation for risk.

The main concern with RO1 is that the unavoidable presence of some impurities, not intentionally added to the inks, could result in some inks currently allowed on the market to not be allowed due to the proposed restriction. These unavoidable traces are dealt with in a practical manner in national legislation (on the basis of Article 17 of the CPR), which will be difficult under the setting of Annex XVII of REACH. This could lead to costs to society that are difficult to estimate on the basis of the currently available information.

It is difficult to enforce a restriction without a specific limit value as the default enforcement may be the limit of detection which is linked to the performance of the available analytical methods. Therefore, manufacturers may face some difficulties complying with the restriction and possibly be subject to different treatment in different Member States, depending on the analytical method used by the enforcement authorities. On the other hand, it is not the first time that Annex XVII to REACH includes an entry without a limit value. It is expected that the development of a guideline or harmonised analytical methods will overcome this disadvantage.

The remaining sections of this annex demonstrate that RO1 is effective, practical and monitorable.

2.2.3. Proposed restriction option: RO2

The scope of RO2 differs from that of RO1 only in terms of concentration limits (for substances with harmonised classification and those on Annex II and IV of CPR) and the management of the interlinkages with the CPR.

a) Concentration limits

i. Substances with harmonised classification

The maximum concentration of substances with harmonised classification as CMRs, skin sensitisers, corrosives or irritants or eye corrosives or damaging is proposed to be limited to the generic or specific concentration limit of the substances set in the CLP Regulation. For irritants the concentration limit applies to individual substances and the CLP rules for additivity are not applied in this restriction proposal.

ii. Substances on Annex II and IV (column g) of the CPR

For substances on Annex II, a practical limit of 0.1% w/w is proposed. (See Supplementary Table C.) Similarly, the substances on Annex IV with a restriction on their use in cosmetic products specified in column g of the CPR (i.e., not to be used on mucous membranes, in the vicinity of the eye, or only allowed in rinse off products) are proposed to be restricted in tattoo inks with a practical limit of 0.1% w/w. (See Supplementary Table D.) This will simplify the restriction requirements for stakeholders.

b) Interlinkages with the CPR

While RO1 proposes that any future changes in Annexes II and IV of the CPR are taken up in the proposed restriction automatically, RO2 proposes that only substances on Annex II and Annex IV (columns g-i) at the time of the writing of this restriction dossier are included in the scope.

The other conditions and elements of RO2 are the same as for RO1. See introduction of section 2.2 for further detail.

2.2.4. Justification for the selected scope of RO2

The main rational for considering a restriction option with different concentration limits than RO1 is that colourants in particular are often of low purity and therefore, a number of currently unknown impurities could potentially be contained in tattoo inks. As explained previously, the Member States that currently have national legislation on tattoo inks in place, enforce prohibition on substances on Annex II, CMRs and Annex IV substances (column g) similar to cosmetic products whose use is regulated by the CPR. This means if these substances are found in trace amounts in tattoo inks (i.e., due to Article 17 of the CPR), they would not be considered non-compliant. As pigments are not manufactured by the formulators of tattoo inks, many such impurities of the manufacturing process could also be contained in the tattoo inks, which are mixtures of a colourant in a solution with auxiliary ingredients. As it is extremely complex to catalogue all impurities that can be found in tattoo inks, a broad brush approach is taken, where a restriction is proposed on substances which can cause skin and systemic effects in humans in order to encourage the use of higher purity, lower risk pigments and auxiliary ingredients in tattoo inks. However, as the list of impurities is unknown, in particular for those pigments that are currently

not widely used in the manufacture of tattoo inks, there is the risk of the regulation to render a great share of tattoo inks currently the market as non-compliant if unobtainable concentration limits are imposed. Therefore, this second – RO2 – restriction option is proposed with higher practical limit (0.1% w/w) for CPR substances in scope and the CLP limits for those with relevant harmonised classification.

Another reason harmonised classification limits are convenient concentration limits for a restriction on tattoo inks is that, according to the CLP Regulation, substances in mixtures with harmonised classification need to be specified on the label and the safety data sheet. This will facilitate industry compliance and lead to lower testing costs. It will also facilitate enforcement by competent authorities.

RO2 is also proposed to decouple the restriction from future updates of Annex II and IV of the CPR. Although there is an advantage to take on board changes implemented in the CPR Annex II and IV (on the premise that what poses human health risk for application on the skin would also pose risks for injection in the dermis), a static list of substances (i.e., those included in the CPR as of the writing of the dossier) evaluated for the purpose of a restriction on tattoo inks would avoid legislative gaps that could arise in cases such as these for example:

- If the restriction is dynamically linked to Annex II of the CPR, tattoo inks containing these substances could not be placed on the market (if intentionally added). The CPR has provisions for CMR category 2 substances to be allowed in cosmetic products if the SCCS concludes they are safe to use, leading to their inclusion in Annex III-VI, instead of II. If the cosmetic industry is not interested in making the case for this substance, it will directly be included in Annex II (even though theoretically safe use can be demonstrated under certain conditions). This is creating a situation, where in order to defend a use in tattoo inks for a CMR category 2 substance, the tattoo industry would have to create a fictitious application for use in cosmetics to be evaluated by the SCCS with a recommendation for inclusion in Annex III-VI instead of Annex II. This does not comply with the objective of good administrative practices of the European Commission.

- If the restriction is dynamically linked to Annex IV of the CPRs, a colourant A allowed for rinse off products only will be restricted in tattoo inks. Following an SCCS evaluation, colourant A is removed from Annex IV (altogether or placed on Annex III for example) because it can no longer be demonstrated that it is safe for rinse off use. The colourant will no longer be banned for use in tattoo inks and its removal from Annex IV on grounds of new evidence of greater hazard and risk could lead to more flexible regulation for tattoo inks, paving the way for its reintroduction in tattoo inks.

Therefore, RO2 is proposed as avoiding legislative gaps as the above theoretic examples can be considered more desirable than the possibility to future proof the restriction by dynamically linking it to analysis of relevant substances, specifically under the CPR. The absence of future proofing of RO2 with respect to the CPR can be overcome by periodic examination of the restriction. This may be warranted given the high complexity of the proposed legislation. See section 2.2 for possible ways to facilitate this.

The main advantages of RO2 are that it:

- will likely lead to lower testing costs as the safety data sheets contain information on substances with harmonised classifications that are present in concentrations above their classification limits;
- is easy to communicate to law makers, enforcement and industry that must comply with the restriction; proposes concentration limits that are derived on the basis of the argumentation for risk, as they are based on CLP limits;
- will allow greater share of inks currently on the market containing some impurities to continue to be supplied.

The main disadvantages RO2 are that it:

- allows higher concentrations of hazardous substances (including substances of very high concern) to be injected under the skin. Tattooed persons can theoretically have a lower level of protection than persons using cosmetics on the surface of the skin. For some substances, it may result in a lower level of protection in Member States that already have national legislation based on ResAP;
- is less consistent as substances on Annex II of CPR will have different concentration limits even though they have similar concerns with respect to human health risks (i.e., those with various classifications and those without).

On the other hand, there is currently no information suggesting that industry is unable to meet lower concentration limits for some of these substances in particular since many of the substances have not been found (although, also possibly not measured) yet in tattoos inks. Higher concentration limits can reduce the incentive for industry to continue to seek ways to reduce exposure to hazardous substances in tattoo inks and may reverse replacement that has taken place or is taking place as a result of national legislation based on ResAP.

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3.3.2.2 Restriction option 3: RO3

a) Concentration limits

- Substances with relevant hazard classification in the GB MCL list and on Annexes II or IV of the CPR

Rather than adopt the “shall not contain” approach to CPR substances and substances classified as carcinogens or mutagens that is outlined in RO1, RO3 proposes concentration limits. The “shall not contain” approach means that the presence of substances in tattoo inks and PMU will be enforced at the limit of detection for the available analytical methods. Differences between laboratories could lead to different standards being applied in different Member States. For this reason, the EU considered that the use of concentration limits was a better approach than the “shall not contain” approach in RO1.

Although concentration limits were proposed under RO2, the concentration limits that were adopted in the EU restriction are much lower in many cases. This means that RO3 potentially provides greater protection for consumers compared with RO2.

There are also some differences between RO3 and the two alternative options in the concentration limits proposed for substances listed in table 3 of ResAP(2008)1.

- Substances on table 3 in the CoE ResAP(2008)1, impurities in tattoo inks and PMU

Under this restriction option, the EU adopted a concentration limit of 0.0005% w/w for all PAHs which are classified as carcinogens and/or mutagens. As an exception, a lower limit of 0.0000005% by weight (5 ppb) was applied to benzo[a]pyrene (BaP). This is the limit that was adopted for BaP in CoE (2008).

For the remaining 13 substances the following approach was taken:

Barium, copper, zinc, nickel and arsenic: RAC developed substance specific concentration limits and these were adopted into the EU restriction.

Lead: The concentration limit proposed by ECHA was adopted into the EU restriction.

Selenium: the concentration limit from CoE (2008) was carried into the EU restriction.

Cadmium, chromium VI, mercury, antimony and organotin: the generic concentration limit of 0.0005% w/w that was proposed for substances classified as carcinogens and mutagens was applied to these impurities.

b) Interlinkages with the CPR

As for RO1, it is proposed that there should be a dynamic link with Annex 2 and Annex IV of the CPR so that any future updates to this legislation will automatically be reflected in this restriction.

This would avoid the need to amend Annex 17 of REACH each time substances are added to these Annexes and therefore has the benefit of regulatory efficiency.

See section 3.3.1 above for information on other conditions and elements of these three restriction options.

c) Justification for the selected scope of RO3

The main advantages of RO3 are that it:

- closely follows the scope of the implemented EU restriction. This may simplify the work that supply chains need to undertake to reformulate inks for GB because inks that are compliant for the EU will also be compliant in GB. If GB were to adopt even stricter standards than had been adopted in the EU, which could be the case if the “shall not contain” approach that is proposed under RO1 is adopted, given that most tattoo ink and PMU ink is manufactured outside GB, this could mean that it is not profitable for suppliers to reformulate inks to meet these strict standards for such a small market.

- avoids the difficulties for enforcement that were identified with RO1 due to the “shall not contain” approach. It will be beneficial for both manufacturers and enforcers to have the clear targets that are provided by setting concentration limits for the various substances and substance groups that are in scope.

- retains the dynamic links with the GB MCL list and Annexes II and IV of the CPR and the GB MCL list that was proposed under RO1 which simplifies the process to update this restriction when substances are newly classified or reclassified or are added to relevant Annexes of the CPR.

The main disadvantage of RO3 is that this reinstates the potential for legislative gaps to arise depending on which Annexes of the CPR are used to govern the way colourants are used in cosmetics. This is explained further in the above justification for RO2. The Agency expects that this situation will rarely if ever arise in practice because such a substance is likely to be caught under one or more of the CLP criteria.

Finally, the Agency notes that none of the proposed options include positive lists of substances that are permitted in tattoo inks and PMU. While this simplifies the

process for regulators to update the restriction, this also means that the restriction is relying on actions taken under other legislation to bring additional hazardous substances into scope. Hazardous substances that have not yet been classified (and may not have sufficient data sets to permit hazard classification decisions to be taken) also, hazardous substances that have not yet been included in relevant Annexes of the CRP will not be captured. This means that in reformulating inks to comply with this restriction, tattoo ink and PMU manufacturers could choose hazardous alternatives. This will therefore reduce the level of risk reduction that may be achieved by this restriction. It is not possible to quantify this loss of risk reduction capacity because this is dependent on the hazardous properties of specific substances.

3.4 Response to restriction scenario(s)

In response to the proposed restriction options (RO1, RO2 and RO3), actors in the supply chain and society as a whole are expected to react as follows:

- With the exception of certain colourants, the EU work has demonstrated that it is possible to substitute hazardous substances that are used in tattoo ink and PMU with less hazardous alternatives.
- Companies that place tattoo inks and PMU onto the GB market will need to develop and begin marketing alternative inks that comply with the adopted restriction option. This has the potential to incur higher production costs relating in particular to the need to source raw materials of greater purity than those currently used. Some companies may stop production of inks altogether if they are not able to keep up with the increased costs of producing compliant inks. This process will be simplified if the requirements relating to the composition of inks that are supplied to GB correspond with requirements that exist elsewhere to avoid the situation where manufacturers are having to manufacture a specific line of inks for a very small market.
- Higher costs of production for industry will be passed onto downstream users of ink such as the tattoo artists and PMU practitioners. They will incur higher costs and pass these costs onto consumers in the form of higher prices.
- It will be necessary for supply chains (including distributors, tattoo artists and PMU practitioners) to deplete existing stocks of ink that will become non-compliant when the restriction is introduced. Information provided in the call for evidence suggests that unopened inks have a shelf life of 2-3 years and once opened, have a shelf life of 6-12 months. If inks that have been reformulated for the EU are likely to meet the requirements of the GB

restriction, it may be possible for distributors, tattoo artists and PMU practitioners to purchase compliant inks well ahead of the date from which new requirements will apply in GB, thereby limiting the impact of this transition.

- A GB restriction that matches the EU restriction will make it easier for GB manufacturers to trade with the EU. Inks that comply with the EU restriction can also be exported to non-EU countries providing those countries have less stringent requirements or no requirements on the composition of inks.

- If certain inks have no alternatives available, or if the costs of producing new compliant inks are too high, manufacturers may have to stop production, and this gives consumers less choice in terms of available ink on the market.

- If tattoo artists lose key pigments, it is possible that some will be prepared to operate “underground” using non-compliant inks purchased via the internet, particularly if they consider this is their only option to retain their livelihood. Information provided in the call for evidence suggests that large numbers of unregistered tattoo artists operate in GB, therefore it is plausible that currently registered tattoo artists may choose to operate as an unregistered artist.

- ECHA (2019a) has assumed that between 30 – 50% of tattoo inks and up to 20% of PMU on the EU market are compliant with the EU restriction. It is unclear if and how much compliant ink exists on the GB market however, ECHA’s assumptions above are used within section 3.5.1.1 on substitution costs in the absence of better information. A key difference between the restriction in the EU and proposed restriction in GB is that there is no national legislation in GB around tattoo inks and PMU therefore it is difficult to determine the true level of compliant inks on the GB market and how these inks meet the requirements of RO1, RO2 and RO3.

- The derogation that has been proposed for 21 colourants is expected to benefit tattoo artists in particular because this will mean that they do not need to lose key pigments. This proposed derogation removes a major concern that industry has expressed with the EU restriction and will therefore make this restriction more acceptable to tattoo artists in GB. It is not known if any of the pigments included in the proposed derogation are used in PMU and whether the derogation will also benefit PMU practitioners.

- While it will not be possible to supply inks that contain the derogated pigments to the EU (because those pigments are or will shortly be restricted in the EU), if such inks are manufactured in GB, these could still be exported to other countries that permit these pigments to be used in tattoo ink and PMU.

- By preventing the use of hazardous substances in tattoo inks, consumers in GB could experience fewer complications if they choose to receive a tattoo or PMU. Reducing the potential for substance related complications could improve the quality of life of consumers that might develop complications and could reduce healthcare burdens relating to the need to treat severe complications.

- However, if the result of the restriction is that compliant inks are of poorer quality meaning that tattoo artists and PMU practitioners need to work over the area of the tattoo or PMU more times in order to achieve the intended effect, this could result in an increase in complications relating to physical damage to the skin as a result of the tattooing and PMU process. A claim was made in information received in response to the call for evidence that inks which comply with the EU restriction are of poorer quality than inks which were available before the restriction was introduced.

- Also, if the outcome of the restriction is to increase the numbers of tattoo artists and PMU practitioners operating from unlicenced premises, this could increase complications due to infections as a result of poor hygiene.

- Given that analytical methods may not be available for every substance that is in scope of this restriction, it may be necessary for enforcement authorities to develop strategies to help identify non-compliant inks.

3.5 Assessment of restriction options

3.5.1 Economic impacts - costs

The costs in this restriction dossier are analysed in full and fall largely to the tattoo and PMU industry with some costs falling to government and/or local authorities and consumers.

The costs generated by the proposed restriction can be split into four main categories:

- **Substitution costs** arise because manufacturers and formulators of ink need to stop production of current inks and begin R&D, testing, reformulation for new compliant inks which are likely to be more expensive. These costs are expected to be passed down the supply chain onto consumers.

- **Enforcement costs** arise as local authorities will need to conduct the relevant administrative processes, testing and checks of new inks on the market to ensure they are safe and meet the requirements of the proposed restriction.

- **Familiarisation costs** arise as all actors in the tattoo inks and PMU industry will need to understand and familiarise themselves with the new rules of the proposed restriction.
- **Non-monetised costs** (loss of consumer surplus) are incurred as manufacturers and/or formulators of inks may stop production of particular inks which would mean they are no longer available on the market, and this means that customers face a loss of choice/colours of ink that can be used in their tattoos/PMU.

3.5.1.1 Substitution costs[63]

In the event the proposed restriction options come into force, tattoo inks that are non-compliant and don't meet the requirements of the restriction would no longer be available. Therefore, the market would have to transition to compliant tattoo inks which tend to have similar or slightly higher market price than non-compliant inks (based on stakeholder interviews). This price difference is seen to reflect the higher costs tattoo ink and PMU manufacturers would incur to comply with the proposed restriction options: research and development costs for manufacturers to develop compliant tattoo inks and PMU, increased testing and labelling costs to ensure compliance with the proposed regulatory requirements and potentially higher costs to procure the necessary purity colourants. These costs are likely to be passed down the supply chain.

The incremental substitution costs estimated to be incurred by downstream users of tattoo ink and PMU as a result of RO1 are about €4.4 million annually during the temporal scope of the analysis (in 2016 values).

The substitution costs are based on the following formulas (ECHA, 2019d):

1. *Volume of ink on the market in year N = (volume of ink on the market in 2016) x (incidence year N / incidence rate[64] 2016)*
2. *Substitution costs year N = (volume of ink on the market in year N) x (share of non-compliant ink) x (price difference between compliant and non-compliant ink)*

[63] This section is based on and borrows heavily from ECHA 2019c and ECHA 2019d.
[64] The incidence rate refers to the incidence of people getting tattooed in a particular year. See appendix 6.1 for more information on incidence rates.

The estimation is based on a number of inputs and assumptions made by ECHA which can be found in Appendix 6.2.

As RO2 imposes less strict requirements than RO1, it is anticipated that more tattoo inks and PMU on the market are already compliant with RO2. Therefore, RO2 substitution costs are likely to be lower.

SEAC (ECHA, 2019d) write that it is difficult to quantify the differences in substitution costs between RO3 and RO1 or RO2. Overall, RO3 has lower limits in comparison to RO2, therefore, it can be expected that it would lead to the reformulation of more tattoo inks in comparison to RO2. RO3 has some higher concentration limits (e.g. for CMRs) but lower for other (e.g. nickel, cobalt) in comparison to RO1 with the overall effect on costs being unclear. The difference in the mechanism to update the future scope of the proposed restriction has unpredictable effects in terms of substitution costs difference between RO1, RO2 and RO3.

The substitution costs that fall to GB under RO1 have been calculated following a similar approach to ECHA[65]. As part of the substitution process, manufacturers/formulators of ink will need to reformulate current inks to ensure they meet the requirements of the proposed restriction. It should be noted that costs provided in this analysis are estimates which are based on ECHA's assumptions and data from ECHA's restriction dossier which are extrapolated to this analysis for GB therefore they should be understood to be approximate figures and should be seen as illustrative. Moreover, it is possible that costs will decline over time across the appraisal period as certain aspects such as R&D or testing will not need to be carried out each year. However, it also can be assumed that in the long-term, economies of scale may arise whereby some of the productive capacity currently put into producing non-compliant ink will be shifted to producing compliant ink, thereby increasing the supply of compliant ink and reducing the cost. It is uncertain whether or when these effects may be seen but it is likely that they will be there in the longer term if a restriction is imposed and all inks on the market are compliant inks. The reduced cost may be seen over time across the appraisal period and this uncertainty to some degree is covered as part of the discounting.

The substitution costs for GB under RO1 have been calculated using the following methodology:

- Formula 1 above calculates the volume of ink on the EEA31 market, and this has been applied to this analysis to estimate the volume of ink on the GB market. This part of the calculation adopts a top-down approach where the UK

[65] An alternative top-down approach was explored for the substitution cost calculations. Further details on this can be found in appendix 6.2.

population as a proportion of the EEA31 population is calculated (UK population/EEA31 population for a given year ~13%) and the GB population as a proportion of the UK population is calculated (GB population/UK population for a given year ~97%). These proportions are applied to the volume of ink on the EEA31 market to understand the estimated volume of ink on the GB market. ECHA (2019c) has calculated low, central and high estimates for the volume of ink on the EU market for the years 2016, 2021, 2040 and the average of 2021-2040. The central GB estimate for this latter average figure (2021-2040) is used in the substitution cost calculations for GB, and it is kept constant across the appraisal period. This is approximately 22,100 litres of ink on the GB market. Of that ink, some is used for tattoos and some for PMU. To understand how this is split, the total volume of ink is apportioned for tattoos and PMU based on figures provided in table 3.2.2. It is assumed here that the volume of ink on the GB market is proportional to the volume on the EU market. For tattoos this is approximately 93% and for PMU this is approximately 7%.

- Formula 2 is then used to estimate the substitution costs falling to GB under RO1. Part I above (volume of ink on the GB market) is plugged into the calculation and multiplied by the share of non-compliant ink and the price difference between compliant and non-compliant ink.

- Information on the share of non-compliant ink on the GB market and the price difference between compliant and non-compliant ink was gathered through a call for evidence exercise by the HSE. Respondents were asked about the level of ink on the GB market that they estimate to be compliant with the EU restriction as well as how the cost of compliant inks compare with inks currently used on the GB market. For the former question, answers ranged from 0-95%, with lots of answers lying in the middle. Given the broad range of answers, it is difficult to ascertain the true level of compliant tattoo ink and PMU on the GB market. For this reason, the assumptions used by ECHA for tattoo inks (30 – 70%) and PMU (0 – 20%) will be used for the substitution costs in GB in the absence of better and more precise data but this is highly uncertain and therefore should be seen as illustrative. 50% and 10% are used as central estimates for non-compliant tattoo ink and PMU respectively.

- The question on price difference between compliant and non-compliant inks also received varying answers. Some respondents said compliant inks would be more expensive compared to current inks used and other respondents said they would be similar in price. A large number of respondents did not answer the question. Due to the lack of consistency in answers, the assumptions used by ECHA on price difference between compliant and non-compliant inks will also be applied to GB. ECHA (2019c) has included sensitivity scenarios in

their analysis for the price difference which presents a central (15% for tattoo inks and 20% for PMU) and high (30% for tattoo inks and 40% for PMU) scenario for the price difference. As part of the sensitivity analysis in section 4.2 and appendix 6.6, a no price difference (between compliant and non-compliant inks) scenario is also included in this analysis. The price difference assumptions are applied to the current price of ink on the market – this information was gathered through the call for evidence whereby a number of respondents said the current price of ink on the GB market was approximately £15 for 30ml. By extrapolation of this figure, we can estimate the baseline cost for one litre of ink to be £500. The price difference for tattoo ink is £500 *15% = **£75** and for PMU it is £500 * 20% = **£100** The assumptions and estimates above are inputted into the substitution cost formula (formula 2) presented by SEAC (2019c) to understand the substitution costs falling to GB under RO1 for 2021/22:

= (22,100 * 93% * 50% * £75) + (22,100 * 7% * 10% * £100)

Substitution cost in 2021/22 = £789,000

Substitution costs for GB under RO1 across the appraisal period can be found below in table 3.5.1.1.

As with SEAC's (ECHA, 2019d) conclusions, it is likely that costs under RO2 are lower than RO1 due to requirements being less strict and more inks on the GB market already being compliant with RO2. It is however difficult to provide a quantitative comparison in costs between RO1, RO2 and RO3.

As mentioned earlier, there is a high degree of uncertainty around these costs. This uncertainty is explored further in the sensitivity analysis which looks at various scenarios which alter the volume of ink on the market, the share of non-compliant ink and the price difference between compliant and non-compliant ink.

Table 3.5.1.1: Substitution costs for RO1, 2021/22 – 2040/41, £ thousand.

Substitution costs	**2021-22**	**2022-23**	**2023-24**	**2024-25**	**2025-26**	**2026-27**	**2027-28**	**2028-29**	**2029-30**	**2030-31**	**2031-32**	**2032-33**	**2033-34**	**2034-35**	**2035-36**	**2036-37**	**2037-38**	**2038-39**	**2039-40**	**2040-41**	**Total Cost (PV)**
Central scenario	789	783	773	761	750	740	727	715	703	691	679	667	654	642	630	619	607	595	583	572	**13,680**

3.5.1.2 Enforcement costs[66]

To estimate the costs of enforcement, ECHA contacted jurisdictions with national legislation i.e. Germany, Norway and Sweden. Appendix 6.3 provides details from ECHA (2019c) around enforcement of current national legislation in the EU.

ECHA estimate the total incremental enforcement costs to be incurred over the temporal scope of the analysis at €235,000 annually. This is likely an overestimation as it assumes that the same level of enforcement efforts will be required over the entire temporal scope, while in reality enforcement efforts decline with industry compliance, and industry compliance improves as familiarity of the restriction requirements increase over time.

SEAC (ECHA, 2019d) note that the available information does not allow for a quantitative differentiation of enforcement costs between RO1, RO2 and the RO3. Under a strictly "fixed enforcement budget" approach the options would have the same costs for enforcement authorities. However, assuming stricter concentration limits would lead to higher analytical testing and development costs, in the absence of a "fixed enforcement budget" approach, testing costs for enforcement authorities could be expected to be the highest for RO1, followed by RO3 and RO2. Testing and administrative costs for industry can be expected to follow a similar pattern.

In GB, there is no specific national legislation in place regulating tattoo inks and PMU. Therefore, local authorities across England, Scotland and Wales are focused on hygiene and infection control, rather than the health risks associated with certain substances in tattoo inks and PMU. As a result of the proposed restriction, any additional enforcement activities relating to checking the composition of inks in workplaces will be carried out by local authorities[67]. There is no GB specific historical cost to compare or use as a proxy for this analysis so, ECHA's enforcement cost for the EU has been extrapolated and apportioned to fit the geographical scope of GB.

The enforcement cost estimates should therefore be seen as approximate figures as they are illustrative. Further information on enforcement activities will be sought at public consultation stage.

Using the figures provided by ECHA, a top-down approach can be adopted to understand the estimated costs to be incurred by enforcement authorities in GB as a result of the proposed restriction on substances in tattoo inks and PMU. ECHA have calculated their substitution cost to be approximately €235,000 annually which includes analytical testing and administrative costs. This analysis calculates the GB

[66] This section is based on and borrows heavily from ECHA 2019a and ECHA 2019c.
[67] HSE is the enforcing authority where tattooing or PMU is carried out in domestic homes.

population as a proportion of the EEA31 population and applies this to ECHA's enforcement costs to estimate the enforcement costs to be incurred by GB.

The enforcement costs for GB under RO1 have been calculated using the following methodology and assumptions:

i. ECHA's annual enforcement cost of €235,000 is adjusted to exclude the 4% discount rate, where t=0 in year 1 [(€235,000/(1/1.04^t) = €285,913)]

ii. This figure is then converted to GBP using the exchange rate[68] for 2016 (€285,913 = £245,501)

iii. Figures are then inflated from 2016 prices to 2021 prices using HMT GDP deflators (2016 prices: £245,501 → 2021 prices: £274,318)

iv. Costs are discounted using the HMT 3.5% discount rate, where t=0 for year 1 [(£274,318 * (1/1.035^t) = £274,318)[69]

v. The UK population as a proportion of the EEA31 population is calculated (UK population/EEA31 population for a given year ~13.4%)

vi. The GB population as a proportion of the UK population is calculated (GB population/UK population for a given year ~97.2%)

vii. Discounted figures from iv are multiplied by the UK population as a proportion of the EEA31 population (~13.4%) to calculate the UK enforcement costs (£274,318 * 13.4% = £36,881)

viii. To calculate GB enforcement costs, vii is multiplied by ~97.2% and this estimates costs for the central scenario (£36,881 * 97.2% = £35,837)

The costs mentioned above are calculated for the year 2021/22. Costs have been calculated over a 20-year appraisal period in this analysis - this approach was also used by ECHA as this is a suitable timeframe to ensure full cost realisation.

The estimated enforcement costs for GB under RO1 are approximately £36,000 in 2021/22 with costs across the appraisal period presented in table 3.5.1.2. Costs are presented in 2021/22 prices and apply the HMT discount rate of 3.5%.

In the context of this analysis for GB, it can also be assumed that enforcement costs are highest under RO1 (illustrated in table 3.5.1.2), followed by RO3 and RO2. It is

[68] Exchange rate is available at: https://www.exchangerates.org.uk/GBP-EUR-spot-exchange-rates-history-2016.html

[69] The HMT discount rate of 3.5% is applied to costs across the 20-year appraisal period and costs provided in the methodology explained above are for year 1, hence year 1 costs appear not to be discounted as time (t) is zero in the first year.

difficult to provide a quantitative differentiation of enforcement costs between the three options, and this therefore means that these figures are highly uncertain and should be seen as illustrative.

As with ECHA's assumptions, enforcement cost estimates are based on a fixed enforcement budget but are expected to reduce across the appraisal period as industry becomes compliant. This is not demonstrated in the cost estimates as it is unknown how much costs will diminish over the appraisal period; therefore, costs carry a degree of uncertainty so should be seen as illustrative as they are likely to be an overestimate.

Table 3.5.1.2: Enforcement costs for RO1, 2021/22 - 2040/41, £ thousand.

Enforcement costs	**2021-22**	**2022-23**	**2023-24**	**2024-25**	**2025-26**	**2026-27**	**2027-28**	**2028-29**	**2029-30**	**2030-31**	**2031-32**	**2032-33**	**2033-34**	**2034-35**	**2035-36**	**2036-37**	**2037-38**	**2038-39**	**2039-40**	**2040-41**	**Total Cost (PV)**
Central scenario	36	36	35	35	34	34	33	32	32	31	31	30	30	29	29	28	28	27	27	26	**623**

3.5.1.3 Familiarisation costs

Familiarisation costs refer to the costs associated with understanding the new legislation and restriction around tattoo inks and PMU. Familiarisation costs will fall to various groups in the tattoo inks and PMU industry including manufacturers, distributors, importers, exporters, tattoo artists and PMU practitioners.

In order to estimate these costs, data for the number of people in the tattoo and PMU industry, their hourly wage and the average time it would take for them to understand the proposed restriction must be obtained. Due to data limitations, it has been extremely difficult to obtain this data at a granular level and with the view to remain proportionate given the size of this cost, the figures should be understood to be approximate figures as they are illustrative.

The familiarisation costs have been calculated using the following formula:

Familiarisation cost = (average time taken to familiarise with the restriction) x (hourly wage) x (number of people affected in industry)

The high-level methodology used to calculate the familiarisation costs for GB under RO1 is presented below. Further details on methodology, assumptions and data are explained in Appendix 6.4.

i. The average time taken to familiarise with the new rules – this estimate is dependent on how long the legislation document is (in pages) and the actor's pre-existing knowledge of the restriction.

ii. The hourly wage is taken for actors in the tattoo inks and PMU industry. The hourly wage data has been estimated using the ONS Annual Survey of Hours and Earnings (ASHE)[70]. Wage differs between actors and across geographical region within GB, therefore some wage data has been taken from other relevant sources.

iii. The number of actors in industry is unclear as granular data is not yet available for each of the actors mentioned above. Therefore, in its absence, estimates have been produced based on stakeholder information and available data which has been extrapolated to estimate the number of actors in GB industry.

[70] Available at: https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation2digitsocashetable3

iv. The three parameters (i, ii, iii) are multiplied together to give an estimated familiarisation cost. Low, central, and high estimates are produced to account for the great degree of uncertainty around both the data and assumptions used.

The familiarisation costs for GB under RO1 are approximately £69,000 - £2,551,000 with a central estimate of £867,000. This is a one-off cost presented in 2021/22

prices, but it is expected to be incurred in the year that the restriction is implemented[71]. Full details on the familiarisation cost calculations can be found in Appendix 6.4.

The familiarisation costs in this analysis have been estimated for RO1 however, RO2 and RO3 will still require industry to understand the proposed restriction, therefore it is expected that familiarisation costs under RO2 and RO3 would be similar to RO1. It is difficult to provide a quantitative differentiation between options.

3.5.1.4 Non-monetised costs

The monetised costs mentioned in earlier sections fall to various groups in the tattoo inks and PMU industry but there are also some non-monetisable costs that are incurred by society and consumers of tattoo inks and PMU.

The proposed restriction will lead to a loss of pigment colours available on the market and potential discontinuation. This is known as the loss of consumer surplus as consumers will have less choice of ink colours available for their tattoos and PMU.

The performance and quality of tattoo inks and PMU on the GB market may be impacted by the proposed restriction as a result of the need to reformulate these products with other ingredients which may not have the functional performance of the original substances in the inks. It is possible that the performance and quality of the corresponding tattoo inks and PMU produced following the restriction is lower than the tattoo inks and PMU produced prior to the restriction.

[71] Although familiarisation costs are one-off and are expected to be incurred in the year that the restriction is implemented, costs are apportioned across the appraisal period in section 3.5.5.2 cost-effectiveness and section 3.5.5.3 breakeven to ensure that these measures have not been skewed.

3.5.2 Other impacts

3.5.2.1 Social and distributional impacts

a) Tattoo ink and PMU formulators

Regulations of this scale can be challenging for smaller businesses. Many formulators are small (10-50 employees) or micro (less than 10 employees) enterprises on the basis of number of employees. Few can be considered truly global scale companies, although via Internet direct sales their products can reach all parts of the world. As such, many companies may lack the resources to keep abreast on regulatory issues or to invest in extensive research and development and hazard and risk investigation of their products. The highest regulatory burden from the proposed restriction options would likely be on micro or small businesses which do not have compliant inks. Those most likely are located and conducting business in Member States and international jurisdictions without legislation on the chemical composition on tattoo inks and PMU and where the tattoo industry and cosmetic practitioners are not well organised. It is likely that those companies that currently do not have compliant tattoo inks (and to a lesser extent, PMU) on the market would likely bear the lion's share of these costs. It is expected that these additional costs would not lead to closures and lay-offs. To date, industry concerns have been primarily associated with inconsistencies in ResAP recommendations, their different interpretation nationally and diversity in analytical methods used, leading to different treatment of the same products in different Member States, all with national legislations based on ResAP. Larger, US brands are also particularly concerned with the counterfeiting of their products. The establishment of an EU-based registry may assist with this problem.

b) Tattoo artists

The proposed restriction options are not expected to impact employment or the ability of tattoo artists to perform their profession and art, although it is possible that the available colour palette could become less diverse in the short term. Not all artists work with a broad palette of colours (usually those specialising in realistic tattoos primarily do so), although with experience tattoo artists grow accustomed and develop preferences for particular colour (or brand) due to its brightness, permanence, viscosity, healing properties, etc. As a result of RO1 or RO2, many artists would have to ensure that the inks they continue to use are compliant with the regulatory requirements. This will be of particular importance for those who buy directly from manufacturers or internationally, via internet based resellers, as opposed to EEA31-based distributors, some of whom reportedly take measures to ensure sales of safe, genuine brands. The latter may be challenging in particular for home-based tattoo artists who are not often members of associations, are not engaged in industry information exchanges on regulatory issues, and sometimes

cannot purchase from distributors who may sell to registered artists only. In general, participation in industry associations varies greatly in EEA31 and so does the level of engagement on regulatory issues.

c) Pigment manufacturers

The tattoo ink industry is a small market segment for large pigment manufacturers, therefore any changes in the tattoo ink business would likely not lead to significant impacts on the pigment industry. Currently, another concern of some tattoo manufacturers is having to purchase pigments using separate legal name as some pigment manufacturers do not sell to the tattoo ink industry. It is possible that as a result of the more transparent requirements for tattoo inks and PMU, more pigment manufacturers may increase their sales to the tattoo industry.

The excerpt above has been produced by ECHA (2019c) for their restriction dossier. It describes the social and distributional impacts faced by actors in the EEA31 within the tattoo inks and PMU industry. Similar impacts can be expected to be seen in GB as a result of the proposed restriction.

The Better Regulation Framework has defined small businesses as those employing between 10-49 employees and micro businesses as those employing between 1-9 employees[72]. In the context of substances in tattoo inks and PMU, we can assume that a large proportion of industry is comprised of SMBs[73].

There are thought to be a very small number of ink manufacturers in GB and data on their size and characteristics will be sought as part of the public consultation.

Based on responses from the GB call for evidence, participants have said that there are no alternatives for certain pigments used in tattoo inks and PMU, namely Pigment Blue 15:3 and Pigment Green 7 (See Section 3.3. on risk management options and the summary section for full details). Participants were asked what outcomes they would expect if a restriction were to be enforced in GB and the answers received included a loss of revenue, clientele, innovation, no more full colour tattoos, bankruptcy, unemployment, and some suggested that artists may operate underground.

This will be explored further at public consultation stage.

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[72] Small and micro business definitions can be found here The Better Regulation Framework (publishing.service.gov.uk) and here RPC_Small_and_Micro_Business_Assessment__SaMBA___August_2019.pdf (publishing.service.gov.uk)

[73] It can be assumed that a large proportion of the tattoo inks and PMU industry is comprised of tattoo artists. Tattoo artists provided information to HSE as part of the call for evidence - they were asked about the size of their business and large majority stated that they were SMBs.

3.5.2.2 Wider economic impacts

A significant share of tattoo inks (about 70-80%) are imported from jurisdictions without regulation on the content of tattoo inks. Import of PMU is lower: 20-30%. (JRC, 2015b) Therefore, it is possible that as a result of the proposed restriction options, some imported products may no longer be available. By the same token, some EEA31 manufactured tattoo inks and PMU also may not be available. From that perspective it is not expected that the proposed restriction options would distort the trade balance, but no historical information is available about the trade in tattoo inks and PMU to ascertain their impact on extra-EEA31 trade (although any historical information would be difficult to interpret due to the inconsistent application of ResAP recommendations across EEA31.)

Specific data for GB imports of tattoo inks and PMU is unavailable[74], but as mentioned earlier in section 3.2, a large proportion of ink on the UK market is imported from the US and China so it can be assumed that a large proportion of tattoo inks and PMU on the GB market is imported from jurisdictions without regulation on the content of ink. Therefore, as with ECHA's (2019c) assumptions, it is possible that some imported tattoo inks and PMU into GB may no longer be available.

3.5.3 Human health and environmental impacts

3.5.3.1 Human health impacts

a) Introduction

Potentially any component in tattoo or PMU ink could cause an adverse reaction either at the site of the tattoo or PMU or systemically. This includes colourants. Although it is important that a certain amount of colourant remains at the site of the tattoo or PMU, information reported by Lehner *et al*., (2011), Engel *et al*., (2010) and Engel *et al*., (2008) suggested that good visibility for the tattoo or PMU is still possible when more than two thirds of the colourant that was initially inserted into the skin has been lost from the tattoo or PMU.

Although adverse reactions can appear within days or weeks of getting a tattoo or PMU, it can take months or years for an adverse reaction to become apparent. It is known that colourants can break down over time because of the effects of solar radiation releasing substances that were not necessarily present in the tattoo ink or

[74] See section 3.2 for estimates on the manufactured, imported and exported volume of ink on the GB market.

PMU at the time it was inserted into the skin. Macrophage and enzyme induced degradation can also occur over time. The time lag between exposure and the development of reactions, variability of the components of inks and possible contaminants that could be inserted into the skin, possible degradation of colourants and other components and the lack of registries and epidemiological studies mean that it is very challenging to pinpoint which components are causing the majority of adverse reactions.

b) Adverse effects related to the chemical composition of tattoo inks and PMU

Adverse effects caused by the chemical components of tattoo inks may be classified in a number of ways. For the purpose of this dossier, adverse effects are grouped here as: non-infectious inflammatory, systemic and clinical complications, reprotoxic effects. A summary of the most common effects are described here, but further information can be found in Annex D in ECHA (2019c), attached as Document 1.

As this dossier focuses on the risks of chemical substances found in tattoo inks, infection risks, contraindications of tattooing and adverse effects from procedures to remove tattoos (other than those that may arise from the decomposition of substances in tattoo inks as a result of the removal process) are not covered.

Non-infectious inflammatory reactions

Non-infectious, inflammatory reactions are the most commonly reported adverse effect. Individuals who undergo a tattoo procedure may experience discomfort, swelling, pruritis and erythema during the procedure and after. This acute reaction is usually a result of the healing phase and can last 1-4 weeks, with superficial crusting and induration taking place in the tattooed area. In principle, this is an aseptic process, but it is recognised that bacterial contamination may cause similar inflammatory reactions. It is possible that these symptoms can persist and/or develop into chronic issues.

A clear classification of the non-infectious inflammatory reactions has proven challenging owing to variation in the reports by clinical appearance versus the histological pattern (Huisman *et al.,* 2020). In the case of this dossier, the reactions are classified as allergic or non-allergic.

Allergic

Allergic reactions are an abnormal immune response to a substance (allergen) that does not normally cause a reaction (Papameletiou *et al.*, 2003). Sensitisation, or an initial exposure to the allergen is required; subsequent contact with the allergen then results in a broad range of inflammatory responses. Diagnosis of allergic reactions, specifically dermatitis, may involve observing clinical manifestations and rarely, a

positive patch test to a specific substance.

According to Kluger, allergic reactions to tattoo pigments are the most common complication observed. They make up the majority of all adverse effects. Symptoms of allergic reactions are described as tender, swollen, pruritic, and infiltrate the colour (Kluger, 2019). These effects can range from minor with a mild degree of swelling to strong keratinisation and an ulcerating appearance. Allergic reactions may be grouped based on clinical appearance - patterns such as plaque-like, hyperkeratotic and ulceronecrotic.

Plaque-like presentations are characterised by thickening and elevation in tattooed areas with the problem colour. They may be scaly (eczematous) or smooth (lichenoid). This pattern is commonly associated with red ink. Hyperkeratotic patterns also have thickening of the skin that resembles sandpaper, but with a flat surface that is able to ulcerate or necrotise; it could be considered a variant of the plaque-like pattern but with a more excessive epidermal reaction (Silvestre and González-Villanueva, 2019).

Ulceronecrotic patterns are aggressive inflammatory reactions which result in ulceration in areas with the allergen ink. Severe dermal inflammation is followed by rejection of dead tissue which creates an ulcer. Ulceration can affect the dermal layer and may extend deeply into the dermis towards the subcutaneous fat layer. Necrosis can extend into deep muscle tissue and lymph nodes where the pigment migrates, potentially provoking vasculitis, delayed wound healing and bullous reactions. All these patterns can progress to a final stage with a loss of pigment, colour change and scarring (Serup *et al*. 2015).

Lichenoid and granulomatous inflammation may be caused by allergy, presenting with polygonal papules and plaques in the former, and firm indurated nodules in the latter. This reaction is mainly reported in red ink. Although granulomatous reactions are used in literature, the term is solely histological and may have a different underlying diagnosis. In particular, granulomatous inflammation has been observed as a precursor to systemic disease, including sarcoidosis and uveitis (Weiß *et al.,* 2020).

Photosensitivity is an immune reaction triggered by sunlight. Some reactions include solar urticaria and polymorphous light eruption, which is characterised by an itchy eruption on patches of sun-exposed skin. They are associated with darker coloured tattoos such as black, red and blue; it is thought that red colours in particular are more frequently associated with photosensitivity, indicating that their photochemical decomposition may play a role in this type of reaction (Serup *et al.,* 2016).

Other urticarial-like reactions may occur in response to external factors (e.g. heat, stress, activity), but these are less frequently reported and it is not known how such reactions relate to the composition of tattoo ink and PMU. In the literature, red and nuances of red (e.g., purple and violet) are the most common colours involved in

allergic reactions, but reactions have been described with almost all colours except white. In a study by Serup *et al*. (2016), allergic reactions to red and red nuances comprised 85% of all allergic reactions.

Non-allergic

The non-allergic reactions that can be associated with chemical composition include papulo-nodular, lymphopathic and neurosensory reactions.

Papulo-nodular reactions are associated with black ink (Serup *et al*., 2016). This clinical pattern is the appearance of round or elongated papular or nodular thickening on sections of the tattoo with high concentrations of pigment. It is thought that these elevations are an agglomeration of pigment particles, which the skin encapsulates as a foreign body to prevent uptake into the body. The basement membrane beneath the epidermis holds most of the material back in the dermis, but scratching may release these agglomerations and allow the skin to heal (Serup *et al*., 2015). Pigment overload was noted in 42% of papulo-nodular reactions, suggesting that introducing foreign material may trigger this reaction. It should be noted that pigment overload could be caused by a technical error by the tattoo artist, meaning that this reaction type may not be due to the chemical composition itself (Huisman *et al*., 2020).

This type of reaction may have the histology of inflammation and foreign body reaction, granulomatous inflammation or sarcoidosis granuloma.

Other less common non-allergic reactions associated with tattoo pigment exposure includes neurosensory (persistent discomfort, itching, numbness at the site) effects, lymphopathic and pseudolymphomatous reactions. These are further explored in Annex D (ECHA 2019c).

Systemic or general clinical complications

Systemic effects are thought to be associated with the metabolism and diffusion of tattoo inks throughout the body. Clear evidence indicates that pigments are transported to local and regional lymph nodes of humans (Schreiver *et al.,* 2015) and in the livers of animals (Sepehri *et al.,* 2017a). It is unknown whether other organs are targets for deposition of pigments.

Although some substances historically present in tattoo inks have hazard classifications of STOT RE and STOT SE, indicating their acute or chronic toxicity to various internal organs, it is uncertain whether following tattooing procedures the human body is exposed to these substances sufficiently to lead to an effect clearly associated with exposure to tattoo inks. The association between organ toxicity and tattoos has not been confirmed by well-designed animal studies.

Annex B, section B.8 in ECHA (2019c) describes some of the systemic reactions that

can be associated (to a various degree) with the chemical composition of tattoo inks and PMUs. This includes sarcoidosis, eczema and other skin conditions.

Cancer

Following a recent literature review, Huisman *et al*. (2020) concluded that it is currently unclear whether tattoo inks may induce skin or visceral tumours, even though many substances in tattoo inks and their degradation products are classified as mutagenic or carcinogenic. This includes PAHs in black pigments and PAAs in colour pigments. Furthermore, the situation is complicated by the changing composition of inks over the years. For instance, early reports suggested that red inks resulted in the most complications, yet authors suggested this could be attributed to the past use of mercury sulphide in inks (Paprottka *et al*., 2017). A review of skin cancers on tattoo sites found 64 reported cases between 1938 – 2017 (Paprottka *et al.,* 2017). Cases were reported in both sexes, with an age range of 9 – 79 years old[75] across the US and EU. Of these cases, the predominant type of cancer was malignant melanoma (21 cases), occurring most commonly on black/dark blue coloured tattoos. For the sake of analysis, blue and black inks were linked together. Twenty cases of keratoacanthomas occurred on red tattoos. It is possible that these cases might have been attributable to pre-existing conditions or external factors (e.g., sunlight exposure), rather than the inks themselves. The author considered that it remained unclear whether there was an association between these inks and the occurrence of skin cancers. Adubu *et al*., (2019) re-examined this data plus two additional publications and reported basal cell carcinomas on the sites of tattoos in thirteen patients between 1976 – 2019, originating within mostly black and blue tattoos.

Other forms of cancer associated with tattoo procedures, excluding skin cancer, have not been widely reported in medical literature. Substances that have been inserted into the skin in tattoo ink or PMU can be cleared by the body to the lymphatic vessels and lymph nodes, raising questions around whether the substances in tattoo inks can lead to lymphatic cancers. A study on the association between lymphatic cancer risk and tattoos found no significant increase in multiple myeloma or Non-Hodgkin's myeloma in tattooed patients (Warner *et al.,* 2020).

There are no well-designed animal studies that examine the link between tattoo-ink exposure and cancer. Recent studies (Annex B, section 5.6 ECHA (2019c) for details) on tattooed mice are difficult to interpret; time spans, the number of animals used and

[75] The report which featured a 9-year old patient (Sharlit *et al.,* 1938) was an accidental exposure, where an indelible ink pierced the skin. All other reports in Paprottka *et al.,* (2017) where age was a reported measure were in adults with deliberate exposure to the ink. It should also be noted that substances used in indelible inks may not necessarily be present in tattoo inks, due to their different purpose.

the differences between murine and human skin are limitations to the studies (Lerche *et al.,* 2015), (Lerche *et al.,* 2017), (Sepehri *et al*., 2017b).

In summary, no conclusion on the role of tattoo inks in the development of cancer can be made.

Reproductive and developmental effects

There is no information on the potential reproductive effects of the use of substances that are toxic to reproduction in tattoo inks. Similar to systemic and carcinogenic effects, there is a theoretical possibility for constituents of tattoo inks to enter the blood stream and impact other organs and the unborn foetus. Some of the chemicals potentially present in tattoo inks (heavy metals, amines, etc.) can be transferred via the human placenta. There is limited data regarding breast milk. Overall, the potential for systemic distribution of tattoo constituents and by-products via circulation and therefore, possibly through the placenta during pregnancy or in the milk, is not known (Kluger, 2015b).

c) Incidence and prevalence of adverse effects

It is difficult to estimate the true overall incidence and prevalence of adverse effects to chemical components of tattoo inks and PMU because no registry and epidemiological studies are available. Furthermore, direct association with the effects and specific substances is extremely challenging because of the variability in the composition of inks, pigments and contaminants that can be inserted into the skin. Currently there are no publications that describe specific chemicals causing health effects. Few patients will consult their physician regarding skin reactions, opting instead to return to the tattoo parlour (Høgsberg, *et al*., 2013). In addition, many adverse effects can have varying latency periods and other confounding variables that make it challenging for clear diagnosis of causation.

Tables 3.5.3.1a and 3.5.3.1b give an overview of the most important prevalence studies of tattoo related adverse effects in countries in the EU. Further information on these studies are included in Annex D (ECHA, 2019c).

Table 3.5.3.1a. Prevalence of tattoo complaints and complications in the general population

Study	Prevalence	Type of effects	Study population
Renzoni *et al.* 2018	3.3% (32/972)- complications and/or mild complaints Of these: 12.1% consulted a dermatologist 9.2% consulted a general practitioner 27.4% consulted their tattoo artist	Self-reported reactions included pain (39.3%); swelling, blisters, granuloma (27.7%); dermatitis, eczema, itching (26.7%); skin thickening (24.4%); allergic reactions (17.5%). Other reactions included pus, bleeding, dizziness, headache, scabbing and fever.	7608 Italian people as a sample of the general population, interviewed online. 12.8% (972/7608) were tattooed.
Kluger, 2016	In at least one of their tattoos: 42.6% - with a reaction (180/420) Transient itching (45.7%) and swelling (57%) Permanent itching (1%) and swelling (4%) During/after sun exposure: 14%- itch (14%) and swelling (23%)	Transient or permanent itching and swelling; sun induced itching and swelling; allergic reactions (undefined); infection; skin cancer	448 tattoo artists, (members of the French Tattoo Union), self-reported online

Study	Prevalence	Type of effects	Study population
Hutton Carlsten & Serup, 2013	Of 144 tattooed individuals, 42% (60/144) - complaints (after initial healing): Of these: 52% (31/60) sun-induced reactions 48% (29/60) other reactions independent of sun 1.4% (2/60)- complications needing medical assistance	Sun-induced reactions were swelling, itching, stinging, pain, redness; some had more than one of these issues. Reactions independent of sun were swelling, (including after alcohol and consumption of certain food), heat-induced reactions, tenderness to cold and allergic reactions.	467 sunbathers on beaches in Denmark
Klügl *et al.*, 2010	67.0% of participants had immediate adverse reactions following the tattoo (2285/3411) 8.0% still had reactions after 4 weeks (273/3411) 7.0% systemic reactions directly after tattooing (239/3411) 6.0% persistent ongoing reactions (205/3411) 3.0% other issues	Most frequent problems were immediate reactions such as bleeding, crusts, itching, oedema, pain and infection. Systemic reactions directly after tattooing included dizziness, headache, nausea and fever. Persistent reactions included intermittent oedemas, papules, itching and skin elevation.	3,411 German-speaking tattooed persons online: 93% - German (evenly distributed), 6% - Austrian, 1% - Swiss.

Study	Prevalence	Type of effects	Study population
		Other issues were psychosocial problems and light sensitivity.	

Table 3.5.3.1b. Prevalence of tattoo complaints and complications in clinical settings

Study	Prevalence	Type of effects	Study population
Van der Bent *et al.,* 2021	Of complications: 51.8% allergic (162/308) 18.2% chronic inflammatory black tattoo reactions (56/308) 17.2% other inflammatory reactions and miscellaneous reactions (53/308) 2.6% autoimmune dermatoses (8/308) 0.6% neoplasms (2/308) 8.7% other complications and complaints unrelated to the composition of tattoo inks (27/308)	Allergic reactions to red, blue, yellow and green inks- characterised as plaque type, hyperkeratotic and ulceronecrotic. Chronic inflammatory tattoo reactions (black ink) included sarcoidosis (systemic), non-sarcoidosis and tattoo-associated uveitis. Other inflammatory reactions included irritative white tattoos and urticaria. Miscellaneous reactions were related to photosensitivity and removal.	301 patients with 308 tattoo associated complications in a tattoo clinic (Amsterdam University Medical Center, The Netherlands)

Study	Prevalence	Type of effects	Study population
		Neoplasms were all basal cell carcinoma. Other complications were related to infection, henna or aftercare.	
Serup *et al.*, 2016	Of complications: 56% - inflammatory reactions (277/493) 17% - miscellaneous (82/493) 27% - complications unrelated to tattoo ink composition (134/493)	Inflammatory reactions were grouped by allergic, non-allergic and urticarial. Plaque elevation (32.2% of all complications), excessive hyperkeratosis (3.7%) and papulonodular reactions (13%) were frequently observed. Miscellaneous effects were grouped into local, regional and systemic. Sarcoidosis (4.7%), neurosensitivity (2.2%) and keratocanthomas (0.6%) were observed. Those unrelated to tattoo ink	405 patients with 493 tattoo complications in a tattoo clinic (Bispebjerg University Hospital, Denmark, 2008-2015)

Study	Prevalence	Type of effects	Study population
		compositions included infection and psychosocial effects.	
Høgsberg *et al.*, 2013	Early complaints (< 3 months after tattoo): 14.9% (23/154) Later complaints (> 3 months after tattoo): 26.6% (41/154), 3.9% (6/154) had complications in which they consulted a physician Sun induced complaint–15.6% (24/154)	Complaints were related to itching, ulceration, redness, swelling, prolonged healing, fever and malaise, and local infection. Complications were most frequently related to skin elevation and itching.	154 patients with 342 tattoos of a venerology clinic in Denmark
Wollina, 2012	Incidence of 0.02% based on the number of treated patients per year (7/35000)- the actual number of tattooed patients is unknown.	Lichenoid, pruritic, sarcoidal, oedema, systemic, ulceration and infectious (30%) reactions. Mild reactions were excluded.	Patients of dermatology department of Dresden Hospital, Germany (03/ 2001-05/2012)
Kazandjieva & Tsankov, 2007	2.1% with complications (5/234)	Infectious, allergic, and/or granulomatous complications in connection with tattoo pigment	234 patients with tattoos, dermatology clinic in Bulgaria

The EU dossier suggests that on average 1.8%[76] of tattooed people develop an adverse reaction of severity that requires a doctor's consultation[77]. The studies in tables 3.5.3.1a and 3.5.3.1b all took place in EU countries – it is expected that the UK is represented in a similar manner to those countries. There is no reason to suspect that the proportion of those in GB undergoing a tattoo or PMU procedure who subsequently require medical attention would be significantly different to that reported for those EU countries. The regulation of tattooing practices (e.g., licensing, hygienic requirements, compliance with CoE ResAP recommendations, etc.) has increased in the last ten years. Therefore, it can be expected that the prevalence of tattoo complications without any regulations would be higher. On the other hand, the preceding sections demonstrated that the onset of chronic tattoo reactions as well as other health effects can occur from weeks to decades after the tattoo procedure; therefore, the statistics above may not yet reflect the advancements in tattoo practices and inks. In the absence of better information, it is assumed that this is a representative rate of tattoo complications. As no long-term studies on tattoo complaints and complications exist, it is assumed that the annual increase of tattoo complications will be the same as the incidence rate of tattoos/PMU in the EU population.

d) Adverse effects linked to tattoo/PMU removal

Tattoo removal may be sought by individuals, either to simply remove the design or as a method of treating chronic symptoms brought on by the tattoo. Non-infectious inflammatory tattoo complications, although rare, can often be persistent and require prolonged treatment for itching, swelling and pain. The chronic nature of the symptoms often means that more invasive treatments may be considered, usually by removal of the tattoo itself.

Most inflammatory reactions will be treated with topical and intralesional therapies (upon exclusion of infection), such as steroids. Oral corticoid and immunosuppressive treatments may be prescribed for allergy and dermatitis. Many chronic reactions are managed under this line of therapy without a need to progress to further treatment, provided the reaction is treated with regular application of topical and intralesional therapy. However, the recurrence of flare-ups is high and there are side effects to the therapies (e.g., skin thinning under topical steroid use).

A popular method of tattoo removal is laser treatment. Laser treatment leads to the

[76] An average of all studies excluding Wollina 2012 because of the different studied population, i.e., clinical patients vs tattooed population

[77] It should be noted that differences between the UK and EU healthcare systems may affect these numbers. For example, an infection may be treated over the counter in the EU with topical antibiotics, but in the UK treatment is reserved after a GP visit.

chemical decomposition of pigment in the body and bears the risk of evoking additional allergic reactions, as well as blistering from heat or pigment disorders.

Laser removal utilises selective photothermolysis, which allows lasers to break down a specific chromophore when hit by a laser beam of a specific wavelength. Newer technology, such as Q-switched lasers, uses the release of a high amount of energy in a short time (nanoseconds or picoseconds), in order to minimise the thermal destruction of neighbouring tissue (Cannarozzo *et al.,* 2019).

The critical aspect concerning laser treatment is the decomposition of pigments and the substances that can form as a result of the laser. These substances may evoke additional allergic reactions. Local and generalized reactions have been reported to occur as a consequence of laser treatment of previously uninvolved tattoos, which support that laser treatment can alter the antigenicity of tattoo pigment (Shinohara, 2016).

Laser therapy is most effective in black tattoos and less effective on colour, although newer lasers are able to adjust their wavelength to remove colours (Bäumler 2017; Mcilwee and Alster, 2018). Laser removal does not always lead to complete removal of the tattoo. Pigments with titanium dioxide and iron oxides (often in PMU inks) help mimic natural skin tones and lighten the shade of ink. It has been reported that laser treatment can lead to the paradoxical darkening of the skin, as these white compounds darken by redox reactions in response to irradiation. This effect would require further laser treatment, often requiring up to 20 treatments to achieve lightening (Mcilwee and Alster, 2018).

Alternative therapies to laser treatment include surgical excision and dermatome shaving. These are less commonly used but may be options when laser removal is unsuccessful. Impacts of these include scarring and changes in pigmentation – further information can be found in Annex D (ECHA, 2019c).

3.5.3.2 Environmental impacts

Not relevant to this dossier.

3.5.3.3 Risk reduction capacity

The aim for this restriction proposal is to avoid the use of substances and limit the presence of substances that are potentially harmful to health in tattoo inks and PMU because the presence of such substances could cause or exacerbate ill health conditions. This is achieved by setting concentration limits for each substance or group of substances that is in scope. These concentration limits do not necessarily reflect a

level of exposure that is guaranteed to prevent ill health, because it is not always possible to identify such levels from the available data. The concentration limits do indicate of levels of exposure that represent a low level of risk and provide a tool for compliance monitoring.

Different concentration limits are proposed under RO1, RO2 and RO3. RO1 includes a shall not contain approach for certain substance categories and concentration limits for other substances and substance categories and potentially will have the greatest risk reduction capacity. RO3 proposes concentration limits for all substances and substance categories that are in scope. In some cases, these concentration limits are lower than the limits proposed under RO1. The least stringent limits are proposed under RO2 therefore, this potentially will offer the lowest risk reduction capacity.

As substances are newly classified for relevant hazards or newly added to Annexes II or IV of the CPR, these substances will be brought into scope of this restriction. In the case of substances that are added to the GB MCL list with relevant classifications, the dynamic link with the GB MCL list that is proposed under all three restriction options will ensure that newly classified substances are brought into scope of this restriction without delay. In the case of substances that are newly added to Annexes II or IV of the CPR, the dynamic link with the CPR which is proposed under RO1 and RO3 will ensure that these substances are also brought into scope of this restriction without delay. RO2 proposes specific assessments for substances which are added to Annexes II or IV of the CPR to determine if those substances should be brought into scope of this restriction.

Each restriction option therefore has the potential to reduce the number and severity of substance related tattoo and PMU complications. However, it is not clear if any of the proposed restriction options will fully eliminate substance related tattoo/PMU complications.

During the preparation of the proposal a group of substances were identified which based on the self-classifications reported to ECHA’s classification and labelling inventory may have relevant health effects. Due to a lack of toxicological data, it was not possible to determine whether these substances should be restricted for use in tattoo inks and PMU. Further details about these substances are available in Appendix D.1 of ECHA (2019c).

It is also foreseeable that reformulation to meet the requirements of the restriction could result in the use of new colourants with sparse toxicological datasets. There is also uncertainty about the biological mechanisms that underly some of the adverse reactions that have been reported. It is therefore not clear if the proposed restriction addresses all causes of substance related tattoo complications. For these reasons, it is not possible to quantify the risk reduction capacity that will be offered by any of the proposed restriction options.

Another factor that should also be considered is the extent to which people may be prepared to use so called “underground” tattoo artists or tattoo artists working overseas to get their preferred design if this cannot be achieved with inks that are permitted to be used under the scope of this restriction. The ability of tattoo artists working underground to use non-compliant inks will be facilitated by the ready availability of tattoo inks via the internet. This possible outcome could limit the success of this restriction in reducing substance related complications and might increase the risk for complications due to poor hygiene during tattooing or inadequate aftercare if the customer does not receive suitable advice from unregistered artists.

3.5.3.4 Benefits

The proposed restriction in GB will offer benefits to consumers and various groups in the tattoo inks and PMU industry. However, it is difficult to quantify benefits as they involve some effect on human health and impact on industry (such as improved reputation, which are explained further in Appendix 6.5). The proposed restriction would reduce the insertion of these substances into the skin and have subsequent implications for the health and wellbeing of consumers and wider benefits falling to industry. The benefits of the proposed restriction have to be assessed within the context of uncertainty since robust estimation of the impacts of substances in tattoo inks and PMU is not currently possible. Where quantitative data closely related to the benefit is available, this has been provided. Otherwise, benefits have been described qualitatively in this assessment. This therefore does not allow for a fully monetised cost-benefit analysis or net present value (NPV) to be calculated in this analysis.

A detailed description of all benefits can be found in Appendix 6.5. This section focusses only on willingness to pay and monetised treatment benefits.

SEAC (ECHA, 2019d) wrote that the benefits of the proposed restriction do not allow for a quantitative differentiation of health benefits between RO1, RO2 and RO3. However, SEAC conclude that the expected benefits of RO1 will be larger due to the higher risk reduction potential in comparison to RO2 and RO3.

It is also difficult to differentiate the benefits for RO1, RO2 and RO3 in this analysis but it is expected that benefits under RO1 are likely to be larger in comparison to RO2 and RO3. The conclusions made by SEAC (ECHA, 2019d) in relation to benefits which are outlined above, can be applied to this analysis for GB.

Reduction in adverse effects

One of the key benefits to arise from the proposed restriction options RO1, RO2 and RO3 falls to customers. Once the proposed restriction is in place, there should be a reduction in the number and severity of complications/adverse effects relating to tattoos and PMU compared to the baseline. It is difficult to quantify or monetise, but we can expect that the number of severe cases of adverse effects experienced will be reduced under the proposed restriction options and this should reduce discomfort and increase wellbeing for customers that might otherwise have been affected.

Restriction options RO1, RO2 and RO3 also offer a saving in medical costs associated with the reduction in any medical treatments necessary as a result of the health effects to the customer compared to the baseline. Under the baseline, a higher number of customers would face adverse health effects following a tattoo or PMU procedure and severe cases would require medical treatment which can be costly. With respect to chronic non-infectious inflammatory tattoo complications, the most common treatment involves topical, intralesional or oral treatment for milder cases and surgical or laser removal for more serious cases where topical treatment has proven ineffective. By reducing exposure to substances with known hazardous effects in tattoo inks and PMU, the proposed options have the potential to reduce the number of adverse effects experienced by customers and thus the number of cases requiring medical treatment.

Table 3.5.3.4 has been adapted from ECHA and presents a summary of the costs of illness (COI) per case associated with the treatment of a tattoo complication (ECHA, 2019c). The medical costs represent a range of procedures described by ECHA and represent an average of the information collected from the EU member states of Belgium, Denmark, Finland, and the Netherlands (ECHA, 2019c).

It can be assumed that the resource cost of treating these complications in GB is similar to the cost in the EU. Costs in this analysis have been taken from ECHA (2019c) and adjusted to fit this analysis for GB. This is done by converting ECHA's costs to GBP and uplifting to 2021/22 prices. The costs below can be interpreted as the cost savings that would arise following the proposed restriction. It's important to note that there are two groups of customers here: 1) those who experience effects under the baseline scenario but not under the proposed restriction options and therefore these customers avoid the cost of treatment and 2) customers who experience less severe effects under the proposed restriction and therefore incur a lower cost of treatment. Due to the lack of necessary data, it is difficult to quantify the effects i.e., how many people will no longer experience or experience less severe adverse effects under the proposed restriction options.

Table 3.5.3.4: Costs to society of chronic non-infectious inflammatory tattoo complications per case

Treatment	Total cost (GBP) (converted to GBP and presented in 2021/22 prices)
Medical (topical, intralesional, or oral) treatment (annual/case)	£400
Surgical treatment (one-off costs/case) • Dermatome shaving • Excision • Carbon dioxide laser	£2,300
Laser treatment (one-off costs/case)	£2,200
Cost of tattoo removal in the UK (NHS, 2019b)	Can range from £50 - £1,000

Source: (ECHA, 2019c)

Willingness to pay[78]

The benefits of the proposed restriction on substances in tattoo inks and PMU can be calculated where the levels of chemical exposure are associated with health impacts and monetary values are associated with reducing the risks of these health impacts. Quantification of benefits thus requires the identification of well defined, economically meaningful health effects associated with the chemical exposure; the change in health effect expected to result from the proposed restriction that reduces exposure to the chemical; as well as the change in incidence of the health effect in the exposed population. Finally, it is necessary to estimate the economic value of the health effects that would be avoided and multiply this unit value by the reduced incidence of the health effect in the population to derive the monetised benefits. In all cases, the analysis is preceded by a chemical safety (or risk) assessment quantifying the changes in exposures to the hazardous substance for the potentially exposed population. The changes in exposure will be quantified for all relevant populations, for this restriction this is customers of tattoo inks and PMU. The changes in exposure are combined with dose-response or exposure-response relationships to predict changes in the risk of the health effect of interest.

The economic consequences of a case of the adverse health effects will include:

1. Medical and care-giving costs such as costs of health care provision and out-of-pocket medical expenses of the affected individual (or family), for example, on

[78] This section is heavily based on the work of Georgiou, Postle and Rheinberger (2019).

drugs or the need to attend hospital, the opportunity costs of time spent in obtaining treatment, plus in some cases costs associated with insurance, etc. The individual may also be unable to undertake some or all normal chores and thus require additional special care-giving and services not reflected in normal medical costs;

2. Work loss, this includes lost personal income as a result of absence from work or loss of a job, plus lost productivity and output, other admin costs related to a worker's absence such as additional recruitment costs, loss of experience/expertise; and

3. Other social and economic costs, these include intangible "human" costs such as lost opportunities for enjoyment of leisure activities, loss of quality of life, discomfort or inconvenience (pain and suffering), anxiety, concern and inconvenience to family members and others. In addition, individuals may engage in defensive and averting expenditures and activities associated with attempts to prevent the health impacts.

The medical costs, plus work loss (consequences 1 and 2), constitute the measure of welfare known as the Cost of Illness approach. This seeks to identify the real costs of illness in the form of lost productivity and output and the increase in resources devoted to medical care (and hence measures the ex-post or realised damages rather than the ex-ante valuation of WTP at the moment choices are made). Its theoretical legitimacy rests on the assumption that national income is a valid measure of welfare. However, the COI approach is only a partial valuation in that it fails to capture the variety of behavioural responses to illness and the threat of illness. More generally, since the COI approach does not include other social and economic costs, it will not reflect the total welfare impact of a regulatory intervention. Leaving aside for a moment the issue of how it is measured in practice, a more comprehensive measure of welfare is given by the maximum WTP to reduce all the adverse impacts on human health. It can be used to reflect all the reasons an individual might want to avoid an adverse effect, including financial and non-financial concerns. When combined with some of the other direct and indirect resource costs such as admin and health care provision costs borne by taxpayers and employers, this gives a measure of the total social costs associated with the adverse health effect. Care must be taken to avoid double counting of cost elements.

In practice, under REACH, the benefits of a change in exposure to a hazardous chemical are typically calculated using a combination of the COI approach and estimates of the "human" or intangible costs associated with a case of disease/illness. The COI are calculated by multiplying resource costs per individual case of disease by the predicted number of cases occurring under the baseline (reference) and future scenarios. The difference between the two sums provides the estimate of the direct and

indirect resource benefits arising from the avoidance of future cases of disease/illness. It is standard for the “human” or intangible costs associated with a case of disease or ill-health to be measured in terms of society’s aggregate willingness to pay (WTP) for a reduction in the risk of contracting the disease/ill-health.

In such situations, various techniques can be used to estimate WTP measures of value. One possible approach is to ascertain WTP directly through ‘stated preference’ valuation survey approaches i.e., the general public’s willingness to pay for reducing the adverse effects on human health (ECHA, 2015). ECHA (2019c) have gathered evidence for their restriction proposal across the EU and consider society’s willingness to pay (WTP) to avoid a range of illnesses. WTP evidence from ECHA will be used in this analysis and it is assumed that similar results would be seen across GB.

Systemic illnesses that can be associated with exposure to chemicals in tattoo inks and PMU may require years of treatment, thousands of pounds in direct and indirect treatment costs and can lead to loss of productivity and shorter life expectancy, as well as the other intangible effects mentioned earlier (ECHA, 2019c). ECHA’s analysis included a list of the cost of selected relevant illnesses in recent studies as an example of the magnitude of these costs. It can be expected that under the proposed restriction options the prospect of suffering from the illnesses outlined in table 3.5.3.5 are reduced.

It is difficult to estimate the true incidence and prevalence of complications that occur in GB due to substances that are present in tattoo inks and PMU because there is no GB registry of tattoo/PMU related complications and no epidemiological studies have been performed in GB. Most of the available epidemiological studies have been conducted in EU countries where tattoo clinics have been set up. It should be noted that reported numbers are highly variable between these studies. Possible reasons for this variability include:

- Differences between study authors in the severity grading that has been assigned to the effects that they report.

- Where studies rely on self-reported information, there may be a tendency to underreport less severe effects due to memory bias.

- Less severe effects may also tend not to be seen in healthcare settings because people have chosen to get advice on treatment from their tattoo artist or PMU professional; this may increase the likelihood for less severe effects to be underreported in the scientific literature.

More generally, it can be difficult to identify which substances in the tattoo ink or PMU may be responsible for triggering an adverse effect. Sometimes medical professionals may take biopsies at the affected site to help with their diagnosis, but it is not always appropriate to use invasive methods.

Some indication of the occurrence of tattoo related complications can be drawn from existing EU studies. In a group of 972 members of the Italian general population with tattoos, (Renzoni *et al.,* 2018), 3.3% reported complications and mild complaints. In this paper, complaints were defined as any unusual condition in tattooed skin that differs from normal skin, whereas complications were more serious adverse effects. These ranged from persistent pain (39.3%) to allergic reactions (17.5%) and granuloma (27.7%). Of those with complaints, 21.3% decided to consult a healthcare professional (dermatologist or general practitioner). It was not clear if the decision to consult a medical professional was influenced by the type and severity of the complaint/complication.

In another survey carried out in 2010 in German-speaking countries (Klugl *et al.*, 2010), about 68% of tattooed people in the general population reported immediate adverse reactions following the tattoo, and 6.6% reported systemic reactions after tattooing. It is possible these immediate reactions (both local and systemic) reflect the "trauma" of the tattooing process and the normal healing process that occurs in the days after a tattoo has been created and are not substance related adverse effects. This is not clear from the information reported by Klugl *et al*. After four weeks when normal healing reactions should have resolved, Klugl *et al*., (2010) noted that 8% of tattooed people reported they still had health problems and 6% reported they had persistent health problems, such as itching and skin elevation.

In a combined review and study by Wenzel *et al.* (2013), coloured inks were shown to be mainly responsible for adverse reactions reported following persons being tattooed. It was consistently shown through both case reports and self-reported measures that coloured tattoos on the extremities (rather than the trunk) had a higher incidence of issues. Studies and surveys suggest that the majority of all chronic adverse effects are allergic in nature, with red and black colorants being associated with most of the reactions (Kluger, 2019). Reactions can appear months or years after the tattoo was completed. This is a remarkably long period of sensitisation induction and the exact mechanism has not yet been elucidated. The variation in latency periods may indicate that the deposition of substances in tattoo inks in the skin results in lifelong exposure that may potentially have a negative effect on human health (Laux *et al*., 2016). In addition, the pigments are also known to be distributed in the body and have been found in different organs such as the lymph nodes and the liver (Schreiver *et al*., 2015) (Sepehri, *et al.,* 2017a).

ECHA (2019c) presented the costs to society of systemic, reproductive, developmental, or carcinogenic illnesses in Euros and 2016 prices. For this analysis figures have been converted to GBP, uprated to 2021/22 prices and rounded to the nearest hundred, as seen in table 3.5.3.5 below.

Table 3.5.3.5: Examples of costs to society of systemic, reproductive, developmental, or carcinogenic illnesses associated with exposure to chemicals in tattoo inks and PMU

Illnesses	**Costs to society in GB (converted to GBP and presented in 2021/22prices)**
Infertility	WTP = £28,600 Direct and indirect costs = £7,100
Birth of child with very low weight	WTP = £115,600
Hypospadias[79]	Direct, indirect, and intangible costs per case = £19,800
Cryptorchidism[80]	Direct, indirect, and intangible costs per case = £33,700
Cancer[81]	Average case of cancer (sum of morbidity and mortality) = £882,600 (HSE, 2016) Average cost of non-melanoma skin cancer (NMSC) = £32,900
Testicular cancer	£74,200 of direct, indirect, and intangible costs of one testicular cancer case, estimated by Norden (2014)
Obesity	Average direct and indirect costs per case of adult diabetes: £306,600 estimated by Legler *et al* (2015)
Willingness to pay (WTP) to avoid severe, chronic dermatitis (periodic flare ups) (ECHA, 2016f)	£2,000 - £11,800

[79] Hypospadias is a birth defect (congenital condition) in which the opening of the urethra is on the underside of the penis instead of at the tip (Mayo Clinic, 2018).
[80] Cryptorchidism is a common childhood condition where a boy's testicles are not in their usual place in the scrotum (NHS, 2011).
[81] Two average costs have been included for cancer, one is an overall average which includes highly fatal cancers such as lung, mesothelioma, and breast cancer and the other is specific to NMSC. Both costs include human and financial costs. These costs have been taken from the HSE Costs to Britain of Work-Related Cancer report and are presented in 2021 PV. The report is available here: https://www.hse.gov.uk/research/rrhtm/rr1074.htm

Source: ECHA 2019c taken from ECHA (2017b)

There are a number of caveats associated with the WTP values and treatment costs that were noted by SEAC (ECHA, 2019d) and these can be found in Appendix 6.5.

Reduced discomfort and cost saving are just two of the benefits customers may experience from a reduction in adverse reactions from tattoo inks and PMU. There is also an opportunity cost associated with the time spent obtaining the medical treatment. Under RO1, RO2 and RO3; the number of medical treatments obtained should reduce and therefore the time spent obtaining these treatments would also reduce. This gives customers more time to spend on other leisure activities or at work. This can be quantified by understanding the average time it takes to undergo the various medical treatments outlined in table 2.5.3.4 but due to a lack of available data this has not been quantified.

3.5.4 Practicability and monitorability

In order to propose a restriction under Article 69(1) of UK REACH, the Agency must demonstrate that there is risk that is not adequately controlled and that the proposed restriction is the most appropriate measure to manage that risk. The appropriateness of the proposed restriction is assessed on these criteria:

- Effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk.
- Practicality: the restriction must be implementable, enforceable and manageable.
- Monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

Sections 3.5.1 – 3.5.3 demonstrate that the proposed restriction options will be an effective approach to manage the identified risk. The following sections demonstrate that the proposed options are practical and monitorable.

3.5.4.1 Practicality

a) Implementability

- RO1 proposes similar and RO2, slightly less strict measures than the measures that were recommended in CoE (2008) and CoE (2003) relating to the composition of tattoo inks and PMU. These resolutions were used as the basis

for national legislation which was implemented in several EU and EEA Member States. This demonstrates that it will be possible to implement legislation based on these options in GB.

- RO3 proposes measures that are closely related to the implemented EU restriction with the key difference that derogations are proposed for the colourants listed in table B. The proposed derogation removes a major concern that industry has reported with the implementation of the EU restriction.

- Surveillance results from EU enforcement bodies have shown that the majority of tattoo inks and PMU on the EU market before the introduction of the EU restriction were in compliance with existing national legislation in EU Member States which had implemented legislation based on CoE (2003) or CoE (2008), suggesting that products are (or have been) available that will comply with RO1 and RO2. Since tattoo and PMU inks are manufactured outside the EU, these non-EU inks could still be available for the GB market even if they may not comply with the implemented EU restriction.

- The Agency is aware that stakeholders have expressed concerns about aspects of the implementation of the EU restriction, on which RO3 is based. This includes comments made during the call for evidence that it is difficult to track which substances are in scope and difficulties relating to the loss of key pigments. The proposed derogation of the colourants listed in Appendix 1, Table B should avoid the greatest of these difficulties.

- The transitional period of 1 year that is proposed for RO1, RO2 and RO3 reflects the growing awareness that exists in industry about this restriction and its requirements and the expectation that work to reformulate inks to meet the requirements of the EU restriction will speed up the time required if it becomes necessary to reformulate inks for the GB market.

b) Enforceability

- In GB, it is the responsibility of local authorities to oversee the operation of tattoo parlours and PMU practitioners in their area. Due to regional differences in the legislation that governs local authority oversight, licensing and registration requirements differ between local authorities. Currently enforcement focuses on hygiene and infection control, rather than the health risks associated with certain chemicals in tattoo inks. Therefore, enforcement authorities have no experience in enforcing regulations specifying the chemical composition of inks. However, they may have experience with regulations governing the chemicals that may be present in other types of products and could draw upon this experience to inform

their enforcement approaches to tattoo inks and PMU. They could also draw upon the experiences of EU Member States implementing the EU restriction on substances in tattoo inks and PMU and the best practices guidance that ECHA says its Enforcement Forum intends to develop if this information is publicised or could be shared.

- Although no specific legislation governing the composition of tattoo inks and PMU exists in GB, local authorities regulate other aspects of the operation of tattoo parlours and PMU practitioners. It is therefore feasible that these officers could take on the enforcement role for this restriction. These enforcement activities are covered as part of the enforcement costs presented in section 3.5.1.2.

- Within the EU, the Rapid Exchange of Information System (RAPEX) could be used to assist enforce the EU restriction. RAPEX is a tool developed within the context of the General Product Safety Directive (GPSD) to provide enforcement bodies with alerts about dangerous products. The UK no longer has access to RAPEX or the EU Information and Communication System on Market Surveillance (ICSMS); these have been replaced by the UK's Product Safety Database (PSD). Alerts to this database can be used by enforcers to highlight particular products of concern.

- This dossier and information in the EU restriction dossier (ECHA 2019a,c) provides information on the substances found in tattoo inks that present risk to human health and highlights groups of substances that are considered most problematic. This information may help to develop targeted surveillance approaches which focus on those substances that present the greatest level of risk. Such targeted approaches have the potential to reduce the costs to monitor compliance. Targeted surveillance approaches have been used to check compliance with national legislation on the composition of tattoo inks and PMU where this exists in EU/EEA Member States.

- Analytical methods are used to determine the concentration of various substances in tattoo inks and PMU and can be used by industry and enforcers to confirm if the composition of an ink complies with the requirements of this proposed restriction. Methods are available for some groups of substances in the scope of the proposed restriction options. Appendix D.2 of ECHA (2019c) provides information on methods available for the following groups of substances:

    - primary aromatic amines (PAA);

    - colourants;

- elements;
- polycyclic aromatic hydrocarbons (PAHs);
- phthalates;
- nitrosamines.

These groups were selected because they represent substances that are listed in CoE (2008). The lists in Appendix D.2 (ECHA, 2019c) include methods that have been used by EU enforcement authorities in Member States with national legislation on the composition of tattoo inks and PMU to identify inks that contain unacceptably high levels of specific substances. Where analytical methods are available, information on the limits of detection of commonly used methods has been taken into account in setting the concentration limits for individual and groups of substances.

The restriction options described in this dossier cover a much broader range of substances than those listed here. Work is being done by EU Member States to develop and validate analytical methods for use to confirm compliance with the EU restriction. Further work needs to be done to understand whether it is necessary for GB enforcers to be able to quantify every restricted substance that may be present in tattoo ink and PMU or whether alternative targeted strategies will be sufficient. Such targeted approaches have the potential to reduce the costs to monitor compliance. Targeted surveillance approaches have been used to check compliance with national legislation on the composition of tattoo inks and PMU where this exists in EU/EEA Member States.

- Another issue brought up in ECHA's documents (ECHA, 2019c) and the call for evidence is the ready availability of non-compliant tattoo inks and PMU via the internet. It is not clear how easy it will be to prevent such inks being used in GB, particularly if enforcement authorities do not have accurate information about every tattoo parlour and PMU practitioner that is working in their area. If the restriction only targets inks from reputable manufacturers because these are the inks typically used by registered tattoo artists and PMU practitioners who will be inspected by enforcement officers, it may have little or no impact on the occurrence of complications due to the use of non-compliant inks by unregistered professionals and amateurs. This has the potential to reduce the effectiveness of this restriction. It will therefore be helpful for the success of this restriction if online retailers can implement measures to limit the sale of non-

compliant inks via their platforms[82].

- Measures outside the scope of the proposed restriction options such as training and awareness raising could increase levels of compliance.
- The Agency is not aware of any reasons why local authorities cannot be ready to enforce a restriction based on one of the three proposed options within the proposed one-year transitional period.

c) Manageability

- The provisions outlined in RO1 and RO2 are similar to legislation on substances in tattoo inks and PMU that had been implemented in several EU and EEA Member States before the EU restriction was proposed. Compliance rates reported in the EU restriction dossier (ECHA 2019a,c) for these Member States suggest that RO1 and RO2 will be manageable for industry.
- Given the short time that the implemented EU restriction has been in place, the Agency has no information about compliance rates for RO3. However, the proposed derogation of the 21 pigments listed in Table B which is applied to all options proposed by the Agency will remove one of the major difficulties that industry reports it will face with the implemented EU restriction. This will improve the manageability of RO3.
- Since the EU has recently implemented legislation with broadly the same scope as the options that are proposed for GB, industry awareness will be raised about the EU restriction. To ensure the EU restriction is successful, work will be underway to develop solutions for aspects of the EU restriction that are proving difficult to achieve. This raised awareness and the results of work to solve problems for the EU restriction will help GB industry manage a restriction with a similar scope to the EU restriction if it is implemented in GB.
- The provisions in each option are linked to previous recommendations on substances that should not be present in tattoo inks and PMU (CoE, 2008) and existing legislation (the GB MCL list and Annexes of the CPR). This has the potential to simplify the identification of which substances are in scope of the restriction. This does introduce a burden on industry to regularly check the GB

[82] Within ECHA's document (EHCA, 2019c) it was suggested that online retailers could provide warnings with non-compliant inks indicating that the inks are not to be used for tattooing or as PMU. Sales of compliant inks could be accompanied by a guarantee from the seller that these inks are compliant with GB legislation. Such guarantees have been provided by international suppliers of other goods. Some respondents to the call for evidence suggested restricting the sale of inks to registered or licenced tattoo artists and PMU practitioners.

MCL list and the Annexes of the CPR to confirm which substances are in scope.

- The dynamic link that is proposed under RO1, RO2 and RO3 between the way substances are classified in the GB MCL list and the restriction will reduce the administrative burdens to update lists of substances that are in scope when substances are newly classified. Manufacturers can use the GB MCL list to periodically check which substances are in scope.
- The dynamic link that is proposed under RO1 and RO3 (but not RO2) between Annexes II and IV of the CPR and the restriction will reduce the administrative burdens to update lists of substances that are in scope when substances are added to or removed from these Annexes. Manufacturers can periodically check these Annexes to identify which substances are in scope.
- In the case of RO2, it is proposed that when substances are added to Annexes II or IV of the CPR, a separate assessment is performed to determine if those substances should fall into scope of this restriction. This will increase the administrative burden of this option.

3.5.4.2 Monitorability

- The implementation of the proposed restriction options can be monitored by the numbers of alerts made by enforcement officers to the UK's PSD where they deem it necessary to highlight particular to non-compliant tattoo ink and PMU products that are on the GB market.
- It is not known how easy it will be to use reductions in numbers of tattoo and PMU complications as a measure of the success of this restriction owing to the lack of robust data to understand the baseline situation.
- Other tools which were discussed by the EU (ECHA, 2019a,c) and which might provide useful information include:
    - the introduction of separate diagnostic codes for tattoo ink and PMU complications to enable the number and types of complications to be tracked. Such codes will also be useful for future epidemiological studies investigating the association between tattooing and PMU procedures and adverse health outcomes. The development of these codes will require input from the medical community. It will be beneficial to harmonise the codes that are used in GB with any that may have been adopted elsewhere globally, to allow data from multiple countries to be combined for the purposes of epidemiological investigations.

- the introduction of a registry of tattoo inks and PMU placed on the GB market which could collect data on the chemical composition of the mixtures injected intradermally. This could help enforcers track which substances are most commonly used in tattoo inks and whether new substances e.g., new colourants are being used. Since this restriction is not proposing to establish positive lists of substances which can be used in tattoo inks and PMU, knowing when new substances have been introduced will help authorities check whether these new substances are safe for use in tattoo inks and PMU. Ideally this registry would be maintained by manufacturers reporting information on composition to a central database that could be accessed by regulators and medics. It is not clear who would be responsible for the day to day running of this registry.

- During the public consultation on the EU restriction report, it was suggested that a registry of clinical complications (covering infections and other complications) from tattooing similar to that established by the US FDA would be useful. Such registries have already been established in some EU countries e.g., France and Norway. Establishing a similar registry in GB would help to track the success of this restriction but it is not clear who would be responsible for the day to day running of this registry.

3.5.5 Proportionality to the risk

Proportionality in economics is typically considered in terms of a comparison of benefits and costs. In the context of substances in tattoo inks and PMU, benefits assessment will be challenging, if not impossible, based on current scientific knowledge. As a result, assessment of the proportionality of the proposal to regulate such substances cannot typically be undertaken on the basis of comparing quantitative benefit and cost estimates, but rather requires other means to establish proportionality. The approach to proportionality assessment taken in this dossier is a number of lines of evidence and argumentation. The various strands of evidence pertaining to the proportionality of the restriction include the affordability for various groups within the industry, in addition to the cost-effectiveness and break-even of the proposed restriction. As mentioned in ECHA (2019c), the proposed restriction is expected to create higher costs for industry which they can pass onto downstream users therefore the proposed restriction is expected to be affordable. Due to the difficulty in being able to quantify and monetise the benefits and therefore provide a cost-benefit analysis, the cost-effectiveness (£ per litre of ink that needs replacing) has been calculated for RO1 (with qualitative assessment for RO2 and RO3) to understand and differentiate the costs of each option. The break-even looks at the total cost of the restriction and measures the benefits in terms of cost of illness (COI) that need to be avoided so that costs equal benefits.

These measures provide some indication of how affordable the restriction will be for industry, the least costly of the proposed restriction options and the number of avoided illnesses that need to be realised to ensure the restriction breakeven.

3.5.5.1 Affordability

a) Tattoo ink manufacturers

ECHA (2019c) write that manufacturers with ResAP-compliant tattoo inks have reported that their margins have eroded, due to the pressure to compete with non-compliant tattoo inks and their non-discerning customer base (i.e., tattoo artists). However, it is expected that those already compliant with ResAP, would not have to incur substantial additional costs to comply with the proposed restriction options. The largest burden of the regulation would fall on those manufacturers which have not developed tattoo inks meeting ResAP's recommendations. As stated previously, EU manufacturers are reported to have higher compliance rate with ResAP requirements, therefore, the largest burden would fall on non-compliant importers. Currently, non-compliant manufacturers are reported to have a higher profit margin, as their manufacturing costs are about 50% lower than those of ResAP compliant inks, while their products have similar (0-20% lower) market prices. (stakeholder consultations).

It is assumed that tattoo ink and PMU formulators would be able to pass downstream their higher costs to be incurred due to the proposed restriction options in the form of higher market prices for their products. Industry has expressed concerns that they are unable to pass on higher costs. With the entry of the proposed restriction options all formulators would need to comply with the regulation and therefore, the pressure from lower-cost, non-ResAP compliant inks would abate.

It is unclear if and what proportion of GB based ink manufacturers are currently non-compliant with the proposed restriction (as GB industry is not expected to comply with ResAP) which means any non-compliant actors would incur costs to comply with the proposed restriction. However, it is assumed that there are a very small number of GB based ink manufacturers as section 3.2 mentioned that a large majority of tattoo inks and PMU on the UK market (and assumed GB market) are imported from the US and China, who don't have restrictions in place. Therefore, these international exporters and manufacturers would be impacted with high costs to comply.

b) Tattoo artists

Tattoos can be very diverse and their price, amount of time, and ink used varies greatly, depending on the skill of the tattoo artist, design (custom or pre-designed, realistic or

abstract), black or multi-colour, outline or shaded, etc. The prices of sought-after tattoo artists can be significantly higher. (ECHA CfE, 2016) (stakeholder consultation).

The average hourly rate for a tattoo is around £150 in London whereas in Leeds, the price is between £80-100 per hour (Barber DTS, 2021). Prices of tattoos not only vary depending on geographical region of administration, but also size, detail, and complexity of the tattoo.

Tattoo artists incur total costs per tattoo between £15 – 60[83] for supplies, rent, labour, and other overheads. Costs are expected to be lower in different regions across GB i.e., north of England compared to London.

The cost for tattoo ink is estimated to account for up to 14% (in Western Europe) to 31% (in Eastern European Member States) of the total cost per tattoo for tattoo artists. Therefore, if as a result of the proposed restriction options, the share of the tattoo ink of total costs per tattoo would increases to 16% (in Western Europe) to 35% (in Eastern European Member States). In other words, the marginal costs of the proposed restriction would be less than €1 per tattoo. It is expected that this increase would have a minor impact on the profit margin of a tattoo.

The cost for tattoo ink as a proportion of total cost per tattoo is not available for GB, but we can expect the proportion both before and after the proposed restriction, to lie within the same ranges as the proportions provided for Western Europe by ECHA (2019c). The marginal cost of the proposed restriction has been estimated using the 14% and 16% assumptions provided by ECHA (2019c) and the estimated total cost per tattoo (£15 – £60). The marginal cost of the proposed restriction is estimated to be approximately £1.

c) PMU practitioners

Prices of PMU procedures such as eyeliner, lip liner, or eyebrow enhancement also vary substantially across GB. Prices for PMU procedures can range from £75 for a beauty spot to £500 for lip liner in the UK - prices can also rise to a few hundred or few thousand pounds depending on the type of procedure[84] (NHS, 2019a).

PMU procedures also depend on the reputation of the studio (which could also be a tattoo studio) or beauty (spa) centre and whether the centres offer packages (bundles) of various procedures. If as a result of the proposed restriction options, the cost of PMU increases by 20%, the share of the PMU of total costs per procedure would increases

[83] This cost is based on responses from the call for evidence conducted in GB.
[84] The price of PMU procedures quoted by the NHS are taken from a 2019 source and these figures have not been uprated to 2021/22 prices.

from 14% to 16% or the marginal cost of a restriction would be about €4/procedure. It is expected that this increase would have a minor impact on the profit margin of PMU procedures.

The cost for PMU as a proportion of total cost per PMU procedure is not available for GB therefore it is not possible to calculate the marginal cost of the proposed restriction.

d) Customers

It is likely that any tattoo and PMU cost increases caused by the proposed restriction options will be passed on to consumers. According to market research in the US demand for tattoo and PMU services is inelastic. It is driven primarily by demographics and cultural (including fashion) trends rather than other economic forces. The industry was hardly affected during the last recession despite having the hallmark of a luxury service. The price of a tattoo was also not seen as a priority among those deciding on a tattoo: only 8% of respondents to a survey stated that price is an important factor in their decision to get a tattoo. Demand in the future is expected to continue to be unaffected by changes in disposable income. (IBISWorld, 2016) (SB, 2015).

In conclusion, even though it is likely that the introduction of one of the restriction options would lead to higher costs for industry, those would likely be affordable for downstream users: tattoo artists, PMU professionals and consumers.

3.5.5.2 Cost-effectiveness

As shown, the proposed restriction options would likely lead to costs and other impacts to industry and society as whole. Table 3.6 shows that these are expected to be relatively small and manageable for industry and social actors. The cost-effectiveness of RO1 is estimated at approximately £83/litre non-compliant tattoo ink replaced in GB. RO2 and RO3 are likely to be more cost-effective in comparison to RO1 as substitution costs are expected to be somewhat lower than those estimated for RO1.

3.5.5.3 Break-even analysis

Between 62 (calculated using cost of illness (COI) plus higher WTP values) and 205 (COI plus lower WTP values) cases of chronic allergic reactions (requiring surgical removal) need to be avoided annually for RO1 to breakeven. This is between 0.018-0.059% of the estimated number of people getting a tattoo for the first time each year in GB (1 – 2 removals for every 100,000 tattooed people). There is a high degree of uncertainty around the number of people with PMU in the GB population, but it is

estimated that this would equate to approximately 1 – 3 removals for every 100,00 people with PMU.

Breakeven has been calculated by taking the average COI, in this analysis the cost of surgical treatment is used (as was done by ECHA, 2019c) which is £2,255. Low and high estimates for the WTP to avoid symptoms of tattoo reactions are added to the COI figure, these are £1,974 and £11,844 respectively. The total cost of the restriction (£868,168[85]) is then divided by the COI+WTP (£4,229 and £14,099 for the low and high estimates respectively) to estimate the breakeven scenarios. The calculations behind the low and high estimates are presented below:

Low estimate = (£868,168) / (£2,255+£1,974) = 205 cases need to be avoided

High estimate = (£868,168) / (£2,255+£11,844) = 62 cases need to be avoided

It is reasonable to expect that these cases would be avoided as a result of the proposed restriction measure as the estimated average prevalence rate of tattoo complications is 1.8% (see section 3.5.3 on human health impacts) and not all costs are taken into account. In the absence of better information, ECHA's estimated average prevalence rate for tattoo complications is assumed to apply to this analysis for GB.

In addition, the removal of tattoos due to an allergic or papulo-nodular reaction is just one group of the health outcomes. As stated in section 3.5.3, a number of people experience complications that require topical or systemic corticosteroids as well as experience mild ongoing complaints from their tattoos and PMU. This is in addition to the potential contribution of tattoo ink and PMU exposure to carcinogenic, reproductive, developmental and other systemic adverse effects.

Therefore, although full cost-benefit comparison it is not possible, it is reasonable to assume that the benefits would outweigh the costs, as very few cases of only one type of adverse effects (non-infectious, inflammatory) are necessary for the restriction to break even. Quantification and monetisation of other adverse effects (systemic, carcinogenic, reproductive or developmental) would lead to higher overall value of benefits from RO1.

As the concentration limits of RO2 and RO3 are higher than RO1, it can be hypothesised that RO2 and RO3 offer a lower level of protection and therefore, fewer benefits. However, as costs for RO2 and RO3 are also lower than RO1, it is difficult to determine the overall proportionality of RO2 and RO3 in comparison to RO1.

[85] This is the total cost of the proposed restriction with the familiarisation costs apportioned across the 20-year appraisal period to ensure the breakeven is not skewed.

The conclusions made by ECHA also apply to this analysis for GB. Consequently, RO2 and RO3 are likely to offer fewer benefits compared to RO1 due to their lower levels of protection. At the same time, they are less costly in comparison to RO1 therefore, it is difficult to determine the relative proportionality of RO1, RO2 and RO3.

3.6 Comparison of restriction options

As shown in the preceding sections and summarised in table 3.6, restriction options RO1, RO2 and RO3 would likely lead to costs and other negative impacts to industry that are of similar nature and magnitude. The main difference between the restriction options are the concentration limits. As the concentration limits of RO2 and RO3 are higher than RO1, it can be hypothesised that RO2 and RO3 offer a lower level of protection and therefore, lower risk reduction capacity and fewer benefits.

At the same time, as more tattoo inks currently on the market likely already comply with RO2 and RO3 requirements, the substitution costs would be lower than RO1. Testing costs for RO2 and RO3 would also be possibly lower than RO1 as the information on classified substances is required to be included in the label and the substance data sheet if they are present in concentrations exceeding their CLP limits in mixtures. Therefore, as the costs of RO2 and RO3 are anticipated to be slightly lower, these options would be slightly more cost-effective (in terms of £ per volume of non-compliant tattoo ink substituted), slightly more affordable for stakeholders and would require fewer avoided cases to break even. At the same time, it is expected that the risk reduction capacity, and therefore, the benefits, of RO2 and RO3 would also be slightly lower. It is uncertain whether they are sufficiently different than RO1 to conclude that RO2 and RO3 is more proportionate than RO1 on a cost-benefit basis.

Table 3.6 compares RO1, RO2 and RO3 qualitatively. An overall conclusion on which option is more proportionate is difficult to reach.

Table 3.6: Annual compliance costs and cost-effectiveness of the proposed restriction options[86](adapted from ECHA 2019a)

2021 prices, GBP £, annual	**RO1**	**RO2**	**RO3**
Total compliance costs	£1,692,000	Lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2

[86] Figures in this table have been rounded and totals may not add up precisely.

2021 prices, GBP £, annual	RO1	RO2	RO3
Substitution	£789,000	Lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2
Enforcement	£36,000	Similar to RO1 and RO3	Possibly similar or lower than RO1 but higher than RO2
Familiarisation	£867,000 (one-off cost in year 1)[87]	Similar to RO1 and RO3	Similar to RO1 and RO2
Social and distributional impacts[88]	This is non-monetised but RO1 is expected to have moderate impacts.	Similar to RO1 and RO3	Similar to RO1 and RO2
Wider economic impacts[89]	This is non-monetised but RO1 is expected to have minimal impacts.	Similar to RO1 and RO3	Similar to RO1 and RO2
Cost-effectiveness[90]	£83/litre of non-compliant tattoo inks removed from the market	Higher than RO1 and RO3	Higher than RO1 but lower than RO2
Risk reduction capacity	It would reduce risks but not fully eliminate them	Possibly lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2

[87] To note, this is a one-off cost which will be incurred the year that the restriction is implemented. To apportion this cost across the 20-year appraisal period, annual familiarisation costs would be approximately £43,000 (in 2021/22 PV).
[88] This refers to the impact to businesses in the tattoo and PMU industry, specifically tattoo and PMU formulators, tattoo artists and pigment manufacturers as a result of the proposed restriction.
[89] This refers to the availability of inks and trade impacts as a result of the proposed restriction.
[90] Cost-effectiveness examines the costs and health outcomes (benefits) of the proposed restriction by estimating how much it costs to gain a unit of the health outcome (CDC, 2021).

2021 prices, GBP £, annual	RO1	RO2	RO3
Benefits	Equivalent to the avoided cases of tattoo adverse effects (cutaneous, systemic, and potential reproductive, developmental, malignant)[91]	Possibly lower than RO1 and RO3	Possibly similar to RO1 but higher than RO2
Break-even[92]	Approximately 62 – 205 avoided cases of tattoo removal due to non-infectious inflammatory complications	Possibly fewer cases required for breakeven than RO1 and RO3	Similar to RO1 and more cases required for break-even than RO2
Affordability	Affordable	Likely more affordable than RO1 and RO3	Similar to RO1 but less affordable than RO2

For this analysis in GB, given that the break-even point can be met with only 1 – 2 and 1 – 3 avoided cases where tattoo and PMU removal is required due to the severity of the complication, it is concluded that the proposed restriction options are proportionate. This does not consider the additional benefits of avoided cases of milder complications which may mean that break-even can be achieved with even fewer cases where tattoo or PMU removal is required. This further supports the view that this restriction, which is being proposed as a precautionary measure to address concerns about potential adverse effects if hazardous substances are present in tattoo inks and PMU, is a proportionate regulatory measure.

[91] It is not possible to assess the magnitude of the number of cases avoided as the necessary data is unavailable.

[92] Break-even in economics describes the point at which costs, and benefits are equal. For this analysis, the total cost of the restriction is approximately £1.7 million, and this equates to between 62-205 cases of avoided tattoo removals (benefit), see section 3.5.5.3 for further information.

4 Assumptions, uncertainties and sensitivities

4.1 Related to the risk assessment

There are several sources of uncertainty in the information that has been used to prepare this proposal. This means that various assumptions have needed to be made in the risk assessments underpinning the concentration limits that are proposed. Table 22, which is reproduced from ECHA 2019c, summarises the assumptions made by ECHA to calculate an amount of ink that is inserted into the skin in a typical tattoo session and how these assumptions affect the concentration limits that are being proposed. Additional uncertainties related to the risk assessment are described in Annex E (ECHA, 2019c) which is Document 1 in the Annex to this Agency document.

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Table 22. Overview of the main sources of uncertainty concerning the exposure assessment, impact on RCRs, concentration limits and the sensitivity of the final results

Source of uncertainty	Description	Effect on RCR	Effect on CL	Sensitivity of results
Amount of pigment/ink deposited in a tattoo (mg/cm^2)	The estimate for used ink may be an overestimation because the 75th percentile from experimental data was used and the calculation includes multiplication of the estimate by 4 (due to 25% pigment in the ink). The data set applied is very limited (9 reported numbers + unknown total number of experiments). Comparison with other literature data also suggests that the typical value of deposited ink may be smaller. If the professional tattoo artist does apply less ink per cm^2 than 14.36 mg ink/cm^2, which have been indicated in expert judgements, then the risk assessed in this assessment would overestimate the risk and set the concentration limits too low (where	↑	↓	High

	based on the exposure assessment).			
Application of different tattoo equipment	In the study by Engel *et al.,* (2008) the variability in the amount of pigment in the skin may also be due to the use of different tattoo application equipment.	↕	↕	Medium
Amount of pigment in the ink	In the calculation the content of pigment in the ink is assumed to be 25 %. As in some cases 25% will be too low (presumably leading to the use of less ink in total) and in some cases too high (presumably leading to the use of more ink in total) this may influence the result in both ways.	↕	↕	Low
Uptake of pigment	In the scenario a 100% distribution of pigment in the system is assumed. This is most likely not the case. In the study by (Engel *et al.*, 2008) a reduction of only 32% was observed during 6 weeks. If there is not a 100% distribution of pigment in the system the estimated RCR values will be too high and the concentration limits too low (where based on the exposure assessment).	↑	↓	Low
Uptake of soluble substances	In the scenario a 100% uptake of soluble substances such as impurities are assumed. This is likely to be the case. However, in case a 100% uptake does not take place the estimated RCR values will be too high and the concentration limits too low (where based on the exposure assessment).	↑	↓	Low
Continuous release of impurities from	A continuous release of impurities from pigments may possibly give rise to additional exposure. However, since the solubility of pigments	↓	↑	Low

pigments	generally is very low this is unlikely to occur to a greater extent. Further, the release should supply a higher amount than was originally supplied with the liquid in the tattoo ink when excretion takes place. If impurities are released in such high amounts the risk estimated would be too low and the concentration limits too high (where based on the exposure assessment).			
Excretion of pigments	In the scenario it is assumed that the absorbed pigments are excreted after having had their effect within the body system. It is possible that this may occur due to observations of coloured lymph nodes. If the pigment is not excreted the RCR values will be too low and the concentration limits too high (where based on the exposure assessment).			Medium
Excretion of impurities	In the scenario it is assumed that the absorbed impurities are excreted after having had their effect within the body system. This is likely to be the case. If the known impurities were e.g., known as being hydrophobic the excretion may be less likely to occur. However, the known impurities are not known to be hydrophobic. However, if the impurities are not excreted the RCR values will be too low and the concentration limits too high (where based on the exposure assessment).			Medium
Lack of excretion of continuously released	In case that a continuous release of impurities from pigments takes place and that these impurities are not excreted the system will experience a			High

impurities	higher concentration than what is present in the tattoo ink. However the assumption that impurities are not excreted may not be likely.			

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4.2 Sensitivities related to the socio-economic analysis

The proposed restriction options (RO1, RO2 and RO3) remain proportionate even when allowance for uncertainties is made. Table 4.2 shows the impact on the cost-effectiveness and the break-even points as a result of the relaxation of the main assumptions regarding the volume of tattoo inks and PMU on the market, the share of alternatives currently on the market, the anticipated price increase and their combined impact. A number of other scenarios are assessed as part of the sensitivity analysis and these can be found in Appendix 6.6.

Table 4.2 shows that the combined impact of these assumptions has the highest effect on the proportionality of the proposed restriction options. The combination of low volume/low share of alternatives/high price difference leads to the highest deterioration of the cost-effectiveness of RO1. For the proposed restriction options to break even in the worst-case scenario 358 surgical removals due to complication of tattoo inks would need to be avoided (calculated using cost of illness (COI) plus low WTP values) or 108 (COI plus high WTP values). Appendix 6.6 provides further information on the results of table 4.2.

It is reasonable to expect that these cases would be avoided as a result of the proposed restriction options as the estimated average prevalence rate of tattoo complications is 1.8% (see in section 3.5.3.) and not all costs are taken into account.

In addition, removal of tattoos due to an allergic or papulo-nodular reaction is just one group of the health outcomes. As stated in the section on human health impacts, a number of people experience complications that require topical or systemic corticosteroids as well as experience mild ongoing complaints from their tattoos and PMU. This is in addition to the potential contribution of tattoo ink and PMU exposure to carcinogenic, reproductive, developmental and other systemic adverse effects.

In summary, it can be concluded that the proposed restriction options are proportionate even when allowance for uncertainties is made.

Table 4.2: Impact of alternative volume scenarios on the proportionality of RO1.

Alternative volume scenarios	Main alternative	Low volume	High volume	High share alternatives	Low share alternatives	Higher price difference	No price difference	Low volume/Low share of alternatives/ High price difference	High volume/High share of alternatives/No price difference
Total restriction costs (annual)	£797,500	£684,700	£910,300	£1,092,800	£502,200	£1,515,800	£79,200	£792,300	£79,200
Replaced tattoo ink & PMU (litres/year)	9,500	8,000	11,000	5,600	13,400	9,500	9,500	11,300	6,500
Cost-effectiveness (£/litre non-compliant tattoo inks replaced)	£84	£85	£83	£194	£37	£159	£8	£70	£12

Alternative volume scenarios	**Main alternative**	**Low volume**	**High volume**	**High share alternatives**	**Low share alternatives**	**Higher price difference**	**No price difference**	**Low volume/Low share of alternatives/ High price difference**	**High volume/High share of alternatives/No price difference**
Breakeven – low (only effects on skin) (# cases avoided)	189	162	215	258	119	358	19	187	19
Breakeven – high (only effects on skin) (# cases avoided)	57	49	65	78	36	108	6	56	6

5 Conclusion

This restriction aims to reduce the numbers of complications that occur due to the presence of hazardous substances in tattoo inks or PMU. Since it is not known which of the many substances that may be present in these inks cause complications, the restriction takes a precautionary approach by capturing any substance that, based on its known hazards, could potentially lead to complications if it is present in tattoo inks or PMU and is inserted into the skin.

Three restriction options are proposed. Restriction option 1 (RO1) and restriction option 2 (RO2) largely replicate the options that ECHA proposed for the EU restriction but also take account of revisions that were introduced during the EU opinion forming process. These options retain ECHA's proposal to derogate 21 colourants that are prohibited for use in hair dyes in Annex II of the CPR but are permitted for use as colourants in cosmetics in Annex IV of the CPR. RO1 and RO2 also include a clarification to indicate that inks that are placed on the market for use exclusively as a medical device or an accessory to a medical device are exempted from the scope of the restriction.

Restriction option (RO3) reflects the implemented EU restriction with one key difference. Whereas the EU granted a time limited derogation for Pigment Blue 15:3 and Pigment Green 7 until 4 January 2023, the Agency is proposing to retain the derogation proposed for these and the 19 other pigments under RO1 and RO2.

For all three restriction options, it is proposed that this derogation should remain in place until changes are introduced within the Annexes of the CPR that would bring the colourant into scope of the general provisions of this restriction.

Table 5.1. Advantages and disadvantages of the three options:

	RO1	RO2	RO3
Advantages	Provides a level of protection that is similar to that provided by legislation based on CoE (2008). Since this resolution was not implemented into legislation in GB, this option has the potential to increase protection over the current situation. Since CoE (2008) was implemented into national legislation in certain EU and EEA Member States, legislation that closely follows the scope of this recommendation will be easy to communicate because ink manufacturers are already aware of the requirements. The dynamic link to Annex II and Annex IV of the CPR and the GB MCL list will ensure that updates to these regulations apply	A greater share of inks currently on the market will be compliant because of the less stringent concentration limits that will apply. Basing concentration limits on the CLP requirements means that information in safety data sheets can be used to determine if concentration limits are exceeded for certain categories of substances which will reduce costs for compliance testing. CLP limits should already be understood by ink manufacturers and enforcement officers which will make it easier for these actors to understand the restriction. Proposes concentration limits based on limits set by existing legislation.	For substances in scope, the concentration limits are the same as those implemented in the EU meaning that inks which are formulated for the EU market will be available for the GB market. The proposed derogation for key colourants in GB removes a major concern that industry has expressed about the impacts that the EU restriction will have for their industry. Avoids the enforcement challenges that have been identified with RO1 due to the lack of concentration limits. The dynamic link to Annex II and Annex IV of the CPR and the GB MCL list will ensure that updates to these regulations apply

	RO1	RO2	RO3
	automatically to this restriction. Proposes concentration limits based on risk assessments.		automatically to this restriction. Proposes concentration limits based on risk assessments.
Disadvantages	It is possible that the unavoidable presence of trace impurities in some inks could mean inks that are currently used will not comply with the restriction and will have to be removed from the market. Where concentration limits are not specified, manufacturers and enforcers are reliant on the limits of detection of the available analytical methods. Manufacturers could unknowingly supply non-compliant ink if their analytical laboratory uses less precise methods than those used by enforcers. Since concentration limits have been specified by the EU, if a “shall not contain” approach was adopted for GB, this would mean that inks	This option proposes the least stringent concentration limits which means that this option provides the lowest level of protection to those getting a tattoo or PMU. Regulators will need to carry out additional assessments each time a substance is added to Annex II or IV of the CPR to determine if the substance should be restricted in tattoo inks and PMU. This will increase the burdens to the regulator and will mean that potentially hazardous substances may continue to be present in tattoo and PMU inks while this assessment is carried out. Could lead to inconsistencies if CMRs that are listed in Annex II of	People responding to the call for evidence reported that the EU restriction is complex and difficult to understand.

	RO1	RO2	RO3
	that complied with the EU restriction may not comply with the GB restriction. This could very severely limit the availability of inks for the GB market, particularly if ink suppliers chose not to formulate inks specifically to meet GB requirements.	the CPR have different concentration limits to any generic concentration limits that are applied to CMRs which appear on the GB MCL list even though they have similar concerns with respect to human health risks.	

Each option is considered to meet the requirements that a restriction should be effective (i.e., is targeted to the effects or exposures that cause the identified risk, is capable of reducing these risks to an acceptable level within a reasonable period of time and is proportional to the risk), practical and monitorable.

The proposed restriction options are effective because:

- Adverse effects (often referred to as complications) have been reported as a consequence of someone receiving a tattoo or PMU. These include allergic and other skin reactions at the site of the tattoo or PMU. The evidence linking tattoos with adverse systemic effects is less clear, though there are reports in the literature that suggest that systemic complications can occur.

- Criteria have been identified which target substances that may cause complications if they are present in tattoo inks based on their assigned hazard classification in the GB MCL list, their inclusion on Annexes II or IV of the CPR and/or their inclusion in table 3 of CoE (2008).

- The restriction proposes to limit exposure by setting concentration limits to minimise the presence of those substances in tattoo inks and PMU. Concentration limits have been used for other restrictions in Annex 17 of REACH which apply to broad groups of substances. This approach therefore can be an effective approach to reduce risks to an acceptable level.

- Since it is not always possible to identify the causal agents for the various tattoo and PMU complications that have been reported, it is not known if any of these options will eliminate the risk entirely. However, it seems likely that the proposed options will reduce the occurrence of complications relating to substances that may be present in tattoo ink and PMU. Options proposing more stringent concentration limits are expected to provide the greatest benefits for health.

The proposed options are proportionate:

- The estimated substitution costs in GB under RO1 are approximately £789,000 in 2021/22. It is difficult to monetise substitution costs for RO2 and RO3. However, as RO2 and RO3 impose less strict requirements than RO1, it is anticipated that more tattoo inks and PMU on the market are already compliant with RO2 and RO3. Therefore, RO2 and RO3 substitution costs are likely to be lower.

  SEAC (ECHA, 2019d) writes that it is difficult to quantify the differences in substitution costs between RO3 and RO1 or RO2. Overall, RO3 has lower limits in comparison to RO2, therefore, it can be expected that it would lead to the reformulation of more tattoo inks in comparison to RO2. RO3 has some

higher concentration limits (e.g., for CMRs) but lower for other (e.g., nickel, cobalt) in comparison to RO1 with the overall effect on costs being unclear. The difference in the mechanism to update the future scope of the proposed restriction has unpredictable effects in terms of substitution costs difference between RO1, RO2 and RO3. The assumptions made by ECHA (2019d) around the difficulty in quantifying differences between restriction options can also be applied to this analysis for GB.

- The estimated enforcement costs for GB under RO1 are approximately £36,000 in 2021/22. As with ECHA's (2019c) assumptions, enforcement costs are expected to reduce across the appraisal period[93] with industry compliance. This is not demonstrated in the cost estimates as it is unknown how much costs will diminish over the appraisal period; therefore, costs carry a degree of uncertainty so should be seen as illustrative as they are likely to be an overestimate. Further information on the relationship between enforcement costs and compliance is provided in section 3.5.1.2.

SEAC (ECHA, 2019d) notes that the available information does not allow for a quantitative differentiation of enforcement costs (calculated by ECHA for the EU) between RO1, RO2 and RO3. Further information is provided in section 3.5.1.2.

- The familiarisation costs for GB under RO1 are approximately £69,000 - £2,551,000 with a central estimate of £867,000. This is a one-off cost presented in 2021/22 prices, but it is expected to be incurred in the year that the restriction is implemented. The familiarisation costs in this analysis have been estimated for RO1 however, RO2 and RO3 will also require industry to understand the proposed restriction, therefore it is expected that familiarisation costs under RO2 and RO3 would be similar to RO1. It is difficult to provide a quantitative differentiation between options.

- The restriction is expected to provide benefits relating to avoided cases of complications and any associated need to seek tattoo removals, also avoided cases of adverse effects arising as a result of tattoo removal procedures.

- Many formulators are small or micro enterprises. Those not already compliant with ResAP would experience the largest regulatory burden from the proposed restriction options.

- The restriction options are expected to provide benefits related to avoided

[93] Appraisal period refers to the timeframe that costs and benefits are assessed as part of the socioeconomic analysis. The appraisal period in this restriction dossier is 20 years (2021/22 – 2040/41).

cases of tattoo removal due to complications as well as avoided cases of other adverse effects. Owing to the lack of good baseline information on the incidence and prevalence of tattoo and PMU complications in GB it is not possible to quantify the benefits that will be gained by this restriction.

The proposed restriction options are practical and monitorable because:

- Prior to the EU restriction, legislation with a similar scope to RO1 and RO2 was implemented in several EU and EEA Member States. ECHA (2019a) states that the majority of the inks on the EU market were compliant with this legislation. Several ink manufacturers are based outside the EU but supply inks to the EU. It seems reasonable to assume that inks that were supplied from the non-EU manufacturers to EU Member States with this legislation could be made available to the GB market. Hence industry should be able to source replacement products if the products they currently use do not comply.

- The Agency has no information on compliance rates with the EU restriction or the effect that this has had on the tattoo and PMU industry in the EU. However, the proposed derogation of the 21 pigments listed in Table B will remove a major difficulty that industry reports it will face due to the loss of key pigments under the terms of the EU restriction. This change should make it easier for tattoo artists and PMU practitioners to obtain a sufficient variety of colours for their work.

- The enforcement of legislation governing the composition of tattoo inks and PMU will be a new activity for GB. In EU and EEA member states which implemented legislation on the content of tattoo ink and PMU based on COE (2003) and (2008), surveillance approaches were targeted to measure certain substances.

- Tying the conditions of the restriction to the way substances are classified in the GB MCL list and the way substances are regulated under the CPR will reduce the administrative burdens to update lists of substances that are in scope when substances are newly classified or added to Annexes of the CPR.

- RO1, RO2 and RO3 should therefore be implementable, enforceable, and manageable. It is not clear how easy it will be to prevent the sale of non-compliant inks via online retailers. Since such inks could account for a large share of tattoo and PMU complications, it is not clear how this might affect the success of this restriction.

- The success of the restriction can be monitored by the numbers of alerts about non-compliant tattoo ink and PMU products that are made to the UK's PSD. Due to the lack of robust baseline data on the incidence and prevalence

of tattoo and PMU complications in GB, it may not be so easy to use reductions in ill health as a measure of success.

In conclusion, each of the proposed options provides an effective, practical and monitorable approach to reduce the risks to human health from hazardous substances that may be present in tattoo inks.

6 Glossary

AATCC	American Association of Textile Chemists and Colourists
AF	Assessment factor
ASHE	Annual Survey of Hours and Earnings
ATSDR	Agency for Toxic Substances and Disease Registry
BaP	Benzo(a)pyrene
BMD	Benchmark dose
BMDL	Benchmark dose level
BPR	EU Biocidal Products Regulation
C	Carcinogens
CAS	Chemical Abstract Service of the American Chemical Society
CfE	Call for evidence
CI	Colour Index number
CICN	Colour Index Constitution Number
CIGN	Colour Index Generic Names
CL	Concentration limit
CLP	Classification, labelling and packaging regulation
CM	Carcinogenic and/or mutagenic
CMR	Carcinogens, mutagens and reprotoxic
CNS	Central nervous system
CoE	Council of Europe
COI	Cost of illness
COSHH	Control of Substances Hazardous to Health
CPD	Cosmetic Products Directive
CPR	Cosmetic Products Regulation, EUR 2009/1223
DBP	Dibutyl phthalate

DEFRA	Department for Environment, Food and Rural Affairs
DEHP	Diethyl hexyl phthalate/bis(2-ethylhexyl) phthalate
DG SANCO	Directorate General for Health and Consumer Protection of the European Commission
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EC	European Community number
ECHA	European Chemicals Agency
ED	Endocrine disrupting
EEA	European Economic Area
EEA31	Denotes the European Economic Area at a time when there were 31 Member States
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation
GB	Great Britain
GBP	Pound sterling
GCL	Generic concentration limits
GDP	Gross domestic product
GFR	Glomerular filtration rate
GPSD	General Product Safety Directive
HMT	Her Majesty's Treasury
HSE	Health and Safety Executive
HtLF	High to low dose risk extrapolation factor
ICSMS	Information and Communication System on Market Surveillance
IQ	Intelligence quotient
IUPAC	International Union of Pure and Applied Chemistry

JRC	EU Joint Research Centre
LOAEL	Lowest observed adverse effect level
LoD	Limit of detection
M	Mutagens
MCL	Mandatory Classification and Labelling List
MDR	Medical Device Regulations
NHS	National Health Service
NI	Northern Ireland
NMSC	Non-melanoma skin cancer
NOAEL	No observed adverse effect level
NPV	Net present value
NTP	National Toxicology Programme
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
ONS	Office for National Statistics
PAA	Primary aromatic amines
PAH	Polycyclic-aromatic hydrocarbons
PMU	Permanent make up
PNEC	Predicted no effect concentration
POD	Point of Departure
PSD	Product Safety Database
PV	Present values
R	Reproductive toxicants
R&D	Research and Development
RAC	Risk Assessment Committee of the European Chemicals Agency

RAPEX	Rapid Exchange of Information System
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RISEP	REACH Independent Scientific Expert Pool
RMM	Risk management measures
RO	Restriction option
RO1	Restriction option 1
RO2	Restriction option 2
RO3	Restriction option 3
SAG-CS	Scientific Advisory Group for Cosmetics
SCCS	Scientific Committee on Consumer Safety
SCL	Specific concentration limits
SDC	Society of Dyers and Colourists
SDS	Safety Data Sheet
SEAC	Socioeconomic Assessment Committee of the European Chemicals Agency
SMB	Small and micro businesses
SS	Skin Sensitisers
STOT RE	Single target organ toxicity (repeated exposure)
STOT SE	Single target organ toxicity (single exposure)
UK	United Kingdom
US EPA	US Environmental Protection Agency
US FDA	US Food and Drug Administration
US/USA	United States of America
WHO	World Health Organisation
WTP	Willingness to pay

7 References

Abudu, B., Erickson, C.P., Calame, A. and Cohen, P.R. (2019). Basal Cell Carcinoma Originating in a Tattoo: Case Report and Review of an Uncommon Complication in Tattoo Recipients. Dermatology Practical & Conceptual, pp.265–270.

Barber DTS. 2021. Tattoo Prices in the UK–- A Guide with Tips | Barber DTS. [online] Available at: <https://www.barberdts.com/uk/advice-hub/tattoo-prices-in-the-uk/> (accessed 30 September 2021).

Bäumler, W. (2017). Laser Treatment of Tattoos: Basic Principles. Diagnosis and Therapy of Tattoo Complications, [online] 52, pp.94–104.

British Pound to US Dollar exchange rate., 2021. [online] Available at: <https://www.poundsterlinglive.com/bank-of-england-spot/historical-spot-exchange-rates/gbp/GBP-to-USD-2007> (accessed 30 September 2021).

BfR (2020). Tattoo inks: risk assessment for Pigment Blue 15:3 and Pigment Green 7. BfR Opinion No 039/2020 issued 8 September 2020. DOI 10.17590/20201006-102053. [Online] Available at: https://www.bfr.bund.de/cm/349/tattoo-inks-risk-assessment-for-pigment-blue-15-3-and-pigment-green-7.pdf (accessed 31 March 2022)

Cannarozzo, G., Negosanti, F., Sannino, M., Santoli, M., Bennardo, L., Banzola, N., Negosanti, L. and Nisticò, S.P. (2019). Q-switched Nd:YAG laser for cosmetic tattoo removal. Dermatologic Therapy, [online] 32(5), p.e13042. Available at: https://pubmed.ncbi.nlm.nih.gov/31361928/.

Centers for Disease Control and Prevention (CDC). 2021. *Cost-Effectiveness Analysis*. [online] Available at: <https://www.cdc.gov/policy/polaris/economics/cost-effectiveness/index.html#:~:text=Cost%2Deffectiveness%20analysis%20is%20a,gained%20or%20a%20death%20prevented.> (accessed 29 March 2022).

CoE (2003). Council of Europe Resolution ResAP(2003)2 on tattoos and permanent make-up. [Online] Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805df8e5 (accessed 25 February 2022)

CoE (2008). Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up). [Online] Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805d3dc4 (accessed 25 February 2022)

Department for Business, Energy and Industrial Strategy, 2020. Better Regulation

Framework. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/916918/better-regulation-guidance.pdf

ECHA, 2015. *Annex XV Restriction Report - Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5)*. [online] Echa.europa.eu. Available at: <https://echa.europa.eu/documents/10162/8d1fa738-ab82-2793-afd3-2cde40fa08e5> (accessed 1 April 2022).

ECHA, 2016. Valuing selected health impacts of chemicals. Summary of the Results and a Critical Review of the ECHA study. European Chemicals Agency 2016

ECHA (2017). Annex XV restriction report: Proposal for a restriction. [Online] Available at: https://echa.europa.eu/documents/10162/6f739150-39db-7e2c-d07d-caf8fb81d153 (accessed 9 March 2022)

ECHA (2019a). Background document to the Opinion on the Annex XV dossier proposing restrictions on substances in tattoo inks and permanent make up. [Online] Available at: https://echa.europa.eu/documents/10162/2f5b2f8c-430e-34db-2966-2f2d3e6c0bd6 (accessed 25 February 2022)

ECHA (2019b). Appendix to the background document to the Opinion on the Annex XV dossier proposing restrictions on substances in tattoo inks and permanent make up. [Online] Available at: https://echa.europa.eu/documents/10162/6fc65bb4-cfde-de7b-9d5f-a21b85817db5 (accessed 25 February 2022)

ECHA (2019c). Annex to the background document to the Opinion on the Annex XV dossier proposing restrictions on substances in tattoo inks and permanent make up. [Online] Available at: https://echa.europa.eu/documents/10162/d4637427-99fd-52c0-e81e-1404f31a8e0b (accessed 25 February 2022)

ECHA (2019d). Opinion on the Annex XV dossier proposing restrictions on substances in tattoo inks and permanent make up. [Online] Available at: https://echa.europa.eu/documents/10162/dc3d6ea4-df3f-f53d-eff0-540ff3a5b1a0 (accessed 25 February 2022)

ECHA (2019e). Comments on the SEAC draft opinion and specific information requests [Online] Available at: https://echa.europa.eu/documents/10162/7a105f39-d55c-1bdb-b730-0eedeb7a6667 (accessed 25 February 2022)

ECHA (2019f). 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. [Online] Available at: https://echa.europa.eu/documents/10162/13c2a9c6-9a1d-5567-834c-aa73d1a29439 (accessed 25 February 2022)

Engel, E. *et al.*, (2008). Modern tattoos cause high concentrations of hazardous pigments in skin. Contact Dermatitis, 58 (4), pp. 228-233. DOI: DOI 10.1111/j.1600-0536.2007.01301.x.

Engel, E. *et al*., (2010). Tattooing of skin results in transportation and light-induced decomposition of tattoo pigments--a first quantification in vivo using a mouse model. Exp Dermatol, 19 (1), pp. 54-60. DOI: 10.1111/j.1600-0625.2009.00925.x.

Exchangerates.org.uk. 2021. British Pound to Euro Spot Exchange Rates for 2016. [online] Available at: <https://www.exchangerates.org.uk/GBP-EUR-spot-exchange-rates-history-2016.html> (accessed 30 September 2021).

Exchangerates.org.uk. 2021. Euro to British Pound Spot Exchange Rates for 2010. [online] Available at: <https://www.exchangerates.org.uk/EUR-GBP-spot-exchange-rates-history-2010.html#:~:text=This%20is%20the%20Euro%20(EUR,rate%20in%202010%3A%200.8583%20GBP> (accessed 30 September 2021).

Tracie Giles. 2017. *How to Become a Permanent Make Up Artist | Tracie Giles*. [online] Available at: <https://www.traciegiles.co.uk/permanent-makeup-artist-tg-tips/> (accessed 8 April 2022).

Georgiou, S., Postle, M. and Rheinberger, C., 2019. Valuation of Health Impacts Under the EU's REACH Chemicals Regulation. *Encyclopaedia of Environmental Health*,.

Giulbudagian, M. *et al*., (2020). Safety of tattoos and permanent make-up: a regulatory view. Archives of Toxicology (2020) 94:357–369. https://doi.org/10.1007/s00204-020-02655-z.

Hauri (2014). Inks for tattoos and permanent make-up—pigments, preservatives, aromatic amines, polyaromatic hydrocarbons and nitrosamines. Swiss National Investigation Campaign 2014. Department of Health, Kanton Basel-Stadt. [Online] Available at: https://scholar.google.com/scholar?q=+Hauri+U+:+Inks+for+tattoos+and+permanent+make-up%E2%80%94pigments,+preservatives,+aromatic+amines,+polyaromatic+hydrocarbons+and+nitrosamines.+Swiss+National+Investigation+Campaign+2014.+Department+of+Health,+Kanton+Basel-Stadt.+2014 (accessed 8 December 2021)

Hauri (2021). Inks for tattoos and permanent make-up. Preservatives, colourants, primary aromatic amines, polyaromatic hydrocarbons and nitrosamines. Samples from the cantons of Aargau, Bern, St. Gallen, Thurgau and Basel-Stadt (lead laboratory) as well as samples for private analyses. Department of Health, Kanton Basel-Stadt. [Online] Available at:

https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjYzNvJsPr2AhXVMMAKHZrwAxkQFnoECAcQAQ&url=https%3A%2F%2Fwww.kantonslabor.bs.ch%2Fdam%2Fjcr%3Ad71126f3-85c9-42fb-a16d-8d21f7fc5ee8%2F2020-Tattootinten.Englisch.pdf&usg=AOvVaw0kmz__83FqHrHuTNHOoHbl (accessed 8 December 2021)

HM Treasury. Assets.publishing.service.gov.uk. 2021. The Green Book. [online] Available at: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/938046/The_Green_Book_2020.pdf> (accessed 30 September 2021).

Høgsberg, T., Hutton Carlsen, K. and Serup, J. (2013). High prevalence of minor symptoms in tattoos among a young population tattooed with carbon black and organic pigments. Journal of the European Academy of Dermatology and Venereology, 27(7), pp.846–852

HSE, 2016. *Costs to Britain of Work-Related Cancer*. [online] Hse.gov.uk. Available at: <https://www.hse.gov.uk/research/rrhtm/rr1074.htm> (Accessed 15 February 2022).

Huisman, S., van der Bent, S.A.S., Maijer, K.I., Tio, D.C.K.S. and Rustemeyer, T. (2020). Cutaneous non-allergic complications in tattoos: An overview of the literature. La Presse Médicale, 49(4), p.104049.

Hutton Carlsen, K. and Serup, J. (2013). Photosensitivity and photodynamic events in black, red and blue tattoos are common: A 'Beach Study'. Journal of the European Academy of Dermatology and Venereology, 28(2), pp.231–237.

JRC (2015a). Joint Research Centre, Institute for Health and Consumer Protection, Piccinini, P., Bianchi, I., Pakalin, S., et al., Safety of tattoos and permanent make-up: compilation of information on legislative framework and analytical methods, Publications Office, 2017, https://data.europa.eu/doi/10.2788/542617. (accessed 3 March 2022).

JRC (2015b). Joint Research Centre, Institute for Health and Consumer Protection, Raemaekers, T., Piccinini, P., Contor, L., et al., Safety of tattoos and permanent make-up: state of play and trends in tattoo practices, Publications Office, 2016, https://data.europa.eu/doi/10.2788/924128. (accessed 3 March 2022).

JRC (2016a). European Commission, Joint Research Centre, Contor, L., Piccinini, P., Bianchi, I., et al., Safety of tattoos and permanent make-up: adverse health effects and experience with the Council of Europe Resolution (2008)1, Publications Office, 2016, https://data.europa.eu/doi/10.2788/177900. (accessed 3 March 2022).

JRC (2016b). European Commission, Joint Research Centre, Senaldi, C., Pakalin, S., Contor, L., et al., Safety of tattoos and permanent make-up: final report, Publications Office, 2017, https://data.europa.eu/doi/10.2788/011817. (accessed 3 March 2022).

Kazandjieva, J. and Tsankov, N. (2007). Tattoos: dermatological complications. Clinics in Dermatology, 25(4), pp.375–382.

Kluger, N., 2015a. Epidemiology of tattoos in Industrialized Countries. In: J. Serup, N. Kluger & W. Bäumler, eds. Tattoed Skin and health. Current Problems in Dermatology. s.l.:s.n., pp. 6-20. [Online]. Available at: https://www.karger.com/Book/Toc/262372. (accessed 7 April 2022)

Kluger, N. (2015b). Contraindications for Tattooing. Tattooed Skin and Health, pp.76–87.

Kluger, N. (2016). Self-reported tattoo reactions in a cohort of 448 French tattooists. International Journal of Dermatology, 55(7), pp.764–768.

Kluger, N. (2019). An update on cutaneous complications of permanent tattooing. Expert Review of Clinical Immunology, 15(11), pp.1135–1143.

Kluger, N. (2021). Nickel and tattoos: Where are we? Contact Dermatitis. 2021;1–5. DOI: 10.1111/cod.13869.

Klügl, I., Hiller, K.-A., Landthaler, M. and Bäumler, W. (2010). Incidence of Health Problems Associated with Tattooed Skin: A Nation-Wide Survey in German-Speaking Countries. Dermatology, 221(1), pp.43–50.

Laux, P., Tralau, T., Tentschert, J., Blume, A., Dahouk, S.A., Bäumler, W., Bernstein, E., Bocca, B., Alimonti, A., Colebrook, H., de Cuyper, C., Dähne, L., Hauri, U., Howard, P.C., Janssen, P., Katz, L., Klitzman, B., Kluger, N., Krutak, L. and Platzek, T. (2016). A medical-toxicological view of tattooing. The Lancet, [online] 387(10016), pp.395–402.

Lehner, K., Santarelli, F., Penning, R., Vasold, R., Engel, E., Maisch, T., Gastl, K., König, B., Landthaler, M. and Bäumler, W. (2011). The decrease of pigment concentration in red tattooed skin years after tattooing. Journal of the European Academy of Dermatology and Venereology, 25(11), pp.1340–1345.

Lerche, C.M., Sepehri, M., Serup, J., Poulsen, T. and Wulf, H.C. (2015). Black tattoos protect against UVR-induced skin cancer in mice. Photodermatology, Photoimmunology & Photomedicine, 31(5), pp.261–268.

Lerche, C.M., Heerfordt, I.M., Serup, J., Poulsen, T. and Wulf, H.C. (2017). Red tattoos, ultraviolet radiation and skin cancer in mice. Experimental Dermatology,

26(11), pp.1091–1096.

Mayo Clinic, 2018. Hypospadias. Available at: https://www.mayoclinic.org/diseases-conditions/hypospadias/symptoms-causes/syc-20355148. (accessed 25 January 2022).

McIlwee, B.E. and Alster, T.S. (2018). Treatment of Cosmetic Tattoos. Dermatologic Surgery, 44(12), pp.1565–1570.

Michel, R. (2015). Manufacturing of tattoo Ink Products Today and in Future: Europe. In: J. Serup, N. Kluger & W. Bäumler, eds. Tattoed Skin and health. Current Problems in Dermatology. s.l.:s.n., pp. 103-111. [Online] Available at: https://www.karger.com/Article/Pdf/370012

NHS, 2019a. Cosmetic procedures - Permanent make-up. [online] nhs.uk. Available at: <https://www.nhs.uk/conditions/cosmetic-procedures/permanent-make-up/> (accessed 5 October 2021).

NHS, 2019b. Cosmetic procedures - Tattoo removal. [online] nhs.uk. Available at: <https://www.nhs.uk/conditions/cosmetic-procedures/tattoo-removal/> (accessed 8 October 2021).

NHS, 2021. Cryptorchidism/Undescended testicles. Available at: https://www.nhs.uk/conditions/undescended-testicles/. (accessed 25 January 2022).

OECD SIDS (1997) Copper phthalocyanine Pigment Blue 15, CAS no. 147-14-8. [Online] Available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.738.6358&rep=rep1&type=pdf (accessed 31 March 2022)

ONS. 2021a. Annual Survey of Hours and Earnings. Available at: https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation2digitsocashetable3 (accessed 12 November 2021).

ONS. 2021b. Average Sterling exchange rate: Euro - Office for National Statistics. [online] Available at: <https://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/timeseries/thap/mret> (accessed 30 September 2021).

ONS. 2021c. Overview of the UK population - Office for National Statistics. [online] Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/overviewoftheukpopulation/january2021> (accessed 30 September 2021).

Papameletiou, D., Zenié, A., Schwela, D. & W, B. (2003). Risks and health effects from tattoos, body piercing and related practices, s.l.: JRC.

Paprottka, F.J., Krezdorn, N., Narwan, M., Turk, M., Sorg, H., Noah, E.M. and Hebebrand, D. (2017). Trendy Tattoos—Maybe a Serious Health Risk? Aesthetic Plastic Surgery, 42(1), pp.310–321.

Regulatory Policy Committee, 2019. Small and Micro Business Assessments: guidance for departments, with case history examples. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/827960/RPC_Small_and_Micro_Business_Assessment__SaMBA___August_2019.pdf

Renzoni, A., Pirrea, A., Novello, F., Lepri, A., Cammarata, P., Tarantino, C., D'Ancona, F. and Perra, A. (2018). The tattooed population in Italy: a national survey on demography, characteristics and perception of health risks. Annali dell'Istituto Superiore di Sanità, [online] 54(2), pp.126–136. Available at: https://annali.iss.it/index.php/anna/article/view/543/400 (accessed 5 April 2022).

Salary Expert., 2022. *Salary Expert - Tattoo Artist Salary London, United Kingdom*. [online] Salary Expert. Available at: <https://www.salaryexpert.com/salary/job/tattoo-artist/united-kingdom/london#:~:text=The%20average%20tattoo%20artist%20gross,average%20bonus%20of%20%C2%A3365.> [Accessed 5 April 2022].

Schreiver, I., Hutzler, C., Laux, P., Berlien, H.-P. and Luch, A. (2015). Formation of highly toxic hydrogen cyanide upon ruby laser irradiation of the tattoo pigment phthalocyanine blue. Scientific Reports, 5(1).

Sepehri, M., Sejersen, T., Qvortrup, K., Lerche, C.M. and Serup, J. (2017a). Tattoo Pigments Are Observed in the Kupffer Cells of the Liver Indicating Blood-Borne Distribution of Tattoo Ink. Dermatology, 233(1), pp.86–93.

Sepehri, M., Lerche, C.M., Hutton Carlsen, K. and Serup, J. (2017b). Search for Internal Cancers in Mice Tattooed with Inks of High Contents of Potential Carcinogens: A One-Year Autopsy Study of Red and Black Tattoo Inks Banned in the Market. Dermatology, 233(1), pp.94–99.

Serup, J., Hutton Carlsen, K. & Sepehri, M., (2015). Tattoo Complaints and Complications: Diagnosis and Clinical Spectrum. In: J. Serup, N. Kluger & W. Bäumler, eds. Tattoed Skin and health. Current Problems in Dermatology, vol 48, pp 48-60. s.l.:s.n., pp. 48-60.

Serup, J., Sepehri, M. and Hutton Carlsen, K. (2016). Classification of Tattoo Complications in a Hospital Material of 493 Adverse Events. Dermatology, 232(6),

pp.668–678.

Shinohara, M.M. (2016). Complications of decorative tattoo. Clinics in Dermatology, 34(2), pp.287–292.

Silvestre, J.F. and González Villanueva, I. (2019). Diagnostic Approach for Suspected Allergic Cutaneous Reaction to a Permanent Tattoo. Journal of Investigational Allergology & Clinical Immunology, [online] 29(6), pp.405–413.

Spence, M., 2022. *Tattoo nation: when did we all start getting inked?*. [online] Thetimes.co.uk. Available at: <https://www.thetimes.co.uk/article/tattoo-nation-start-getting-inked-business-booming-hackney-nqdjf2dzm> (accessed 15 February 2022).

van der Bent, S.A.S., Rauwerdink, D., Oyen, E.M.M., Maijer, K.I., Rustemeyer, T. and Wolkerstorfer, A. (2021). Complications of tattoos and permanent makeup: overview and analysis of 308 cases. Journal of Cosmetic Dermatology, 20(11), pp.3630–3641.

Wang, X. *et al*., (2021). Analytical survey of tattoo inks – A chemical and legal perspective with focus on sensitising substances. Contact Dermatitis, 85(3), 340-353. [Online] Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/cod.13913 (accessed 8 December 2021)

Warner, F.M., Darvishian, M., Boyle, T., Brooks-Wilson, A.R., Connors, J.M., Lai, A.S., Le, N.D., Song, K., Sutherland, H., Woods, R.R., Bhatti, P. and Spinelli, J.J. (2020). Tattoos and Hematologic Malignancies in British Columbia, Canada. Cancer Epidemiology Biomarkers & Prevention, 29(10), pp.2093–2095.

Weiß, K.T., Schreiver, I., Siewert, K., Luch, A., Haslböck, B., Berneburg, M. and Bäumler, W. (2021). Tattoos – more than just colored skin? Searching for tattoo allergens. JDDG: Journal der Deutschen Dermatologischen Gesellschaft, 19(5), pp.657–669.

Wenzel, S.M., Rittmann, I., Landthaler, M. and Bäumler, W. (2013). Adverse Reactions after Tattooing: Review of the Literature and Comparison to Results of a Survey. Dermatology, 226(2), pp.138–147.

Wollina, U. (2012). Severe adverse events related to tattooing: An retrospective analysis of 11 years. Indian Journal of Dermatology, 57(6), p.439.

Appendix 1 – Supplementary tables A – F

Supplementary table A to RO1 and RO2: The list of substances for which specific concentration limits are being proposed under RO1 and RO2.

This list includes methanol, impurities listed in Table 3 of CoE (2008), certain primary aromatic amines, certain azo dyes, DEHP and DBP.

Substance name	CAS	Proposed concentration limit	CPR Annex II	CPR Annex IV	In tattoo inks*	Mandatory classification (as of 25 Feb 22)
Mercury	7439-97-6	0.00002% w/w	221		Yes	Repr. 1B Acute Tox. 2* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1
Nickel	7440-02-0	0.001% w/w	1,093		Yes	Carc. 2 STOT RE 1 Skin Sens. 1. In addition, nickel powder is classified as Aquatic Chronic 3
Tin	7440-31-5	0.005% w/w			Yes	Not listed
Antimony	7440-	0.0002% w/w	40		Yes	Not listed

	36-0					
Arsenic	7440-38-2	0.0000008% w/w	43		Yes	Acute Tox. 3* Acute Tox. 3* Aquatic Acute 1 Aquatic Chronic 1
Barium**	7440-39-3	0.84% w/w			Yes	Not listed
Cadmium	7440-43-9	0.00002% w/w	68		Yes	Carc. 1B Muta. 2 Repr. 2 Acute Tox. 2* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1 In addition, pyrophoric cadmium is classified as Pyr. Sol. 1
Chromium‡	7440-47-3	0.00002% w/w	97		Yes	Not listed
Cobalt	7440-48-4	0.0025% w/w			Yes	Carc. 1B Muta. 2 Repr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4

Copper**	7440-50-8	0.025% w/w		132	Yes	The GB MCL entry applies to granulated copper; [particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm]
Zinc**	7440-66-6	0.23% w/w			Yes	Aquatic Acute 1 Aquatic Chronic 1 Pyr. Sol. 1 Water-react. 1 Aquatic Acute 1 Aquatic Chronic 1
Lead	7439-92-1	0.00007% w/w	289		Yes	Repr. 1A Lact. In addition, lead powder; [particle diameter, <1 mm] is classified as Aquatic Acute 1 Aquatic Chronic 1
Selenium	7782-49-2	0.0002% w/w	297		Yes	Acute Tox. 3* Acute Tox. 3* STOT RE 2* Aquatic Chronic 4

Methanol	67-56-1	10.9% w/w			Yes	Flam. Liq. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT SE 1
o-Anisidine** (2-methoxyaniline)	90-04-0	0.0005% w/w	708		Yes	Carc. 1B Muta. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 *
o-toluidine** (2-aminotoluene)	95-53-4	0.0005% w/w			Yes	Carc. 1B Acute Tox. 3 * Acute Tox. 3 * Eye Irrit. 2 Aquatic Acute 1
,3'-dichlorobenzidine** (4-(4-amino-3-chlorophenyl)-2-chloroaniline)	91-94-1	0.0005% w/w	712		Yes	Carc. 1B Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
4-methyl-m-phenylendiamine** (2,4-toluenediamine)	95-80-7	0.0005% w/w	364		Yes	Carc. 1B Muta. 2 Repr. 2 Acute Tox. 3 * Acute Tox. 4 * STOT RE 2 * Skin Sens. 1 Aquatic Chronic 2

4-chloroaniline**	106-47-8	0.0005% w/w			Yes	Carc. 1B Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
5-nitro-o-toluidine**	99-55-8	0.0005% w/w	1,195		Yes	Carc. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Aquatic Chronic 3
3,3'-dimethoxybenzidine** (o-dianisidine)	119-90-4	0.0005% w/w	709		Yes	Carc. 1B Acute Tox. 4 *
4,4’-bi-o-toluidine**	119-93-7	0.0005% w/w	721		Yes	Carc. 1B Acute Tox. 4 * Aquatic Chronic 2
4,4'-Thiodianiline**	139-65-1	0.0005% w/w	1,159		Yes	Carc. 1B Acute Tox. 4 * Aquatic Chronic 2
4-chloro-o-toluidine**	95-69-2	0.0005% w/w			Yes	Carc. 1B Muta. 2 Acute Tox. 3 * Acute Tox. 3 *

						Acute Tox. 3 * Aquatic Acute 1 Aquatic Chronic 1
2-naphthylamine**	91-59-8	0.0005% w/w	242		Yes	Carc. 1A Acute Tox. 4 * Aquatic Chronic 2
Aniline**	62-53-3	0.0005% w/w	22			Carc. 2 Muta. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * STOT RE 1 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1
Benzidine** (1,1'-biphenyl-4,4'-diamine 4,4'-diaminobiphenyl biphenyl-4,4'-ylenediamine)	92-87-5	0.0005% w/w	26			Carc. 1A Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1
p-toluidine** (4-aminotoluene)	106-49-0	0.0005% w/w				Carc. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Eye Irrit. 2

						Skin Sens. 1 Aquatic Acute 1
2-methyl-p-phenylenediamine** (2,5-toluenediamine)	95-70-5	0.0005% w/w				Acute Tox. 3 * Acute Tox. 4 * Acute Tox. 4 * Skin Sens. 1 Aquatic Chronic 2
Biphenyl-4-ylamine** (4-Aminobiphenyl xenylamine)	92-67-1	0.0005% w/w	726			Carc. 1A Acute Tox. 4 *
4-o-tolylazo-o-toluidine** (Solvent Yellow 3/ CI 11160 4-amino-2',3-dimethylazobenzene AAT fast garnet GBC base o-aminoazotoluene)	97-56-3	0.0005% w/w	989			Carc. 1B Skin Sens. 1
4-methoxy-m-phenylenediamne** (2,4-diaminoanisole)	615-05-4	0.0005% w/w	376			Carc. 1B Muta. 2 Acute Tox. 4 * Aquatic Chronic 2
4,4'-methylenedianiline**	101-	0.0005% w/w	705			Carc. 1B Muta. 2

4,4'-diaminodiphenylmethane (MDA)	77-9					STOT SE 1 STOT RE 2 * Skin Sens. 1 Aquatic Chronic 2
4,4'-methylenedi-o-toluidine**	838-88-0	0.0005% w/w	707			Carc. 1B Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
6-methoxy-m-toluidine** (p-cresidine)	120-71-8	0.0005% w/w	1,162			Carc. 1B Acute Tox. 4 *
4,4'-methylenebis[2-chloro aniline]** (2,2'-dichloro-4,4'-methylenedianiline (MOCA))	101-14-4	0.0005% w/w				Carc. 1B Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1
4,4'-oxydianiline** (p-aminophenyl ether)	101-80-4	0.0005% w/w	1,160			Carc. 1B Muta. 1B Repr. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Aquatic Chronic 2
2,4,5-trimethylaniline**	137-	0.0005% w/w	1,158			Carc. 1B Acute Tox. 3 *

	17-7					Acute Tox. 3 * Acute Tox. 3 * Aquatic Chronic 2
4-Aminoazobenzene** (Solvent Yellow 1/ CI 11000 4-phenylazoaniline)	60-09-3	0.0005% w/w	990			Carc. 1B Aquatic Acute 1 Aquatic Chronic 1
p-Phenylenediamine**	106-50-3	0.0005% w/w			Yes	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
Sulphanilic acid** (4-aminobenzenesulphonic acid)	121-57-3	0.0005% w/w	1,257			Eye Irrit. 2 Skin Irrit. 2 Skin Sens. 1
4-amino-3-fluorophenol**	399-95-1	0.0005% w/w	1,242			Carc. 1B Acute Tox. 4 * Skin Sens. 1 Aquatic Chronic 2
2,6-xylidine (2,6-dimethylaniline)	87-62-7	0.0005% w/w				Carc. 2 Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 *

						STOT SE 3 Skin Irrit. 2 Aquatic Chronic 2
Pigment Red 7 (PR7)/CI 12420 (N-(4-chloro-2-methylphenyl)-4-[(4-chloro-2-methylphenyl)azo]-3-hydroxynaphthalene-2-carboxamide)	6471-51-8	0.1% w/w		12	Yes	Not listed
Pigment Red 9(PR9)/CI 12460 (4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide)	6410-38-4	0.1% w/w			Yes	Not listed
Pigment Red 15 (PR15)/CI 12465 (4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide)	6410-39-5	0.1% w/w			Yes	Not listed
Pigment Red 210(PR210)/CI 12477	61932-63-6	0.1% w/w			Yes	Not listed
Pigment Orange 74 (PO74)	85776-14-3	0.1% w/w			Yes	Not listed
Pigment Yellow 65 (PY65)/CI 11740 (2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-	6528-34-3	0.1% w/w			Yes	Not listed

3-oxobutyramide)						
Pigment Yellow 74 (PY74)/CI 11741 (2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide)	6358-31-2	0.1% w/w			Yes	Not listed
Pigment Red 12 (PR12)/CI 12385 (3-hydroxy-4-[(2-methyl-4-nitrophenyl)azo]-N-(o-tolyl)naphthalene-2-carboxamide)	6410-32-8	0.1% w/w			Yes	Not listed
Pigment Red 14 (PR14)/CI 12380 (4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxy-N-(2-methylphenyl)naphthalene-2-carboxamide)	6471-50-7	0.1% w/w			Yes	Not listed
Pigment Red 17 (PR17)/CI 12390 (3-hydroxy-4-[(2-methyl-5-nitrophenyl)azo]-N-(o-tolyl)naphthalene-2-carboxamide)	6655-84-1	0.1% w/w			Yes	Not listed
Pigment Red 112 (PR112)/CI 12370 (3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide)	6535-46-2	0.1% w/w	1,346	11	Yes	Not listed
Pigment Yellow 14 (PY14)/CI 21095 (2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-	5468-75-7	0.1% w/w			Yes	Not listed

(2-methylphenyl)-3-oxobutyramide])						
Pigment Yellow 55 (PY55)/CI 21096 (2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide])	6358-37-8	0.1% w/w			Yes	Not listed
Pigment Red 2 (PR2)/ CI 12310 (4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-phenylnaphthalene-2-carboxamide)	6041-94-7	0.1% w/w			Yes	Not listed
Pigment Red 22 (PR22)/ CI 12315 (3-hydroxy-4-[(2-methyl-5-nitrophenyl)azo]-N-phenylnaphthalene-2-carboxamide)	6448-95-9	0.1% w/w			Yes	Not listed
Pigment Red 146 (PR146)/ CI 12485 (N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide)	5280-68-2	0.1% w/w			Yes	Not listed
Pigment Red 269 (PR269)/ CI 12466 (N-(5-chloro-2-methoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide)	67990-05-0	0.1% w/w			Yes	Not listed

Pigment Orange 16 (PO16)/ CI 21160 (2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutyramide])	6505-28-8	0.1% w/w			Yes	Not listed
Pigment Yellow 1 (PY1)/ CI 11680 (2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide)	2512-29-0	0.1% w/w		4	Yes	Not listed
Pigment Yellow 12 (PY12)/CI 21090 (2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutyramide])	6358-85-6	0.1% w/w	1,263		Yes	Not listed
Pigment Yellow 87 (PY87)/ CI 21107:1 (2,2'-[(3,3'-dichloro-4,4'-biphenylylene)bis(azo)]bis[2',5'-dimethoxyacetoacetanilide])	15110-84-6, 14110-84-6	0.1% w/w			Yes	Not listed
Pigment Yellow 97 (PY97)/ CI 11767 (N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide)	12225-18-2	0.1% w/w			Yes	Not listed
Pigment Orange 13 (PO13)/ CI 21110 (4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-	3520-72-7	0.1% w/w			Yes	Not listed

pyrazol-3-one])						
Pigment Orange 34 (PO34)/ CI 21115 (4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one])	15793-73-4	0.1% w/w			Yes	Not listed
Pigment Yellow 83 (PY83)/ CI 21108 (2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide])	5567-15-7	0.1% w/w		48	Yes	Not listed
Solvent Red 1 (SR1)/ CI 12150 (1-[(2-methoxyphenyl)azo]-2-naphthol)	1229-55-6	0.1% w/w	1,231			Not listed
Acid Orange 24 (AO24)/ CI 20170 (Sodium 4-[[3-[(dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo]benzenesulphonate)	1320-07-6	0.1% w/w	1,232			Not listed
Solvent Red 23 (SR23)/ CI 26100 (1-(4-(phenylazo)phenylazo)-2-naphthol)	85-86-9	0.1% w/w	1,353	51		Not listed
Acid Red 73 (AR73)/ CI 27290 (Sodium 6-hydroxy-5-(4-phenylazophenylazo)naphthalene-2,4-disulphonate)	5413-75-2	0.1% w/w	1,233			Not listed

Disperse Yellow 3/ CI 11855 (N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]acetamide)	2832-40-8	0.1% w/w	1,055			Carc. 2 Skin Sens. 1
Acid Green 16 (sodium 4-{[4-(diethylamino)phenyl][4-(diethyliminio)cyclohexa-2,5-dien-1-ylidene]methyl}naphthalene-2,7-disulfonate)	12768-78-4	0.1% w/w				Not listed
Acid Red 26 (Disodium 1-(2,4-dimethylphenylazo)-2-hydroxynaphthalene-3,6-disulphonate)	3761-53-3	0.1% w/w				Not listed
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)	4129-84-4	0.1% w/w				Not listed
Basic Red 1 (9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride)	989-38-8	0.1% w/w			Yes	Not listed
Disperse Blue 106 (Ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-)	12223-01-7	0.1% w/w				Not listed
Disperse Blue 124	61951-	0.1% w/w				Not listed

	51-7					
Disperse Blue 35	12222-75-2	0.1% w/w				Not listed
Disperse Orange 37 (Propanenitrile, 3-[[4-[2-(2,6-dichloro-4-nitrophenyl)diazenyl]phenyl]ethylamino]-	12223-33-5	0.1% w/w				Not listed
Disperse Red 1 (2-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]ethanol)	2872-52-8	0.1% w/w				Not listed
Disperse Red 17 (2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol)	3179-89-3	0.1% w/w				Not listed
Disperse Yellow 9 (N-(2,4-dinitrophenyl)benzene-1,4-diamine)	6373-73-5	0.1% w/w				Not listed
Pigment Violet 3 (4-[(4-Aminophenyl)-(4-methyliminocyclohexa-2,5-dien-1-ylidene)methyl]aniline)	1325-82-2	0.1% w/w				Not listed
Pigment Violet 39 (Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, molybdatephosphate)	64070-98-0	0.1% w/w				Not listed

Solvent Yellow 2 (4-dimethylaminoazobenzene)	60-11-7	0.1% w/w				Not listed
Bis(2-ethylhexyl) phthalate† (DEHP)	117-81-7	0.07% w/w	677		Yes	Repr. 1B
Dibutyl phthalate† (DBP)	84-74-2, 93952-11-5	0.009% w/w	675		Yes	Repr. 1B Aquatic Acute 1

Notes: *Substances found in tattoo inks and PMU. **Soluble. ‡Chromium VI. †RO2 only.

Supplementary table B to RO1, RO2 and RO3: lists 21 colourants that are prohibited for use as hair dyes under Annex 2 of the CPR but permitted for use as colorants in cosmetics without conditions under Annex 4 of the CPR.

The Agency proposes that the substances on this list should be derogated from the scope of this restriction.

Substance name	**Market name**	**CAS**	**EU REACH Registered**	**CPR Annex II #**	**CPR Annex IV #**	**Allowed subject to conditions**	**In tattoo inks ***	**Has impurity**	**Self-classification notified to ECHA's C+L inventory**	**ECHA's C+L inventory notification #**
1,4-bis(p-tolylamino)anthraquinone	Solvent Green 3, CI 61565	128-80-3	Y	1364	91			Y	Not Classified (93.0%), Aquatic Chronic 4 (4.1%), Eye Irrit. 2 (2.4%), Skin Irrit. 2 (2.4%), STOT SE 3 (2.2%), Carc. 2 (0.2%),	1,680

									Muta. 2 (0.2%), STOT RE 2 (0.2%), Skin Sens. 1 (0.1%)	
29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper	Pigment Blue 15, CI 74160	147-14-8	Y	1367	105		Y	Y	Not Classified (97.9%), Aquatic Chronic 4 (1.4%), Skin Sens. 1 (1.4%), Aquatic Chronic 1 (0.4%), Aquatic Chronic 3 (0.4%), Aquatic Acute 1 (0.3%), Eye Irrit. 2 (0.1%),	1,403

									Skin Irrit. 2 (0.1%)	
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	2353-45-9	Y	1357	61			Y	Eye Irrit. 2 (42.2%), STOT SE 3 (42.2%), Skin Irrit. 2 (42.2%), Not Classified (24.3%), Muta. 2 (18.9%), Carc. 2 (13.5%)	185
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	2379-74-0	Y	1365	100		Y	N	Not Classified (86.8%), Aquatic Acute 1 (10.5%), Aquatic Chronic 1 (10.5%), Skin Sens.	219

									1 (0.5%)	
Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate	Red, CI 14700	4548-53-2	Y	1341	18			Y	Not Classified (100.0%)	185
N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide	Pigment Red 5, CI 12490	6410-41-9	Y	1347	14		Y	Y	Not Classified (98.7%), Skin Sens. 1 (1.3%)	223
Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate	Pigment Red 63:1, CI 15880	6417-83-0	Y	1349	29		Y	Y	Not Classified (97.9%), Aquatic Chronic 3 (0.4%)	243
1,2-dihydroxyanthraquinone	Pigment Red 83, CI 58000	72-48-0		1361	86			N	Acute Tox. 4 (56.8%), Eye Irrit. 2	44

									(27.3%), Skin Irrit. 2 (22.7%), Not Classified (20.5%)	
1-hydroxy-4-(p-toluidino)anthraquinone	Solvent Violet 16, CI 60725	81-48-1		1363	89			Y	Not Classified (90.7%), Aquatic Chronic 4 (4.9%), Skin Sens. 1 (4.1%)	1,420
Sodium 4-(2,4-dihydroxyphenylazo) benzenesulphonate	Acid Orange 16, CI 14270	547-57-9		1330	17			N	Not Classified (100.0%)	8
4-(phenylazo)resorcinol	Solvent Orange 1, CI 11920	2051-85-6		1343	7			N	Eye Irrit. 2 (51.9%), STOT SE 3 (51.9%), Skin Irrit. 2	135

									(51.9%), Not Classified (48.1%)	
Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate	Food Black 2, CI 27755	2118-39-0		1354	52		Y	N	Not Classified (100.0%)	32
Polychloro copper phthalocyanine when used as a substance in hair dye products, Polychloro copper phthalocyanine	Pigment Green 7; CI 74260	1328-53-6	Y	1369	107[94]		Y	N	Not Classified (97.3%), Eye Irrit. 2 (2.7%), Acute Tox. 4 (2.1%), STOT SE 3 (0.4%)	845
1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085)	CI 12085/R	2814-77-9	Y	1345	9	3%	Y	Y	Not Classified (90.4%),	240

[94] According to Annex IV of the CPR, Pigment Green 7 is allowed in cosmetic products except when used in eye products (column g). It is also not allowed for use in hair colours (Annex II of CPR).

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	ed								Aquatic Chronic 4 (9.6%), Eye Irrit. 2 (9.6%)	
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	915-67-3	Y	1350	33	Purity criteria as set out in Commission Directive 95/45/EC (E 123)		Y	Not Classified (63.0%), Eye Irrit. 2 (36.3%), STOT SE 3 (36.3%), Skin Irrit. 2 (36.3%), Aquatic Chronic 3 (0.7%)	146
Ethanaminium, N-(4-((4-diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-	CI 42051 / ACID BLUE 3	3536-49-0		1356	60	Purity criteria as set out in Commission		Y	Not Classified (100.0%)	134

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						Directive 95/ 45/EC (E 131)				
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	518-47-8	Y	1332	74	6%		Y	Not Classified (87.0%), Eye Irrit. 2 (11.4%), Skin Irrit. 2 (10.6%), Acute Tox. 4 (0.8%), Muta. 1A	254

									(0.8%)	
	CI 45350/ Yellow	2321-07-5	Y					N	Eye Irrit. 2 (88.7%), Not Classified (8.3%), STOT SE 3 (0.6%), Skin Irrit. 2 (0.6%)	168
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	596-03-2	Y	1,333	75	Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-		N	Not Classified (56.4%), Acute Tox. 3 (41.8%), Eye Irrit. 2 (1.8%), STOT SE 3 (1.8%), Skin Irrit. 2 (1.8%)	55
		4372-02-5								

						3H-xanthen-9-yl) benzoic acid				
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	15086-94-9	Y	1334	76	Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid		Y	Acute Tox. 4 (60.4%), Not Classified (37.5%), Skin Sens. 1 (2.1%)	48
	CI 45380 / PIGMENT RED 90:1 ALUMINUM LAKE	15876-39-8	Y					N	Not Classified (100.0%)	6
	CI 45380 / ACID RED 87	17372-87-1	Y					Y	Eye Irrit. 2 (84.4%), Not Classified	443

									(10.6%), Eye Dam. 1 (4.5%), Acute Tox. 4 (0.5%)	
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	12227-78-0	Y	1337	80	Purity criteria as set out in Commission Directive 95/45/EC (E 127)		N	Not Classified (92.1%)	63
	CI 45430 / ACID RED 51	16423-68-0	Y					Y	Acute Tox. 4 (93.2%), Aquatic Chronic 4 (26.1%), Not Classified (5.9%), Aquatic Chronic 3 (0.9%)	222

Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	CI 15865/Red	3564-21-4		1348	28			N	Not Classified (100%)	70

Notes: *Substances found in tattoo inks and PMU. Source (JRC, 2015b)

The EU public consultation also indicated that Pigment Red 4 (CI 12085), Pigment Red 5 (CI 12490), Pigment Red 63 :1 (CI 15880), and Pigment Red 181 (CI 73360) are also used in tattoo inks.

Supplementary table C to RO2: This table will be developed if RO2 is the restriction option that is recommended by the Agency to the Defra Secretary of State. Table C will list all substances that appear on Annex II of the CPR at the time that the Agency makes this recommendation. Annex II of the CPR can be consulted here: https://www.legislation.gov.uk/eur/2009/1223/annex/II.

Supplementary table D to RO2: This table will be developed if RO2 is the restriction option that is recommended by the Agency to the Defra Secretary of State. Table D will list all substances that appear on Annex IV of the CPR subject to conditions in column g: i) Colouring agents in cosmetic products intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover, ii) Colouring agents in cosmetic products intended not to come into contact with the mucous membranes, iii) Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin (rinse-off products) at the time that the Agency makes this recommendation. Annex IV of the CPR can be consulted here: https://www.legislation.gov.uk/eur/2009/1223/annex/IV.

Supplementary table E to RO2: This table will be developed if RO3 is the restriction option that is recommended by the Agency to the Defra Secretary of State. Table E will list all substances that appear on Annex 4 of the CPR which are permitted to be used in cosmetic products subject to conditions in columns h to i of that Annex (e.g., purity requirements, maximum allowed concentrations of the substances themselves or their constituents) at the time that the Agency makes this recommendation. Annex IV of the CPR can be consulted here: https://www.legislation.gov.uk/eur/2009/1223/annex/IV.

Supplementary table F to RO3: The list of substances for which specific concentration limits are being proposed under RO3.

This list reproduces Appendix 13 to COMMISSION REGULATION (EU) 2020/2081 and makes reference to the GB MCL list where appropriate.

Substance name	CAS no.	Concentration limit (by weight)
Mercury	7439-97-6	0.00005 %
Nickel	7440-02-0	0.0005 %

Organometallic tin	7440-31-5	0.00005 %
Antimony	7440-36-0	0.00005 %
Arsenic	7440-38-2	0.00005 %
Barium **	7440-39-3	0.05 %
Cadmium	7440-43-9	0.00005 %
Chromium‡	7440-47-3	0.00005 %
Cobalt	7440-48-4	0.00005 %
Copper **	7440-50-8	0.025 %
Zinc **	7440-66-6	0.2 %
Lead	7439-92-1	0.00007 %
Selenium	7782-49-2	0.0002 %
Polycyclicaromatic Hydrocarbons (PAH), classified in the GB MCL list as carcinogen or germ cell mutagen category 1A, 1B or 2		0.00005 % (individual concentrations)
Methanol	67-56-1	11 %
o-Anisidine **	90-04-0	0.0005 %
o-toluidine **	95-53-4	0.0005 %
3,3'-dichlorobenzidine **	91-94-1	0.0005 %
4-methyl-m-phenylenediamine **	95-80-7	0.0005 %
4-chloroaniline **	106-47-8	0.0005 %
5-nitro-o-toluidine **	99-55-8	0.0005 %
3,3'-dimethoxybenzidine **	119-90-4	0.0005 %
4,4'-bi-o-toluidine **	119-93-7	0.0005 %

4,4'-Thiodianiline **	139-65-1	0.0005 %
4-chloro-o-toluidine **	95-69-2	0.0005 %
2-naphthylamine **	91-59-8	0.0005 %
Aniline **	62-53-3	0.0005 %
Benzidine **	92-87-5	0.0005 %
p-toluidine **	106-49-0	0.0005 %
2-methyl-p-phenylenediamine **	95-70-5	0.0005 %
Biphenyl-4-ylamine **	92-67-1	0.0005 %
4-o-tolylazo-o-toluidine **	97-56-3	0.0005 %
4-methoxy-m-phenylenediamine **	615-05-4	0.0005 %
4,4'-methylenedianiline **	838-88-0	0.0005 %
6-methoxy-m-toluidine **	120-71-8	0.0005 %
4,4'- methylene-bis-[2-chloro aniline] **	101-14-4	0.0005 %
4,4'-oxydianiline **	101-80-4	0.0005 %
2,4,5-trimethylaniline **	137-17-7	0.0005 %
4-Aminoazobenzene **	60-09-3	0.0005 %
p-Phenylenediamine **	106-50-3	0.0005 %
Sulphanilic acid **	121-57-3	0.0005 %
4-amino-3-fluorophenol **	399-95-1	0,0005 %
2,6-xylidine	87-62-7	0.0005 %
6-amino-2-ethoxynaphthaline	293733-21-8	0.0005 %
2,4-xylidine	95-68-1	0.0005 %

Pigment Red 7 (PR7)/CI 12420	6471-51-8	0.1 %
Pigment Red 9(PR9)/CI 12460	6410-38-4	0.1 %
Pigment Red 15 (PR15)/CI 12465	6410-39-5	0.1 %
Pigment Red 210(PR210)/CI 12477	61932-63-6	0.1 %
Pigment Orange 74 (PO74)	85776-14-3	0.1 %
Pigment Yellow 65 (PY65)/CI 11740	6528-34-3	0.1 %
Pigment Yellow 74 (PY74)/CI 11741	6358-31-2	0.1 %
Pigment Red 12 (PR12)/CI 12385	6410-32-8	0.1 %
Pigment Red 14 (PR14)/CI 12380	6471-50-7	0.1 %
Pigment Red 17 (PR17)/CI 12390	6655-84-1	0.1 %
Pigment Red 112 (PR112)/CI 12370	6535-46-2	0.1 %
Pigment Yellow 14 (PY14)/CI 21095	5468-75-7	0.1 %
Pigment Yellow 55 (PY55)/CI 21096	6358-37-8	0.1 %
Pigment Red 2 (PR2)/CI 12310	6041-94-7	0.1 %
Pigment Red 22 (PR22)/CI 12315	6448-95-9	0.1 %
Pigment Red 146	5280-68-2	0.1 %

(PR146)/CI 12485		
Pigment Red 269 (PR269)/CI 12466	67990-05-0	0.1 %
Pigment Orange16 (PO16)/CI 21160	6505-28-8	0.1 %
Pigment Yellow 1 (PY1)/CI 11680	2512-29-0	0.1 %
Pigment Yellow 12 (PY12)/CI 21090	6358-85-6	0.1 %
Pigment Yellow 87 (PY87)/CI 21107:1	15110-84-6, 14110-84-6	0.1 %
Pigment Yellow 97 (PY97)/CI 11767	12225-18-2	0.1 %
Pigment Orange 13 (PO13)/CI 21110	3520-72-7	0.1 %
Pigment Orange 34 (PO34)/CI 21115	15793-73-4	0.1 %
Pigment Yellow 83 (PY83)/CI 21108	5567-15-7	0.1 %
Solvent Red 1 (SR1)/CI 12150	1229-55-6	0.1 %
Acid Orange 24 (AO24)/CI 20170	1320-07-6	0.1 %
Solvent Red 23 (SR23)/CI 26100	85-86-9	0.1 %
Acid Red 73 (AR73)/CI 27290	5413-75-2	0.1 %
Disperse Yellow 3/CI 11855	2832-40-8	0.1 %
Acid Green 16	12768-78-4	0.1 %

Acid Red 26	3761-53-3	0.1 %
Acid Violet 17	4129-84-4	0.1 %
Basic Red 1	989-38-8	0.1 %
Disperse Blue 106	12223-01-7	0.1 %
Disperse Blue 124	61951-51-7	0.1 %
Disperse Blue 35	12222-75-2	0.1 %
Disperse Orange 37	12223-33-5	0.1 %
Disperse Red 1	2872-52-8	0.1 %
Disperse Red 17	3179-89-3	0.1 %
Disperse Yellow 9	6373-73-5	0.1 %
Pigment Violet 3	1325-82-2	0.1 %
Pigment Violet 39	64070-98-0	0.1 %
Solvent Yellow 2	60-11-7	0.1 %

**Soluble. ‡Chromium VI.

Appendix 2 – Stakeholder information

1. Stakeholder mapping and engagement

Before launching a call for evidence for the restriction proposal, HSE undertook stakeholder mapping to identify companies, industry or trade associations, trade unions, training providers, NGOs and OGDs that could be affected by the restriction proposal on tattoo inks and PMU. HSE directly notified these stakeholders when the call for evidence opened. HSE also directly notified more than 60,000 subscribers to its REACH e-bulletin service when the call for evidence launched. (HSE also notified GB Local Authorities (LAs) using its HELex internal communication system). Information about the call for evidence was also cascaded via social media.

2. Call for evidence

The call for evidence was published on HSE's consultation hub website to gather information from relevant stakeholders on substances used in tattoo inks and PMU. HSE sought information on the following topics:

- Substances that are used in tattoo inks and PMU and their function e.g., pigment, diluent, solvent etc
- Quantities that are supplied and used
- Costs
- The availability of alternatives, including information about their cost, hazard and risk profile and technical characteristics (e.g., will these alternatives affect the quality of the tattoo or PMU)
- Tattooing and PMU services
- Existing regulations and standards governing the safety of tattoo ink and PMU and the enforceability of these regulations/standards

The call for evidence opened on 3 September 2021 and closed on 2 November 2021. In total, 88 respondents provided information to the call for evidence.[1] 5 confidential attachments and 7 non-confidential attachments were also provided by respondents. Respondents included companies, industry or trade associations, NGOs and individuals. The comments were taken into account in the development of the report. Where possible, HSE also contacted respondents to clarify their comments.[2]

The comments included information on substances used in tattoo inks and PMU and their function; quantities, costs, alternatives, etc. More information was published with the call for evidence on the types of substances that were covered in HSE's

analysis of hazardous substances that may be present in tattoo inks PMU (see restrictionproposal002backgroundinfo.pdf (hse.gov.uk)).

3. Direct enquiries with major GB-based tattoo inks suppliers

Following the call for evidence, HSE contacted tattoo ink suppliers directly (using stakeholder mapping and analysing respondents to the call for evidence who consented to be contacted by HSE) to gather more evidence on the total numbers of manufacturers and distributors.

4. Attendance at 5th World Congress of Tattoo and Pigment Research (WCTP 2021)

On 24-26 August 2021, HSE attended (online) the 5th World Congress of Tattoo and Pigment Research (WCTP 2021). The conference was held as a hybrid event including both face to face and online participation by representatives from around 20 different countries and included speakers from Denmark, France, Germany, Italy Finland, the Netherlands, Switzerland, Russia, Australia, Brazil and the US. Information from presentations given at this conference was considered while developing its restriction dossier.

5. Presentation to Chartered Institute of Environmental Health (CIEH) Beauty Conference

On 21 October 2021, HSE attended (online) the Chartered Institute of Environmental Health (CIEH) Beauty Conference. HSE also provided a presentation on the tattoo inks and PMU restriction proposal. The presentation outlined:

1. How the regulatory framework of UK REACH is used to control the supply of chemicals; and introduce a restriction
2. The key features of a restriction
3. How the restriction process works
4. The health risks from specific substances in tattoo inks and PMU
5. The tattoo inks and PMU restriction proposal on these specific substances
6. The call for evidence for this proposal

The conference was attended by about 100 representatives who were mostly Environmental Health Officers (EHOs) from LAs. HSE welcomed questions and comments at the end of the presentation and these were considered while developing its restriction dossier.

6. Attendance at 2nd International Conference on Tattoo Safety

On 18–19 November 2021, HSE attended (online) the 2nd International Conference on Tattoo Safety at the Berlin Museum of Natural History (via livestream). The conference was attended by representatives from around the world and included 25 speakers from Denmark, Germany, Italy and the US. HSE noted the feedback and this was considered while developing its restriction dossier.

Appendix 1. Call for evidence overview; background note; HSE's Confidentiality and GDPR statements; and submission instructions

Call for evidence: substances in tattoo inks and permanent make-up (PMU)

Overview

We are gathering information and evidence to support the development of a UK REACH restriction dossier (report) on risks to human health arising from the use of certain pigments and other substances in tattoo ink and permanent make-up (PMU). UK REACH came into force at the end of the EU exit transition period (31st December 2020) and regulates the access of chemicals to the GB market. Under the Northern Ireland Protocol, EU REACH continues to regulate the access of chemicals to the Northern Ireland market.

Please support your contribution with references and reliable data (facts and figures).

Background note

Tattoos and permanent make-up (PMU) have increasing popularity. The need for tattoo inks and PMU, and the equipment used to apply these products, to be sterile is widely recognised. However, less attention has been paid to risks that could arise from the chemical ingredients used to make these inks and PMU.

The pigments used in tattoo inks are not necessarily specifically produced for tattooing, i.e. injection under the skin. These pigments are often of low purity and can contain, intentionally or as an impurity, hazardous substances. Exposure to these hazardous substances can lead to health effects. Surveys have shown that a significant proportion of people report skin problems, such as bleeding, crusts, and itching after tattooing.

More serious issues (e.g. allergies caused by substances used in ink and possible carcinogenicity) could also arise from exposure to these substances.

Tattoo inks and permanent make up, unlike cosmetics, are not currently subject to any specific regulations that control their composition.

From January 2022, the European Union (EU) will restrict the use of certain harmful chemicals in tattoo inks and PMU. You can learn more about the EU action on the website of the European Chemical Agency (ECHA).

The EU restriction aims to prevent the use of chemicals in tattoo inks and PMU that we know have specific hazardous properties which make it more likely that someone might experience harmful effects.

HSE intends to examine the evidence presented in the restriction dossier prepared by ECHA along with other available information, particularly where it describes the situation in Great Britain (GB), to decide if a restriction on certain harmful chemicals in tattoo inks and PMU is an appropriate regulatory measure for GB. HSE will analyse the risks to human health presented by certain chemicals if they are used in tattoo ink or PMU, the availability of alternatives and the socio-economic impacts of a possible restriction if this was implemented in GB. HSE is holding this call for evidence to gather information that will help with this analysis.

This call targets companies (manufacturers, importers, distributors, retailers) and professional users of tattoo inks and PMU, trade associations, environmental organisations, consumer organisations, medical professionals and any other organisations and members of the public holding relevant information.

We are seeking information on the following topics:

- Substances that are used in tattoo inks and PMU and their function e.g., pigment, diluent, solvent etc.
- Quantities that are supplied and used.
- Costs.
- The availability of alternatives, including information about their cost, hazard and risk profile and technical characteristics (e.g., will these alternatives affect the quality of the tattoo or PMU).
- Tattooing and PMU services.
- Existing regulations and standards governing the safety of tattoo ink and PMU and the enforceability of these regulations/standards.

We welcome any information on these general topics.

HSE's Confidentiality and GDPR statements

HSE tries to make its call for evidence procedure as thorough and open as possible.

Information provided in response to this call for evidence may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the General Data Protection Regulations (GDPR) and the Environmental Information Regulations 2004 (EIR)). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide as confidential, please make this

clear in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data in accordance with the GDPR. This means that personal data will not normally be disclosed to third parties and any such disclosures will only be made in accordance with the Regulations.

How to submit comments

Basic information can be provided in the call for evidence survey below. More detailed information should be provided in document(s) which can be submitted as attachments at the end of each section. We will not automatically publish information submitted in response to a call for evidence. However, it will be helpful if a "public version" of your information can be provided to help us understand which information we can include in the restriction proposal which will be published. If you also want to include confidential information in your submission, please additionally complete a "confidential version" and submit both versions as attachments.

The call for evidence lasts for 8 weeks (unless otherwise specified) and closes at 23:59 London time (BST).

Appendix 2. Call for evidence questions

Contents

About you

1. First name:
2. Last name:
3. E-mail:
4. Country of Residence:
5. Are you submitting information as an individual or on behalf of an organisation/institution?*

   Individual ☐

   Organisation/institution ☐
6. Where did you learn about this consultation? (please

select all that apply)

HSE website ☐

HSE e-bulletin ☐

Social media ☐

Trade association ☐

Press ☐

Other (please specify) ☐

If you selected other, please provide more information below

7. Type of organisation / institution: [drop-down list – Company, National authority, Regional or local authority, Academic institution, National NGO, International NGO, Industry or trade association, National institution, International organisation, Trade union, Other contributor]
8. Name of organisation

Do you give permission for your company/institution name to be published on the HSE website?

Yes ☐

No ☐

Type of your organisation/institution cannot be claimed confidential and will always be disclosed

9. Country where the organisation or institution is legally established

I am content to be contacted by HSE or the Environmental Agency on the basis of the information I provide

Yes ☐

No ☐

Non-confidential comments

General comments

* ☐ I understand that it is my responsibility not to include confidential information in any responses given in this call for evidence (e.g. company names, email addresses, phone numbers and signatures etc.)

Please note: HSE will not be liable for any damages incurred by making non-confidential responses publicly available.

Specific questions

HSE would like to gather detailed GB-specific information. The information relevant for the development of an Annex XV restriction dossier, includes substances potentially within scope of the restriction including information on hazard, exposure and potential to migrate away from the site of application; analytical methods and other information relevant for enforcement; socio-economic information, such as information on alternatives (availability, technical and economic characteristics), impacts on stakeholders, etc.

Any relevant information is welcome. HSE would like to also draw your attention to the following specific topics:

- Existing regulations and standards that apply to the use and safety of tattoo inks and PMU
- Availability of alternatives, their hazards and risks and technical and economic feasibility
- Impact on industry and professionals
- Number of tattoo sessions and PMU procedures, professionals working as tattoo artists and carrying out PMU procedures, manufacturers and volume of inks and PMU
- Costs

Existing regulations and standards that apply to the use and safety of

tattoo inks and PMU

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

Yes ☐

No ☐

Don't know ☐

If you answered 'yes', please expand

1. To what extent do you agree or disagree with the following statement: "In my experience, these regulations and standards are easy to understand and comply with". Please state the reasons for your response.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐
Don't know/prefer not to say ☐

Please provide more information below

2. Before today, were you aware that the EU is introducing a restriction on the use of certain substances in tattoo ink and PMU?

Yes ☐

No ☐

- If you answered yes, please also answer the questions directly below
- If you answered no, please move onto the next section

3. To what extent do you agree/disagree with the following statement: "The EU action has had an impact on the availability of tattoo inks or PMU, or pigments that may be used in tattoo inks or PMU"

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐
Don't know/prefer not to say ☐

4. What impact on availability do you think the EU action has had on tattoo inks or PMU, or pigments that may be used in tattoo inks or PMU?

Significantly more available than before ☐
More available than before ☐
The same availability as before☐
Less available than before ☐
Significantly less available as before ☐
Not available at all ☐

Don’t know ☐

5. In your best estimate, what proportion of tattoo ink and PMU on the GB market is already compliant with the EU restriction?

Non-confidential attachment:

Confidential attachment:

Availability of alternatives, their hazards and risks and technical and economic feasibility

Considering the types of substances that we expect will be in scope of this assessment (see the background document for more information about the types of substances that we will be assessing).Could you please provide the following information on tattoo inks and PMU that you think will **not** contain these types of substances:

1. To the best of your knowledge, are you aware of any health risks associated with inks and PMU that you think will NOT contain these types of substances?

   Yes ☐

   No ☐

   Don’t know ☐

Please provide details about these ink or PMU products and the health risks you think may be associated with these products (if you have supporting evidence about these health risks please provide this. Links to submit attachments are available at the end of this call for evidence).

2. What information do you have on the quality and technical characteristics of these inks and PMU? For example, are they less effective/vibrant than the inks or PMU that you currently use, might you need to use greater quantities to achieve the same effect?

3. Please provide information, if any, that you may have on the extent to which these substances migrate away from the site of injection and the potential for these substances to break down within the body?

4. Please provide information, if any, that you may have on the average prices for these inks and PMU?

5. How does the cost of these inks and PMU compare with the products that you currently use?

6. What is the availability of these inks and PMU on the GB market (tonnages produced, imported and exported by GB)?

7. Are there any other technical or economic feasibility issues associated with these alternatives?

8. What timescales/phase-in (if any) would be necessary in order to switch to an alternative?

9. Are you aware of any pigments that are used in tattoo inks or PMU that are within scope of the assessment for which a suitable alternative is NOT available?

Yes ☐

No ☐

If yes, please specify which pigments

10. To what extent do you agree/disagree with following statement: "I would be more likely to formulate my own ink/PMU as a result of the restrictions on certain substances"? Please give reasons for your answer.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐
I never formulate my own ink/PMU ☐

Please provide more information below

Non-confidential attachment:

Confidential attachment:

Impact on industry and professionals

1. What, if any, impact (positive or negative) do you think a restriction on using specific substances in tattoo inks and PMU would have on your business? Please provide further details on the type of business you are (manufacturer, distributor, importer, tattoo artist, PMU practitioner) and whether this is a small

business, employing between 10 and 49 full-time employees, or a micro business, employing between one and 9 employees).

2. In the instance of a restriction on manufacture, import and use of tattoo ink and PMU being introduced, please briefly describe what the likely consequences for your business and others in the supply chain would be.

3. If a restriction on the manufacture and use of tattoo and PMU inks were introduced, what, if any, substitution costs would you incur? Please provide as detailed a breakdown of annual costs as possible.

4. What would be the cost impact on consumers following a potential restriction on the use of certain hazardous substances in tattoo ink and PMU?

5. If you are a manufacturer, formulator, distributor or importer, is your business a small or micro business (SMB)?

6. What is the proportion of tattoo and PMU ink manufacturers, formulators, distributors and importers in GB that are SMBs?

7. What difference would it make to you in terms of impacts if such a restriction was introduced over a longer time scale e.g. 5 years instead of 2 years?

8. What difficulties, if any, do you expect if the

concentration limits that have been adopted by the EU for substances in tattoo inks and PMU are also adopted in GB?

9. What information, if any, do you have on any adverse health effects or reactions (e.g. skin irritation, allergy) as a result of application of tattoos or PMU that can be directly attributed to the substances in the tattoo ink or PMU? Please be as specific as possible and provide supportive information or documentation. (Links to submit attachments are available at the end of this call for evidence)

10. What information, if any, do you have about the possible migration of substances in tattoo inks and PMU away from the site of injection and potential for substances to break down within the body?

Non-confidential attachment:

Confidential attachment:

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

1. What information, if any, do you have on the number of tattoo artists and PMU practitioners in GB (both registered/licenced and unregistered/unlicensed)? You do not need to identify specific premises in your response. Links to submit attachments or confidential information are provided at the end of this call for

evidence.

2. What information, if any, do you have on the number of tattoo sessions performed in GB (or performed by your business) per year, we assume that a typical tattoo session lasts between 1.5 and 2 hours?

3. What information, if any, do you have on the number of PMU procedures performed in GB (or by your business) per year?

4. How much time would a typical PMU procedure take to carry out?

5. If you work as a tattoo artist or provide PMU services, where do you purchase your ink or PMU?

6. What information, if any, do you have on the number of tattoo ink and PMU manufacturers in GB? Of these, how many do you think manufacture either tattoo ink or PMU but not both?

7. What is the volume of tattoo ink manufactured in GB and what is the annual sales/turnover?

8. If you are a manufacturer/formulator of ink or PMU or you blend your own inks or PMU, what factors do you take into consideration when deciding which ingredients to purchase?

9. If you are a manufacturer/formulator of ink or PMU or you blend your own inks or PMU, how important is cost over quality when determining which ingredients to purchase? Please provide any further details in the space below.

Very important ☐
Important ☐
Not important ☐
Irrelevant ☐
Don't know/prefer not to say ☐
Please provide more information below

10. If you are a manufacturer/formulator of ink or PMU or you blend your own inks or PMU, do you consider the purity of pigments when deciding which pigments to purchase?

11. What information, if any, do you have on the number of tattoo ink and PMU importers/exporters to and from GB? Of these, how many import or export either tattoo ink or PMU but not both?

12. If you are a manufacturer/distributor/importer, what would you say is the volume of tattoo ink and PMU you import to GB annually? A link to submit confidential information is available at the end of this call for evidence.

Non-confidential attachment:

Confidential attachment:

Costs

1. What is the average total cost (including supplies, rent, labour, overhead) incurred per tattoo/PMU procedure by the tattoo artist/PMU practitioner? If possible, please specify what proportion of this average total cost is accounted for by the cost of tattoo ink or PMU.

2. What is the average price you charge to customers per tattoo or PMU procedure?

3. How much do prices of tattoos and PMU procedures vary according to geographic region within GB?

4. If you are an importer or manufacturer of tattoo/PMU ink, what is the annual average bulk sale price per litre?

Non-confidential attachment:

Confidential attachment:

[1] ECHA's call for evidence started on 31 August 2016 and ended on 23 November 2016. In total 12 comments were received.

[2] Respondents were able to indicate if they were content to be contacted by HSE on the basis of the information they provided.

Appendix 3 – Stakeholder organisations

The following bullet point list identifies associations of tattoo artists and PMU practitioners relevant for GB. It is not clear what percentage of tattooist and PMU practitioners in GB are members of any of these associations.

- British Tattoo Artists Federation (BTAF)
- Tattooist and Piercing Industry Union (TPIU)
- Association of Aesthetics, Injectables and Cosmetics (AAIC)
- Association of Cosmetic Practitioners (ACPB)
- British Association of Cosmetic Nurses (BACN)
- British Association of Beauty Therapy & Cosmetology (BABTAC)
- Hair and Beauty Industry Authority (HABIA)

Some tattoo artists and PMU practitioners may also be members of the Federation of Small Business (FSB).

In addition to these GB/UK associations, these EU-based organisations may have relevance in GB.

- Council of European Tattoo Associations (CETA)
- Tattoo Ink Manufacturers of Europe (TIME)
- European Society of Tattoo and Pigment Research (ESTP)

Appendix 4 – Legislation

Existing GB measures

The General Product Safety Regulations (GPSR)

Currently, there is no GB legislation that governs which substances may or may not be present in tattoo inks or PMU. As they can be seen as products intended for, supplied, used or made available in the course of a commercial activity to consumers, they fall in the scope of the General Product Safety Regulations (GPSR). GPSR implements the EU General Product Safety Directive 2001/95/EC (GPSD). GPSR requires all products to be safe in their normal or reasonably foreseeable usage and enforcement authorities have powers to take appropriate action when this obligation is not met. There are also specific regulations for some product sectors, setting out essential safety requirements. Where there is crossover with the GPSR, the product-specific legislation usually takes precedence.

Therefore, GPSR acts as a 'fallback' safety regulation. The actual policy about any particular product or decisions about whether to use a ban on sales as a tool to meet a particular policy aim would still rest with the relevant department responsible for enforcement even if they rely on GPSR for any aspects. As any restriction on the supply and use of tattoo inks and PMU would be a consequence of UK REACH, GPSR would not be the appropriate framework to use.

Product safety alerts

GPSD led to the development of the Rapid Exchange of Information System (RAPEX). RAPEX is the EU's alert system for unsafe non-food consumer products and includes cosmetics which may have potentially harmful content. The Information and Communication System on Market Surveillance (ICSMS) enables the information to be stored and exchanged throughout the EU.

The UK no longer has access to RAPEX or ICSMS and this has been replaced by the UK's Product Safety Database (PSD). Market surveillance authorities, including the Office for Product Safety and Standards (OPSS) and Local Authority Trading Standards, have responsibility for regulating product safety in the UK.

PSD is used by UK market surveillance authorities to notify unsafe and noncompliant products, including those that present a risk to the health and safety of consumers. It includes Product Safety Alerts issued by OPSS to draw attention to the most serious risks, where issues have been identified across entire product categories or sectors.

Individual products that have been investigated and found to present a risk to the health and safety of consumers can also be found below in the Unsafe Product Reports which are published weekly. These reports include products notified on the

PSD by a market surveillance authority, notified to the OPSS Incident Management Team and validated.

Due to the number of products affected by the restriction proposal, it is unlikely that PSD would be used to alert LAs to all restricted tattoo ink products (although it may be used to highlight particular products of concern).

Other relevant GB legislation

The Health and Safety at Work etc Act 1974 (HSWA)

HSWA applies to all employers, whether a business is registered with its local authority or not; it serves to protect employees and others, such as members of the public, who may be affected by a work activity.

Local authorities (LAs) will enforce the provisions of the HSWA 1974 where tattooing and PMU application takes place in premises to which the Health and Safety (Enforcing Authority) Regulations 1998 Regulation 3 Schedule 1 applies. (e.g., beauty salons, leisure centres, high street operators, exhibitions etc.) LAs require businesses to obtain licences to carry out certain treatments, such as acupuncture, tattooing and ear piercing.

HSE is the enforcing authority where someone works at a variety of locations and has no fixed premises.

HSWA is primary legislation expressed as broad general duties in the Act but are supported in some circumstances by subsidiary regulations (secondary legislation) such as those dealing with the management of health and safety and specific health and safety issues.

The Control of Substances Hazardous to Health Regulations 2002 (COSHH)

COSHH are domestic regulations which outline an employer's responsibilities in GB to protect the health and safety of people exposed to the occupational use of substances hazardous to health. (Asbestos and lead have separate regulations).

If tattoo inks or PMU contain hazardous substances, they are subject to COSHH when being applied in an occupational setting. Under COSHH, dutyholders are required to prevent, or, where this is not reasonably practicable, control exposure to hazardous substances to protect the health of people affected by their work activities. Schedule 2A of COSHH provides 8 generic principles of good control practice, which include steps to:

a) Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.

b) Take into account all relevant routes of exposure – inhalation, skin absorption and ingestion – when developing control measures.

c) Control exposure by measures that are proportionate to the health risk.

d) Choose the most effective and reliable control options which minimise the escape and spread of substances hazardous to health.

e) Where adequate control of exposure cannot be achieved by other means, provide, in combination with other control measures, suitable personal protective equipment.

f) Check and review regularly all elements of control measures for their continuing effectiveness.

g) Inform and train all employees on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.

h) Ensure that the introduction of control measures does not increase the overall risk to health and safety.

More generally, if substances have an uncertain or not clearly defined toxicology; and where sound evidence is not available on the hazards, HSE expects dutyholders to adopt a precautionary approach to comply with their legal obligations. A precautionary approach means ensuring that exposure is reduced to as low as is reasonably practicable.

COSHH implemented the EU-wide Chemical Agents Directive (CAD), Biological Agents Directive (BAD) and Carcinogen and Mutagens Directive (CMD) in GB.

Although COSHH regulates the use of tattoo inks and PMU in an occupational setting, COSHH is not suitable to prohibit the supply of tattoo inks or PMU. If prohibited or restricted under other legislation (e.g. UK REACH), their use under COSHH would depend upon compliance with that prohibition or restriction.

UK Health and Security Agency enforcement

There is public health legislation which provides local authorities with health protection powers to impose restrictions or requirements to protect public health where voluntary cooperation to avert a health risk cannot be secured; and where other methods of control are ineffective, unsuitable or disproportionate to the risk involved.

Local Authorities

In GB, it is the responsibility of local authorities to oversee the operation of tattoo

parlours and PMU practitioners in their area. Due to regional differences in the legislation that governs local authority oversight, licensing and registration requirements differ between local authorities.

i) England

The primary means of enforcing infection control arrangements is by use of the licensing or registration provisions. These are prescriptive methods with offences and penalties for non-compliance. The licensing and registration provisions are largely concerned with setting requirements for good standards by requiring the maintenance of established hygiene controls in respect of premises, equipment, procedures and practices.

There are provisions in Part VIII of the Local Government (Miscellaneous Provisions) Act 1982 (LGMPA82) for local authorities in England to require the registration of persons carrying on the practices of acupuncture, tattooing, ear piercing or electrolysis. These powers are adoptive, and local authorities are able to choose which of these practices would be required to be registered in their area. The Local Government Act 2003 (LGA03), Section 120, added semi-permanent skin-colouring and cosmetic piercing to this list of activities for which registration can be required.

The Act allows for local authorities to make byelaws, for the purpose of securing:

a) The cleanliness of premises and fittings in such premises;

b) The cleanliness of persons so registered and persons assisting persons so registered in their practice and;

c) The cleansing and, so far as is appropriate, the sterilization of instruments, materials and equipment used in connection with the registered practices.

Further information is available in the Tattooing and body piercing guidance toolkit.

ii) Wales

The new licensing scheme for 'special procedures' was introduced under Part 4 of the Public Health (Wales) Act 2017 in 2020. (‘Special procedures’ includes tattooing and semi-permanent skin colouring).

The main requirements mean:

- practitioners must be licensed to carry out special procedures - it will be an offence to carry out special procedures without a licence
- business premises or vehicles must be approved - it will be an offence for a practitioner to perform any procedures from premises or vehicles that are not approved

- a full licence will last for three years and a temporary licence will last for seven days (to allow for events and conferences).
- the licence will have to be displayed in the premises where the special procedure takes place
- licence conditions will cover a practitioner's competence, the premises, the equipment and practices used, advice given before and after the special procedure and the records kept

Competence will relate to infection control and first aid in context of the special procedure practised.

The licensing system means the council will be responsible for enforcing the licensing requirements and for keeping an up-to-date public register.

There will be greater powers to enforce this legislation than those currently in place, as well as the ability to revoke a licence and immediately stop unsafe practices.

Fines will be unlimited where a prosecution is successful.

The Act allows for further legislation to amend the list of special procedures so that the legislation stays up to date.

Further information is available at Public Health (Wales) Act - special procedures | Newport City Council

iii) Scotland

The Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006 came into force in Scotland on 1st April 2006 and gives Local Authorities the power to license individuals who carry out skin piercing or tattooing activities as a business. The Order lays out a number of requirements in relation to key issues aimed at reducing, if not removing, risks to public health from these practices.

One basic requirement of the Order is that any premises within which skin piercing or tattooing activities are conducted should be in a good state of general repair. This requirement covers not only general cleanliness of premises but also advises that adequate levels of lighting and ventilation, commensurate with the practices being carried out on that premises, should be available. Another general requirement of the premises is that all walls and floor surfaces should be both smooth, washable and durable in order to ensure that cleanliness can be maintained.

Further information is available in the Local Authority Implementation Guide. For inks, the Guide (section 5.2.5, pp. 25-26) states: ‘Regardless of the form in which

inks are purchased, operators should be advised that they require to obtain (and retain for inspection) evidence from the ink supplier of the sterility of the ink in terms of microbiological contamination and the absence of potentially toxic metals – operators should be advised against purchasing inks from manufacturers or suppliers who cannot provide this evidence.'

Local authorities across England, Scotland and Wales are focused on hygiene and infection control, rather than the health risks associated with certain chemicals in tattoo inks. In addition, licensing and registration conditions differ in terms of their premises and duration in each local authority. Therefore, local authority licensing or registration would not be suitable to prohibit or restrict the supply and use of tattoo inks and PMU. However, similar to COSHH, if prohibited or restricted under other legislation (e.g. UK REACH), their use under the conditions of the licence or registration would depend upon compliance with that prohibition or restriction.

Other measures considered

Cosmetics Products Regulation (CPR)[95]

During the preparation of the EU dossier, it was considered whether tattoo inks could be regulated under the framework of the Cosmetics Products Regulation (CPR).

The EU CPR was retained in GB law at the end of the transition period on 31 December 2020 (with modifications to address aspects that were inoperable due to the requirements of the Withdrawal Agreement including the Northern Ireland Protocol). The Office for Product Safety and Standards (OPSS) on behalf of the Secretary of State, is a UK competent authority for UK CPR.

Since EU exit, responsible persons (cosmetic suppliers) must now notify the Secretary of State of any cosmetic products made available on the GB market. The UK Government has established the Submit Cosmetic Product Notification (SCPN) service for this purpose. In addition, the UK CPR uses independent scientific advice from the Scientific Advisory Group for Cosmetics (SAG-CS) which forms a proportionate part of the evidence used to make decisions on whether specific substances are included in the technical annexes of the CPR that control their use in cosmetics manufacturing.

Decisions on the permissible use of substances under the CPR are based on human health risks. The Secretary of State has powers to amend the UK CPR on the basis of scientific evidence. Therefore, changes proposed by the EU may also be

[95] Regulation 2009/1223 and the Cosmetic Products Enforcement Regulations 2013 As they apply to cosmetic products being supplied in or into Great Britain from 1 January 2021 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/968602/Guide-to-cosmetic-products-regulations-2013-tp.pdf

considered independently by the SAG-CS and in turn the UK Government will make a decision on any necessary changes. In addition, as part of the broader role of the SAG-CS and OPSS horizon scanning for other human health risks (e.g., traces of asbestos and cannabis in cosmetic products) will also be undertaken.

The UK CPR does not require public consultation for changes. Human health risks must take primacy over economic impacts. However, in line with general practice, an impact assessment must be made if an SI needs to be laid to enforce a change in the law.

Tattoo inks and PMU are not directly regulated by UK CPR (because they do not fall within the definition of “cosmetic product”), but inks used on skin are in scope and there are 1000’s of chemicals which are prohibited or restricted in cosmetic products as set out in the technical Annexes (II and III) of CPR. Industry may make a case for exemptions of certain carcinogenic, mutagenic, or toxic for reproduction substances (CMRs) to be used in cosmetics. These are considered on a case-by-case basis and there are strict circumstances for an exemption.

Therefore, UK CPR cannot be used to prohibit the supply and use of tattoo inks and PMU as they are administered into the skin and therefore do not fall within the definition of cosmetic product under UK CPR.

Biocidal Products Regulation (BPR)

Annex D.1.3 in ECHA (2019c) (pp. 406-407) outlines the background to how the EU Biocidal Products Regulation (BPR) covers tattoo inks. ECHA states:

‘The EU Biocides Regulation 528/2012 covers a very diverse group of products, including preservatives. As tattoo inks are not considered cosmetics, the in-can preservative used in tattoo inks are not subject to the cosmetics regulation, and therefore are de facto subject to the BPR rules. This includes rules regarding the placing on the market of the active substance and biocidal products, and since 2012, additional rules on the placing on the market of "treated articles" (as defined in Article 3(1)(l) of the BPR, such as mixtures preserved with in-can preservatives). In practice, it means that:

- since 1 September 2006, only active substances in the Biocidal Review Programme (i.e., listed in Annex II to Regulation (EU) No 1062/2014), or approved, for Product-type 6 "in-can preservatives" can be made available on the market and used in the EU by EU manufacturers of tattoo inks.
- since 1 March 2017, only tattoo inks preserved with in-can preservatives approved or under assessment on 1 September 2016 (see article 94 of BPR) can continue to be placed on the EU market (also relevant for imported tattoo inks).

The obligations concern the "placing on the market" as defined in Article 3(1)(j) of the BPR, and not the subsequent supplies. Tattoo inks already supplied or further in the supply chain are not concerned by these provisions (i.e., they might still contain preservatives not assessed and approved in the EU). As well, it does not forbid the use of tattoo inks which were preserved with preservatives not assessed and approved in the EU.

The approval decisions on active substances are usually not specific, and do not forbid or put restrictions on the use of active substances unless specific risks have been identified at the approval stage. Therefore, the question of tattoo inks is not likely to be looked at the approval stage of active substances but would rather be assessed at the biocidal product authorisation stage, where the use of each product must be precise enough, as a biocidal product shall only be used in the EU for its authorised used. Therefore, if the use in tattoo inks is not mentioned in the authorisation of the biocidal product, it is de facto not authorised for that. To date, there are no known biocidal product applications for authorisation for tattoo inks.'

The EU Biocidal Products Regulation (EU BPR) was retained in GB law as the Biocidal Products Regulation (GB BPR) at the end of the transition period on 31 December 2020 (with modifications to the GB to address aspects that were inoperable due to the requirements of the Withdrawal Agreement and the Northern Ireland Protocol).

Active substance approvals granted under EU BPR before 1 January 2021 will be considered approved under GB BPR with the same terms and conditions/ restrictions. Consequently, GB may still be able to rely on assessments of Technical Equivalence which have been undertaken by ECHA before 1 January 2021. However, this would be dependent on the degree and quality of information which is made available to HSE.

Applications for new technical equivalence assessments in GB after 31 December 2020 will be dependent on the level of information relating to the reference source which is available to HSE to make a decision.

As BPR has been brought into GB law mainly unchanged, the scope of the restriction will not change BPR obligations. As ECHA stated:

'As the BPR regulates only preservatives as part of the tattoo ink mixture, the use of pigments, additives and fillers in tattoo inks is not in its scope. The proposed restriction would not change the obligations under the BPR but would limit the type of preservatives that can be authorised for the use, i.e., to only those that are not classified as CMRs, skin sensitisers, irritants or corrosives and eye corrosive or damaging.'

Therefore, GB BPR cannot be used to prohibit the supply and use of tattoo inks and PMU, but rather regulate only preservatives as part of the tattoo ink mixture.

Classification and labelling

The GB CLP Regulation adopts the United Nations Globally Harmonized System (GHS) on the classification, labelling and packaging of chemicals.

The latest consolidated version of CLP is available on the CLP Legislation page of the European Chemicals Agency's (ECHA's) website. This link is for EU CLP, however it is still largely relevant to GB CLP as the EU CLP Regulation was retained in GB law at the end of the transition period on 31 December 2020 (with modifications to address provisions that were either inoperable or deficient for effective GB operation. These modifications[96] were made under the requirements of the EU Withdrawal Acts, Withdrawal Agreement and the Northern Ireland Protocol).

GB CLP, like EU CLP, is designed to determine the intrinsic hazardous properties of a substance or mixture that is placed on the market. The legal obligations to identify these properties (classification) is placed on suppliers: manufacturers, importers, downstream users (e.g. formulators) and distributors (e.g. retailers). GB CLP does not contain any provisions that allows the control, restriction or approval of chemicals in any way. Such controls exist in other chemical legislation. Classifications cover physical hazards (e.g. flammability, explosivity etc); human health hazards (e.g. carcinogenicity, mutagenicity, toxic to reproduction etc); and environmental hazards (not exhaustive).

The hazard classification of tattoo inks and PMU is generally calculated by considering the classification of the individual ingredient substances in the mixture and the concentration at which they are present as data on the mixture itself is often unavailable. Information on any hazards posed by the ingredients should be contained in the safety data sheets (SDS) provided by suppliers. GB-based suppliers should already ensure that their substances and mixtures are classified and labelled according to GB CLP.

Substances within the mixture may be classified for a number of different hazards (e.g. could cause skin sensitisation/irritation or serious eye damage/irritation (not exhaustive)), and there are different levels (generic and specific concentration limits) to consider for the different types of hazards identified. The generic concentration limits to consider and the calculations to follow for each type of hazard (i.e., each

[96] The modifications are outlined in The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (legislation.gov.uk) and The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (legislation.gov.uk).

hazard class) are provided in Annex I of the GB CLP.

GB Mandatory Classification and Labelling list

Under GB CLP, substances within the mixture may be listed in the GB Mandatory Classification and Labelling list (The GB MCL List (.xlsx)). Mandatory classification is a classification that has been made legally binding within GB and is the equivalent to the 'harmonised classifications' that exist under EU CLP. The mandatory classifications and the accompanying hazard labelling (MCL) are listed in the GB mandatory classification and labelling list. Where a substance within the mixture has a GB MCL for some or all hazard classes, suppliers to the GB market must apply it, including any specific concentration limits for the relevant hazard class or differentiation and any supplemental labelling requirements.

If tattoo inks or PMU are classified as hazardous according to GB CLP, they need to be labelled and packaged in accordance with GB CLP too (see ECHA guidance, version 4.2 last updated March 2021, document on labelling and packaging). CLP requires that the hazard information is displayed clearly on the label to allow safe supply, storage, use and disposal. Article 31 of CLP requires that the label is firmly affixed to the immediate packaging of the hazardous substance or mixture. Where the immediate packaging is contained in additional layers of packaging (e.g., a bottle in a box), these outer (and any intermediate) layers must also be labelled in accordance with GB CLP. This applies unless the outer layer is labelled for transport or the label on the inner/intermediate packaging can be seen through it.

The basic labelling requirements are provided in Article 17 of CLP and include:

- Contact details of the supplier
- Nominal quantity (if supplied to the public)
- Hazard pictograms
- Signal word – either ‘warning’ or ‘danger’
- Hazard statements – which explain the nature of the intrinsic hazards present
- Precautionary statements – safety instructions
- Supplemental information – either obligatory or non-obligatory

Therefore, GB CLP cannot be used to prohibit the supply and use of tattoo inks and PMU. GB CLP identifies the hazardous properties of chemicals and how information about these hazards is then passed to users.

Other voluntary industry actions

Given the complexity of the assessments that are required to identify which substances are safe to use in tattoo ink and PMU and the limited toxicological data that are available to inform these assessments, it is not realistic to expect industry actors to be able to identify all substances that would create risk to human health when used in tattoo inks or PMU and reformulate products accordingly. It is also not clear how easy it would be for industry actors across GB to develop consistent information to customers on the ingredient substances that are present within the inks that they are using. For these reasons, voluntary action seems unlikely to achieve the aims for this restriction.

Separate legislation on tattoo inks

In addition to the chemical composition of tattoo inks, there are many other factors that influence the safety of tattoo practices. The European Committee for Standardisation (CEN) developed standard EN 17169:2020 which specifies hygiene requirements before and during tattooing and for aftercare. It gives guidelines for tattooists and their routine interactions with clients and public authorities. It also provides guidelines for the correct procedures to be used to ensure optimum protection of the client, the tattooist and others in the tattoo work area. This standard has been adopted in the UK by the British Standards Institution (BSI) as standard BS EN 17169:2020 [97]. Guidance is also available in the UK Tattooing and Body Piercing Guidance Toolkit published in 2013 [98].

Standalone legislation would have the advantage that it could cover all aspects of tattooing and PMU application in one piece of legislation, including hygiene, aftercare, and the chemical composition of ink. REACH will only address the chemical composition of the inks. REACH does not provide a framework to assess the safety of substances used as preservatives in tattoo inks and PMU since this assessment falls under the scope of the Biocidal Products Regulation (BPR). Standalone legislation could more readily be tailored to the specific needs of tattooing and PMU application rather than REACH.

During the EU public consultation on the proposed restriction, three submissions specifically favoured standalone legislation. Two submissions favoured the establishment of a positive list of substances allowed in tattoo inks. Standalone legislation was dismissed as a viable approach by the EU because it was expected to be difficult and time-consuming to negotiate legislation that would be acceptable to all EU Member States. REACH was seen as a good alternative because it can be applied to chemical substances that create risks to human health and its provisions will apply in a consistent manner across all Member States. Such an option may be

[97] https://shop.bsigroup.com/products/tattooing-safe-and-hygienic-practice/standard.
[98] https://www.cieh.org/media/2004/tattooing-and-body-piercing-guidance-toolkit-july-2013.pdf.

worthy of consideration for GB. A detailed analysis of this option cannot be a part of this REACH restriction proposal.

Appendix 5 – General assumptions underpinning the socio-economic analysis

The main assumptions that underpin the socioeconomic analysis are as follows:

- The text in this analysis is largely based on the work of ECHA (2019a, 2019c and 2019d). Where ECHA has used data and evidence specific to the EU or EEA, this has been replaced by estimated data for GB to ensure fit for the geographical scope of this analysis.

- ECHA's analysis has been produced to fit the geographical scope of the EU and obtaining data specific to GB for this analysis has been difficult due to unavailability. Therefore, this analysis uses figures produced by ECHA and adjusts them using proportions for the population[99] to estimate the volume of ink on the GB market and costs falling to GB under the proposed restriction. This has been calculated as follows: the UK population as a proportion of the EEA31 population is calculated (~13%) and the GB population as a proportion of the UK population is calculated (~97%). These proportions are applied to the volume of ink on the EU market to estimate the volume of ink on the GB market and also the costs calculated by ECHA to estimate the enforcement costs for GB.

- This analysis includes costs and benefits that are projected into the future. ECHA apply a 4% discount rate to their costs so where ECHA's cost have been used in this analysis, this 4% discount rate has been excluded. It is important that monetised impacts are expressed in present values, to enable comparison over time. A discount rate of 3.5% is applied throughout this analysis to monetise costs and benefits to generate these present values, as is recommended in the Green Book[100] for any appraisal period of less than 30 years.

- ECHA's costs are mainly presented in 2016 prices, as this is the year their restriction dossier was produced, therefore these costs have been adjusted for in this analysis by uprating costs to 2021 prices using the HMT GDP

[99] Population has been used as a proxy as this data was readily available and most suitable when scaling down EU data for the volume of ink on the market. Other measures such as GDP were an option, this data may have been more appropriate when scaling down areas such as enforcement costs, but GDP data was more difficult to attain particularly for all EEA countries and enforcement costs are a small proportion of total costs, therefore this method is deemed proportionate for this analysis.

[100] Available at: The Green Book: appraisal and evaluation in central government - GOV.UK (www.gov.uk)

deflators.[101] Any costs or figures from other years used within this analysis have also been uprated to 2021 prices unless stated otherwise.

- ECHA presents costs in Euros consequently, where costs from ECHA have been used in this analysis, these have been converted to GBP using the exchange rate from 2016 (or the relevant price year for monetised benefits/human health impacts).

- All costs calculated within this analysis carry a high degree of uncertainty. Substitution and enforcement costs are presented as main scenarios as application of +-10% for a low and high scenario is not a robust way of presenting uncertainty. The substitution costs are explored further as part of the sensitivity analysis in section 3.5.1.1 where components within the substitution formula are altered. Familiarisation costs are presented as low, central and high scenarios using the available data and assumptions.

- All figures presented in the SEA have been rounded depending on appropriacy. As individual figures have been rounded, totals in tables may not add up precisely. All figures, methodology and calculations can be found in the cost model for this SEA.

- The large majority of benefits in this analysis are non-monetised and therefore do not apply the inflation and discounting uplifts mentioned above. Where benefits such as WTP values have been included in the SEA, they have been appropriately uplifted to 2021 prices, unless stated otherwise.

- An appraisal period of 20-years has been used throughout the analysis as this timeframe allows for full cost and benefit realisation. This appraisal period is also used by ECHA (2019c) in their restriction dossier.

- The estimates presented in this socioeconomic analysis do not account for the impact of Covid-19 which could have a significant impact on the number of people getting a tattoo or PMU procedure and the volume of ink on the GB market. Business closures and measures such as social distancing during the Covid-19 pandemic may have contributed to lower levels of tattoo and PMU administration, but evidence behind this is unavailable. It is difficult to understand the impact that Covid-19 had on the volume of ink on the GB market. It is possible that imports of ink into GB were limited for a period of time, but this is another area of uncertainty.

[101] December 2021 update available at: https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-december-2021-quarterly-national-accounts

Appendix 6 – Additional information related to the socioeconomic analysis

6.1 Baseline

The prevalence rate scenarios outlined in table 6.1 have been derived using total GB population data from the ONS (Nomis) and application of ECHA's incidence rate (in table 6.2). This is calculated by taking the GB population with tattoos and dividing by the total GB population. This is different to the tattoo prevalence rate used by ECHA (2019c) as their prevalence is determined by the total EU population and number of people in that specific population with a tattoo, which differs in GB.

Table 6.1: Prevalence scenarios for GB

Prevalence rate scenarios	2014	2016	2021	2040
Low	12.1%	13.0%	15.2%	17.6%
Central	12.1%	13.0%	15.2%	24.1%
High	12.1%	13.5%	17.1%	26.9%

Table 6.2 presents the incidence rate scenarios used by ECHA in their restriction dossier. This is the best information available on incidence; therefore, these assumptions are used in this analysis for GB. The central incidence rate scenario is used to calculate the average incidence from 2021-2040 seen earlier in section 3.2 baseline, table 3.2.1.

Table 6.2: Incidence rate scenarios

Incidence rate scenarios	2015-2025	2025-2030	2030-2042
Low	0.53%	0.27%	0.13%
Central	0.53%	0.53%	0.53%
High	0.80%	0.53%	0.53%

Source: This has been extracted from ECHA (2019d)[102].

Table 6.3 applies the incidence rate scenarios in table 6.2 to data for the total GB population. This provides an estimate for the incidence of tattoos in GB across the 20-year appraisal period. The values in table 6.3 are only provided for selected years from 2014 – 2040.

Table 6.3: Estimated incidence values for tattoos in GB (for selected years)

Incidence scenarios	2014	2016	2021	2025	2030	2035	2040
Low	333,000	338,000	348,000	180,000	183,000	90,000	91,000
Central	333,000	338,000	348,000	354,000	360,000	365,000	370,000
High	502,000	510,000	525,000	354,000	360,000	365,000	370,000

In the SEAC opinion (ECHA, 2019d) both prevalence and incidence rates are used to understand the projected volume of ink on the EEA31 market which is dependent on the number of tattoos per person per year. As the prevalence rate includes everyone in the population that has a tattoo at a certain point in time, it assumes that tattooed people will continue to get more tattoos annually throughout their lifetime and this is therefore an overestimate for the true volume of ink on the GB market. Incidence on the other hand doesn't consider people who already have a tattoo, instead it considers new people with a tattoo which is therefore an underestimate. SEAC (ECHA, 2019d) recognise that both prevalence and incidence have their limitations but conclude that the incidence rate can be used to gain an indicative assessment of the future volume of ink on the market bearing in mind that this will be an underestimate of projected volumes. The incidence and prevalence assumptions used in this analysis should therefore be understood to be approximate figures and seen as illustrative.

Table 6.4 has been extracted from ECHA (2019c) and shows the size of tattoos (using percentage of body surface) for men and women in Europe. It can be

[102] The methodology used to derive the incidence rate scenarios is presented in ECHA (2019d) and is as follows: this incidence of people getting tattooed for the first time of 0.53% at the beginning over the study period (2015-2042) is estimated based on the past period 2003-2014, using information on population (from Eurostat) and prevalence in 2003 (6%) and 2014 (12.1%) (JRC 2015b). The Dossier Submitter made, using assumptions, three scenarios for future incidence rates (Low, Main, and High), that are used to derive three (Low, Main, and High volume) scenarios for the volumes of tattoo inks placed on the market annually.

assumed that distribution of tattoo size amongst men and women in GB are similar to trends in Europe.

Table 6.4: Tattoo size in Europe

Size (% of body surface)	Women	Men	Total
≤0.1%	10.0%	3.4%	7.2%
>0.1–≤1%	45.5%	35.0%	41.0%
>1–≤4%	24.2%	25.1%	24.6%
>4–≤6%	11.7%	18.2%	14.5%
>6%	8.7%	18.3%	12.8%
Total	**100%**	**100%**	**100%**

Note: A skin surface of 1% roughly corresponds to the area of the palm and fingers of the hand.

Table 6.5 shows the estimated population in the UK and GB with a PMU procedure in 2016. The estimates have been calculated using total UK and GB population from the ONS and application of ECHA's prevalence rates (3, 10 and 20%) to estimate the GB population with PMU.

It should be noted that it is likely that majority of the population that obtain a PMU will be young women, but this is an assumption without any evidence. If ECHA's prevalence rates were applied to a subset of the GB population for young women, the prevalence would appear high and be inaccurate. This assumption is not accounted for in table 6.5 as the prevalence rate is applied to the total population for UK and GB. There is therefore a great degree of uncertainty in this area and no better information in its place so figures for PMU should be seen as illustrative.

Table 6.5: Estimated population with PMU in 2016 (number)

Geographic Area	Low	Central	High
UK	1,969,000	6,565,000	13,130,000
GB	1,914,000	6,379,000	12,757,000
Prevalence rate	3%	10%	20%

Sources: For further information on tattoo and PMU prevalence, see the JRC report (JRC, 2015b).

Table 6.5 has been extrapolated from ECHA (2019c) and adjusted to fit the UK and GB. The figures present the estimated population with PMU in 2016. As seen earlier with tattoos, the prevalence rate increases over time with popularity. However, with PMU, there is no information on what PMU prevalence looks like beyond 2016 and it would be incorrect to assume that the prevalence rate remains constant over time until 2040. For this reason, the population with PMU is not estimated beyond 2016 as it is unclear how these trends will look like in the future. It is likely that PMU will become more popular but difficult to determine the associated incidence and prevalence in GB. This is an area of uncertainty that will be explored further during the public consultation.

6.2 Substitution costs

The substitution cost estimates presented by ECHA (2019c) are based on the following inputs and assumptions:

- Between 30-70% (50% as a mid-point in the main scenario and 30% and 70% in the High and Low share of alternatives scenarios shown in Annex E) of tattoo inks on the EEA31 market do not meet the requirements of the proposed restriction options. As shown in section Risk reduction, technical and economic feasibility, and availability of alternatives, surveillance results of national campaigns in Member States with national legislation and other countries in EEA31 have shown that in excess of 50-70% of inks are compliant with the ResAP recommendations. As the requirements of RO1 and RO2 are similar to the ResAP recommendations, and in some cases less strict (in particular for RO2), it is expected that those inks compliant with ResAP would take over the share of non-compliant inks after the entry info effect of the proposed restriction options. It is assumed that the proportion of ResAP compliant inks in the remaining EEA22 Member States is similar, as some Member States without national legislation enforce ResAP recommendations to a degree (e.g., Italy, Denmark), while others are vigilant with respect to RAPEX notified products. Furthermore, surveillance is often targeted at high risk suppliers and products, therefore, the 50-70% compliance rate of tattoo inks is likely a conservative assumption. In addition, interviews with manufacturers revealed some of those that are compliant with ResAP recommendations do not have separate product lines for jurisdictions with and without national legislation (e.g., due to for example economies of scale some manufacturers do not use different formulations for sales in countries with or without national legislation based on ResAP). Furthermore,

interviews with industry have shown that the majority of EU-manufactured tattoo inks are compliant with ResAP, and that non-compliant are primarily imported products, largely from China. Therefore, it can be concluded that the assumptions that 30- 70% (or 50% on average) would not be substituted is considered a reasonable assumption.

- Up to 20% of PMU (10% in the main scenario) currently on the EEA31 market are not compliant with the proposed restriction options. The reasons for making this assumption are similar to those described above for tattoo inks, i.e., similarity between ResAP and the requirements under RO1 and RO2, surveillance results that show generally better compliance for PMU in comparison to tattoo inks, and low product differentiation for markets without national legislation. Interviews with industry have revealed that PMU on the EU market are largely compliant, although there are national differences when it comes to treating some impurities (e.g., nickel). Manufacturers explain this with the more demanding customer base for PMU in comparison to tattoo inks.

- Projected volumes of tattoo inks (and PMU) on the EEA market as shown in Table 1 in Annex A. It is also assumed that compliant and non-compliant tattoo inks have the same effectiveness, i.e., the same volume of tattoo ink would be required to make a tattoo with compliant and non-compliant inks. - The price difference between compliant and non-ResAP-compliant tattoo inks and PMU currently on the EEA31 market is about 15%.

- The price difference is derived on the basis of the average retail price per 30 ml tattoo ink and 15 ml PMU bottle reported by stakeholders, excluding average value added tax (VAT). The price difference is seen to reflect the main difference in the costs of manufacturers of compliant inks in excess of those incurred by non-compliant formulators: higher pigment, testing, research and development costs. With respect to the latter, stakeholders have reported that these can range from €100 000 to €400 000 for materials and testing of the newly developed product. As colourants can be of lower purity (60-80%) (JRC, 2015b), a number of tattoo ink and PMU manufacturers are testing their input materials in order to meet national regulations or to ensure consistent product. These testing costs for compliant tattoo inks have been reported up to €80 000 per year.

Alternative methodology for substitution costs in GB under RO1

An alternative top-down methodology was explored for the substitution cost calculations. This method was produced for the purpose of comparison to the current bottom-up approach and was used as a sense check – this showed that the central estimates for the substitution costs had a difference of approximately £100,000

which provided some level of assurance to the current methodology adopted.

The bottom-up approach was preferred and adopted in this analysis as it is more robust through use of specific values and assumptions for volume of ink on the market, share of compliant ink and price difference. The bottom-up approach also produced the higher cost estimate for the substitution costs. As there is a high degree of uncertainty around the data and assumptions, it is preferred to overestimate the costs than to underestimate.

The top-down methodology used to understand the substitution costs falling to GB under RO1 is presented below. This method produced estimates ranging from £602,000 - £736,000, with a central estimate of £669,000.

i. ECHA's annual substitution cost of €4.4 million was adjusted to exclude the 4% discount rate, where t=0 in year 1 [(€4,400,000/(1/1.04^t) = €5,353,000)

ii. This figure is then converted to GBP using the exchange rate for 2016 (€5,353,000 = £4,597,000)

iii. Costs are then uprated from 2016 prices to 2021 prices using the HMT GDP deflators (2016 prices: £4,597,000 à 2021 prices: £5,123,000)

iv. Costs are discounted using the HMT 3.5% discount rate, where t=0 in year 1 [£5,123,000 * (1/1.035^t) = £5,123,000)] [103]

v. The UK population as a proportion of the EEA31 population is calculated (UK population/EEA31 population for a given year ~13.4%)

vi. The GB population as a proportion of the UK population is calculated (GB population/UK population for a given year ~97.2%)

vii. Discounted figures from line (iv) are multiplied by the UK population as a proportion of the EEA31 population (~13.4%) to calculate the UK substitution costs (£5,123,000* 13.4% = £689,000)

viii. To calculate GB substitution costs, line vii is multiplied by ~97.2% (£689,000 * 97.2% = £669,000). This is the estimated substitution cost under the central scenario.

6.3 Enforcement costs

[103] The HMT discount rate of 3.5% is applied to costs across the 20-year appraisal period in this analysis. Costs provided in the methodology explained above are for year 1, hence year 1 costs appear not to be discounted as time (t) is zero (0) in the first year.

The following excerpt has been extracted from ECHA's restriction dossier (2019c) and explains how enforcement costs in the EU were calculated.

To estimate the costs to be incurred by enforcement authorities, jurisdictions with national legislation were contacted (i.e., Germany, Norway, Sweden). On the basis of the information received, the following can be deduced about the enforcement of current national legislation:

- Enforcement of tattoo ink legislation is closely integrated with enforcement of the CPR at Member State level. This is natural as the basis for national legislation - ResAP - is linked to the CPD and its successor, the CPR.
- While a number of other aspects of the legislation involve ongoing monitoring (e.g., inspection of tattoo parlours, national registry of tattoo inks and PMU), surveillance of the chemical composition of tattoo inks and PMU occurs less frequently (the highest frequency reported was every 4-5 years). This is because national legislation competes for a limited national budget for surveillance which is allocated in terms of risks and priorities among various projects.
- Based on past experience, it can be assumed that about 100 tattoo inks and PMU are tested for the presence of a broad range of substances with combined cost of these tests of €500/sample, as per information from one-member state. The combined cost per sample consists of €200/sample for testing impurities and €300/sample for testing aromatic amines, i.e., the most problematic substances in tattoo ink. This assumes that each of the 100 samples will test for both groups of substances, although the aromatic amines tests may not be relevant for all tested inks. The assumption was made to reflect that there may be other substances tested, e.g., CMRs. Extrapolating to EEA22 results in an annual average incremental cost for analytical testing of about €200 000. Member States with national legislation are anticipated to continue having the same level of spending on analytical testing to ensure compliance with the proposed restriction options. They are not anticipated to have incremental testing costs associated with the proposed restriction options.

In addition to the analytical costs, Member States are expected to incur administrative costs for enforcing the proposed restriction. These costs constitute opportunity costs as Member States with predominantly fixed enforcement resources, would need to reallocate budget for the enforcement of a new restriction from already existing restrictions. These total opportunity costs are estimated at €53,800 annually for EU28. (ECHA, 2017i) Member States already with national legislation are anticipated to have some costs to restructure their enforcement

administration in accordance with the proposed restriction options. These are assumed to have a minor impact.

Therefore, ECHA estimate the total incremental enforcement costs to be incurred over the temporal scope of the analysis at €235,000 annually. This is likely an overestimation as it assumes that the same level of enforcement efforts will be required over the entire temporal scope, while in reality enforcement efforts decline with industry compliance, and industry compliance improves as familiarity of the restriction requirements increase over time.

During the public consultation, the Dutch competent authority submitted information on their surveillance projects. Between 2014-2016 they organised an annual surveillance projects with average administrative budget of about €150 000. Their average cost per sample in 2016 was less than €490.

SEAC (ECHA, 2019d) note that the available information does not allow for a quantitative differentiation of enforcement costs between RO1, RO2 and the RO3. Under a strictly "fixed enforcement budget" approach the options would have the same costs for enforcement authorities. However, assuming stricter concentration limits would lead to higher analytical testing and development costs, in the absence of a "fixed enforcement budget" approach, testing costs for enforcement authorities could be expected to be the highest for RO1, followed by RO3 and RO2. Testing and administrative costs for industry can be expected to follow a similar pattern.

6.4 Familiarisation costs

The familiarisation costs in this restriction dossier have been calculated using the following formula:

Familiarisation cost = (average time taken to familiarise with the restriction) x (hourly wage) x (number of people affected in industry)

The following methodology and assumptions underpin the familiarisation cost calculations:

- Familiarisation costs are calculated based on the amount of time it takes for industry to understand the rules of the new restriction, the hourly wage, and the number of people in industry that would be impacted. These three elements are multiplied together and are presented as low, central and high estimates to account for uncertainty around the data and assumptions used.

1. The **time taken for industry to familiarise** themselves with the new restriction is uncertain. This assumption is based on the length of the legislation document (in pages) and the pre-existing knowledge of actors in industry. We assume for the purpose of this analysis that the length of the legislation document is 4 pages as this is the length of similar legislation for COSHH and REACH bitesize leaflets and the associated time it takes for actors to understand this is 30 minutes – this is based on estimates used in regulatory impact assessments. It is likely that HSE will also host a webinar to help actors in industry access the necessary information about the proposed restriction in a verbal way. ECHA held a similar seminar which lasted 2 hours including time for Q&A. It is assumed that actors are familiar with the proposed restriction in GB due to the restriction imposed in the EU. This means it would potentially take actors less time to familiarise with the GB legislation document due to their pre-existing knowledge. It is possible that actors across industry have varying degrees of pre-existing knowledge of the restriction i.e. a manufacturer may have a greater understanding of the restriction and subsequently take less time to read the legislation document compared to a tattoo artist or PMU practitioner who have some understanding. It is however unclear how much this differs and across which actors so for this reason, this level of granularity has not been implemented into this assumption and the time assumption should there be treated as an approximate figure. To account for the uncertainty, **30 minutes** will be used as a low estimate as the time required to read the guidance document and **2.5 hours** will be used as **a high estimate** to account for the time required to read the guidance and attend the webinar. A **central estimate** of **1.5 hours** is used as this is the average between 30 minutes and 2.5 hours.

   It is assumed that within industry, the person that will be reading the legislation document will be the regulatory affairs officer. Therefore, for manufacturers, distributors, importers, and exporters the median hourly wage is taken from the ASHE (ONS, 2021a) of a ‘quality and regulatory professional’. Tattoo artists and PMU practitioners will be reading the legislation themselves and their hourly wage is not available in the ASHE therefore this has been obtained using other available sources which provide a range, so the average is used as a central estimate. For regulatory affairs officers, the **hourly wage** is approximately **£21.57**, for **tattoo artists** it is **£13.39** (Salary expert, 2022) and for **PMU practitioners** it is **£21.69** (Giles, 2017). These hourly wages apply the appropriate uplifts to ensure they are presented in 2021/22 prices and PV. Wages also apply a 20% uplift to account for overheads, national insurance contributions etc.

2. The number of actors that would be impacted by this restriction has been estimated based on information from stakeholders and calculations. The

methodology for this element of the calculation is explained below and should be understood to be a best guess using the available data and information.

- For manufacturers, distributors, importers, and exporters it is difficult to ascertain the true number of businesses impacted in GB. Based on discussions with stakeholders, it can be assumed that there are up to **10 tattoo ink and PMU manufacturers in GB** as most ink on the GB market is imported from other countries – **10 is used a central estimate** for the number of manufacturers in GB. the **high estimate uses a figure if 30** which is from Michel (2015) which quotes that there are *approximately 30 tattoo ink manufacturers in Europe, and they are mainly based in England, Germany, France, Italy and Spain.* A low estimate is produced by taking **10% of the high estimate (3).** Data for distributors, importers and exporters is limited and manufacturers and tattoo artists/PMU practitioners are likely to be importers of ink and there are likely to be few exporters since GB does not produce a large quantity of ink. In order to refrain from double counting and in the absence of better information, it is assumed that the number of distributors, importers and exporters is proportional to the number of manufacturers. The number of exporters is likely to be smaller given that GB does not produce and therefore export a large quantity of ink, but in the absence of better information and assumptions and with the intention to not underestimate figures, it is assumed exporters are also proportional to manufacturers, distributors and importers. The number of regulatory officers would depend on the size of the business – for these calculations it is assumed that there is one regulatory officer per (manufacturing, distributing, importing, and exporting) business who will be reading the legislation document. Therefore, one is multiplied by the number of businesses so estimates for number of people reading the legislation document in manufacturing, distributing, importing and exporting businesses are **3, 10 and 30** for **low, central and high scenarios**.

- Data for the number of tattoo artists and PMU practitioners is limited and has been estimated using available data and assumptions. Data is available on the number of tattoo artists and PMU practitioners for some regions in **Scotland** (total of **375 tattoo artists and 293 PMU practitioners**). This has been extrapolated using the population of England and Wales to produce a low estimate for the number of tattoo artists and PMU practitioners in GB (**England = 3,903 tattoo artists and 3,049 PMU practitioners and Wales = 217 tattoo artists and 170 PMU practitioners**). This provides a **low estimate for the number of tattoo artists (4,495) and PMU practitioners (3,512) in GB.**

For the high estimate, the call for evidence conducted by HSE asked respondents if they had any information on the number of tattoo artists and PMU practitioners in

GB. Three borough councils provided data and of the three, Cheltenham borough council had the highest number of tattoo artists and PMU practitioners. Only East Lindsey council provided a breakdown for tattoo artists and PMU practitioners, the other two boroughs provided a total figure, so it is assumed that Ipswich and Cheltenham have the same proportion of tattoo artists and PMU practitioners as East Lindsey, and these proportions are applied to the total figures for Ipswich and Cheltenham. The figures for Cheltenham borough council (as they are the highest of the three) are multiplied by the number of local authorities in GB (387) to provide a **high estimate** for the **number of tattoo artists (40,164)** and **PMU practitioners (21,756)** in GB.

The **central estimate** for the number of tattoo artists and PMU practitioners in GB takes the average of the low and high estimates mentioned above (**22,330 for tattoo artists and 12,634 for PMU practitioners).**

- The final costs are calculated by multiplying each of the three elements together:

  - Low *time taken to familiarise with the restriction* * hourly wage * low *number of people affected in industry*

  - Central *time taken to familiarise with the restriction* * hourly wage * central *number of people affected in industry*

  - High *time taken to familiarise with the restriction* * hourly wage * high *number of people affected in industry*

Familiarisation costs are estimated as a one-off cost as this analysis assumes that actors will understand the new rules when reading them for the first time and not have to incur costs again in the future.

6.5 Benefits

The following points were noted by SEAC (ECHA, 2019d) in reference to WTP values and treatment costs presented in tables 3.5.3.4 and 3.5.3.5. They can be extended to this analysis for GB and should therefore consider the values for WTP and treatment as rough estimates:

- Figures presented in table 3.5.3.4 assume that no follow-up treatment is required, and this could potentially underestimate the treatment costs.

- Treatment costs could vary considerably between countries which means the treatment costs presented in table 3.5.3.4 for the EU member states may vary compared to treatment costs in GB.

- It is assumed that treatment is initiated within one year after the start of symptoms and in every case is 100% successful. Therefore, the estimated social cost of one case of severe non-infectious inflammatory reactions could be an underestimation if the time between developing symptoms and treatment is longer than one year or the success rate is lower than 100%.

- SEAC note that two aspects should be considered when using the ECHA WTP figures for severe chronic dermatitis as proxy for tattoo complications; representativeness of the symptoms assessed in the WTP study for skin complications as a result of tattooing and representativeness of the studied population relative to the tattooed population. The lower and higher ECHA reference values for WTP to avoid severe chronic dermatitis are based on studies done with psoriasis and eczema patients (ECHA, 2016). The reduction of quality of life is described to be similar between psoriasis and eczema patients and patients with tattoo complications (Hutton Carlsen & Serup, 2015).

- A difference between the populations that would potentially be of influence on the WTP is disposable income of population. One factor linked with disposable income is age, i.e., it increases with age. The ECHA WTP values are based on populations with a mean age of 55 years. It is likely that the tattooed population that is potentially at risk for tattoo-related skin complications is younger. In the Hutton Carlsen & Serup (2015) survey the mean age among patients with tattoo complications was reported to be 33 years. In general, disposable income is lower for younger age groups (at least for most of the study period, since the age of tattooed population would likely increase in the future under the “high” scenario). Hence, the lower expected average age of the EU tattooed population may be seen as having the consequence of the ECHA WTP figures being an upper bound of society’s valuation. However, the fact that a sub-population of the EU would have less financial resources than the overall EU population does not necessarily mean that the overall societal WTP to protect them from a risk should be adjusted to the WTP of that sub-population.

- Overall, SEAC consider the ECHA WTP values sufficiently representative of the societal WTP to avoid severe tattoo complications.

The following non-monetised benefits are likely to be realised as a result of the proposed restriction:

Improved wellbeing and increased leisure time

Under the baseline scenario, if a customer were to experience severe adverse effects from a tattoo or PMU procedure, this could have impacts on other aspects of their life such as their wellbeing and it would prevent them from participating in leisure activities. By reducing exposure to substances with known hazardous effects in tattoo inks and PMU, the proposed options have the potential to reduce the number/severity of adverse reactions experienced. This would allow customers to see improvements in their wellbeing and allow more people to enjoy their leisure time (compared to the baseline) without the worry of an adverse reaction hampering this. It is difficult to quantify and monetise the number of less people experiencing adverse effects under options RO1, RO2 and RO3 and understand how much more leisure time or improvements in wellbeing this would translate to[104]. Quantification and monetisation would be possible if data was available for the average number of hours spent on these activities and the number of people affected.

Participation and productivity at work

Under the baseline scenario, if a customer were to experience severe adverse effects from a tattoo or PMU procedure, this could have significant impacts on their participation and productivity at work. By reducing exposure to substances with known hazardous effects in tattoo inks and PMU, the proposed options have the potential to reduce the impacts experienced. This would mean that anybody that suffered an adverse reaction which prevented them from working or hampered their productivity, may see improvements under the proposed restriction options, compared to the baseline. By reducing exposure to substances with known hazardous effects in tattoo inks and PMU, the proposed options have the potential to give customers the ability to work more hours or be more productive. As with the previous benefit, this may be possible to quantify and monetise if data was available for the average number of hours spent at work and the number of people affected. It's also worth considering that severe adverse reactions may lead to long-term illnesses that could put a person out of work which would reduce their level of income, potentially cause unemployment and uncertainty for future job prospects.

Improved reputation for industry

[104] It is possible that adverse health effects mentioned here have some overlap with the WTP values produced by ECHA in table 3.5.2.1.

By reducing exposure to substances with known hazardous effects in tattoo inks and PMU, the proposed options have the potential to reduce adverse reactions experienced by customers in comparison to the baseline. This may increase customer satisfaction making the customer more willing to return to the studio for a future tattoo or PMU procedure due to their positive experience. Customers may recommend the tattoo or PMU studio to friends and family which would give the artist a good reputation and potentially more customers compared to the baseline.

6.6 Sensitivities related to the socio-economic analysis

This section discusses the impact of the main SEA assumptions on total restriction costs, cost-effectiveness, break-even and overall proportionality of RO1, RO2 and RO3 (ECHA, 2019c).

Part a has been written specifically for this SEA and parts b-f are based heavily on the work of ECHA (2019c) and adapted to GB. Figures in this section have been rounded to the nearest hundred where appropriate.

a) Alternative baseline scenarios

The SEA assumes that under the baseline, GB based actors have not reacted to the EU restriction and are therefore non-compliant towards both the EU restriction and the proposed GB restriction.

This section will assess alternative baseline scenarios where GB based actors have i) partially reacted and ii) fully reacted to the EU restriction i.e.: by making the necessary changes to their production processes and consequently being already compliant with the proposed restriction in GB before it is implemented.

i) Partial reaction to the EU restriction

A partial reaction to the EU restriction refers to some actors having made the necessary changes to become compliant whilst others have done nothing. This will mean the actors that have reacted will have undertaken research and development, testing, reformulation, labelling and procuring of necessary purity colourants (substitution costs) as well as having become familiar with the EU restriction. The other group will not have reacted and will continue with the status quo.

It is assumed for the purpose of this scenario that 50% of GB industry have reacted and 50% have not reacted to the EU restriction. Those that have reacted incur substitution costs and familiarisation costs the first time they change their production processes and understand the EU restriction and enforcement and familiarisation

costs are incurred when the GB restriction is in place. GB based actors who have reacted to the EU restriction will have done so by choice given the restriction will not have yet been enforced in GB. Therefore, there will be no enforcement costs falling to government or local authorities in GB as a result of the EU restriction, but enforcement costs will be incurred when the restriction is implemented in GB. Familiarisation costs will be incurred once the GB restriction is in place to ensure actors have understood the necessary GB guidance.

If this scenario of a partial reaction to the EU restriction is compared to the main option within this analysis of imposing RO1, this would mean that only 50% of substitution costs and full costs for enforcement and familiarisation will be incurred (see table 6.6). 50% of benefits would be realised under RO1 as the other half would be attributed to the EU restriction.

ii) Full reaction to the EU restriction

A full reaction to the EU restriction refers to all GB based actors having made changes to their production processes to comply with the EU restriction. Given the proposed GB restriction will be very similar to the existing EU restriction, they will not need to make any further changes in terms of the substitution process, when the GB restriction is in place. This means that they will incur substitution costs at the time of compliance with the EU restriction but not again for the proposed GB restriction. As with part i, enforcement costs will be incurred by government and local authorities when the GB restriction is implemented, but not prior to this when the EU restriction is in place. Familiarisation costs will also be levied on industry to ensure they have understood this restriction in GB. If the scenario of a full reaction to the EU restriction is compared to option RO1, this would mean that GB industry would face smaller costs compared to scenario i as substitution costs would have already been incurred (see table 6.6) and the costs incurred under RO1 would be enforcement costs (refer to section 3.5.1.2) and familiarisation costs (refer to section 3.5.1.3). There would be no benefits attributable to the GB restriction as they would be seen as result of GB industry's reaction to the EU restriction.

The estimated costs for RO1 under scenarios i) and ii) are presented in table 6.6 below. As options RO2 and RO3 are less strict than RO1, it can be assumed that the total costs under scenarios i and ii would be lowest for RO2 then RO3 and then RO1.

Table 6.6: Annual costs for RO1 under the alternative baseline scenarios in 2021/22 prices

Scenario	Substitution costs	Enforcement costs	Familiarisation costs	Total costs
i)Partial reaction to the EU restriction	£394,500	£35,800	£867,500	**£1,297,000**
ii)Full reaction to the EU restriction	£0	£35,800	£867,500	**£903,300**

Given that the benefits in this analysis are non-monetised, it is difficult to ascertain the number or quantity of benefits that will be realised under the two alternative baseline scenarios. However, it can be assumed that under scenario ii, a greater quantity of benefits are realised (compared to scenario i) as all actors are compliant with the restriction and the large majority of benefits fall to GB based consumers. However, it is important to note that these benefits would arise as a result of the EU restriction being in place and would not be attributed to the proposed restriction in GB.

The tables below look at alternative scenarios for the volume of ink of the market, share of non-compliant ink on the market and price difference between compliant and non-compliant inks and the impacts these have on total restriction costs, cost-effectiveness, break-even and overall proportionality. As mentioned in section 3.5.1.3, familiarisation costs are a one-off cost that will be incurred in the first year that the restriction is implemented. However, the tables below look at an annual restriction cost therefore with the aim to ensure that the costs, cost-effectiveness and breakeven are not skewed and overestimated, the familiarisation costs (as part of the total restriction costs) have been apportioned across the 20-year appraisal period in the tables below.

b) Tattoo ink and PMU on the GB market

Section 3.2 already noted that the future volumes of tattoo ink and PMU on the GB market is uncertain. There is no historical information regarding the volumes of ink placed on the GB market to extrapolate short and long-term growth. Therefore, information about future volumes can be inferred only on the basis of information available on the demand for tattoos and PMU in the future. The long-term demand for tattoo inks and PMU would depend not only on how many new people get tattoos

but also how many tattoos a person tends to have, their size, style and colour. How these trends change creates uncertainty. It is assumed that the demand will grow at similar rates as the demand in recent years. Therefore, for the purpose of the analysis of the impacts of the proposed restriction options, it is assumed that the amount of tattoo ink and PMU on GB market is expected to remain at current levels – approximately 22,100 litres annually on average. For sensitivity purposes, the effects of two additional scenarios presented in table 6.7 are tested. The low volume baseline scenario assumes that future generations would not have the same desire to have a tattoo as their parents, while the high-volume scenario assumes that preferences for tattoos will grow faster in the short term and continue at the same rate as during 2003-2014 after that.

Table 6.7 shows projections for tattoo ink and PMU on the GB market. The cost-effectiveness for RO1 would deteriorate in the low volume baseline scenario but would not change significantly in the high-volume baseline scenario. The impacts for RO2 and RO3 are expected to be similar.

Table 6.7: Tattoo ink and PMU on the GB market in 2021/22 – projections

Scenario	Low volume	Main baseline	High volume
Total restriction costs (annual)	£580,400	£868,200	£1,049,600
Replaced tattoo ink & PMU (litres/year)	6,700	10,500	12,900
Cost-effectiveness (£/litre non-compliant tattoo inks replaced)	£87	£83	£82
Breakeven – low (only effects on skin) (# cases avoided)	137	205	248
Breakeven – high (only effects on skin) (# cases avoided)	41	62	74

c) Share of compliant ink currently on the GB market

As stated in section 3.5.1.1 on substitution costs, the assumptions on the share of compliant tattoo inks and PMU with the restriction options currently on the market will impact the conclusions with respect to substitution costs. The main analysis

presented earlier in section 3.5.1.1 is developed on the basis of the assumption that about 50% of the tattoo inks and about 90% of the PMU on the market are compliant with RO1, RO2 and RO3 requirements and therefore, would not need to be reformulated and their prices would not increase as a result of the proposed restriction options.

Therefore, for sensitivity purposes, it is tested if the impact of the lower and higher share of alternatives (compliant tattoo inks and PMU) currently on the market, i.e., in the high share of alternatives scenario assumes that only 30% of tattoo inks and no PMU currently on the market would not be compliant with RO1, while in the low share of alternatives scenario – 70% of tattoo inks and 20% of PMU would not be compliant with the proposed restriction options.

Table 6.8 shows that these assumptions have an impact on the proportionality of the restriction: i.e., the cost-effectiveness for RO1 will improve in the high share of alternatives scenario and deteriorate in the low share of alternatives scenario.

Table 6.8: Impact of the assumption related to the share of tattoo inks and PMU currently on the market that would have to incur cost as a result of RO1

Indicator	High share of alternatives	Central scenario	Low share of alternatives
Total restriction costs (annual)	£543,800	£868,200	£1,192,600
Replaced tattoo ink & PMU (litres/year)	6,200	10,500	14,700
Cost-effectiveness (£/litre non-compliant tattoo inks replaced)	£88	£83	£81
Breakeven – low (only effects on skin) (# cases avoided)	129	205	282
Breakeven – high (only effects on skin) (# cases avoided)	39	62	85

d) Price difference between compliant and non-compliant tattoo inks

As stated in section 3.5.1.1 on substitution costs, the price difference between compliant and non-compliant tattoo inks and PMU on the market is assumed 15% and 20% respectively. This is taken from ECHA (2019c) and based on the average response from stakeholders. The price difference was reported to range from "none" to close to 40% for tattoo inks and 70% for PMU. (stakeholder consultations). To test the impacts of these assumptions, two additional scenarios are prepared: no price difference and high price difference. The latter assumes that the price difference between compliant and non-compliant tattoo inks and PMU would be double those in the central scenario: respectively, 30% and 40%.

Table 6.9 shows that these assumptions have a substantial impact on the proportionality of the restriction: in the event the prices of tattoo inks and PMU increase by 30% or 40% respectively, the proportionality of RO1 can be demonstrated. The situation for RO2 and RO3 is expected to be similar.

Table 6.9: Impact of price difference assumption on RO1

Indicator	No price difference	Central scenario	High price difference
Total restriction costs (annual)	£79,200	£868,200	£1,657,100
Replaced tattoo ink & PMU (litres/year)	10,500	10,500	10,500
Cost-effectiveness (£/litre non-compliant tattoo inks replaced)	£8	£83	£158
Breakeven – low (only effects on skin) (# cases avoided)	19	205	392
Breakeven – high (only effects on skin) (# cases avoided)	6	62	118

e) Combined impact on proportionality

Table 6.10 shows that the combined impact of these three assumptions would lead to the highest deterioration in the cost-effectiveness of RO1: The combination of low volume and low share of alternatives and high price difference leads to the highest deterioration of the cost-effectiveness of RO1. The impact of the polar opposite combination of assumptions on the cost effectiveness is substantial; however, the largest improvement of the cost-effectiveness is due to the price difference assumption (while all other assumptions remain as in the central scenario). The situation is expected to be similar for RO2 and RO3.

Table 6.10: Combined impact of assumptions on RO1

Indicator	Low volume/Low share of alternatives/High price difference	High volume/High share of alternatives/No price difference	No price difference
Total restriction costs (annual)	£669,500	£79,200	£79,200
Replaced tattoo ink & PMU (litres/year)	9,400	7,600	10,500
Cost-effectiveness (£/litre non-compliant tattoo inks replaced)	£71	£10	£8
Breakeven – low (only effects on skin) (# cases avoided)	158	19	19
Breakeven – high (only effects on skin) (# cases avoided)	47	6	6

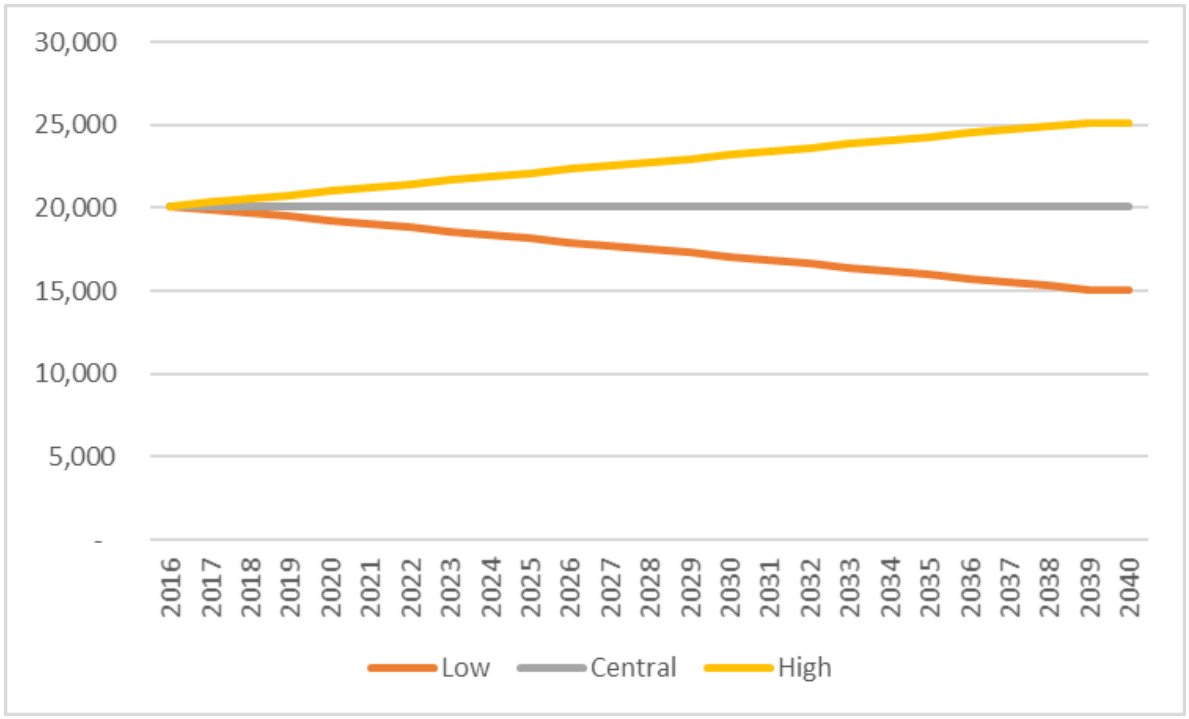
Therefore, the proposed restriction options to break even in the worst-case scenario 158 surgical removals due to complication of tattoo inks would need to be avoided (calculated using cost of illness (COI) plus low WTP values) or 47 (COI plus high WTP values).

f) Combined impact on proportionality

On request by SEAC, ECHA prepared an alternative sensitivity analysis for the projected volumes of tattoo inks on the market. The intent of these additional scenarios was to remove the uncertainty related to future incidence of tattoo and PMU in the EEA. The scenarios are also presented within this analysis for GB displayed in figure 6.1 and consist of:

- Central alternative scenario: the volumes currently estimated on the market remain stable over the study period
- Low volume: the estimated volumes of tattoo ink decline by 25% by the end of the study period; and
- High volume: the estimated volumes of tattoo ink increase by 25% by the end of the study period.

Figure 6.1: Projected volumes of tattoo ink on the GB market – alternative volume scenarios



The results of the new projection scenarios are shown earlier in section 4.2, table 4.2. Columns 2-5 of table 4.2 can be compared to the impact on the scenarios in table 6.1. The new scenarios demonstrate that the impact on the cost-effectiveness and proportionality of tattoo ink volumes on the market is low. The cost-effectiveness ranges from £83 - £85/litre of non-compliant tattoo ink on the market and the number of break-even cases of surgical removal: from 162 to 215 (using low WTP values)

and from 49 to 65 (using high WTP values). This is a similar impact as shown in table 6.7 in the central and low volume scenario but less volatile than in the low volume scenario where the cost-effectiveness was lower, i.e., £87/litre.

As shown in table 4.2, the scenario which leads to the greatest deterioration of the cost effectiveness is the scenario when the price difference between non-compliant and compliant inks is twice as high as in the central scenario, i.e., 30% higher for tattoo and 40% higher than PMU. The total restriction costs for RO1 under this scenario are about £1,515,800. This means that about 358 surgical removals due to complication of tattoo inks would need to be avoided (calculated using cost of illness (COI) plus low WTP values) or 108 (COI plus high WTP values).

These results, albeit slightly lower, do not differ significantly under the worst-case scenario presented in table 4.2. Therefore, in summary, it can be concluded that the proposed restriction options are proportionate, as they are cost-effective, affordable and would lead to benefits in terms of avoided complications of tattoo inks and PMU associated with exposure to chemicals and other health effects (systemic, carcinogenic, reproductive or developmental) even when main assumptions are relaxed.