Agency opinion on the Annex 15 dossier proposing restrictions on

Substances in tattoo ink and permanent make-up

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AGENCY OPINION ON A PROPOSAL FOR A RESTRICTION

1. Basis for the proposal

The Health and Safety Executive, in its capacity as the Agency for UK REACH (hereafter referred to as the Agency) has prepared a proposal to restrict the presence of hazardous substances in inks used for tattooing and permanent make-up (PMU) in accordance with Article 69(1) of UK REACH. The proposal aims to address potential human health risks to adults in Great Britain (GB) who choose to get a tattoo or PMU that arise because of substances that may be present in inks used for these procedures. Measures to protect tattoo artists and PMU practitioners carrying out procedures are not in scope of this restriction.

Regulations are in place to ensure tattooing and PMU procedures are hygienic. However, there are currently no legislative controls on the composition of inks for tattooing and PMU supplied to the GB market. In theory, therefore, tattoo and PMU inks might contain substances which are carcinogenic, potentially harmful to reproduction or otherwise hazardous to human health. By their nature, tattoos and PMU involve exposure to substances in inks over extended periods of time which may extend to the remaining lifetime of an individual, and via a route of exposure, the intradermal route, that is not normally considered in human health risk assessments for chemicals. It is reasonable for the general public to expect that products which are supplied and used for tattooing and PMU should be safe for this purpose. However, it is not currently known whether these inks contain substances with the potential to cause adverse effects under the exposure conditions that are created when a tattoo or PMU is received.

There is evidence that substances in tattoos can trigger adverse health effects, including allergic reactions. However, there is uncertainty about how often someone with a tattoo or PMU will develop an adverse reaction that is sufficiently severe for them to seek medical attention. Moreover, where effects only materialise after an extended period of time and/or elsewhere in the body, it might be impossible to link those effects to an individual's tattoo or PMU. There is, as yet, no definitive evidence that tattoos and PMUs have caused cancer or other similarly serious health problems, but for the reasons highlighted, this cannot be ruled out.

This restriction therefore addresses a *potential* public health problem. It aims to protect those receiving tattoos and PMU from adverse health impacts which could be caused by tattoo inks but which it will generally be difficult to link definitively to those inks. It also imposes a responsibility on ink suppliers and the tattoo and PMU industries in general to check that their inks do not contain potentially harmful substances, and to reformulate or remove any inks in which such substances are found. The restriction therefore targets hazardous substances that have the potential to trigger adverse reactions if used for tattooing or PMU. By limiting the amount of

these substances in a tattoo or PMU ink, the restriction seeks to minimise the potential for substance related adverse reactions.

Since the restriction has been developed in the context of the UK REACH regulation, it does not address other risks associated with tattooing and PMU such as infection risks. Adverse effects arising from procedures to remove tattoos or PMU, other than those that may arise from the decomposition of substances in inks as a result of the removal process, are also beyond its scope. The Agency acknowledges that the greatest burden of tattoo and PMU-related ill health is caused by infections rather than substances in inks. In proposing options for this restriction, the Agency has given consideration to different approaches that could be used by formulators to limit microbial contamination during production, transport and storage and how those could also affect ink composition.

The REACH Regulation defines a supplier of a substance or mixture as any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture. The requirement to ensure that tattoo inks placed on the GB market comply with the requirements of the restriction will predominantly be incurred by the actors at the top of the GB supply chain i.e. GB-based formulators and GB-based importers who first-place tattoo inks on the GB market. In circumstances where the product is purchased from outside of GB, a non-GB formulator could work with the GB importer to assist in determining compliance.

2. Proposed restriction

The restriction options proposed by the Agency apply to mixtures supplied in GB for tattooing procedures and 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).

In the documents that accompanied the public consultation held between May and November 2022 the Agency identified three options for this restriction. These options, referred to as Restriction Option 1 (RO1), Restriction Option 2 (RO2) and Restriction Option 3 (RO3) in the consultation, each targeted substances with hazards that could potentially cause ill health if used for tattooing or PMU. Based on information received from the public consultation, the Agency rejected RO1 and RO3 and identified two options, both based on a modified version of RO2.

The first option (referred to as modified RO2) applies to the following substances if they are present in tattoo or PMU ink:

- Substances classified in the GB Mandatory Classification and Labelling (MCL) list as:
    - Carcinogens (H350, H351) or mutagens (H340, H341)

    - Toxic to reproduction (H360, H361)
    - Skin sensitisers (H317)
    - Skin corrosive or skin irritants (H314, H315)
    - Substances that cause serious eye damage/eye irritant substances (H318, H319)

- Substances that are listed in Annex II of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (as amended) (hereafter referred to as the Cosmetic Products Regulation or CPR) or in Annex IV of the CPR with conditions in column 'g' relating to the product types in which that substance can be used. Where links are made between this restriction and the CPR, the link is to the legislation as it has been enacted in GB.
- Substances listed in resolution ResAP(2008)1 (CoE, 2008) of the Council of Europe that are not covered by one or more of the above categories.

The second option (referred to as modified RO2a) is identical to modified RO2 except that it does not include in its scope substances that are classified in the GB MCL list for skin irritation (H315) and/or eye irritation (H319). Modified RO2a is the Agency's preferred option. Section 4.2 provides further information about these options, the reasons why the Agency rejected RO1 and RO3 and the reasons why modified RO2a is the Agency's preferred option.

It is proposed that only mandatory classifications should be taken into account when determining the status of a substance under this restriction. This is because companies may take different decisions regarding the self-classification that they apply to substances, potentially leading to a lack of clarity for duty holders about the way this restriction applies to a substance.

Both options aim to prevent inks for tattooing and PMU from being:

a) placed on the GB market; or

b) used for tattooing or PMU procedures

if they contain any substance in scope of the restriction above the specified concentration limit.

Both options include a dynamic link with the GB MCL list. This means that when substances with relevant hazard classifications are added to the GB MCL list or relevant hazard classifications in this list are updated, those changes will take effect in this restriction without the need for additional scientific assessment.

Although the proposed restriction applies to substances which are already listed in Annex II or IV (with conditions) of the CPR, the Agency is proposing that there should be no future link between this restriction and the CPR. Risk assessment-based and socioeconomic-based arguments can be made for and against different types of links. For the reasons outlined in section 4.2.3, the Agency's preferred option is for there to be no future link.

The Agency proposes a derogation from requirements arising because of the status of those colourants under the CPR for the 19 substances listed in Appendix 1, Supplementary Table B. Appendix 1, is provided as a separate document owing to its length.

These pigments are brought into scope because they are listed in Annex II of the CPR, which identifies substances that are prohibited for use in cosmetics. The Annex II prohibition of these 19 substances is limited to use in hair dyes. These pigments are also listed in Annex IV of the CPR, which is a list of permitted colourants. Inclusion in Annex IV means that these pigments may be used in products intended to remain on the skin for prolonged periods and/or those such as lipsticks which have a high potential for daily human ingestion.

The Agency has conducted its own review of the available hazard information for these pigments. The Agency did not identify evidence indicating they are unsafe if used in tattoo or PMU ink and has taken into account the widespread concern expressed by the tattooing community about the impacts to tattooing if two of these pigments, Pigment Blue 15:3 (PB 15:3) and Pigment Green 7 (PG 7), are withdrawn from use. Indeed, members of the tattooing community have raised petitions in the EU and in GB asking for PB 15:3 and PG 7 to be derogated. Given that, despite the intensive efforts of ink formulators, technically effective and safe alternatives for these two pigments have not been identified, the Agency considers it is appropriate to permit the continued use of these and the 17 other pigments which are listed in Supplementary Table B. Section 3.3.1d and Appendix 7 of the background document provide further information about the proposed derogation.

The Agency's original proposed derogation also included Pigment Red 83 (CAS: 72-48-0) and Solvent Violet 13 (CAS: 81-48-1). These have been removed because the review conducted by the Agency identified data indicating potential concerns for skin sensitisation for both substances.

If evidence emerges indicating that any of the derogated pigments causes or has the potential to cause ill health when used for tattooing or PMU, either because of its inherent properties or because it can break down to form hazardous substances in the body, the need to amend or introduce a mandatory classification under the GB Classification Labelling and Packaging Regulation (Regulation (EC) No 1272/2008 as retained and amended for GB (hereafter referred to as GB CLP)) for that substance should be considered.

The restriction also introduces labelling requirements to:

- list ingredients that would not be identified on the label under GB CLP;
- include the statement “Mixture for use in tattoos or permanent make-up”;
- include a reference number for the ink to uniquely identify each batch; and
- provide instructions for use. As a minimum, this should include the expiry date for an ink product.

The Agency is proposing a transitional period of around two years for formulators and suppliers. This recognises the need for reformulation and testing of inks (which are complex mixtures) and to check healing times with the new formulations, within the backdrop that formulators will be learning from the work undertaken for the EU restriction. Additionally, the Agency has taken note of the concerns about costs to artists and PMU practitioners if they have to discard stocks of unused inks. For this reason, the Agency is proposing an extra transitional period of one year to allow tattoo artists and PMU professionals time to use up non-compliant inks purchased before the end of the transitional period for formulators and suppliers (further details are available in section 4.2.3).

A date of 2027 for full adoption of this restriction is proposed, on the basis of an indicative timescale of introduction of an amendment to Annex 17 of UK REACH in 2024. This means that from 2026, formulators/suppliers will be required to supply compliant inks and from 2027, tattoo artists and PMU practitioners will be required to use compliant inks.

Modified RO2 is described in Table 1. Modified RO2a is described in Table 2. These options take into account information provided to the Agency during public consultation 1, public consultation 2, and in meetings with stakeholders. They also take into account advice provided to the Agency by independent scientific experts from the REACH Independent Scientific Expert Pool (RISEP).

Tables 1 and 2 differ only in respect of the hazard classes which are in scope. Both reflect the case where there is no future link with the CPR.

Table 1. Modified RO2 – proposed scope

NOTE: Tables A – E are provided in Appendix 1. Each concentration limit applies to the individual substance.

Substances falling within one or more of the following points:	1. Shall not be placed on the market in mixtures for use for tattooing purposes after **[**….**]**, and mixtures containing any such substances shall not be used for tattooing purposes after **[**….**]**, if the substance or

a) Substances included in the GB MCL list with a classification as: • carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation • 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 • 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 in Table A c) Substances in Table C d) Substances in Table D e) Substances in Table E The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply	substances in question is or are present in the following circumstances: a. the following substances in concentrations greater than the relevant generic concentration limit in Part 3 of Annex 1 of 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. Carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, ii. Substances toxic to reproduction, category 1A, 1B and 2 iii. Skin irritant and corrosive substances, category 1, 1A, 1B, 1C, and 2 iv. Eye damaging and irritant substances, category 1 and 2 b. skin sensitising substances in excess of 0.01% w/w for category 1A and 0.1% for category 1 or 1B. In the case of substances for which a specific concentration limit has been assigned for skin sensitisation, it is the concentration limit for elicitation that applies: 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. Mixtures for use for tattooing purposes shall not be placed on the market if they contain the substances listed in Table A, exceeding the concentration limits specified in Table A. 3. Unless already covered by paragraphs 1 or 2, mixtures for use for tattooing purposes shall not be placed on the market if they contain the substances in:

to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (e) of this column of this entry.	a. Table C in concentrations exceeding 0.1% w/w and b. Table D in concentrations exceeding 0.1% w/w. 4. Unless already covered by paragraphs 1 to 3, mixtures for use for tattooing purposes shall not be placed on the market if they do not meet the conditions for the substances in Table E. 5. By way of derogation, paragraph 3 shall not apply to substances (colourants) listed in Table B. 6. If the GB MCL list is amended to classify or re-classify a substance such that the substance then becomes caught by point (a) or (b) 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 application of that new or revised classification is after the end of the transition period for this restriction, 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. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that after **[**….**]** 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 an 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) 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) – (d), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes after **[**….**]**, 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 are not labelled with the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes after **[**….**]**. 9. Definitions for the purpose of this restriction entry a. A mixture for use for tattooing purposes (tattoo ink) is a mixture consisting of colourants and auxiliary ingredients administered by intentional insertion into the skin, mucous membrane or eyeball, whereby a mark 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 intentional insertion 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, semi-permanent make-

	up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on that person's body. 10. The restriction shall apply **[**….**]** after its entry into force. 11. 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). 12. 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. 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.

Table 2. Modified RO2a – proposed scope

NOTE: Tables A – E are provided in Appendix 1. Each concentration limit applies to the individual substance.

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 mutagen category 1A, 1B or 2, but excluding any such substances classified	1. Shall not be placed on the market in mixtures for use for tattooing purposes after **[**….**]**, and mixtures containing any such substances shall not be used for tattooing purposes after **[**….**]**, if the substance or substances in question is or are present in the following circumstances: a. the following substances in concentrations greater than the relevant generic concentration limit in Part 3 of Annex 1 of the GB CLP Regulation, unless a specific concentration limit is listed in the GB MCL

due to effects only following exposure by inhalation • 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 • serious eye damage category 1 b) Substances in Table A c) Substances in Table C d) Substances in Table D e) Substances in Table E 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 (e) of this column of this entry.	list in which case the specific concentration limit applies. i. Carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, ii. Substances toxic to reproduction, category 1A, 1B and 2 iii. Skin corrosive substances, category 1, 1A, 1B, and 1C iv. Eye damaging substances category 1 b. skin sensitising substances in excess of 0.01% w/w for category 1A and 0.1% for category 1 or 1B. In the case of substances for which a specific concentration limit has been assigned for skin sensitisation, it is the concentration limit for elicitation that applies: 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. Mixtures for use for tattooing purposes shall not be placed on the market if they contain the substances listed in Table A, exceeding the concentration limits specified in Table A. 3. Unless already covered by paragraphs 1 or 2, mixtures for use for tattooing purposes shall not be placed on the market if they contain the substances in: a. Table C in concentrations exceeding 0.1% w/w and b. Table D in concentrations exceeding 0.1% w/w. 4. Unless already covered by paragraphs 1 to 3, mixtures for use for tattooing purposes shall not be placed on the market if they do not meet the conditions for the substances in Table E.

	5. By way of derogation, paragraph 3 shall not apply to substances (colourants) listed in Table B. 6. If the GB MCL list is amended to classify or re-classify a substance such that the substance then becomes caught by point (a) or (b) 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 application of that new or revised classification is after the end of the transition period for this restriction, 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. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that after **[**….**]** 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 an 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) 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) – (d), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes after **[**….**]**, 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 are not labelled with the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes after **[**….**]**. 9. Definitions for the purpose of this restriction entry a. A mixture for use for tattooing purposes (tattoo ink) is a mixture consisting of colourants and auxiliary ingredients administered by intentional insertion into the skin, mucous membrane or eyeball, whereby a mark 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 intentional insertion 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, semi-permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on that person's body. 10. The restriction shall apply **[**….**]** after its entry into force. 11. 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). 12. 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. 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.

The exemption listed in Clause 12 grants an exemption for mixtures placed on the market or used for tattooing purposes exclusively as a medical device or an accessory to a medical device, within the meaning of the MDR. The Agency has not identified examples of uses that appear to meet the requirements for this exemption. Since mixtures used for medical procedures such as areola reconstruction or for targeting during surgical or x-ray procedures can also be used for aesthetic tattooing or PMU purposes, these do not appear to meet the requirements for this exemption. However, if a tattoo ink was supplied exclusively for medical procedures, then potentially, this could meet the requirements for this exemption. The Agency considers that this exemption is needed to ensure that any restriction in GB does not inadvertently prohibit essential medical uses now or if novel procedures are developed in the future.

2.1 Alternatives to a REACH restriction

One element which is not included in either of these options but (on the basis of information provided to the Agency during the first public consultation) might help ink formulators identify suitable substances for their products, is the option to include positive lists of substances permitted for use in tattoo and PMU inks where this use can be demonstrated to be safe. This approach could be particularly useful for substances used as preservatives and for widely used colourants. However, it could also limit the reformulation and product development opportunities for ink formulators if they can only work within the range of substances included in a positive list.

Before such lists could be considered, work would need to be undertaken to establish the criteria according to which a substance would be added to such a list, including (particularly for preservatives) considerations around efficacy as well as safety for the intended use. It will also be necessary to establish the administrative

framework for processing information packages and amending positive lists and allocate responsibility for oversight of the process.

Early work that could contribute to the development of an agreed risk assessment framework for tattoo and PMU ink products has been initiated by the German Federal Institute for Risk Assessment (BfR), which has proposed a set of minimum requirements for health-based risk assessment of substances in tattoo inks. As a follow on activity, BfR is establishing a panel of external experts, including experts in health risk assessment and analytical chemistry, to explore how these minimum requirements could be developed into a risk assessment framework (with associated test methods and guidelines) for substances intended for use in tattoo and PMU inks. The panel will operate between 2023 and 2025. It is likely that any recommendations that emerge from this panel will need to be further developed after 2025 before progress can be made to establish a formal risk assessment framework for tattoo and PMU inks.

Until this work is complete, it will not be feasible to establish positive lists of preservatives or other substances that could be used in tattoo inks.

Another approach to managing all the risks associated with tattooing and PMU, including those due to substances present in the inks used, could be to establish standalone legislation regulating the composition of inks, hygiene requirements and suitable training regimes. The Agency did not perform a detailed analysis of this option because it cannot be a part of the UK REACH restriction proposal dossier. Standalone legislation should take into account the following guidance and recommendations:

- Council of Europe resolution ResAP(2008)1 (CoE, 2008)
- CIEH Tattooing and body piercing guidance toolkit
- BS EN 17169 (2020): Tattooing. Safe and hygienic practice
- Tattoo inks: minimum requirements and test methods (bund.de)

Standalone legislation could also provide a framework for the establishment of positive lists.

The Agency notes that work is underway to improve the regulatory oversight of non-surgical cosmetic procedures such as Botox and fillers. There are parallels between these procedures and the application of PMU and tattoos. For all of these procedures, foreign substances are purposefully introduced into a person's skin/body with the intention that they remain in the body for extended periods of time. Covering similar aesthetic procedures in one scheme would help to ensure consistency in adopted risk assessment procedures and regulatory approaches. The Agency recommends that the Appropriate Authorities (Defra Secretary of State and Scottish

and Welsh Ministers) consider whether regulations on the composition of tattoo and PMU inks would fit within regulations covering other non-surgical cosmetic procedures.

The option of taking no action also exists, often referred to as the do-nothing option. This could be justified on the basis of the high levels of uncertainty in the evidence base for this restriction and a desire to avoid unintended consequences, possibly including an increase in cases of tattoo and PMU-related ill health. This could occur, for example, if the use of less effective sterilisation methods gave rise to an increase in infections or because inks are reformulated using substances that have sparse toxicological data sets and possibly unidentified health hazards. Given that inks which have been reformulated for the EU market will be available in GB, where these inks are found to provide good quality tattoos and PMU with few or no adverse reactions, there is the potential for these inks to gain market share in GB in preference to older formulations, without the need for specific legislation. In terms of the socioeconomic analysis, this option would incur no costs or benefits given that the *status quo* (i.e. no GB restriction) would be maintained.

3. Procedure for adoption of the opinion

On 14th December 2020, the European Union (EU) published Commission Regulation (EU) 2020/2081 which amended Annex XVII to EU REACH, bringing in restrictions on substances in tattoo inks or permanent make-up. The need for a similar legislation for GB was considered by the Appropriate Authorities in a prioritisation exercise addressing restrictions that had not been included as retained law. As a result of this exercise the Agency, on 29th April 2021, received a request under Article 69(1) of UK REACH from the Defra Secretary of State, with the agreement of the Scottish and Welsh Governments, to prepare an Annex 15 restriction dossier assessing the risks to humans from substances in inks used for tattooing and PMU and consider the need for further measures, beyond those already in place.

Table 3: Procedure for the adoption of the opinion

Article under which the restriction dossier has been prepared:	Article 69(1)
Risks to be addressed:	This restriction aims to address human health risks to adults in Great Britain (GB) who choose to get a tattoo or permanent make-up (PMU) that arise because of substances that may be present in inks used for these procedures.

	This restriction does not address other risks that are associated with tattooing and PMU, such as infection risks or adverse effects arising from procedures to remove tattoos or PMU (other than those that may arise from the decomposition of substances in inks resulting from the removal process).
Date the Registry of Restriction Intentions was updated in accordance with Article 69(5):	29th April 2021
Stakeholder mapping:	☒Yes ☐No Reasons why this was not carried out:
Key information sources used:	The EU Joint Research Centre's (JRC's) Science for Policy report on the 'Safety of tattoos and permanent make-up' (2016) The European Chemical Agency's (ECHA's) dossier proposing a restriction on 'substances in tattoo inks and permanent make-up' (2019) The opinion of ECHA's Risk Assessment and Socioeconomic Assessment committees (RAC and SEAC) on the Annex XV dossier proposing restrictions on substances in tattoo inks and permanent make-up (2019) The text of the implemented EU restriction (Commission Regulation (EU) 2020/2081 of 14th December 2020) Literature search and call for evidence (2021) Literature search focussing on the pigments which are the subject of the Agency's proposed derogation (2022)

Call for evidence:	☒Yes Start date: 3rd September 2021 End Date: 2nd November 2021 ☐No Reasons why this was not carried out:
Information received during the call for evidence:	88 respondents provided information to the call for evidence. Five confidential attachments and seven non-confidential attachments were also provided by respondents. A member of the case team also contacted tattoo ink suppliers directly to try to gather more information about numbers of formulators and distributors of inks.
Stakeholder Consultation meetings held during the drafting stage:	☐Yes ☒No
Attendance at external events during the drafting stage:	5th World Congress of Tattoo and Pigment Research (WCTP 2021), 24th – 26th August 2021, one member of the case team participated online. Chartered Institute of Environmental Health (CIEH) Beauty Conference, 21st October 2021, HSE gave a presentation online about the restriction. 2nd International Conference on Tattoo Safety, 18–19 November 2021, one member of the case team participated online.
Public consultation in accordance with Article 69(6):	Start date: 6th May 2022 End Date: 6th November 2022
Information received during the first public consultation:	Eight respondents provided information.

Stakeholder Consultation meetings held and meetings with other interested parties/OGDs also attendance at external events during the first public consultation:	☒Yes 4th August 2022 (online) – Meeting with an Environmental Health Officer based in Wales to obtain further information about costs of enforcement and enforcement practices. 2nd September 2022 (online) – Meeting with HSENI to discuss how they are enforcing the EU restriction. 22nd September 2022 (online) – Meeting with the European Society of Tattoo and Pigment Research (ESTP) to obtain information about the impact that the EU restriction is having and analytical challenges. 28th September 2022 (online) – Presentation given to the London Special Treatment Group to stimulate discussions on enforceability. 29th September 2022 (online) – Discussions with tattoo artists. 30th September 2022 (online) – Discussion with an ink supplier. 30th September 2022 (online) – Discussion with the Office for Product Safety and Standards (OPSS) about overlaps with the proposed restriction and the Cosmetic Products Regulation. 3rd October 2022 (online) – Discussions with tattoo artists. 6th October 2022 (online) – Discussions with the Midlands Special Treatment Group on enforceability. 27th October 2022 (online) – Meeting with an economist at the Regulatory Policy

	Committee (RPC) to discuss approach to enforcement costs. 28th October 2022 (online) – Discussion with an ink formulator on the challenges posed by the EU restriction including the lack of analytical methods. 11th November 2022 (online) – Discussion with Prof J Serup on the nature of adverse reactions seen in tattoo clinics. 15th November 2022 (online) – Discussion with a second ink formulator on the challenges posed by the EU restriction including the lack of analytical methods.
Relevant scientific advice sought in accordance with Article 77(1A):	☒Yes Challenge Panel meetings held on: 18th July 2022 (hybrid) 18th November 2022 (hybrid) 1st February 2023 (hybrid) 4th May 2023 (hybrid) ☐No Justification if not sought:
Challenge Panel advice on Risk Assessment Opinion:	☒Yes ☐No ☒ by Challenge Panel meeting on 1st February 2023: ☒ Support (10) ☐ Support with advisory (number) ☐ Do not support (number)

	NOTE: Comments provided by the Challenge Panel in writing before the meeting on 1st February and verbally during the meeting have been taken into account in the final risk assessment opinion.
Challenge Panel advice on draft Socioeconomic Assessment Opinion:	☒Yes ☐No ☒ by Challenge Panel meeting on 1st February 2023: ☒ Support (10) ☐ Support with advisory (number) ☐ Do not support (number) NOTE: Comments provided by the Challenge Panel in writing before the meeting on 1st February and verbally during the meeting have been taken into account in the draft socioeconomic opinion.
Date of formulation of the risk assessment opinion in accordance with Article 70:	1st February 2023
Public consultation in accordance with Article 71(1):	Start date: 13th February 2023 End Date: 14th April 2023
Information received during the second public consultation:	Seven respondents provided information.
Stakeholder Consultation meetings held and meetings with other interested parties/OGDs also attendance at external events during the second public consultation:	☒Yes • 2nd March 2023 (phone call) – Discussion with a GB-based ink formulator to obtain socioeconomic information. • 22nd March 2023 (online) – Discussion with an ink formulator to clarify aspects of the

	socioeconomic information which they provided during the first public consultation, confirm that the modified restriction options are technically feasible and seek information about what transition period could be achievable. • 30th March 2023 (online) – Discussion with a second ink formulator to clarify aspects of the socioeconomic information which they provided during the first public consultation, confirm that the modified restriction options are technically feasible and seek information about what transition period could be achievable.
Challenge Panel advice on final Socioeconomic Assessment Opinion:	☒Yes ☐No ☒ by Challenge Panel meeting on 4th May 2023: ☒ Support (9 (+ 1 tacit approval)) ☐ Support with advisory (number) ☐ Do not support (number) NOTE: Comments provided by the Challenge Panel in writing before the meeting on 4th May and verbally during the meeting have been taken into account in the final socioeconomic opinion.
Date of formulation of the socioeconomic opinion on accordance with Article 71(2):	4th May 2023

4. Opinion of the Agency

4.1 Justification for action

Tattoo and PMU inks are complex mixtures which are inserted into the skin to make marks or designs. Their complex nature is illustrated by a paper by Bauer *et al.* (2022). These researchers published the results of chemical analyses of one green ink product as formulated for the EU and for Asia. The ink was found to contain hundreds of different substances. The concentrations for the majority of these substances were not reported. Further details of this analysis are provided in Section 1.1.5 of the background document.

The substances used to formulate tattoo and PMU inks are not, typically, produced specifically for this purpose. In addition to substances that have a specific function in tattoo and PMU ink, impurities derived from the raw materials from which the ink was made may also be present. Other unintended substances may form *in situ* because of the conditions in which the ink has been sterilised (e.g., heating, U.V. irradiation or x-ray sterilisation), stored or transported have triggered chemical transformations in the product. Some of these impurities and unintended substances may be hazardous to human health or could undergo transformations in the body into substances that are hazardous to health.

In recent years, the practices of tattooing and PMU have become more popular. In a YouGov survey of 2224 adults in GB in July 2022, 26% of respondents reported having one or more tattoos. Less information is available on the proportion of the population that has had one or more PMU treatments. Based on information from three EU Member States (not including the UK), it has been claimed that up to 20% of the general EU adult population may have had PMU procedures carried out (JRC, 2016b). The Agency cannot determine if the EU data is representative for GB because specific data for GB on PMU procedures is not available.

The literature contains evidence linking substances in tattoo ink and PMU to various skin reactions.

Adverse effects serious enough to require medical attention are often collectively referred to as complications. Some complications, such as those due to infection caused by bacterial contamination of inks, poor hygiene in the studio or poor aftercare by the client, emerge within days or weeks of getting a tattoo or PMU. Substances in inks may also trigger complications shortly after the tattoo or PMU has been administered. Other complications, for example granuloma formation or some allergic type reactions, may appear months or years after the tattoo has apparently healed normally.

Less serious reactions, including transient reactions that occur intermittently and subside without treatment, have been referred to in the literature as complaints.

There is no agreed medical definition of the distinction between a complication and a complaint.

It is difficult to estimate the true incidence and prevalence of complications and complaints that occur in GB from substances present in tattoo inks and PMU because there is no GB registry of tattoo/PMU-related adverse health effects. Furthermore, no epidemiological studies have been performed in GB; most of the available studies have been conducted in EU countries where tattoo clinics have been established. Reported numbers are highly variable between these studies. Possible reasons for this variability include:

- Differences in the severity grading assigned to the effects reported.
- Where studies rely on self-reported information, a possible tendency to under-report less severe effects owing to memory bias.
- Infrequent presentation of minor effects in healthcare settings because people prefer to obtain advice on treatment from their tattoo artist or PMU professional or manage their symptoms themselves.

The latter two phenomena may increase the likelihood that less severe effects are under-reported in the scientific literature.

It can be difficult to identify which substances in the tattoo ink or PMU may be responsible for triggering an adverse effect. Medical professionals may take biopsies at the affected site to analyse for substances present in the affected skin and help with their diagnosis, but it is not always appropriate to use invasive methods. Even where biopsies have been taken, as discussed in this review of nickel in tattoo ink and skin allergies, the presence of multiple substances in the skin sample makes it difficult to pinpoint which substance may have trigged skin reactions (Kluger, 2021).

In a combined review and study by Wenzel *et al.* (2013), coloured inks were shown to be mainly responsible for adverse reactions reported following tattooing. Both case reports and self-reported adverse effects were consistently associated with coloured tattoos on the extremities rather than the trunk suggesting a possible role for substance related phototoxicity in a proportion of adverse reactions.

Other studies and surveys suggest that the majority of chronic adverse effects are allergic in nature, red colorants being most commonly associated with allergic reactions (Kluger, 2019). Reactions can appear months or years after tattooing is completed. The mechanisms underlying tattoo-related allergic reactions have not been elucidated. Some allergic reactions may be triggered by a transformation product and not the parent substance. The potential for exposure to substances in tattoos over a period of decades and variation in latency periods adds to the complexities when studying links between tattooing and ill health (Laux *et al.*, 2016).

The ability of substances in tattoo and PMU ink (including pigments) to translocate away from the site of the tattoo or PMU to organs such as the lymph nodes and the liver (Schreiver *et al*., 2015) (Sepehri, *et al.,* 2017a) means that adverse effects may occur at sites remote from the original tattoo or PMU.

Concerns have been raised that tattoos and PMU present a possible risk for adverse reproductive effects and cancer; however, this is an area where the evidence base is very weak. The Agency has not identified robust evidence for these outcomes and has been unable to draw definitive conclusions on links between tattooing and adverse reproductive effects or cancer. This is a key source of uncertainty in the present risk assessment.

Some indication of the frequency with which tattoo-related complications occur can be drawn from existing EU studies. Of 972 members of the Italian general population with tattoos, 3.3% (i.e. 32/972) reported complications and/or mild complaints (Renzoni *et al.,* 2018). 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. Of those 32 people, health effects ranged from persistent pain (39.3%) to allergic reactions (17.5%) and granuloma (27.7%). Only 21.3% of the 3.3% (i.e. around seven people) who reported complications and mild complaints 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 of the general population in German-speaking countries (Klügl *et al.*, 2010), about 68% of respondents with tattoos reported immediate adverse reactions following the tattoo (2302/3411), and 6.6% of the study population (225/3411) reported systemic reactions after tattooing. It is possible these immediate reactions (both local and systemic) reflect physical “trauma” due to the tattooing process and the normal healing process that occurs in the days after a tattoo has been created rather than substance-related adverse effects. Klügl *et al*. (2010) noted that after four weeks, when normal healing reactions should have resolved, 8% of tattooed people in the study population (264/3411) still had health problems and 6% of the study population (206/3411) reported persistent skin problems such as itching and skin elevation.

ECHA (2019c) estimated that on average around 1.8% of tattooed people may experience an adverse reaction to substances in tattoo ink or PMU requiring medical attention. This estimate was obtained from a small number of studies, none of which were GB-based; however, there is no reason to think that the incidence of adverse reactions in GB will differ from that in the EU. Applying this 1.8% figure to the numbers with one or more tattoos in GB suggests approximately 13,600 people in GB might be affected by a tattoo-related adverse reaction each year (further details are available in section 4.4.4).

During the public consultation, the Agency received no information from the medical community in GB about adverse reactions to tattoos or PMU which would allow it to refine this estimate. The National Health Service (NHS) does not have any centrally-held records about numbers of tattoo-related ill health cases. A small amount of information was received via direct contacts with hospitals, dermatology societies and GB-based medics who had published papers on tattoo-related ill health. One medical professional reported seeing one to two complications per year and that in some cases, laser treatment or surgical excision was performed. One reaction to a red ink and one to a blue ink had been observed in recent years but the reactions and substances involved were not further described. Another dermatology specialist at a separate hospital reported seeing four to six reactions, mostly allergic in nature and mostly associated with red or pink colours, over a 20-year period. This specialist has never recommended the removal of a tattoo. The lack of readily available information suggests that tattoo-related ill health is an infrequent occurrence in GB. This lack of data creates a high level of uncertainty as to how often people need medical care for tattoo-related adverse effects, what these effects are, how many consultations relate to infections or trauma from the tattoo and PMU process vs substance-related effects and what treatment is required to alleviate the patients' symptoms.

It is not known whether poor quality inks make a greater contribution to the incidence of tattoo-related complaints and complications compared with inks from reputable brands. This could happen for example if poor quality ink:

- contains higher levels of impurities;
- 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 tattoo fades 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.

The removal of tattoos and PMU may also be associated with risks which may, if laser removal techniques are used, include those due to generation and release of degradation products of substances in the ink during the treatment. Risks to health from the removal process itself may compound existing ill health effects 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 of the background document. The Agency does not have information on numbers of tattoo removals that are performed each year or the reasons for these removals.

Guidance from the Interdepartmental Liaison Group on Risk Assessment (ILGRA), summarised in this Regulatory Policy Committee (RPC) note, advises that precautionary action may be warranted when:

- there is good reason to believe that harmful effects may occur to human, animal or plant health, or to the environment; and
- the level of scientific uncertainty about the consequences or likelihoods is such that risk cannot be assessed with sufficient confidence to inform decision-making.

It is difficult to quantify the risks associated with substances in tattoo and PMU ink because:

- Mixtures used for tattooing and PMU are complex in nature.
- The full spectrum of substances in any given ink product cannot currently be determined.
- Some substances are present as poorly soluble particles. Although micron scale particles are more suitable for use for tattooing and PMU, the particle size distribution of poorly soluble substances may include nanoscale particles. It is not known if the particulate nature of these substances is having a negative effect on the health of people with tattoos or PMU.
- It is impossible to predict how each component of the mixture may interact with other substances within the product or once inserted into the skin.
- Uncertainty surrounds the transformations substances may undergo when in the skin or following translocation to other parts of the body.
- The length of time that a substance resides in the skin and other parts of the body is not known.
- It is not clear which substances in inks are causing tattoo and PMU-related ill health.
- It is not clear what the socioeconomic consequences at the level of the individual and at the level of wider society are of tattoo and PMU-related ill health.
- The possibility of severe adverse health effects such as cancer cannot be excluded. The Agency has not identified evidence demonstrating a link between tattooing and cancer; however, the literature on long term adverse health effects is sparse.

This restriction is therefore proposed on the hypothesis that certain hazardous substances when used in tattoo ink or PMU have the potential to trigger adverse reactions.

Currently, unlike the situation for cosmetics that are applied onto the surface of the skin, there are no legislative controls in GB on which substances can be present in tattoo and PMU ink products. Since it is possible for anyone in GB who is over 18 years old to get a tattoo or PMU (it is illegal to tattoo someone under the age of 18 in GB under the Tattooing of Minors Act 1969), this creates a potential risk to health for any member of the adult population in GB that chooses to get a tattoo or PMU. This action aims to minimise the impacts of this potential risk.

The underlying socioeconomic rationale for risk management action is that as discussed earlier, there is reason to believe that human health harm could occur due to the presence of hazardous substances in mixtures used for tattooing and PMU which could create a burden to society as the private (industry) costs of using these hazardous substances in tattoo inks and PMU will not fully reflect the cost to society. The evidence of harm is uncertain, but a sound theoretical explanation and plausible link to hazardous substances in mixtures used for tattooing and PMU has been established. It is assumed that customers of tattoos and PMU are not well informed about the health impacts that may arise if hazardous substances are present in tattoo and PMU inks. Given the proportion of the GB population that is estimated to have tattoos and PMU, such adverse human health reactions not only represent a risk to the health of the individual receiving a tattoo or PMU but also an associated economic burden to society. In the face of such uncertainty regarding possible significant health effects government action to reduce the market failure associated with this risk and burden is thus justified on a precautionary basis.

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.

Since the restriction options proposed by the Agency target substances that are known to be hazardous, this restriction targets substances which have the potential to cause adverse effects if they are present in ink used for tattooing or PMU.

Currently there are no legislative controls in GB on the composition of tattoo and PMU ink. By limiting the amounts of hazardous substances in tattoo and PMU ink, this restriction will, immediately upon entry into application, reduce potential risks arising from hazardous substances that may be present in inks. The Agency therefore considers that this restriction meets the effectiveness criterion. However, it is not possible to quantify the risk reduction potential for this restriction.

The restriction options proposed by the Agency are practical. In deciding on the concentration limits proposed, the Agency has taken into account stakeholder information on the analytical challenges presented by the EU restriction regarding chemical analyses which may need to be carried out by ink formulators or enforcers. The Agency acknowledges that there will be similar challenges for the restriction options proposed for GB, but also that work has begun to find solutions, including the work described in Section 2.1 initiated by BfR. In the Agency's opinion, analytical challenges will not prevent this restriction meeting the practicality criterion.

The Agency has included a derogation including two widely used pigments for which ink formulators have not yet identified clearly safer alternatives that provide the same level of technical performance (further information is available in Section 4.6). This derogation will help ink formulators provide a good range of colours while avoiding the need to substitute pigments which have been used in tattoo ink for many years (decades) with few reports of adverse health effects with alternatives whose effectiveness is less well established and whose safety profile may not have been fully characterised. The Agency therefore considers both modified RO2 and modified RO2a to be implementable, enforceable and manageable.

There may be challenges in monitoring the result of the implementation of the proposed options because until now little attention has been paid in GB to the composition of tattoo inks or to collating information on cases of ill health relating to tattoos and PMU. There is, therefore, no baseline data against which to evaluate future trends. Options that the Agency has identified to potentially monitor the success of this restriction are:

- Track numbers of alerts to the UK's Product Safety Database made by enforcement officers where they deem it necessary to highlight particular tattoo and PMU inks that are on the market. In this case, it will be important to differentiate between alerts relating to concerns about the sterility of products and alerts relating to the presence of restricted substances in products.
- Track numbers of interventions against suppliers/users of inks that contravene the requirements of this restriction.

4.2 Rationale for the scope of the proposed options

4.2.1 Overview of the options that have been considered

The restriction options proposed by the Agency focus on substances which, due to their inherent hazardous properties and/or known potential to break down to hazardous derivatives in the body, have the potential to cause adverse health effects if used for tattooing or PMU. These options apply to mixtures supplied for tattooing procedures, 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 MDR.

The Agency initially identified three options for this restriction, referred to as RO1, RO2 and RO3. RO1 and RO2 were based on the options that ECHA proposed for the EU restriction but also took 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).

RO3 reproduced the implemented EU restriction with one key difference. Whereas the EU granted a time limited derogation for PB 15:3 and PG 7 until 4th January 2023, RO3 retained the derogation proposed by ECHA for these and 19 other pigments which 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. As indicated in Section 2, two substances have since been removed from the proposed derogation.

RO1, RO2 and RO3 applied to the following substances if they are present in tattoo or PMU ink:

- Substances that are classified in the GB MCL list as:
    - Carcinogens (H350, H351) or mutagens (H340, H341)
    - Toxic to reproduction (H360, H361)
    - Skin sensitisers (H317)
    - Skin corrosive or skin irritants (H314, H315) (skin irritants are excluded from modified RO2a)
    - Substances that cause serious eye damage/eye irritant substances (H318, H319) (eye irritants are excluded from modified RO2a)
- Substances that listed in Annex II or Annex IV of the CPR with conditions in column ‘g’ relating to the product types in which they can be used.
- Additional substances listed in resolution ResAP(2008)1 (CoE, 2008) of the Council of Europe that are not covered by one or more of the above categories.

RO1 proposed that tattoo and PMU inks shall not contain substances that are listed in Annex II of the CPR or have conditions of use in column ‘g’ of 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 also proposed that tattoo inks shall not contain substances classified in the GB MCL list as carcinogens or mutagens. For other substances in scope, concentration limits were proposed. It was also proposed that there should be dynamic links between the GB MCL list, these Annexes of the CPR, and the restriction. This means that when updates are made to the GB MCL list or to these Annexes of the CPR, these changes would take effect under this restriction without the need for further scientific assessment.

Instead of the ‘shall not contain’ approach, RO2 proposed concentration limits for each substance in scope of the restriction. RO2 retained the proposal for a dynamic link with the GB MCL list but proposed a static link with the Annexes of the CPR meaning 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.

RO3 reproduced the implemented EU restriction setting concentration limits for all substances in scope (in most cases lower than those proposed under RO2) and including dynamic links with the GB MCL list and Annexes II and IV of the CPR.

All options proposed a derogation for 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.

In light of information provided to the Agency by stakeholders during the public consultation and in meetings, and taking account of the advice provided to the Agency by RISEP the Agency has rejected RO1 and RO3. The Agency introduced modifications to RO2 (modified RO2) and identified a fourth option (modified RO2a) which retains most of the elements of modified RO2 but reduces the hazard classes which are in scope. Table 4 provides a side-by-side summary of the four options (taking account of the modifications implemented to arrive at modified RO2 and modified RO2a). Further details of the feedback received from stakeholders on the options that were initially proposed by the Agency is summarised in section 3.3.2 of the background document.

Table 4: Summary of the four restriction options proposed by the Agency (the Agency has rejected RO1 and RO3 for the reasons given)

	RO1	Modified RO2	Modified RO2a	RO3
Provisions relating to mandatory hazard classifications	Shall not contain C&M substances. Concentration limits for R, skin sensitisers, skin corrosives, skin irritants, eye damaging and eye irritants. Moving forwards there will be a dynamic link with CLP.	Concentration limits for CMR, skin sensitisers, skin corrosives, skin irritants, eye damaging and, eye irritants. Moving forwards there will be a dynamic link with CLP.	Concentration limits for CMR, skin sensitisers, skin corrosives and eye damaging substances. Moving forwards there will be a dynamic link with CLP.	Concentration limits for CMR, skin sensitisers, skin corrosives, skin irritants, eye damaging and, eye irritants. Moving forwards there will be a dynamic link with CLP.
Provisions relating to the status of substances under the CPR	Shall not contain substances listed in Annex II or IV (with conditions in column ‘g’) of CPR. Substances listed in Annex IV with conditions in columns ‘h’ or ‘i' are permitted providing those conditions are adhered to. Moving forwards there will be a dynamic link with the CPR	Concentration limits for substances listed in Annex II or in Annex IV (with conditions in column ‘g’) of the CPR. Substances listed in Annex IV with conditions in columns ‘h’ or ‘i' are permitted providing those conditions are adhered to. Moving forwards there will be no link between this restriction and the CPR.	Concentration limits for substances listed in Annex II or in Annex IV (with conditions in column ‘g’) of the CPR. Substances listed in Annex IV with conditions in columns ‘h’ or ‘i' are permitted providing those conditions are adhered to. Moving forwards there will be no link between this restriction and the CPR.	Concentration limits for substances listed in Annex II or in Annex IV (with conditions in column ‘g’) of the CPR. Substances listed in Annex IV with conditions in columns ‘h’ or ‘i' are permitted providing those conditions are adhered to. Moving forwards there will be a dynamic link with the CPR.
Additional	Concentration limits for	Concentration limits for	Concentration limits for	Concentration limits for

	RO1	Modified RO2	Modified RO2a	RO3
substance specific concentration limits	additional substances which are in scope including metallic impurities, PAHs, PAAs that are listed in Appendix 1, Supplementary Table A and azo dyes that are listed in Appendix 1, Supplementary Table A – includes substances specifically identified in ResAP(2008)1 (CoE, 2008)	additional substances which are in scope including metallic impurities, PAHs, PAAs that are listed in Appendix 1, Supplementary Table A and azo dyes that are listed in Appendix 1, Supplementary Table A – includes substances specifically identified in ResAP(2008)1 (CoE, 2008)	additional substances which are in scope including metallic impurities, PAHs, PAAs that are listed in Appendix 1, Supplementary Table A and azo dyes that are listed in Appendix 1, Supplementary Table A – includes substances specifically identified in ResAP(2008)1 (CoE, 2008)	additional substances which are in scope including metallic impurities, PAHs, PAAs that are listed in Appendix 1, Supplementary Table A and azo dyes that are listed in Appendix 1, Supplementary Table A – includes substances specifically identified in ResAP(2008)1 (CoE, 2008)
Labelling requirements	Includes labelling requirements	Includes labelling requirements	Includes labelling requirements	Includes labelling requirements
Number of pigments which are derogated from provisions relating to their status under the CPR	Derogation for 21 pigments including pigment blue 15:3 and pigment green 7	Derogation for 19 pigments including pigment blue 15:3 and pigment green 7	Derogation for 19 pigments including pigment blue 15:3 and pigment green 7	Derogation for 21 pigments including pigment blue 15:3 and pigment green 7

Note: C = Carcinogens, M= Mutagens, R= Substances toxic to reproduction.

4.2.2 Rationale for rejecting RO1 and RO3

RO1 was rejected because the “shall not contain” approach for carcinogens and mutagens, also CPR Annex II and Annex IV (rinse-off, mucous membranes, eye products) relies on the limits of detection for available analytical methods. This does not provide legal certainty for suppliers and could create difficulties for enforcers in bringing prosecutions if there is room for doubt about the standard that needs to be met. As methods are improved, and new methods are developed, an option which is reliant on the limits of detection will create a moving target.

The “shall not contain” approach is also inconsistent with the “as low as is reasonably practicable” (ALARP) or the “as low as is reasonably achievable” (ALARA) approaches used in other GB legislation to manage risks to health from carcinogens, mutagens and radiological risks. “Shall not contain” does not provide a workable solution in cases where it is technically impossible to remove all traces of an impurity, for example impurities in mined minerals. ALARP (and ALARA) are based on a balance of practicability, weighing the level of risk involved against the effort, time and cost needed to reduce the risk. This means that standards required are case-specific, unlike the legal certainty that is provided by clearly stated concentration limits.

Finally, the “shall not contain” approach places more stringent requirements on suppliers than the implemented EU restriction does. This would require formulators to create a line of inks specifically for the GB market which may be cost-prohibitive.

The Agency rejected RO3 because the very strict concentration limits cannot be justified based on the evidence for health risks linked to the chemical composition of current ink formulations. Ink formulators have reported difficulties in identifying substances that can act as preservatives to help maintain ink sterility and which conform with the requirements of this option. The use of inadequately sterilised inks for tattooing and PMU creates a risk for infection. It is not clear to the Agency whether alternatives to the currently used chemical preservatives will be as effective or whether there is a risk that alternatives (including non-chemical alternatives such as heat treatment or U.V. irradiation) could provide scope for *in situ* generation of hazardous substances. Given this uncertainty, the Agency considers that RO3 is not a good regulatory option for GB.

The modifications introduced by the Agency to RO2 (modified RO2 and modified RO2a) aim to provide workable and proportionate solutions to the problems identified with RO1 and RO3.

4.2.3 Rationale for modified RO2 and modified RO2a

Substances which are in scope because of the way they are classified in the GB MCL list

Modified RO2 and modified RO2a differ in respect of the mandatory classifications that bring substances into scope of the restriction. In all other respects modified RO2 and modified RO2a are the same. The rationale for the concentration limits proposed for various substances and substance categories is outlined in Section 4.3.

Modified RO2 proposes concentration limits for any substance that is classified for carcinogenicity, mutagenicity, reproductive toxicity, skin sensitisation, skin corrosivity, skin irritation, eye damage and eye irritation. These concentration limits are based on the concentration limits used in the GB CLP regulation to classify mixtures containing classified hazardous substances. The concentration limits established in the GB CLP regulations are intended to be protective of health. In the case of substances that are classified for skin sensitisation, the Agency proposes that the concentration limit for elicitation is used. The Agency has not identified evidence indicating a need to move away from the GB CLP limits for mixtures that are used for tattooing and PMU.

Modified RO2a proposes concentration limits for any substance that is classified for carcinogenicity, mutagenicity, reproductive toxicity, skin sensitisation, skin corrosivity and eye damage. The concentration limits for these hazards are the same as those that apply under modified RO2. Skin and eye irritants are not in scope. This modification has been introduced to allow ink formulators to continue to use substances that have preservative properties at the levels required for this effect, and therefore help limit microbial contamination, but which are captured by modified RO2 because they are classified for skin and/or eye irritation and no other endpoints in scope of this restriction. This modification aims to address clear risks to health that are created if mixtures used for tattooing and PMU are inadequately sterilised. This option is subject to uncertainty about the extent to which substances with these hazard classifications could be contributing to the reported health effects in people with tattoos and PMU.

Experts from RISEP indicated a preference for modified RO2a and this is the Agency’s preferred option. This option provides greater flexibility for ink formulators to use substances they know will provide preservative properties in inks at the levels required for this effect. It is important to minimise the risks for infection if inks are inadequately sterilised. There is no evidence that substances that are classified for skin and/or eye irritation and no other hazards which are in scope of this restriction are causing persistent and/or serious ill health when present in inks used for tattooing and PMU. It will be difficult to separate mild irritant reactions, if these occur, from the trauma of the tattooing process.

Substances which are in scope because of their status in the CPR

Both options specify concentration limits for substances that are listed in Annex II or in Annex IV of the CPR with conditions in column ‘g’ relating to the product types in which they can be used. These concentration limits are listed in section 4.3, table 5. The substances to which these concentration limits apply are listed in Appendix 1, Supplementary tables C and D. Other substances listed in Annex IV of the CPR with conditions relating to the maximum allowed concentration (column ‘h') or purity requirements (column ‘i’) are permitted providing the conditions in Annex IV of the CPR are adhered to in respect of their use in tattoo and PMU inks. These substances and the conditions of use that apply are listed in Appendix 1, Supplementary table E.

The Agency received mixed views from consultees responding to a question in the second public consultation on links with the CPR. Those in favour of a dynamic link thought this would be more protective of health. Those against a dynamic link thought this could create unnecessary costs. Previously, stakeholders raised concerns about a lack of transparency on the reasons why some substances are listed in particular Annexes of the CPR.

The Agency discussed with RISEP whether it is useful to include links between this restriction and Annex II and IV of the CPR and if so, what type of link (dynamic or static or none) would be most appropriate.

The introduction of a dynamic link would mean that when changes are made to Annexes II and IV of the CPR, no scientific assessment is needed to decide how the affected substances should be regulated for use in tattoo and PMU inks. Instead, a procedure similar to that used to bring newly classified/reclassified substances into scope of UK REACH restrictions 28 to 30 will be required to bring substances into scope of this restriction. This has the advantage that there is a lower burden for authorities compared with a procedure in which scientific assessments are required. However, some resource will be required. A dynamic link has the disadvantage that it will not take into account factors such as the availability of alternatives or other socioeconomic or hazard and risk factors. There is the possibility that a substance which is brought into scope of this restriction because of actions under the CPR could be replaced with a hazardous alternative. This could happen, for example, if an alternative substance with an incomplete hazard data set is chosen. It is not therefore possible to conclude that every substitution which is driven by the implementation of a dynamic link with the CPR will improve the safety of tattoo and PMU inks.

It is also important to reflect that the exposure patterns and routes of exposure for cosmetics are different to the exposure pattern and route of exposure for substances in tattoo and PMU inks; conclusions on risks for use in cosmetics may not, therefore, be applicable to use for tattooing and PMU. This approach hinders the ability of the

tattoo and PMU sector to have a say in the way their industry is regulated because they have no opportunity to contribute to discussions on how substances are regulated under the CPR, even though the CPR is affecting the way substances can be used in tattoo and PMU inks. It will therefore be necessary to implement a procedure that allows policy makers to take account of stakeholder objections in their decision making.

If a static link is introduced, this will mean that when changes are made to Annexes II and IV of the CPR, a scientific assessment must be carried out to decide how the affected substance should be regulated for use in tattoo and PMU inks. Static links would place a legal obligation on the Agency to conduct risk assessments for use in tattoo inks and this work could conflict with other, potentially more urgent priorities. Also, given the absence of an agreed risk assessment framework for tattoo and PMU inks, and the high level of uncertainty that exists in the risk assessments underpinning this restriction, there does not seem to be any justification to adopt a static link.

If no link is introduced, then the CPR will not provide a feedstock of new substances into this restriction. Changes in the way substances are classified under the GB CLP regulation are the main driver of the way substances are regulated under the CPR therefore, it is likely that the links between CLP and this restriction will ensure substances which have hazards of concern can be brought into scope based on the hazard classification for the substance in the GB MCL list. Hazard classifications are a key driver for measures under several pieces of legislation, therefore the Agency places a high priority on updating the GB MCL list where necessary. Removing links between this restriction and the CPR has the potential to improve transparency about the reasons for bringing new substances into scope of this restriction. However, there remains a possibility that on occasion, a substance which should be restricted for use in tattoo and PMU inks slips through the net.

Risk assessment-based and socioeconomic-based arguments can be made for and against a dynamic link or a static link or no link with the CPR. For the reasons outlined above, the Agency rejected a static link. The Agency did not receive information during the public consultations to push the balance of arguments in favour of either a dynamic link or no link. Each option has benefits and disadvantages in terms of the potential for that option to reduce possible risks (if these are created by substances which are being added to Annexes II or IV of the CPR), and the socioeconomic implications of that option. On balance, experts from RISEP supported a proposal for there to be no future link between this restriction and Annexes II or IV of the CPR. This is the Agency’s preferred option.

Other specific concentration limits

Other specific concentration limits have been proposed where the Agency has information to show that the generic limits that stem from the GB CLP regulation are

not sufficiently protective of health. The Agency is aware of a need to ensure that substances that transform in the body to generate hazardous substances at concentrations that could potentially result in adverse health effects are subject to controls on their use in tattoo ink, even if this transformation does not trigger hazard classification of the parent substance. Limits for such substances where these have been identified are listed in Appendix 1, supplementary table A. In general, for substances which are intentionally used in tattoo and PMU inks, where data is available to suggest the concentration limit that is specified in this restriction for the substance is not sufficiently protective of health, that data should be used to derive a substance specific concentration limit.

In the light of information provided by stakeholders around technical and analytical feasibility for some of the concentration limits proposed in version one of the background document (version one was the Annex 15 dossier that was published to support the public consultation which opened in May 2022), for modified RO2 and modified RO2a the Agency has increased the concentration limits for cadmium, chromium, mercury and arsenic which may be present as impurities. It has also increased the concentration limits for primary aromatic amines (PAAs) in scope to match those specified in the EU restriction. The Agency has also lowered the concentration limit for benzo[a]pyrene (BaP) to match the limit adopted for this substance in the EU restriction. Concentration limits for these substances are listed in Appendix 1, Supplementary Table A.

The Agency is aware that problems have been identified regarding the ability of current analytical methods to measure every substance that is in scope of the EU restriction and will be in scope of the restriction options proposed for GB. The extent of this problem in relation to the EU restriction is demonstrated by this analysis of available analytical methods (BfR, 2021). The assessment concluded that existing analytical methodology could be applied to the analysis of PAAs, PAHs (in black carbonaceous pigment raw material), residual solvents from the formulation process, some nitrosamines and some metal elements (mercury, nickel, organometallic tin, antimony, arsenic, cadmium, cobalt, lead, selenium and chromium VI) with a detection level appropriate for the restriction in force in the EU. However, in some cases it was noted that the existing methods would benefit from future standardisation. The limits proposed for these substances are the same or higher for GB therefore this conclusion also applies to the restriction options proposed for GB.

This analysis also identified substances for which no current method is considered suitable and where future development is necessary. These include analyses for: specific pigments and dyes which may be subject to restriction, PAHs (in formulated inks containing black carbonaceous pigments), formaldehyde, phthalates and soluble barium, copper and zinc. Since there are higher concentration limits in GB for e.g. formaldehyde, there may be some cases where the BfR conclusions are not directly applicable to the situation in GB. However, this assessment does indicate

that chemical analyses for the GB restriction will not be possible for all substances that are subject to this restriction.

Transitional period

The Agency has considered how long the transitional period for this restriction should be. The Agency is aware that the short transitional period of one year which was adopted for the EU restriction set a very challenging timescale for formulators. This is because contrary to the expectations described in the background document for the EU restriction that many inks supplied to the EU market would comply, in reality ink formulators found that they needed to reformulate most if not all of the inks in their product ranges. This meant that new products were brought to market close to the end of the transitional period, and there was not enough time for formulators to test the performance of their reformulated inks in volunteers before the new formulations were brought to market. Further information on the impact of the EU restriction is described by Serup (2023).

The Agency has been informed about messages circulating in tattoo artist online chat forums reporting an increase in allergic reactions to red colours compared with levels seen prior to the implementation of the EU restriction. Ink formulators have also raised concerns that the provisions of the EU restriction are creating challenges in relation to sterilisation of inks.

Given the uncertainty about the way the EU restriction is impacting the health of those getting tattoos or PMU with reformulated inks, and the uncertainty around the burden of ill health created by the tattoo inks and PMU currently supplied to GB, an argument could be made that it would be precautionary to adopt a longer transitional period or even pause the GB action pending a review of the success of the EU restriction.

<u>Short transitional period of one year for formulators and suppliers</u>

One argument in favour of a short transitional period is that since inks have been reformulated for the EU market and since it is likely that many of these will comply with the requirements of this GB restriction, it will be possible for this sector to adapt to the requirements of the GB restriction within one year.

When asked in the public consultations held by the Agency and in meetings, the general view from formulators was that a longer period would be necessary because they have so far not managed to replicate the same range of colours in EU compliant inks compared with the colours that they can offer in other product ranges. A longer period will also provide time to test the performance of new inks (if these are produced for GB) in volunteers. On the basis of this information and given the uncertainties about the risks to health posed by the current ink formulations supplied to GB and about possible impacts to health from new EU inks the Agency is rejecting a short transitional period.

Longer transitional period for formulators and suppliers

The Agency's preferred option is for a longer transitional period of around two years for formulators and suppliers. This will provide additional time for ink formulators to identify which of their products already complies with the requirements of the proposed GB restriction and to test the performance of reformulated inks. However, it will still put pressure on formulators to take action to check that their inks do not contain potentially harmful substances, and to reformulate or remove any inks in which such substances are found.

Pause/ do-nothing

A suggestion has been made that:

- given the uncertainties about whether or not current tattoo and PMU inks supplied to GB are creating an unacceptable risk to health, and
- given that there is insufficient time to understand whether or not the EU restriction has resulted in fewer cases of tattoo and PMU related ill health (this includes substance related ill health and ill health due to infections if the provisions of the EU restriction are making it difficult to adequately sterilise inks before these are supplied to market),

it could be precautionary to pause the development of the GB restriction pending an evaluation of the success of the EU restriction. However, given the uncertainty of when or if any evaluation would be carried out, there is a chance that this would result in this restriction not restarting which would mean that no action was taken, in effect a do-nothing option.

The Agency does not consider this to be a good approach. Currently there is no legislation in GB governing the composition of tattoo and PMU inks. If the restriction does not restart (do-nothing), this situation will remain. The Agency's preferred option aims to strike a balance between the need to avoid the use of potentially harmful substances, while permitting the use of substances which have not been identified as a cause of serious ill health when used for tattooing or PMU, this includes substances which may help to maintain ink sterility. It is not clear what evaluation of the EU restriction will be undertaken and the timescales for any evaluation to be reported upon. It is therefore not clear if the uncertainties which currently exist could be reduced within the short or medium term.

The Agency discussed these options with experts from RISEP who supported a transitional period of two to three years for formulators and suppliers, but had no strong preference for either two or three years.

The Agency has taken note of the concerns about costs to tattoo artists and PMU practitioners if they have to discard stocks of unused inks. For this reason, the

Agency is proposing an extra transitional period of one year to allow tattoo artists and PMU professionals time to use up non-compliant inks purchased before the end of the transitional period for formulators and suppliers. This will also help tattoo artists plan the timings for larger pieces which may take several sessions to complete. Experts from RISEP supported this additional year. The rationale for the transitional periods proposed by the Agency is also discussed in section 3.3.1g of the background document.

A date of 2027 for full adoption of this restriction is proposed, on the basis of an indicative timescale of introduction of an amendment to Annex 17 of UK REACH in 2024. This means that from 2026, formulators/suppliers will be required to supply compliant inks and from 2027, tattoo artists and PMU practitioners will be required to use compliant inks.

4.2.4 Scope of derogation for specific colourants

Based on its own assessment of the hazard profile of the 19 pigments listed in Appendix 1, supplementary table B, the Agency proposes that these are derogated from provisions relating to their status under the CPR. The Agency is intending to take forward a proposal for mandatory classification of Pigment Red 83 and Solvent Violet 13 for skin sensitisation under GB CLP and has therefore removed these from the derogation.

From January 2023, all of these pigments are restricted in inks supplied to the EU. Derogating these 19 pigments will extend the range of colours that will be able to be supplied in GB compared with the EU. The derogation includes PB 15:3 and PG 7.

The Agency discussed the proposed derogation of 19 pigments with the Challenge Panel. No panel member disagreed with this proposal.

Since there is uncertainty about which substances are causing ill health if they are present in tattoo inks or PMU, if evidence emerges for any substance (including any of the derogated pigments) that shows that it is causing ill health or has the potential to cause ill health when it is used for tattooing or PMU, either because of its inherent properties or because it can break down to form hazardous substances in the body, assessments should be performed to decide on the need to add that substance to the list in Supplementary Table A. This work might be undertaken in the context of hazard classification work under the GB CLP Regulation, but may need to consider additional aspects of the hazard profile such as photodegradation or phototoxicity which might not routinely be considered within a GB CLP technical report. For a REACH restriction, these assessments might alternatively be triggered by a request from the Appropriate Authorities to the Agency.

4.2.5 Description of proposed labelling requirements

Each restriction option proposes that tattoo and PMU inks should be labelled with the following information:

- The statement “Mixture for use in tattoos or permanent make-up”;
- A 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 are 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;
- Safety instructions for use insofar as they are not already required to be stated on the label by the GB CLP Regulation. As a minimum, this should include the expiry date for an ink product.

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

Where necessary because of the size of the package, the information labelling (with the exception of the statement “mixture for use in tattoos or permanent make-up”) 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 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.

A concern was raised by an ink formulator that a requirement to provide a comprehensive list of ingredients could result in formulators having to disclose proprietary information about the formulation. The Agency takes note of this concern but is also aware that a comprehensive list of ingredients could be of use to tattoo and PMU clients if they know they have an allergy to certain substances. A member of the public responding to the second public consultation as a tattoo client noted that currently ingredients are often identified in an ambiguous manner and thought that ingredients should be listed with their CAS numbers for better clarity. The Agency considers that a comprehensive list of ingredients could also be of use to medical professionals who may be trying to make links between a patient’s symptoms and substances in a tattoo or PMU ink. The Agency is therefore retaining the requirements to provide substance names.

The options initially identified by the Agency included a proposal to provide warnings on ink bottles about the possible presence of nickel and hexavalent chromium (CrVI) in the ink at levels below the concentration limit specified for these substances. While nickel allergies are known to occur in connection with tattoos, the source of the nickel causing the skin reaction is open to question. Traces of nickel can arise from the equipment used to formulate inks and could potentially be present in inks below the limit of detection for currently available analytical methods. It is therefore not possible for an ink formulator to guarantee that there will be no nickel or CrVI in their product. It has also been suggested that particles containing nickel might be generated from the tattoo needle during the tattooing process owing to the abrasive action of e.g. pigment particles in the ink. Given these uncertainties, it is not clear how helpful such warnings will be. However, if someone knows that they react to nickel or CrVI, they may want to know that they are at increased risk from an allergic reaction if they get a tattoo.

The Agency notes that the concentration limits that are proposed in Section 4.3, Table 6 for both nickel (0.001%) and CrVI (0.00005%) are already low enough to confer little risk for induction and/or elicitation. The Agency therefore proposes to remove this labelling requirement. Experts from RISEP supported this approach.

In the case of this change to the proposed labelling requirements, the Agency does not consider that removing the need to provide warnings of the possible presence of nickel or CrVI creates a requirement for GB specific labels. A label that included such information would still be compliant, providing that it also included all of the other information that the restriction requires. For this reason, removing the requirement to provide warnings about the possible presence of nickel or CrVI does not introduce potential relabelling costs.

4.2.6 Further information about the proposed restriction

The proposed restriction options take account of the following:

- It is preferable to avoid using substances in tattoo and PMU inks if those substances are restricted for use in cosmetic products because the foreseen conditions of use in cosmetics create concerns for public safety. However, there are differences between the exposure and risk profile that arises from use in cosmetics and the exposure and risk profile arising from use in tattoo and PMU inks. These differences mean that there may be cases where substances which are restricted for use in cosmetics create low risks if they are used in tattoo and PMU inks.

- Substances classified as carcinogens (C), mutagens (M) and/or toxic to reproduction (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 UK REACH), should not be used in tattoo inks that will be inserted into the skin.

- Substances classified as skin sensitisers should not be inserted into the skin.
- It is preferable to avoid using substances classified as skin and/or eye irritants in products that will be used for tattooing or PMU. However, it is important to ensure tattoo and PMU inks are sterile at the point of use. There is no evidence that substances classified as skin and/or eye irritants are contributing to persistent and/or serious tattoo and PMU-related ill health. There is evidence that infections are making a large contribution to tattoo and PMU-related ill health. It is therefore important to ensure ink formulators have the flexibility to use substances which they know can provide a preservative function in inks. Options may therefore be considered which permit the use of substances which are classified as skin and/or eye irritants, if this use reduces the potential for inadequately sterilised inks to cause infections.
- 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 specific pigments, and the outcome of Agency hazard assessments on these 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.

The restriction options proposed by the Agency (including modified RO2 and modified RO2a) cannot tackle all causes of ill health relating to tattoos or PMU. The most common cause is infection which could be caused by inadequate sterilisation of ink, poor hygiene in the studio or poor aftercare by the client. This restriction also cannot tackle cases where ill health arises because the amount of ink placed by the tattoo artist or PMU practitioner in the skin triggers an exaggerated foreign body response. Clinically, this exaggerated response may present as the formation of granulomas at the site of the tattoo or PMU. On occasion localised granulomas can develop into a more widespread systemic reaction known as sarcoidosis. Granuloma formation is most commonly seen in association with black tattoos but has also been reported with red tattoos.

The restriction options proposed by the Agency have the potential to reduce cases of skin allergies which are most often reported with red tattoos. Analyses of biopsies can identify pigments that are present in tissues showing allergic reactions. So far it

has been very difficult to pinpoint the sensitising agent. This may be a breakdown product rather than the pigment itself. Currently there is insufficient experience with the EU restriction to understand if cases of skin allergies are reducing. The Agency has been made aware of messages circulating in tattoo artist online chat forums reporting an increase in allergic reactions to red colours compared with levels seen prior to the implementation of this restriction. No clinical evidence is available to confirm this.

The restriction options proposed for GB have the potential to reduce other ill health events if these are caused by substances in tattoo and PMU ink. However, there is no clear evidence to show what these events are or how frequently such events arose prior to the implementation of the EU restriction. It is therefore difficult to judge what impact the EU restriction is having and what impact the options proposed for GB might have.

4.3 Risk Assessment

The restriction options proposed by the Agency (modified RO2 and modified RO2a) target all substances that are classified in the GB MCL list for carcinogenicity, mutagenicity, reproductive toxicity, skin sensitisation, skin corrosivity (category 1, 1A, 1B and 1C) and/or eye damage category 1. Modified RO2 also targets substances that are classified in the GB MCL list as skin irritant category 2 and/or eye irritant category 2. Skin and eye irritants are excluded from the scope of modified RO2a. Both options also target substances that are listed in Annex II or in Annex IV with conditions relating to the product types in which they can be used and additional substances which were listed in resolution ResAP(2008)1 (CoE, 2008) of the Council of Europe that are not covered by one or more of the above categories. Since these substances and substance categories are similar to those covered by the EU restriction, the Agency has made extensive use of the hazard and risk assessment information published by ECHA to inform its restriction proposals and has not duplicated work unnecessarily.

4.3.1 Derivation of concentration limits based on qualitative assessments

Substances that are classified in the GB MCL list as carcinogens, mutagens, toxic to reproduction, skin sensitisers, skin corrosives, skin irritants, eye damaging and eye irritants.

Concentration limits for substances which are classified for one or more of these endpoints in the GB MCL list are based on the generic and specific concentration limits specified in the CLP regulation. Under modified RO2a, only carcinogens, mutagens, substances that are toxic to reproduction, skin sensitisers, skin corrosives and eye damaging substances are in scope. The concentration limits proposed by the Agency are outlined in Table 5.

This approach has been taken because the available toxicology data for these endpoints do not, in many cases, allow thresholds of effect to be identified. It aims to minimise the potential for adverse effects to arise from substances that are present in tattoo or PMU ink while specifying concentration limits that are manageable for duty holders and enforcers. Where specific concentration limits have been derived for a substance under the CLP Regulation or within this restriction, these take precedence over a generic concentration limit established in the CLP Regulation.

The concentration limits proposed for category 1A/B carcinogens, mutagens and reproductive toxicants are consistent with the limits that apply to these substances in UK REACH Annex 17 entries 28, 29 and 30. These restrictions prohibit the supply of specified substances (listed in the associated appendices) with these classifications to the general public as substances or in mixtures above their respective CLP concentration limits.

For substances that are classified for skin sensitisation, the Agency proposes that the concentration limit for elicitation, which triggers labelling requirements under the GB CLP regulation, is also used as the concentration limit for these substances in tattoo and PMU ink. It follows that for sensitising substances with specific concentration limits lower than 0.1 % for category 1 or 1B, or 0.01% for category 1A, the concentration limit for this restriction should be set at one tenth of the specific concentration limit. This approach was proposed in the Agency's Annex 15 dossier. As an example, 2-methylisothiazol-3(2H)-one (MIT), which has been used as a preservative in consumer products, is classified in the GB MCL list (Index no: 613-326-00-9) as Skin Sens 1A with a specific concentration limit of 0.0015%. Under this approach, the concentration limit for this substance in tattoo or PMU ink would be 0.00015%.

Substances that are listed in Annex II of the CPR or have conditions in column 'g' of Annex IV of the CPR relating to the product types in which they can be used.

The Agency proposes a concentration limit of 0.1% w/w for these substances in tattoo inks and PMU unless a more stringent concentration limit applies based on the hazard classification of the substance. The 0.1% w/w concentration limit is proposed as a practical limit aiming to discourage intentional use. Substances in Annex II of the CPR are listed in Appendix 1 Supplementary Table C and substances in Annex IV of the CPR with conditions in column 'g' are listed in Appendix 1, Supplementary Table D.

Substances listed in Annex IV of the CPR with conditions in column 'h' relating to the maximum concentration in which they can be present in cosmetics or column 'i' are permitted for use in tattoo inks providing they are used in accordance with the requirements in Annex IV. These substances and the conditions that apply are listed in Appendix 1, Supplementary Table E.

Polycyclic aromatic hydrocarbons (PAHs).

For PAHs classified in the GB MCL list as carcinogens and mutagens, a concentration limit of 0.00005% is proposed to match the concentration limit that applies to the eight PAHs listed in UK REACH Annex 17, entry 50 (6), for toys and childcare articles. If changes to the limit in entry 50 are made, these changes should also be implemented in this restriction. As an exception, it is proposed that a lower limit of 0.0000005% by weight (5 ppb) should apply to BaP. BaP is a polycyclic aromatic hydrocarbon. The limit proposed for this restriction is the limit adopted for BaP in ResAP(2008)1 (CoE, 2008); it also applies to BaP as an impurity in carbon black when used as a colourant in cosmetics.

Table 5. Concentration limits derived from qualitative assessments

Endpoint	**Concentration limit (% w/w)**
Carcinogenicity category 1A or 1B	0.1%
Carcinogenicity category 2	1%
Mutagenicity category 1A or 1B	0.1%
Mutagenicity category 2	1%
Reproductive toxicity category 1A or 1B (Note 1)	0.3%
Reproductive toxicity category 2	3%
Skin sensitisation category 1A	0.01%
Skin sensitisation category 1 or 1B	0.1%
Skin corrosivity category 1A, 1B, 1C or 1	1%
Skin irritation category 2	10% (not in scope of modified RO2a)
Eye damage category 1	1%
Eye irritation category 2	10% (not in scope of modified RO2a)

Endpoint	Concentration limit (% w/w)
Substances listed in Annex II of the CPR	0.1% (unless a lower limit applies based on hazard classification)
Substances listed in Annex IV of the CPR with conditions in column ‘g’ relating to the product types in which they can be used	0.1% (unless a lower limit applies based on hazard classification)
Substances listed in Annex IV of the CPR with conditions in column ‘h’ and ‘i'	Permitted in tattoo and PMU inks providing that the conditions in columns ‘h’ and ‘i' are adhered to.
Polycyclic aromatic hydrocarbons classified in the GB MCL list for carcinogenicity or mutagenicity	0.00005%
Benzo[a]pyrene (BaP)	0.0000005%
Bis(2-ethylhexyl) phthalate (DEHP)	0.07%
Dibutyl phthalate (DBP)	0.009%

4.3.2 Derivation of concentration limits based on (semi-)quantitative assessments

Where possible, ECHA used a quantitative (or in the case of non-threshold substances, semi-quantitative) risk assessment approach to support proposed concentration limits. The Agency has used these assessments to inform the concentration limits it is proposing for methanol, DEHP, DBP, the primary aromatic amines (PAAs) and azo colourants which are listed in Supplementary Table A and the impurities that are listed in table 3 of ResAP(2008)1 (CoE, 2008).

In ECHA’s approach, Derived No Effect Levels (DNELs) and Derived Minimal Effect levels (DMELs) were calculated and used to estimate the maximum dose of that substance that could be administered to a 60 kg adult. A concentration limit was then derived by dividing this maximum dose by the weight of ink that is assumed to be delivered during a single tattoo or PMU session using this calculation:

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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.

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The Agency makes the following observations about the hazard and risk assessments that underpin concentration limits derived in this way:

- Derived No Effect Levels are derived for substances where there is a clear threshold of effect. The calculation method starts with a no or low effect level and applies assessment factors to take account of interspecies and interindividual variability to arrive at a dose level that should not cause adverse effects. DNELs can be compared with an estimated exposure to a substance 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.

- Derived Minimal Effect Levels are calculated for substances with so called “non-threshold” effects (e.g. some carcinogens). Although DMELs were used to calculate concentration limits for arsenic, the PAAs listed in Appendix 1, Supplementary Table A and lead, the concentration limits which are proposed for arsenic and these PAAs under modified RO2 and modified RO2a are based on levels which are technically achievable.

- The exposure assessment relies on a single so-called “worst-case” scenario 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 includes people getting full body tattoos as well as those getting a single or a few tattoos or having PMU applied. For people who get occasional PMU treatments, one or two small tattoos and even for people that are extensively tattooed, this assessment will overestimate (in many cases substantially overestimate) their exposure to substances in tattoo and PMU ink.

- There is uncertainty about the amount of tattoo ink inserted into the skin during the tattooing process or a PMU procedure. During this process, a drop of ink is placed onto the area where the colour is required and the needles in the tattoo machine push the ink into the skin. The artist will frequently wipe excess ink from the site to ensure accurate placement of colour within the design and repeat this process as required until the design is complete. This means that only a fraction of the ink taken from the bottle ends up in the skin. This will hold true for both tattooing and PMU. The amount of ink inserted during a tattooing session (per cm^2) will depend on factors including the level of experience of the tattoo artist or PMU practitioner and the intensity of colour required for the design. The estimate used for these exposure calculations that 14.36 mg ink/cm^2 will be inserted into the skin during this single tattooing session is derived from a small number of studies which provide highly variable results. This value was chosen because it represents the 75^{th} percentile of values obtained in one experimental tattooing study which provided a good description of the experimental approach, and which was thought to represent worst case conditions. This value has the potential to overestimate exposure to substances in ink.

- There is also uncertainty about the amount of any given substance that will be lost from the tattoo or PMU after the procedure has been completed. During the healing process, some ink will be lost through exudation/bleeding from the wound. There will be migration away from the site of the tattoo or PMU owing to dispersion within the skin, translocation to other body locations and/or phagocytosis by local and/or migratory macrophages and other phagocytes. Metabolism in the skin will also be relevant for some substances. No studies providing quantitative information about how much of any given substance is removed via these processes or the timescales involved are available. In meetings with the Agency, one formulator suggested that in the long term, for colour tattoos around 6 – 10% of the colourant may remain at the site of the tattoo and for black and grey tattoos only 1 – 2% of the colourant may remain at the site of the tattoo. This is consistent with the experimental data discussed in section 1.2.5 of the background document which suggest between 1.0 – 13.0% of the colourant remains at the tattoo site.

- When substances including colourants translocate away from the tattoo or PMU, there is uncertainty about how much will be eliminated from the body and how much is retained elsewhere. Pigments are substances of low solubility, which means they are likely to be in a particulate form in the body and could be biopersistent as they may not be broken down by natural metabolic or immune processes. Pigments are frequently visible in the lymph nodes of deceased people with tattoos. The Kupffer cells of the liver have also been reported to retain tattoo pigments. It therefore cannot be assumed that all substances in tattoo ink will be eliminated between tattooing sessions (this

assumption was made by ECHA). However, there are no data that allows retention to be quantified. It is also worth noting that tattoo inks are not the only source of exposure to some of the substances covered by this restriction, including some colourants. The contribution to total body burden that is made by tattoos or PMU may represent a minor fraction of the total body burden.

- Mixture effects have generally not been taken into account in the risk assessments performed to derive concentration limits. Given the complex composition of tattoo and PMU ink products, there will be very little data to inform mixture risk assessments. The possible consequences of interactions between components in inks is therefore another source of uncertainty.

For these reasons, the Agency considers that although the concentration limits derived by ECHA are likely to be precautionary, there is a high level of uncertainty about the level of risk associated with any of the concentration limits that have been presented in the background document.

Methanol

This substance is potentially of concern if it is present in tattoo and PMU inks because it is classified in the GB MCL list for STOT SE 1 based on its effects on the optic nerve (*nervus opticus*) and central nervous system, which may be seen after a single exposure. The proposed concentration limit of 10.9% (rounded to 11%) has been derived from the occupational exposure limit, to which an assessment factor of 5 has been applied.

Certain phthalates

The risk assessments performed by ECHA identified that if the concentration limits for substances toxic to reproduction that derive from hazard classification rules are used, this results in limits for bis(2-ethylhexyl) phthalate (DEHP) and dibutyl phthalate (DBP) that appear to be insufficiently protective. Both substances have been found in tattoo inks. To ensure that the limits for these substances are protective of health, alternative concentration limits of 0.07% (DEHP) and 0.009% (DBP) were proposed within RO2 as described in the Agency's background document. Details of the calculations underpinning these concentration limits are available in ECHA (2019c) which is document 1 in the Annex of the Agency's background document. The Agency proposes retaining these alternative concentration limits for DEHP and DBP.

Primary aromatic amines (PAAs) and azo colourants that can degrade to form PAAs

Primary aromatic amines are of concern owing to their mutagenic, carcinogenic and skin sensitising properties. These substances are used to manufacture certain azo colourants and may be present in the colourant as an impurity. Supplementary Table A includes 29 PAAs which are classified in the GB MCL list for mutagenicity,

carcinogenicity and/or skin sensitisation. The Agency is proposing a limit of 0.0005% (5 ppm) for each of these PAAs. The limit applies to the dissolved fraction.

The Agency proposes adding a further two PAAs to the list in Supplementary Table A. 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 ResAP(2008)1 (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. The reasons why these substances were included in Table 1 of ResAP(2008)1 (CoE, 2008) are not traceable.

As of February 2023, neither substance had a GB mandatory classification for mutagenicity, carcinogenicity or skin sensitisation. However, Lhasa Limited's expert knowledge-based prediction tool Derek Nexus indicates that both substances contain structural alerts that could plausibly result in mutagenic and carcinogenic properties. Additionally, skin sensitisation was plausible for 2,4-xylidene. The OECD QSAR Toolbox identified structural alerts for genotoxic carcinogenicity for both substances. The Agency therefore considers that there is justification to include these substances in this restriction.

Some azo colourants are classified in the GB MCL list for carcinogenicity and skin sensitisation. There is also the potential for some azo colourants to break down to form PAAs on exposure to sunlight or laser also via enzymatic or bacterial degradation. All azo colourants classified in the GB MCL list for relevant health hazards, listed in Annex II or IV of the CPR or table 2 of ResAP(2008)1 (CoE, 2008) are in scope of this restriction. Other azo colourants that are in scope are those that:

- could decompose via amide hydrolysis into PAAs with carcinogenic, mutagenic or skin sensitising properties; or
- are based on 3,3'-dichlorobenzidine, and could form 3,3'-dichlorobenzidine during photo-decomposition; or
- have a scientific evaluation by Scientific Committee on Consumer Products (SCCP, now Scientific Committee on Consumer Safety, SCCS), stating that they may release one or more carcinogenic aromatic amines.

For the azo colourants listed in Supplementary Table A, a practical concentration limit of 0.1% is proposed to discourage intentional use unless a lower concentration limit applies based on the hazard classification assigned to that substance in the GB MCL list.

Impurities listed in Table 3 of ResAP(2008)1 (CoE, 2008)

In the light of information provided by stakeholders around technical and analytical feasibility for the concentration limits proposed in version one of the background

document for cadmium, chromium, mercury and arsenic, the Agency has increased these to match the concentration limits specified for these substances in the EU restriction. For this reason, the limit of 0.00002% which was proposed for cadmium, chromium and mercury and the limit of 0.00000082% which was proposed for arsenic are all raised to 0.00005%. For the remaining impurities, the Agency proposes retaining the limits that were proposed RO2 as presented in version one of the background document. Table 6 lists the limits that are proposed by the Agency for these impurities.

Table 6. Proposed concentration limits for impurities listed in table 3 of ResAP(2008)1 (CoE, 2008)

Impurity	**Concentration limit (% w/w)**
Cadmium	0.00005
Hexavalent chromium compounds	0.00005
Mercury	0.00005
Copper (Note 1)	0.05
Zinc (Note 1)	0.23
Barium (Note 1)	0.84
Nickel	0.001
Selenium	0.0002
Antimony	0.0002
Lead	0.00007
Cobalt	0.0025
Arsenic	0.00005

Note 1: The concentration limit applies to soluble forms.

4.4 Socioeconomic/Impact Assessment

This section presents a summary of the Socio-Economic Analysis (SEA) undertaken to estimate and compare the costs and benefits associated with the proposed restriction. The full SEA is presented in Section 3 of the background document.

The SEA presents the impacts of the proposed restriction in GB. It considers the number of people with tattoos and volume of ink on the market under the baseline as

well as the costs, health impacts and proportionality of the restriction. The evidence presented within the SEA does not necessarily provide justification for action in terms of the benefits and costs of reducing risks of actual harm. It should therefore be seen to be illustrative as the rationale for this restriction is the potential impact on human health which is covered as part of the risk assessment.

4.4.1 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 boundary for this restriction is GB.

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 the volume of tattoo and PMU ink on the GB market. These areas are assessed as a reference point to understand the current demand for tattoos without the restriction in place.

The SEA considers one-off monetised costs (see Section 4.4.2 for substitution and familiarisation costs) and non-monetised impacts. Regardless of this, an appraisal period of 20 years is considered for the purpose of the sensitivity analysis and allows for full cost and benefit realisation. This timeframe was also used by ECHA in their restriction dossier (2019c).

Number of people with tattoos and PMU

a) Tattoos

The tattoo prevalence has been explored as part of the opinion-making stage to ensure estimates are up-to-date and specific to the GB population. The estimates have been derived using information received from the public consultation on tattoo prevalence in GB. This information was from a YouGov survey in 2022 which estimates the tattoo prevalence in GB amongst the adult population to be 26%. Another YouGov survey was conducted in 2015 and this estimated the tattoo prevalence amongst the GB adult population to be 19%. These prevalence rates refer to the adult population so when they are calculated for the general GB population, the tattoo prevalence rates are 15% and 20.5% for 2015 and 2022 respectively. The 15% and 20.5% tattoo prevalence rates are used to forecast tattoo prevalence rates up to the year 2040. Full details on these calculations are provided in the background document.

The prevalence rates are applied to the total GB population to understand the tattoo prevalence. This is presented in table 7 below alongside the average incidence between 2022-2040.

Table 7: Estimated number of people with tattoos in GB, 2015-2040.

Geographic area	Estimated prevalence in 2015	Estimated prevalence in 2022	Estimated prevalence in 2030	Estimated prevalence in 2040	Average incidence 2022-2040
GB	9,485,000	13,525,000	18,100,000	23,667,000	758,000
Prevalence rate (central scenario)	15.0%	20.5%	26.7%	33.9%	

b) PMU

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.

Table 8 shows the estimated population in GB with a PMU procedure in 2016. The estimates have been calculated using total GB population from the ONS and application of ECHA's prevalence rates (3, 10 and 20%) to estimate the GB population with PMU. The uncertainties around these estimates are provided in Section 3.2 of the background document.

Table 8: Estimated population with PMU in 2016 (number)

Geographic Area	Low	Central	High
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).

Volume of tattoo inks and PMU on the GB market

As part of the opinion forming stage, the Agency engaged with various stakeholders and conducted further work to refine the calculations for the volume of ink on the GB market. The volume of ink on the GB market is estimated using three different methods owing to the large degree of uncertainty in this area.

The Agency spoke with two ink formulators who have provided the annual volumes of ink they supply to GB. The volumes provided by the formulators are used and extrapolated within one of the methods for calculating the volume of ink.

The figures produced under each of the three methods are then considered to produce a final set of estimates for the volume of ink on the GB market (figures in this section have been rounded where appropriate, therefore totals may not always sum up precisely). Detail behind the three methods is provided in Section 3.2 of the background document. This opinion summarises the final set of values for the volume of ink on the GB market.

Across the three methods presented for the volume of ink on the GB market (see Section 3.2 of the background document), there are a wide range of estimates. This analysis assumes that the volumes information provided by the formulators is robust and accurate and that the total volume of ink on the GB market cannot be less than the volumes supplied to GB by the formulators. Therefore, any estimates from the three methods that are low and fall below the volumes that the formulators supply to GB are discarded given they are likely to an underestimate.

Therefore, the lowest credible estimate for the volume of ink is the central estimate from method 1 of 50,200 litres and the highest estimate is 118,700 litres from method 2. These are used in the final set of values for the volume of ink on the market and the central estimate is calculated by taking the average of these two values (84,500).

Table 9: Estimated volume of ink on the GB market in 2022.

Scenario	Estimated volume of ink on the GB market in 2022 (litres)
Low	50,200
Central	84,500
High	118,700

As part of the second public consultation on the socioeconomic aspects of the opinion, the Agency received information from an ink formulator/distributor on the volume of ink on the GB market. They believe that the annual volume of ink on the GB market is closer to the low estimate of 50,200 litres, with 10% of this produced domestically in GB. This figure aligns with the Agency's estimates presented in table 9 however, these estimates should be considered to be approximate values.

4.4.2 Costs

The costs presented in this analysis fall largely to the tattoo and PMU industry with some costs falling to government, local authorities and consumers.

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

- **Substitution costs** arise because formulators of ink need to begin research and development activities, testing and reformulation for compliant inks which are likely to be more expensive and require alternative materials. It is possible that existing inks are compliant, but formulators, suppliers and GB importers will need to check whether they are. These costs are incurred by ink formulators and are expected to be passed down the supply chain onto suppliers, including GB importers, and consumers.

- **Labelling costs** arise as GB based importers and formulators will need to relabel inks to ensure the information that is provided meets the requirements of the GB restriction.

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

- **Familiarisation costs** arise as all actors in the tattoo 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 formulators of inks may stop supplying 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. Reformulated products might be of lower quality than the originals (if they are not long lasting in the skin and offer a reduced colour range), meaning consumers derive less benefit from their use.

Substitution costs

As part of the opinion-making stage, the Agency contacted a range of different stakeholders and refined parts of the analysis within this restriction dossier.

Substitution costs are calculated for modified RO2 and assume that the volume of ink produced domestically in GB accounts for 32% of all ink on the GB market (see Appendix 5 of the background document for further information and origin of the 32%). This is the best information available on GB-produced ink, but this assumption is associated with a large degree of uncertainty so should be understood to be illustrative. This analysis assumes that international formulators are compliant with the GB restriction as they will have already reformulated for the EU restriction and GB industry are non-compliant. The Agency does not hold exact information on the number or proportion of industry who are compliant with modified RO2. Therefore, the substitution cost estimates should be understood to be illustrative.

It is important to note that the reformulation costs estimated here are expected to fall to GB-based ink formulators as it is assumed they are not supplying inks to the EU and have therefore not needed to reformulate their products already to comply with the EU restriction. Formulators based outside of GB who do supply to the EU have already incurred substitution costs which are attributed to the EU restriction. These substitution costs for non-GB formulators might be reflected in the price of EU compliant inks which may already be available on the GB marker alongside other non-EU compliant inks.

It is assumed that formulators will either absorb costs or pass them down the supply chain (either partially or fully). It is not known what proportion of the substitution costs will fall to various actors or customers in the tattoo and PMU industry.

GB based suppliers and importers will need to ensure that compliant inks are on the GB market when the proposed restriction is implemented. The compliant inks are likely to be more expensive compared to non-compliant inks and this will in turn increase costs for suppliers and importers.

As part of the public consultation, the Agency received information on the substitution costs incurred by an ink formulator to comply with the EU restriction and the volume of ink this formulator supplies to GB and the EU. This information is confidential and has therefore not been detailed in this opinion. The full methodology behind this calculation is included in Section 3.5.1.1 of the background document.

a) One-off reformulation cost

A principal component of the total costs of substitution will be accounted for by the costs of reformulating inks to ensure they are compliant with the restriction. This reformulation only needs to be undertaken once for non-compliant inks, and hence the costs are incurred as a 'one-off'. An ink formulator responding to the public consultation provided information on the costs it had incurred from reformulating inks in response to the EU restriction. By taking the formulator's cost of reformulation and dividing by the annual volume of ink they supply to the EU market, we can estimate the cost to replace a litre of non-compliant ink.

$$\frac{formulator's\ reformulation\ cost}{volume\ of\ ink\ supplied\ to\ the\ EU} = £\ per\ litre\ of\ non-compliant\ ink\ replaced$$

The cost to replace a litre of non-compliant ink is used to estimate the reformulation costs in GB. As seen earlier in the baseline section, there are approximately 84,500 litres of ink on the GB market and it is assumed that around 32% of this is non-compliant ink, which is produced domestically and needs replacing. Therefore, the cost of reformulation for GB industry is estimated at = **£1,740,000.**

This is a one-off cost and would be incurred by GB based ink formulators during the first year that the restriction is implemented. The annualised cost across the 20-year appraisal period is approximately £87,000.

a) Ongoing substitution cost

The ink formulator informed the Agency that there were ongoing costs to substitution which comprised of:

1. Inventory; introducing a new line of products to comply with specific regulatory requirements results in duplication of products.
2. Holding inventory; the time required to complete chemical analyses to confirm batches comply with regulatory requirements means inventory needs to be stored for longer before it can be supplied to market. This will require additional warehouse space and could reduce the shelf-life of products for artists/PMU practitioners.
3. Increased price of new raw materials due to more stringent purity requirements.
4. Testing; chemical analyses may need to be carried out on incoming raw materials as well as formulated products to ensure products meet regulatory requirements.

The Agency has sought information from an ink formulator on the ongoing substitution costs but has received limited information on this. It has therefore not been possible to monetise the ongoing substitution costs for this GB restriction.

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 reformulation cost for approach 1. A list of general assumptions underpinning the SEA can be found in appendix 5.

It is likely that costs under modified RO2 and modified RO2a are lower than were estimated for RO1 and RO3 in the background document because the requirements are less stringent. As modified RO2a is less stringent than modified RO2, it is likely that more inks currently on the GB market are already compliant with modified RO2a and therefore the costs of substitution are likely to be lower compared to modified RO2. It is however difficult to provide a meaningful quantitative comparison between options.

The background document also presents a second approach to estimating substitution costs. This ‘indirect approach’ mirrors the approach adopted in ECHA’s background document (2019c) and is based on a comparison of the prices of compliant and non-compliant inks. The difference in price is assumed to reflect the costs of substitution and hence can be seen as an indirect measure of those costs. ECHA’s background document used the indirect approach because it was compiled

in advance of the restriction and no information was available at that time from which to estimate substitution costs directly. However, even the assessment of the difference in prices between compliant and non-compliant inks was a judgement based on limited actual evidence. Although there is some evidence available now that prices for EU-compliant inks are higher than other inks, this evidence is not comprehensive, it is not clear whether any such differential reflects substitution costs (alone), and it is not known whether this differential will persist over time. Further, as reported, the Agency has received information directly from inks formulators on the costs of substitution. Thus, the preferred approach is to estimate the costs of substitution directly based on this information. The second 'indirect' approach is presented in the Agency's background document for comparison, with the direct approach and with ECHA's background document estimates, but is not used in subsequent calculations or analysis.

The Agency has gathered the available evidence to estimate the substitution costs for this proposed restriction in GB. The Agency expects the substitution costs to be low given that the EU restriction exists and inks formulated for the EU market will already comply with the GB restriction. Furthermore, based on the Agency's checks there are a small number of GB based formulators (whom the substitution costs in this restriction fall to). Overall, the evidence in this area is weak but the Agency expects the substitution costs falling to GB industry to be relatively low.

Labelling costs

The proposed restriction will impose labelling costs on GB-based formulators and importers who choose to import inks from other countries. The Agency has estimated the cost to relabel a substance for a company based on previous work for CLP. This is estimated at approximately £150 to £500 per ink. It is however unknown how many inks will need labelling on the GB market; it is therefore not possible to quantify or monetise this cost.

Enforcement costs

If the proposed restriction is enforced in GB, enforcement activities will be split between HSE and local authorities, as stipulated in REACH Enforcement Regulations 2008.

It is understood that there will be no additional funding or resource allocated to enforcement of this restriction. Therefore, any enforcement activities put towards this restriction will come out of existing budgets and resource and will need to be prioritised by HSE and local authorities individually. Further information on enforcement costs and responsibilities is provided in Section 3.5.1.3 of the background document.

It has not been possible to monetise the enforcement costs, however, costs under all options are expected to be similar.

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 formulators, 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. Owing to data limitations, it has been extremely difficult to obtain this data at a granular level. Therefore, low, central and high values have been estimated and should be understood to be approximate values as they carry a high degree of uncertainty.

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 familiarisation costs for GB under modified RO2 are approximately £69,000 - £2,546,000 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. Costs are apportioned across the appraisal period in Section 4.4.6 for the break-even analysis and cost-effectiveness to ensure that these measures have not been skewed.

The familiarisation costs in this analysis have been estimated for modified RO2. However, all options will require industry to understand the proposed restriction, therefore it is expected that familiarisation costs across all options are similar. It is difficult to provide a quantitative differentiation between options.

Non-monetised costs

This section describes the non-monetised costs incurred by society and people receiving tattoos and PMU.

Reduced colour palette

It is understood that the EU restriction has led to a loss of pigment colours and potential discontinuation of available inks on the market. This could result in a loss of consumer surplus as consumers will have a reduced colour palette available for their tattoos and PMU. Tattoo artists will also have a reduced colour palette to work with and this may have impacts on the number of customers wanting a tattoo (if their preferred choice of tattoo pigment is no longer available) and hence incomes for tattoo artists. Also, during the second public consultation, one artist who performs areola reconstructions for mastectomy patients indicated that the range of flesh tones required for areola work is not available in reformulated EU inks. This would

reduce the value of areola reconstruction to mastectomy patients and might induce them to take some compensating actions such as seeking treatment elsewhere. The loss of pigment palettes is a distributional effect which reflects the loss in value (of a tattoo/PMU procedure) to customers. The Agency has contacted various stakeholders including two ink formulators. One of the ink formulators informed the Agency that as a result of the EU restriction, all pigment palettes have been reduced.

Given that the GB restriction proposes a derogation for PB 15:3 and PG 7 and 17 other colourants that are restricted for use in EU inks, we are uncertain as to whether these problems will be faced by GB industry. However, it is unclear what impact modified RO2 and modified RO2a will have on the colour palette.

Lower performance and longevity

The Agency asked ink formulators about their experiences with the longevity of tattoos made using EU compliant inks. Limited time has elapsed to fully understand the longevity for both tattoos and PMU with EU compliant inks. Anecdotally, reformulated tattoo and PMU inks appear to have less longevity and appear to be harder to work with (though this may be a case of artists needing to adapt techniques for new formulations). Alternatives that are being trialled for PB 15:3 do not have the same hue and tattoo artists will need to learn how to work with it. This demonstrates a loss of functionality as a result of needing to reformulate with alternative substances and materials. Additionally, formulators don't currently have the data to understand how alternative colourants behave in skin. It is likely that ink formulators will continue to reformulate for the EU market until more long-lasting inks are obtained.

The impacts described above are in relation to the EU restriction and we expect there to be ongoing reformulation until suitable inks are obtained and the issues seen in the EU are resolved. The GB restriction potentially provides industry with a wider range of substances to work with compared with the EU restriction, but it is not clear what impacts the GB restriction will have on the performance and longevity of inks.

4.4.3 Social and distributional impacts

As part of the opinion-forming stage, the Agency spoke to two ink formulators about their experience with the EU restriction, and they said that they had been able to afford to go through the substitution process required to produce EU-compliant inks. They thought that other smaller formulators might not have been able to reformulate for the EU market because of the costs. This demonstrates the social impact this could have in terms of lower incomes and potential unemployment for GB formulators.

If tattoo artists are unable to afford the cost of substitute materials and reformulation, they might decide to purchase non-compliant inks when the restriction is imposed.

One of the ink formulators that the Agency spoke to said that they have seen this occurring via internet sales since the EU restriction was imposed. The ink formulator also mentioned that they were only selling compliant inks to customers with shipping addresses in countries where there is legislation on ink composition. However, not all non-EU suppliers are restricting sales of non-compliant inks in the same way.

4.4.4 Health impacts

As indicated in Section 4.1, the Agency does not have GB specific information on the numbers of tattooed people that will be affected by a tattoo-related adverse reaction. It has therefore been necessary to rely on the estimate derived in ECHA (2019c). Section 4.1 borrows from ECHA and mentions that on average, around 1.8% of tattooed people may experience an adverse reaction to substances in tattoo ink or PMU which requires medical attention. This estimate was obtained from a small number of studies which did not include any GB-based studies. The Agency expects that GB will be represented in a similar manner to study participants from the EU meaning that approximately 13,600 people in GB might be affected by a tattoo-related adverse reaction each year between 2022-2040 (1.8% of the estimated annual average incidence of 758,000 (Table 7)). However, it is not known if any of these incidents would be prevented as a result of the restriction.

4.4.5 Benefits

The available information does not allow for a quantitative differentiation of health benefits between modified RO2 and modified RO2a. If only substance-related adverse effects are considered, the expected benefits of modified RO2a may be smaller than modified RO2 owing to the inclusion of a greater number of hazardous substances in modified RO2. However, we have no evidence that the substances which are excluded from modified RO2a are making a contribution to tattoo and PMU-related ill health. The substances which were excluded from modified RO2a were excluded on the basis that this would make it easier for formulators to use substances which have preservative properties at the levels required for this effect. A large contribution to tattoo and PMU-related ill health is made by infections rather than substances in inks. However, not all infections will have been caused by inadequately sterilised inks. For all of these reasons, it is very difficult to identify which of these options may provide the greatest overall benefits to health.

Reduction in adverse health effects

Most benefits that arise from the proposed restriction options (modified RO2 and modified RO2a) are expected to fall to customers of tattoos and PMU. Sections 4.1 and 4.4.4 on human health impacts describe the different adverse effects that can arise from insertion of tattoo inks and PMU into the skin. Following the proposed restriction, there should be a reduction in the number and severity of adverse effects relating to tattoos and PMU compared with the baseline. Some customers who

would have experienced an adverse health reaction in the baseline might experience no such reaction under the restriction; other customers might experience a less severe reaction under the restriction than they would have under the baseline.

A reduction in the number and severity of adverse health impacts on tattoo customers would be expected to have the following benefits:

- A reduction in medical treatment costs
- A reduction in employment-related losses if customers would have been required to take time off work
- An improvement in personal wellbeing from not having to experience the negative impacts on health (pain, discomfort, impacts on mobility etc).

However, it is not known if any of these costs would be prevented as a result of the restriction. It would in any case be difficult to quantify these benefits given the lack of data on number and severity of adverse health effects. ECHA (2016) provides estimates for employment-related losses arising from severe chronic dermatitis; however, it is unclear whether the impacts described by ECHA would be seen as a result of this restriction on tattoo inks and PMU in GB.

4.4.6 Proportionality

Proportionality in policy appraisal is typically considered in terms of a comparison of benefits and costs. In the context of substances in tattoo inks and PMU, benefits assessment is challenging, and not wholly possible, 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 comprises a number of lines of evidence and argumentation. The strands of evidence include the affordability for various groups within the industry, the break-even point of the proposed restriction, and measures of its cost-effectiveness. As mentioned in ECHA (2019c), the proposed restriction is expected to create higher costs for formulators which they might be expected to be able to pass on, at least in part, to customers. The break-even point has been calculated for modified RO2 (with qualitative assessment for modified RO2a) to understand and differentiate the costs of each option. The break-even point looks at the total cost of the restriction and calculates the number of cases, valued in terms of cost of illness (COI) and willingness to pay (WTP) which would need to be prevented by the restriction so that benefits equal costs. If the break-even point is small relative to the potential number of cases, this gives some confidence that the policy could prevent enough cases for it to pass a cost-benefit test (if it was possible to conduct one). Cost-effectiveness of a policy to address health impacts would normally be framed in terms of the cost of preventing each case, to be compared with the cost-effectiveness of other policies to

see whether this intervention appears ‘cheaper’ or ‘more expensive’. However, for the same reasons of not being able to quantify the number of cases prevented, this measure of cost-effectiveness cannot be calculated in this case. Instead, for this dossier, the cost-effectiveness takes the total costs of the restriction and the volume of non-compliant ink on the market that needs replacing and calculates how much it costs to replace a litre of non-compliant ink on the market.

Break-even analysis

The break-even point has been calculated based on the total costs of the restriction (annualised), the cost of treating dermatitis and WTP to avoid the symptoms of tattoo reactions. This provides some indication on the number of cases that would need to be avoided on an annual basis for the restriction to break-even.

For modified RO2 to break-even, between 63 (calculated using COI plus higher WTP value) and 572 (COI plus lower WTP value) cases of mild, acute and severe chronic dermatitis would need to be avoided annually for the estimated benefits of the restriction to outweigh the estimated costs. This is between 0.009% and 0.081% of the estimated number of people getting a tattoo for the first time each year in GB (0 to 4 removals for every 100,000 tattooed people). For modified RO2a to break-even, fewer cases of dermatitis would need to be avoided in comparison to modified RO2.

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 to 9 removals for every 100,000 people with PMU. Details behind the break-even calculations can be found in Section 3.5.5.1 of the background document.

Overall, the calculations suggest that between 63 and 572 cases of dermatitis need to be avoided on an annual basis for the proposed GB restriction to break-even. Comparing these figures to the incidence from 2022 to 2040 i.e. the number of people getting a tattoo for the first time (approximately 758,000) this appears to be a relatively small proportion.

Cost-effectiveness

As shown, the proposed restriction options would likely lead to costs and other impacts to industry and society as whole, these are presented in table 11. The cost-effectiveness of modified RO2 is estimated at approximately £5/litre non-compliant tattoo ink replaced in GB (compared with retail prices for ink of around £500 per litre). Modified RO2a is likely to be more cost-effective than modified RO2 as substitution costs are expected to be somewhat lower whilst RO1 and RO3 are likely to be less cost-effective in comparison to modified RO2 and modified RO2a.

Affordability

a) Ink formulators

The Agency spoke to a number of different stakeholders. Following these conversations, it is unclear whether GB-produced inks are compliant with the EU restriction. ECHA (2019c) assumed that approximately 32% of ink on the UK market is formulated domestically, 40% is imported from the US, 10% from Asia and 4% from the EU. No information was provided about the remaining 14%. These assumptions are used for this analysis for GB. Depending on which of the restriction options are taken forward, ink formulators would incur substitution costs to comply with the GB restriction. If international formulators are already supplying ink to the EU market, then they would incur some costs (if the GB restriction differs from the EU restriction) but these may be minimal or even zero (if the GB restriction is the same or very similar to the EU restriction) to supply ink to the GB market once the restriction is implemented.

b) Tattoo artists

The average hourly rate for a tattoo is around £150 in London whereas in Leeds, the price is between £80 to £100 per hour (Barber DTS, 2021). Two tattoo artists responding to the HSE public consultation indicated that their hourly fee was around £70.

The average duration and hence price of a tattoo varies as this is dependent on the size, style and intricacy of the tattoo as well as the skill of the tattoo artist. Total costs per tattoo consider the various costs incurred by tattoo artists (for supplies, rent, labour and other overheads) and take an average of this cost by dividing by the average number of tattoos they administer. Based on the call for evidence, it is understood that tattoo artists in GB incur between £15 to £60 in the administration of tattoo. Costs are expected to be lower in different regions across GB i.e., north of England compared to London.

ECHA (2019c) estimated that in Western Europe, the cost for tattoo ink as a proportion of the total cost per tattoo is 14% and following the proposed restriction this would rise to 16%. This means the marginal cost of the EU restriction would be less than €1 per 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 by ECHA for Western Europe (2019c).

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 (NHS, 2019a). 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.

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 not clear what the costs will be in terms of costs per tattoo following the proposed restriction. However, it is likely that costs are either absorbed by the tattoo and PMU industry or passed through to customers (or a combination of both). If costs are passed to customers, this will mean the price of tattoos and PMU procedures will be more expensive compared to the baseline.

Customer's reaction to this price increase will depend on their elasticity of demand. The ECHA dossier (2019c) mentioned that according to market research in the US, demand for tattoo and PMU services is inelastic. Therefore, it is unlikely that demand for tattoo and PMU procedures will decline with a small price increase.

4.4.7 Comparison of restriction options

Table 11 summarises the costs and other impacts of the proposed restriction options. The main difference between the restriction options are the concentration limits. There is no evidence that the limits which are proposed under modified RO2 and modified RO2a will not be protective of health. By excluding skin and eye irritants from the scope of modified RO2a, the Agency aims to strike a balance between restricting the use of hazardous substances while providing flexibility for formulators to use substances that have preservative properties at the levels required for this effect. This modification has been proposed to address clear risks to health that are created if mixtures used for tattooing and PMU are inadequately sterilised. However, it will be difficult to separate mild irritant reactions, if these occur, from the trauma of the tattooing process. Given the high level of uncertainty that is associated with the evidence base for this restriction, including a lack of certainty about which substances are causing the greatest number of substance-related adverse tattoo reactions, it is not possible to make robust judgements about the risk reduction capacity for any option from the currently available evidence.

More tattoo inks on the GB market are likely to already comply with modified RO2 and modified RO2a. Therefore, the substitution costs for modified RO2 and modified RO2a are likely to be low. Testing costs for formulators and enforcers under modified RO2 and modified RO2a would also be possibly low. Costs for modified RO2 and modified RO2a are expected to be low but so is the volume of ink affected. Therefore, it is unclear whether the cost per litre of ink replaced will be lower in comparison to RO1 and RO3. It is also unclear whether modified RO2 and modified RO2a will be more affordable for industry compared to RO1 and RO3.

Modified RO2 and modified RO2a would require fewer avoided cases of dermatitis to reach the break-even point than RO1 and RO3. This comparison does not take account of possible costs relating to infections if these arise because the restriction has impacted the ability of ink formulators to take measures to prevent bacterial contamination during production (further details can be found in section 3.3.2.4c of the background document).

Table 11: Socioeconomic assessment of the proposed restriction options[1] (adapted from ECHA 2019a) (2021 prices, GBP £, one-off costs)

(2021 prices, GBP £, one-off costs)	RO1	Modified RO2	Modified RO2a	RO3
Total compliance costs	Higher than modified RO2 and modified RO2a	£2,606,000 (sum of one-off costs)[2]	Lower than modified RO2	Higher than modified RO2 and modified RO2a but lower than RO1
Substitution	Likely to be higher than modified RO2 and modified RO2a	£1,740,000 (one-off cost under approach 1[3])	Likely to be lower than modified RO2	Likely to be higher than modified RO2 and modified RO2a but lower than RO1
Labelling	This is not monetised, but costs are likely to be similar to be similar across all options	This is not monetised	This is not monetised, but costs are likely to be similar across all options	This is not monetised, but costs are likely to be similar across all options
Enforcement	This is not monetised, but costs are likely to be similar	This is not monetised	This is not monetised, but costs are likely to be	This is not monetised, but costs are likely to be

[1] Figures in this table have been rounded and totals may not add up precisely.
[2] This is the sum of the one-off substitution and familiarisation costs which will be incurred the year that the restriction is implemented. To apportion this cost across the 20-year appraisal period, annual costs for this restriction would be approximately £130,000 (in 2021/22 PV).
[3] 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 substitution costs would be approximately £87,000 (in 2021/22 PV).

(2021 prices, GBP £, one-off costs)	RO1	Modified RO2	Modified RO2a	RO3
	across all options		similar across all options	similar across all options
Familiarisation	Similar to modified RO2 and modified RO2a	£867,000 (one-off cost in year 1)[4]	Similar to modified RO2	Similar to modified RO2 and modified RO2a
Social and distributional impacts[5]	This is non-monetised and expected to have moderate impacts for all options	This is non-monetised but modified RO2 is expected to have moderate impacts	This is non-monetised but modified RO2a is expected to have moderate impacts	This is non-monetised and expected to have moderate impacts for all options
Wider economic impacts[6]	This is non-monetised and expected to have minimal impacts for all options	This is non-monetised but modified RO2 and modified RO2a are expected to have minimal impacts	This is non-monetised but modified RO2 and modified RO2a are expected to have minimal impacts	This is non-monetised and expected to have minimal impacts for all options
Risk reduction capacity and benefits	Equivalent to the avoided cases of tattoo and PMU-related adverse effects and associated medical	Equivalent to the avoided cases of tattoo and PMU-related adverse effects and associated medical treatment costs	Equivalent to the avoided cases of tattoo and PMU repeated adverse effects and associated	Equivalent to the avoided cases of tattoo and PMU-related adverse effects and associated medical

[4] 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).

[5] 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.

[6] This refers to the availability of inks and trade impacts as a result of the proposed restriction.

(2021 prices, GBP £, one-off costs)	RO1	Modified RO2	Modified RO2a	RO3
	treatment costs		medical treatment costs	treatment costs

Table 12 provides the proportionality for modified RO2 with qualitative assessment for modified RO2a, RO1 and RO3. For all options, the costs of substitution are proportional to the volume of ink affected, but other types of cost are essentially fixed. This means that cost-effectiveness (cost per litre) will be better for the options with wider scope (since fixed costs are spread across greater volumes). Affordability is a measure of the ratio of costs to revenue/income, so is generally expected to be negatively related to scope (volume), which is associated with higher costs. This shows the monetised assessment for cost-effectiveness and break-even, and a qualitative assessment for affordability. Costs for modified RO2 and modified RO2a are expected to be lower but so is the volume of ink affected. Therefore, it is unclear whether the cost per litre of ink replaced will be lower in comparison to RO1 and RO3. It is also unclear whether modified RO2 and modified RO2a will be more affordable for industry compared to RO1 and RO3. Higher costs also mean a higher break-even point, although this could be countered by possible higher potential benefits of a restriction with wider scope providing the restriction does not result in increased infections or substitutions with substances that have as yet unrecognised hazards when used for tattooing or PMU.

Modified RO2 and modified RO2a would require fewer avoided cases of dermatitis to reach the break-even point than RO1 and RO3.

Table 12: Proportionality of the proposed restriction options[7] (adapted from ECHA 2019a)

2021 prices, GBP £	RO1	Modified RO2	Modified RO2a	RO3
Cost-effectiveness	More cost-effective than modified RO2	£5/litre/p.a of non-compliant inks removed from the market	Less cost-effective than modified RO2	Less cost-effective than RO1 but more than modified RO2
Break-even	More cases required for	Approximately 63 to 572	Possibly fewer cases required	Similar to RO1 and more cases

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

2021 prices, GBP £	RO1	Modified RO2	Modified RO2a	RO3
	break-even than modified RO2	avoided cases of tattoo removal due to mild acute and severe chronic dermatitis	for break-even than modified RO2	required for break-even than modified RO2
Affordability	Less affordable than modified RO2	The marginal cost of a tattoo is not monetised for this restriction	More affordable than modified RO2	Similar to RO1 but less affordable than modified RO2

At £5 per litre (compared with retail prices for ink of around £500 per litre), it seems possible that RO2 is cost-effective, but these measures are not objective and hence any assessment based on them is necessarily subjective. Further, although 63 to 572 avoided cases for break-even of modified RO2 does not sound high compared with reported rates of tattoo complications, it must be recalled that there is no evidence to suggest that these tattoo complications are related to substances which would be caught by the requirements of the restriction. Finally, although measures have not been calculated for other options, it does not seem that there is likely to be significant variation across options in terms of their proportionality. The nature of available evidence and data means that the results of these socio-economic and proportionality assessments are ultimately inconclusive.

4.5 Practicality and monitorability

In order to propose a restriction under Article 69(1) of UK REACH, the Agency must demonstrate that the proposed action is practical (i.e. implementable, enforceable and manageable) and the results of the proposed restriction can be monitored.

Implementability

The Agency understands implementability to mean something that can be enacted into legislation that provides legal certainty for dutyholders and enforcers.

This restriction is clear on the types of products that are in scope. The restriction applies to products that are placed on the market for use for tattooing purposes, and mixtures that are used for tattooing and PMU. Modified RO2 and modified RO2a use concentration limits to specify the maximum amounts of restricted substances that may be present in tattoo and PMU inks. It is therefore clear to dutyholders what requirements they must meet. This indicates that the options proposed by the Agency are implementable.

A similar type of restriction has been enacted into EU legislation which supports the view that restrictions based on these options can be implemented.

Enforceability

The Agency understands enforceability to mean the ease with which duty holders can verify that their products are in compliance, the ease with which enforcers can intervene where there are suspicions of non-compliance and the ease with which non-compliance can be unequivocally demonstrated if legal action is required.

During the opinion forming process, the Agency held meetings with individuals from some enforcement bodies regarding enforceability.

There are several aspects of this restriction that could be subject to some level of enforcement activity including:

- Compliance with labelling requirements
- Use (or not) of products that purport to comply with the restriction
- Compliance with ink formulation requirements

Chemical analyses will not be required to underpin enforcement activity in all instances.

Based on the assessment carried out by BfR (2021) and information provided by stakeholders, analytical methods are not currently available to quantify the levels of every substance that is in scope of this restriction. In particular, it may be difficult to quantify the concentrations of specific pigments and dyes which may be subject to restriction, also PAHs (in formulated inks containing black carbonaceous pigments), phthalates and soluble barium, copper and zinc. Where there are no methods or there are other issues associated with analytical capability, it may not be possible to enforce based on composition.

The current inability to reliably detect and analyse for all substances within scope of the restriction to their respective concentration limits is not an absolute barrier to taking any enforcement action on ink composition. The work being undertaken by EU Member States and Industry to address analytical challenges arising with respect to the EU restriction is expected to be of relevance to the GB situation too. Consequently, longer term it should be possible to detect and enforce against a wider range of substances within tattoo inks and PMU where they are present at levels which do not conform with the requirements of the proposed restriction.

An issue brought up in ECHA's documents (ECHA, 2019c) and the call for evidence in relation to enforceability is the ready availability of non-compliant tattoo inks and PMU via the internet. Linked to this is the emergence in the EU of a new market for so called "practice inks", whose composition may not comply with the EU restriction,

but which are labelled as “not to be used on human skin”. It is not known if artists are using these inks only for practice or if these inks are being used on clients in contravention of the restriction. This may be done if the artist considers that the practice ink will give a better appearance to the tattoo compared with a reformulated compliant ink. If the restriction came into force, supply of practice inks (labelled as not for use on human skin) within GB would not be illegal, but use of those products for tattooing purposes would be. This would fall to Local Authorities to address and would rely on them being able to evidence their use.

Supply of non-compliant product has the potential to undermine benefits arising from the introduction of the restriction. This could occur when a GB-based supplier decides to intentionally source and supply products which do not comply with the restriction or when a supplier is unaware of the law and does not ensure the products they supply are compliant. The ability to purchase both compliant and non-compliant products via the internet also means that both suppliers and tattoo artists and PMU practitioners can access all types of products via this route. In circumstances where the product is purchased from outside of GB, the legal duty will be on the “importer” to ensure the product complies with the conditions of the restriction, rather than the supplier of the product (although in certain instances the non-GB entity will work with the GB importer to assist in determining compliance). The circumstances described are the same for substances and mixtures associated with other REACH restrictions and are consistent with the EU situation. It would be helpful to the success of the restriction if non-GB-based suppliers implemented measures to stop supply of non-compliant product to GB, such as those advised to the Agency during the public consultation. However, any such measures would have to be on a voluntary basis.

It is not clear how easy it will be to prevent non-compliant 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 registered tattoo artists and PMU practitioners who will be inspected by enforcement officers typically use inks which are from reputable formulators (who aim to produce GB-compliant products), the restriction may have little or no impact on the occurrence of complications due to the use of non-compliant inks if they continue to be used by unregistered professionals and amateurs. This has the potential to reduce the effectiveness of this restriction.

Measures outside the scope of the proposed restriction options such as training and awareness raising could increase levels of compliance.

<u>Manageability</u>

The Agency understands manageability to mean the ease with which duty holders can comply with the requirements of the restriction. In the case of this restriction, manageability might be considered in terms of:

- the ease with which formulators can obtain raw materials of an appropriate purity;
- the ease with which formulators and GB importers/suppliers can verify that their products meet the composition requirements of the restriction; and,
- the costs to the duty holder to verify their compliance.

Modified RO2 and modified RO2a propose concentration limits which are for many substances less stringent than those in the EU restriction. These concentration limits are based on limits set out in the GB CLP Regulation for classification of mixtures containing hazardous substances and are intended to be protective of health.

By proposing less stringent concentration limits, the Agency aims to make some of the chemical analyses that will be required for the GB restriction more feasible than those required to verify compliance (as far as this is possible) with the EU restriction. Formulators have informed the Agency that the low concentration limits specified in the EU restriction require sophisticated equipment and specialist expertise to measure which is not available in many commercial analytical laboratories. Also, several concentration limits are close to the limits of quantification of currently available methods creating the potential for analyses to yield false positive and false negative results. Both of these factors count against a restriction that is closely aligned the EU restriction meeting a requirement (RO3) that it should be manageable.

With the higher concentration limits proposed by the Agency, a greater number of laboratories may be able to perform the required analyses and there will be a greater distance between the limits of quantification and the levels that need to be measured. This should therefore make compliance with the GB restriction somewhat more manageable than the EU restriction. Where no analytical methods are available, or where the lack of reference standards means that it is not possible to quantify levels, it will not be possible for formulators to confirm that their products comply with all aspects of the GB restriction.

In terms of the costs to verify compliance, ink formulators have told the Agency that in addition to carrying out chemical analyses to confirm compliance, they are also having to fund method development work. If the costs to verify compliance are too high, companies may choose to stop supplying to the GB market or may only test to the extent that can easily be managed. Until the gaps in analytical capabilities that have been identified by the BfR work are resolved, it will not be possible for any actor to have complete confidence that they are supplying a fully compliant product to GB. This problem also exists for EU inks.

The Agency is proposing a derogation for a group of 19 pigments which includes the widely used PB 15:3 and PG 7. This derogation will help formulators to provide the same range of colours that are currently available. The Agency therefore considers

both modified RO2 and modified RO2a to be manageable for GB. Modified RO2a is likely to be more manageable because fewer substances are in scope.

Monitorability

There may be challenges in monitoring the result of the implementation of the proposed options because until now little attention has been paid in GB to the composition of tattoo inks or to collating information on cases of ill health relating to tattoos and PMU. The Agency has identified the following strategies to potentially monitor the success of this restriction:

- Track the numbers of alerts to the UK's Product Safety Database made by enforcement officers where they deem it necessary to highlight particular tattoo and PMU inks that are on the market. In this case, it will be important to differentiate between alerts relating to concerns about the sterility of products and alerts relating to the presence of restricted substances in products.
- Track numbers of interventions taken against suppliers/users of inks that contravene the requirements of this restriction.

4.6 Risk reduction capacity and potential unintended consequences

Risk reduction capacity

The aim for this restriction proposal is to limit the presence of substances that are potentially harmful to health in tattoo inks and PMU because the presence of such substances could cause ill health conditions. This is achieved by setting concentration limits for each substance or group of substances that is in scope. The dynamic link with the GB MCL list that is proposed under both modified RO2 and modified RO2a will ensure that as substances are added to the GB MCL list or a mandatory classification for a relevant endpoint is updated, these substances will be brought into scope of this restriction without delay. Before substances are added to the GB MCL list, formulators could voluntarily avoid substances with relevant self-classifications. This has the potential to limit regrettable substitution.

The concentration limits that are proposed 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 are indicative of levels of exposure that represent a low level of risk and provide a tool for compliance monitoring.

The restriction options proposed by the Agency cannot tackle all causes of ill health relating to tattoos or PMU. The most common cause is infection which could be caused by inadequate sterilisation of ink, poor hygiene in the studio or poor aftercare by the client. This restriction also cannot tackle cases where ill health arises because

the amount of ink placed by the tattoo artist or PMU practitioner in the skin triggers an exaggerated foreign body response.

The restriction options proposed by the Agency have the potential to reduce cases of skin allergies which are most often reported with red tattoos. Currently there is insufficient experience with the EU restriction to understand if cases of skin allergies are reducing. The Agency has been informed about messages circulating in tattoo artist online chat forums reporting an increase in allergic reactions to red colours compared with levels seen prior to the implementation of this restriction. No clinical evidence is available to confirm this.

By limiting the amounts of substances that have the potential to trigger adverse reactions if used for tattooing or PMU, this restriction seeks to minimise the potential for substance-related adverse reactions. Since there is no clear evidence to show how frequently substance-related adverse reactions arose prior to the implementation of the EU restriction and which substances cause the greatest numbers of substance-related adverse reactions, we cannot easily identify whether the EU restriction is reducing such events. For these reasons, it is not possible to quantify the risk reduction capacity that will be offered by either of the proposed restriction options for GB.

It is also possible that reformulation to remove restricted substances might result in the use of alternatives with sparse toxicological datasets and unidentified hazards. This could potentially mean that reformulated inks also carry risks to human health.

Potential unintended consequences

Based on the information that the Agency has obtained from the public consultation and during stakeholder engagement, the following are identified as possible unintended consequences which could potentially mean the burden of ill health rises as a result of a restriction that was closely aligned with the EU restriction:

- Substitution of currently used pigments which have a long history of use with few reported skin (or systemic) reactions with alternatives that are less safe or less technically effective. The Agency has been made aware of two triarylcarbonium dyes which are being used as alternatives to PB 15:3 in inks supplied to the EU in 2022. According to one source, these dyes (which would need to be precipitated onto an insoluble carrier (laking) to make them useful for tattooing) have very poor lightfastness which would make this group of compounds ineffective when used in tattoo ink (MacEvoy, 2015). In addition to any other concerns that might arise for this class of colourants, the poor lightfastness means that a tattoo made with this colour may fade quickly which could prompt the tattooed person to redo their tattoo or get a new tattoo over the earlier tattoo. In this case, the skin at the site of the tattoo is subjected to the tattooing process multiple times, increasing the tissue

damage at the site and giving new opportunities for the site to become infected. The two dyes are:

  - Alkali Blue (Pigment Blue 61, CAS 1324-76-1; EC 215-385-2). This substance does not meet any of the criteria that would exclude it from use in tattoo and PMU inks but in an aqueous environment, the imine group in the molecule could undergo hydrolysis to produce a ketone and aniline. The health concerns associated with aniline include carcinogenicity, mutagenicity and skin sensitisation. Pigment Blue 61 therefore appears to be less safe than PB 15:3.

  - Blue 1 (CAS 3844-45-9; EC 223-339-8). This substance is used as a food colourant (E133). It does not meet any of the criteria that would exclude it from use in tattoo and PMU inks, but it is listed in Annex III of the CPR with a restriction for use in hair dyes (entry 190 - restricted for use in hair dyes with maximum threshold of 0.5%). The EU restriction and our restriction options currently do not have any requirements for substances that are listed in Annex III of the CPR. Given this and the poor lightfastness that has been identified for this colourant this does not seem to be a good alternative to PB 15:3.

- Substitution of currently used pigments with alternatives such as resin or acrylic-based colourants that could give rise to greater health risks during procedures such as laser removal. The Agency has been advised that, unlike mineral-based pigments, acrylics can solidify in the skin during laser treatment.

- Reformulated inks performing less well than existing formulations. Ink formulators are in the early days of reformulating products and there is limited experience of the way new inks behave in the skin in respect of healing times and longevity of the tattoo. Any change that extends the time a tattoo takes to heal increases the opportunities for infections to arise. If a tattoo does not have the longevity that the client desires, this could result in more people seeking to have tattoos redone or covered over with new tattoos or potentially seeking removal where they might otherwise have been happy with the original tattoo. Each of these procedures carries its own health risks and financial costs.

- Inks being supplied that have been inadequately sterilised during production. The Agency has been informed that currently there are no chemical preservatives that are permitted to be used in EU compliant inks which also comply with the requirements of the Biocidal Products Regulation. It has been reported to the Agency that alternative methods such as heat or x-ray sterilisation can cause chemicals in the ink to degrade, generating levels of aldehydes that exceed levels permitted within the EU restriction.

- Formulators supplying potentially non-compliant inks labelled as “practice ink” with the instruction not for use in human skin. The Agency has not been able to confirm if practice inks were supplied prior to the EU restriction or if this type of product only became available after the restriction was implemented. Such labelling could be used by suppliers to continue to supply inks with the same range of colours that were available before the EU restriction entered into application. One formulator reports that such inks seem to be taking market share in the EU away from inks that have been reformulated to comply (as far as the formulator can determine) with the EU restriction. It is not known if artists are using these inks only for practice or if these inks are being used on clients in contravention of the restriction. This may be done if the artist considers that the practice ink will give a better appearance to the tattoo compared with a reformulated compliant ink. This information could mean that in the EU, supply chains are finding ways to circumvent the EU restriction. A restriction that encourages non-compliance because it has very demanding requirements does not seem to be effective or practical.

- Customers receiving tattoos and PMU procedures assume that the relevant health and safety measures are in place therefore there is potential for some unintended consequences to arise in terms of adverse reactions if tattoo artists are administering non-compliant inks without the customers’ knowledge. Customers may go to tattoo artists who offer cheaper tattoos using non-compliant inks unaware of any potential health impacts.

- 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.

- The Agency is also aware that a petition has been opened in the EU (No. 0712/2022) requesting changes to the implemented EU restriction. The petitioner is calling on the European Commission to extend the transition period for pigments PB15 and PG7 to January 2026 and to make a realistic adjustment to the threshold values in Annex XVII to Regulation (EC) No 1907/2006 (REACH). It seems unlikely that such a petition would be raised (and as of 6 December 2022 garner 1207 supporters) unless this legislation as it is currently implemented is creating difficult to resolve problems for the industry. An earlier EU petition (No. 1072/2020) which opened in October

2020 and sought to remove PB 15:3 and PG 7 from the scope of the EU restriction garnered 178201 supporters.

4.7 Assumptions, uncertainties and sensitivities

4.7.1 Uncertainties related to the risk assessment

There are several sources of uncertainty in the information that has been used to prepare this proposal. They are summarised here. A more detailed description of the uncertainties and assumptions underpinning the risk assessment is provided in section 4 of the background document.

- There is considerable uncertainty around the scale of tattoo and PMU-related ill health in GB. It is therefore difficult to determine what impact a restriction that aims to regulate the composition of tattoo and PMU inks could have on tattoo and PMU-related ill health.
    - The NHS does not gather information about the number of tattoo-related ill health cases meaning there is no concrete information on how often people need medical help with tattoo related adverse effects. The Agency is therefore relying on data from a small number of studies looking at EU populations to estimate that on average, 1.8% of the GB population with tattoos or PMU may need medical attention.
    - The NHS also does not gather information about the types of ill health that are associated with tattoos or PMU. We don't know how many consultations relate to infections or trauma as opposed to substance related effects, and what treatment was required to alleviate the patients' symptoms. During the opinion forming stage, the Agency received anecdotal information from two hospitals suggesting tattoo complications are rarely seen and don't necessarily require removal of the tattoo.
    - The possibility of serious adverse health effects such as cancer cannot be excluded. The Agency has not identified any evidence demonstrating a link between tattooing and cancer; however the literature on long-term adverse health effects is sparse.
- There is also uncertainty about whether or not current ink products have the potential to cause harm owing to substances that may be present in those products.
    - Mixtures used for tattooing and PMU are complex in nature.
    - The full spectrum of substances in any given ink product cannot currently be determined. Also, we cannot currently quantify the amount of many substances which may be present in tattoo and PMU products.

- It is impossible to predict how each component of the mixture may interact with other substances within the product or once inserted into the skin.
- Some substances are present as poorly soluble particles. Although micron scale particles are more suitable for use for tattooing and PMU, the particle size distribution of poorly soluble substances may include nanoscale particles. It is not known if the particulate nature of these substances is having a negative effect on the health of people with tattoos or PMU.
- It is also not clear to what extent substances with phototoxic properties are contributing to adverse reactions.

- There are several sources of uncertainty in the data that underpin the exposure scenario which has been used to estimate the amount of substances which are delivered during a tattoo or PMU procedure.
  - The amount of ink that is delivered during a tattoo or PMU session will vary depending on the size of tattoo or PMU that is created, the skill of the person carrying out the procedure and the equipment being used. Experimental data on the amount of ink that is delivered into the skin is sparse meaning that assumptions have been made which aim to reflect a worst-case situation. While the exposure scenario is likely to overestimate the amount of substance that is delivered in the majority of cases, this cannot be guaranteed for all cases.
  - Little is known about the subsequent toxicokinetic behaviour of substances once the tattoo or PMU has been created. For example, the length of time that a substance resides in the skin, the amount that is translocated to other parts of the body, where in the body substances are located and the time the substance remains in the body have not been studied in any depth. Uncertainty also surrounds the transformations substances may undergo when in the skin or following translocation to other parts of the body. It has been suggested by medics that transformation products may be responsible for some cases of tattoo or PMU-related skin allergy.

- Taken together, the uncertainty about which substances are causing tattoo and PMU-related ill health, along with the uncertainty about the amount of substance that is delivered, the amount of substance that is retained in the body, the amount that is eliminated or transformed and the nature of any transformation products makes it impossible to provide meaningful estimates of the risks to an individual from substances that are present in tattoo and PMU inks. This also means that it is impossible to provide quantitative

estimates of the risks associated with each of the proposed restriction options or with any of the concentration limits that are proposed within the options.

4.7.2 Sensitivities related to the socio-economic analysis

This section draws on the work of ECHA (2019c) and is adapted to GB. Full details on the sensitivity analysis can be found in sections 4.2 and 6.3 of the background document. The sensitivity analysis considers alternative scenarios for the volume of ink on the market, share of non-compliant ink and increase/decrease of the total reformulation cost and the impacts these have on total restriction costs, cost-effectiveness, break-even and overall proportionality. Figures in this section have been rounded to the nearest hundred where appropriate.

The sensitivity scenarios show the impact on the total cost of the restriction, volume of non-compliant ink that needs replacing, 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. The measures are explained further in the bullet points below. Further detail and other scenarios are assessed as part of the sensitivity analysis in appendix 6.3 of the background document.

- **The total costs of the restriction** consider the sum of the substitution costs (when altered under the scenarios and annualised over 20 years) and the familiarisation costs (annualised over 20 years)
- **Replaced tattoo ink and PMU** is the volume of non-compliant ink on the GB market that would need replacing under the scenario
- **Cost-effectiveness** considers how much it costs to undertake each scenario. This takes the total costs of the restriction (bullet point 1) and divides by the volume of non-compliant ink on the market that needs replacing (bullet point 2)
- **Break-even** is presented as two scenarios; low and high, as this uses the low and high WTP figures seen earlier in the sections on benefits and break-even analysis.

The impact of these assumptions in isolation and when combined on the proportionality of the proposed restriction option modified RO2 are explained. The sensitivity scenarios show that the total costs of the restriction range from £86,800 to £173,800, the volume of ink that needs replacing on the market ranges from 16,100 to 37,900, the cost-effectiveness ranges from £3 to £9 per litre of non-compliant ink replaced on the market and the number of avoided surgical removals due to complications of tattoo inks break-even ranges from 381 to 763 (using low WTP values) and 42 to 84 (using high WTP values).

Overall, the total costs of the restriction are low (given they fall below the EANDCB threshold). The volume of ink that needs replacing on the market is low (compared to an annual volume of approximately 84,500 litres on the GB market). The restriction is deemed cost-effective and requires a relatively small number of cases to break-even.

5 Glossary

ALARA	As Low as Reasonably Achievable
ALARP	As Low as Reasonably Practicable
BaP	benzo[a]pyrene
BfR	German Federal Institute for Risk Assessment
CIEH	Chartered Institute of Environmental Health
CLP	Classification, Labelling and Packaging
CMR	Carcinogen/Mutagen/Reproductive Toxicant
COI	Cost of Illness
CPR	Cosmetic Products Regulation
CrVI	Hexavalent Chromium
DBP	dibutyl phthalate
DEHP	bis(2-ethylhexyl) phthalate
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
ECHA	European Chemical Agency
EU	European Union
GB	Great Britain
GBP	Great British Pound (*Pound Sterling*)
HSE	Health and Safety Executive
HSENI	Health and Safety Executive Northern Ireland
ILGRA	Interdepartmental Liaison Group on Risk Assessment
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
MCL	Mandatory Classification and Labelling
MDR	Medical Devices Regulation 2002
MIT	2-methylisothiazol-3(2H)-one
NHS	National Health Service
OPSS	Office for Product Safety and Standards
PAA	Primary Aromatic Amine
PAH	Polycyclic Aromatic Hydrocarbon
PMU	Permanent make-up
RAC	Risk Assessment Committee

RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RISEP	REACH Independent Scientific Expert Pool
RO	Restriction Option
RPC	Regulatory Policy Committee
SCCP	Scientific Committee on Consumer Products (*now Scientific Committee on Consumer Safety, SCCS*)
SEA	Socio-Economic Analysis
SEAC	Socio-Economic Assessment Committee
STOT RE	Specific Target Organ Toxicity- Repeat Exposure
STOT SE	Specific Target Organ Toxicity – Single Exposure
U.V.	Ultra-Violet
U.S.	United States
WCTP	World Congress of Tattoo and Pigment Research
WTP	Willingness To Pay

6 References

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Further information

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