ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): Substances in tattoo inks and permanent make up

IUPAC NAME(S): not applicable

EC NUMBER(S): not applicable

CAS NUMBER(S): not applicable

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

ECHA with Denmark, Italy and Norway[1].

VERSION NUMBER: 1.2

DATE: October 2017

[1] In addition, Germany has significantly contributed to the development of the dossier.

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

Definitions used in the proposal

Tattooing (tattoo procedure) is a practice whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is administered by intradermal injection of a tattoo ink.

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

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

Dyes are organic molecules that are soluble in general. Certain substances like titanium dioxide (TiO2) or barium sulphate (BaSO4) can be used as carriers for dyes used in tattoos, thereby forming "lakes" which are insoluble in water.

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

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

Tattoo ink is a mixture consisting of colourants and auxiliary ingredients, including possible impurities, that is ready to use and administered by intentional intradermal injection whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is made.

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

Summary

The preparation of this restriction dossier on substances in tattoo inks and permanent make-up (PMU) was initiated on the request of the Commission from 3 December 2015.[2]

It is estimated that 12% of European citizens are tattooed and that the prevalence in the younger generations (18 - 35 year olds) may be double that (JRC, 2016b). Tattoos may be injected into the dermis or other parts of the body (e.g. submucosal, intraocular, or under the tongue) of consumers. Cosmetic tattoos, also known as PMU, are used to resemble make-up (JRC, 2016b). It is estimated that between 3-20 % of the general population, depending on the Member State, may have PMU procedures carried out (JRC, 2016b).

The health effects reported after tattooing are mainly skin problems, 68% of persons being tattooed reported issues in one survey (Klugl, et al., 2010). However, the pigments in tattoo inks are known to distribute in the body and have been found in different organs such as the lymph nodes and the liver (Sepehri, et al., 2017a). In the same survey, 6.6 % of tattooed persons reported systemic reactions after tattooing. (Klugl, et al., 2010).

Seven Member States already have national legislation on tattoos based on a Council of Europe (CoE) resolution (ResAP(2003)2 and ResAP(2008)1) and have several year experience of enforcing this legislation. This restriction proposal has built on these existing laws.

The requested scope of the proposal by the Commission was to include all substances listed in the Council of Europe resolution ResAP(2008) and potentially any additional substances with a harmonised classification as CMR Category 1A and 1B or as skin sensitiser. In addition, the Dossier Submitter assessed other substances with effects on the dermis or eye tissue.

The conclusion of the Dossier Submitter's examination of the risk is that the use of certain threshold substances in tattoo inks and PMU mixtures is not adequately controlled. In addition, the Dossier Submitter has assessed that the use or presence of certain non-threshold substances in tattoo inks is also not adequately controlled based on the conclusions of a number of (semi)qualitative assessments. Therefore, an analysis was conducted of diverse risk management options (RMOs), such as other REACH regulatory measures than restriction, existing EU legislation and other possible Union-wide actions, to identify the most appropriate measure to address these risks and to define the scope and conditions of the restriction proposal.

On the basis of the analysis of the effectiveness, practicality and monitorability of these RMOs, it is proposed to introduce a restriction.

Proposed restriction

The Dossier Submitter has developed two restriction options (RO1 and RO2), that mainly differ in terms of the concentration limits proposed for the substances in the scope of the restriction and how the links with the Cosmetic Products Regulation (CPR) Annexes are managed.

[2] https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf/ed07424a-328d-88e0-b7c6-412251426582

Table 2 (Restriction option 1) and Table 3 (Restriction option 1) give the wording of the proposed restriction options: RO1 and RO2. They both restrict tattoo inks or permanent make-up from being:

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

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

Several definitions for tattoo ink, tattoo or PMU procedures are introduced. In addition, a labelling requirement is also proposed to list ingredients that would not be normally required under the classification, labelling and packaging regulation 2008 (CLP), the intended use of the mixture as a tattoo ink, a reference number and any relevant instructions for use. A transitional period of one year after its entry into force is proposed.

Both restriction options take into account the following:

- If a substance is not permitted in cosmetic products because it is not considered safe to apply on human skin, it is reasonable to assume that it is also not safe to be applied under the skin, i.e., where the substance is deposited in the dermis for a prolonged period of time.
- Substances classified as CMR (category 1A and 1B), are not permitted to be placed on the market or used for supply to the general public as substances on their own or as constituents of other substances or in mixtures (by virtue of entries 28 to 30 of Annex XVII to REACH) and should not be used in tattoo inks and PMU injected under the skin of members of the public.
- Substances whose hazard profile suggests that they lead to skin sensitisation, irritation or corrosion of the epidermis or eye damage or irritation, should not be applied under the skin (or in the eye), leading to exposure for a prolonged period of time.
- Conclusions of (semi-)quantitative risk assessment of substances that can be found in tattoo inks, on the basis of reasonable exposure estimates, demonstrate the need to take action.
- Industry will find it difficult to substitute some substances, in particular selected colourants. Taking into account the hazards and risks of the exposure to the relevant pigments, derogations are proposed for these substances.
- As it is possible for tattoo artists to stockpile pigment in powder form and mix tattoo inks, the restriction also puts the onus on tattoo artists and PMU practitioners to ensure that non-compliant inks are not used for tattoo or PMU purposes. This is done by proposing that tattoo inks and PMU not meeting the requirements are not used in tattoo and PMU procedures.

The main rational for considering two restriction options with different concentration limits is that colourants are often of low purity and therefore, a number of currently unknown impurities could potentially be contained in tattoo inks. As colourants are not manufactured by the formulators of tattoo inks, many such impurities of the manufacturing process could also be contained in the tattoo inks, which are mixtures of a colourant in solution of auxiliary ingredients.

Another reason a second restriction option is proposed is to decouple the restriction from future updates of Annex II and IV of the CPR. Although there is an advantage to take on board future changes implemented in the CPR Annex II and IV, as they would be relevant for tattoo inks, the decoupling of the restriction from a regulation not specifically geared towards tattoos and PMU would avoid legislative gaps that could arise.

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

Summary of the justifications

Identified hazard and risk

For the substances within the scope of the proposal, quantitative risk assessments were made for a number of threshold substances, such as substances toxic to reproduction and selected impurities with other threshold effects. In addition, certain non-threshold substances and impurities were risk assessed in a semi-quantitative way.

The remaining substances in the scope were assessed by a qualitative approach. However, the exposure scenario developed for intradermal injection of tattoo inks and PMU implies that exposure also to non-threshold substances would constitute a risk for consumers. The purpose of this qualitative risk characterisation is to assess the likelihood that these effects are avoided when receiving a tattoo. In addition, traditional operational conditions (OC) and risk managements measures (RMM), such as level of containment and use of personal protective equipment, do not have relevance to the intradermal injection of tattoo inks and PMU. The only way to manage the risk in the case of receiving tattoos is to limit the presence of unwanted substances in tattoo inks.

The Dossier Submitter therefore proposes that the substances should be restricted in tattoo inks based on the hazard classification for all substances classified with regard to skin sensitisation/irritation/corrosion, eye damage/ irritation, mutagenicity and carcinogenicity and with consideration to the exposure as described in 1.2.5 and Annex B.9, even if a quantitative risk assessment could not be performed. For the large number of substances that are covered by the qualitative risk assessment approach, an important assumption is that the effects when these substances are injected into the skin will be more severe than when applied on the skin.

The output of the quantitative assessment is a proposal for setting concentration limits for hazardous substances in tattoo ink. A total ban is not realistic, as this would ban tattooing as such, so the risk is proposed to be managed by setting concentration limits for the chemical substances in tattoo ink, as proposed in the chapter on risk management options (see 2.2).

For the substances assessed in a (semi-)quantitative manner, DN(M)ELs were derived and compared to the exposure assessment in the exposure scenario (see B.9). To identify the concentration limit, the content of the hazardous substance corresponding to a Risk Characterisation Ratio (RCR) < 1 or an excess risk < 10^{-6} was calculated.

When the content of the substances in tattoo and PMU ink is limited to the proposed concentration limits described below, the risk from exposure described in the exposure scenario for tattoos is considered to be adequately controlled for threshold substances with a quantitative approach. For non-threshold substances, such as carcinogens, a

cancer risk level of 10^{-6} could be seen as indicative tolerable risk level for the general population and has been used by the Dossier Submitter with derivation of DMELs for the purposes of deriving concentration limits. After introduction of concentration limits in tattoo inks, the risk defined as the probability that exposure to a hazardous substance will result in an adverse effect, such as the incidence of skin sensitisation observed and reported after receiving a tattoo, will also assumingly decrease.

Although no full quantitative analysis of the risks of all substances that are currently used in tattoo inks is possible, the available measured values for certain hazardous substances indicate that risks for human health cannot be excluded.

Justification that action is required on a Union-wide basis

The risks associated with EU manufactured or imported tattoo inks need to be addressed on a Union-wide basis for two reasons:

a) a harmonised high level of protection of human health and the environment, and

b) the free movement of goods within the Union.

Effectiveness

The proposed restriction is targeted at those substances that present risks to human health, through intradermal exposure.

The proposed restriction will reduce the risks to human health to an acceptable level from 2020.

The proposed restriction is considered to be proportionate to the risk because it is cost-effective, affordable for the impacted supply chains and requires very few avoided cases for its benefits to exceed its costs:

- The majority tattoo inks currently on the market meet the ResAP recommendations and requirements of national regulation in several Member States. As both restriction options (RO1 and RO2) propose concentration limits that are similar or higher than those enforced by Member State national legislation, it is expected that a high proportion of tattoo inks and PMU currently on the EU market will meet the proposed requirements.
- Technically feasible alternatives with similar or better hazard and risk profiles exist. For those where alternatives have not yet been identified, a derogation is proposed. (See Table 4 and section 2.2)
- The incremental substitution costs estimated to be incurred by downstream users of tattoo ink and PMU as a result of RO1 are about €4.4 million annually during the temporal scope of the analysis (in 2016 values). As RO2 imposes less strict requirements than ResAP and RO1, it is anticipated that more tattoo inks and PMU on the market are already compliant with RO2. Therefore, the substitution costs for RO2 would likely be lower than those estimated for RO1.
- Incremental enforcement (analytical testing and administrative) costs to be incurred over the temporal scope of the analysis are estimated at €235 000 annually for EEA31 (European Economic Area).
- Many formulators are small or micro enterprises. Those not already compliant with the CoE resolutions would experience the largest regulatory burden from the proposed restriction options.

- The adverse effects associated with exposure to chemicals in tattoo inks are grouped in: non-infectious inflammatory *(*plaque-like, papulo-nodular pattern, ulcerating patterns, hyperkeratotic, photosensitivity, other urticarial-like reactions, lymphopathic pattern, neurosensory reactions*),* systemic*,* malignant tumours, and reproductive and developmental.
- The restriction is expected to provide benefits related to avoided cases of tattoo removal due to complications caused by the substances in tattoo inks as well as avoided cases of other adverse effects (non-infectious inflammatory, systemic, reproductive, developmental, malignant). The proposal is affordable, cost effective and likely to be proportionate to the risk. The conclusions hold true also when allowance for uncertainties is made.

Table 1: Summary of costs and benefits of both restriction options

2016 values, euro, annual	Restriction Option 1 (RO1)	Restriction Option 2 (RO2)
Total Compliance Costs	€4.6 million	lower
Substitution	€4.4 million	lower
Enforcement	€0.2 million	similar
Social impacts	moderate	similar
Wider economic impacts	minimal	similar
Distributional impacts	minimal	similar
Cost-effectiveness	€60/litre non-compliant tattoo inks removed from the market	higher
Risk reduction capacity	it would reduce risks	possibly lower
Benefits	equivalent to the avoided cases of tattoo adverse effects (non-infectious inflammatory, systemic, reproductive, developmental, malignant)	possibly lower
Break-even	Lower than 320 – 1 050 avoided cases of tattoo removal due to non-infectious inflammatory complications	possibly fewer cases required for break-even

It is concluded that the proposed restriction is effective because it is targeted to the exposure that causes the risk, is capable of reducing the identified risk in a reasonable period, and it is likely to be proportionate to the risk.

Practicality

The proposed restriction options are practical because they are implementable, enforceable and manageable:

Implementability

- The proposed restriction options propose similar, and in the case of RO2, slightly less strict than the recommended measures in ResAP, which have been used as a basis for national legislation in seven Member States and two additional EEA members.
- Surveillance results have shown that the majority of tattoo inks and PMU are in compliance with national legislation, which suggests industry's ability to comply with the proposed restriction options.
- The proposed transitional period reflects the industry capability to comply with the proposed restriction options.

Enforceability

- Enforcement of national legislation based on ResAP is already taking place in just under a third of EEA31 Member States.
- Systems are in place (under the General Product Safety Directive) to monitor compliance of CoE resolution and to share information on non-compliant products – RAPEX.
- The dossier provides information on the substances found in tattoo inks that present risk to human health and highlights groups of substances that are considered most problematic. This will enable targeted surveillance at high risk substances, which would contribute to effective, lower cost monitoring.
- Analytical methods exist for all groups of substances in the scope of the proposed restriction options. Harmonisation of the applied analytical methods will be beneficial.
- Information on the limit of detection of the currently used methods has been taken into account in the setting of the concentration limits for individual and groups of substances in the scope of RO1 and RO2.

Manageability

- Given the similarity with existing measures (ResAP, the CPR, and the CLP Regulation) and the stakeholder's raised awareness of the issue, RO1 and RO2 should be clear and understandable to all the actors involved.
- The level of administrative burden is not expected to be higher than in the Member States with national legislation.
- The current compliance rate suggests that the existing regulations are manageable for industry.

<u>Monitorability</u>

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

- Member State surveillance programs and compliance controls, with the continued use of RAPEX.
- Tattoo artists and PMU practitioners who will have the obligation to inject intradermally only compliant inks.
- The introduction of separate, EU-harmonised diagnostic codes for tattoo ink and PMU complications by national health boards to enable tracking of adverse effects.

Proposed restriction

The scope of the two proposed restriction options (RO1 and RO2) are presented below.

Table 2 Restriction option 1 (RO1) – proposed scope

a) Substances in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as: – carcinogenic, mutagenic, or toxic to reproduction category 1A, 1B, and 2 – skin sensitising, category 1, 1A or 1B – skin irritant or corrosive, category 1A, 1B, 1C, or 2 – eye damaging and irritant, category 1 or 2 b) Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009 c) Substances on Annex IV of Regulation (EC) 1223/2009 that are subject to conditions in columns g to i of that Annex d) Substances in Table A[3]	1. Tattoo inks shall not be placed on the market if they contain the following substances as specified below. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) to 1.c), the stricter condition applies: a. Tattoo inks shall not contain the following substances, unless a concentration limit is specified under paragraph 2: i. Carcinogenic or mutagenic substances, category 1A, 1B and 2 excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation) ii. Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009 iii. The following substances in Annex IV of Regulation (EC) 1223/2009 with the following conditions in column g of that Annex: • Rinse-off products • Not to be used in products applied on mucous membranes • Not to be used in eye products b) Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than 0.1% w/w, unless a concentration limit is specified under paragraph 2: i. Skin sensitising substances, category 1, 1A and 1B ii. Skin irritant or corrosive substances, category 1A, 1B, 1C, and 2 iii. Eye damaging and irritant substances, category 1 and 2 c) Tattoo inks shall not be placed on the market if they contain substances toxic to reproduction: i. Category 1A and 1B in concentrations greater than 0.0014 % w/w ii. Category 2 in concentrations greater than 0.014% w/w 2. Tattoo inks or permanent make-up shall not be placed on the market if they contain substances listed in Table A,[3] exceeding the specified concentration limits, and Polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.0005% w/w 3. By way of derogation, paragraph 1 does not apply to substances (colourants) listed in Table B. 4. Substances in Annex IV of Regulation (EC) 1223/2009 allowed in cosmetic products are also allowed in tattoo inks, subject to the conditions in columns h to i of that Annex, unless a lower concentration limit is specified in paragraphs 1 and 2. 5. Tattoo inks not meeting the requirements specified in paragraphs 1 to 4 shall not be used in tattoo and permanent make-up procedures. 6. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides, in addition to that required by

[3] Table A contains methanol, impurities listed in Table 3 of CoE ResAP(2008)1, PAAs, and azo dyes.

	Regulation (EC) No 1272/2008, the following information: a. The intended use of the mixture as a tattoo ink; b. A reference number to uniquely identify the batch; c. The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal; d. The name of substances covered by the restriction proposal that are present in the ink at a lower concentration limit than the proposed one; e. Any relevant instructions for use. The labelling shall be clearly visible, easily legible and appropriately durable. The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information labelling shall be included on the instructions for use. The information on the label shall be made available to any person who will undergo the tattooing procedure before the procedure is undertaken. 7. Definitions for the purpose of this restriction entry a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional intradermal injection whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is made. b. Tattoo or permanent make-up procedure is the intradermal injection of tattoo ink (or permanent make-up). 8. The restriction shall apply one year after its entry into force.

Note: Supplementary Table A is included in Table 4 and Supplementary Table B in Table 5

Table 3 Restriction option 2 (RO2) – proposed scope

a) Substances in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as: - carcinogenic, mutagenic, or toxic to reproduction category 1A, 1B, and 2 - skin sensitising, category 1, 1A or 1B - skin irritant or corrosive, category 1A, 1B, 1C, or 2 - eye damaging and irritant, category 1 or 2 b) Substances in Table A[3] c) Substances in Table C[4] d) Substances in Table D[5] e) Substances in Table E[6]	1. Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than the relevant generic concentration limit in Part 3 of Annex I of Regulation (EC) No 1272/2008, unless a specific concentration limit is set in Part 3 of Annex VI of Regulation (EC) No 1272/2008: a. Carcinogenic and mutagenic substances, category 1A, 1B, and 2, excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation) b. Substances toxic to reproduction, category 1A, 1B and 2 c. Skin sensitising substances, category 1, 1A, and 1B d. Skin irritant and corrosive substances, category 1A, 1B, 1C, and 2 e. Eye damaging and irritant substances, category 1 and 2 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) to 1.e), the stricter condition applies. 2. Tattoo inks shall not be placed on the market if they contain the substances listed in Table A[3], exceeding the specified concentration limits, and polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.0005% w/w 3. Unless already specified in paragraphs 1 or 2, tattoo inks shall not be placed on the market if they contain the substances in Table C[4] and Table D[5], in concentrations exceeding 0.1 w/w. 4. Unless already specified in paragraphs 1 to 3, tattoo inks shall not be placed on the market if they do not meet the conditions for the substances in Table E.[6] 5. By way of derogation, paragraphs 1 to 4 do not apply to substances (colourants) listed in Table B 6. Tattoo inks not meeting the requirements specified in paragraphs 1 to 5 shall not be used in tattoo and permanent make-up procedures. 7. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides, in addition to that required by Regulation (EC) No 1272/2008, the following information: a. The intended use of the mixture as a tattoo ink; b. A reference number to uniquely identify the batch; c. The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal; d. The name of substances covered by the restriction proposal that

[4] Table C contains substances in Regulation (EC) 1223/2009 as of July 2017 prohibited for use in cosmetic products, i.e., Annex II.

[5] Table D contains substances in Regulation (EC) 1223/2009 as of July 2017 on Annex IV allowed for use in cosmetic products with conditions in column g: i) Colouring agents in cosmetic products intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover, ii) Colouring agents in cosmetic products intended not to come into contact with the mucous membranes, iii) Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin (rinse-off products).

[6] Table E contains substances in Regulation (EC) 1223/2009 as of July 2017 in Annex IV allowed in cosmetic products with conditions in columns h to i of that Annex (e.g., purity requirements, maximum allowed concentrations of the substances themselves or their constituents). These substances can be used in tattoo inks if the conditions in Annex IV of the CPR (and transferred in Table E) are met.

	are present in the ink at a lower concentration limit than the proposed one; e. Any relevant instructions for use. The labelling shall be clearly visible, easily legible and appropriately durable. The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information labelling shall be included on the instructions for use. The information on the label shall be made available to any person who will undergo the tattooing procedure before the procedure is undertaken. 8. Definitions for the purpose of this restriction entry a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional intradermal injection whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is made. b. Tattoo or permanent make-up procedure is the intradermal injection of tattoo ink (or permanent make-up). 9. The restriction shall apply one year after its entry into force.

Note: Supplementary Table A is included in Table 4 and Supplementary Table B in Table 5. Supplementary Table C, D and E are included in Appendix 1 of this report.

Table 4 Supplementary Table A to RO1 and RO2

Substance name	Other regulatory process names	EC#	CAS#	Proposed concentration limit	CPR Annex II	CPR Annex IV	In tattoo inks *	Harmonised classification (CLP Regulation)
Mercury		231-106-7	7439-97-6	0.00002% w/w	221		Yes	Repr. 1B Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1
Nickel		231-111-4	7440-02-0	0.001 % w/w	1093		Yes	Carc. 2 STOT RE 1 Skin Sens. 1 Aquatic Chronic 3 Carc. 2 STOT RE 1 Skin Sens. 1
Tin		231-141-8	7440-31-5	0.005 % w/w			Yes	
Antimony		231-146-5	7440-36-0	0.0002 % w/w	40		Yes	
Arsenic		231-148-6	7440-38-2	0.00000008% w/w	43		Yes	Acute Tox. 3 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1
Barium**		231-149-1	7440-39-3	0.84% w/w			Yes	
Cadmium		231-152-8	7440-43-9	0.00002% w/w	68		Yes	Carc. 1B Muta. 2 Repr. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1 Pyr. Sol. 1 Carc. 1B Muta. 2 Repr. 2 Acute Tox. 2

								STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1
Chromium‡		231-157-5	7440-47-3	0.00002% w/w	97		Yes	
Cobalt		231-158-0	7440-48-4	0.0025 % w/w			Yes	Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4
Copper**		231-159-6	7440-50-8	0.05% w/w		132	Yes	
Zinc		231-175-3	7440-66-6	0.23% w/w			Yes	Aquatic Acute 1 Aquatic Chronic 1 Pyr. Sol. 1 Water-react. 1 Aquatic Acute 1 Aquatic Chronic 1
Lead		231-100-4	7439-92-1	0.00007% w/w	289		Yes	Repr. 1A Lact.
Selenium		231-957-4	7782-49-2	0.0002 % w/w	297		Yes	Acute Tox. 3 Acute Tox. 3 STOT RE 2 Aquatic Chronic 4
Methanol		200-659-6	67-56-1	10.9% w/w			Yes	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT SE 1
o-Anisidine**	2-methoxyaniline	201-963-1	90-04-0	0.0005 % w/w	708		Yes	Carc. 1B Muta. 2 Acute Tox. 3
o-toluidine**	2-aminotoluene	202-429-0	95-53-4	0.0005 % w/w			Yes	Carc. 1B Eye Irrit. 2 Acute Tox. 3 Aquatic Acute 1
3,3'-dichlorobenzidine**	4-(4-amino-3-chlorophenyl)-2-chloroaniline	202-109-0	91-94-1	0.0005 % w/w	712		Yes	Carc. 1B Skin Sens. 1 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1
4-methyl-m-phenylendiamine**	2,4-toluenediamine	202-453-1	95-80-7	0.0005 % w/w	364		Yes	Carc. 1B Muta. 2 Skin Sens. 1 Repr. 2 Acute Tox. 3 Acute Tox. 4 STOT RE 2 Aquatic Chronic 2
4-chloroaniline**	-	203-401-0	106-47-8	0.0005 % w/w			Yes	Carc. 1B Skin Sens. 1 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1
5-nitro-o-toluidine**	-	202-765-8	99-55-8	0.0005 % w/w	1195		Yes	Carc. 2 Acute Tox. 3 Aquatic Chronic 3
3,3'-dimethoxybenzidine**	o-dianisidine	204-355-4	119-90-4	0.0005 % w/w	709		Yes	Carc. 1B Acute Tox. 4
4,4'-bi-o-toluidine**	-	204-358-0	119-93-7	0.0005 % w/w	721		Yes	Carc. 1B Acute Tox. 4 Aquatic Chronic 2
4,4'-Thiodianiline**	-	205-370-9	139-65-1	0.0005 % w/w	1159		Yes	Carc. 1B Acute Tox. 4 Aquatic Chronic 2
4-chloro-o-toluidine**	-	202-441-6	95-69-2	0.0005 % w/w			Yes	Carc. 1B Muta. 2 Acute Tox. 3 Aquatic Acute 1

								Aquatic Chronic 1
2-naphthylamine**	-	202-080-4	91-59-8	0.0005 % w/w	242		Yes	Carc. 1A Acute Tox. 4 Aquatic Chronic 2
Aniline**	aniline	200-539-3	62-53-3	0.0005 % w/w	22			Carc. 2 Muta. 2 Skin sens. 1 Eye Dam. 1 Acute Tox. 3 STOT RE 1 Aquatic Acute 1
Benzidine**	1,1'-biphenyl-4,4'-diamine 4,4'-diaminobiphenyl biphenyl-4,4'-ylenediamine	202-199-1	92-87-5	0.0005 % w/w	26			Carc. 1A Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1
p-toluidine**	4-aminotoluene	203-403-1	106-49-0	0.0005 % w/w				Carc. 2 Skin sens. 1 Eye Irrit. 2 Acute Tox. 3 Aquatic Acute 1
2-methyl-p-phenylenediamine**	2,5-toluenediamine	202-442-1	95-70-5	0.0005 % w/w				Skin Sens. 1 Acute Tox. 3 Acute Tox. 4 Aquatic Chronic 2
Biphenyl-4-ylamine**	4-Aminobiphenyl xenylamine 4-aminobiphenyl xenylamine	202-177-1	92-67-1	0.0005 % w/w	726			Carc. 1A Acute Tox. 4
4-o-tolylazo-o-toluidine**	4-amino-2',3-dimethylazobenzene AAT fast garnet GBC base o-aminoazotoluene	202-591-2	97-56-3	0.0005 % w/w	989			Carc. 1B Skin sens. 1
4-methoxy-m-phenylenediamne**	2,4-diaminoanisole	210-406-1	615-05-4	0.0005 % w/w	376			Carc. 1B Muta. 2 Acute Tox. 4 Aquatic Chronic 2
4,4'-methylenedianiline**	4,4'-diaminodiphenylmethane (MDA)	202-974-4	101-77-9	0.0005 % w/w	705			Carc. 1B Muta 2 Skin sens. 1 STOT SE 1 STOT RE 2 Aquatic Chronic 2
4,4'-methylenedi-o-toluidine**	-	212-658-8	838-88-0	0.0005 % w/w	707			Carc. 1B Skin sens. 1 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1
6-methoxy-m-toluidine**	p-cresidine	204-419-1	120-71-8	0.0005 % w/w	1162			Carc. 1B Acute Tox. 4
4,4'-methylenebis[2-chloroaniline]**	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4	0.0005 % w/w				Carc. 1B Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1
4,4'-oxydianiline**	p-aminophenyl ether	202-977-0	101-80-4	0.0005 % w/w	1160			Carc. 1B Muta. 1B Repr. 2 Acute Tox. 3 Aquatic Chronic 2
2,4,5-trimethylaniline**	-	205-282-0	137-17-7	0.0005 % w/w	1158			Carc. 1B Acute Tox. 3 Aquatic Chronic 2
4-Aminoazobenzene**	4-phenylazoaniline	200-453-6	60-09-3	0.0005 % w/w	990			Carc. 1B Aquatic Acute 1 Aquatic Chronic 1
p-Phenylenediamine**		203-404-7	106-50-3	0.0005 % w/w			Yes	Skin sens. 1 Eye Irrit. 2 Acute Tox. 3

								Aquatic Acute 1 Aquatic 1
Sulphanilic acid**	4-aminobenzenesulphonic acid	204-482-5	121-57-3	0.0005 % w/w	1257			Skin sens. 1 Skin Irrit. 2 Eye Irrit. 2
4-amino-3-fluorophenol **	-	402-230-0	399-95-1	0.0005 % w/w	1242			Carc. 1B Skin sens. 1 Acute Tox. 4 Aquatic Chronic 2
2,6-xylidine	2,6-dimethylaniline	201-758-7	87-62-7	0.0005 % w/w				Carc. 2 Skin Irrit. 2 Acute Tox. 4 STOT SE 3 Aquatic Chronic 2
Pigment Red 7 (PR7)/CI 12420	N-(4-chloro-2-methylphenyl)-4-[(4-chloro-2-methylphenyl)azo]-3-hydroxynaphthalene-2-carboxamide	229-315-3	6471-51-8	0.1% w/w		12	Yes	-
Pigment Red 9(PR9)/CI 12460	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	229-104-6	6410-38-4	0.1% w/w			Yes	-
Pigment Red 15 (PR15)/CI 12465	4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	229-105-1	6410-39-5	0.1% w/w			Yes	-
Pigment Red 210(PR210) /CI 12477		612-766-9	61932-63-6	0.1% w/w			Yes	-
Pigment Orange 74 (PO74)			85776-14-3	0.1% w/w			Yes	-
Pigment Yellow 65 (PY65)/CI 11740	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	229-419-9	6528-34-3	0.1% w/w			Yes	-
Pigment Yellow 74 (PY74)/CI 11741	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	228-768-4	6358-31-2	0.1% w/w			Yes	-
Pigment Red 12 (PR12)/CI 12385	3-hydroxy-4-[(2-methyl-4-nitrophenyl)azo]-N-(o-tolyl)naphthalene-2-carboxamide	229-102-5	6410-32-8	0.1% w/w			Yes	-
Pigment Red 14 (PR14)/CI 12380	4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxy-N-(2-methylphenyl)naphthalene-2-carboxamide	229-314-8	6471-50-7	0.1% w/w			Yes	-
Pigment Red 17 (PR17)/CI 12390	3-hydroxy-4-[(2-methyl-5-nitrophenyl)azo]-N-(o-tolyl)naphthalene-2-carboxamide	229-681-4	6655-84-1	0.1% w/w			Yes	-
Pigment Red 112 (PR112)/CI 12370	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	229-440-3	6535-46-2	0.1% w/w	1346	11	Yes	-
Pigment Yellow 14 (PY14)/CI 21095	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-	226-789-3	5468-75-7	0.1% w/w			Yes	-

	methylphenyl)-3-oxobutyramide]							
Pigment Yellow 55 (PY55)/CI 21096	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]	226-789-3	6358-37-8	0.1% w/w			Yes	-
Pigment Red 2 (PR2)/ CI 12310	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-phenylnaphthalene-2-carboxamide	227-930-1	6041-94-7	0.1% w/w			Yes	-
Pigment Red 22 (PR22)/ CI 12315	3-hydroxy-4-[(2-methyl-5-nitrophenyl)azo]-N-phenylnaphthalene-2-carboxamide	229-245-3	6448-95-9	0.1% w/w			Yes	-
Pigment Red 146 (PR146)/ CI 12485	N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	226-103-2	5280-68-2	0.1% w/w			Yes	-
Pigment Red 269 (PR269)/ CI 12466	N-(5-chloro-2-methoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	268-028-8	67990-05-0	0.1% w/w			Yes	-
Pigment Orange16 (PO16)/ CI 21160	2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutyramide]	229-388-1	6505-28-8	0.1% w/w			Yes	-
Pigment Yellow 1 (PY1)/ CI 11680	2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide	219-730-8	2512-29-0	0.1% w/w		4	Yes	-
Pigment Yellow 12 (PY12)/CI 21090	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutyramide]	228-787-8	6358-85-6	0.1% w/w	1263		Yes	-
Pigment Yellow 87 (PY87)/ CI 21107:1	2,2'-[(3,3'-dichloro-4,4'-biphenylylene)bis(azo)]bis[2',5'-dimethoxyacetoacetanilide]	239-160-3	15110-84-6, 14110-84-6	0.1% w/w			Yes	-
Pigment Yellow 97 (PY97)/ CI 11767	N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide	235-427-3	12225-18-2	0.1% w/w			Yes	-
Pigment Orange 13 (PO13)/ CI 21110	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]	222-530-3	3520-72-7	0.1% w/w			Yes	-
Pigment Orange 34 (PO34)/ CI 21115	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-	239-898-6	15793-73-4	0.1% w/w			Yes	-

	dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]							
Pigment Yellow 83 (PY83)/ CI 21108	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	226-939-8	5567-15-7	0.1% w/w		48	Yes	-
Solvent Red 1 (SR1)/ CI 12150	1-[(2-methoxyphenyl)azo]-2-naphthol	214-968-9	1229-55-6	0.1% w/w	1231			-
Acid Orange 24 (AO24)/ CI 20170	Sodium 4-[[3-[(dimethylphenyl)azo]-2,4-dihydroxyphenyl]azo] benzenesulphonate	215-296-9	1320-07-6	0.1% w/w	1232			-
Solvent Red 23 (SR23)/ CI 26100	1-(4-(phenylazo)phenylazo)-2-naphthol	201-638-4	85-86-9	0.1% w/w	1353	51		-
Acid Red 73 (AR73)/ CI 27290	Sodium 6-hydroxy-5-(4-phenylazophenylazo)naphthalene-2,4-disulphonate	226-502-1	5413-75-2	0.1% w/w	1233			-
Disperse Yellow 3/ CI 11855	N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]acetamide	220-600-8	2832-40-8	0.1% w/w	1055			Carc. 2 Skin Sens. 1
Solvent Yellow 1/ CI 11000	4-aminoazobenzene 4-phenylazoaniline	200-453-6	60-09-3	0.1% w/w	990			Carc. 1B Aquatic Acute 1 Aquatic Chronic 1
Solvent Yellow 3/ CI 11160	4-amino-2',3-dimethylazobenzene 4-o-tolylazo-o-toluidine AAT fast garnet GBC base o-aminoazotoluene	202-591-2	97-56-3	0.1% w/w	989			Carc. 1B Skin Sens. 1
Acid Green 16	sodium 4-{[4-(diethylamino)phenyl][4-(diethyliminio)cyclohexa-2,5-dien-1-ylidene]methyl}naphthalene-2,7-disulfonate	603-214-8	12768-78-4	0.1% w/w				
Acid Red 26	Disodium 1-(2,4-dimethylphenylazo)-2-hydroxynaphthalene-3,6-disulphonate	223-178-3	3761-53-3	0.1% w/w				
Acid Violet 17	Hydrogen [4-[[4-(diethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	223-942-6	4129-84-4	0.1% w/w				
Basic Red 1 , Basic red 1	9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride	213-584-9	989-38-8	0.1% w/w			Yes	
Disperse Blue 106	Ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-	602-285-2	12223-01-7	0.1% w/w				

Disperse Blue 124	Disperse Blue 124	612-788-9	61951-51-7	0.1% w/w				
Disperse Blue 35	C.I. dDisperse Blue 35	602-260-6	12222-75-2	0.1% w/w				
Disperse Orange 37	Propanenitrile, 3-[[4-[2-(2,6-dichloro-4-nitrophenyl)diazenyl]phenyl]ethylamino]-	602-312-8	12223-33-5	0.1% w/w				
Disperse Red 1	2-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]ethanol	220-704-3	2872-52-8	0.1% w/w				
Disperse Red 17	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	0.1% w/w				
Disperse Yellow 9	N-(2,4-dinitrophenyl)benzene-1,4-diamine	228-919-4	6373-73-5	0.1% w/w				
Pigment Violet 3	4-[(4-Aminophenyl)-(4-methyliminocyclohexa-2,5-dien-1-ylidene)methyl]aniline	603-635-7	1325-82-2	0.1% w/w				
Pigment Violet 39	Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, molybdatephosphate	264-654-0	64070-98-0	0.1% w/w				
Solvent Yellow 2	4-dimethylaminoazobenzene	200-455-7	60-11-7	0.1% w/w				
Bis(2-ethylhexyl) phthalate†	DEHP	204-211-0	117-81-7	0.07% w/w	677		Yes	Repr. 1B
Dibutyl phthalate†	DBP	201-557-4	84-74-2, 93952-11-5	0.009 % w/w	675		Yes	Repr. 1B Aquatic Acute 1

Notes: *Substances found in tattoo inks and PMU. **Soluble. ‡Chromium VI. †RO2 only.

Table 5 Supplementary Table B to RO1 and RO2

Substance name	Substance market name	EC #	CAS #	Registered	CPR Annex II #	CPR Annex IV #	Allowed subject to conditions	In tattoo inks*	Has impurity	Hazard classification with percent notifications	Notification #
1,4-bis(p-tolylamino)anthraquinone	Solvent Green 3, CI 61565	204-909-5	128-80-3	Y	1364	91			Y	Not Classified (93.0%), Aquatic Chronic 4 (4.1%), Eye Irrit. 2 (2.4%), Skin Irrit. 2 (2.4%), STOT SE 3 (2.2%), Carc. 2 (0.2%), Muta. 2 (0.2%), STOT RE 2 (0.2%), Skin Sens. 1 (0.1%)	1680
29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper	Pigment Blue 15, CI 74160	205-685-1	147-14-8	Y	1367	105		Y	Y	Not Classified (97.9%), Aquatic Chronic 4 (1.4%), Skin Sens. 1 (1.4%), Aquatic Chronic 1 (0.4%), Aquatic Chronic 3 (0.4%), Aquatic Acute 1 (0.3%), Eye Irrit. 2 (0.1%), Skin Irrit. 2 (0.1%)	1403
Dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)amino](4-hydroxy-2-sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, disodium salt	Fast Green FCF, CI 42053	219-091-5	2353-45-9	Y	1357	61			Y	Eye Irrit. 2 (42.2%), STOT SE 3 (42.2%), Skin Irrit. 2 (42.2%), Not Classified (24.3%), Muta. 2 (18.9%), Carc. 2 (13.5%)	185
6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one	VAT Red 1, CI 73360	219-163-6	2379-74-0	Y	1365	100		Y	N	Not Classified (86.8%), Aquatic Acute 1 (10.5%), Aquatic Chronic 1 (10.5%), Skin Sens. 1 (0.5%)	219
Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate	Red, CI 14700	224-909-9	4548-53-2	Y	1341	18			Y	Not Classified (100.0%)	185
N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide	Pigment Red 5, CI 12490	229-107-2	6410-41-9	Y	1347	14		Y	Y	Not Classified (98.7%), Skin Sens. 1 (1.3%)	223
Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate	Pigment Red 63:1, CI 15880	229-142-3	6417-83-0	Y	1349	29		Y	Y	Not Classified (97.9%), Aquatic Chronic 3 (0.4%)	243

1,2-dihydroxyanthraquinone	Pigment Red 83, CI 58000	200-782-5	72-48-0		1361	86			N	Acute Tox. 4 (56.8%), Eye Irrit. 2 (27.3%), Skin Irrit. 2 (22.7%), Not Classified (20.5%)	44
1-hydroxy-4-(p-toluidino)anthraquinone	Solvent Violet 16, CI 60725	201-353-5	81-48-1		1363	89			Y	Not Classified (90.7%), Aquatic Chronic 4 (4.9%), Skin Sens. 1 (4.1%)	1 420
Sodium 4-(2,4-dihydroxyphenylazo)benzenesulphonate	Acid Orange 16, CI 14270	208-924-8	547-57-9		1330	17			N	Not Classified (100.0%)	8
4-(phenylazo)resorcinol	Solvent Orange 1, CI 11920	218-131-9	2051-85-6		1343	7			N	Eye Irrit. 2 (51.9%), STOT SE 3 (51.9%), Skin Irrit. 2 (51.9%), Not Classified (48.1%)	135
Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate	Food Black 2, CI 27755	218-326-9	2118-39-0		1354	52		Y	N	Not Classified (100.0%)	32
Polychloro copper phthalocyanine when used as a substance in hair dye products, Polychloro copper phthalocyanine	Pigment Green 7; CI 74260	215-524-7	1328-53-6	Y	1369	107		Y	N	Not Classified (97.3%), Eye Irrit. 2 (2.7%), Acute Tox. 4 (2.1%), STOT SE 3 (0.4%)	845
1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085) and its salts when used as a substance in hair dye products, 1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol and its insoluble barium, strontium and zirconium lakes, salts and pigments, Pigment red 4	CI 12085/Red	220-562-2,	2814-77-9	Y	1345	9	3%	Y	Y	Not Classified (90.4%), Aquatic Chronic 4 (9.6%), Eye Irrit. 2 (9.6%)	240
Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate (Acid Red 27; CI 16185) when used as a substance in hair dye products, Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate	CI 16185 / ACID RED 27	213-022-2	915-67-3	Y	1350	33	Purity criteria as set out in Commission Directive 95/ 45/EC (E 123)		Y	Not Classified (63.0%), Eye Irrit. 2 (36.3%), STOT SE 3 (36.3%), Skin Irrit. 2 (36.3%), Aquatic Chronic 3 (0.7%)	146
Ethanaminium, N-(4-((4-diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-	CI 42051 / ACID BLUE 3	222-573-8	3536-49-0		1356	60	Purity criteria as set out in Commissio		Y	Not Classified (100.0%)	134

2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1) (Acid Blue 3; CI 42051) when used as a substance in hair dye products, Ethanaminium, N-(4-((4-(diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethylhydroxide, inner salt, calcium salt (2:1) and its insoluble barium, strontium and zirconium lakes, salts and pigments							n Directive 95/ 45/EC (E 131)				
2-(6-Hydroxy-3-oxo-(3H)xanthen-9-yl)benzoic acid; Fluorescein and its disodium salt (Acid Yellow 73 sodium salt; CI 45350) when used as a substance in hair dye products, Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate	CI 45350/ Yellow	208-253-0	518-47-8	Y					Y	Not Classified (87.0%), Eye Irrit. 2 (11.4%), Skin Irrit. 2 (10.6%), Acute Tox. 4 (0.8%), Muta. 1A (0.8%)	254
	CI 45350/ Yellow	219-031-8	2321-07-5	Y	1332	74	6%		N	Eye Irrit. 2 (88.7%), Not Classified (8.3%), STOT SE 3 (0.6%), Skin Irrit. 2 (0.6%)	168
4′,5′-Dibromo-3′,6′-dihydroxyspiro[isobenzofuran-1(3H),9′-[9H]xanthene]-3-one; 4′,5′-Dibromofluorescein; (Solvent Red 72) and its disodium salt (CI 45370) when used as a substance in hair dye products, 4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one and its insoluble barium, strontium and zirconium lakes, salts and pigments		209-876-0	596-03-2	Y			Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid		N	Not Classified (56.4%), Acute Tox. 3 (41.8%), Eye Irrit. 2 (1.8%), STOT SE 3 (1.8%), Skin Irrit. 2 (1.8%)	55
	CI 45370 / SOLVENT RED 72/ Orange	224-468-2	4372-02-5		1333	75					
2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)benzoic acid; Fluorescein, 2′,4′,5′,7′-tetrabromo-; (Solvent Red 43), its	CI 45380/ Red	239-138-3	15086-94-9	Y			Not more than 1 % 2-(6-hydroxy-3-oxo-3H-		Y	Acute Tox. 4 (60.4%), Not Classified (37.5%), Skin Sens. 1 (2.1%)	48
	CI 45380 / PIGMENT	240-005-7	15876-39-8	Y	1334	76			N	Not Classified (100.0%)	6

disodium salt (Acid Red 87; CI 45380) and its aluminium salt (Pigment Red 90:1 Aluminium lake) when used as a substance in hair dye products, Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	RED 90:1 ALUMINUM LAKE CI 45380 / ACID RED 87	241-409-6	17372-87-1	Y			xanthen-9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid		Y	Eye Irrit. 2 (84.4%), Not Classified (10.6%), Eye Dam. 1 (4.5%), Acute Tox. 4 (0.5%)	443
2',4',5',7'-Tetraiodofluorescein, its disodium salt (Acid Red 51; CI 45430) and its aluminium salt (Pigment Red 172 Aluminium lake) when used as a substance in hair dye products, Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthen-9-yl)benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	CI 45430 / PIGMENT RED 172 ALUMINUM LAKE CI 45430 / ACID RED 51	235-440-4 240-474-8	12227-78-0 16423-68-0	Y Y	1337	80	Purity criteria as set out in Commission Directive 95/ 45/EC (E 127)		N Y	Not Classified (92.1%) Acute Tox. 4 (93.2%), Aquatic Chronic 4 (26.1%), Not Classified (5.9%), Aquatic Chronic 3 (0.9%)	63 222

Notes: *Substances found in tattoo inks and PMU. Source *(JRC, 2015b)*

Report

1. The problem identified

1.1. Scope and general information

1.1.1. Introduction

The popularity of tattoos and permanent make-up (PMU) has been steadily increasing in the last few decades (JRC, 2016a). It is estimated that 12% of European citizens are tattooed and that the prevalence in the younger generations (18 - 35 year olds) may be double that (JRC, 2016b). Traditionally used dyes and pigments (hereafter also termed colourants) are being replaced by new colourants. Colourants based on toxic heavy metals like mercury and lead have largely been replaced by azo colourants. This development coincides with an increase in reports of adverse reactions to tattoo inks and thus, poses a challenge for their regulation and risk assessment (Laux, et al., 2016). Tattoos may be injected into dermis or other parts of the body (e.g. submucosal, intraocular, or under the tongue) of consumers.

The prevalence of PMU in Europe has only seldom been reported and where reported, it varies quite a bit between countries. The only data available estimates a prevalence of PMU between 3-20 % of the general population, depending on country (JRC, 2016b). In this Annex XV report, the term "tattoo inks" is used to denote inks used for both tattoos and PMU, unless specifically stated otherwise.

In a 2010 survey carried out in German-speaking countries (Klugl, et al., 2010), about 68% of tattooed people reported skin problems and 6.6% reported systemic reactions after tattooing. After several weeks, 9% of tattooed people reported they still had health problems and 6% reported they had persistent health problems. Coloured tattoo inks have been shown to be mainly responsible for the adverse skin reactions reported following persons being tattooed (Wenzel, et al., 2013). Studies or surveys in Denmark show that chronic adverse effects are dominated by reactions of an allergic nature, with red colourants being associated with the majority of the allergic reactions (Danish EPA, 2012). Reactions can appear months or years after the tattoo was completed. This is a remarkably long period of sensitisation induction and, although the exact mechanism has not yet been elucidated, this delayed complication is an indication that intradermal deposit of tattoo pigments results in lifelong exposure and can potentially have a negative effect on human health (Laux, et al., 2016). In addition, the pigments are also known to be distributed in the body and have been found in different organs such as the lymph nodes and the liver (Sepehri, et al., 2017a). In the case of PMU applications, the most common complications are patients' dissatisfaction resulting from "misapplication of the pigment, pigment migration, and pigment fanning[7]" (De Cuyper, 2010).

Most tattoo inks on the EU market are manufactured in the United States, while PMU inks are generally produced in Europe, in particular in Germany, Italy, Spain and the United Kingdom. Currently, as the tattoo ink market represents only a marginal fraction of the global production of colourants, the pigments used in tattoo and PMU inks are not specifically produced for such purposes. (JRC, 2016b) They may therefore contain levels

[7] Pigment fanning is unintentional migration of pigmentation in the surrounding areas of the tattoo or PMU.

of impurities that are not appropriate when such colourants are injected into humans. A report by the Joint Research Centre (JRC, 2016b) states that more than 100 colourants and additives are in use in tattoo inks, with numerous impurities found. However, it is possible that other substances not identified by the JRC may currently be used or might be used in the future as substitutes. This means a narrow scope in terms of the substances included will not suitably address the risk.

Tattoo inks are used by tattoo artists to produce tattoos in a variety of sizes and designs. The total number of tattoo artists (professional artists) in the EU is not known but in six Member States with national legislation, 14 700 – 27 000 artists are registered. Approximately 162 800 litres of tattoo inks (and PMU) are estimated to be placed on the EEA market (European Economic Area) per year. It is also estimated that there are large numbers of non-registered tattooists, outnumbering the professional tattoo artists in many countries (perhaps 1:2.5).

The absence of appropriate data for ink composition, information on the intrinsic properties of some components/impurities and on the fate of inks in the body makes assessing the risks a major challenge (Laux, et al., 2016). However, it is well known that tattoo inks can and do contain substances of concern such as identified carcinogens and skin sensitisers. Polycyclic aromatic hydrocarbons (PAH) (43%), primary aromatic amines (PAA) (14%), and heavy metals (9%) were detected in the indicated percentages of the analysed samples in one report (JRC, 2016b). In addition, the formulations used for tattooing might also contain phenols or formaldehyde. Risks of health effects other than dermal effects, such as systemic cancers, reproductive effects etc. cannot be ruled out.

Another major challenge is the lack of harmonised analytical methods for the analysis of some of the components of tattoo/PMU inks, e.g., for azo dyes. There is a need for such methods to be developed. However, it should be noted that Member States do enforce the current Council of Europe resolution ResAP(2008)1 (CoE, 2008) where the numbers and types of substances are similar to the proposed restriction.

The number of chemicals in the scope of the restriction proposal are substantial, and this may raise the difficulty of analysing all the substances to ensure compliance. Therefore, it may be necessary to take a similar enforcement response to the current Member State legislation and concentrate on analysing for certain key substances.

1.1.2. Commission request

The Commission requested ECHA to assess the human health risk, the relevant socio-economic impacts and the need for European Union-wide action beyond any national measures already in place by preparing an Annex XV dossier for a restriction of tattoo inks. This request was due to concerns for public health (e.g., allergies and possible carcinogenicity) owing to the composition of tattoo inks. Seven Member States already have national legislation in place that regulates, among others, the chemical composition of tattoo inks, while three others have notified their intention to introduce similar legislation.

The Commission requested that the Annex XV dossier address all substances listed in the Council of Europe (CoE) resolution ResAP(2008)1 (CoE, 2008) and any additional substances with a harmonised classification as CMR Category 1(a) and 1(b) and 2 or as a skin sensitiser. Four Member States, Denmark, Germany, Italy and Norway supported ECHA in developing the restriction proposal. Before making the request, the Commission

considered several options to deal with this issue, such as a stand-alone measure, using Article 68(2) of REACH and the current option of requesting ECHA to prepare a dossier under Article 69(1) of REACH. In conclusion, the Commission decided to make the current request to ECHA due to the Article 68(2) option being limited to CMR category 1A and 1B substances and the stand alone measure could not be implemented in a short-medium term.

1.1.3. National legislation

In 2000, the Scientific Committee on Cosmetics and Non Food Products (SCCNFP) in its opinion[8] noted the large number of colourants used in tattooing for which the chemical structure, identity, and toxicological profile are incomplete or unknown, thereby precluding a proper risk assessment. As a result, the SCCNFP called for a systematic information gathering by the JRC and DG SANCO, which was done in collaboration with the CoE. On the basis of this review (Papameletiou, et al., 2003), the SCCNFP concluded in its opinion of 20 October 2003 that tattooing colourants and piercing materials represent a legal paradox in the EU. Although they are used for cosmetic purposes, the route for their administration (injection/skin penetration) puts them outside the scope of the Cosmetics Directive (76/768/EEC). Tattooing dyes were therefore to be considered as general consumer products and hence, to be regulated under the General Product Safety Directive (92/59/EEC) or possibly under the Limitations Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC, today REACH). (SCCNFP, 2003).

In 2003, the CoE published a resolution on requirements and criteria for the safety of tattoos and permanent make-up ResAP(2003)2,[9] which was revised in 2008 by Resolution ResAP(2008)1.[10] The Resolutions laid out a number of provisions related to the chemical composition of tattoo inks as well as tattoo practices to ensure that tattoo and PMU products do not endanger the health and safety of humans. With respect to the chemical composition, ResAP (2008)1 specifies the following requirements for tattoo and PMU products:

[8] Opinion of The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning the Safety of Tattoos adopted by the SCCNFP during the 11th Plenary meeting of 17 February 2000 available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out108_en.htm

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

[10] Adopted by the Committee of Ministers on 20 February 2008 at the 1018th meeting of the Ministers' Deputies of the CoE https://wcd.coe.int/ViewDoc.jsp?p=&Ref=ResAP(2008)1&Language=lanEnglish&Ver=original&direct=true

- they do not contain or release the aromatic amines listed in Table 1 of ResAP (2008)1[11] in concentrations that are technically avoidable according to good manufacturing procedures; the presence or release of these aromatic amines should be determined by using appropriate test methods which should be harmonised across the member states in order to ensure comparable health protection of the consumer and to avoid divergent enforcement, drawing on existing methods which can serve as models (specified in Tables 4.a-c of ResAP (2008)1);
- they do not contain substances listed in Table 2 of ResAP (2008)1) (i.e., selected colourants);[12]
- they do not contain substances listed in Cosmetic Products Directive (CPD) - now CPR Annex II;
- they do not contain substances with specified conditions in CPD Annex IV (columns 2 to 4) – now CPR column g;
- they do not contain carcinogenic, mutagenic and reprotoxic substances of categories 1A, 1B or 2 which are classified under CLP;
- they comply with maximum allowed concentrations of impurities listed in Table 3 of ResAP (2008)1 (metals and PAHs) and the minimum requirements for further organic impurities for colourants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC;
- preservatives should only be used to ensure the preservation of the product after opening and not as a correction of insufficient microbiologic purity in the course of manufacture and of inadequate hygiene in tattooing and PMU practice;
- preservatives should only be used after a safety assessment and in the lowest effective concentration (ResAP (2008)1).

The main differences between ResAP(2008)1 and its predecessor (ResAP(2003)2) are their recommendations with respect to preservatives and impurities (Table 3).

The European Commission launched a research project in 2014 to gather and scrutinise all available information to enable the consideration of the need for a coordinated initiative on tattoo and PMU inks at EU level. The work of the European Commission is summarised in four publications on the Safety of tattoos and permanent make-up. The reports present an updated review of the national legislative framework, ink ingredients in use and reported adverse health effects, as well as new data on analytical methods, statistics, market surveillance and RAPEX (Rapid alert system for non-food dangerous products) notifications, risk perception and communication and experience with the implementation of the CoE resolutions. (JRC, 2015a), (JRC, 2015b), (JRC, 2016a), (JRC, 2016b)

A number of EU Member States have translated the CoE ResAP(2008)1 into national law:

[11] List of aromatic amines, particularly with regard to their carcinogenic, mutagenic, reprotoxic and sensitising properties, which should neither be present in tattoos and PMU products, nor released from azo colourants

[12] Non-exhaustive list of substances, particularly with regard to their carcinogenic, mutagenic, reprotoxic and/or sensitising properties, which tattoo and PMU products should not contain

- Seven EU Member States have a specific national tattoo legislation in place based either on CoE ResAP(2003)2 (Belgium, France, Germany and the Netherlands), or on CoE ResAP(2008)1 (Spain, Slovenia, and Sweden);
- Three EU Member States – Austria, Denmark and Latvia – have prepared draft legislation based on the CoE ResAP(2008)1;[13]
- Other EFTA countries with legislations are: Liechtenstein – based on the CoE ResAP(2008)1, while those of Norway and Switzerland are based on the CoE ResAP(2003)2; however, Switzerland has also introduced the recommended thresholds for heavy metals and PAHs of the ResAP(2008)1. No data were available on Iceland (JRC, 2015a), (Hauri, 2016).

In Italy, ResAP(2008)1 is not mandatory but the Legislative Decree # 206/2005, on the basis of Directive 2001/95/CE, confirms its binding power. For this reason, tattoo inks placed on the Italian market need to be in accordance with this legal framework (Renzoni, et al., 2015). However, there are differences on a regional level in Italy (ECHA CfE, 2016).

Of all Member States who have incorporated ResAP in their national legislation, only Spain maintains a positive list of tattoo inks that can be placed on the market. Tattoo inks in Spain are covered by the national legislation on cosmetics. In addition to adopting the principles of ResAP, tattoo inks have to be approved by the Spanish Agency for Medicines and Health Products on the basis of toxicological and quality data supplied by the distributor. Approved products are included in the positive list (Laux et al 2015).

1.1.4. General composition of tattoo inks and PMU

The substances in the scope of the proposed restriction belong to three distinct groups: colourants, impurities, and other auxiliary ingredients. Additional information on the function of the substances and composition of tattoo inks is presented in a report by the JRC (JRC, 2015b). More extensive information is also contained in Annex A and D.

a) Colourants

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

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

[13] Denmark and Austria in 2013 and Latvia in 2014 have notified draft national legislation on tattooing products and services. The proposed drafts are currently put on hold by the Commission as they are in conflict with REACH provisions.

2015b), which make them more compatible with the natural tones observed on the human body.

b) Impurities

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

c) Auxiliary ingredients

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

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

Preservatives in tattoo inks are under the scope of the Biocidal Products Regulation (BPR), therefore this category of substances will not be further examined as the continuing use of these substances is subject to the authorisation regime of the BPR. However, it should be noted that certain preservatives may be restricted for use in tattoo inks due to their harmonised classification (e.g., formaldehyde, 2-phenoxyethanol, triclosan, 3-iodo-2-propynyl butylcarbamate).

1.1.5. Scope of the restriction

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

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

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

1. Substances included based on their harmonised classification(s)[14]:

   - Substances classified as carcinogenic and mutagenic (CM), categories 1A, 1B and 2 are included in the restriction based on their hazardous properties of very high concern. This inclusion is justified based on their normally non-threshold hazards. Azo colourants that are not classified as CM category 1 or 2 may undergo decomposition to, contain residual aromatic amines that are so classified or are in table 2 of ResAP 2008 but not covered elsewhere). These azo colourants are also included in this qualitative or semi-quantitative risk argumentation (see Annex B.5.7/8 for more detail).

     - Substances classified as carcinogens or mutagens in Categories 1A, 1B and 2 only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation) are not included in scope. These substances are classified as carcinogens and mutagens through the inhalation route only, and are excluded from the scope of the restriction based on the current knowledge that their intrinsic carcinogenic and mutagenic properties will only be manifested as cancer and genetic defects after inhalation. This exclusion takes into account that most of the inks available on the market are liquid[15] and not inhaled by the recipient of the tattoo. In addition, the restriction does not cover the manufacture of the tattoo ink ingredients or formulation of the tattoo inks where inhalation may be a relevant exposure route.

   - Substances classified for reproductive toxicity (repro), categories 1A and 1B and 2 are normally considered to have a toxicological threshold and are therefore proposed to be restricted based on a quantitative assessment. This quantitative approach was established using 34 substances with harmonised classifications as repro 1A and 1B based on their individual thresholds for reproductive toxicity (see Annex B.5.9 for more detail). Substances classified for repro, category 2, are proposed to be restricted based on 'the principles used in the quantitative assessment of repro 1A and 1B substances.

   - Substances classified as skin sensitisers (SS) are included in the restriction proposal based on a qualitative assessment of their hazardous properties. This inclusion is justified as no reliable dose descriptor (i.e., a DNEL) can be set for skin sensitisation (see Annex B.5.5 for more detail).

   - Substances classified as skin corrosives, skin or eye irritants or as eye damaging are included in the restriction proposal based on a qualitative assessment of their hazardous properties (see Annex B.5.3/4 for more detail).

   - Lead compounds are included in the proposed restriction based on their non-threshold reproductive toxicity effects (EFSA's CONTAM Panel (EFSA 2013). These were acknowledged by RAC in the lead in jewellery and consumer product

[14] It has been proposed only to use harmonised classifications as using self-classifications may lead to a non-harmonised implementation of the measure due to differences in how companies assess the date for a substance. However, the Dossier Submitter has used the available notifications to propose priorities for future action on potential ingredients (see Appendix D.1).

[15] Some Tattoo inks may be provided in powder form and made up by tattoo artists into the final mixture.

restrictions, where it was concluded that there is no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity (including from *in utero* exposure), increases in systolic blood pressure and renal effects (e.g., changes in proteinuria, glomerular filtration rate (GFR) or creatinine levels and clearance)) (see Annex B.5.9 for more detail).

2. Substances included in the restriction based on their inclusion in the Cosmetic Products Regulation (CPR):
    - Substances on Annex II of the CPR (the list of substances prohibited in cosmetic products) are included in this restriction proposal as they are in Annex II of CPR on the basis of their risk to human health (see Article 14 of CPR). Therefore, no further risk assessment is needed (as an assessment under the CPR has been carried out, Annex I para 0.5 of REACH applies here). This justification is further supported by a specific assessment that substances prohibited in cosmetic products applied to the skin should also be prohibited from injection under the skin due to the potentially increased risk through circumventing the dermal barrier (see Annex B.5.11 for more detail).
    - A number of substances on Annex IV[16] of the CPR (the positive list of colourants allowed in cosmetic products) are included in this restriction proposal because their conditions in columns g-i of Annex IV (specific use restriction, maximum allowed concentration limits, purity requirements, etc.) mean if the substances are used in tattoo inks they may represent a risk to the consumer. (See Annex B.5.12 for more detail.)
3. Substances included in the restriction based on the CoE resolution (and national legislation):
    - Substances on the CoE Resolution lists that are not considered in the previous categories, i.e.:
        - 22 substances in Table 3 of ResAP(2008)1. Six substances are present in tattoo inks according to the JRC report (JRC, 2015b) and 14 other substances require individual assessment (see Annex B.5.13 for more detail).
        - 14 azo colourants in Table 2 of ResAP(2008)1 without harmonised classification and not included in point 1 above.

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

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

Table 6: Breakdown of substances in the restriction proposal

Total number of substances in scope:	Approximately **4 130**
1. Substances with harmonised classification in the CLP Regulation (EC) No 1272/2008 as:	Approximately **2 390**
a. carcinogenic and mutagenic Categories 1A, 1B, and 2	Only classified as Categories 1A and 1B: **862** Classified as Categories 1A, 1B, and 2 (including other relevant classifications): **1287**
b. reproductive toxicant Categories 1A, 1B, and 2	Only classified as Categories 1A and 1B: **74** Only classified as Category 2: **36** Classified as Categories 1A, 1B and Category 2 (with other relevant classifications): **368**
c. skin sensitisers Categories 1, 1A, and 1B	Only classified as skin sensitiser Categories 1, 1A and 1B: **415** Classified as skin sensitiser Categories 1, 1A and 1B (with other relevant classifications): **1 159**
d. skin irritant (Category 2), skin corrosive (Categories 1, 1A, 1B, 1C), eye irritant (Category 2) or eye damaging (Category 1) Irritation, corrosive.	Only classified as skin irritant (Category 2), skin corrosive (Category 1, Categories 1A, 1B, 1C), eye irritant (Category 2) or eye damaging (Category 1) Irritation, corrosive: **895** Classified as skin irritant (Category 2), skin corrosive (Categories 1, Categories 1A, 1B, 1C), eye irritant (Category 2) or eye damaging (Category 1) Irritation, corrosive (with other relevant classifications): **1 577**
2. Substances on CPR Annex II:	Total: **1 490** Classified as CMR Categories 1A, 1B and 2: **795** Classified as skin sensitiser Cat 1, 1A and 1B: **103**
3. Substances on CPR Annex IV: a. restricted due to conditions on use (in column g of Annex IV) b. allowed in tattoo inks under specific conditions (columns i-h of Annex IV):	Total on Annex IV: **260** Restricted due to conditions on use: **74** Allowed under specific conditions: **119** Classified as CMR or skin sensitiser/irritant/corrosive or eye irritant/damaging: **1**
4. Substances on CoE ResAP(2008)1 (CoE, 2008)	Approximately in total: **4 130** Excluding those in points 1-3: **36**

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

It should be noted that all the aspects not covered by the restriction proposal, such as general hygiene requirements or chemicals with no hazard classification, can therefore continue to be regulated at the Member State level provided that such national

requirements comply with the Treaty provisions on free movement and provision of services.

1.2. Hazard, exposure/emissions and risk

1.2.1. Identity of the substances, and physical and chemical properties

Please see 1.1.5 Scope and Appendix B1 for identity of the substances.

Physical and chemical properties are not included in this report due to the high number of substances included in scope (some specific parameters are included for specific substances assessed on a case-by-case basis).

1.2.2. Justification for targeting

The justification for targeting the substances in this restriction is explained under 1.1.1 introduction and 1.1.5 scope.

1.2.3. Classification and labelling

See appendix B1.

1.2.4. Hazard assessment

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

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

According to REACH Annex I para 1.1.2 and ECHA Guidance R.8 (ECHA, 2012), when no reliable dose descriptor can be set for a given endpoint, a qualitative approach (analysis) has to be taken. The relevant endpoints/hazard categories where a qualitative analysis is appropriate are: irritation/corrosion, sensitisation, carcinogenicity and mutagenicity. For most of these, a threshold cannot be identified. For endpoints where a threshold could be defined and DNELs could be derived, this was done for a selection of substances. In addition, for certain substances DMELs were derived for the purposes of risk characterisation and proposing concentration limits.

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

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

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

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

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

- substances with inherent properties that may cause an effect with no threshold. This is the case for most substances with C and M classifications (Annex B.5.7/8), as well as for lead compounds[17] (EFSA CONTAM Panel, 2013) (Annex B.5.9).
- substances classified as skin sensitisers, based on the observation that when allergens are deposited into the dermis via an injection, stronger sensitisation/elicitation reactions may occur and with lower doses than when deposited on the skin (Annex B.5.5). In theory skin sensitisers have thresholds, but data is very seldom available to set the threshold.
- substances classified as skin irritants / skin corrosive and eye irritants / eye damaging, based on the assumption that the effects will be more severe when these substances are injected into the skin rather than applied on the skin (Annex B.5.3/4). This assumption also applies to these substances when injected into the eyes.

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

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

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

- Methanol, due to its classification as STOT SE (Annex B.5.2).
- Primary aromatic amines (PAAs) and azo colourants (Annex B.5.7/8 and Appendix B.2).
- Substances classified for reproductive toxicity in hazard category Repr. 1A/B and 2 (Annex B.5.9 and Appendix B.3).
- Certain substances listed on table 3 of the CoE ResAP(2008)1 considered to be impurities in tattoo inks and PMU (Annex B.5.13 and appendices B.6-B.11).

Methanol

Methanol is classified for STOT SE 1 based on its effects on the optic nerve (nervus opticus) and central nervous system seen after a single exposure. Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values, specifies an OEL for methanol of 260 mg/m3 or 200 ppm for an 8 hour exposure, giving an exposure of 2.6 g/person/day, equivalent to 40 mg/kg bw/day.

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

This OEL is considered to be, in the majority of cases, also protective for very slight, sub-clinical Central Nervous System (CNS) effects of methanol inhalation, which are reported to start to appear at 270 mg/m3 (FIOH 2008). A NOAEL/LOAEL as basis for the OEL is not available. A DNEL of 8 mg/kg bw/day for the general population was calculated by the Dossier Submitter based on the exposure of 40 mg/kg bw/day and an assessment factor (AF) of 5.

Primary aromatic amines (PAAs) and azo colourants

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

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

Table 7 DMELs for PAAs

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

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

Substances classified for reproductive toxicity

Substances classified for reproductive toxicity in hazard category repro 1A/B due to their effects on sexual function and fertility in adults and developmental toxicity in offspring may exert their adverse effects when tattoo inks containing them are injected into dermis or other parts of the body (e.g. submucosal, intraocular, or under the tongue) of

consumers. To demonstrate a risk and to derive concentration limits for substances toxic to reproduction in tattoo inks and PMUs, a quantitative hazard assessment approach is used that considers the group of all currently known repro 1A/B-classified substances.

As a starting point all substances classified in CLP category repro 1A/B and not also classified as CM or SS were listed and named "reprotoxic only" substances. Traditionally, reprotoxic substances have been assumed to have an individual threshold level below which no adverse effect is expected, thus a quantitative hazard assessment approach was used to derive DNELs for the "reprotoxic only" substances. In line with this, dose descriptors (NOAEL/LOAEL) were identified from available studies and DNELs were derived in accordance with ECHA guidance R.8 (ECHA, 2012). Some of the substances that were assessed are known to have endocrine disrupting properties, e.g., phthalates. The Dossier Submitter still assessed reproductive toxicity as a threshold endpoint in this restriction proposal as this will indicate a minimum level of risk where the concern may be higher if there was no threshold due to any ED effects.

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

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

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

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

Table 3 in the CoE ResAP(2008)1 is a list of maximum allowed concentrations of impurities in products for tattoos and PMU. Some of the substances on this list were assessed in a (semi-)quantitative way, and DN(M)ELs were derived for these: arsenic, barium, copper, lead and zinc. Certain other substances on the list were included in the scope of the restriction due to the CM/SS qualitative approach (cadmium, cobalt, chromium (VI), mercury, nickel, polycyclic aromatic hydrocarbons (PAHs) and benzene-a-pyrene) (1.2.4.1). No assessment was carried out for the remaining substances on

Table 3 (selenium, antimony, and tin). The Dossier Submitter proposes that these substances are included in the scope of the proposed restriction as they are regulated in some Member States national restrictions based on CoE ResAP Table 3 and not including them may reduce the level of protection in those Member States. See the section on Risk Characterisation below for more explanation (1.2.6).

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

Substance	**Point of departure, POD**	**Information on key study**	**DMEL, general population, carcinogenic effects or DNEL STOT-RE**
Arsenic (As)	Excess lifetime risk of lung tumours = 1.7 x 10^{-3} per µg As/kg bw/day (as a systemic exposure)	Based on the WHO/FAO risk estimates from the Taiwanese drinking water cohort, using data from the most recent publications of Chen et al (2010a, 2010b), and 10^{-6} as an indicative tolerable risk level.	DMEL 0.0005882 µg As/kg bw/d
Barium (Ba)*	NOAEL 60 mg/kg bw/d	Nephrotoxicity in male rats at 60 mg/kg bw/d in NTP 13 week study, also supported by findings in female rats and in male/female mice (NTP 13 week study), as well as interim findings in female rats in the NTP 2 year study	DNEL 0.60 mg/kg bw/d
Copper (Cu)*	2 mg/L drinking water, equalling 2.2 mg Cu/day	Two mg/l equals a mean total copper intake of 2.2 mg/day (95th percentile would be 5.6 mg), if assuming a bw of 60 kg and a water intake of 1.1 l/d (or with the 95th percentile 2.8 l/d) to avoid GI irritation (WHO guidelines for drinking-water quality, 2004)	DNEL 0.037 mg/kg bw/d
Lead (Pb)	$BMDL_{01}$ 0.50 ug Pb/kg day	Effects on the developing nervous system including in utero (EFSA 2010/2013), applied by RAC (ECHA 2011; 2013).	DMEL 0.05 µg
Zinc (Zn)*	NOAEL 0.83 mg/kg bw/d	An EFSA report from 2006 (EFSA 2006) and supported by the SCCS opinion from 2017 (SCCS/1586/17) adopted a NOAEL of 50 mg/day or 0.83 mg Zn^{2+}/kg bw/day which is based on the absence of any adverse effects on a wide range of relevant indicators of copper-status as critical endpoint.	DNEL 0.166 mg/kg bw/d

* Soluble

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

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

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

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

1.2.5. Exposure assessment

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

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

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

Amount of ink injected

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

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

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

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

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

Tattooed Skin Area

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

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

According to a recent Danish survey (see Appendix F.1), repeated tattooing (i.e. repeated exposure) is quite common. For some persons repeated tattooing results in a full body part tattoo and for some even in a full body tattoo. With reference to both JRC (JRC, 2016b) and DEPA (Appendix F.1), it is assumed that 300 cm^2 skin is covered in a single tattoo session, and that this is repeated until the whole body, except for the face and hands, is covered. In the exposure scenario, it is assumed that the area of 300 cm^2 is completely covered with tattoo ink, although noticing that in many cases tattoos have a much simpler design, e.g. in many cases consisting only of written words and not covered 100% with ink.

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

Conclusion - The Realistic Worst Case Exposure Scenario

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

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

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

Comparison of the exposure with the long-term DNEL

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

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

Further, according to ECHA CSA Guidance R15 "as a conservative approach, the risk for a consumer exposure scenario can be characterised by comparing the event exposure over a day to this DNEL" (ECHA, 2016). Accordingly, in the risk characterisation the DN(M)EL related to lifetime exposure is still relevant even if the exposure event results from an "only one use"-event for a person receiving a single tattoo.

Exposure Scenario – Summary

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

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

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

1.2.6. Risk characterisation and derivation of concentration limits

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

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

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

According to ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012), a qualitative approach has to be chosen when no reliable dose descriptor (without identified thresholds) can be set for a given endpoint. In this proposal this applies to the effects skin irritation/corrosion, eye damage/eye irritation, sensitisation, and mutagenicity/carcinogenicity, with a few exceptions for substances for which a (semi-) quantitative approach was applied. The purpose of the qualitative risk assessment is to assess 'the likelihood that effects are avoided when implementing the exposure scenario…' as expressed in REACH Annex 1, Section 6.5.

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

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

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

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

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

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

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

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

When the content of the substances in tattoo and PMU ink is limited to the proposed concentration limits described below, the risk from exposure described in the exposure scenario for tattoos is considered to be adequately controlled for threshold substances with a quantitative approach. For non-threshold substances, such as carcinogens, a

cancer risk level of 10^{-6} could be seen as indicative tolerable risk level when setting DMELs for the general population and has been used by the Dossier Submitter to derive concentration limits ((ECHA, 2012) R. 8-14 Evaluating carcinogenicity risk levels).

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

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

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

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

1.2.6.1. Derivation of concentration limits for substances assessed in a qualitative manner

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

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

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

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

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

For the PAHs, under both RO1 and RO2, the Dossier Submitter proposes the same concentration limit for all PAHs with harmonised classification as CM as for the eight PAH

substances in REACH Annex XVII, entry #50 (6), for toys and childcare articles, namely: 0.00005% w/w.

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

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

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

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

Following the same rationale for substances on Annex II, under RO1 it is proposed that those substances on Annex IV with specific use restriction (i.e., allowed in cosmetic products with restrictions on their use on mucous membranes or eye products, and allowed in rinse-off products only) are not allowed in tattoo inks and PMU.

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

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

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

General approach for derivation of risk-based concentration limits:

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

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

Bodyweight 60 kg

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

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

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

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

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

Methanol

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

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

Primary aromatic amines (PAAs) and azo colourants

For primary aromatic amines (PAAs), the $DMEL_{general\ population,\ carcinogenic\ effects}$ of 2 x 10^{-5} mg/kg bw/day for aniline (see Table 7 in 1.2.4.2) was the lowest of the derived DMELs. This DMEL was carried forward to the risk characterisation as the most sensitive DMEL and used to establish a general concentration limit for all PAAs. This results in a risk-based concentration limit for PAAs in the ink of 0.00003% w/w (dissolved fraction) for each individual PAA. However, due to practicality and socio-economic reasons another concentration limit (5 ppm) is proposed in RO1 and RO2, see Annex D.

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

Substances classified for reproductive toxicity

Reprotoxic substances classified as "reprotoxic only" (classified as Repr. 1 A/B without being simultaneously classified as carcinogen, mutagen or sensitiser), were considered as a group and the lowest DNEL for this group (0.001 mg/kg bw/d) was carried forward to the risk characterisation as being protective for all reprotoxic substances classified as repro 1 A/B. This DNEL is also assumed sufficiently conservative to protect against potential risks from all substances which will be classified as repro 1 A/B in the future. The general approach for derivation of risk-based concentration limits described above was then used to derive a concentration limit. The proposed concentration limit for reprotoxic “only” substances under RO1 is 0.0014% w/w.

Under RO1 it is further proposed to extend the concept of ‘one concentration for all reprotoxic substances classified as category 1A/B to include also reprotoxic substances of category 2 assuming that the most sensitive DNEL of 0.001 mg/kg and the concentration limit of 13.9 ppm will be conservative enough to cover also the risks from

category 2 reprotoxins. Based on the fact that the generic concentration limit for category 2 reprotoxic substances in mixtures is tenfold higher than for category 1A/B reprotoxic substances, a pragmatic approach to include category 2 substances and to consider the potentially lower/uncertain potency has been implemented by applying a factor of 10 to the concentration limit for category 1A/B. The proposed concentration limit for category 2 reprotoxicants under RO1 is therefore 0.014% w/w.

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

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

The impurities on Table 3 in the CoE resolution (ResAP(2008)1) have recommended limits for maximum concentration in products for tattoo and PMU. The limits are demonstrated to be technically achievable as a large share of tattoo inks and PMU currently on the market in Member States with national legislation are compliant with them. For some of these impurities – arsenic, barium, copper, lead, and zinc – the Dossier Submitter has performed a risk assessment and has derived DN(M)ELs that concludes the need for different concentration limits than those recommended by ResAP(2008)1 (see Annex B.5.13 and corresponding appendices B.6-10). The general approach for derivation of risk-based concentration limits described above was used to derive concentration limits for these substances. For PAHs and BaP the CL in Annex XVII entry 50(6) are used (see 1.2.6.1). For the remaining substances on Table 3, the Dossier Submitter proposes to carry forward the limits in the CoE, except for nickel (Ni) where a practical concentration limit of 0.001% w/w, based on surveillance/monitoring data.

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

An overview of the proposed concentration limits is shown in Table 11.

Table 11. Concentration limits in RO1 and RO2

Substance group	Concentration limit (% w/w)	
	RO 1	RO 2
CPR Annex II	Shall not contain	0.1
CLP Carcinogenic 1a/b	Shall not contain	0.1
CLP Carcinogenic 2	Shall not contain	1
CLP Mutagenic 1/ab	Shall not contain	0.1
CLP Mutagenic 2	Shall not contain	1
CLP Reprotoxic 1a/b	0.0014	0.3¤
CLP Reprotoxic 2	0.014	3
CPR Annex IV (column g)	Shall not contain	0.1
CPR Annex IV (column h-i)	See Supplementary Table E	See Supplementary Table E
PAH with harmonised classifications as CM	0.00005	0.00005
PAA (dissolved fraction)	0.00003#	0.00003#
Azo dyes	0.1	0.1
CLP Skin sensitisers 1a	0.1	0.1
CLP Skin sensitisers 1, 1b	0.1	1
CLP Skin irritant & corrosive 1a/b/c, 2	0.1	1, 3, 5 or 10
CLP Eye irritant & damaging 1, 2	0.1	1, 3, 5 or 10
Methanol	10.9	10.9
Impurities (ResAP(2008)1 Table 3)		
- Cadmium	0.00002	0.00002
- Chromium**	0.00002	0.00002
- Mercury	0.00002	0.00002
- Copper*	0.05	0.05
- Zinc	0.23	0.23
- Barium*	0.84	0.84
- Nickel	0.001	0.001
- Selenium	0.0002	0.0002
- Antimony	0.0002	0.0002
- Lead	0.00007	0.00007
- Cobalt	0.0025	0.0025
- Arsenic	0.00000082	0.00000082
- Tin	0.005	0.005

*Soluble, **Chromium VI compounds, #A CL of 0.00005 % is proposed due to socio-economic reasons (see Annex D), ¤For certain Repr 1A/B (DEHP and DBP) specific CL are proposed, see Supplementary Table A.

1.2.6.3. Risk characterisation based on the measured content of selected substances in tattoo inks reported by JRC (JRC 2015b)

The source for data on content of substances in tattoo inks results from national surveys and market surveillance activities compiled by JRC (JRC, 2015b):

Table 12. Content of selected substances in tattoo inks (facsimile from JRC 2015b)

Table 4.38: PAAs presence in tattoo and PMU inks.

Substance	CAS nr	Number of analysed samples	% non compliant samples	ResAP (2008)1 limit (mg/kg)	Range (min-max) (mg/kg)
PAA (total)		3283	14 (468)		0.1-68
4-Aminoazobenzene	60-09-3			0	>0
Aniline	62-53-3			0	5-61
o-Anisidine	90-04-0	3655	10 (347)	0	0.52-2197

Table 4.39: Metals present in tattoo and PMU inks.

Substance	CAS nr	Number of analysed samples	% non compliant samples	ResAP (2008)1 limit (mg/kg)	Range (min-max) (mg/kg)
Antimony (Sb)	7440-36-0	932	7 (70)	2	0.02 - 147
Arsenic (As)	7440-38-2	1164	5 (62)	2	0.2-60
Barium (Ba)	7440-39-3	886	20 (180)	50	50-17737
Cadmium (Cd)	7440-43-9	1863	5 (93)	0.2	0.01-7.84
Cr (VI)	7440-47-4			0.2	0.3-147
Cobalt (Co)	7440-48-4	350	4 (14)	25	0.003-31310
Copper (Cu) soluble	7440-50-8	283	32 (90)	25	2.5-45000
Lead (Pb)	7439-92-1	2175	8.5 (195)	2	0.015-401.5
Mercury (Hg)	7439-97-6	809	2.5 (20)	0.2	0.2-0.253
Nickel (Ni)	7440-02-0	886		ALTA	0.03-78
Selenium (Se)	7782-49-2	166	17 (28)	2	2.0-290
Tin (Sn)	7440-31-5	277	1.4 (4)	50	0.5-101
Zinc (Zn)	7440-66-6	459	21 (99)	50	0.3-1690

Table 4.40: Preservatives, nitrosamines and phthalates presence in tattoo and PMU inks.

Chemical class	Substance	CAS nr	Number of analysed samples	% non compliant samples	Range (min-max) (mg/kg)
Phthalates	Dibutyl phthalate (DBP)	84-74-3	25		0.12-691.2
Phthalates	Di-(2-ethylhexyl) phthalate (DEHP)	117-81-7	11		0.2-19.3

The RCRs given in Table 13 were calculated from DNELs and information on the content of substances in tattoo ink. The risk levels given in Table 14 were calculated from DMELs and information on the content of substances in tattoo ink.

To calculate the risk characterisation ratio (RCR) for methanol, data on the ethanol concentration of 48% reported by JRC 2015b was used. As the maximum content of methanol used as denaturing agent of ethanol (see CPR Annex III) is 5%, the maximum concentration of methanol in tattoo ink is estimated to be 2.4%. This results in an RCR for methanol of 0.22. These calculations demonstrate that the currently known use of methanol in tattoo inks does not pose a risk. No risk is demonstrated for the use of methanol as impurity in tattoo inks. However, to prevent its possible use as a solvent in its own right a concentration limit has been proposed below which the RCR would be less than 1.

It was not possible to calculate the RCR or a lifetime cancer risk comparison for azo colourants as such since no DN(M)EL were derived for these, but these may contain PAAs as impurities from production or decomposition and are usually analysed for content of PAAs (see the table below).

For reprotoxic "only" substances classified as Repr. 1A/B, the DNEL was derived by a group approach. The content range of a single reprotoxic substance (dibutyl phthalate, DBP) reported in JRC was compared to this group DNEL and risk was demonstrated as the RCR could be as high as 50 (RO1).

The RCR for soluble barium was found to be in the range of 0.006-2.11. This could indicate a risk. However, it should be noted that most/all analytical methods cannot differentiate between soluble and insoluble barium (see further details in Appendix B7).

For soluble copper, the RCR was calculated from a DNEL and the content range resulting in an RCR in the range of 0.005-90. A risk could be demonstrated, but is questioned by the fact that not all analytical methods distinguish between soluble and solid copper.

No risk could be demonstrated for soluble zinc with RCR in the range of 0.018-0.73.

Table 13. RCRs for substances at various content ranges in tattoo inks

Substance	**Concentration limit (% w/w) (RO1 & RO2)**	**RCR**	**Content range (min-max)(mg/kg) (JRC 2015b)**	**Content range (min-max) (% w/w) (JRC 2015b)**	**RCR range (min – max)**
Methanol	10.9	1	-	2.4[a]	0.22
Azo colourants	0.1	N/A[b]	N/A	-	-
PAHs with harmonised classification as CM	0.00005	N/A	0.5 - 55000	0.00005 – 5.5	-
Reprotoxic substances 1A/B	0.0014 (RO1)	1	0.12 – 691.2 (DBP)	0.000012 – 0.07	0.009 - 50
Reprotoxic substances 2	0.014 (RO1)	1[c]	N/A	-	-
Barium	0.84	1	50 - 17737	0.005- 1.77	0.006 - 2.11
Cadmium	0.00002	N/A	0.01 – 7.84	0.000001 – 0.00078	-
Cobalt	0.0025	N/A	0.003 – 31310	0.0000003 – 3.13	-
Chromium (VI)	0.00002	N/A	0.3 – 147	0.00003 – 0.015	-
Copper (soluble)	0.05	1	2.5 – 45000	0.00025 – 4.5	0.005 - 90
Mercury	0.00002	N/A	0.2 – 0.253	0.00002 – 0.000025	-
Nickel	0.001	N/A	0.03 -78	0.000003 – 0.0078	-
Selenium	0.0002	N/A	2.0 - 290	0.0002 – 0.029	-
Antimony	0.0002	N/A	0.02 - 147	0.000002 – 0.015	-
Tin	0.005	N/A	0.5 – 101	0.00005 – 0.01	-
Zinc	0.23	1	0.3 - 1690	0.00003 – 0.17	0.018 - 0.73

[a]Estimated from ethanol concentration in JRC 2015b
[b]N/A = not applicable
[c]Estimated from RCR for Repr. 1A/B (10x)

RCRs could not be calculated for some of the substances in the table above because no DNELs have been derived for these (PAHs, cadmium, cobalt, chromium (VI), mercury, nickel, selenium, antimony and tin). However the content range is given and can be compared to the proposed concentration limits. These substances are included in the CoE Table 14.

For PAAs, arsenic and lead, concentration limits were derived based on DMELs. In the table below, there is a comparison of risks based on the proposed concentration limits and measured content in tattoo inks reported by JRC (JRC, 2015b).

In a group approach, the lifetime cancer risk < 10^{-6} for PAAs is based on the DMEL for aniline expressed as a concentration limit of 0.00003%. The content range for aniline and total PAA is in the same order of magnitude; 5-61 and 0.1–68 mg/kg, respectively. This results in a high risk up to 2.27 x 10^{-4}.

For arsenic, the lifetime cancer risk < 10^{-6} was calculated from a DMEL and the content range resulting in a high risk up to 7.5 x 10^{-3}.

For lead, the extra risk of developmental toxicity was calculated from a DMEL and the content range resulting in risk >> RO1 and RO2, i.e., a high risk was demonstrated.

Table 14 Risk from exposure to PAAs, arsenic and lead at various content ranges in tattoo inks

Substance	**Concentration limit (% w/w) (RO1 & RO2)**	**Risk from RO1 and RO2**	**Content range (min-max) (mg/kg) (JRC 2015b)**	**Content range (min-max) (% w/w) (JRC 2015b)**	**Risk from content range (min – max)**
PAAs	0.00003	Cancer risk $<10^{-6}$	0.1 – 68 (total PAA)[a]	0.00001 – 0.0068	0.33×10^{-6} – 2.27×10^{-4}
Arsenic	0.0000008	Cancer risk $<10^{-6}$	0.2 - 60	0.00002 – 0.006	2.5×10^{-5} – 7.5×10^{-3}
Lead	0.00007	0.1% extra risk of developmental neurotoxicity at 0.05 µg Pb/kg bw per day ($BMDL_{01}$/10)	0.015 – 401.5	0.0000015 – 0.04	Up to >> Risk from RO1 and RO2

[a]5-61 mg/kg aniline

In conclusion, although no full quantitative analysis of the risks of all substances that are currently used in tattoo inks is possible, the available measured values for certain hazardous substances indicate that risks for human health cannot be excluded.

1.3. Justification for an EU-wide restriction measure

One of the primary reasons to act on a Union-wide basis is the cross-boundary human health problem: a risk from exposure exists in all Member States including those with national legislation, as compliance rate with national legislation varies and because trans-boundary trade between Member States is possible. One Union-wide regulatory measure would also ensure a harmonised high level of protection for human health across the Union.

A Union-wide action to address the risks associated with tattoo inks containing hazardous substances is needed to ensure the free movement of goods within the EU. The fact that tattoo inks, imported as well as manufactured in the EU, need to circulate freely once on the EU market, stresses the importance of an EU-wide action rather than action by individual Member States, as these actions could differ significantly from Member State to Member State. In addition, a Union-wide action would eliminate the distortion of competition on the European market between markets with and without national legislation on the chemical composition of tattoo inks and PMU.

1.4. 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 options. No pending legislative changes of relevance have been identified, except the uncertainty associated with the status of the UK within the European Union (EU28) and the European Economic Area (EEA31) following their activation of article 50 of the Lisbon Treaty.

The geographical boundaries for the assessment are the territories of Member States of EEA31. In addition, selected statistics are presented for those Member States who currently do not have national legislative measures for tattoo inks (denoted as EEA22).[19]

The study period – entry into effect (assumed for analytical purposes to be 2021) plus 20 years – is selected on the basis of the time anticipated for the costs and benefits (in particularly those quantified and monetised) of the proposed restriction options to fully develop. The selection was also influenced by best practices for similar assessments.

The most critical aspects of the baseline are discussed below, i.e., the number of people exposed to tattoo inks and PMU as well as volume of tattoo and PMU ink on the EEA31 market. For further information describing the industry, see Annex A.

A. Number of people with tattoos and PMU

a) Tattoos

For the purpose of assessing the impacts of the proposed restriction options, an important component of the baseline is the number of people exposed to tattoo inks and PMU or the total number of people in the EEA31 who are estimated to have a tattoo (excluding removals) over the study period. The future population with at least one tattoo is estimated on the basis of incidence and current and anticipated trends of getting a tattoo. (See Table 15.)

The incidence of obtaining a tattoo (getting tattooed for the first time) in the population is estimated on the basis of EuroStat population projections and JRC reports (JRC, 2015b). It is estimated that the number of people with at least one tattoo in the EEA31 increased from close to 30 million people in 2003 to more than 62 million people in 2014. This implies that, annually, on average, about 0.5% of the EEA31 population got tattooed for the first time. Assuming the trend between 2003 and 2014 continues in the future (Main scenario), more than 81 million people in EEA31 will have at least one tattoo by 2021 – the assumed year of entry into effect of the proposed restriction. Of those, about 43.5 million would be living in a Member State where there is currently no national regulation on the chemical composition of tattoo inks and PMU (EEA22). By the end of the study period, the population of people with at least one tattoo is expected to double under the Main scenario. This implies a prevalence rate for EEA31 of 26%.

Table 15 shows that on average, under the main scenario, 2.8 million new people would get a tattoo for the first time over the study period in EEA31. This number is not a proxy for the number of visits of tattooists, number of tattoos obtained, or number of tattoo sessions per year. These latter estimates would be much higher, as about half of the people with tattoos have more than one tattoo. In two-thirds of the Member States responding to a survey, the group of people with 2-5 tattoos was the largest (JRC, 2015b) and the total body surface tattooed for about 15% of men is greater than 20% (Høgsberg, et al., 2013). These larger tattoos would require more visits to tattooists, sometimes over the course of a year or more, in particular if the tattoo design is complex (e.g., realistic style) and is comprised of several colours. Therefore, the number of sessions, the size and complexity of the tattoo, the amount of inks used, etc. – all

[19] These include: Austria, Bulgaria, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Luxemburg, Malta, Poland, Portugal, Romania, Slovakia, United Kingdom, and Iceland (EEA). Italy is also included in this group, as the ResAP(2008)1 recommendations are not enforced in all parts of the country.

important components for determining risks of exposure and the likelihood of developing an adverse effect – are discussed qualitatively in the analysis. Another important factor discussed qualitatively is tattoo removal. See section D.2.3.2. Human health and environmental impacts for further details.

Table 15 Estimated population with tattoos

Geographic Area	Prevalence over study period				Average incidence 2021-2040
	2014	2016	2021	2040	
EU28	61 363 400	66 788 900	80 431 900	133 032 300	2 766 900
EEA31	62 025 600	67 510 600	81 309 500	134 603 900	2 803 200
EEA22	33 221 200	36 156 200	43 535 800	71 972 400	1 495 900
UK	7 722 100	8 413 800	10 181 200	17 365 100	377 100
EU27*	53 641 300	58 375 100	70 250 700	115 667 200	2 389 800
EEA30*	54 303 500	59 096 800	71 128 300	117 238 800	2 426 100
EEA21*	25 499 100	27 742 400	33 354 600	54 607 300	1 118 800
Prevalence rate	12.1%	13.1%	16.2%	26.1%	

Notes: 2014 data based on EuroStat and (JRC, 2015b). 2016-2040 – projected based on EuroStat data. *The data stands for respectively EU28, EEA31, and EEA22, excluding the UK.

Table 15 also shows the projected prevalence and average incidence over the study period on the basis of anticipated future trends of obtaining tattoos. These are associated with high uncertainty but some indication can be obtained from:

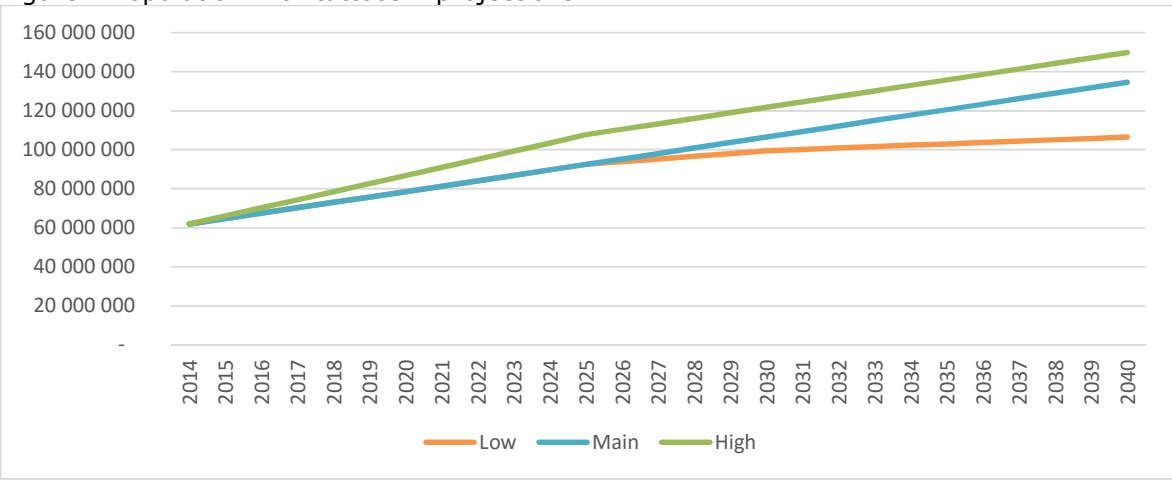
- Trends in other countries: e.g., US and Canada, where the tattoo revival began and where the current prevalence is higher, 20% and 21% respectively. (JRC, 2015b) Considering the cultural similarities between North America and Europe, it can be anticipated that the prevalence in Europe would in the near future reach theirs.
- Fashion trends: The substantial growth in the number of people with tattoos and number of tattoos per person, was boosted by the embracing of tattoos by fashion setters (icons) such as some elite performance artists and athletes. Future fashion trends cannot be predicted but according to people in the tattoo and PMU industry, given the still somewhat rebellious nature of tattoos in particular, it is possible that future generations would not be interested in tattoos like their parents were.
- Other impacts: It is possible that the increased perception of the safety of the tattoos and PMU and the decline in the social stigma would encourage more people in the future to have similar body enhancements.

Therefore, to test this uncertainty, two other scenarios are prepared in addition to the Main scenario:

- Low prevalence scenario: assumes that the current incidence rate will decline by 50% in 2025 and again in 2030. Under this scenario, the overall prevalence is estimated at 15.7% as of 2021 and 20.3% as of 2040.
- High prevalence scenario: assumes that more people will choose to get a tattoo for the first time (i.e., 50% higher incidence rate) in the short term. After 2025, the incidence of getting a tattoo will return to current levels. Under this scenario, the overall prevalence is estimated at 17.5% in 2021 and 28.5% in 2040.

The effects of these assumptions are displayed on Figure 1 and further assessed in section Assumptions, uncertainties and sensitivities of this report and Annex E.

Figure 1 Population with tattoos – projections



Notes: 2014 data based on EuroStat and (JRC, 2015b). 2016-2042 – projected based on EuroStat data.

b) PMU

There is very limited information on the prevalence of PMU in the EEA. On the basis of data from three Member States, the PMU prevalence in the general population in the EEA31 is between 3% and 20% (JRC, 2015b). Thus, it can be estimated that about 53 million people in EEA31 have had at least one PMU procedure (on the basis of mid-point estimate). Due to the limited information and the possibility that a person with a PMU could also have one or several tattoos, these estimates are not projected and added to the population with tattoos. The popularity of PMU has increased due to advancements in PMU techniques, plastic surgery and fashion trends. Industry expects that PMU would continue to replace traditional cosmetics and to be used as a technique for enhancing human features in the long term.

B. Volume of tattoo inks and PMU

The tattoo and PMU ink segment is fairly small and statistics about the EU or international markets are not available. Annex A describes the industry, primarily composed of micro and small enterprises, which formulate the tattoo and PMU inks using ingredients (colourants and auxiliary ingredients) manufactured by and for the purpose of other industries: industrial applications (such as paints, plastics, automotive, etc.) as well as cosmetics, food and medical sectors.

Table 16 shows that about 152 000 litres of tattoo ink and 10 800 litres of PMU are estimated to be placed on the EEA31 market in 2016, taking into account the following:

- Tattoo inks: the volume of tattoo ink on the EEA31 market is derived on the basis of information on the amount of tattoo ink used by tattoo artist on average annually: between 0.5 and 3 litres for full-time professional tattoo artist, with amateur artists 25-50% of this. (JRC, 2015b) (stakeholder consultation) The number of tattoo artists was established by the JRC (JRC, 2015b) via questionnaires. (See also Annex A) The results, presented in Table 16, were verified with industry representatives. Information from the same JRC report provided the share of EU manufactured (20-30% of ink volume), exported (about

5% of EU manufactured ink) and imported (70-80%) volumes for the EEA31 market. (JRC, 2015b) (Michel, 2015)[20]

- PMU: the volume of PMU placed on the EEA31 market was estimated on the basis of information from the JRC report (JRC, 2015b), supplemented by interviews with industry. In contrast to tattoo inks, the majority of PMU placed on the EEA31 market is manufactured in the EU (80-90%). EU PMU manufacturers[21] also export nearly 20% of their production internationally. Less than 5% of PMU on the EEA31 market is imported according to estimates, primarily from the US or China. (JRC, 2015b)

Table 16 Tattoo inks and PMU on the EEA31 market – 2016 estimates (litres)

	Tattoo ink	**PMU**	**Total**
EU31 manufactured	40 100	11 300	51 400
Exported	2 100	2 100	4 200
Imported to EU31	114 000	1 600	115 600
Total on EU31 market	**152 000**	**10 800**	**162 800**

Notes: Estimates based on interviews with selected manufacturers and JRC data (JRC, 2015b). See Annex C: Baseline for further information.

Estimation of the tattoo ink and PMU volumes is hampered by lack of statistical data and the numerous variables that impact the amount of ink used per procedure, e.g., style (realistic vs abstract), mono vs multi-coloured, size, etc. Therefore, information about future tattoo ink volume can only be inferred on the basis of information available on the demand for tattoos and PMU in the future. For the purpose of the analysis of the impacts of the proposed restriction options, similarly to the projections of tattoo prevalence, it is assumed in the Main scenario that the amount of tattoo ink and PMU on EEA31 market is expected to remain at about current levels for the study period. For sensitivity purposes, two more scenarios, in line with the Low and High prevalence scenarios, are prepared and the effects of these changes are assessed in section Assumptions, uncertainties and sensitivities of this report and Annex E.

Table 17 Tattoo inks and PMU on the EEA31 market – projections (litres)

Scenario	**2016**	**2021**	**2040**	**Average 2021-2040**
Low	162 800	164 100	48 600	86 100
Main	162 800	164 100	166 300	166 000
High	162 800	240 800	167 400	184 700

Notes: Estimates based on interviews with selected manufacturers and JRC data (JRC, 2015b). See Annex C: Baseline for further information.

[20] The main EU manufacturers of tattoo inks are based in the UK and Germany, other EU Member States include Italy, Spain, Sweden, and Poland, although there is uncertainty of the exact place of origin of some products. (JRC, 2015b) In total, the study suggests that there are about 90 EU-based and international manufacturers of tattoo inks on the EEA31 market.

[21] Germany dominates the EU-based manufacturing of PMU, other EU Member States include Italy, Spain, France, Austria, and the Netherlands, although study notes that the EU and global market is complex and "it is not easy to understand who is producing what", as one manufacturer may produce more than one brand (own or for private label). In total, the study suggests that there are 55 PMU EU-based and international manufacturers on the EEA31 market. (JRC, 2015b)

2. Impact assessment

2.1. Introduction

The Dossier Submitter evaluated a number of other EU-wide and national legislative and voluntary measures. These are assessed in Annex D (section D.1.2. Discarded restriction options and D.1.3. Other Union-wide risk management measures other than restriction). Following an assessment of the current Member States' national legislation, the recommendations by the CoE, and an assessment of the substances in tattoo inks that can present a risk to human health when injected intradermally, two restriction options are proposed: Restriction option 1 (RO1), presented in Table 2 and Restriction option 2 (RO2), presented in

Table *3*. Supplementary Table A is included in

Table *3*, Table B in Table 4 and Table C, Table D and Table E in Appendix 1. Their impacts were assessed and those monetised are reported in 2016 values and compared as of 2016 year, using discount rate of 4%.

2.2. Risk management options

The two restriction options proposed: RO1 and RO2 differ primarily in terms of the proposed concentration limits for selected substance groups and how the links with the CPR are managed. Both options have advantages and disadvantages (discussed in detail in sections 2.2.2 and 2.2.4) which makes it difficult to weigh one option against the other.

The following section briefly outlines the common aspects of the proposed restriction options. Their differences are discussed in sections 2.2.1 and 2.2.3.

a) Rational for the proposed restriction options

The proposed restriction options are formulated taking into account the following:

- If a substance is not permitted in cosmetic products because it is not considered safe to apply on human skin (in general or under specific conditions listed in the CPR), it is logical to assume that it is also not safe to be applied under the skin, i.e., in a tattoo or permanent make-up where the skin is damaged and the substance is deposited in the dermis for a prolonged period of time.
- The substances classified as CMR, and thereby not permitted to be placed on the market or used for supply to the general public as substances on their own or as constituents of other substances or in mixtures (by virtue of entries 28 to 30 of Annex XVII to REACH), should not be used in tattoo inks that will be applied under the skin of members of the public.
- Substances whose hazard profile suggests that they lead to skin sensitisation, irritation or corrosion or eye irritation and damage, should not be applied under the skin (or in the eye), i.e., in a tattoo or permanent make-up where the skin is damaged and the substance deposited in the dermis or in the eye for a prolonged period of time.
- Conclusions of (semi-)quantitative risk assessment by the Dossier Submitter of substances that can be found in tattoo inks, on the basis of reasonable exposure estimates.
- Industry will find difficult to substitute some substances, in particular selected colourants. Taking into account the hazards and risks of the exposure to the relevant pigments, derogations are proposed for these substances.

b) Concentration limits

The proposed concentration limits are derived on the basis of either the substances hazard classification, presence in the Cosmetic Products Regulation or a quantitative or qualitative risk assessment carried out by the Dossier Submitter. One of the main differences between RO1 and RO2 are the proposed concentration limits for CPR substances in scope (i.e., Annex II and Annex IV with use restriction in column g) and substances with harmonised classification. Both options aim to discourage intentional use and the rational for the different approaches is explained in section 2.2.1 and 2.2.3 for RO1 and RO2 respectively.

The concentration limits for the remaining substances are the same for both RO1 and RO2: PAHs, PAAs, azo colourants, methanol, and impurities listed on Table 3 of ResAP(2008)1. The limits for the remaining substances are derived on the basis of (semi-) quantitative risk assessment (e.g., barium, copper) carried out by the Dossier Submitter, considerations for technically achievable limits (e.g., nickel), limits established under other measures (e.g., PAHs), etc. In some cases, several considerations are taken into account in the setting of the limit. For example, while semi-quantitative risk assessment of PAAs derived a risk-based concentration limit of 0.3 ppm (see Appendix B.2), considerations related to limits of detection, technically achievable concentrations and availability of alternatives necessitated the proposal of a higher concentration limit: 5 ppm. For details on these substance categories, see the relevant sections in Annex B and the respective appendixes.

c) Derogations

i. Selected colourants

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

To date, there is no information for a possible substitute of Pigment Blue 15:3. Although there are other blue pigments, these have been found lacking in brilliance and change colour (e.g., turn grey) when mixed with white pigments – a common practice to achieve different colour tones. (ECHA CfE, 2016) Pigment blue 15:3, together with a number of other colourants were added to Annex II of the CPR with the condition 'not to be used in hair colours'. At the same time, Pigment Blue 15:3 and 24 other pigments are on the positive list for colourants allowed in cosmetic products (CPR, Annex IV) without conditions of use. Many of the pigments prohibited in hair colours were included in Annex II of the CPR on the basis of the cosmetic industry not providing relevant information to justify continued use in this application. As tattoo inks and PMU do not fall within the scope of the CPR, the tattoo industry was not able to participate in the process, even though the Annex II requirements applied to them via national legislation. Therefore a derogation is proposed for Pigment Blue 15:3 and for the 24 other pigments prohibited in hair colours in Annex II but allowed in Annex IV of CPR (included Table B).

Pigment Green 7 was used in tattoo inks prior to the introduction of the national legislation based on ResAP, on the grounds that it is banned from use in hair colours (Annex II of CPR) and use in products applied on mucous membranes (Annex IV of CPR, column g). According to industry, this pigment has largely been replaced with pigment Green 36 which is a brominated version of Pigment Green 7 raising questions related to Green 36's hazard and risk. (ECHA CfE, 2016) No other technically feasible alternatives to Pigment Green 7 have been identified to date. Furthermore, both Pigment Green 7 and Blue 15:3 are phthalocyanines, which are insoluble in water and stable in most solutions. As shown in Appendix B.9, risk for these substances cannot be demonstrated with the currently available information. Therefore, a derogation is also proposed for Pigment Green 7. (See Supplementary Table B marked as Table 5 in the report).

ii. Classified substances for inhalation exposure only: As risks associated with the inhalation route only are not relevant for tattoo and PMU exposure,

substances classified as carcinogenic via this route only are derogated (e.g., titanium dioxide).

d) Labelling requirements

Both ROs foresee a labelling requirements for tattoo inks and PMU. The CoE resolution contains a number of labelling requirements, in addition to its various bans and restrictions. These requirements are:

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

Some of these requirements may be necessary under the CLP Regulation. However, it is proposed to include a labelling requirement under this restriction, as it is specified under certain Member States national legislation, to require in addition to any information required under the CLP, the following information on the label of the product:

The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides, in addition to that required by Regulation (EC) No 1272/2008, the following information:

- The intended use of the mixture as a tattoo ink;
- A reference number to uniquely identify the batch;
- The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal;
- The name of substances covered by the restriction proposal that are present in the ink at a lower concentration limit than the proposed one;
- Any relevant instructions for use.

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

The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

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

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

The requirement would ensure that substances not covered by the restriction proposal but which may nevertheless present a risk to human health will be listed to inform

consumers who intend to undergo a tattoo procedure. This is particularly important in the case of tattoo inks when hazardous substances are deliberately injected under the skin and may have unforeseen consequences due to this route of exposure. It is also important that consumers who are already (cross)sensitised to certain substances can check to see these are not in tattoo inks.

e) Additional conditions

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

Some colourants used in cosmetic products have been shown to pose a risk to human health when applied to the skin in concentrations exceeding the maximum allowed concentrations specified in Annex IV of CPR or when not meeting the other conditions in columns "h" to "i" of the Annex (e.g., purity requirements). (See Supplementary Table E.) Therefore, given the similarities in exposure potential (not allowed if not complying with these conditions in cosmetic products which by definition (Article 2 of CPR) are applied, among other, on the external parts of the human body, which include the epidermis), a comparable restriction for use of these colourants in tattoo inks and PMU is proposed.

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

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

f) Transitional period

The restriction proposes a transitional period of one year, which will allow sufficient time for actors in the supply chain to meet the proposed requirements. See section 2.3 for further detail.

g) Definitions and other enforcement considerations

To assist with enforcement, the proposed restriction text includes definitions of tattoo and PMU practices. The dossier also lists the substances included in the scope. (See Supplementary tables A-E.) These lists also include information on whether the substances have been found in tattoo inks and PMU according to surveillance results or literature review as per JRC report (JRC, 2015b). This will assist enforcement authorities to focus their initial efforts checking compliance on the presence of key substances. This list of key substances can be periodically updated on the basis of selected detailed analysis of tattoo inks.

To assist with future risk management measures on tattoo inks, the dossier includes substances listed in Appendix D1 relevant for any future re-evaluation of the restriction. These substances have been identified as problematic for tattoo inks via detailed stakeholder consultations during the development of ResAP by the CoE or during the preparation of this dossier. However, the current level of information available for these substances (as well as workload) did not allow sufficient assessment to include them in the scope of the proposed restriction options. The dossier calls attention to these substances for future investigation of their hazards (in the context of CLP for example) and their risks in the context of future regulation on tattoo inks and PMU.

Furthermore, the establishment of EU-wide registry for tattoo inks and PMU can be considered, to assist with the revisiting of the restriction. The registry, also recommended by some stakeholders (similar to existing national registries), will provide the regulators with relevant information on the substances found in tattoo inks and PMU, which is essential for the assessment of exposure and risk. In addition, by providing photos and other identification features to a centralised database accessible by enforcement authorities, the acute issue of counterfeiting of inks identified by some manufacturers (primarily US-based) may also be addressed. (ECHA CfE, 2016)

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

2.2.1. Proposed restriction option: RO1

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

a) Concentration limits

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

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

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

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

- CMR substances

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

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

- Substances with harmonised classification as sensitisers, irritants and corrosives

A practical limit of 0.1% w/w is proposed for the substances with harmonised classification as skin sensitising, corrosive or irritant and eye irritant or damaging to discourage the use of these substances in tattoo inks. This will simplify the restriction requirements for stakeholders. (See respective appendixes to Annex B for further justification.)

b) Interlinkages with the CPR

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

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

2.2.2. Justification for the selected scope of RO1

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

The main advantages of RO1 are that it:

- follows national legislation to the extent possible and it will therefore, provide similar level of protection currently applied by national rules in seven EU Member States (and two additional EEA members) that are based on the recommendations of the CoE ResAP;
- is easy to communicate as the proposed restriction scope follows to the extent possible existing current legislation based on the recommendations of ResAP. Tattoo ink manufacturers are already aware of these requirements (although some substances are added). This will facilitate compliance with the proposed restriction;
- will ideally be dynamically linked to Annex II and IV to the CPR and Annex IV of the CLP to ensure future changes to those annexes apply directly to the restriction;
- proposes concentration limits that are derived on the basis of the argumentation for risk.

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

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

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

2.2.3. Proposed restriction option: RO2

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

a) Concentration limits

i. Substances with harmonised classification

The maximum concentration of substances with harmonised classification as CMRs, skin sensitisers, corrosives or irritants or eye corrosives or damaging is proposed to be limited to the generic or specific concentration limit of the substances set in the CLP Regulation.

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

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

b) Interlinkages with the CPR

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

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

2.2.4. Justification for the selected scope of RO2

The main rational for considering a restriction option with different concentration limits than RO1 is that colourants in particular are often of low purity and therefore, a number of currently unknown impurities could potentially be contained in tattoo inks. As explained previously, the Member States that currently have national legislation on tattoo inks in place, enforce prohibition on substances on Annex II, CMRs and Annex IV substances (column g) similar to cosmetic products whose use is regulated by the CPR. This means if these substances are found in trace amounts in tattoo inks (i.e., due to Article 17 of the CPR), they would not be considered non-compliant. As pigments are not manufactured by the formulators of tattoo inks, many such impurities of the manufacturing process could also be contained in the tattoo inks, which are mixtures of a colourant in a solution with auxiliary ingredients. As it is extremely complex to catalogue all impurities that can be found in tattoo inks, a broad brush approach is taken, where a restriction is proposed on substances which can cause skin and systemic effects in humans in order to encourage the use of higher purity, lower risk pigments and auxiliary ingredients in tattoo inks. However, as the list of impurities is unknown, in particular for those pigments that are currently not widely used in the manufacture of tattoo inks, there is the risk of the regulation to render a great share of tattoo inks currently the market as non-compliant if unobtainable concentration limits are imposed. Therefore, this second – RO2 – restriction option is proposed with higher practical limit (0.1% w/w) for CPR substances in scope and the CLP limits for those with relevant harmonised classification.

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

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

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

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

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

The main advantages of RO2 are that it:

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

The main disadvantages RO2 are that it:

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

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

The remaining sections of this annex demonstrate that RO2 is effective, practical and monitorable.

2.3. Response to restriction scenario(s)

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

- Manufacturers (placing tattoo inks on the EEA31 marked) to develop and begin marketing alternative tattoo inks and PMU compliant with the proposed restriction options. As explained in Annex D, the proposed Union-wide measures are, by and large, similar or less strict than existing national legislation in nine of the 31 EEA members based on the CoE resolutions. According to surveillance results, currently the majority of tattoo inks on the market are compliant with these national measures. Therefore, industry has knowledge and experience to manufacture tattoo inks and PMU compliant with the CoE resolutions and therefore, with the proposed restriction options. Thus, it is expected that the transitional period proposed would provide sufficient time to develop and begin marketing new tattoo inks and PMU prior to the entry into effect of the proposed restriction options.
- The supply chain (including distributors and tattoo artists) to deplete tattoo inks in stock prior to the entry into effect of RO1 and RO2.
- The requirements of the restriction measures on the chemical composition of tattoo inks to be communicated in the supply chain: It is expected that the transitional period will be sufficient as the issue of safe use of tattoo inks has been in focus for the past 20 years.
- Enforcement authorities in Member States currently without national legislation to put in place the necessary measures for control and those Member States with national legislation, to amend current national practices. This would also include the development of standardised testing methods for key groups of substances (e.g., PAAs and azo colourants).

Tattoo ink mixtures contains a number of substances. They belong in three distinct groups: colourants, impurities, and other auxiliary ingredients (fillers, binders, surfactants, solvents, preservatives). Of these, colourants are the most critical components as they can represent up to 60% of the mixture and are responsible for the long-lasting design (marking) on the human body. There are approximately 31 000 colourants listed on the Colour Index (C.I. ™) database.[22] Not all of them (154 colourants according to (JRC, 2015b) have been reportedly used in tattoo inks. Of those less than 20% are impacted by the proposed restriction options. The main qualities of importance for tattoo inks and PMU are the colour hue (of particular importance for PMU where tones close to the natural complexion and features are essential), brilliance (maintained even after mixing with other colours), permanence (the colour does not change over time), as well as good workability (viscosity) and healing properties. Particle size is also of importance, the optimal being 1-5 microns. (stakeholder consultation)

[22] The Colour Index™ (C.I. ™), www.colour-index.com, published by the Society of Dyers and Colourists (SDC) and the American Association of Textile Chemists and Colourists (AATCC), promotes a universally accepted dual classification system for dyes and pigments. It lists approximately 31 000 dyes and pigments listed under 11 691 Colour Index™ (C.I. ™) Generic Names (CIGN) and the corresponding Colour Index™ (C.I. ™) Constitution Number (CICN).

The proposed restriction might influence the marketing and use of about 30-50% of tattoo inks and up to 20% of PMUs, as surveillance by national enforcement authorities have shown that the majority of tattoo inks currently on their market meet the requirements of national regulation in several Member States based on ResAP recommendations. The share of PMU compliant with national requirements is higher (assumed close to 90% in the main case, on the basis of information about the locations of the main manufacturers of PMU marketing their products in the EEA). Stakeholders have explained this with the more demanding requirements of downstream users. As both restriction options propose concentration limits that are by and large similar or higher than those enforced by Member State national legislation based on the CoE ResAP recommendations, it is expected that a similar proportion of tattoo inks and PMU currently on the EU market will meet the proposed restriction requirements (of a slightly higher share for RO2).

The results show that technically feasible alternatives with similar or better hazard and risk profiles exist. Notable exceptions are Pigment Blue 15:3, Pigment Green 7 and other pigments prohibited for use in hair dyes under Annex II of the CPR, listed in Supplementary Table B of the proposed restriction options. Therefore, of the basis of technical feasibility and hazard and risk considerations, a derogation is proposed for these colourants. (See section 2.2.) The transition to alternative tattoo inks and PMU will likely lead to higher additional costs due to higher R&D, material and testing costs, which influence the final price of tattoo inks and PMU on the market. These costs are discussed in the forthcoming sections.

2.4. Assessment of restriction options

2.4.1. Economic impacts

2.4.1.1. Substitution costs

In the event the proposed restriction options come into force, tattoo inks not meeting the requirements (non-compliant tattoo inks) would no longer be available. The incremental substitution costs estimated to be incurred by downstream users of tattoo ink and PMU are about €4.4 million annually during the temporal scope of the analysis (in 2016 values). The estimation is based on the following inputs and assumptions:

- Between 30-70% of tattoo inks on the EEA31 market (50% as a mid-point in the main scenario and 30% and 70% in the Low and High share of alternatives scenarios shown in section 3) do not meet the requirements of the proposed restriction options. The assumptions for 50% and 70% share of alternatives shown was in accordance with surveillance results of Member States assessing compliance with ResAP recommendations. These can be seen as conservative assumptions, as surveillance is often targeted at high risk suppliers and products, therefore, the market share of compliant inks is likely higher. The third scenario, with only 30% of tattoo inks on the EEA31 market meeting the requirements for RO1, tests for the potentially lower share of alternative inks on the EEA22 market (i.e., Member States without national legislation). This is seen as conservative as well, as interviews with manufacturers revealed some of those that are compliant with ResAP recommendations do not have separate product lines for jurisdictions with and without national legislation. Also, some Member States without national legislation enforce ResAP recommendations to a degree (e.g., Italy, Denmark), while others are vigilant with respect to RAPEX notified products.

- Up to 20% of PMU currently on the EEA31 market are not compliant with the proposed restriction options. The reasons for making this assumption are similar to those described above for tattoo inks, i.e., similarity between ResAP and the requirements under RO1 and RO2, surveillance results that show generally better compliance for PMU in comparison to tattoo inks, and low product differentiation for markets without national legislation. Interviews with industry have revealed that PMU on the EU-market are largely compliant, although there are national differences when it comes to treating some impurities (e.g., nickel). Manufacturers explain this with the more demanding customer base for PMU in comparison to tattoo inks.
- Projected volumes of tattoo inks (and PMU) on the EEA market as shown in Table 17.
- The price difference between compliant and non-ResAP-compliant tattoo inks and PMU currently on the EEA31 market is about 15%. The price difference is derived on the basis of the average retail price per 30 ml tattoo ink and 15 ml PMU bottle reported by stakeholders, excluding average value added tax (VAT). The price difference is seen to reflect the main difference in the costs of manufacturers of compliant inks in excess of those incurred by non-compliant formulators: higher pigment, testing, research and development costs.

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

2.4.1.2. Enforcement costs

The total incremental enforcement (analytical testing and administrative) costs to be incurred over the temporal scope of the analysis are estimated at €235 000 annually. This is likely an overestimation as it assumes that the same level of enforcement efforts will be required over the entire temporal scope, while in reality enforcement efforts decline with industry compliance, and industry compliance improves as familiarity of the restriction requirements increase over time. The estimate is based on assumptions that Member States with national legislation would continue to incur similar costs in the future, administrative costs are about €55 800 annually and analytical cost are about €200 000 per campaign run on average every 4-5 years. These costs are expected to be similar for RO1 and RO2.

2.4.2. Other impacts

2.4.2.1. Social and distributional impacts

a) Tattoo ink and PMU formulators

Regulations of this scale can be challenging for smaller businesses. Many formulators are small (10-50 employees) or micro (less than 10 employees) enterprises. Few can be considered truly global scale companies, although via Internet direct sales their products can reach all parts of the world. As such, many tattoo and PMU manufacturers may lack the resources to keep abreast of regulatory issues or to invest in extensive research and development and hazard and risk investigation of their products.

The largest regulatory burden from the proposed restriction options would likely be on micro or small businesses who have not been engaged in the work related to ResAP.

Those most likely are located and conducting business in Member States and international jurisdictions without legislation on the chemical composition on tattoo inks and PMU and where the tattoo industry and cosmetic practitioners are not well organised. It is likely that those companies that currently do not have compliant tattoo inks on the market would bear the lion's share of these costs. However, it is not expected that these additional costs would lead to closures and lay-offs.

b) Tattoo artists

The proposed restriction options are expected to have a minimal impact on the employment and the ability of tattoo artists to perform their profession and art, although it is possible that the available colour palette could become less diverse in the short term. Not all artists work with a broad palette of colours (usually those specialising in realistic tattoos primarily do so), although with experience tattoo artists grow accustomed and develop preferences for particular colour (or brand) due to its brightness, permanence, viscosity, healing properties, etc.

As a result of RO1 or RO2, many artists would have to ensure that the inks they continue to use are compliant with the regulatory requirements. This will be of particular importance for those who buy directly from manufacturers or internationally, via internet based resellers, as opposed to EEA31-based distributors, some of whom reportedly take measures to ensure sales of safe, genuine brands. This may be challenging in particular for home-based tattoo artists who are not often members of associations, are not engaged in industry information exchanges on regulatory issues, and sometimes cannot purchase from distributors who may sell to registered artists only.

c) Pigment manufacturers

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

2.4.2.2. Wider economic impacts

The proposed restriction options are not expected to distort the trade balance but no historical information is available about the trade in tattoo inks and PMU to ascertain their impact on extra-EEA31 trade. It is anticipated that the majority of tattoo inks will continue to be imported, while the majority PMU to be manufactured within EEA31 for the foreseeable future.

2.4.3. Human health and environmental impacts

2.4.3.1. Human health impacts

a) Introduction

Following the dermal injection of the tattoo ink and PMU, pigments and other ink constituents and impurities are absorbed, distributed via the lymph and blood system (Lerche, et al., 2015), (Lerche, et al., 2017), (Sepehri, et al., 2017a), metabolised, stored or excreted of the human body. The precise mechanism is not well-understood but studies have shown that not all pigment remains in the dermis indefinitely: the

pigment, initially rapidly, decreases over time (Engel, et al., 2008) with only 1-13% remaining in the skin after several years (Lehner, et al., 2011) but because of the refractory properties and the colour strength of the pigments, this substantial decrease of the pigment is not easily gauged with the human eye. Bäumler suggests that the reduction of the pigment in the dermis is due to three main mechanisms: part of the colourant may leave the skin with the bleeding during or directly after tattooing; part of the colourant may be transported away from the skin via the lymphatic or blood vessel systems; and part of the colourant decomposes months or years after tattooing due to repeated exposure to solar radiation. Furthermore, any process that reduces the size of the particles assists in the reduction of the pigment concentration in the skin. The larger pigment particles (that stay in the dermis because they cannot pass the lymph nodes) undergo a process of disintegration due to light-induced decomposition of pigment molecules. Other mechanisms such as enzymatic activities or recurring activities of the macrophages also contribute to the transport off the tattoo site. (Bäumler, 2015)

As described in the exposure scenario, after tattooing, substances in tattoo inks injected into the dermis become bioavailable in the human body, exposing the skin and other internal organs over extended period of time to the effects of the numerous substances some of which have hazardous properties leading to risk to human health.

The study of adverse effects related to tattoos and PMU have been hampered by lack of registries and epidemiological studies. Furthermore, direct association with the effects and specific substances is extremely challenging due to variability of the components of inks, pigments, and contaminants that can be injected into the dermis.

b) Effects related to the chemicals composition of tattoo inks and PMU

The adverse effects due to exposure of tattoo inks are diverse and can be categorised in a variety of ways as described in Annex D, Section D.6.1. The discussion below focuses on chemical-related adverse effects only as these could be directly influenced by regulation on the chemical composition of tattoo inks and PMU. The remaining effects may increase the severity of chemical-related effects by, e.g., increasing the metabolism of the pigment particles in the body, others can abate them by, e.g., leading to faster expelling of the pigment particles from the body. However, as these adverse effects are not considered triggered by the substances present in tattoo inks, therefore, they are not discussed further in this dossier.

Although, there are various categorisations of tattoo reactions, for the purpose of this dossier the adverse effects associated with exposure to chemicals are grouped in: non-infectious inflammatory, systemic, malignant tumours, and reproductive and developmental. The following are some of the more commonly observed effects. For further information, see Annex D, section D.6.1.

<u>Non-infectious inflammatory allergic and non-allergic reactions</u>

Table 18 presents a summary of the description in Annex D of non-infectious inflammatory allergic and non-allergic reactions which have been associated with exposure to substances in tattoo inks. These effects are among those best researched.

Table 18 Non-infectious inflammatory (allergic and non-allergic) reactions

Adverse effect	Description	Reported effects in studies
Plaque-like	Plaque elevation is the most common cutaneous reaction. It is of allergic nature. The clinical appearance of this allergic reaction is thickening and elevation of the tattoo, with or without large adherent scales. Inflammation with lymphocytes concentrated in the outer dermis is observed, also sometimes extending to the non-tattooed skin. (Serup, et al., 2015b) Associated with red and colour tattoos (Serup, et al., 2016).	32.2% of 493 tattoo associated adverse effects. (Serup, et al., 2016). Skin elevation was reported by 0.7% of respondents as persistent problem (Klügl, et al., 2010)
Papulo-nodular pattern	Papulo-nodular reactions are the main example of non-allergic, non-infectious inflammatory reactions. The papules and nodes appear clinically as round or elongated papular or nodular thickening or elevation in sections of the tattoo with high concentration of pigment. The nodules appear as an agglomeration of black (carbon black) pigment nanoparticles, which the skin regards as foreign body and attempts to eliminate transdermally; however, the basement membrane holds back most of the material in the dermis. Scratching may release these agglomerations enabling the skin to heal, leaving a white spot. (Serup, et al., 2015b) Papules and nodules may have the histology of pain inflammation and foreign body reaction, granulomatous inflammation or sarcoidosis granuloma (isolated to the tattoo or widespread involving lungs and other organs). (Serup, et al., 2016) The production of Reactive Oxygen Species (ROS) in the agglomerated black pigment may be the reason for the inflammation. (CHDP, 2015) The study (Serup, et al., 2016) associates also papulo-nodular patterns with pigment overload, which may also be a result of the technique used by the tattoo artist.	Account for 13% of all tattoo reactions according to (Serup, et al., 2016) and are associated primarily with black tattoos and pigment agglomeration. Skin papules was one of the persistent skin problems reported by 0.4% of respondents in (Klügl, et al., 2010).
Ulcerating patterns	The ulceration may invade the dermis entirely and approach the subcutaneous fat. Necrosis may extend further into deep tissues (e.g., muscle connecting tissue) and regional lymph nodes where the pigment has migrated. The allergy may progress to autoimmunity, with an attack on non-tattooed skin, presenting itself as vasculitis, bullous reactions and generally delayed wound healing thought the skin. (Serup, et al., 2015b)	Seen in 1.4% of the reactions, primarily associated with red and colour tattoos (Serup, et al., 2016).
Hyperkeratotic	A thickening and elevation of the epidermis (in severe reactions as high as 6-8 mm above the surrounding healthy skin) resembling sand paper due to keratinisation or cornification of the surface of the skin. This allergic reaction is usually associated with red pigments. (Serup, et al., 2016) (CHDP, 2015)	Observed in 3.7% of tattoo reactions in (Serup, et al., 2016)
Photosensitivity	Light (solar or laser) induced reactions range from minor (swelling, itching, stinging, redness) to pain or thickening in the tattoo. They are associated primarily with darker coloured tattoos, e.g., black, red and blue. The symptoms can begin immediately after light exposure to the following day, lasting from 20 minutes to several weeks. (Hutton Carlsten & Serup, 2014) Some urticarial (wheal-and-flare or hives) reactions can be light-induced. These can be acute and of short duration, sometimes with spontaneous healing, and occasionally lasting days. Red colours were more frequently associated with light-induced reactivity, indicating to the authors that azo pigments and their photochemical decomposition products may play a role in photosensitivity reactions.	The results of beach study by Hutton Carlsten & Serup showed that about 24% of complaints were sun-related. In (Serup, et al., 2016), in total 11% of reactions were provoked by light.

Other less common non-infectious inflammatory reactions that can be associated with exposure to chemicals include: neurosensory, other urticarial-like, lymphopathic, pseudolymphomatous. These are explained Annex D, section D.6.1.

Systemic or general clinical complications

Self-reported systemic problems directly after tattooing were mentioned by 6.6% of respondents, while 3% reported persistent problems in other than the skin (Klügl, et al., 2010). However, the data does not provide sufficient detail to conclude on the prevalence of systemic effects after the initial healing process of the tattoo.

The metabolism and diffusion of tattoo inks in the human body is not well-established; although, there is clear evidence that pigments are transported to local and regional

lymph nodes of humans. (Schreiver, et al., 2017) Furthermore, animal studies have revealed the presence of pigments in Kupffer cells in the liver, which suggests that the pigments as well as soluble substances present in tattoo inks enter the blood and can be transported to virtually any human organ but it is unknown whether other internal organs can be targets for deposition of tattoo pigments. (Sepehri, et al., 2017a)

Additionally, modern-day tattoo inks contain nanoparticles. (Høgsberg, et al., 2011) The extent to which pigment containing nanoparticles may reach internal organs and lead to clinical symptoms has not been studied and is unknown. (CHDP, 2015) Animal studies of nanoparticles in general (quantum dots, silver, and gold, injected respectively intradermally, subcutaneously/orally or intratrecheally) show their deposition in organs such as kidney, liver, spleen, lung as well as brain, leading to the blood-brain barrier destruction. The translocation is shown to depend on the particle size, chemical composition, shape, electrical charge, coating, etc. (Gopee, et al., 2007), (Loeschner, et al., 2001), (Sadauskas, et al., 2009), (Sepehri, et al., 2017a), (Tang, et al., 2009)

Although, some substances historically present in tattoo inks have harmonised classification of STOR RE and STOT SE, indicating their acute or chronic toxicity to various internal organs, it is uncertain whether the human body is exposed to these substances sufficiently to lead to an effect clearly associated with exposure to tattoo inks. The association between organ toxicity and tattoos has not been interrogated by animal or epidemiological studies.

Annex D, section 6.1 describes systemic reactions with cutaneous manifestations that are associated to a various degree with the chemical composition of tattoo inks such as general eczema, sarcoidosis, and other associated skin diseases. These systemic reactions represented 8% of all primary diagnoses and were associated mainly with black tattoos. (Serup, et al., 2016)

Malignant tumours

A literature review concluded that it is unclear whether tattoo inks may induce skin or visceral tumours, even though many substances contained in tattoo inks (such as PAHs primarily in black pigments or PAAs in colour pigments) and their degradation products, sometimes with increased solubility properties, are classified as mutagenic or carcinogenic. (JRC, 2016a) (JRC, 2016b) (Kluger & Koljonen, 2012).

A review of skin cancer cases on tattoos reported in literature between 1938 and 2011 found 50 cases: 16 cases of melanoma, 11 cases of basal cell carcinoma (BCC), and 23 cases of squamous cell carcinoma (SCC) and keratoacanthoma (KA) with an onset soon after to more than 50 years after the tattoo procedure. Melanoma and BCC cases were primarily associated with darker colours (black and blue), while SCC and KA with red tattoo pigments.[23] (Kluger & Koljonen, 2012) As the number of skin cancers in tattoos is seemingly low in comparison to the prevalence of skin cancers in the general population, the authors concluded on the basis of literature review the association between tattoos and skin cancers coincidental. (Kluger & Koljonen, 2012) Kluger & Koljonen, however, note that more recent reports pertain to younger patients and have shorter delay of

[23] Of note is that there is difficulty to distinguish SCC and KA (JRC, 2016b), the latter considered by some benign and self-limiting (CHDP, 2015) and others as borderline lesions (Kluger & Koljonen, 2012).

malignancy presentation. This they suggest could be explained with the overall predisposition to malignancies of younger people or due to substances in more recent inks with carcinogenic properties. (Kluger & Koljonen, 2012)

Cancer, other than the skin cancer associated with tattoos, has not been documented in medical literature. (CHDP, 2015) This includes cancers in internal organs and or in the lymph nodes (i.e., malignant lymphoma or leukaemia), i.e., the first organ, as noted by (CHDP, 2015), that the substances in tattoo inks reach in their most concentrated form and which in contrast to the dermis contains many proliferating cells, which may be exposed to a carcinogen. At the same time, the association between tattoos and malignancies has not been studied clinically and epidemiologically (Kluger & Koljonen, 2012).

Also, there are no well-designed animal studies which examine the link between tattoo ink exposure and cancer, which is also the case for many other carcinogenic substances. Three recent studies (briefly outlined in Annex D, section D.6.1) of tattooed hairless mice observed up to 356 days have similar deficiencies. (Lerche, et al., 2015), (Lerche, et al., 2017), (Sepehri, et al., 2017b) As the protocol for carcinogenicity[24] calls for an 18-24-month animal study, the timespan and number of animals studied, makes it difficult to conclude on carcinogenic effects. In addition, the mouse skin is different than the human skin and mini pigs would have been a more appropriate study animal.

In summary, the conclusion on the role of tattoo inks in the development of skin or internal organ malignancies cannot be made on the basis of clinical observations. Cancer is a multifactorial disease, which can take decades to express. Therefore, direct causality between tattoos and malignancies will not be easy to demonstrate and the relationship will need to be established on the basis of the hazard properties of the substances in tattoo inks and the limited information available on the degradation and metabolism of substances in the skin and their diffusion in the human body over time.

<u>Reproductive and developmental effects</u>

The effects of injecting into the skin of tattoo inks containing substances with known reprotoxic effects remains an area for research as several aspects of health consequences of tattoos are unclear. Similar to systemic and carcinogenic effects, there is a theoretic possibility for constituents of tattoo inks to enter the blood stream and impact other organs and the unborn foetus. Some of the chemicals in tattoo inks (heavy metals, amines, etc.) can be transferred via the human placenta. There is limited data regarding breast milk and the potential systemic distribution of tattoo constituents and by-products in the circulation and therefore, possibly through the placenta during pregnancy or in the milk in not known. (Kluger, 2015b) The existence of nanoparticles in tattoo inks increases the uncertainty.

This issue of the effects of tattoos on pregnancy and the unborn child is an issue that has become more relevant because of the large number of women in childbearing age acquiring a tattoo, it is a practice by tattoo artists in many Member States to advise

[24] Test method B.32 (Carcinogenicity studies) in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

against getting a tattoo while pregnant. Currently, no data exist to suggest additional risks for the mother or the baby in the presence of tattoos. (Islam, et al., 2016) Reproductive toxic damage in the form of abortion, deformities and malformations resulting from tattoos of fertile women before, up to or during pregnancy has not been shown. On the other hand, this has not been studied systematically either and evaluations have not ruled out that tattoos and tattoo ink may lead to such adverse effects. (CHDP, 2015) Of particular concern is if the tattoo procedure takes place in the critical development period of sexual differentiation as the bioavailability of tattoo inks at that point is the largest. Additionally, the risk of foetal development in heavily tattooed mothers is not known either. Observation of 25 tattooed women – professional tattoo artists – in France shows 36 favourable outcome pregnancies. (Kluger, 2015b)

c) Incidence and prevalence

It is difficult to estimate the true overall incidence and prevalence of complications because no registry and epidemiological studies are available. Furthermore, direct association with the effects and specific substances is extremely challenging due to variability of the components of inks, pigments, and contaminants that can be injected into the dermis. Also, few patients consult their physician regarding minor cases, opting instead to return to the tattoo parlour. (Høgsberg, et al., 2013) A number of studies have attempted to estimate the prevalence (in specific sub-populations) of discomfort (complaints) and complications due to tattoo and PMU procedures.

Table 19 gives an overview of the most important incidence and prevalence studies of tattoo related adverse effects in countries in the EU. Further Information on the studies is included in Annex D, section D.6.1.

Table 19 Prevalence of tattoo complains and complications

Study	Prevalence	Type of effects	Study population
(ISS, 2017)	3.3% of tattooed with complications or mild reactions, of these, only 21.3% consulted a dermatologist or a general practitioner	pain (39.3%); swelling, blisters, granuloma (27.7%); dermatitis, eczema, itching (26.7%); skin thickening (24.4%); allergic reactions (17.5%); other: pus, bleeding, dizziness, headache, scabs & fever	Sample of Italian population (7 600 people)
(Kluger, 2016b)	In at least one of their tattoos: 42.6% - with reaction Permanent: 4% - mild swelling & 1% - itch During/after sun exposure: 14%- itch & 23%- swelling	Transient or permanent itch and swelling; itch and swelling after/during sun exposure; infectious; allergic (not defined); skin cancer	448 tattoo artists members of French tattoo union

(Serup, et al., 2016)	Of complications: 37% - allergic 13% - papulo-nodular 9% - psycho-social 11% - infectious 30% - other 5% - sarcoidosis	Allergic reactions consisted of plaque elevation (32.2% of all complications), excessive hyperkeratosis (3.7%) and ulceration (1.4%). Other include photosensitivity, pain syndrome and lymphopathy	Patients with tattoo complications, Tattoo clinic, Bispebjerg University Hospital, Denmark (2008 to 2015)
(Hutton Carlsten & Serup, 2014)	Of 144 tattooed individuals: 42% - complaints (after initial healing): 52% sun-induced & 48% other (34% persistent) 1.4% - complications	Sun-induced (swelling, itching, stinging, pain, redness) & other (constant swelling, long-lasting tenderness, heat-induced, "allergic", acne-like, tenderness when cold, swelling after alcohol or tomatoes)	467 sunbathers on beaches in Denmark
(Høgsberg, et al., 2013)	> 3 months after tattoo: 27% of participants - complaints, 4% - complications < 3 months after tattoo: 15% - complaints After sun exposure– 15.6%	Complaints related to itching, ulceration, redness, swelling, prolonged healing, fever and malaise, and local infection. Complications most frequently related to skin elevation and itching.	154 patients with 342 tattoos of a venerology clinic in Denmark
(Wollina, 2012)	Incidence of 0.02% based on the number of treated patients per year	Lichenoid, pruritic, sarcoidal, edema, systemic, ulceration and infectious (30%) reactions. Mild reactions are excluded	Patients of Academic Teaching Hospital Dresden-Friedrichstadt (03/ 2001-05/2012)
(Klügl, et al., 2010)	67.5% of participant skin problems 6.6% systemic reactions 7.7% health problems after 4 weeks 6% persistent skin problems 3% other	Most frequent problems included: bleeding, crusts, itching, edema & pain, followed by a burning sensation, blister formation & puss-filled skin. Systemic reactions included: dizziness, headache, nausea or fever. Other included, e.g., psychic problems or light sensitivity	3 411 German-speaking tattooed persons: 93% - German (evenly distributed), 6% - Austrian, 1% - Swiss.
(Kazandjieva & Tsankov, 2007)	2.1% with complications	Infectious, allergic, and/or granulomatous complications in connection with tattoo pigment	234 dermatological patients with tattoos

Table 19 shows that on average 1.7%[25] of tattooed people develop adverse reaction of severity that requires a doctor's consultation. As can be seen, the studies are primarily of countries where the regulation of tattoo practices (e.g., licensing, hygienic requirements, compliance with CoE ResAP recommendations, etc.) has increased in the last ten years, while many Member States have not taken such steps. Therefore, it can be expected that the prevalence of tattoo complications in Member States without any national regulations would be higher. On the other hand, the preceding sections demonstrated that the onset of chronic tattoo reactions as well as other health effects can occur from weeks to decades after the tattoo has been made; therefore, the statistics above may not yet reflect the advancements in tattoo practices and inks. In the absence of better information, it is assumed that this is a representative rate of tattoo complications for the EEA31. As no long term studies on tattoo complaints and complications exist, it is assumed that the annual increase of tattoo complications will be the same as the incidence rate of tattoos/PMU in the EU population.

c) Treatment

Non-infectious, inflammatory tattoo complications, although relatively rare, are often persistent (chronic), disturbing daily life as they lead to itching, swelling, and pain. They require prolonged treatment and maintenance to avoid flare up of the symptoms or more invasive intervention such as surgical excision, dermatome shaving, or laser removal. As shown in the preceding sections, the most common non-infectious, inflammatory complications related to tattoos are plaque elevation or papulo-nodular reactions. Of the allergic reactions, excessive hyperkeratosis and ulcero-necrotic reactions are very rare. Extremely rare are also cases where hospitalisation of several days is required, accompanied by acute excision (e.g., in severe allergic reactions with deep pigment deposition into the subcutis or the underlying muscle or fat tissue), skin graft, painkillers and antibiotics, as well as several months of aftercare during skin recovery.

The treatment of tattoo complications is individualised to the patient and type of tattoo reaction. Some chronic reactions can be managed with regular application of topic or intralesional steroids, e.g., allergic reactions of small tattoos with limited amount of pigment concentrated in the outer dermis. However, the rate of recurrence is high and the treatment can be limited in time because of the risk of atrophy (local steroids) or other side effects (oral treatment).

In the event that allergic reactions persist after local treatment with steroids, a removal of the pigment is considered. Laser treatment (with Q-switch lasers (neodymium: yttrium-aluminium-garnet [Nd:YAG], alexandrite, or ruby) and newer picosecond lasers) has become increasingly popular solution for removal. However, as lasers lead to chemical decomposition of the pigment in the body, laser treatment bears the risk of evoking an additional allergic reaction. (Aberer, et al., 2010) Therefore, the use of lasers for allergic reactions is highly controversial and contraindicated. However, they can be effective in reducing the pigment load in some papulo-nodular reactions. (Serup, 2017)

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

After tattoo reactions have been diagnosed unlikely to respond to medical treatment and when there are concerns laser therapy triggering allergic reactions, surgical removal of the pigment can be pursued, i.e., via a surgical excision or dermatome shaving.

Surgical excision is practiced in many Member States to remove recurring tattoo reactions. It can be technically difficult and cosmetically deforming for large tattoos (Islam, et al., 2016), and when the excision reaches the lower one-third of the dermis, scarring is unavoidable. The excision site often shows hyper- or hypopigmentation along with scarring. (Sepehri & Jorgensen, 2017) It may make plastic surgery necessity and cosmetic considerations should be given in the treatment selection. (Aberer, et al., 2010)

Another procedure, is dermatome shaving. This procedure involves consecutive shaving of thin horizontal layers of the skin area where the pigment reaction is occurring. The main goal of the surgery is to remove the culprit pigment. At the same time, the aim of the shave is to be as superficial in the dermis as possible, typically, at the mid-dermal level or just below. (Sepehri & Jorgensen, 2017)

Ablative carbon dioxide laser is another technique of pigment removal. The carbon dioxide laser emits an invisible infrared beam at 10 600 nm, targeting both intracellular and extracellular water. When light energy is absorbed by water-containing tissue, skin vaporization occurs. (Shankar, et al., 2009) With carbon dioxide laser therapy, the pigment, together with the top layer of the skin is incinerated.

Some chronic papulo-nodular reactions, when cutaneous granulomatous reactions reveal or trigger underlying diagnosis of systemic sarcoidosis, are often treated with oral immuno-suppressive medications for the cutaneous manifestations of the illness. Depending on the other organs impacted, other specialist appointments (e.g., ophthalmologist or pulmonologist), CT scans or ex-rays, biopsy, and other medical treatment that can last months to years may be required.

Other systemic, reproductive, developmental or carcinogenic diseases associated with exposure to tattoo inks may require years of treatment, thousands of euro in direct and indirect treatment costs and can lead to loss of productivity and shorter life expectancy.

c) Costs to society of adverse reactions to tattoos and PMU

As described above and in Annex D, adverse effects to the chemical composition of tattoo inks can be non-infectious inflammatory, systemic, malignant, reproductive and developmental.

With respect to chronic non-infectious inflammatory tattoo complications, the most common treatment involve topical, intralesional or oral treatment for milder cases and surgical or laser removal for more serious cases where topical treatment has proven ineffective. Table 20 presents a summary of the medical costs per case associated with the treatments of chronic non-infectious inflammatory tattoo and PMU complication. The medical costs represent the costs of the procedures described in section c) and do not include indirect costs such as loss of productivity.

Table 20 Cost to society of chronic non-infectious inflammatory tattoo complications per case

Treatment	Total cost*
Medical (topical, intralesional, or oral) treatment (annual/case)	€460
Surgical treatment (one-off costs/case) - dermatome shaving - excision - carbon dioxide laser	€2 100
Laser treatment (one-off costs/case)	€2 250
Willingness to pay (WTP) to avoid symptoms of tattoo reactions, annual/case	€2 000 - €12 000**

Notes: *Costs can differ substantially for Member States and similar treatments. ** 2014 Values (ECHA, 2016b)

In addition to costs for treatment, the patients suffer due to their symptoms while awaiting recovery (end of treatment). These symptoms include itching and burning sensations that affect their quality of life. Hutton Carlson & Serup concluded that sufferers of tattoo reactions experienced reduced quality of life similar to known skin diseases such as psoriasis, pruritus, and eczema, albeit the typical tattooed affected areas are smaller. (Hutton Carlsen & Serup, 2015a) These results suggest that the quality of life impacts of the severe chronic dermatitis estimated by ECHA (ECHA, 2016b) are similar to those of tattoo complications. This is despite differences in the treatment, which are reflected in the medical and indirect costs (not estimated in Table 20) or any possible aesthetic effects. For the purpose of this analysis, the valuation scenario for severe chronic dermatitis in (ECHA, 2016b) and thus, the derived willingness to pay value to avoid this experience (equal to €2 000/case (lower value) or to €12 000/case (higher value) as shown in Table 20), is considered a suitable proxy for the willingness to pay for avoiding symptoms related to negative health impacts on the skin.

Other systemic, reproductive, developmental or carcinogenic illnesses have much higher willingness to pay to avoid (e.g., the willingness to pay to avoid cancer morbidity is €410 000 in 2012 values (ECHA, 2016b)).

2.4.3.2. Environmental impacts

As the rationale for this restriction proposal is human health, the environmental impacts arising from substances in tattoo inks and PMU are not discussed further.

2.4.3.3. Risk reduction capacity

The restriction options include in their scope substances that could contribute to adverse effects from tattoos. Any new substances, meeting the criteria for inclusion in the scope of the proposed restriction options, will be progressively added, i.e., any new substances classified as CMR, skin sensitisers/irritants/corrosives, eye irritants/damaging or included in Annex II and IV of the CPR (the latter for RO1 only). A few substances not included in the scope of RO1 and RO2 but suspected to lead to human health effects due to their injection in the dermis are highlighted for consideration in future assessment as currently there is no sufficient information to conclude on their risks to human health. (See Appendix D.1. Substances for future evaluation)

However, it is theoretically possible that the implementation of the proposed restriction options as well as future tattoo ink and PMU development could lead to the introduction of colourants never used before in this application, with limited information about their

effects on human health, including when injected intradermally. This will necessitate continued examination of the substances found in tattoo inks.

Therefore, while RO1 would lead to a decline in the number of cases of adverse tattoo effects, it is not expected to fully eliminate them due to the uncertainty associated with a number of currently used, or to be used in the future, substances that are not well-researched, and therefore, their impacts on human health are not well understood.

As RO2 proposes less strict concentration limits in comparison to RO1, it is possible that it would lead to the avoidance of fewer cases of adverse effects in comparison to RO1, leading to comparatively slightly lower risk reduction capacity.

2.4.4. Practicability and monitorability

2.4.4.1. Practicality

Practicality in the context of an Annex XV restriction dossier under REACH is defined in terms of three criteria: implementability, enforceability and manageability.

a) Implementability

The restriction options propose similar, and in the case of RO2, likely slightly less strict than the recommended measures in ResAP, which have been used as a basis for national legislation in seven Member States and two EEA members. Surveillance results have shown that the majority of tattoo inks and PMU are in compliance with national legislation, which suggests industry's ability to comply with the proposed restriction options. The proposed transitional period reflects the industry capability to comply with RO1 and RO2. It is anticipated that formulators who currently do not meet the requirements will be able to develop and begin marketing compliant tattoo inks within this transitional period.

b) Enforceability

Enforcement of national legislation based on ResAP already takes place in just under a third of EEA31 States. They have systems in place to monitor compliance and to share information on non-compliant products – RAPEX. Member States that have no national legislation in place could build on this experience.

To assist with compliance check of relevant actors, the dossier provides information on the substances found in tattoo inks that present risk to human health and highlights groups of substances that are considered most problematic: PAHs for black and dark inks, PAAs for red inks and its nuances, as well as selected problematic impurities commonly found in a variety of tattoo inks (see section Table 3 of CoE ResAP(2008)1: Impurities). To achieve greater return on their enforcement efforts, Member States can focus on ensuring that these substances are no longer present in tattoo inks and PMU. Occasional detailed analysis of selected tattoo inks and PMU may help prioritise other substances for future frequent screening.

Analytical methods exist for all groups of substances in the scope of the proposed restriction options, except for azo colourants which may decompose to PAAs with CMR properties. Appendix D.2 provides information on the analytical methods that can be used to enforce the restriction: an update of the earlier work by the JRC (JRC, 2015a),

with contributions from the Forum for Exchange of Information on Enforcement (Forum), the ECHA Call for Evidence ran (ECHA CfE, 2016), Germany and Dossier Submitter representatives (Denmark, Italy and Norway).

Information on the limit of detection of the currently used methods has been taken into account in the setting of the concentration limits for individual and groups of substances in the scope of RO1 and RO2. Stakeholders identified the need for harmonisation of analytical methods to avoid different treatment in different Member States. To select an appropriate method, one of the important questions to be resolved is under what conditions metals can be considered soluble and therefore, bioavailable (i.e., in terms of the solvent, pH, temperature, time, etc.), as some metals can be found as impurities in tattoo inks but are also part of the complex bounded matrix of the pigment and therefore, potentially not bioavailable. (ECHA CfE, 2016)

Another issue brought up by stakeholders is the sales of non-compliant tattoo inks and PMU via the internet. (ECHA CfE, 2016) The collaboration of online resellers in the enforcement of the restriction measure will be paramount for its success.

c) Manageability

Given the similarity with existing measures (ResAP, the CPR, and the CLP Regulation) and the stakeholder's raised awareness on the issue, RO1 and RO2 should be clear and understandable to all the actors involved. The level of administrative burden is not expected to be higher than in the Member States with national legislation. The current compliance rate suggests that the existing regulations are manageable for industry. Furthermore, Section 2.4.5.1 shows that the impact on individual actors (tattoo ink and PMU manufacturers, tattoo artists, PMU practitioners and customers) of the proposed restriction options are affordable and manageable, although selected stakeholders (e.g., those manufacturers who have not begun to develop alternatives) may experience larger impacts.

2.4.4.2. Monitorability

The implementation of the proposed restriction options can be monitored via surveillance programs and existing tools such as RAPEX. Of particular importance would be the monitoring of the use of tattoo inks and PMU by tattoo artists and PMU practitioners who would have the obligation under the proposed restriction options to use only compliant inks. This is important due to the numerous possibilities to procure tattoo inks, including to mix them from pigments in powder form in their studios.

In addition, the following could assist with the monitoring of the impact of the proposed restriction measure and the assessment of necessary further measures:

- the introduction by national health boards of a separate, EU-harmonised diagnostic codes for tattoo ink and PMU complications to enable tracking of adverse effects and to provide relevant epidemiological information for long-term studies of the association between tattooing (and PMU procedures) and cancer, reproductive and developmental issues, sarcoidosis, or other systemic illnesses for which there is currently limited information
- the introduction of an EEA-wide registry of tattoo inks, which among other information, to gather data on the chemical composition of the mixtures. This will

provide information on new substances finding application in tattoo inks and PMU, which in turn will help with the assessment of the effectiveness of the proposed measure and the need for further regulatory action.

2.4.5. Proportionality to the risk

2.4.5.1. Affordability

a) Tattoo ink and PMU manufacturers

Manufacturers with ResAP-compliant tattoo inks have reported that their margins have eroded, due to the pressure to compete with non-compliant tattoo inks and their non-discerning customer base (i.e., tattoo artists). However, it is expected that those already compliant with ResAP, would not have to incur substantial additional costs to comply with the proposed restriction options. The largest burden of the regulation would fall on those manufacturers which have not developed tattoo inks meeting ResAP's recommendations. As stated previously, EU manufacturers are reported to have higher compliance rate with ResAP requirements, therefore, the largest burden would fall on non-compliant importers. Currently, non-compliant manufacturers are reported to have a higher profit margin, as their manufacturing costs are about 50% lower than those of ResAP compliant inks, while their products have similar (0-20% lower) market prices. (stakeholder consultations)

For the purpose of this analysis, it is assumed that tattoo ink and PMU formulators would be able to pass downstream their higher costs to be incurred due to the proposed restriction options in the form of higher market prices for their products. Industry has expressed concerns that they are unable to pass on higher costs. With the entry of the proposed restriction options all formulators would need to comply with the regulation and therefore, the pressure from lower-cost, non-ResAP compliant inks would abate.

b) Tattoo artists

Tattoos can be very diverse and their price, amount of time and ink used varies greatly, depending on the skill of the tattoo artist, design (custom or pre-designed, realistic or abstract), black or multi-colour, outline or shaded, etc. The starting price for customers of smaller tattoos in many Western and Northern European Member States is on average €80-100, which is also similar to the average rate per hour of tattoo service. In Eastern Europe, prices have been reported somewhat lower: €30-40 euro for a very small tattoo. However, everywhere the prices of sought-after tattoo artists can be significantly higher. (ECHA CfE, 2016) (stakeholder consultation)

Tattoo artists incur total costs per tattoo between €20-40 for supplies, rent, labour, and other overhead. Costs can be lower for sought-after tattoo artists as they are often sponsored and receive complimentary tattoo ink, needles, equipment and other supplies from manufacturers. Costs could also be expected to be lower in some Eastern European Member States.

The cost for tattoo ink is estimated to account for up to 14% (in Western Europe) to 31% (in Eastern European Member States) of the total cost per tattoo for tattoo artists. Therefore, if as a result of the proposed restriction options, the share of the tattoo ink of total costs per tattoo would increases to 16% (in Western Europe) to 35% (in Eastern European Member States). In other words, the marginal costs of the proposed restriction would be less than €1 per tattoo. It is expected that this increase would have a minor impact on the profit margin of a tattoo.

c) PMU practitioners

Prices of PMU procedures such as eyeliner, lip liner, or eyebrow enhancement also vary substantially in different Member States. They also depend on the reputation of the studio (which could also be a tattoo studio) or beauty (spa) centre and whether the centres offer packages (bundles) of various procedures. Stakeholder consultations have reported an average price of a procedure of about €350 but prices in Eastern and Southern European Member may be lower. Therefore, if as a result of the proposed restriction options, the cost of PMU increases by 20%, the share of the PMU of total costs per procedure would increases from 14% to 16% or the marginal cost of a restriction would be about €4/procedure. It is expected that this increase wold have a minor impact on the profit margin of PMU procedures.

d) Customers

It is likely that any tattoo and PMU cost increases caused by the proposed restriction options will be passed on to consumers, as according to market research in the US demand for tattoo and PMU services is inelastic. It is driven primarily by demographics and cultural (including fashion) trends rather than other economic forces. Despite having the hallmark of a luxury service, the industry revenue hardly declined during the most recent recession. The price of a tattoo was also not seen as a priority among those deciding on a tattoo: only 8% of respondents to a survey stated that price is an important factor in their decision to get a tattoo. Demand in the future is expected to continue to be unaffected by changes in disposable income. (IBISWorld, 2016) (SB, 2015)

In conclusion, even though it is likely that the introduction of one of the restriction options would lead to higher costs for industry, those would likely be affordable for downstream users: tattoo artists, PMU professionals and consumers.

2.4.5.2. Cost-effectiveness

As shown in the preceding sections and Annex D, the proposed restriction options would likely lead to costs and other impacts to industry and society as whole. Table 21 shows that these are expected to be relatively small and manageable for industry and social actors. The cost-effectiveness of RO1 is estimated at about €60/litre non-compliant tattoo ink replaced in EEA31. The cost-effectiveness of RO2 is likely to be higher as substitution costs are expected to be somewhat lower than those estimated for RO1.

2.4.5.3. Break-even analysis

For RO1 to break even, between 320 (calculated using cost of illness (COI) plus higher WTP values) and 1 050 (COI plus lower WTP values) cases of chronic allergic reactions (i.e., requiring surgical removal) need to be avoided on an annual basis. This is between 0.02-0.06% of the estimated number of people getting tattoos for the first time each year (19-63 avoided removals for every 100 000 tattooed people) in EEA22 – the Member States currently without national legislation.

It is reasonable to expect that these cases would be avoided as a result of the proposed restriction measure as the estimated average prevalence rate of tattoo complications is 1.7% (see point d) in section 2.4.3.1) and not all costs are taken into account (see point c) in the same section).

In addition, the removal of tattoos due to an allergic or papulo-nodular reaction is just one group of the health outcomes. As stated in section 2.4.3.1, a number of people

experience complications that require topical or systemic corticosteroids as well as experience mild ongoing complaints from their tattoos and PMU.[26] This is in addition to the potential contribution of tattoo ink and PMU exposure to carcinogenic, reproductive, developmental and other systemic adverse effects.

Therefore, although full cost-benefit comparison it is not possible, it is reasonable to assume that the benefits would outweigh the costs, as very few cases of only one type of adverse effects (non-infectious, inflammatory) are necessary for the restriction to break even. Quantification and monetisation of other adverse effects (systemic, carcinogenic, reproductive or developmental) would lead to higher overall value of benefits from RO1.

As the concentration limits of RO2 are higher than RO1, it can be hypothesised that RO2 offers a lower level of protection and therefore, fewer benefits. However, as costs for RO2 are also lower than RO1, it is difficult to determine the overall proportionality of RO2 in comparison to RO1.

2.5. Comparison of restriction options

As shown in the preceding sections and summarised in Table 21, both restriction options (RO1 and RO2) would likely lead to costs and other negative impacts to industry that are of similar nature and magnitude. The main difference between the two restriction options are the concentration limits. As the concentration limits of RO2 are higher than RO1, it can be hypothesised that RO2 offers a lower level of protection and therefore, lower risk reduction capacity and fewer benefits.

At the same time, as more tattoo inks currently on the market likely already comply with RO2 requirements, the substitution costs would be lower than RO1. Testing costs for RO2 would also be possibly lower than RO1 as the information on classified substances is required to be included in the label and the substance data sheet if they are present in concentrations exceeding their CLP limits in mixtures. Therefore, as the costs of RO2 are anticipated to be slightly lower, this option would be slightly more cost-effective (in terms of euro per volume non-compliant tattoo ink substituted), slightly more affordable for stakeholders and would require fewer avoided cases to break even. At the same time, it is expected that the risk reduction capacity, and therefore, the benefits, of RO2 would also be slightly lower. It is uncertain whether they are sufficiently different than RO1 to conclude that RO2 is more proportionate than RO1 on a cost-benefit basis.

Table 21 compares the two options qualitatively. An overall conclusion on which option is more proportionate is difficult to reach.

[26] Various studies have reported mild complaints after sun exposure as shown in Annex D: 14% reported itch and 23% swelling after sun exposure (Kluger, 2016b); 52% of complaints (42% of total respondents reported a complaint) were sun induced (Hutton Carlsten & Serup, 2014); 15.6% of respondents expressed complaints after sun exposure (Høgsberg, et al., 2013).

Table 21 Total compliance costs and cost-effectiveness of the proposed restriction options

2016 values, euro, annual	Restriction Option 1 (RO1)	Restriction Option 2 (RO2)
Total Compliance Costs	€4.6 million	lower
Substitution	€4.4 million	lower
Enforcement	€0.2 million	similar
Social impacts	moderate	similar
Wider economic impacts	minimal	similar
Distributional impacts	minimal	similar
Cost-effectiveness	€60/litre non-compliant tattoo inks removed from the market	higher
Risk reduction capacity	it would reduce risks	possibly lower
Benefits	equivalent to the avoided cases of tattoo adverse effects (non-infectious inflammatory, systemic, reproductive, developmental, malignant)	possibly lower
Break-even	required 320 – 1 050 avoided cases of tattoo removal due to non-infectious inflammatory complications	possibly fewer cases required for break-even

In summary, it can be concluded that the proposed restriction options are proportionate, as they are cost-effective, affordable and would lead to benefits in terms of avoided complications of tattoo inks and PMU associated with exposure to chemicals and other health effects.

3. Assumptions, uncertainties and sensitivities

3.1. Related to risk assessment

The main assumptions and uncertainties in the risk assessment section of this report are listed below.

Table 22 Overview of the main sources of uncertainty and how they will drive the RCR, concentration limits and the sensitivity of the final result

Source of uncertainty	Description	Effect on RCR	Effect on CL	Sensitivity of results
Amount of pigment/ink deposited in a tattoo (mg/cm^2)	The estimate for used ink may be an overestimation because the 75th percentile from experimental data was used and the calculation includes multiplication of the estimate by 4 (due to 25% pigment in the ink). The data set applied is very limited (9 reported numbers + unknown total number of experiments). Comparison with other literature data also suggests that the typical value of deposited ink may be smaller. If the professional tattoo artist does apply less ink per cm^2 than 14.36 mg ink/cm^2,which have been indicated in expert judgements, then the risk assessed in this assessment would overestimate the risk and set the concentration limits too low (where based on the exposure assessment).	↑	↓	High
Application of different tattoo equipment	In the study by Engel et al. (2008) the variability in the amount of pigment in the skin may also be due to the use of different tattoo application equipment.	Both ways	Both ways	Medium
Amount of pigment in the ink	In the calculation the content of pigment in the ink is assumed to be 25 %. As in some cases 25% will be too low (presumably leading to the use of less ink in total) and in some cases too high (presumably leading to the	Both ways	Both ways	Low

	use of more ink in total) this may influence the result in both ways.			
Uptake of pigment	In the scenario a 100% distribution of pigment in the system is assumed. This is most likely not the case. In the study by (Engel et al., 2008) a reduction of only 32% was observed during 6 weeks. If there is not a 100% distribution of pigment in the system the estimated RCR values will be too high and the concentration limits too low (where based on the exposure assessment).			Low
Uptake of soluble substances	In the scenario a 100% uptake of soluble substances such as impurities are assumed. This is likely to be the case. However, in case a 100% uptake does not take place the estimated RCR values will be too high and the concentration limits too low (where based on the exposure assessment).			Low
Continuous release of impurities from pigments	A continuous release of impurities from pigments may possibly give rise to additional exposure. However, since the solubility of pigments generally is very low this is unlikely to occur to a greater extent. Further, the release should supply a higher amount than was originally supplied with the liquid in the tattoo ink when excretion takes place. If impurities are released in such high amounts the risk estimated would be too low and the concentration limits too high (where based on the exposure assessment).			Low
Excretion of pigments	In the scenario it is assumed that the absorbed pigments are excreted after having had their effect within the body system. It is possible that this may occur due to observations of coloured lymph nodes. If the pigment is not excreted the RCR values will be too low and the concentration limits too high (where based on the exposure assessment).			Medium
Excretion of impurities	In the scenario it is assumed that the absorbed impurities are excreted after having had their effect within the body system. This is likely to be the case. If the known impurities were e.g. known as being hydrophobic the excretion may be less likely to occur. However, the known impurities are not known to be hydrophobic. However, if the impurities are not excreted the RCR values will be too low and the concentration limits too high (where based on the exposure assessment).			Medium
Lack of excretion of continuously released impurities	In case that a continuous release of impurities from pigments takes place and that these impurities are not excreted the system will experience a higher concentration than what is present in the tattoo ink. However the assumption that impurities are not excreted may not be likely.			High

- There still remain uncertainties regarding the appropriate methodology for assessing risks due to intradermal exposure and risks arising from mixtures. The challenges for risk assessment of pigments in tattoo inks has been raised by Serup (Serup, 2017a). The Dossier Submitter recognizes these challenges. However, as no other alternative and appropriate method has been found, the Dossier Submitter has applied the approach for risk assessment in REACH.
- The Dossier Submitter assumes that the risks associated with exposure to a substance at an equivalent dose are expected to be at least as high, if not higher, for intradermal exposure via tattooing compared to exposure to substances applied on the skin. However, it is acknowledged that in some cases this conclusion may not hold true considering that a tattoo may only be applied once, or a limited numbers of times, and while it leads to long-term exposure, this exposure may be different than the exposure associated with

for example a cosmetic product applied and removed multiple times (up to daily application over most of a lifetime).

- The number of substances included in the scope that have actually been used in tattoo inks is unknown. A restriction would therefore likely cover various substances that would never find use in tattoo inks.
- The rationale for inclusion of some of the CPR Annex II substances is clear, particularly in relation to recent amendments to the CPR/CPD where there is an associated opinion of the SCCS. However, for many of the substances there are no such associated opinions. For example, some of the inclusions relate specifically to certain uses in cosmetic products (e.g., hair dyes or substances used as a fragrance ingredient) and not others. It is uncertain to what extent other uses have been examined in the decision to place the substance on Annex II and what the implications are for risks associated with potential use in tattoo inks.
- While Annex II of the CPR does not include any concentration threshold for substances prohibited from use and for only a few of the substances in the 'restricted field of application' product types in Annex IV, adapting this for a restriction on tattoo inks might require consideration of such a low concentration limit. In particular, some substances might be present in detectable but toxicologically negligible concentrations, with their removal being impractical or would require substantial resources, exceeding any benefits of their elimination. Examples of such situations have not been collected on the basis of the experience of the Member States with national legislation based on the two resolutions. However, enforcement of Annex II and IV under the CPR allows for the non-intended presence of traces of some substances, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, unless a purity requirement is stated. The concentration thresholds for cosmetic products would also presumably require updating to make them relevant for tattoo inks.
- This restriction carries only forward concerns about the conditions related to colourants used in cosmetic products and regulated under the CPR. Historical information shows that pigments other than those on Annex IV have also been used in tattoo inks. There are currently no conditions on their use, other than those related to the groups of substances included in the scope of this restriction proposal.
- Column h lists maximum concentrations for colourants allowed in Annex IV CPR which are intended to come into contact with the skin. The inclusion of the provisions of column h into the restriction is based on the argument that concentrations which are not allowed on the skin should also not be allowed under the skin. This would be a minimum requirement because the skin barrier, which is a factor in the absorption of substances applied on the skin, is circumvented in the case of injection of tattoo inks. A degree of uncertainty lies in the fact that no risk assessment of the respective substances has been performed for the application "injection under the skin". It is possible that for

tattooing, a lower maximum concentration needs to be allocated to certain substances.

- The justification for the maximum allowed concentrations of impurities in products for tattoos and PMU included in CoE ResAP(2008)1 Table 3 is not available to the Dossier Submitter.
- The content ranges for selected substances reported by JRC and used in the calculation of RCRs are based on a large variety of national surveys and market surveillance activities and are difficult to compare. Statistical details, such as mean, median and percentile values are to a large degree lacking.
- The detection limits for PAAs vary across different laboratories who apply different standards.
- The detection limits the Dossier Submitter used for setting the concentration limits for PAHs may be under estimated (set based on detection limit as the risk based concentration was below this) and therefore a lower concentration limit for PAHs could be achievable.
- Most/all analytical methods cannot differentiate between soluble and insoluble barium and copper and measure only the total content of elements.
- The solubility of different compounds varies, so the conclusions on the risk will depend on which substances/pigments/compounds are present in any given tattoo ink. The extent to which the risk will vary depending on solubility is unknown.
- Dose response relationships for substances included in the restriction are investigated by the Dossier Submitter only for a small number of the substances included in the scope.
- As highlighted by the RAC (ECHA, 2013), dose response relationships for arsenic were derived by linear extrapolation. Extrapolating outside the range of observation inevitably introduces uncertainties. As set out by the RAC, the mechanistic evidence is suggestive of non-linearity; it is therefore acknowledged that the excess risks in the low exposure range might be an overestimate.
- The different entries in the legislative text of CPR Annex IV are mainly identified by a Colour index number (CI number). Since several of the relevant CI numbers can be associated with more than one substance, the European Commission's database for information on cosmetic substances (Cosmetic ingredient database, CosIng) has been used as a source file to identify the correct CAS and EC numbers for the entries in Annex IV. There are uncertainties related to the use of CosIng to match the CI numbers with their corresponding CAS and EC numbers for some of the entries in CPR Annex IV, i.e. how the following legal text in Annex IV should be interpreted: "substance name….. and its insoluble barium, strontium and zirconium lakes, salts and pigments". The legal text indicates that at least 4 individual CAS/EC numbers should be associated with these entries in Annex IV, but this cannot be confirmed by the information in CosIng. The Dossier Submitter can therefore not be certain that all relevant substances on CPR Annex IV are captured by the scope of the restriction.

- There is a strong indication that photo-decomposition of azo colourants that contain 3,3'-dichlorobenzidine and azo colourants that may decompose via amide hydrolysis are 99,5% responsible for the PAAs (with harmonised classification) observed in tattoo inks. However, this could also be verified by other investigations, which have not been performed.
- Since azo colourants not described by the stakeholder as being used could be used in the future, all possible relevant PAAs have been identified and included in the scope of the restriction proposal. Thus PAAs that may not be relevant is also included in the restriction proposal.
- The critical aspect concerning laser treatment is the decomposition and the substances formed during laser treatment. The hazard and risk from laser treatment of tattoos implies uncertainties in the hazard and risk assessment which the Dossier Submitter has not addressed in detail.
- At present TiO2 is not in the scope of the proposal as it is only classified as a category 2 carcinogen through the inhalation route. The study of Schreiver et al. 2017 reported translocation of tattoo particles in the nano- and micrometre range from skin to lymph nodes. It is unknown if this exposure can lead to any risk and is therefore an uncertainty in the risk assessment.

There are several sources of uncertainties in the risk assessment of substances to reproduction in the present restriction proposal. Hereby, uncertainties related to identification/derivation of NOAEL/LOAEL and DNEL values have been discussed individually for each substance in Appendix B.3.

- The applied general approach of the DNEL setup following the REACH Guidance does not consider higher risks of sensitive population groups. The estimated RCRs may underestimate risks for young adults, children or adults with weakened immune defence (To the knowledge of the DS an EU-wide ban of tattooing for under the age of 18 is not existing).
- Further uncertainties arise from the chosen risk assessment strategy based on one overall DNEL for reprotoxic effects and setting of group concentration limits for substances toxic to reproduction as described in RO 1 & 2 that should cover the relevant range of risk levels. The risk of individual substances based on their estimated concentration limits were not considered in this proposal. This may lead to under- or overestimation of the risk level for the individual substances. Underestimation may have occurred for potent reprotoxic substances with DNELs lower than 0.001 mg/kg bw/d (as for example for tributyltin chloride). Overestimation is obviously given for other substances with DNELs higher than 0.001 mg/kg bw/d which may be true for the majority of known reprotoxic substances.
- There is general uncertainty for the Category 2 reprotoxicants. The DS proposes to include those in RO 1 & 2 with a group concentration limit 10 fold higher than the group concentration limit proposed for Category 1A/B reprotoxicants. Category 2 reprotoxicants were not subject of an individual hazard assessment and were not quantitatively assessed with regards to their risk level.
- The group concentration limits proposed for Category 1 and 2 reprotoxicants do not differentiate between effects on fertility (on male and female adults) and

development effects (e.g. on the progeny that may be affected by tattooing pregnant females). There is uncertainty in this approach as fertility and developmental effect are not necessarily comparable. Separate DNELs for fertility and developmental toxicity may exist. However the difference will not come into effect for most of the substances (those with DNEL above 0.001 mg/kg bw/d).

- The proposal suggests concentration limits on individual reprotoxic substances which do not reflect exposure to several compounds from one or multiple tattoo inks that may act on the reproduction system via similar or different modes of action.
- The exposure to reprotoxic substances may also be expected from other sources which have (in this proposal) not been considered.
- If present, risk estimates should be compared with biomonitoring data. Within this proposal concentration levels in urine or blood could be present for some of the assessed substances (e.g. for the reprotoxic phthalates), but have not been considered as this verification would have required to estimate the exposure from several sources. This was not feasible for the high amount of substances assessed.
- With regards to RO2 and the option to apply an individual concentration limit, there are uncertainties due to the imbalance of considering the individual concentrations only for those substances that have already been found in tattoo inks in comparison to other substances which would need an individual concentration limit to ensure RCR <1. This would result in a higher protection level for those already identified in tattoo inks than those not yet examined on.

3.2. Related to impact assessment

The proposed restriction options (RO1 and RO2) remain proportionate even when allowance for uncertainties is made. Table 23 shows the impact on the cost-effectiveness and the break-even points as a result of the relaxation of the main assumptions regarding the volume of tattoo inks and PMU on the market, the share of alternatives currently on the market, the anticipated price increase and their combined impact.

Table 23 shows that the combined impact of these assumptions has the highest effect on the proportionality of the proposed restriction options. The combination of Low volume/Low share of alternatives/High price difference leads to the highest deterioration of the cost-effectiveness of RO1 by 65%. For the proposed restriction options to break even in the worst case scenario 2 050 surgical removals due to complication of tattoo inks would need to be avoided (calculated using cost of illness (COI) plus low WTP values) or 620 (COI plus high WTP values). This is respectively about 0.12% or 0.04% of the estimated number of people getting tattoos for the first time each year in EEA22.

It is reasonable to expect that these cases would be avoided as a result of the proposed restriction options as the estimated average prevalence rate of tattoo complications is 1.7% (see point e) in section 2.4.3.1) and not all costs are taken into account (see point c)).

In addition, removal of tattoos due to an allergic or papulo-nodular reaction is just one group of the health outcomes. As stated in section Human health impacts a number of people experience complications that require topical or systemic corticosteroids as well

as experience mild ongoing complaints from their tattoos and PMU.[27] This is in addition to the potential contribution of tattoo ink and PMU exposure to carcinogenic, reproductive, developmental and other systemic adverse effects.

In summary, it can be concluded that the proposed restriction options are proportionate even when allowance for uncertainties is made.

Table 23 Restriction option 1 (RO1) – impact of assumptions

Indicator	Main Baseline	Low Tonnage	High Tonnage	High share alternatives	Low share alternatives	Higher price difference	No Price difference	Low tonnage/Low share of alternatives/High price difference	High tonnage/High share of alternatives/No price difference
Total restriction costs (yr)	4 589 609	3 042 190	5 174 969	2 331 456	6 847 762	8 943 456	235 762	8 943 456	235 762
Replaced tattoo ink & PMU (litres/yr)	78 693	38 859	87 911	46 567	110 820	78 693	78 693	55 032	52 078
Cost-effectiveness (€/litre non-compliant tattoo inks replaced)	58	78	59	50	62	114	3	163	5
Break-even - low (only effects on skin) (# cases avoided)	1 050	700	1 190	540	1 570	2 050	50	2 050	50
Break-even - high (only effects on skin) (# cases avoided)	320	210	360	160	480	620	20	620	20
Percent change		-26%	-1%	16%	-6%	-49%	1847 %	-64%	1188%

4. Conclusion

Qualitative and (semi-)quantitative risk assessment of over 4 000 substances concluded that risks for human health due to exposure to these substances injected intradermally cannot be excluded. In addition, the risks need to be addressed on a Union-wide basis to achieve a harmonised high level of protection of human health and the environment and free movement of goods within the Union.

Two restriction options are proposed to address these risks on Union-level: RO1 and RO2. The proposed restriction options are targeted at those substances that present risks to human health, through intradermal exposure. They will reduce the risks to human health to an acceptable level from current levels. Both options have different advantages and disadvantages, as shown in Table 24.

[27] Various studies have reported mild complaints after sun exposure as shown in

Table 19: 14% reported itch and 23% swelling after sun exposure (Kluger, 2016b); 52% of complaints (42% of total respondents reported a complaint) were sun induced (Hutton Carlsten & Serup, 2014); 15.6% of respondents expressed complaints after sun exposure (Høgsberg, et al., 2013).

Table 24: Advantages and disadvantages of the two options:

	RO1	RO2
Advantages	• Maintains similar level of protection applied by national rules that are based on the recommendations of the CoE ResAP; • Easy to communicate as the proposed scope closely follows national legislation. Tattoo ink manufacturers are already aware of CoE ResAP requirements. This will facilitate compliance with the proposed restriction; • Linked dynamically to Annex II and IV to the CPR and Annex IV of the CLP Regulation to ensure future changes to those annexes apply to the restriction; • Proposes concentration limits that are derived on the basis of argumentation for risk.	• Allow greater share of inks currently on the market containing some impurities to continue to be supplied • Lower testing costs as ingredient safety data sheets contain information on substances with harmonised classifications that are present in concentrations above their classification limits. • Easy to communicate to law makers, enforcement and industry as they are based on CLP limits. • Proposes concentration limits that are derived on the basis of existing legislation.
Disadvantages	• The unavoidable presence of some impurities not intentionally added to tattoo inks could result in some inks currently allowed on the market to not meet the requirements of RO1 • It is difficult to enforce a restriction without a specific limit as the default enforcement may be the limit of detection which is linked to the performance of the available analytical methods. Manufacturers may face some difficulties complying with the restriction and possibly face different treatment in different Member States, depending on the chosen analytical method by the enforcement authorities.	• Allows higher concentrations of hazardous substances (including substances of very high concern) to be injected under the skin. Tattooed persons will have a lower level of protection than persons using cosmetics on the surface of the skin. • For many substances, the proposed concentration limits may lead to a lower level of protection in Member States that already have national legislation based on ResAP; • Is less consistent as substances on Annex II of CPR will have different concentration limits than, e.g., CMRs, even though they have similar concerns with respect to human health risks.

Both proposed restriction options are considered to be proportionate to the risk because they are cost-effective, affordable for the impacted supply chains and require very few avoided cases for its benefits to exceed its costs:

- The majority of tattoo inks currently on the market meet the ResAP recommendations and the requirements of national regulation in several Member States. As both restriction options (RO1 and RO2) propose concentration limits that are similar or higher than those enforced by Member State national legislation, it is expected that a high proportion of tattoo inks and PMU currently on the EU market will meet the proposed requirements.
- Technically feasible alternatives with similar or better hazard and risk profiles exist. For those where alternatives have not yet been identified, a derogation is proposed. (See Table 4 and section 2.2)
- The incremental substitution costs estimated to be incurred by downstream users of tattoo ink and PMU as a result of RO1 are about €4.4 million annually during the temporal scope of the analysis (in 2016 values). As RO2 imposes less strict requirements than ResAP and RO1, it is anticipated that more tattoo inks and

PMU on the market are already compliant with RO2. Therefore, the substitution costs for RO2 would likely be lower than those estimated for RO1.

- Enforcement (analytical testing and administrative) costs to be incurred over the temporal scope of the analysis are estimated at €235 000 annually for EEA31.
- Many formulators are small or micro enterprises. Those not already compliant with ResAP would experience the largest regulatory burden from the proposed restriction options.
- The adverse effects associated with exposure to chemicals are grouped in: non-infectious inflammatory *(*plaque-like, papulo-nodular pattern, ulcerating patterns, hyperkeratotic, photosensitivity, other urticarial-like reactions, lymphopathic pattern, neurosensory reactions*),* systemic*,* malignant tumours, and reproductive and developmental.
- The restriction options are expected to provide benefits related to avoided cases of tattoo removal due to complications as well as avoided cases of other adverse effects. The conclusions hold true also when allowance for uncertainties is made. The proposal is affordable, cost effective and likely to be proportionate to the risk.

Table 25: Summary of costs and benefits of both restriction options

2016 values, euro, annual	Restriction Option 1 (RO1)	Restriction Option 2 (RO2)
Total Compliance Costs	€4.6 million	lower
Substitution	€4.4 million	lower
Enforcement	€0.2 million	similar
Social impacts	moderate	similar
Wider economic impacts	minimal	similar
Distributional impacts	minimal	similar
Cost-effectiveness	€60/litre non-compliant tattoo inks removed from the market	higher
Risk reduction capacity	it would reduce risks	possibly lower
Benefits	equivalent to the avoided cases of tattoo adverse effects (non-infectious inflammatory, systemic, reproductive, developmental, malignant)	possibly lower
Break-even	Lower than 320 – 1 050 avoided cases of tattoo removal due to non-infectious inflammatory complications	possibly fewer cases required for break-even

The proposed restriction options are practical because they are:

- Implementable: alternatives are available and industry is familiar with the proposed requirements as they are similar to existing national measures and CoE ResAP recommendations.
- Enforceable, as systems are in place in close to one-third of EEA Member States, analytical methods exist although harmonisation is necessary, and information on key substances leading to risk is available to help with targeted surveillance.
- Manageable, as RO1 and RO2 are similar or less strict than existing measures (ResAP, the CPR, and the CLP Regulation), the proposed measures should be clear, understandable and manageable to all the actors involved.

Both options can be monitored by: Member State surveillance programs and compliance controls (including RAPEX) as well as tattoo artists and PMU practitioners who will have the obligation to inject intradermally only compliant inks.

In conclusion, both RO1 and RO2 are effective, practical and monitorable measures targeted at addressing risk to human health from exposure to substances in tattoo inks on a Union-wide basis.

Appendix 1

Supplementary Table C
(See attached file)

Supplementary Table D
(See attached file)

Supplementary Table E
(See attached file)