Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restriction on

Substances used in tattoo inks and permanent make-up

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

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

Agreed

29 November 2018

20 December 2018

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

29 November 2018

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name:	**Substances used in tattoo inks and permanent make-up**
EC No.:	**-**
CAS No.:	**-**

This document presents the opinion agreed by SEAC and the Committee's justification for its opinion. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the Public Consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/18114/term on **20/12/2017**. Interested parties were invited to submit comments and contributions by **20/06/2018**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Veda VARNAI

Co-rapporteur, appointed by RAC: Boguslaw BARANSKI

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **20 November 2018**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Richard LUIT

Co-rapporteur, appointed by SEAC: Jean-Marc BRIGNON

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **29 November 2018.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/restrictions-under-consideration/-/substance-rev/18114/termon **12 December 2018**. Interested parties were invited to submit comments on the draft opinion by **11 February 2019**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***[date of adoption of the opinion]***. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by ***[number of days]*** by the ECHA

decision ***[number and date]***[1].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**]** **[**No comments were received from interested parties during the Public Consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted ***by*** **[*consensus*.][*a simple majority*]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)

Contents

A. OPINION OF RAC AND SEAC

The restriction options proposed by the Dossier Submitter are shown in Table 1 and Table 2:

Table 1 Restriction option 1 (RO1)

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, or 2 – skin sensitising, category 1, 1A or 1B – skin irritant or corrosive, category 1A, 1B, 1C, or 2 – eye damaging and irritant, category 1 or 2 b) Substances prohibited for use in cosmetic products as listed in Annex II of 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[4]	1. Tattoo inks shall not be placed on the market if they contain the substances specified below, unless a concentration limit is specified under paragraph 2. 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: i. Carcinogenic or mutagenic substances, category 1A, 1B or 2 excluding those substances classified only with the hazard statements H350 (inhalation) (May cause cancer by inhalation), H351 (inhalation) (Suspected of causing cancer by inhalation), H340 (inhalation) (May cause genetic defects via inhalation) and H341 (inhalation) (Suspected of causing genetic defects by inhalation) ii. Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009[2] iii. Substances in Annex IV of Regulation (EC) 1223/2009 with the following conditions in column g of that Annex: • Rinse-off products • Not to be used in products applied on mucous membranes • Not to be used in eye products b. Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than 0.1% w/w: i. Skin sensitising substances, category 1, 1A and 1B ii. Skin irritant or corrosive substances, category 1A, 1B, 1C, and 2[3] iii. Eye damaging and irritant substances, category 1 and 2[3] c. Tattoo inks shall not be placed on the market if they contain substances toxic to reproduction: i. Category 1A and 1B in concentrations greater than 0.0014 % w/w ii. Category 2 in concentrations greater than 0.014% w/w 2. Tattoo inks shall not be placed on the market if they contain substances listed in Table A,[4] exceeding the specified concentration limits, or Polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.00005% w/w. 3. By way of derogation: a. paragraph 1.a.ii) and 1.a.iii) does not apply to substances (colourants) listed in Table B or

[2] This provision is recommended to apply one year after the substance is listed on Annex II
[3] The concentration limit applies to each individual substance
[4] Table A contains methanol, impurities listed in Table 3 of CoE ResAP(2008)1, PAAs, and azo dyes.

	b. paragraph 1 does not apply to substances that are gases at standard temperature and pressure.[5] 4. Substances in Annex IV of Regulation (EC) 1223/2009 allowed in cosmetic products (except those in paragraph 1.a.iii) 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 procedures. 6. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides 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 used in the tattoo ink classified for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction entry, unless the name is already required to be stated on the label by Regulation (EC) No 1272/2008; d. The name of any additional substances covered by this restriction entry that are used in the tattoo ink, unless the name is already required to be stated on the label by Regulation (EC) No 1272/2008; e. The phrase "Contains nickel. Can cause allergic reactions." if the tattoo ink contains nickel below the concentration limit specified in Table A. f. The phrase "Contains chromium (VI). Can cause allergic reactions." if the tattoo ink contains chromium (VI) below the concentration limit specified in Table A. g. Any relevant instructions for use, unless this duplicates a precautionary statement already required to be stated on the label by Regulation (EC) No 1272/2008. 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 labelling information shall be included in the instructions for use. The information on the label shall be made available to any person before undergoing tattooing procedure by the person performing the procedure. 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 procedure (also referred to as permanent make-up, microblading, cosmetic tattooing, micropigmentation) is any intentional introduction of tattoo ink into human skin. 8. The restriction shall apply one year after its entry into force.

Note: Supplementary Table A is included in **Error! Reference source not found.** and Supplementary Table B in **Error! Reference source not found.** of the Background Document

Table 2 Restriction option 2 (RO2)

a) Substances in	1. Tattoo inks shall not be placed on the market if they contain:

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

Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as: - carcinogenic, mutagenic, or toxic to reproduction category 1A, 1B,ord 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[4] c) Substances in Table C[6] d) Substances in Table D[7] e) Substances in Table E[8]	a. the following substances in concentrations greater than the relevant generic concentration limit in Part 3 of Annex VI 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: i. Carcinogenic and mutagenic substances, category 1A, 1B, or 2, excluding those substances classified only with the hazard statements H350 (inhalation) (May cause cancer by inhalation), H351 (inhalation) (Suspected of causing cancer by inhalation), H340 (inhalation) (May cause genetic defects via inhalation) and H341 (inhalation) (Suspected of causing genetic defects by inhalation) ii. Substances toxic to reproduction, category 1A, 1B and 2 iii. Skin irritant and corrosive substances, category 1A, 1B, 1C, and 2[9] iv. Eye damaging and irritant substances, category 1 and 2[9] b. skin sensitising substances in excess of 0.01% w/w for category 1A and 0.1% for category 1 or 1B. These provisions shall apply unless the substances are included in paragraph 2. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) and 1.b), the stricter condition applies. 2. Tattoo inks shall not be placed on the market if they contain the substances listed in Table A[4], exceeding the specified concentration limits, or polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.00005% w/w. 3. Unless already specified in paragraphs 1 or 2, tattoo inks shall not be placed on the market if they contain the substances in: a. Table C[6] in concentrations exceeding 0.1 % w/w and b. Table D[7] 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.[8] 5. By way of derogation: a) paragraph 3 shall not apply to substances (colourants) listed in Table B or b) paragraph 1 shall not apply to substances that are gases at standard temperature and pressure.[10] 6. Tattoo inks not meeting the requirements specified in paragraphs 1 to 5 shall not be used in tattoo procedures. 7. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides the following information:

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

[7] 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).

[8] 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.

[9] The concentration limit applies to each individual substance.

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

	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 used in the tattoo ink classified for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction entry, unless the name is already required to be stated on the label by Regulation (EC) No 1272/2008; d. The name of any additional substances covered by this restriction entry that are used in the tattoo ink, unless the name is already required to be stated on the label by Regulation (EC) No 1272/2008; e. The phrase "Contains nickel. Can cause allergic reactions." if the tattoo ink contains nickel below the concentration limit specified in Table A. f. The phrase "Contains chromium (VI). Can cause allergic reactions." if the tattoo ink contains chromium (VI) below the concentration limit specified in Table A. g. Any relevant instructions for use, unless this duplicates a precautionary statement already required to be stated on the label by Regulation (EC) No 1272/2008. 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 labelling information shall be included in the instructions for use. The information on the label shall be made available to any person before undergoing tattooing procedure by the person performing the procedure. 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 procedure (also referred to as permanent make-up, microblading, cosmetic tattooing, micropigmentation) is any intentional introduction of tattoo ink into human skin. 9. The restriction shall apply one year after its entry into force.

Note: Supplementary Table A is included in **Error! Reference source not found.** and Supplementary Table B in **Error! Reference source not found.** of the Background document. Supplementary Table C, D and E are included in Appendix 1 of the Background document.

A.1. THE OPINION OF RAC

See the opinion of RAC.

Table 3: RAC modified Restriction Option 1 (RO1)

See the opinion of RAC.

A.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on **substances used in tattoo inks and permanent make-up**[6] is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the the

proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified, as proposed by RAC and SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Table 4: SEAC modified RO1 (in accordance with RAC modified RO1)

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, or 2 – skin sensitising, category 1, 1A or 1B – skin irritant or corrosive, category 1A, 1B, 1C, or 2 – eye damaging and irritant, category 1 or 2 b) Substances prohibited for use in cosmetic products as listed in Annex II of 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[4]	1. Tattoo inks shall not be placed on the market if they contain the substances specified below, unless a concentration limit is specified under paragraph 2. 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. Carcinogenic or mutagenic substances, category 1A, 1B or 2 in concentration greater than 0.00005 % w/w, excluding those substances classified only with the hazard statements H350 (inhalation) (May cause cancer by inhalation), H351 (inhalation) (Suspected of causing cancer by inhalation), H340 (inhalation) (May cause genetic defects via inhalation) and H341 (inhalation) (Suspected of causing genetic defects by inhalation); b. Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009in concentration greater than 0.00005 % w/w; c. The following substances in Annex IV of Regulation (EC) 1223/2009 in concentration greater than 0.00005 % w/w 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. d. Skin sensitising substances, category 1, 1A and 1B in concentration greater than 0.001 % w/w, unless a concentration limit is specified under paragraph 2; e. Skin irritant or corrosive substances, category 1A, 1B, 1C, and 2 and eye damaging and irritant substances, category 1 and 2, in concentrations greater than 0.01 % w/w;[11] f. Toxic to reproduction Category 1A, 1B or 2 in concentrations greater than 0.001 % w/w. 2. Tattoo inks shall not be placed on the market if they contain substances listed in Table A,[12] exceeding the specified concentration limits. 3. By way of derogation: paragraph 1 does not apply to substances that are gases at standard temperature and pressure.[13] 4. Substances in Annex IV of Regulation (EC) 1223/2009 allowed in cosmetic products (except those in paragraph 1.c) 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

[11] The concentration limit applies to each individual substance.
[12] Table A contains methanol, PAHs, other impurities listed in Table 3 of CoE ResAP(2008)1, PAAs, and azo dyes.
[13] Substances which are gaseous at temperature of 20° C and standard pressure of 101.3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50° C.

	4 shall not be used in tattoo procedures. 6. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides 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 used in the tattoo ink classified for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction entry, unless the name is already required to be stated on the label by Regulation (EC) No 1272/2008; d. The name of any additional substances covered by this restriction entry that are used in the tattoo ink, unless the name is already required to be stated on the label by Regulation (EC) No 1272/2008; e. The phrase "Contains nickel. Can cause allergic reactions." if the tattoo ink contains nickel below the concentration limit specified in Table A; f. The phrase "Contains chromium (VI). Can cause allergic reactions." if the tattoo ink contains chromium (VI) below the concentration limit specified in Table A; g. Any relevant instructions for use, unless this duplicates a precautionary statement already required to be stated on the label by Regulation (EC) No 1272/2008. 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 labelling information shall be included in the instructions for use. The information on the label shall be made available to any person before undergoing tattooing procedure by the person performing the procedure. 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 procedure (also referred to as permanent make-up, microblading, cosmetic tattooing, micropigmentation) is any intentional intradermal injection of tattoo ink into human skin. 8. The restriction shall apply one year after its entry into force.

Note: Supplementary Table A to the RAC/SEAC modified RO1 is in Appendix 1 of this opinion.

B. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

B.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

B.1.1. Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

B.1.1.1. Summary of proposal:

See the opinion of RAC.

B.1.1.2. RAC conclusion(s):

See the opinion of RAC.

B.1.1.3. Key elements underpinning the RAC conclusion:

See the opinion of RAC.

B.1.2. Description of the risk(s) addressed by the proposed restriction

B.1.2.1. Information on hazard(s)

B.1.2.1.1. Summary of proposal:

See the opinion of RAC.

B.1.2.1.2. RAC conclusion(s):

See the opinion of RAC.

B.1.2.1.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

C. Information on emissions and exposures

C.1.1.1.1. Summary of proposal:

See the opinion of RAC.

C.1.1.1.2. RAC conclusion(s):

See the opinion of RAC.

C.1.1.1.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

C.1.1.2. Characterisation of risk(s)

C.1.1.2.1. Summary of proposal:

See the opinion of RAC.

C.1.1.2.2. RAC conclusion(s):

See the opinion of RAC.

C.1.1.2.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

C.1.1.3. Uncertainties in the risk characterisation

See the opinion of RAC.

C.1.2. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

C.1.2.1. Summary of proposal:

See the opinion of RAC.

C.1.2.2. RAC conclusion(s):

See the opinion of RAC.

C.1.2.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

C.1.3. Evidence if the existing regulatory risk management instruments are not sufficient

C.1.3.1. Summary of proposal:

See the opinion of RAC.

C.1.3.2. RAC conclusion(s):

See the opinion of RAC.

C.1.3.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

C.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

C.2.1. Summary of proposal:

The Dossier Submitter concluded that, although no fully quantitative analysis of the risks of all substances that are currently used in tattoo inks is possible, the qualitative and quantitative assessment has demonstrated that non-adequate control of the risks for human health cannot be excluded. Therefore, 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.

C.2.2. SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC supports the view that any necessary action to address risks associated with hazardous substances in tattoo inks should be implemented in all Member States. Tattoo inks are marketed and used throughout the EU. Therefore, action is required and it should be taken on a Union wide basis.

C.2.3. Key elements underpinning the SEAC and RAC conclusion(s):

SEAC recognises that the placing on the market and use of tattoo inks takes place Union-wide and hence, any measure aiming to effectively reduce the risks for the general public needs to be taken in all Member States of the European Union (as well as the 3 EEA members: Norway, Iceland and Liechtenstein). At present, the level of protection differs among Member States.

The Council of Europe resolutions ResAP(2003)2 and ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up are non-binding recommendations to its signatories (including many EEA Member States). Seven Member States within the European Union (Belgium, France, Germany, the Netherlands, Spain, Slovenia and Sweden) as well as 2 EEA Members (Norway and Liechtenstein) have already implemented national legislation on tattoos based on either one of the two Council of Europe resolutions, and have experience in enforcing this legislation. Three other EU Member States (Austria, Denmark and Latvia) have prepared draft legislation. In addition, among the Member States that have implemented the Council of Europe resolutions, there are some differences in the application of specific concentration limits for impurities. The requirements for labelling of tattoo inks also differ (JRC 2015a).

The majority of EU Member States (21 of 28) currently have no legislation in place to protect the general public from risks of hazardous chemicals in tattoo inks. Hence, the level of protection is different across the Union. The proposed restriction options aim to set equally high standards of health protection with regard to the presence of hazardous substances in tattoo inks throughout the Union. SEAC agrees that the proposed restriction options are appropriate to harmonise the level of health protection across the Union.

In addition, the proposed restriction will apply a set of common requirements across all affected supply chains at the EU level. Such common provisions will enhance clarity for stakeholders in the supply chain (including importers of inks) and the free movement of goods within the EEA.

Levels of non-compliance identified via surveillance projects by those countries that have already implemented legislation is in the range of 30-50% for tattoo inks and up to 20% for PMU. The currently reported levels of non-compliance provide additional justification for a Union-wide measure. Non-compliance in those countries that have implemented ResAP(2003)2 or ResAP(2008)1 may be partly due to absence of ResAP requirements on tattoo inks in a larger part of the EU territory which may increase the availability on the EU market of tattoo inks not complying with ResAP.

Also see the opinion of RAC.

C.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

C.3.1. Summary of proposal:

The Dossier Submitter (ECHA in particular) was requested by the European Commission to prepare an Annex XV restriction proposal restricting the placing on the market and use of certain substances in tattoo inks and permanent make-up. The Dossier Submitter has analysed the appropriateness of other risk management options, including legislative and non-legislative measures, to address the risks from hazardous chemicals in tattoo inks. Specifically, measures in the scope of the EU Cosmetic Products Regulation (CPR), the Biocidal Products Regulation (BPR), the Classification, Labelling and Packaging (CLP) Regulation, the EU Ecolabel Regulation, separate legislation on tattoo inks and other voluntary actions were analysed. The Dossier Submitter considers none of these options to be appropriate to address the risks of hazardous substances in tattoo inks, because they are not as practical (CPR and separate legislation), effective (BPR, CLP and voluntary actions) or consistent and harmonised (EU Ecolabel) as a restriction under REACH. As a result, the Dossier Submitter proposed and further evaluated the effectiveness, practicality and monitorability of two restriction options, RO1 and RO2.

C.3.2. SEAC and RAC conclusions:

Overall, the analysis conducted has provided sufficient justification for SEAC to conclude that the proposed restriction is the most appropriate EU-wide measure to address the risk from hazardous chemicals in tattoo inks. SEAC agrees with the Dossier Submitter's conclusion that the other risk management options assessed are not as appropriate as a restriction under REACH due to limitations in scope and effectiveness. Amendment of the CPR or standalone legislation could also be effective legal measures and were mentioned by some stakeholders in the Public Consultation and in the Forum advice as a more logical approach since the tattoo ink market is not well acquainted with REACH.

SEAC considers the option of a standalone legislation or amended CPR less appropriate as these legal actions would require a longer and more complex process of implementation compared to a restriction under REACH.

Also see the opinion of RAC.

C.3.3. Key elements underpinning the SEAC and RAC conclusions:

Prior to asking ECHA to prepare a restriction dossier, the European Commission determined that a REACH restriction would be the most suitable EU-wide measure based on a comparative assessment of several EU-wide risk management options. SEAC was not provided with this previous assessment and therefore could not verify the rationale for this conclusion.

SEAC agrees with the scope of the Dossier Submitter's analyses in which many possible relevant other EU-wide measures have been assessed. SEAC notes that taxation of inks based on their composition was not considered by the Dossier Submitter. Although SEAC considers that there may be some arguments to merit the use of taxation, there is limited scope for their introduction at EU level. Such fiscal measures were not proposed by the

Dossier Submitter, and therefore, not further assessed.

The Dossier Submitter explained that currently tattoo inks containing hazardous substances are outside the **scope of the CPR** because they are injected into the dermis. SEAC notes that the definition of 'cosmetic product', as laid down in article 2.1(a) of the CPR, excludes this route of administration as only substances and mixtures 'intended to be placed in contact with the external parts of the human body' are in the scope. In order to address the risks of hazardous substances in tattoo inks, the CPR Regulation would need substantial changes. The Dossier Submitter has not further assessed the broadness and exact nature of these changes or the amount of work and time needed to implement such changes. SEAC recognises that, in general, extending the scope of the existing CPR to cover also tattoo inks may be legally complicated, time consuming and costly. On the other hand, SEAC considers that extending the scope of CPR to also cover substances in tattoo inks could have efficiencies because of the ease of implementation and enforcement by the same public bodies in Member States that are currently responsible for the cosmetics rules of the CPR[14], since current (and proposed restriction) legislation is closely linked to the CPR (Annex II and IV). Further information for more in-depth assessment is not available to SEAC. Based on the above, SEAC considers that the use of the CPR to regulate risks of hazardous substances in tattoo inks is likely to be a less appropriate option compared to the proposed restriction under REACH, because of the legal complexity of changing the scope of a regulation on cosmetics compared with amending Annex XVII of REACH through a regular regulatory process. SEAC notes however, that for national bodies regulatory management through a CPR amendment might have been a possible approach but SEAC has no further information to assess fully potential advantages and disadvantages.

The Dossier Submitter describes why risks of hazardous substances in tattoo inks are not controlled by the **BPR** (only preservatives are regulated) and **CLP** (does not restrict the placing on the market of mixtures containing these substances). SEAC agrees with the Dossier Submitter's conclusion that these regulations cannot fully address the identified risks. The BPR provides limited possibilities because of its narrow scope (preservatives used in tattoo inks should already be regulated under BPR but other types of substances could not be) and the CLP Regulation is designed only for hazard classification and communication on hazardous substances and mixtures. As such, the CLP cannot restrict the placing on the market and use of specific substances and mixtures for use in tattoo inks. A harmonised classification under the CLP results in regulatory consequences in other legislation (such as REACH or worker legislation) but for tattoo inks it only invokes labelling requirements and does not restrict the use of specific substances. The EU CLP labelling requirements already apply to tattoo ink mixtures for those substances that exceed the limits for classification as hazardous. CLP labelling of hazardous tattoo ink formulations however is targeted at informing the supply chain and consumers on hazards rather than implementing mitigation measures protecting against human health risks arising from the application of tattoo inks in the skin. Furthermore, as concluded by RAC, some of these CLP limits are not sufficient to mitigate risks. CLP labelling requirements therefore will only to a certain extent inform consumers about hazardous ingredients in tattoo inks and will not sufficiently protect them against risks.

Voluntary actions taken by industry in EU Member States were also included in the

[14] In some Member States with national legislation on tattoo inks in place, enforcement bodies responsible for the CPR are also responsible for tattoo inks.

analysis of risk management options. The Dossier Submitter concluded that due to the large number of often non-organised operators, as well as the high percentage of non-registered tattoo service providers, it is likely that voluntary measures that effectively control the risk will be difficult to agree and implement uniformly within the EU. SEAC takes note of the JRC reports (JRC 2015b; JRC 2016b) and other information in the Background Document that support the conclusion of the Dossier Submitter. SEAC notes that the questionnaire and literature analysis performed by the JRC revealed a complex EU market with many different manufacturers, distributers and private labels. Furthermore, the Background Document provides information demonstrating a generally low level of sectoral cooperation and organisation (low memberships in associations, as well as the high percentage of non-registered tattoo service providers). In addition, the majority of inks for tattooing available on the European market (70-80%) are manufactured outside the EU (about 20-30% for PMU) and are imported, primarily from the United States. SEAC considers that the low level of organisation in the supply chain and of service providers, the complexity of the EU tattoo inks market and its partial dependence on non-EU manufacturers, is not a favourable situation for implementing a scheme of voluntary actions such as Good Manufacturing practices. For successful implementation of voluntary measures SEAC considers proper sectoral cooperation and organisation as a key element and the aspects mentioned above do not facilitate this. Furthermore, after the Council of Europe introduced their recommendations (ResAP 2003 and ResAP 2008), the tattoo ink sector has not fully adopted these recommendations as has been demonstrated during the numerous surveillance campaigns in various Member States. However, SEAC notes the ResAP is not a binding legislative instrument, and is also not a voluntary industry initiative, and the Background Document contains no information on the reasons for the tattoo ink sector not adopting voluntarily the recommendations. Overall, SEAC concurs with the Dossier Submitter's assessment that voluntary measures by industry to control the risk from hazardous substances in tattoo inks are unlikely to be effective.

SEAC considers regulatory actions by individual Member States based on the non-binding ResAP recommendations (i.e. national law), as not appropriate to address the EU-wide concern. The ResAP has been in place since 2003 and 2008 and only a minority of EU Member States have adopted (or intended to adopt) the recommendations in national law. This clarifies that such nationally introduced legal measures are inappropriate to address the identified risks at EU level in a harmonised and timely manner. SEAC also takes note of RAC's conclusion that the risk management options based on previous Council of Europe recommendations, i.e., CoE ResAP(2003)2 or CoE ResAP(2008)1, do not sufficiently address all risks arising from hazardous substances in tattoo inks. Therefore, these two other restriction measures were not assessed further.

The Dossier Submitter also briefly described the use of the **EU Ecolabel Regulation** as a regulatory management option and concludes that it currently does not apply to tattoo inks and it is uncertain whether it will in the future. SEAC considers in theory the EU Ecolabel Regulation could be amended to cover tattoo inks comparable with the coverage of textile products for which the presence of harmful substances was introduced as an exclusion criterion for awarding the ecolabel. SEAC notes the EU ecolabel is a "market-based instrument" whose primary function is to stimulate the supply and demand of products with a reduced environmental (ecological) impact. In general, labels such as the EU ecolabel are known for the level of trust consumers place on them and various studies report on a willingness to pay for eco-labelled products over non-labelled products. SEAC however has no information of the impact on the ecolabel on consumer behaviour in relation to the

preference for tattoo inks. SEAC therefore considers that an EU ecolabel would offer no guarantee that all consumers are protected against the risks of tattoo inks. Furthermore it would take time to develop criteria for a tattoo ink ecolabel.

The option of a **standalone EU-wide legislation** on tattoo inks is assessed by the Dossier Submitter. The main advantage of such standalone legislation is that it would offer the possibility to include in one piece of legislation an array of factors that influence the safety of tattoo practices. In particular, different safety aspects (not only chemical, but also microbiological safety) but also possibly training and licensing could be covered in a single harmonised framework. The main disadvantage identified is that it would be difficult and time consuming to negotiate such legislation EU-wide as the hygiene and certification aspects are normally within the jurisdiction of local and regional authorities, although the existence and the nature of these requirements varies substantially among Member States (i.e. in some Member States no legislation is in place while in others (e.g. in the Netherlands) legislation stipulates in detail hygienic measures to be taken by tattoo shops). In the Public Consultation comments were received that favour a standalone EU-wide legislation. The main argument provided is that aspects such as training, certification, and hygienic requirements are essential for the safety of those who would like to get a tattoo and hence should be included in one piece of legislation covering also chemical safety. In addition, comments were received calling for a so-called "positive list", i.e., a list of chemicals allowed in tattoo inks, instead of a restriction. The elements to justify such a list were not provided and SEAC notes that the resources needed to define such a list could be substantial.

The restriction proposal aims to regulate only the chemical risks through REACH and hence, cannot be compared with standalone legislation that would have a broader safety scope. SEAC recognises that, in principle establishing standalone legislation would entail a legally complex and time-consuming process, though would provide a more holistic approach to managing all risks associated with tattooing and tattooing procedures. However, it is outside SEAC's remit to compare the introduction of a new standalone legislation that covers a broader scope with the implementation of a restriction focusing on chemical safety by amendment of Annex XVII of REACH.

Also see the opinion of RAC.

C.3.4. Scope including derogations

Justification for the opinion of RAC

C.3.4.1. Summary of proposal:

See the opinion of RAC.

C.3.4.2. RAC conclusion(s):

See the opinion of RAC.

C.3.4.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Justification for the opinion of SEAC

C.3.4.4. SEAC conclusion(s):

SEAC in general agrees with the scope of the restriction as proposed by the Dossier Submitter including the adaptations made during the opinion development.

SEAC has reservations with respect to the technical feasibility and ease of enforcement of some **concentration limits** proposed in RO1. SEAC supports RACs proposal for modified RO1 with respect to concentration limits for selected substances based on risk assessment, enforceability and feasibility considerations.

SEAC understands the need for a **derogation** of Pigment Green 7 and Pigment Blue 15:3 expressed by some stakeholders during the Public Consultation but regards the information provided limited to justify it. SEAC also notes RAC's conclusion on the derogation. During the Public Consultation of the Annex XV dossier information was submitted on unavailability of safer technically equivalent alternatives for these pigments that are essential to the tattoo ink industry. SEAC will use the Public Consultation on its draft opinion to gather further information on the need for a derogation and the consequences of no derogation for the industry and society as a whole.

SEAC does not support derogations of the other 19 colourants listed in supplementary Table B of the Background Document since the Public Consultation revealed only some of the pigments are used and for all of them alternatives are available. SEAC agrees with the proposed **labelling requirements** for tattoo inks including the changes made in the proposal during the opinion development as a result of Forum advice.

SEAC supports a 1 year **transitional period** as a reasonable timeframe for implementation.

Taking several aspects into consideration, SEAC supports a dynamic link with CLP for substances included due to relevant harmonised classifications. SEAC has a slight preference for a **static link with the CPR** as it has the advantage of regulating appropriately chemicals for their use in tattoo inks, taking into account the costs to industry as well as the delay in possible health benefits of the restriction.

C.3.4.5. Key elements underpinning the SEAC conclusion(s):

a) Concentration limits

SEAC finds that the concentration limits have been set using both risk-based as well as pragmatic considerations (fixed to discourage intentional use). Some concentrations limits have been set in analogy with existing limits for the same substances in other legislation. SEAC notes that, although every concentration limit is well explained and justified, the Dossier Submitter is not consistent in its overall approach how concentration limits are set. For PAAs, the Dossier Submitter explained that the concentration limits have been set applying the "As Low As Reasonably Achievable (ALARA)" principle although lower risk-based concentration limits have been derived. It appears that since the technical and economic feasibility of reaching the risk-based limits is unknown, these limits have been set to ensure that 75% of inks could comply with the limit (as a percent signifying technical achievability), according to available information. In contrast, the proposed concentration limit for arsenic is solely based on the risk assessment resulting in a very low limit. The Dossier Submitter in this case considered the detection limit of available analytical methods but did not specifically consider the technical feasibility of achieving such low concentrations in tattoo inks. Public Consultation comments state that the proposed limit for arsenic is not technically feasible and instead a concentration limit of 2 ppm is proposed [PC #1905; PC #1928; PC #1931].

In the Public Consultation industry expressed its concern regarding the feasibility of lowering the concentration limits for some heavy metals from the ResAP limits due to fluctuations in their concentration in raw materials [PC #1883; PC #1931]. Specifically, the proposed limits for chromium and lead (when pigment black CI 77266 is used) were considered technically infeasible and instead a concentration limit of 2 ppm is proposed [PC # 1893; PC #1928; PC #1931]. However, the comments did not specify whether other black pigments faced the same issues. Comments by industry were also received on the proposed limit for skin irritant/corrosive and eye irritant/damaging substances as this may restrict detergents and surfactants currently used in tattoo inks for ink dispersal [PC# 1928], although no specific substances were mentioned that could not be substituted.

The Forum expresses a preference for RO2 partly based on the argument that specified limit values are easier to enforce than a 'shall not contain' requirement that is part of RO1. According to Forum, this could also jeopardise harmonised enforcement as laboratories in various Member States could apply different analytical methods and limits of detection. This latter issue could be resolved with harmonisation of analytical methods.

Based on the information from the Background Document, the Forum advice and information from the Public Consultation, RAC has proposed a modification of RO1 concentration limits. RAC considers some concentration limits in RO1 and RO2 are not protective enough. Furthermore the 'shall not contain' provisions in RO1 are considered more difficult to enforce than a specific concentration limit (also confirmed by Forum) and for some substances practical considerations were taken into account. SEAC concurs with the approach followed by RAC to arrive at modified concentration limits for RO1 and SEAC supports these limits.

SEAC considers that, while concentration limits are set on a sensible rationale, information in the Background Document on whether the proposed limits are technically and economically feasible for all substances in the scope of RO1 and RO2 is limited. SEAC concurs with the Dossier Submitter's argument that concentration limits higher or equal to the CoE ResAP(2008)1 (such as proposed for chromium) are in theory technically and economically feasible because of proven level of compliance with ResAP. The proposed limit for lead in the amended RO1 appears feasible for most of the black inks on the market (NVWA 2017) and can act as alternatives to pigment black CI 77266. The Public Consultation did not provide information why other black pigments are not suitable as alternatives for pigment black CI 77266. The proposed limit for arsenic in the RAC modified RO1 appears to be technically feasible for at least white pigments with the highest grade of purity [PC #1905]. No information has been received on its economic feasibility. Concerning the proposed limit for irritant or corrosive/eye damaging substances, SEAC concurs with the Dossier Submitter's assumption that alternatives without harmonised classifications in the scope of this proposal would be available.

Further information on the feasibility of concentration limits will be gathered in the Public Consultation of the SEAC Draft Opinion. This section will be amended if necessary.

b) Derogations

The Dossier Submitter proposes to derogate 21 colourants on the basis of the hazards and risks and availability of alternatives (See Supplementary table B in Table 5 of the Background Document). These 21 pigments were included in the frame of the restriction on the basis of their ban in all cosmetic products under Annex II of the CPR whilst at the same time they are allowed in all cosmetic products without conditions of use under Annex IV of the CPR.[15] These pigments were placed on Annex II following a group approach based on epidemiological evidence of an increased risk of bladder cancer among women who made regular use of permanent hair dyes over many years. The chemical identity of the permanent hair dyes used in the study is unknown. In response to this finding, the regulatory strategy of the European Commission was to put all hair dye pigments on Annex II unless the cosmetic industry provided information to ensure safe continued use of the specific pigment in the hair dyes application. As stated in the Background Document, tattoo inks do not fall in the scope of the CPR and the tattoo industry was not able to participate in the process even though the CPR Annex II requirements applied to them via national legislation in those Member States that implemented the Council of Europe resolutions. The Dossier Submitter argues that since their risks are not specifically demonstrated, these pigments should be derogated. For one of these 21 pigments, Pigment Blue 15, the unavailability of suitable alternatives is also an argument for derogation. Additionally, Pigment Green 7 (not allowed for use in hair colours by Annex II of the CPR and in eye products by Annex IV, column g), is proposed to be derogated on the basis of not being able to demonstrate risk and unavailability of safer suitable alternatives.

[15] All 21 pigments are banned in hair colours but allowed in all cosmetic products except Pigment Green 7. The latter is banned in hair colours (under Annex II) and allowed in all cosmetics except eye products according to Annex IV of the CPR.

The use of and the availability of alternatives for these pigments was tested during the Public Consultation. The comments provided supported the Dossier Submitter's assessment that Pigment Blue 15:3 and Pigment Green 7 are necessary for the tattoo industry to cover this spectrum of colors and no safer and technically adequate alternatives were identified. [PC #1883; PC #1893; PC #1905; PC #1928; PC #1931]. Information for Pigment Blue 15:3 revealed that other blue pigments are lacking in brilliance and change colour (turn grey) when mixed with white pigments (common practice in tattooing). Pigment Green 7 has been largely replaced by its brominated version Pigment Green 36 (which is not in the scope of this restriction as it does not have relevant harmonised classification). Based on limited hazard information available RAC concludes Pigment Green 36 is not a less hazardous alternative to Pigment Green 7. No other alternatives to Pigment Green 7 have been identified to date.

The Public Consultation indicated limited use of the other 19 pigments proposed by the Dossier Submitter to be derogated and for those that are currently used, alternatives are available [PC #1893; PC #1928]. Other stakeholders indicated these pigments are not used in their formulations [PC #1883] or supported the removal of pigments currently not used in tattoo inks from the Supplementary Table B as most of them are not suitable for tattoos [PC #1931].

SEAC notes RAC's opinion that the exemption of the 21 colourants cannot be based on a lack of hazard and risk. RAC concludes this is due to lack of adequate information on their hazard properties and risk for human health.

SEAC finds that there is some socio-economic information to assess a possible derogation of Pigment Blue 15:3 and Pigment Green 7. Some responses in the Public Consultation on the Annex XV dossier made it clear that these pigments are essential for the tattoo industry and safer alternatives with similar technical performance are lacking. SEAC notes the comments but regards the information limited to justify their derogation. Taking into consideration the opinion of RAC on the derogation due to uncertainties about hazard and risk, SEAC considers health benefits are correspondingly uncertain and therefore no clear recommendation on an exemption is currently possible. SEAC will use the Public Consultation on its final draft opinion to gather further information on the need for a derogation and the consequences of no derogation.

SEAC finds that there is limited socio-economic information and argumentation to support a derogation of the remaining (19) pigments in Supplementary Table B (see Table 5 of the Background Document). SEAC takes note of the fact that the tattoo industry could not participate in the process under the CPR to provide relevant information on safe use to qualify for an exception of inclusion on Annex II for example (according to the provisions in article 15 of the CPR). However, the Public Consultation of this restriction proposal revealed only some of the pigments are used in tattoo inks but all of them can be replaced by alternatives. Furthermore, SEAC takes note of RAC's lack of support for derogating these pigments. As no other socio-economic arguments on the proposed derogations are available, SEAC does not support derogation of the remaining pigments in Supplementary Table B.

SEAC acknowledges that the proposed restriction is structured in a way that any derogation granted on the colourants under consideration will cease in the event of their harmonised classification in Annex VI of CLP for properties in scope of the proposed restriction and considering a dynamic link with Annex VI of CLP will be implemented.

SEAC notes the proposal to exempt substances classified for carcinogenicity via inhalation exposure as well as gaseous substances only due to lack of relevancy of this hazard classification for the restriction under consideration. Therefore, socio-economic considerations for these derogations were not further examined.

c) Labelling requirements

The same labelling requirements are included in RO1 and RO2 in addition to any CLP requirements that also apply to the tattoo ink mixture. SEAC notes that the proposal aims to inform the general public, i.e. consumers have the possibility to receive information on the chemicals in the tattoo ink before they get a tattoo. The Forum advice supports a labelling provision stating "the information handed to the consumer about the tattoo ink, might be the only way to track which tattoo ink that was used, for example if the consumer experiences unwanted health effects after tattooing". To prevent double information (e.g. in case the name of a hazardous substance is already on the CLP label or the instructions for use for the tattoo ink overlap with the CLP precautionary statements) on the label, SEAC supports the alignment of the labelling provision with CLP.

SEAC notes that the labelling provision in RO1, RO2 and RAC/SEAC modified RO1 equally applies to all substances that are "used" (instead of 'present' as in the original Dossier Submitter's proposal) in these inks at concentrations below the proposed limits. This provision intends to generate as much information as possible for consumers undergoing a tattooing procedure without the need for tattoo ink importers or formulators to check for all substances in the scope of the restriction on tattoo inks, including impurities. In other words, the labelling provision applies only to those substances that are intentionally added to the tattoo ink formulation and that are either covered in the scope of the proposed restriction (and used in the ink below the prohibited concentration level) and/or otherwise classified for human health hazards in Annex VI of CLP. SEAC considers the reference to 'use' as advised by Forum an important amendment to make the labelling provisions manageable for tattoo ink formulators. The drawback of this is that the label will not contain information on hazardous impurities present in the ink that are not added intentionally by the formulator. This may reduce the risk management potential of the label for consumers. SEAC notes in general, limited information is available regarding the impact of labelling of tattoo inks on formulator and consumer behaviour. Based on information obtained during the Public Consultation, SEAC concludes that the proposed labelling provision is implementable. SEAC considers additional labelling costs to be a minor fraction of the total estimated €4.4 million incremental substitution costs incurred by downstream users under RO1.

During the opinion making process, two additional labelling requirements were added for nickel and chromium (VI) as these labels are in the CoE resolution but had not been included in the Dossier Submitters proposal. The labels will apply in situations where the substances are in the tattoo ink at concentrations lower than that which would mean the ink is restricted but higher than the limits of detection for these substances.

d) Additional conditions

Colourants in Annex IV of CPR with conditions on their use

SEAC has taken note of the inclusion in the scope of the restriction proposal of colourants included in Annex IV of CPR and RAC's conclusion that a restriction on these colourants in tattoo inks using the CPR specified conditions is justified. SEAC has no socio-economic arguments supporting or questioning the inclusion of these Annex IV colourants in the scope of the restriction, nor did the Public Consultation provide information on this matter.

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

The restriction covers the placing on the market as well as use of tattoo inks by tattoo artists. A restriction targeting only the placing on the market without obligations for the tattoo artists would be less effective as stockpiled tattoo formulations and concentrated pigments in a tattoo shop would in such case not be covered. Although SEAC notes the dossier contains limited information on the extent to which tattoo artists formulate tattoo inks using pigments in powdered form, SEAC supports this clause to prevent use of non-compliant inks. Furthermore, SEAC notes the assumption by the Forum that inspections will also take place at the premises of professional users of tattoo inks (e.g., tattoo studios, beauty parlours). Possession by tattoo artist of inks or concentrated pigments would direct towards an 'intention to use' and thus, would be enforceable.

Transitional period

The Dossier Submitter has assessed the proposed transitional period against four different elements: availability of alternatives and time required to reformulate tattoo inks, depletion of stocks in the supply chain (including of distributors and tattoo artists), communication in the supply chain and enforcement.

The Dossier Submitter's argumentation is that as the majority of tattoo inks on the EU market are compliant with existing national legislations in those Member States that have implemented the Council of Europe resolutions, industry therefore has knowledge and experience to formulate tattoo inks that are compliant with the proposed restriction. The Dossier Submitter further argues that a transitional period of one year will be sufficient for enforcement authorities to put the necessary systems in place to monitor and enforce the proposed restriction (by building on experience of Member States with national legislation) and to reduce available stocks. Based on this reasoning, the Dossier Submitter expects that the transitional period of 1 year is sufficient to comply with the proposed restriction.

SEAC agrees in principle with the Dossier Submitter's argument. However, with respect to the first argument: high compliance with ResAP, as such this finding does not provide a rationale for a specific 1 year transitional period as proposed. In fact, SEAC notes a generally high level of compliance could point to an even shorter transitional period. On the other hand, SEAC sees that there will be a need for some formulators to reformulate their products, which takes time. The Public Consultation indicated the need for a longer transitional period of 4 or 5 years [PC #1928; PC #1931]. The 4 year period included a 2-year period for the production of compliant inks and another 2 years for stock depletion in the supply chain [PC #1931]. SEAC notes that no further information about R&D and reformulation steps is provided in the Public Consultation to explain or justify the requested transition period. Based on the expiration time for products and average shelf-lives at formulators and resellers, SEAC expects no additional costs for resellers and tattoo artists in case of a 2-year transitional period. A shorter transitional period could have an impact on resellers that have non-compliant inks in stock meaning they would incur some sunk costs. For the reformulation of compliant tattoo inks, SEAC could not verify the Dossier Submitter's expectation that one year would be sufficient nor did the Public Consultation provide sufficient information to justify a different transitional period.

The Background Document contains very limited information on the formulation process and states that colourants can comprise up to 60% of the final formulation of tattoo inks. Those colourants often contain impurities. Many of these colourants are produced by pigment manufacturers for industrial applications where a higher content of impurities is not problematic (although pigments with higher purities are manufactured for food, cosmetics, and medical applications). Although some tattoo ink formulators request purity certificates from their pigment manufacturers, it is not known whether this information is sufficient for the average tattoo ink formulator to know the level of impurities in their raw materials, especially as the level of impurities fluctuates between different batches. The assumed relationship between compliance and the manufacturing process cannot be verified by SEAC; however, SEAC assumes that these practices exist today and notes that the majority of inks currently on the market are compliant with ResAP limits.

The time required for stock depletion is dependent on the average shelf-life and expiration time for unopened and opened products. The limited available information in literature and online does not contradict the Dossier Submitter's assessment that a transitional period of one year is sufficient time for stock depletion of non-compliant ink. No information is available on any costs associated with retailers, formulators or tattoo artists not being able to deplete stock in time or whether costs would be higher than benefits for human health of having a very short transitional period. Hence, information regarding the time needed to deplete stocks is not available and cannot be used as an argument setting an appropriate transitional period. Inks are only a minor fraction of the PMU/tattooing procedures costs; therefore, the cost of not using some stocks could be low and transferable to consumers.

SEAC also has some concerns regarding the need to harmonise and sometimes develop analytical methods. The lack of information in the dossier does not allow a judgement whether a one year transitional period would be sufficient in that respect. On the other hand, it is possible to start enforcement of the proposed restriction while analytical developments are ongoing, as long as enforcement authorities take into account that stakeholders do not have fully harmonised analytical methods available. In the Forum advice on the enforceability of the restriction proposal, the 1 year transitional period is not flagged as a major issue of concern: a representative of an enforcement body of one smaller Member State having no national law on tattoo inks in place expressed concern on the short period for implementation. Another (again a representative of an enforcement body of a smaller Member State without a national legislation) stated that they will be ready within one year. SEAC considers there may be differences between Member States as regards the work that needs to be undertaken to enforce the new restriction. Enforcement bodies in Member States that have not implemented the Council of Europe resolutions would need to build experience. In the Forum advice it is recommended to create a forum for exchange of experience and to update the Compendium of analytical methods for types of substances that have commonly been found in past Member State's enforcement actions. A comment in the Forum advice, however, noted that the restriction can be enforced already on the basis of labelling.

In conclusion, SEAC sees there are some arguments for both a shorter as for a longer transitional period compared to 1 year as proposed by the Dossier Submitter. No clear socio-economic arguments are available supporting any specific transitional period. A longer transitional period would lead to a delay in potential benefits of the restriction taking effect and reduce potential sunk costs for manufacturers and resellers (e.g., associated with depletion on existing stock, which as explained are expected to be minor and affordable for the supply chain). SEAC considers such reduction of sunk costs is however likely to be considerably lower than any expected human health benefits of the restriction being implemented with less delay. SEAC does not have sufficient information to quantitatively assess how different transitional periods would influence the expected costs and benefits. SEAC considers that alternatives are available for most chemicals that will be banned for use in tattoo inks. Time needed to reformulate and deplete stocks across the board may be expected not to exceed a period of 1 year after entry into force. Hence, SEAC supports the proposed transitional period of 1 year as a reasonable timeframe for implementation.

Preservatives

As tattoo inks are not in scope of the CPR, preservatives used in tattoo formulations fall under the authorisation regime of the BPR. According to the Dossier Submitter, the proposed restriction would not change the obligations under the BPR but would limit the type of preservatives that can be authorised for the use. For example, 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). SEAC considers that the proposed restriction does not introduce challenges as regards the link with the BPR (see also section B.3.6.1.3 on the availability of alternatives for preservatives).

e) Linkage with CPR

RO1 proposes a dynamic link between REACH Annex XVII and the CPR Annexes II and IV, which ensures any future updates are reflected in REACH. This option aims to ensure the Annex XVII entry for tattoo inks is up-to-date with the latest relevant developments on substances that are in the scope of Annex II and IV of the CPR. RO2 proposes a static link, ensuring that any new CPR (Annex II and IV) substances are added to the restriction only after specific assessment of their risks to human health when injected intradermally, the availability of alternatives and technical feasibility for achieving the proposed concentration limits (i.e., via a new Annex XV dossier).

SEAC notes that dynamic and static link can in principle be applied to any of the proposed restriction options and therefore, focuses on discussing the approach in principle below. The main differences between dynamic link and static link that are considered by SEAC are summarised in Table 5.

Table 5 Comparison socio-economic aspects of Dynamic and Static link with the Cosmetic Products Regulation

Effect	Dynamic Link	Static Link
Time needed to regulate	REACH Annex XVII tattoo entry up-to-date with amendments made in CPR Annexes II and IV (immediate benefits) Limited time for substitution/reformulation	REACH Annex XVII tattoo entry updated only after initiative and tattoo specific assessment (delayed benefits) Time needed hence more predictable for transitioning
Scientific scrutiny	Annex XVII amendments will partly lack tattoo use specificity (risk of overregulation)	Annex XVII updates will be targeted to tattoo use and will enable scrutiny on risks, concentration limits and alternatives Group approach possible
Resources authorities	Less resource intensive as no separate Annex XV dossiers needed	Burden on Annex XV dossier development member states or Commission/ECHA

All currently proposed restriction options contain a dynamic link between harmonised classifications in CLP and the regulation of substances with such classifications in tattoo inks. The restriction will dynamically take effect for those substances in future receiving harmonised classification of relevance, i.e., CMRs, skin sensitisers/irritants/corrosives and eye irritants/damaging. SEAC notes RAC's support for this dynamic link with Annex VI of CLP and their conclusion that these substances should not be present in tattoo inks. SEAC considers that this should take precedence over technical and economic feasibility of alternatives, which would not be assessed under the dynamic link. Therefore, SEAC supports the dynamic link on the grounds that it will lead to fast realisation of human health benefits following the grouped approach including establishment of proper concentration limits as in the initial restriction proposal and it is consistent with existing regulatory practices (e.g., REACH Annex XVII entry 28-30)., SEAC takes note of RAC's conclusions that these substances should not present in tattoo inks.

As regards a dynamic link with CPR, SEAC notes that updating the REACH Annex XVII entry for tattoo inks with CPR Annex II and IV changes would in principle be consistent with the dynamic link that the restriction proposes for future substances with harmonised classifications. Its main advantage would be faster realisation of health benefits due to reduced exposure to these substances in tattoo inks, which is also the reason for RAC's support of dynamic link. Such a dynamic link will also be similar to the link that is in place between REACH and CLP for CMR substances and mixtures supplied to the general public. Currently updates of REACH Annex XVII entry 28-30 prohibiting supply of CMR substances to the general public follows a simplified mechanism. Any changes to the CLP Annex VI as a result of a RAC opinion on harmonised classification proposal and a REACH Committee decision, lead to an amendment of entries 28-30 with a decision in the REACH Committee without scrutiny by RAC and SEAC. This system follows the principle that CMR substances should not be made available to the general public in concentrations above the generic or specific concentration limits as laid down in the CLP Regulation (or the specific Annex VI entry). This amendment of Annex XVII entries 28-30 hence does not require any separate assessment of the level of the maximum allowable concentration, nor does it require an assessment of alternatives. SEAC considers a dynamic link between CPR and REACH could probably take effect in a similar way. However, SEAC recognises that the reason many substances will be included in the CPR is due to their CMR properties and stresses that the dynamic link with the CLP Regulation would take precedence in these cases for the reasons already explained.

SEAC considers as a drawback of a dynamic link the fact that it does not foresee any scientific scrutiny of the use of the newly added substances in the CPR in tattoo inks based on socio-economic considerations (e.g., availability of alternatives) and does not allow a concentration limit to be applied, specifically for tattoo inks (as the CPR sets requirements for cosmetic products only). As a consequence the tattoo industry could be confronted with unintended consequences (e.g. ban of use in tattoo inks of hard to substitute substances or concentration limits that are not tested for their feasibility). SEAC notes that also in this initial proposal no substance specific assessment on availability of alternatives or feasibility is performed except for an overall conclusion on availability of ResAP compliant tattoo inks based on surveillance results, although it is noted that this reflects the current conditions on the market.

SEAC notes a static link between REACH and CPR would be more in line with the general restriction process in which authorities have the legal task of initiating restriction proposals in case of unacceptable risks identified at EU level. The downside of such static link would be that it is more resource intensive for authorities and it will be a time consuming process, leading to delay in the realisation of potential health benefits due to reduced exposure. SEAC notes that for the substances currently included in the restriction based on Annex II and Annex IV of the CPR, a group approach is taken for the assessment of their risks and such approach could also prove feasible for future updates of the restriction by member states. In addition, the Dossier Submitter argues the static link could avoid legislative gaps that could arise from a dynamic link. SEAC finds these examples theoretic and not compelling.

SEAC notes RAC's support for a dynamic link with the CPR and concurs that such a link would ensure immediate benefits for human health as new information on hazard and risk becomes available. The dynamic link has some disadvantages, e.g. there will not be any assessment of technical and economic feasibility of alternatives and tattoo ink formulators will have very limited time to transition to any potential alternatives. SEAC notes this impact of the dynamic link could be dampened by introducing transitional periods between the entry into force and entry into effect of each update taking place, although this will not eliminate the requirement for the tattoo industry to track developments under the CPR in order to comply with requirements for the tattoo inks. Furthermore, there would be no assessment of the technical feasibility of concentration limits for their tattoo ink use, rather the applicable limit for cosmetics would be carried forward. It is unclear what consequences any future changes to the CPR may have on the tattoo industry.

A static link would have the benefit of assuring risk assessment of (groups of) substances (including technical feasibility of concentration limits) and analysis of alternatives. The main disadvantage would be that for any future changes to the CPR Annex II and IV to apply to the tattoo inks, REACH Annex XVII would need to be amended through a Member State or ECHA (on request of the Commission) proposing an amendment to the restriction. This would result in a time lag for regulating CPR Annex II and IV substances for tattoo ink uses and substantial associated costs incurred by Member States or ECHA for dossier development (e.g. a proposal developed by ECHA as a minimum would require 1 FTE for a period of 34 months (12 dossier preparation, 14 opinion development, 8 decision making phase), which including some consultancy fees would result in 170 000 Euro total costs) Given the large number of possible alternatives to the restricted substances and a number of substances currently used in tattoo inks for which there is no sufficient information on hazard and risk, it is possible, that updates of the proposed restriction may be required regardless of whether static link is established due to the considerable uncertainties associated with what substances may be used in tattoo inks in the future if their risks are not addressed under the CLP or if dynamic link with the CLP is not implemented.

Taking all aspects into consideration, SEAC has a slight preference for a static link as it has the advantage of proper regulating chemicals for their use in tattoo inks Furthermore, it offers scientific scrutiny on the analyses of alternatives and feasibility of concentration limits that are defined specific for the use in tattoo inks. Similar scrutiny would not be foreseen in case of a dynamic link, which could result in the tattoo industry being confronted with unintended consequences (e.g. ban of use in tattoo inks of hard to substitute substances or concentration limits that are not tested for their feasibility). SEAC notes that irrespective the type of link with CPR, future updates of the restriction may be required anyway due to large uncertainties about future use of substances in tattoo inks.

C.3.5. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

C.3.5.1. Summary of proposal:

See the opinion of RAC.

C.3.5.2. RAC conclusion(s):

See the opinion of RAC.

C.3.5.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

C.3.6. Socio-economic impact

Justification for the opinion of SEAC

C.3.6.1. Costs

C.3.6.1.1. Summary of proposal:

The Dossier Submitter estimates that the incremental substitution costs for downstream users of tattoo ink and PMU as a result of RO1 will likely be low as technically feasible alternatives with similar or better hazard and risk profiles exist. For those colourants where alternatives have not yet been identified, a derogation is proposed. The majority of 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 at national level, it is expected that a high proportion of tattoo inks and PMU currently on the EU market will meet the proposed requirements.

Therefore, the incremental substitution costs are estimated at about €4.4 million annually during the temporal scope (2021-2040) of the analysis (in 2016 values) for EEA31 (European Economic Area). 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.

C.3.6.1.2. SEAC conclusion(s):

SEAC agrees with the methodology used by the Dossier Submitter to assess the cost of the proposed restriction. However, due to lack of information, several assumptions regarding key parameters were made by the Dossier Submitter. Overall, SEAC agrees that the proposed estimate provides an indication of the order of magnitude of the costs, with possible underestimation due to using incidence as a proxy, and to the design of the "high volumes" scenario.

C.3.6.1.3. Key elements underpinning the SEAC conclusion(s):

SEAC agrees that the geographical boundary for the calculations (the EEA 31) is appropriate.

Substitution costs

Review of the methodology to estimate the substitution costs

To estimate the substitution costs, the Dossier Submitter multiplied the annual amounts of non-compliant inks that would be placed on the market in the absence of a restriction (2012-2040) by the unit substitution costs of the inks:

$$Substitution\ cost\ Year\ N = (Volume\ put\ on\ market\ Year\ N)\ \mathrm{x}\ (Share\ of\ non-compliant\ inks)\ \mathrm{x}(Price\ difference)$$

Then a Net Present Value (and an annualised value) of the substitution costs for the period 2021-2040, in 2016 values, were calculated using a discount rate of 4%.

Therefore, substitution costs depend on

1) the annual volumes of non-compliant inks (themselves computed as annual volumes of inks put on the market multiplied by the share of non-compliant inks)
2) unit substitution costs

For the current 2016 volumes of ink, the principle followed by the Dossier Submitter is to multiply the current number of tattooists in the EU by the estimated average volume of tattoo ink used currently by each tattooist on an annual basis (JRC 2015b, stakeholder info). Then the future annual volumes placed on the market are, for future year N, estimated as the 2016 volumes corrected by the ratio of tattoo incidences between year N and 2016:

$$Volume\ put\ on\ market\ Year\ N = (Volume\ put\ on\ market\ 2016)\ \mathrm{x}\left(\frac{incidence\ Year\ N}{incidence\ Year\ 2016}\right)$$

This is a simplification, since the annual volumes are also dependant among others, on the number of tattoos per person per year, size and style of tattoos. SEAC agrees that, due to the lack of data, how these parameters change in the future is unknown, and that they cannot be taken into account in the calculation of tattoo ink volumes. Using incidence could lead to underestimation of future volumes over the study period because it does not take explicitly into account inks used for people already having at least one tattoo. In order to provide an idea of the sensitivity of using incidence as a proxy, SEAC also used prevalence (therefore tending in this case to overestimate volumes, because of the underlying assumption that every tattooed individual will continue getting more tattoos annually for the rest of their life) and found that volumes in 2040 in the Main scenario would then be double those projected using the ratio of incidences.

SEAC concludes that it is acceptable to base an indicative assessment of the future volumes on the incidence of getting tattooed for the first time, but keeping in mind it could underestimate future volumes.

This incidence of people getting tattooed for the first time of 0.53% at the beginning over the study period (2015-2042) is estimated based on the past period 2003-2014, using information on population (from Eurostat) and prevalence in 2003 (6%)[16] and 2014 (12.1%) (JRC 2015b). The Dossier Submitter made, using assumptions, three scenarios for future incidence rates (Low, Main, and High), that are used to derive three (Low, Main, and High volume) scenarios for the volumes of tattoo inks placed on the market annually.

Table 6 Incidence rate scenarios

Incidence	2015-2025	2025-2030	2030-2042
Low	0.53%	0.27%	0.13%

[16] The value of 6% for 2003 adopted by the Dossiers Submitter is a mean between 4 and 8% values that are reported *in JRC, 2015b. Safety of tattoos and permanent make-up – State of play and trends in tattoo practices, Report on Work Package 2, s.l.: European Commission Joint Research Centre.* This JRC report adapted existing information for tattooed and pierced population to tattooed-only population from the prevalence for tatooed and pierced population (5 to 10% in 2003) reported in a DG SANCO 2003 Document "Recommendations for regulatory action in the EU on the safety of tattoos, body piercing and of related practices in the EU".

Main	0.53%	0.53%	0.53%
High	0.80%	0.53%	0.53%

Legend:
Calculated
Scenario

In terms of prevalence of tattooing in the EEA population, the above incidence assumptions give the following results:

Table 7 Prevalence scenarios

Prevalence	2014	2016	2021	2040
Low	12.10%		15.70%	20.30%
Main	12.10%	13.10%	16.20%	26.10%
High	12.10%		17.50%	28.50%

Legend:
JRC study
Derived using incidence assumptions and EuroStat population projections

The Dossier Submitter highlighted the uncertainty in projecting fashion trends and, based on consultations with formulators and tattoo artists, considered that the future trends of tattooing could be similar to the way fashion evolves over time, and that after a period of growth, it could probably progressively become out of fashion under the Low scenario, or stabilise under the Main incidence scenario. SEAC finds the Main and Low incidence scenario are plausible but only illustrative since long-term projection of fashion and cultural trends is inherently uncertain. However, SEAC has reservations regarding the consistency of the High scenario, where incidence would return back to levels assumed under the Main scenario after 2025. This leads to prevalence in 2040 only slightly higher than the Main scenario (28.5% versus 26.1%). SEAC agrees that this is a possibility but finds that to get a broader view of the impact on the conclusions of assumptions for different future scenarios, a High scenario in which incidence is continuously growing could have been more informative. A High scenario where an incidence of 0.8% is assumed for the remainder of the study period will result in a prevalence of 32.5%. Therefore, SEAC overall agrees with the future projections, but finds they are uncertain, more to be understood as being illustrative of possible future situations than predictive, and that their upper range could be underestimated.

In terms of uncertainties of projected volumes, SEAC also notes that given that no information from stakeholders has pointed otherwise, an assumption is made that to get to the same effects (in terms of aesthetics, longevity, etc.) the same volume of a compliant ink compared to a non-compliant ink has to be used. SEAC agrees with this assumption.

A key assumption of the substitution costs assessment is that they can be approximated with the price difference between compliant and non-compliant inks. The price difference is set by a) the (constant) price for non-compliant inks, and b) an assumption of the relative price difference in percent. The price difference is assumed to be constant over the study period. This assumption tends to overestimate the substitution costs, since it could be expected that, with the increasing market for compliant inks, the price could decrease in the future due to economies of scale (considering no major supply problem).

SEAC notes that the Dossier Submitter uses a mean value of the price, but notes that this price is very variable (between €6 and €25 per 30 ml for tattoo inks) and using a mean value introduces uncertainty. SEAC finds that the price estimation is based on a reliable dataset, however with the observation that it was difficult to check with the information available whether the prices reported by the JRC reports are only for non-compliant inks.

Regarding the relative price difference, the Dossier Submitter assumes in the Main scenario that conforming inks are 15% (High scenario 30%) more expensive for tattoo inks, and 20% (High scenario 40%) for PMU inks. The price difference between compliant and non-compliant inks comes from interviews with a total of seven manufacturers[17], from the call for evidence (one answer by a manufacturer), from surveys of tattoo artists and reports by the JRC. The information provided varies from 0% to 40% for tattoo inks and from 0% to 70% for PMU inks. Given the low response rate to surveys by the Dossier Submitter, SEAC considers that the chosen figures for price difference are acceptable but uncertain (large contrast between estimates from different information sources). No additional information was received during the Public Consultation on the dossier.

For the share of non-compliant tattoo inks, the Dossier Submitter used a constant value over the study period, with 3 possible scenarios: 30%, 50% and 70% for tattoo inks. For PMU inks, the assumptions are respectively 0, 10% and 20%. These values are combined with the three Low, Main, High scenarios for the volumes of inks put on the market, in the following way, to provide a set of 9 values for the total substitution costs:

Table 8 *Total annualised substitution costs for 2016 estimated by the Dossier Submitter (in euro)*

	Non compliance scenario	**Tattoo : 30% PMU : 0%**	**Tattoo : 50% PMU : 10%**	**Tattoo : 70% PMU : 30%**
Volumes scenario				
Low		1 177 471	2 806 428	4 435 385
Main		2 095 694	4 353 847	6 612 000
High		2 437 107	4 939 207	7 441 308

[17] For confidentiality reasons, SEAC could not have access to the information provided in each interview.

The 30% - 70% range reflects the range of non-conformity reported for tattoo inks in market surveys analysed by the Dossier Submitter (with actual range from 15% to 70% non-compliance with chemical requirements). In the Main scenario, the Dossier Submitter used a non-compliance for tattoo inks of 50%, but indicated that this non-compliance rate is conservative. SEAC agrees that the information available from surveys carried out in several countries in the EEA (Germany, Italy, Sweden, and Switzerland) indicate in general of lower non-compliance rate (mean around 35% across available studies), and that non-compliance is expected to decrease with time. The observed non-conformity rates are based on the legislation that was in place where and when the surveys were carried out. These legislations were based on CoE ResAP (different versions) which are similar to the proposed restriction. SEAC however finds that the adequate non-conformity range depends on the specific restriction option because different concentration limits could lead to different non-conformity ranges. While SEAC can draw a parallel to ResAP compliance rates and these expected for the DS and RAC proposed restriction options on the basis of similarities of concentration limits, it notes the possible differences with (RAC modified) RO1 where the limits for some impurities are stricter. Overall, SEAC agrees to use the non-conformity rates in the Main scenario (50% and 10% for tattoo inks and PMU inks respectively) but does not consider it a conservative assumption that would overestimate the costs (given the level of non-compliance in Member States with national legislation). SEAC thus agrees overall with the estimates presented by the Dossier Submitter.

Difference between RO1, RO2 and RAC modified RO1 in terms of substitution costs

The Dossier Submitter could not quantify the differences in substitution costs between RO1 and RO2 arising from the different concentration limits and the different mechanisms to update the scope of the proposed restriction in the future. SEAC agrees that the available information does not appear to enable a quantitative distinction between the two options in terms of substitution costs. Since concentration limits are less stringent in RO2, it can be assumed that more tattoo inks would meet these requirements, and that fewer tattoo inks would require reformulation or have higher testing costs. This would mean lower substitution costs under RO2 compared to RO1. Given the lack of information on technical and economic constraints to manufacture tattoo inks, no quantitative assessment is possible.

It is also difficult, for similar reasons, for SEAC to quantify the differences in substitution costs between RAC modified RO1 and RO1 or RO2. Overall, the RAC modified RO1 has lower limits in comparison to RO2, therefore, it can be expected that it would lead to the reformulation of more tattoo inks in comparison to RO2. The RAC modified RO1 has some higher concentration limits (e.g. for CMRs) but lower for other (e.g. nickel, cobalt) in comparison to RO1 as proposed by the DS with the overall effect on costs being unclear. However, the technical feasibility of the limits proposed by RAC will be further tested in the SEAC DO Public Consultation.

The difference in the mechanism to update the future scope of the proposed restriction has unpredictable effects in terms of substitution costs difference between RO1, RO2 and the RAC modified RO1.

Availability of alternatives

SEAC agrees that the fact that there are already compliant inks with the legislation in several Member States is a strong indicator that there are alternatives available. This was also the conclusion of a survey made by the Danish authorities. Also, in response to ECHA's Call for Evidence, no company claimed that there were no alternatives available (other than for Pigment Blue 15:3 and Pigment Green 7 that are proposed to be derogated). This was echoed in the comments in the Public Consultation.

There is a significant level of non-compliance in the Member States having a legislation based on CoE, and this could be indeed a consequence of lack of EU-wide legislation (as well as counterfeiting), but also implies an uncertainty in the availability of alternatives to all supply chains, because in some cases non-compliance could also be due to the inability to source raw materials meeting the proposed requirements.

An important particular case is that of preservatives, that have the function to ensure the microbiological safety of inks. From the information gathered by the Dossier Submitter it appears that only a small fraction of the preservatives listed in the CPR or actually found in tattoo inks during surveys, would be under the scope of the proposed restriction. The Dossier Submitter concludes from that information that there are many available alternatives for the few preservatives impacted by the proposed restriction. SEAC tends to agree with this conclusion, although the Dossier Submitter did not include information on technical performance requirements and constraints of using preservatives in inks. No information was received during the Public Consultation to indicate that the proposed restriction would limit the availability of suitable preservatives.

Enforcement costs

For all cost components, the annual cost is first calculated by the Dossier Submitter and then converted to a NPV value over the study period (using a 4% discount rate as for other costs).

Analytical testing costs

For public authorities

The costs for an analytical campaign have been based on past experience, and then annual costs are computed assuming that the analytical campaign occurs every 4.5 years. Only costs for those 22 Member State which do not have national legislation are taken into account in the incremental costs of the proposed restriction. The costs of each campaign are based on 100 samples at €500, for each country. The number of samples has been considered by analogy to the four phthalates restriction (in which it was used as an illustrative assumption by SEAC). The €500 per sample is assumed to cover testing for impurities, aromatic amines and some other substances (CMRs). Given the lack of background technical information, SEAC cannot confirm the €500 figure on a technical basis. SEAC finds this can be considered as an uncertain assumption of the reasonable expense per sample for public authorities.

These estimated analytical testing costs may not reflect all the analytical development costs (costs for harmonising methods and knowledge transfer between Member States, or costs for developing new analytical methods). Given the high number of substances involved and lack of harmonised methods in tattoo inks, it is possible that these costs are not negligible. However, efforts have already started in the EU (with a multi-country initiative) to develop harmonised methods in a concerted way between enforcement authorities.

The way in which, due to absence of information, some concentration limits have been set (see above discussion on substitution costs), also creates an uncertainty regarding analytical testing costs.

SEAC notes that no further information was received during the Public Consultation and agrees to use the estimates provided by the Dossier Submitter. SEAC agrees that given public spending constraints, the actual amount spent by public authorities for analytical costs cannot be dramatically higher than the estimated by the Dossier Submitter. SEAC however underlines that given the lack of information, the estimates should only be taken as an illustrative figure. It is uncertain that the actual budget being necessary for the enforcement of the proposed restriction will be actually spent by MS (because of both exogenous budget constraints, and possibly higher analytical testing costs than expected). This could result in analytical campaigns carried out less frequently and with limited chemical scope, which may have negative impacts on the enforcement and risk reduction capacity of the proposed restriction.

For supply chains

Supply chains will carry out internal testing to ensure conformity of their products. The Dossier Submitter explained that these costs are included in the substitution costs, since the price difference between compliant and non-compliant inks (the basis for estimation of substitution costs) reflects the operational costs, including analytical testing costs that manufacturers have to carry out to comply with CoE legislation.

The Dossier Submitter attempted to gather information on the testing costs through interviews and survey of formulators. Limited information was received with answers ranging from €20 000 - €50 000 annually, with some mentioning that they also performed testing prior to ResAP. It is unclear what share of these costs can be assumed to be incremental to the proposed restriction as many formulators already market their products in Member States with national legislation and therefore, already perform tests to ensure compliance. SEAC also noted that, in response to the call for evidence, one German ink manufacturer claimed the proposed restriction would entail significant workload and costs in terms of compliance testing. No further information was received during the Public Consultation.

Furthermore, supply chains will also have to adapt to future harmonised analytical methods that are not currently available and this may also have implication on analytical costs.

Therefore, based on the available information, SEAC concludes that the testing costs may also have higher impact on the supply chain than estimated in the Main substitution cost scenario. It is possible however, that this uncertainty is captured to a certain extent in the Higher price difference scenario presented by the Dossier Submitter, in which some testing costs could be captured in the assumed higher price difference between compliant and non-compliant inks.

Administrative costs

For public authorities

The estimation of administrative costs is based on ECHA study of Member State costs of enforcing restrictions, which was used in several other restriction dossiers. Given the comparatively higher complexity of this restriction (wide scope of substances, high number of small actors that may be difficult to reach, comprehensive labelling requirements), it could be that some Member States allocate more resources to the proposed restriction. SEAC however, also acknowledges that given public spending constraints, this may not be possible. Furthermore, there is already a degree of familiarity with the CoE ResAP requirements and transferrable experience in Member States with national legislation which will facilitate enforcement by public authorities.

SEAC also notes that the Dossier Submitter suggested the creation of an EU-wide registry of inks to strengthen the efficiency of the proposed restriction. The cost of this registry is not included in the impact assessment as it was a suggestion for future consideration. The registry might be important to know how to conduct enforcement, e.g., which substances to target in compliance campaigns, especially in the future when the composition of inks might change due to the proposed restriction or other factors such as changes in customer demand, or innovation in tattooing or ink manufacturing techniques.

SEAC will use in its assessment the approach proposed by the Dossier Submitter (based on a "fixed budget" approach for restrictions) but in the event the restriction is not allocated sufficient administrative enforcement budget, the expected risk reduction and benefits of the proposed restriction may not be fully achieved.

For supply chains

Administrative costs for supply chains are, according to the Dossier Submitter, reflected in the substitution costs in the proposed restriction (estimated on the basis of the price difference between compliant and non-compliant inks). However, this restriction is complex for supply chains: in particular, in terms of scope of substances (with links to CLP, CPR), and requirements for comprehensive labelling of inks. Furthermore, current administrative requirements for supply chains are low in a significant share of the Member States that did not implement CoE resolutions.

SEAC concludes that it cannot be excluded that industry stakeholders could face higher administrative costs than estimated by the Dossier Submitter, but is not able to assess their magnitude. However, this uncertainty could be captured to some extent in the Higher price difference scenario presented by the Dossier Submitter, as higher labour costs (including related to the administration of regulatory requirements), similar to other operational costs, could be captured in the assumed higher price difference.

Difference between RO1, RO2 and RAC modified RO1

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

C.3.6.2. Benefits

C.3.6.2.1. Summary of proposal:

The adverse effects associated with exposure to chemicals in tattoo inks can be grouped in: non-infectious inflammatory (e.g., plaque-like, papulo-nodular, ulcerating, hyperkeratoric, photosensitivity, etc.), systemic, malignant, reproductive and developmental effects. Estimating the true overall incidence and prevalence of health effects is difficult for a number of reasons. Skin complications are better studied, however, even those effects are difficult to estimate due to lack of registry and epidemiological studies among others. On average, it can be estimated, on the basis of surveys of health effects of people with tattoos, that 1.8% of tattooed people develop adverse skin reaction of severity that requires a doctor's consultation.

The Dossier Submitter estimates that the social costs of one case of severe non-infectious inflammatory reaction is approximately €4 350 (lower value) or €14 400 (higher value). This is on the basis of costs for treatment and willingness to pay (WTP) to avoid symptoms such as itching and burning sensations that affect quality of life. For the WTP, a proxy for severe chronic dermatitis is used (ECHA, 2016f) as studies have 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)

The per case social costs of mild discomforts (experienced after the initial healing process, e.g., photosensitivity, other mild effects associated with itching, pain, swelling, redness, etc.) are likely lower than the presented severe effects above. However, studies reveals that a large number of tattooed people (as high as 42% of respondents, Hutton Carlsten & Serup, 2014) may experience these effects. The overall social costs of these mild effects are not monetised.

The social costs to avoid other systemic, reproductive, developmental or carcinogenic illnesses would be much higher, as they tend to have long-term health consequences requiring medical treatment and higher willingness to pay to avoid (e.g., the willingness to pay to avoid cancer morbidity is €410 000 in 2012 values (ECHA, 2016b)).

C.3.6.2.2. SEAC conclusion(s):

SEAC notes RAC's conclusion on the relation between the chemical composition of the tattoo inks and the observed adverse effects. SEAC concludes that the proposed restriction would result in benefits to society in terms of avoided cases of mild discomforts (mild swelling, itching, erythema) and non-infectious inflammatory reactions. Due to difficulties assessing the incidence and prevalence of these effects and quantifying the risk reduction capacity of the proposed restriction options, these benefits to society cannot be quantified. However, SEAC considers that the benefits related to severe non-inflammatory effects are rather certain, considering RAC's conclusion that there is enough evidence to demonstrate the risk of local (skin) effects, and since these effects among the tattooed population are very well documented. SEAC also notes that, other effects (carcinogenic, reproductive, developmental, and other systemic) are important on a "per case" basis, but that the relationship with tattoo inks is less firm according to RAC[18].

SEAC agrees with the Dossier Submitter's analysis that the health benefits of the proposed restriction cannot be quantified and monetised and finds the approach taken by the Dossier Submitter to focus on skin complications for the quantification of benefits justified and understandable. The estimated social cost of severe non-infectious inflammatory effects considers a lower and higher value of the WTP figures used in the analysis. SEAC agrees with the lower and higher value for the social cost given by the Dossier Submitter, although there are arguments that these values could be an under- as well as an overestimation. SEAC acknowledges that there could be other health benefits, also with a higher social cost per case than non-infectious inflammatory effects, from the proposed restriction that cannot be quantified.

C.3.6.2.3. Key elements underpinning the SEAC conclusion(s):

Benefits for human health

SEAC notes that, as confirmed by RAC, the complexity and variability in chemical composition of tattoo inks is associated with a risk of diverse adverse effects but clear epidemiological associations are lacking. The Dossier Submitter gives an extensive overview of the type of adverse health effects that are associated with the tattoo process and of those, which are potentially related to the chemical composition of tattoo inks. SEAC agrees with the Dossier Submitter to focus on chemical-related adverse effects only, as these are affected by the proposed restriction[19]. SEAC notes RAC's conclusion is that chemicals in tattoo inks pose human health risk, i.e., local (skin) effects but also systemic and malignant effects, where the evidence is less clear but risks cannot be excluded on the basis of intrinsic properties of substances (that currently or in the future can be found) in tattoo inks and toxicokinetic data from humans and animals. As noted by RAC, because the incidence and prevalence of these adverse health effects is difficult to assess at the present moment, SEAC concurs with the Dossier Submitter's assessment that the health benefits of the proposal cannot be quantified and monetised (unless a direct valuation study would have been attempted). Instead, individual avoided cases of non-infectious inflammatory effects are monetised by the Dossier Submitter and used in the proportionality assessment in a break-even analysis (see proportionality section below). SEAC finds this approach justified and understandable based on the presented data on tattoo complaints and complications.

[18] RAC states the evidence for systemic (except for general eczema) or malignant effects is much less clear compared to that for local (skin) effects. RAC section B.1.2.3.3.

For the purpose of the break-even analysis, the Dossier Submitter first assesses the type of treatments available for non-infectious, inflammatory tattoo complications and focusses on the severe complications that need pigment removal. SEAC finds the Dossier Submitter's analyses of treatment options following tattoo complications transparent and justified by recent literature from medical experts in the field of tattoo complications.

The cost of treatment is based on medical costs information from dermatologists specialised in tattoo complications from Belgium, Denmark and Finland. The information consisted of either a total cost estimate for medical treatment and dermatome shaving or more specified treatment types and frequency thereof (General Practitioner consult, dermatologist, topical corticosteroids, shaving aftercare, excision, laser treatment, etc.) with subsequent public sector costs. SEAC reviewed the data provided by the dermatologists and how the Dossier Submitter subsequently assessed the treatments costs. SEAC concludes that the Dossier Submitter has adequately estimated an average treatment cost associated with severe skin tattoo complications. SEAC notes that no follow-up treatment is assumed by the Dossier Submitter, potentially underestimating the treatment costs. Also, treatment costs can deviate considerably from the estimated average depending on country, tattoo size and treatment method. SEAC further notes that the Dossier Submitter assumes treatment is initiated within one year after the start of symptoms and in every case is 100% successful. Therefore, the estimated social cost of one case of severe non-infectious inflammatory reactions could be an underestimation if the time between developing symptoms and treatment is longer than one year or the success rate is lower than 100%.

The Dossier Submitter considers also intangible costs for patients with non-infectious inflammatory-type tattoo complications. SEAC finds it likely that such tattoo complications can cause psychological suffering as the Background Document shows a reduced quality of life in tattoo patients that is similar to known skin diseases such as psoriasis, pruritus and eczema. SEAC notes that two aspects should be considered when using the ECHA WTP figures for severe chronic dermatitis as proxy for tattoo complications (ECHA 2016f); representativeness of the symptoms assessed in the WTP study for skin complications as a result of tattooing and representativeness of the studied population relative to the tattooed population. The lower and higher ECHA reference values for WTP to avoid severe chronic dermatitis are based on studies done with psoriasis and eczema patients (ECHA 2016). The reduction of quality of life is described to be similar between psoriasis and eczema patients and patients with tattoo complications (Hutton Carlsen & Serup, 2015a). SEAC finds that this survey (Hutton Carlsen & Serup, 2015a) confirms that the ECHA WTP values used are representative in terms of symptoms.

A difference between the populations that would potentially be of influence on the WTP is disposable income of population. One factor linked with disposable income is age, i.e., it increases with age. The ECHA WTP values are based on populations with a mean age of 55 years. It is likely that the tattooed population that is potentially at risk for tattoo-related skin complications is younger. In the Hutton Carlsen & Serup survey the mean age among patients with tattoo complications was reported to be 33 years. In general, disposable income is lower for younger age groups (at least for most of the study period, since the age of tattooed population would likely increase in the future under the "high" scenario). Hence, the lower expected average age of the EU tattooed population may be seen as having the consequence of the ECHA WTP figures being an upper bound of society's valuation. However, the fact that a sub-population of the EU would have less financial resources than the overall EU population does not necessarily mean that the overall societal WTP to protect them from a risk should be adjusted to the WTP of that sub-population

Other socio-economic characteristics that influence the WTP (like risk-taking behaviour[20]) could be different between the two populations as well, but SEAC did not find convincing evidence of such an influence.

The Dossier Submitter notes that at least in theory a specific survey to directly assess the WTP to reduce risks from tattoo inks could have been considered. SEAC agrees that such a study would also have been faced with the issue that surveyed individuals could not have been informed in quantitative terms regarding the expected risk reduction of the proposed public intervention, but this does not necessarily impede the production of a range of WTP values (however with possibly large uncertainties). SEAC concurs with the Dossier Submitter's assessment that such a study requires substantial resources to obtain useful results while the impact on reducing the uncertainties in the analysis would be marginal and therefore, understands why a direct assessment of the WTP was not pursued.

Overall, SEAC therefore considers the ECHA WTP values sufficiently representative of the societal WTP to avoid severe tattoo complications.

Furthermore, SEAC notes that, although the break-even analysis focusses on non-infectious inflammatory effects, risks of other types of adverse health effects (systemic, malignant tumours, reproductive and developmental, as well as mild effects occurring after the initial healing (>1 month after tattoo procedure) such as photosensitivity, itching, swelling, etc.) could also be impacted by the proposed restriction. SEAC concurs with the Dossier Submitter that the social costs of the other types of systemic, malignant tumours, reproductive and developmental effects are higher per case than the monetised non-infectious inflammatory effects.

Difference between RO1, RO2 and RAC modified RO1

As a general observation, SEAC notes that the available information does not allow for a quantitative differentiation of health benefits between RO1, RO2 and the RAC modified RO1. SEAC takes note of RAC's considerations of the risk reduction capacity of the three options. Therefore, SEAC concludes that the expected benefits of the RAC modified RO1, followed by the Dossier Submitter RO1 will be larger due to their higher risk reduction potential in comparison to RO2.

Benefits for the environment

SEAC took into account RAC's confirmation that the potential for release of chemicals to the environment is limited in the context of tattooing and PMU, and that the environmental impact of the proposed restriction is therefore limited, compared to human health issues.

[20] SEAC only found few and conflicting information regarding whether tattooed population would be more risk-taking than the general population: (Heywood W. et al, 2012) finds that tattooing among Australian adults was associated with risk-taking behaviors, whereas (Swamni V. et al., 2016) find no significant association.

C.3.6.3. Other impacts

C.3.6.3.1. Summary of proposal:

Other impacts that can be expected from the restriction include: social, distributional and wider economic impact. Of these, impacts on SMEs are expected to be the most prominent, as many formulators are small or micro enterprises. However, closures are not expected as any cost increases are expected to be passed on to end consumers.

C.3.6.3.2. SEAC conclusion(s):

SEAC agrees that significant wider economic, social, and distributional impacts are unlikely to occur as a consequence of the proposed restriction.

C.3.6.3.3. Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter examines the wider economic, social, and distributional impacts that the proposed restriction could have on economic actors. The impacts are examined separately for pigment manufacturers, tattoo ink formulators, and tattoo artists, anticipating only small impacts for all the actors.

SEAC considers that the proposed restriction could induce some changes in the sector, such as consolidation among actors (smaller formulators that do not currently have ResAP compliant inks), in order to share and reduce compliance costs. SEAC agrees, however, that it is unlikely that closures would occur, since it is probable for economic actors to pass-on costs to consumers (see discussion on proportionality). SEAC also notes that it is also possible that the proposed restriction lowers the risk perception and hence, increases the confidence of consumers in the safety of tattooing, with a potential positive impact on the price for tattoo services.

C.3.6.4. Overall proportionality to the risk

C.3.6.4.1. Summary of proposal:

The Dossier Submitter has concluded that the restriction is proportionate to the risk because it is affordable, it is cost effective, and it requires very few avoided cases to break even:

- The cost of tattoo inks represents a small share of the costs per tattoo (marginal costs of the proposed restriction would be less than €1 per tattoo) and even smaller share of the final price per tattoo (e.g., €80-100 in many Western and Northern European Member States and about half that in some Eastern) or PMU (about €350). The price increase of tattoo inks are expected to be transferred to end consumers, whose demand for tattoo services appears to be inelastic. Therefore, the costs increases as a result of the proposed restriction options would likely not lead to disproportionate costs to economic actors and society as a whole.
- 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.
- 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 cases 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 1.8% and not all costs are taken into account. In addition, the removal of tattoos due to an allergic or papulo-nodular reaction is just one group of the health outcomes, as a number of people experience complications that require topical or systemic corticosteroids as well as experience mild ongoing complaints from their tattoos and PMU. This is in addition to the potential (unquantified) contribution of tattoo ink and PMU exposure to carcinogenic, reproductive, and other systemic adverse effects.

C.3.6.4.2. RAC and SEAC conclusion(s):

SEAC was not able to quantitatively compare the benefits and costs of the proposed restriction, but concludes that the proposed restriction is likely to be proportionate to the risk because:

i. It will bring significant benefits to society (i.e., avoided adverse skin effects and other health impacts), that are likely to be higher than the compliance costs.
ii. It will not have significant negative economic impacts on supply chains.
iii. It is affordable, because compliance costs are likely to be passed-on to consumers through the price increase of tattoo services, and that this price increase will remain affordable.
iv. The proposed restriction is a grouping approach addressing all substances with similar hazard and risk (to the extent possible given available information on hazards), therefore minimising risks of regrettable substitution. This feature increases the confidence SEAC has that expected risk reduction will be actually realised and that the proposed restriction is proportionate.

SEAC notes that the proposed restriction is only "likely" to be proportionate because of the uncertainty surrounding the fact that benefits actually are higher than costs. This uncertainty is not particularly caused by the absence of quantification of benefits, but by both the uncertainties on the qualitative benefits assessment and the quantitative assessment of costs.

C.3.6.4.3. Key elements underpinning the RAC and SEAC conclusion(s):

SEAC could not base its conclusion on a quantitative comparison of the costs and benefits of the proposed restriction, or on its cost-effectiveness, for the following reasons:

- SEAC agrees with the method to calculate the number of cases of chronic allergic reactions for the break-even analysis, but did not find a way to compare the break-even incidence rate of chronic allergic reactions (0.02-0.06%) to the observed tattoo prevalence in the general population (1.8%). This is because of the complex relation between incidence and prevalence that has not been modelled due primarily to the difficulty to quantitatively estimate baseline risk and the risk reduction capacity of the proposed restriction.
- SEAC could not find a way to interpret the cost-effectiveness of the restriction expressed by the Dossier Submitters as €60 per litre of non-compliant ink removed from the market because there does not seem to be an economic assessment of a similar regulation that could be a point of comparison.

SEAC however could base its conclusion on the following elements:

The proposed restriction is likely to be proportionate:

- The proposed restriction will bring significant benefits to society (avoided health impacts of adverse skin effects and other health impacts), even if their magnitude cannot be assessed.
- SEAC finds that the proposed restriction, also when considering uncertainties regarding its compliance costs, is affordable for consumers. The price increase incurred per PMU or tattoo is low (respectively in the order of magnitude of €4 and €1 per procedure respectively), and demand is quite inelastic to price (as reported in a survey in the US quoted by the Dossier Submitter, in which only 8% of respondents stated that price is an important factor in their decision to get a tattoo). The risk of negative economic impacts for supply chains is low, as discussed in the above section on other impacts, also in particular given the affordability to consumers.
- Furthermore, the risk of increased competition from outside the EU seems very limited: a large share of tattoo inks is currently already imported and consumers are not expected to turn to tattoo artists located outside the EU (more so than currently practiced). No risk of profit losses for the EU economy is therefore to be expected.
- Positive economic impacts for the supply chains are possible, given a potential increased level of confidence of consumers in tattooing practice as a result of the restriction proposal (increase in turnover could create an increase in profits).

Considering the above elements, SEAC was able to compare qualitatively the costs and benefits and found that the proposed restriction will bring health benefits and is not expected to have significant economic impacts, and therefore, concludes that the proposed restriction is likely to be proportionate.

Furthermore, the proposed restriction has the additional benefit of avoiding regrettable

substitution. Targeting in a single restriction proposal all classified hazardous chemicals in inks tends to ensure that no regrettable substitution will take place, even if the actual magnitude of health benefits remains uncertain. Replacement of restricted chemicals by not yet classified chemicals is possible, but industry is likely to use long-term alternatives to avoid substitution costs.

SEAC's conclusions and justifications are valid for the three proposed ROs. As explained in the preceding sections on costs and benefits, because of the uncertainties related to i) the impact on different concentration limits in the three restriction options on compliance costs and ii) the risk reduction capacity and also the magnitude of benefits, it is difficult to quantitatively or qualitatively conclude which of the three options is more proportionate. On the one hand, if the concentration limits are an indication of the difficulty to comply with the restriction option, the costs for RO2 are expected to be lower in comparison to the RAC modified RO1 and RO1 as proposed by the Dossier Submitter. On the other hand, the risk reduction capacity and therefore, the benefits of the restriction options, are likely to be in the same order: with those for RO2 likely to be the lowest, followed by RAC modified RO1 and RO1. Therefore, it is difficult to conclude which restriction option is more proportionate on balance; however, all three options are expected to be proportionate and to lead to low economic impacts on the EEA.

Table 9 Summary of costs and benefits of restriction options

Impact	**Restriction Option 1 (RO1)**	**Restriction Option 2 (RO2)***	**RAC/SEAC modified RO1***
Total Compliance Costs	€4.6 million	Lower than RO1 and RAC/SEAC modified RO1	Possibly similar to RO1 but higher than RO2
- Substitution	€4.4 million	Lower than RO1 and RAC/SEAC modified RO1	Possibly similar to RO1 but higher than RO2
- Enforcement	€0.2 million	Lower than RO1 and RAC/SEAC modified RO1	Possibly similar to RO1 but higher than RO2
Social impacts	Moderate	Similar to RO1	Similar to RO1
Wider economic impacts	Minimal	Similar to RO1	Similar to RO1
Distributional impacts	Minimal	Similar to RO1	Similar to RO1
Risk reduction capacity	It would reduce risks	Possibly lower than RO1 and RAC/SEAC modified RO1	Possibly similar to RO1 but higher than RO2
Benefits	Equivalent to the avoided cases of tattoo adverse effects	Possibly lower than RO1 and RAC/SEAC modified RO1	Possibly similar to RO1 but higher than RO2
Break-even	Fewer than 320 – 1 050 avoided cases of tattoo removal due to non-infectious inflammatory complications	Possibly fewer cases required for break-even than RO1 and RAC/SEAC modified RO1	Similar to RO1 and more cases required for break-even than RO2
Affordability	Affordable	Likely more affordable than RO1 and RAC/SEAC modified RO1	Similar to RO1 but less affordable than RO2

Notes: Qualitative comparison to RO1 of RO2 and RAC/SEAC modified RO1 is based on the assumption that lower concentration limits would require more resources to comply with (therefore, would lead to higher costs) and would lead to higher risk reduction and benefits from the proposed restriction. However, some concentration limits of RO1 are lower while others are higher than RAC/SEAC modified RO1. Furthermore, many of the concentration limits proposed under RAC/SEAC modified RO1 may be similar to the effectively enforced concentration limits under national legislation based on ResAP (e.g., for substances that should not be contained in tattoo inks unless not intentionally added). Therefore, the differences of the impacts of RO1 and the RAC/SEAC modified RO1 are concluded to be smaller than those with RO2.

C.3.6.5. Uncertainties in the proportionality to the risks section

Uncertainties related to the costs, benefits, and proportionality to risk of the proposed restriction options are discussed in the preceding section. Some of the uncertainties discussed previously (i.e. projections of tattoo ink volumes) only affect the total substitution costs of the restriction but not the cost per tattoo service, and therefore, have no impacts on SEAC's conclusions on the affordability (cost per tattoo) of the compliance costs imposed by the restriction.

Some other uncertainties related to assumptions used in the estimation of substitution costs (related to price differences especially) as well as administrative and testing costs (see discussion on costs above) could affect in theory the cost per tattoo service and therefore, the conclusions on affordability. However, even if these costs were severely underestimated, sensitivity scenarios demonstrate that the price increase would still remain low compared to the prices of tattoo services. As stated earlier, the price of tattoo services is not a leading criterion for deciding to get a tattoo, therefore, the price increase is expected to be passed on to consumers and the restriction is expected to remain affordable even in those higher costs scenarios.

As discussed above, it is possible that the budget for enforcement (testing, administrative burdens) is insufficient regarding the large scope and complexity of the restriction. The implication could be insufficient testing and administrative oversight by both supply chains and authorities, leading to higher non-compliance than expected, and lower risk reduction than expected in DS assessment. It is difficult to assess the impact on the proportionality to the risk of the restriction, because it depends on the (unknown) significance of the possible underestimation, and of the reactions of supply chains and administrations (whether for instance there would be efficient and rapid sharing of information among Member States for analytical method development, whether supply chains could and would use for a period non-EU-harmonised but still valid analytical methods to check and eventually change raw materials and formulations). Therefore this is regarded by SEAC as the main source of uncertainty in its assessment.

C.3.7. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

C.3.7.1. Summary of proposal:

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

Implementability

- The proposed restriction options propose similar measures, 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.

C.3.7.2. RAC and SEAC conclusion(s):

Taking into account, among other elements, information in the Background Document, the Public Consultation and the advice given by Forum, SEAC is of the view that the proposed restriction options are practical and enforceable (keeping however in mind uncertainties regarding administrative and testing costs).

SEAC concludes there are no compelling socio-economic arguments favouring either of the restriction options. In its proposal for amended RO1 concentration limits, where information as such was available, RAC accounted for practical considerations of the limits for industry and enforcement authorities. Therefore, it can be concluded that the RAC modified RO1 may be easier to implement, enforce, and manage in comparison to the other two restriction options.

C.3.7.3. Key elements underpinning the RAC and SEAC conclusion(s):

SEAC considers the restriction options to be implementable based on similarity with ResAP recommendations already implemented in national law in seven Member States. Industry's ability to comply with ResAP follows from results of surveillance programmes. SEAC sees there are some arguments for both a shorter as for a longer transitional period compared to 1 year as proposed by the Dossier Submitter. Some stakeholders and one Member State enforcement body argue a 1 year transitional period would be too short to implement the legislation whilst others indicate to be ready in one year. Overall, SEAC agrees with a 1 year transitional period as a reasonable timeframe to implement the restriction (See section B.3.4.5.).

SEAC agrees with the Dossier Submitter that the proposed restriction has a level of similarity with existing measures (CPR, ReSAP, CLP). SEAC notes that some stakeholders in the Public Consultation stated that the proposed legislation covering numerous chemicals would be difficult to manage. Convincing arguments underpinning this claim were not available to SEAC and experiences based on implemented national law following ResAP show comparable measures are manageable in practice. Therefore, SEAC concludes positively on the manageability.

Assuming the concentration limits are an indication for the number of reformulations required, it can be expected that less strict limits will lead to fewer required reformulations and therefore, RO2 may be more manageable and easier to implement than the RAC modified RO1 concentration limits and, lastly, RO1.

According to the Forum, the restriction is enforceable if further development of methods for sampling and chemical analysis is undertaken. Due to the high number of substances within the restriction scope, and the lack of available standard methods or reference materials (e.g. for azo pigments as indicated in the Public Consultation) for the quantification of all chemicals present in tattoo inks, methods applicable to other matrices should be considered and modified. Information on best available analytical practices can be shared among all relevant stakeholders (e.g., through the Forum Compendium on analytical methods for the enforcement of restrictions or through an ad hoc guidance document on tattoo inks restriction). There is an ongoing multi-country project (Denmark, Germany, Switzerland, and Italy) on developing analytical methods. Together with the compendium of analytical methods that the advice is referring to, this work will also improve the enforceability of the proposed restriction. The Public Consultation indicated that enforcement of the proposed arsenic limit of RO1 and RO2, may be difficult as the limit of quantification of arsenic in tattooing agents is 0.1 mg/kg (0.00001%) [PC #1911; PC #1924] which is higher than 0.0000008% as proposed by the Dossier Submitter under RO1 and RO2. RAC proposed a practical concentration limit (0.00005%) which is above the reported limit of quantification.

The Forum acknowledges that enforcement of national legislation based on ResAP is already taking place in just under a third of EEA31 Member States and that systems are in place (under the General Product Safety Directive) to monitor compliance of the Council of Europe resolutions and to share information on non-compliant products– RAPEX (Rapid alert system for dangerous non-food products) and ICSMS (The Information and Communication System on Market Surveillance).

Forum assessed the enforceability of RO1 and RO2. The RAC modified RO1, developed in response to Forum comments, hazard and risk evaluation, and comments from the Public Consultation on the dossier, was not discussed by Forum. As regards ease of enforceability, the Forum has a preference for RO2 based on the fact that a specific limit value would be easier to enforce than a full ban of a substance ("shall not contain"). According to Forum in the latter case, the non-compliance will depend on the limit of detection (LoD) of the analytical method chosen by the enforcement authority. Furthermore, RO2 has a preferable format since it requires less cross-reference to external resources (other regulations). SEAC notes the preferred format could be applied to any of the recommended options and the final format and specification of the legal placement of Tables A-E containing the substances in scope of the restriction is to be decided by the Commission. As regards the LoD, SEAC notes this is rather flagging a need for harmonisation of sampling and analysis than by definition a reason to favour any of the restriction options, the need for harmonisation applies equally to all three. SEAC notes that in proposing the RAC modified RO1 concentration limits, RAC has taken a risk based approach while also considering information on other practical aspects such as technical feasibility and available analytical methods to the extent such was made available.

C.3.8. Monitorability

Justification for the opinion of RAC and SEAC

C.3.8.1. Summary of proposal:

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.

C.3.8.2. RAC and SEAC conclusion(s):

Based on reported existing experience in Member States that have implemented the Council of Europe recommendations and the Forum advice on this aspect SEAC concludes that the proposed restriction options for substances in tattoo inks under REACH are monitorable.

C.3.8.3. Key elements underpinning the RAC and SEAC conclusion(s):

Over a third of EEA31 Member States already monitor compliance of the Council of Europe resolution and share information on non-compliant products through RAPEX and ICSMS.

SEAC takes note of the Forum support for the suggestion in the Background Document of the introduction of an EU wide registry of tattoo inks, which, among other information, will gather data on the chemical composition of the mixtures. Such database would facilitate the identification of substances which are considered most problematic.

Monitoring the effectiveness of the proposed restriction in reducing health effects of exposure to chemicals in tattoo inks would be possible with the introduction of EU-harmonised diagnostic codes for tattoo inks complications by national health boards. SEAC acknowledges that systemic effects such as cancers will remain difficult to attribute to such a specific cause as tattooing. The harmonised diagnostics codes will be specifically helpful to report in a consistent way on effects that appear with relatively high incidences such as skin allergic reactions or local irritations and allow for identifying substances that may be responsible for such effects.

C.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

C.4.1. Summary of proposal:

See the opinion of RAC.

C.4.2. RAC conclusion(s):

See the opinion of RAC.

C.4.3. Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

SEAC

C.4.4. Summary of proposal:

The proposed restriction options (RO1 and RO2) remain proportionate even when allowance for uncertainties is made, i.e., the volume of tattoo inks and PMU on the market, the share of alternatives currently on the market, the anticipated price increase and their combined impact. The 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% and not all costs are taken into account.

In addition, removal of tattoos due to an allergic or papulo-nodular reaction is just one group of the health outcomes. As stated in section **Error! Reference source not found.** a number of people experience complications that require topical or systemic corticosteroids as well as experience mild ongoing complaints from their tattoos and PMU. This is in addition to the potential contribution of tattoo ink and PMU exposure to carcinogenic, reproductive, developmental and other systemic adverse effects.

C.4.5. SEAC conclusion(s):

Uncertainties regarding the cost assessment and their possible implications on the proportionality assessment have been discussed in section B.3.6.5, and it is reminded here that those related to administrative and testing costs could be significant.

SEAC also notes that given the lack of technical information on tattoo inks composition and pigments manufacturing technical constraints, it is not possible to assess the difference between the three restriction options in terms of costs and benefits.

C.4.6. Key elements underpinning the SEAC conclusion(s):

Please see relevant sections on costs, benefits and proportionality for justification.-

C.5. REFERENCES

ECHA 2016 Valuing selected health impacts of chemicals. Summary of the Results and a Critical Review of the ECHA study. European Chemicals Agency 2016

Appendix 1

Table 10 Table A to RO3

Substance name	Other regulatory process names	EC#	CAS#	Proposed concentration limit
Mercury		231-106-7	7439-97-6	0.00005% w/w
Nickel		231-111-4	7440-02-0	0.0005% w/w
Organometallic tin		231-141-8	7440-31-5	0.00005% w/w
Antimony		231-146-5	7440-36-0	0.00005% w/w
Arsenic		231-148-6	7440-38-2	0.00005% w/w
Barium**		231-149-1	7440-39-3	0.05% w/w
Cadmium		231-152-8	7440-43-9	0.00005% w/w
Chromium‡		231-157-5	7440-47-3	0.00005% w/w
Cobalt		231-158-0	7440-48-4	0.00005% w/w
Copper**		231-159-6	7440-50-8	0.025% w/w
Zinc**		231-175-3	7440-66-6	0.2% w/w
Lead		231-100-4	7439-92-1	0.00007% w/w
Selenium		231-957-4	7782-49-2	0.0002% w/w
Benzo[a]pyrene	BaP, Benzo[def]chrysene	200-028-5	50-32-8, 63466-71-7	0.0000005% w/w
Polycyclic-aromatic Hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2				0.00005% w/w (individual concentrations)
Methanol		200-659-6	67-56-1	11% w/w
o-Anisidine**	2-methoxyaniline	201-963-1	90-04-0	0.0005% w/w
o-toluidine**	2-aminotoluene	202-429-0	95-53-4	0.0005% w/w
3,3'-dichlorobenzidine**	4-(4-amino-3-chlorophenyl)-2-chloroaniline	202-109-0	91-94-1	0.0005% w/w
4-methyl-m-phenylendiamine**	2,4-toluenediamine	202-453-1	95-80-7	0.0005% w/w
4-chloroaniline**	-	203-401-0	106-47-8	0.0005% w/w
5-nitro-o-toluidine**	-	202-765-8	99-55-8	0.0005% w/w
3,3'-dimethoxybenzidine **	o-dianisidine	204-355-4	119-90-4	0.0005% w/w
4,4'-bi-o-toluidine**	-	204-358-0	119-93-7	0.0005% w/w
4,4'-Thiodianiline**	-	205-370-9	139-65-1	0.0005% w/w
4-chloro-o-toluidine**	-	202-441-6	95-69-2	0.0005% w/w
2-naphthylamine**	-	202-080-4	91-59-8	0.0005% w/w
Aniline**	aniline	200-539-3	62-53-3	0.0005% w/w
Benzidine**	1,1'-biphenyl-4,4'-diamine 4,4'-diaminobiphenyl biphenyl-4,4'-ylenediamine	202-199-1	92-87-5	0.0005% w/w
p-toluidine**	4-aminotoluene	203-403-1	106-49-0	0.0005% w/w
2-methyl-p-phenylenediamine**	2,5-toluenediamine	202-442-1	95-70-5	0.0005% w/w
Biphenyl-4-ylamine**	4-Aminobiphenyl xenylamine 4-aminobiphenyl xenylamine	202-177-1	92-67-1	0.0005% w/w
4-o-tolylazo-o-toluidine**	Solvent Yellow 3/ CI 11160 4-amino-2',3-dimethylazobenzene AAT fast garnet GBC base o-aminoazotoluene	202-591-2	97-56-3	0.0005% w/w
4-methoxy-m-	2,4-diaminoanisole	210-406-1	615-05-4	0.0005% w/w

Substance name	Other regulatory process names	EC#	CAS#	Proposed concentration limit
phenylenediamne**				
4,4'-methylenedianiline**	4,4'-diaminodiphenylmethane (MDA)	202-974-4	101-77-9	0.0005% w/w
4,4'-methylenedi-o-toluidine**	-	212-658-8	838-88-0	0.0005% w/w
6-methoxy-m-toluidine**	p-cresidine	204-419-1	120-71-8	0.0005% w/w
4,4'-methylenebis[2-chloroaniline]**	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4	0.0005% w/w
4,4'-oxydianiline**	p-aminophenyl ether	202-977-0	101-80-4	0.0005% w/w
2,4,5-trimethylaniline**	-	205-282-0	137-17-7	0.0005% w/w
4-Aminoazobenzene**	4-phenylazoaniline Solvent Yellow 1/ CI 11000	200-453-6	60-09-3	0.0005% w/w
p-Phenylenediamine**		203-404-7	106-50-3	0.0005% w/w
Sulphanilic acid**	4-aminobenzenesulphonic acid	204-482-5	121-57-3	0.0005% w/w
4-amino-3-fluorophenol**	-	402-230-0	399-95-1	0.0005% w/w
2,6-xylidine	2,6-dimethylaniline	201-758-7	87-62-7	0.0005% w/w
6-amino-2-ethoxynaphthaline			293733-21-8	0.0005% w/w
2,4-xylidine		202-440-0	95-68-1	0.0005% w/w
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
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
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
Pigment Red 210(PR210)/CI 12477		612-766-9	61932-63-6	0.1% w/w
Pigment Orange 74 (PO74)			85776-14-3	0.1% w/w
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
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
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
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
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
Pigment Red 112 (PR112)/CI 12370	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-	229-440-3	6535-46-2	0.1% w/w

Substance name	Other regulatory process names	EC#	CAS#	Proposed concentration limit
	trichlorophenyl)azo]naphthalene-2-carboxamide			
Pigment Yellow 14 (PY14)/CI 21095	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]	226-789-3	5468-75-7	0.1% w/w
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
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
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
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
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
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
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
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
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
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
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
Pigment Orange 34 (PO34)/ CI 21115	4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]	239-898-6	15793-73-4	0.1% w/w
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
Solvent Red 1 (SR1)/ CI 12150	1-[(2-methoxyphenyl)azo]-2-naphthol	214-968-9	1229-55-6	0.1% w/w
Acid Orange 24 (AO24)/ CI 20170	Sodium 4-[[3-[(dimethylphenyl)azo]-2,4-	215-296-9	1320-07-6	0.1% w/w

Substance name	Other regulatory process names	EC#	CAS#	Proposed concentration limit
	dihydroxyphenyl]azo]benzene sulphonate			
Solvent Red 23 (SR23)/ CI 26100	1-(4-(phenylazo)phenylazo)-2-naphthol	201-638-4	85-86-9	0.1% w/w
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
Disperse Yellow 3/ CI 11855	N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]acetamide	220-600-8	2832-40-8	0.1% w/w
Acid Green 16	sodium 4-{[4-(diethylamino)phenyl][4-(diethyliminio)cyclohexa-2,5-dien-1-ylidene]methyl}naphthalene-2,7-disulfonate	603-214-8	12768-78-4	0.1% w/w
Acid Red 26	Disodium 1-(2,4-dimethylphenylazo)-2-hydroxynaphthalene-3,6-disulphonate	223-178-3	3761-53-3	0.1% w/w
Acid Violet 17	Hydrogen [4-[[4-(diethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	223-942-6	4129-84-4	0.1% w/w
Basic Red 1 , Basic red 1	9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride	213-584-9	989-38-8	0.1% w/w
Disperse Blue 106	Ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-	602-285-2	12223-01-7	0.1% w/w
Disperse Blue 124	Disperse Blue 124	612-788-9	61951-51-7	0.1% w/w
Disperse Blue 35	C.I. 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

**Soluble. ‡Chromium VI. †RO2 only.