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# POSITION PAPER

## Substance in Tattoo inks and permanent make-up: Proposal for a restriction

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# Summary

**Comments on Restriction option 1 (RO1)**

Restriction for substances with harmonised classifications

The suggested restriction for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant applies only to substances in Part 3 of Annex VI to the CLP Regulation, i.e. only to substances which have a harmonised classification. However, in many cases a harmonised classification is missing but industry has self-classified these substances as falling in the respective hazard classes. Hence, these restrictions should not only apply substances with harmonised classifications but also where 50% or more of the notifiers have self-classified the substances indicating these hazard classes (i.e. where a majority of the notifiers agrees on the classification).

Carcinogenic or mutagenic substances

ANEC appreciates the ban of carcinogenic or mutagenic substances cat. 1A, 1B and 2 but considers that a practical enforcement limit should be introduced and should be e.g. 10 ppm (0,001%) for cat. 1A, 1B and 100 ppm (0,01 %) for cat. 2.

Substances restricted in the Cosmetics Regulation

Further, ANEC supports the ban of substances prohibited for use in cosmetic products as listed in Annex II of the Cosmetics Regulation and substances in Annex IV of that with conditions in column g of that Annex (i.e. rinse-off products, not to be used in products applied on mucous membranes, not to be used in eye products). A practical enforcement limit should be introduced (e.g. 10 ppm).

However, ANEC wishes to draw attention to the fact that both lists have been established bearing in mind the use of the substances in cosmetics rather than inks for tattoos and PMUs. In addition, Annex IV of the Cosmetics Regulation is a positive list of colourants which are allowed in cosmetics. Any substance with a condition removed from this list would result in the ban of the substance in cosmetics, but would be allowed in tattoo inks and PMUs. In addition, it is very unsatisfactory that REACH Annex XVII cannot establish a positive list of substances such as colourants to be exclusively used (see also comments below). Hence, it is problematic to make use of a dynamic link to Annex II and Annex IV of the Cosmetics Regulation taking over its future updates automatically. The provisions can only be accepted on an interim basis.

In the long run a specific lists for substances in inks for tattoos and PMUs should be established. This calls for a simultaneous evaluation of the substances used in cosmetics and tattoos inks or PMUs. It would be highly inefficient to assess the substances in parallel or in sequence. This is a strong argument for having the same regulatory framework for both applications, i.e. to incorporate the proposed provisions in the Cosmetics Regulation. This is all the more important for colourants in Annex IV of the cosmetics regulation. These substances should be re-evaluated for use in tattoo inks and PMUs resulting in positive list of colourants (and also for other

ingredients) exclusively allowed to be used ensuring a similar protection level in both applications. By contrast REACH does not allow to establish positive lists of substances and is, therefore, not an adequate legislative framework for this kind of product.

Alternatively, a separate specific legislation for substances in tattoo inks and PMUs could be established and the concerned substances could be evaluated in parallel.

Skin sensitising substances

A threshold of 0.1% w/w for skin sensitising substances, category 1, 1A and 1B in entirely inappropriate. Annex I Part 3 of the CLP Regulation states clearly that allergic responses in individuals who are already sensitised may be elicited in quantities below the generic concentration limits (see 3.4.3.3.2 and Table 3.4.6). Hence, there are special labelling requirements for substances in mixtures which are 10 times lower compared to the generic concentration limits for triggering classification, i.e. 0.01% for Skin Sens. 1A and 0.1% for Skin Sens. 1 and 1B (see special labelling requirements of Annex II section 2.8) to protect already sensitised individuals. Furthermore, an SCCS opinion on the skin sensitising effects of fragrances in cosmetic products arrived at the conclusion that a limit value of 100 ppm (0.01%) could be used in general for skin sensitising fragrances unless substance specific data are available (SCCS No. 1459, 2012). Hence, a threshold of 0.01% w/w for skin sensitising substances, category 1, 1A and 1B should be used.

Substances listed in Table A (Table 4)

Limits contained in Table A (given in Table 4 of the restriction dossier) for certain colourants classified carc. 2 (Disperse Yellow 3) or carc. 1B (Solvent Yellow 1 and 3) of 0.1% w/w contradict the ban of CM substances above and should, therefore, be removed from Table A (so that the lower threshold suggested by ANEC of 100 ppm or 10 ppm applies).

Polycyclic aromatic hydrocarbons (PAH)

The indicated limit for PAHs of 0.0005% w/w (= 5 mg/kg) is not in line with the intention of the dossier submitter to apply the same limit as in REACH Annex XVII, entry 50 (6) for toys and childcare articles which is 0.00005% w/w (= 0.5 mg/kg) as indicated on pages 37/38 of the restriction report where the correct limit is quoted.

Also in this case the suggested restriction is limited to substances which have a harmonised classification. An extension to substances where 50% or more of the notifiers have self-classified the substances as carcinogenic and mutagenic should be considered (in such case e.g. Indeno[1,2,3-cd]pyrene, CAS no.: 193-39-5, would be covered as it has been notified by the majority of notifiers as carc. 2).

Derogation for substances (colourants) listed in Table B.

A review provision should be included, i.e. the derogation should be reviewed after 3 or 5 years.

Substances in Annex IV of the Cosmetics Regulation subject to the conditions in columns h to i

REACH Annex XVII cannot "allow" substances in form of a positive list (which is a severe limitation) – it can only restrict substances. Hence, the wording needs to be modified.

Labelling

The cosmetics regulation requires to indicate a complete list of ingredients on the label irrespective of any classification or restriction. The CoE Resolution ResAP(2008)1 requires also a list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Colour Index (CI) number. This approach seems preferable to the one indicated here.

The cosmetics regulation also requires to indicate the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function. Information concerning the "date of minimum durability" and "guarantee of sterility of the contents" is also called-for by the CoE Resolution ResAP(2008)1.

**Comments on Restriction option 2 (RO2)**

General comment

RO2 provides a low level of protection and is mostly inacceptable (except for limits shared with RO1). Only the decoupling of provisions from the Cosmetics Regulation is worth discussing.

Restriction for substances with harmonised classifications

See ANEC comment on RO1.

Concentration thresholds for classified substances

The proposed concentration thresholds in line with the generic concentration limit in Part 3 of Annex I of Regulation (EC) No 1272/2008 are entirely unacceptable. They constitute a significant lowering of the safety levels regarding CMR substances compared to RO1 but also to the CMR provisions of the Cosmetics Regulation as well as to the recommendations in the CoE Resolution ResAP(2008)1 (and existing national legislation based on these recommendations). All other thresholds are inadequate as well. RO2 thresholds for classified substances should be rejected. See also ANEC comments on RO1.

Substances listed in Table A (Table 4)

See ANEC comment on RO1.

Polycyclic aromatic hydrocarbons (PAH)

See ANEC comment on RO1.

Concentration threshold for substances in Tables C and D

The proposed concentration threshold of 0.1% w/w is entirely unacceptable. It constitutes a significant lowering of the safety levels regarding these substances compared to RO1 (1.a.ii and 1.a.iii) but also to the respective provisions of the Cosmetics Regulation as well as to the respective recommendations in the CoE

Resolution ResAP (2008)1 (and existing national legislation based on these recommendations). RO2 thresholds for substances in Tables C and D should be rejected. As regards the concept of delinking restriction in the Cosmetics Regulation from restrictions for substances in tattoo inks and PMUs see ANEC comments on RO1.

Derogation for substances (colourants) listed in Table B.

See ANEC comment on RO1.

Labelling

See ANEC comment on RO1.

Additional point: Preservatives

It is formally correct that preservatives are within the scope of the BPR. However, we doubt that any preservative has been ever assessed for being injected into the skin. The relevant product type (PT) for tattoo and PMU inks will be PT6, which is "preservatives for products during storage". The product type is defined as "Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life". It should be noted that the associated BPR guidelines for "Human health" address skin or dermal contact, but not injection under the skin. The guidelines define "actual dermal exposure" as meaning "the amount of active substance or in-use biocide formulation (biocidal product) that reaches the skin through e.g. (work) clothing or gloves and is available for uptake through the skin". Also this definition does not suggest that intradermal application is part of the assessment. There seems to be a dangerous loophole in the BPR as regards preservatives used in tattoo inks and PMUs.

There are several possibilities to overcome this problem. One option is to include in the BPR a separate product type for this kind of application (i.e. preservatives injected into the skin) and to adapt the associated guidelines accordingly. Another option would be to establish a positive list of preservatives in a separate legislative framework (either incorporated in the Cosmetics Regulation or a specific legislation on substances in tattoo inks and PMUs). The list of BPR approved preservatives for PT6 must be immediately reviewed for their suitability to be injected into the skin.

# 1.Background

The European Commission asked ECHA to assess the need for an EU-wide restriction for tattoo inks and to prepare a REACH Annex XV dossier in December 2015. This work was done in cooperation with the Danish, German, Italian and Norwegian authorities.

Several Member States had already national legislation in place based on resolutions of the Council of Europe (CoE). The Commission blocked the implementation of additional national measures notified by some Member States (Denmark and Austria in 2013 and Latvia in 2014). Initial plans to adopt a so-called "emergency measure" under Article 13 of the General Product Safety Directive (2001/95/EC) for tattoo inks were abandoned by the Commission.

A study of the Commission's Joint Research Centre (JRC) entitled "Safety of tattoos and permanent make-up" consisting of 4 reports was published in 2015/2016. It provides a comprehensive overview of the subject in question including available regulations, market surveillance, used substances, analytical methods, health concerns, practices, prevalence and statistics.

In October 2017 a restriction report[1] was presented which contained two restriction options (RO1 and RO2) "that mainly differ in terms of the concentration limits proposed for the substances in the scope of the restriction and how the links with the Cosmetic Products Regulation (CPR) Annexes are managed".

ANEC analysed the content of the proposals making use of a study commissioned by the Consumer Council situated at Austrian Standards International which was conducted by Force Technology (DK)[2]. It contains a critical assessment of the ECHA restriction report and a number of suggestions for improvement. The study provides more detailed justifications and rationales for most of the ANEC comments and proposals.

Both restriction options were reviewed in detail and comments on relevant aspects are provided in chapter 2. The texts of RO1 and RO2 are reproduced and the ANEC comments inserted. In addition, a chapter 3 of this paper deals with missing provisions and discusses how the gaps could be closed. A final chapter 4 is devoted to the question whether REACH Annex XVII is the appropriate legislative framework for regulating tattoo inks and permanent make-ups and what the alternatives are. Concluding remarks are provided in chapter 5.

[1] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/18114/term

[2] http://www.verbraucherrat.at/en/news/studie-zum-thema-tattoofarben

# 2. The Restriction Proposals

### *2.1 Restriction option 1 (RO1)*

*1. Tattoo inks shall not be placed on the market if they contain the following substances as specified below. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) to 1.c), the stricter condition applies:*
*a. Tattoo inks shall not contain the following substances, unless a concentration limit is specified under paragraph 2:*
*i. Carcinogenic or mutagenic substances, category 1A, 1B and 2 excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation).*
*ii. Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009.*
*iii. The following substances in Annex IV of Regulation (EC) 1223/2009 with the following conditions in column g of that Annex:*
- *Rinse-off products*
- *Not to be used in products applied on mucous membranes*
- *Not to be used in eye products*

*b. Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than 0.1% w/w, unless a concentration limit is specified under paragraph 2:*
*i. Skin sensitising substances, category 1, 1A and 1B*
*ii. Skin irritant or corrosive substances, category 1A, 1B, 1C and 2*
*iii. Eye damaging and irritant substances, category 1 and 2*
*c. Tattoo inks shall not be placed on the market if they contain substances toxic to reproduction:*
*i. i. Category 1A and 1B in concentrations greater than 0.0014 % w/w*
*ii. ii. Category 2 in concentrations greater than 0.014% w/w*

**ANEC comments:**
The suggested restriction for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant applies only to substances in Part 3 of Annex VI to the CLP Regulation (Regulation (EC) No 1272/2008), i.e. only to substances which have a harmonised classification. However, in many cases a harmonised classification is missing but industry has self-classified these substances as falling in the respective hazard classes.
ANEC appreciates the ban of carcinogenic or mutagenic substances cat. 1A, 1B and 2 but considers that a practical enforcement limit is missing (in contrast to substances which are toxic to reproduction).
Further, ANEC supports the ban of substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009 and substances in Annex IV of Regulation (EC) 1223/2009 with conditions in column g of that Annex (i.e. rinse-off products, not to be used in products applied on mucous membranes, not to be used in eye products). A practical enforcement limit is missing.

However, ANEC wishes to draw attention to the fact that both lists have been established bearing in mind the use of the substances in cosmetics rather than inks for tattoos and PMUs. In addition, Annex IV of the Cosmetics Regulation is a positive list of colourants which are allowed in cosmetics. Any substance with a condition removed from this list would result in the ban of the substance in cosmetics, but would be allowed in tattoo inks and PMUs. In addition, it is very unsatisfactory that REACH Annex XVII cannot establish a positive list of substances such as colourants to be exclusively used (see also chapter 4). Hence, it is problematic to make use of a dynamic link to Annex II and Annex IV of the Cosmetics Regulation taking over its future updates automatically. The provisions can only be accepted on an interim basis.

A threshold of 0.1% w/w for skin sensitising substances, category 1, 1A and 1B in entirely inappropriate. Annex I Part 3 of the CLP Regulation states clearly that allergic responses in individuals who are already sensitised may be elicited in quantities below the generic concentration limits (see 3.4.3.3.2 and Table 3.4.6). Hence, there are special labelling requirements for substances in mixtures which are 10 times lower compared to the generic concentration limits for triggering classification, i.e. 0.01% for Skin Sens. 1A and 0.1% for Skin Sens. 1 and 1B (see special labelling requirements of Annex II section 2.8) to protect already sensitised individuals. Furthermore, an SCCS opinion on the skin sensitising effects of fragrances in cosmetic products arrived at the conclusion that a limit value of 100 ppm (0.01%) could be used in general for skin sensitising fragrances unless substance specific data are available (SCCS No. 1459, 2012).

**ANEC proposals:**

The restrictions for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant should not only apply substances with harmonised classifications but also where 50% or more of the notifiers have self-classified the substances indicating these hazard classes (i.e. where a majority of the notifiers agrees on the classification).

A practical enforcement limit should be introduced for carcinogenic or mutagenic substances cat. 1A, 1B and 2 of the same order of magnitude as for substances toxic for reproduction, e.g. 10 ppm (0,001%) for cat. 1A, 1B and 100 ppm (0,01 %) for cat. 2.

A ban of substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009 is useful as a provisional measure but in the long run specific lists for substances in inks for tattoos and PMUs should be established. This calls for a simultaneous evaluation of the substances used in cosmetics and tattoos inks or PMUs. It would be highly inefficient to assess the substances in parallel or in sequence. This is a strong argument for having the same regulatory framework for both applications, i.e. to incorporate the proposed provisions in the cosmetics regulation. This is all the more important for colourants in Annex IV of the Cosmetics Regulation. These substances should be re-evaluated for use in tattoo inks and PMUs resulting in positive list of colourants (and possibly other substances) exclusively allowed to be used ensuring a similar protection level in both applications. By contrast REACH does not allow to establish positive lists of substances and is, therefore, not an adequate legislative framework for this kind of product.

Alternatively, a separate specific legislation for substances in tattoo inks and PMUs could be established and the concerned substances could be evaluated in parallel. In any case a practical enforcement limit should be introduced for these substances (e.g. 10 ppm).
A threshold of 0.01% w/w for skin sensitising substances, category 1, 1A and 1B should be used.

*2. Tattoo inks or permanent make-up shall not be placed on the market if they contain substances listed in Table A exceeding the specified concentration limits and polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.0005% w/w.*

**ANEC comments:**
Limits contained in Table A (given in Table 4 of the restriction dossier) for certain colourants classified carc. 2 (Disperse Yellow 3) or carc. 1B (Solvent Yellow 1 and 3) of 0.1% w/w contradict the ban of CM substances above.
The indicated limit for PAHs of 0.0005% w/w (= 5 mg/kg) is not in line with the intention of the dossier submitter to apply the same limit as in REACH Annex XVII, entry 50 (6) for toys and childcare articles which is 0.00005% w/w (= 0.5 mg/kg) as indicated on pages 37/38 of the restriction report where the correct limit is quoted. Also in this case the suggested restriction is limited to substances which have a harmonised classification.

**ANEC proposals:**
Colourants classified carc. 2 (Disperse Yellow 3) or carc. 1B (Solvent Yellow 1 and 3) should be removed from Table A (given in Table 4 of the restriction dossier) as they contradict the generic ban of CM substances above (so that the lower threshold suggested by ANEC of 100 ppm or 10 ppm applies).
The limit for PAHs should be 0.00005% w/w rather than 0.0005% w/w in line with the intention of the dossier submitter and should not only apply substances with harmonised classifications but also where 50% or more of the notifiers have self-classified the substances as carcinogenic and mutagenic (in such case e.g. Indeno[1,2,3-cd]pyrene, CAS no.: 193-39-5, would be covered as it has been notified by the majority of notifiers as carc. 2).

*3. By way of derogation, paragraph 1 does not apply to substances (colourants) listed in Table B (of the proposal).*

**ANEC comments:**
The derogation may be acceptable for the time being but possibly not for prolonged periods.

**ANEC proposals:**
A review provision should be included, i.e. the derogation should be reviewed after 3 or 5 years.

*4. Substances in Annex IV of Regulation (EC) 1223/2009 allowed in cosmetic products are also allowed in tattoo inks, subject to the conditions in columns h to i of that Annex, unless a lower concentration limit is specified in paragraphs 1 and 2.*

**ANEC comments:**

REACH Annex XVII cannot "allow" substances in form of a positive list (which is a severe limitation) – it can only restrict substances. See also comments above on paragraph 1.

**ANEC proposals:**

The wording needs to be changed to clarify that conditions in columns h to i of Annex IV of the cosmetics regulation apply.

*5. Tattoo inks not meeting the requirements specified in paragraphs 1 to 4 shall not be used in tattoo and permanent make-up procedures.*

**ANEC comments:**

No further comment.

**ANEC proposals:**

No further proposal.

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

*a. The intended use of the mixture as a tattoo ink;*

*b. A reference number to uniquely identify the batch;*

*c. The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal;*

*d. The name of substances covered by the restriction proposal that are present in the ink at a lower concentration limit than the proposed one;*

*e. Any relevant instructions for use.*

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

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

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

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

**ANEC comments:**

The cosmetics regulation requires to indicate a complete list of ingredients on the label irrespective of any classification or restriction. The CoE Resolution ResAP(2008)1 requires also a list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Colour Index (CI) number. This approach seems preferable to the one indicated here.

The cosmetics regulation also requires to indicate the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function. Information concerning the "date of minimum durability" and "guarantee of sterility of the contents" is also called-for by the CoE Resolution ResAP(2008)1.

**ANEC proposals:**

A requirement should be included to indicate all ingredients of the tattoo ink or PMU on the label (instead of the suggested information requirements concerning names of substances).
A requirement should be included to indicate the durability of the tattoo ink or PMU.

*7. Definitions for the purpose of this restriction entry*

*a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional intradermal injection whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is made.*

*b. Tattoo or permanent make-up procedure is the intradermal injection of tattoo ink (or permanent make-up).*

**ANEC comments:**
It is difficult to see the need for the second definition
**ANEC proposals:**
Delete b.

*8. The restriction shall apply one year after its entry into force.*

**ANEC comments:**
No comment.
**ANEC proposals:**
No proposal.

### *2.2 Restriction option 2 (RO2)*

*1. Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than the relevant generic concentration limit in Part 3 of Annex I of Regulation (EC) No 1272/2008, unless a specific concentration limit is set in Part 3 of Annex VI of Regulation (EC) No 1272/2008:*

*a. Carcinogenic and mutagenic substances, category 1A, 1B and 2, excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation)*

*b. Substances toxic to reproduction, category 1A, 1B and 2 c. Skin sensitising substances, category 1, 1A and 1B*

*d. Skin irritant and corrosive substances, category 1A, 1B, 1C and 2*

*e. Eye damaging and irritant substances, category 1 and 2*

*These provisions shall apply unless the substances are included in paragraph 2. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) to 1.e), the stricter condition applies.*

**ANEC comments:**
The proposed concentration thresholds in line with the generic concentration limit in Part 3 of Annex I of Regulation (EC) No 1272/2008 are entirely unacceptable. They constitute a significant lowering of the safety levels regarding CMR substances compared to RO1 but also to the CMR provisions of the Cosmetics Regulation as well

as to the recommendations in the CoE Resolution ResAP(2008)1 (and existing national legislation based on these recommendations). All other thresholds are inadequate as well. See further comments on thresholds sensitising substances in RO1.
The suggested restriction for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant applies only to substances in Part 3 of Annex VI to the CLP Regulation (Regulation (EC) No 1272/2008), i.e. only to substances which have a harmonised classification. However, in many cases a harmonised classification is missing but industry has self-classified these substances as falling in the respective hazard classes.
**ANEC proposals:**
This absurd proposal should be dismissed in favour of RO1 (with a practical enforcement level as pointed out in the respective comments on RO1).
The restrictions for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant should not only apply substances with harmonised classifications but also where 50% or more of the notifiers have self-classified the substances indicating these hazard classes (i.e. where a majority of the notifiers agrees on the classification).

*2. Tattoo inks shall not be placed on the market if they contain the substances listed in Table A and polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding 0.0005% w/w*

**ANEC comments:**
Limits contained in Table A (given in Table 4 of the restriction dossier) for certain colourants classified carc. 2 (Disperse Yellow 3) or carc. 1B (Solvent Yellow 1 and 3) of 0.1% w/w contradict the ban of CM substances above.
The indicated limit for PAHs of 0.0005% w/w (= 5 mg/kg) is not in line with the intention of the dossier submitter to apply the same limit as in REACH Annex XVII, entry 50 (6) for toys and childcare articles which is 0.00005% w/w (= 0.5 mg/kg) as indicated on pages 37/38 of the restriction report where the correct limit is quoted. Also in this case the suggested restriction is limited to substances which have a harmonised classification.
**ANEC proposals:**
Colourants classified carc. 2 (Disperse Yellow 3) or carc. 1B (Solvent Yellow 1 and 3) should be removed from Table A (given in Table 4 of the restriction dossier) as they contradict the generic ban of CM substances above.
The limit for PAHs should be 0.00005% w/w rather than 0.0005% w/w in line with the intention of the dossier submitter and should not only apply substances with harmonised classifications but also where 50% or more of the notifiers have self-classified the substances as carcinogenic and mutagenic.

*3. Unless already specified in paragraphs 1 or 2, tattoo inks shall not be placed on the market if they contain the substances in Table C and Table D, in concentrations exceeding 0.1% w/w.*

**ANEC comments:**

The proposed concentration threshold of 0.1% w/w is entirely unacceptable. It constitutes a significant lowering of the safety levels regarding these substances compared to RO1 (1.a.ii and 1.a.iii) but also to the respective provisions of the Cosmetics Regulation as well as to the respective recommendations in the CoE Resolution ResAP(2008)1 (and existing national legislation based on these recommendations). As regards the concept of delinking restriction in the Cosmetics Regulation from restrictions for substances in tattoo inks and PMUs see comments on 1. of RO1 questioning the adequacy of the legal framework.

**ANEC proposals:**

This absurd proposal should be dismissed in favour of RO1 (with a practical enforcement level as pointed out in the respective comments on RO1).

Apart from this ANEC considers that the Cosmetics Regulation would be a more appropriate legal basis for regulating substances in tattoo inks and PMUs (see respective comments on RO1 and chapter 4 below).

*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.*

**ANEC comments:**

As pointed out above ANEC supports in principle a decoupling of the provisions for substances in tattoo inks and PMUs from those used in cosmetics but considers that a separate evaluation of substances for both application areas would be rather inefficient. Apart from that REACH does not allow to establish positive lists of exclusively allowed substances.

**ANEC proposals:**

Incorporate the suggested restrictions for substances in tattoo inks and PMUs in the Cosmetics Regulation (or a separate specific legislation) and use the current lists including the conditions on a temporary basis. In future evaluate all ingredients for both applications simultaneously. Establish a positive list of colourants in the long run.

*5. By way of derogation, paragraphs 1 to 4 do not apply to substances (colourants) listed in Table B.*

**ANEC comments:**

The derogation may be acceptable for the time being but possibly not for prolonged periods.

**ANEC proposals:**

A review provision should be included, i.e. the derogation should be reviewed after 3 or 5 years.

*6. Tattoo inks not meeting the requirements specified in paragraphs 1 to 5 shall not be used in tattoo and permanent make-up procedures.*

**ANEC comments:**

No further comment.

**ANEC proposals:**

No further proposal.

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

*a. The intended use of the mixture as a tattoo ink;*

*b. A reference number to uniquely identify the batch;*

*c. The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal;*

*d. The name of substances covered by the restriction proposal that are present in the ink at a lower concentration limit than the proposed one;*

*e. Any relevant instructions for use.*

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

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

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

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

**ANEC comments:**

The cosmetics regulation requires to indicate a complete list of ingredients on the label irrespective of any classification or restriction. The CoE Resolution ResAP(2008)1 requires also a list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Colour Index (CI) number. This approach seems preferable to the one indicated here.

The cosmetics regulation also requires to indicate the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function. Information concerning the "date of minimum durability" and "guarantee of sterility of the contents" is also called-for by the CoE Resolution ResAP(2008)1.

**ANEC proposals:**

A requirement should be included to indicate all ingredients of the tattoo ink or PMU on the label (instead of the suggested information requirements concerning names of substances).

A requirement should be included to indicate the durability of the tattoo ink or PMU.

*8. Definitions for the purpose of this restriction entry*

*a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional intradermal injection whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is made.*

*b. Tattoo or permanent make-up procedure is the intradermal injection of tattoo ink (or permanent make-up).*

**ANEC comments:**

It is difficult to see the need for the second definition.

**ANEC proposals:**

Delete b.

*9. The restriction shall apply one year after its entry into force.*

**ANEC comments:**
No comment.
**ANEC proposals:**
No proposal.

## 3. Missing Provisions

**ANEC comments:**

The dossier submitters assume that preservatives do not need to be regulated because they are already covered by the Biocidal Products Regulation (BPR) though certain preservatives are restricted for use in tattoo inks due to their harmonised classification (e.g., formaldehyde, 2-phenoxyethanol, triclosan, 3-iodo-2-propynyl butylcarbamate).

It is formally correct that preservatives are within the scope of the BPR. However, we doubt that any preservative has been ever assessed for being injected into the skin. The relevant product type (PT) for tattoo and PMU inks will be PT6, which is "preservatives for products during storage". The product type is defined as "Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life". It should be noted that the associated BPR guidelines[3] for "Human health" address skin or dermal contact, but not injection under the skin. The guidelines define "actual dermal exposure" as meaning "the amount of active substance or in-use biocide formulation (biocidal product) that reaches the skin through e.g. (work) clothing or gloves and is available for uptake through the skin". Also this definition does not suggest that intradermal application is part of the assessment. There seems to be a dangerous loophole in the BPR as regards preservatives used in tattoo inks and PMUs.

As pointed out in the aforementioned study conducted by Force Technology (DK) and commissioned by the Consumer Council situated at Austrian Standards International[4] the number of substances covered would significantly increase if not only substances with harmonised hazard classifications were restricted but also those substances where 50% or more notifiers have self-classified substances as falling in one of the relevant hazard classes.

**ANEC proposals:**

There are several possibilities to overcome this problem. One option is to include in the BPR a separate product type for this kind of application (i.e. preservatives injected into the skin) and to adapt the associated guidelines accordingly. Another option

[3] https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation
[4] http://www.verbraucherrat.at/en/news/studie-zum-thema-tattoofarben

would be to establish a positive list of preservatives in a separate legislative framework (either incorporated in the Cosmetics Regulation or a specific legislation on substances in tattoo inks and PMUs). The list of BPR approved preservatives for PT6 must be immediately reviewed for their suitability to be injected into the skin.

The restrictions for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant should not only apply substances with harmonised classifications but also where 50% or more of the notifiers have self-classified the substances indicating these hazard classes (i.e. where a majority of the notifiers agrees on the classification).

## 4. Is REACH Annex XVII is the appropriate legislative framework?

**ANEC comments:**

As pointed out in previous chapters REACH Annex XVII does not seem to be the most suitable framework for addressing chemicals in tattoo inks and PMUs.

**ANEC proposals:**

Incorporate provisions for chemicals in tattoo inks and PMUs in the Cosmetics Regulation or a separate specific legislation which allows among other to establish positive lists of approved substances for certain purposes (e.g. colourants). Ensure that substance evaluations for use in cosmetics and tattoo inks and PMUs are carried out, wherever possible, in parallel.

## 5. Concluding remarks

Whilst the big effort by the dossier submitters is very much appreciated ANEC considers that the restriction proposal is not yet fit for the purpose. Improvement is needed with respect to the following points:

- RO2 is mostly inadequate providing a level of protection which is significantly below the one associated with RO1 and should, therefore, be rejected.
- The only positive aspect of RO2 is the idea of a decoupling of restrictions for tattoo inks and PMUs from restrictions applicable to cosmetics in the longer term, however it remains unclear how this should work in practice.
- Preferably substances used in tattoo inks and PMUs should be assessed in parallel.
- A key long-term goal should be the establishment of positive lists of substances used in tattoo inks and PMUs (for colourants as a first priority reflecting the current approach for cosmetics).
- From this follows that REACH is not the best framework for regulating substances used in tattoo inks and PMUs as positive lists cannot be established.

- It would be a better choice to include substances used in tattoo inks and PMUs in the Cosmetics Regulation or to establish a separate legal framework following similar principles.
- Irrespective of this the suggested RO1 is a suitable departure point for regulating the substances in question.
- However, some of the proposed limits in RO1 are not stringent enough (e.g. for sensitising substances) and should be lowered.
- Restrictions for substances which are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, skin irritant, corrosive, eye damaging and irritant apply only to substances which have a harmonised classification. However, in many cases the criteria for being classified are fulfilled resulting in classification so that industry has self-classified these substances as falling in the respective hazard classes.
- Hence, the restrictions should also cover self-classified substances where 50% or more of the notifiers have self-classified the substances indicating these hazard classes.
- There seems to be a dangerous loophole as regards preservatives used in tattoo inks and PMUs given that the BPR does not seem to assess preservatives in the relevant product type (PT6 -"preservatives for products during storage") for intradermal application. Hence, a separate product type for this kind of application (i.e. preservatives injected into the skin) must be included in the BPR or a positive list of preservatives is established in a separate legislative framework as pointed out above.

## 6. Acknowledgements

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# About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 33 countries.

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***Raising standards for consumers***


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