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Safety of tattoos and permanent make-up
Compilation of information on legislative framework and analytical methods

Report on Work Package 1
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Analysis conducted on behalf of DG JUST

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Abstract

This document summarises the work carried out within Working Package 1 of the Administrative Arrangement 33617 on tattoos and permanent make-up, signed with Directorate General Health and Consumers (DG SANCO), now DG Justice (DG JUST). It includes: the description of the project; the description of the recommendations contained in the Council of Europe Resolution (2008)1 on requirements and criteria for the safety of tattoos and permanent make-up; the minutes of the meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (CSN-STPM), held on 11 November 2014, in Ispra (VA), Italy; a collection of analytical methods that could be useful to implement the recommendations of the Council of Europe Resolution (2008)1, as well as a review of existing legislation/guidelines frameworks for the safety of tattoo and permanent make-up products in the European countries and some other jurisdictions.

CONTENTS

LIST OF ABBREVIATIONS

ISO two letters country code were used for the abbreviation of country names.

AA or AAS	Atomic Absorption Spectrometry
AATCC	American Association of Textile Chemists and Colourists
AEMPS	Agencia Española de medicamentos y productos sanitarios
ANSM	French National Agency for Drugs and Health Products Safety
ASV	Anodic Stripping Voltammetry
BBP	Benzyl Butyl Phthalate
CE	Capillary Electrophoresis
CE-DAD	Capillary Electrophoresis with Diode Array Detector
CEN	European Committee for Standardization
CFR	US Code of Federal Regulations
CI	Colour Index
CICN	Colour Index Constitution Number
CIGN	Colour Index Generic Name
CLP	Classification, Labelling and Packaging (Regulation (EC) No 1272/2008)
CMR	Carcinogenic, Mutagenic and Reprotoxic substances
CoE	Council of Europe
CSCL	Japanese Chemical Substance Control Law
CSN	Consumer Safety Network
CSN-STPM	Consumer Safety Network Subgroup Tattoos and Permanent Make-up
CSS	Consiglio Superiore di Sanità
CV	Cold Vapour
CVAAS	Cold-Vapour Atomic Absorption Spectrometry
CV_R	Coefficient of Variation of Reproducibility
CV_r	Coefficient of Variation of repeatability
DBP	Dibutyl Phthalate
DEHP	Di-(2-ethylhexyl) Phthalate
DG JRC	Directorate General Joint Research Centre
DG JUST	Directorate General Justice and Consumers
DG SANCO	Directorate General Health and Consumers
DIDP	Diisodecyl Phthalate
DINP	Diisononyl Phthalate
DMEP	Di-(2-methoxyexthyl) Phthalate
DNOP	Di-n-octyl Phthalate
DPD	Dangerous Preparation Directive 1999/45/EC
EDQM	European Directorate for the Quality of Medicines and Health Care
EFTA	European Free Trade Area
EPA	Environmental Protection Agency
EU	European Union
FDA	US Food and Drug Administration
FD&CA	US Food Drug & Cosmetic Act
FLAA	Flame Atomic Absorption Analysis
FLD	Fluorescence Detector
GC	Gas Chromatography
GC-FID	Gas Chromatography coupled with Flame Ionisation Detector
GC-MS	Gas Chromatography coupled with Mass Spectrometer detector
GFAAS	Graphite Furnace Atomic Absorption Spectrometry

GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPSD	General Product Safety Directive (Directive 2001/95/EC)
HPCE	High Performance Capillary Electrophoresis
HPCE-DAD	High Performance Capillary Electrophoresis coupled with Diode Array Detector
HPCHSCL	Japanese Household Products Containing Harmful Substance Control Law
HPLC	High Performance Liquid Chromatography
HPLC-DAD	High Performance Liquid Chromatography coupled with Diode Array Detector
HPLC-FD	High-Performance Liquid Chromatography with Fluorescence Detector
HPLC-MS	High Performance Liquid Chromatography coupled with Mass Spectrometer Detector
HPTLC	High Performance Thin Layer Chromatography
HSA	Irish Health and Safety Authority
HSE	UK Health and Safety Executive
HSNO	Hazardous Substances and New Organisms
ICP-AES	Inductively Coupled Plasma Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
ICP-OES	Inductively Coupled Plasma Optical Emission Spectrometry
IPAC	Infection Prevention and Control
ISHL	Japanese Industrial Safety and Health Law
ISO	International Organization for Standardization
KEMI	Swedish National Chemicals Inspectorate
LC/DAD	Liquid Chromatography coupled with Diode Array Detector
LC/MS/DAD	Liquid Chromatography with Mass Spectrometry/Diode Array Detector
LC-MS/MS	Liquid Chromatography with tandem Mass Spectrometry
LOD	Limit of Detection
LOQ	Limit of Quantification
MALDI	Matrix Assisted Laser Desorption/Ionization
MTBE	Methyl Tert-Butyl Ether
MW	Microwave
NDELA	N-Nitrosodiethanolamine
OECD	Organisation for Economic Co-operation and Development
OTP	German Order on Tattooing Products
PAA	Primary Aromatic Amine
PAH	Polycyclic Aromatic Hydrocarbon
PAO	Period After Opening
PDSCL	Japanese Poisonous and Deleterious Substance Control Law
PMU	Permanent Make-up
PSE	Canadian Personal Services Establishments
r	repeatability limit
R	Reproducibility limit
RAPEX	Rapid Alert System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
ResAP	Resolution
RSD_r	Relative Standard Deviation of repeatability
RSD_R	Relative Standard Deviation of Reproducibility
SDC	Society of Dyers and Colourists

SEC	Size Exclusion Chromatography
SOP	Standard Operating Procedure
SFA	Spectrometry of Atomic Fluorescence
TLC	Thin Layer Chromatography
TOF	Time Of Flight
uHPLC	Ultra High Performance Liquid Chromatography
UV-VIS	Ultra-Violet-Visible

EXECUTIVE SUMMARY

In the last few decades, concerns about the possible health problems associated to tattoos and permanent make up (PMU) when strict hygiene conditions are not respected or due to the possible presence of dangerous chemicals in the ingredients are growing in parallel with their use.

The Council of Europe Resolution (CoE ResAP)(2008)1, on requirements and criteria for the safety of tattoos and permanent make-up, is an internationally recognised benchmark. It includes recommendations for negative lists of substances that should not be present in tattoos and permanent make-up inks, establishing as well maximum concentrations for some impurities.

The European Commission has launched the 18-month project (end in March 2016) "Tattoos - Permanent Make-up" with the aim of collecting data about the use, the ingredients, the EU market and the possible health problems associated to tattoo and permanent make-up inks[1].

This project is divided into 4 work packages.

1. preparatory work: information gathering about tattoo products' testing methods and current national legislative schemes;
2. state of play: fact-finding on tattoo related data, such as clients, service providers and statistics, tattoo and PMU market situation, survey on ink chemical composition;
3. assessment and update of the CoE ResAP(2008)1: review of health effects and risks, risk perception and communication, data gaps and research needs;
4. conclusions.

The first working package of the project aims to collect information about the availability of analytical methods that could be used to control the presence of chemicals listed in the CoE ResAP(2008)1 in tattoo and permanent make-up inks and to review existing legislation and/or guidelines for the safety of tattoos and PMU in the EU/EFTA Member States plus some other jurisdictions.

The collected information was gathered via several ways and sources. Two questionnaires, one on testing methods, the other on national legal schemes, were sent to all EU Member States and EFTA countries. Furthermore, the outcome of an international webinar, which took place in April 2014, has been taken into account as far as other jurisdictions are concerned, together with additional information found on internet.

This report presents the results of a systematic review of available information on existing analytical methods. It comprised search of international and national standardised methods, as well as methods in-house validated and/or described in literature for the analysis of chemicals in tattoo and PMU inks. As only few testing methods are available for tattoo and PMU inks, we extended the search to methods that can be applied to other products, if possible with similar matrices such as cosmetics and food, or toys and textiles. The objective is mainly to give a preliminary overview of the current testing methods, which are meant to

[1] Administrative Arrangement 33617 "Tattoos - Permanent Make-up", signed by the Directorate General Joint Research Centre (DG JRC), Unit I.1 Chemical Assessment and Testing, and the Directorate General Health and Consumers (DG SANCO), Unit B.3 Product and Service Safety, as from 1st January 2015 Directorate General Justice and Consumers (DG JUST), Unit E.3 Product and Service Safety.

be further evaluated, in order to identify data gaps and needs for harmonisation, during work package 3.

The preliminary outcome of this analysis shows that, at ISO and CEN level, there are neither international nor national standard methods for the analysis of aromatic amines, colorants, elements, polycyclic aromatic hydrocarbons, phthalates and nitrosamines in tattoo and PMU products. On the contrary, in-house validated methods are available for all these classes of substances, with the exception of phthalates. In addition, analytical methods for the analysis of colorants, heavy metals, polycyclic aromatic hydrocarbons and nitrosamines in tattoo products are described in the literature.

The report also contains information, updated to November 2014, regarding current national legal/guideline frameworks in 28 EU/EFTA countries, as well as data from five non-EU/EFTA countries. National information has been structured in different subsections dealing with the chemical, hygienic and packaging requirements, as well as the requirements for risk assessment, processes and tattooists.

For the EU Member States that replied to our survey (25/28) the findings show that:

1. Seven of them have a specific national tattoo legislation in place based either on CoE ResAP(2003)2 (Belgium, France, Germany and the Netherlands), or on CoE ResAP(2008)1 (Spain, Slovenia, and Sweden).
2. Three of them (Austria, Denmark and Latvia,) have prepared draft legislation based on the CoE ResAP(2008)1[2].
3. Italy, Malta, Romania, and also to some extent Czech Republic, Finland and Slovakia do regulate tattooing practices and premises safety, in terms of health and hygienic requirements, but they did not transpose the CoE ResAP into their national legislative scheme.
4. Bulgaria, Croatia, Cyprus, Estonia, Greece, Ireland, Luxembourg, Poland and Portugal do not have specific legal texts on tattooing activities.

For the EFTA countries, the legislations in place in Switzerland and Liechtenstein are based on the CoE ResAP(2008)1, whereas the one in force in Norway is based on the CoE ResAP(2003)2. No data were available on Iceland.

The other jurisdictions included in the review (Australia, Canada, Japan, New Zealand and United States of America) have very different laws and/or guidelines, as some of the countries have a federal structure, whose entities regulate tattoo practices at their own level. These regulatory frameworks principally concern tattoo processes and hygiene conditions without focusing on the chemical composition of tattoo and PMU inks, with the noticeable exception of New Zealand.

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

1. Introduction

In the last few decades, the use of tattoos and permanent make-up (PMU) has proven to have grown in popularity in and beyond Europe, particularly amongst the young population. At the same time, the possibility to purchase online tattoo inks has substantially increased. Concerns about possible health risks associated with such practices arise from the absence of a clear legislative framework, the lack of proper risk assessment of the chemicals used, the non-harmonised or missing hygiene and purity requirements, etc.

In 2003, within the European Commission, the Directorate General Joint Research Centre (DG JRC) was asked by the Directorate General Health and Consumers (DG SANCO) to collect and assess all necessary information to establish common knowledge on a basis that could help the conception of future legislation on tattoos at EU level. The work resulted in a document about recommendations for regulatory action in the EU on the safety of tattoos, body piercing and related practices in the EU[3].

In 2003, the Council of Europe (CoE) published a resolution (ResAP) on requirements and criteria for the safety of tattoos and permanent make-up, which was superseded by a revised version in 2008. The ResAP(2008)1 includes negative lists of substances that should not be present in tattoo and permanent make-up inks, like colorants and aromatic amines, as well as the maximum concentrations for some impurities. The recommendation provides criteria for the safety assessment of the used chemicals and encourages establishing a positive list of substances proved to be safe for this use under certain conditions.

The non-binding ResAPs are the reference for the national legislation in those Member States which have it in place, such as France, Germany, the Netherlands, Spain and Sweden, or as a draft, like in Austria, Denmark and Latvia. This document is also recognised as reference in third countries, in particular in New Zealand.

Member States are increasingly asking for an EU harmonised action on tattoo and PMU inks to ensure better consumer protection and facilitate free movement of goods.

[3] Papameletiou D. et al, Recommendations for regulatory action in the EU on the safety of tattoos, body piercing and of related practices in the EU, 2003.

2. Council of Europe Resolution (2008)1 on requirements and criteria for the safety of tattoos and permanent make-up

The Council of Europe[4] is the continent's leading human rights organisation. It includes 47 member states, among which the 28 members of the European Union. Within the Council of Europe, the European Directorate for the Quality of Medicines and Health Care (EDQM) has the mission to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect human and animal health. EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation, and monitoring the application of quality standards for safe medicines and their safe use. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplants and consumer health issues.

In the frame of its activities, the Council of Europe in 2008 published a Resolution (ResAP(2008)1)[5] on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up).

The Council of Europe particularly considered:

- the increasing popularity of body adornment through tattoos or permanent make-up (PMU);
- the fact that these practices may pose a risk to human health due to microbiological contamination and/or to the presence of harmful substances in the inks used for tattoos and PMU and/or to the possibility of being tattooed under questionable hygienic conditions;
- the fact that in most member states tattoos, tattooing and PMU are covered neither by specific national nor by European regulations.

The CoE ResAP(2008)1 takes into consideration chemical, hygienic, packaging, labelling, risk assessment and information requirements. The basic principle is that when applied and used as intended, tattoo and PMU products must not endanger the health or safety of persons or the environment.

The CoE ResAP(2008)1 foresees:

- lists of chemicals that should not be present in tattoo and PMU inks (negative lists);
- the requirements for labelling of products used for tattoos and PMU;
- the risk evaluation required before products used for tattoos and PMU are placed on the market;
- the conditions of the application of tattoos and PMU;
- the obligation to inform the public and the consumer of the health risks of tattoos and PMU and tattooing practices.

<u>Chemicals</u>

The following negative lists are included or mentioned in the CoE ResAP(2008)1:

1. Table 1 lists 27 aromatic amines that should not be present or released from azo-colorants (see Annex I, Table 1);
2. Table 2 contains a non-exhaustive list of pigments that have carcinogenic, mutagenic, reprotoxic or sensitising properties (see Annex I, Table 2);

[4] http://www.coe.int/aboutCoe

[5] http://www.coe.int/t/e/social_cohesion/soc-sp/resap_2008_1%20e.pdf

3. Table 3 lists the maximum recommended concentrations of impurities (see Annex I, Table 3);
4. any ingredient prohibited in cosmetics should not be used in tattoo inks, e.g. substances listed in Directive 76/768/EEC (Annex II), now substituted by EC Regulation 1223/2009 (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&rid=1);
5. colorants specified in Directive 76/768/EEC (Annex IV, columns 2 to 4), now substituted by EC Regulation 1223/2009, Annex IV, column g, (see Annex I, Table 4);
6. carcinogenic, mutagenic and reprotoxic (CMR) substances of categories 1, 2 or 3 which are classified under Directive 67/548/EEC, now substituted by EC Regulation 1272/2008, part 3 of Annex VI Table 3.1 categories 1A, 1B and 2 (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&rid=9).

In addition, tattoo and PMU inks should also comply with the minimum requirements for further organic impurities for colorants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC.

Many of the substances listed in points 1, 2, and 3 are prohibited or have use restrictions in cosmetics (points 4 and 5) and are classified as CMRs in the CLP Regulation (point 6). For instance, 4-aminoazobenzene (CAS 60-09-3) is listed not only in Table 1 of the CoE ResAP(2008)1, but also in Annex II of Regulation (EC) No 1223/2009 on cosmetics and is classified as carcinogenic substance 1B in Table 3.1 in Annex VI of Regulation (EC) No 1272/2008 on CLP.

For completeness sake additional primary aromatic amines, colorants, elements and PAHs, not included in Tables 1-3 of the ResAP(2008)1 but listed in Annex II to EC Regulation 1223/2009 and/or EC Regulation 1272/2008, have been listed in Annex II of the present document.

Preservatives should only be used to ensure the preservation of the product after opening and by no means as a correction of insufficient microbiologic purity in the course of manufacture and of inadequate hygiene in tattooing and PMU practice. Preservatives should only be used after a safety assessment and in the lowest effective concentration.

Labelling

The following information should be available on the packaging of tattoo and PMU products:

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

Risk evaluation

The manufacturer or person responsible for placing the product on the market should perform a risk evaluation based on recent toxicological data and knowledge. This evaluation should be set out in a file that is readily available to the competent authorities.

Conditions of application

Tattoo and PMU products must be sterile and supplied in a container which maintains the sterility of the product until application, preferably in a packaging size appropriate for single use. In case multi-use containers are used, their design should ensure that the contents will not be contaminated during the period of use.

Tattooing and the application of PMU, including treatment and maintenance of the instruments, in particular their sterilisation and disinfection, must be carried out by the tattooist in conformity with the hygiene regulations laid down by national public health services.

Information

Tattooists should necessarily provide the consumer with complete, reliable and comprehensible information on the risks entailed by those practices, including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications.

Potential consumers should be provided with reliable and evidence-based information about the risks of tattooing or PMU by all appropriate means, for example, through mass information campaigns or via the Internet.

The CoE ResAP(2008)1 recommends to the National Authorities to take into account the principles established in the resolution in their national laws and regulations on tattoos and PMU and to regulate the use of ingredients in tattoos and PMU by taking steps towards establishing a positive list of substances proved safe for this use under certain conditions.

3. Tattoos and Permanent Make-up Project

Tattoo inks are consumer products and consequently fall under the umbrella of Directive 2001/95/EC on general product safety (GPSD).

In this context DG SANCO requested DG JRC's support for the collection of information to be used for the preparation of possible EU regulatory action on the safety of tattoos and permanent make-up, like an "emergency measure" to be adopted under Article 13 of the GPSD and, to consider if in a later step a permanent EU legislation would be needed.

In addition to the available information in the 2003 JRC report, DG SANCO shared all the information gathered during the international webinar on tattoos held on 24th April 2014, the discussions at the Consumer Safety Network meetings in 2013 and 2014, and data from Member States including national legislation, scientific publications, market surveillance results and the notifications in the Rapid Alert system for dangerous non-food products (RAPEX).

With a note to the members of the GPSD Committee of 4th April 2014, DG SANCO invited Member States to designate national experts and identify possible stakeholders (tattooist or industry associations, medical societies etc.) to participate in an expert working group as subgroup of the Consumer Safety Network. On 23th June 2014, DG SANCO organised a first meeting of the expert group on tattoos with participants from 13 Member States (and Norway), stakeholders (tattoo ink producers, dermatologist, tattoo associations, Council of Europe, ANEC) and DG JRC. Some additional potential participants, such as tattoo associations from Italy, Germany, Switzerland and the UK and the European Network of Official Cosmetics Control laboratories, will also contribute or participate to the work.

The main goal of the project is to provide scientific/technical support to DG SANCO collecting data to be used for the preparation of future EU legislation on the requirements for tattoo and permanent make-up inks. Chemical, physical, biological health risks from tattoo inks and processes including hygienic conditions shall be taken into consideration for the following specific objectives:

1. Establishment of the state of play
    - % of tattooed persons
    - ink market
    - chemicals present in inks
    - health effects
    - removal processes
    - regulatory review (national legislations on tattoos in and outside EU);
2. Assessment and update of the CoE ResAP(2008)1
    - list of restricted chemicals and limits
    - analytical methods
    - labelling requirements
    - safety assessment
    - hygiene/sterility requirements
    - risk perception and communication
    - data gaps and research needs;
3. Conclusions

- identification of the elements to be addressed by EU action on tattoos.

The project is divided into four work packages: 1) preparatory work; 2) state of play; 3) assessment and update of the CoE ResAP(2008)1; 4) conclusions.

This report presents the outcome of the **first work package**, which includes:

1. a compilation of analytical methods necessary to implement the chemical recommendations of the CoE ResAP(2008)1 and
2. a regulatory review of national legislation and guidelines available in the different Member States and EFTA countries, plus a state of play in some non-EU/EFTA countries.

4. Work package 1: preparatory work

4.1. Meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (11 November 2014)

Following the first meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (CSN-STPM) organised in Brussels in June 2014, DG JRC organised a meeting of this working group in Ispra on 11 November 2014.

There were 23 participants from 11 Member States, plus Norway and Switzerland, including some stakeholders, such as dermatologist, ink producers and ANEC (European consumer voice in standardisation).

The objectives of the meeting were:

1. to define tasks and planning of the future work within the project;
2. to prepare the first deliverables of the project, working package 1 (preparatory work):

    a. collection of analytical methods that could be used to implement the Council of Europe Resolution (2008)1 provisions.
    b. regulatory review of national legislation and guidelines in the different EU Member States, plus the EFTA countries and some other jurisdictions.

Presentations on the objectives of the project and possible EU actions were followed by presentations and discussions on analytical methods for the analysis of tattoo inks and on different national legislations in the EU.

The minutes, agenda and list of participants to this meeting are reported in Annex III.

4.2. Analytical methods to implement the recommendations of the Council of Europe Resolution (2008)1

The CoE ResAP(2008)1 describes only two analytical methods for the determination of aromatic amines in tattoo and permanent make-up inks. Both methods are based on the reduction of pigments using sodium dithionite followed by the analysis of the released primary aromatic amines performed either via GC-MS or LC-MS.

The purpose of this chapter is to present the available analytical methods that can be used for detecting the presence of dangerous chemicals listed in the CoE ResAP(2008)1. Due to the very limited availability of specific analytical methods for the analysis of tattoo inks, the information was collected also with regard to methods applicable to other matrices, such as cosmetics and food. With an adaptation of the sample preparation procedure these methods could be applied to tattoo and PMU products.

The information has been collected through a questionnaire sent to experts from Member States (Table 4.1), as well as through web search of standard methods in the ISO (International Organization for Standardization) and CEN (European Committee for Standardization) catalogues and analysis of Standard Operating Procedures (SOPs). Some analytical methods described in the literature were also collected, but the search was not exhaustive.

A deeper assessment of the suitability of the analytical methods for the enforcement of the provisions of the CoE ResAP(2008)1 in tattoo and PMU inks will be performed in the work package 3 of this project, with the objective of identifying possible gaps and needs for further harmonisation of analytical methods on specific areas.

The chapter has been divided by chemical classes and the first four classes were investigated in more details:

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

For each chemical class, the analytical methods have been divided into:

1. international standard methods (i.e. standard methods harmonised at ISO and/or CEN level);
2. national standard methods (e.g. standard methods harmonised at national level, for instance in Germany by DIN);
3. in-house validated methods (i.e. test methods developed and validated in Member States' laboratories, not harmonised neither at national nor at international level);
4. test methods described in literature.

A short description of the analytical methods is reported in annexes IV-IX. They have been summarised using a standard approach, which includes, when available, information about:

- scope and field of application;
- principle;
- description of test method;
- type of instrumental analysis;
- repeatability (r) and reproducibility (R);
- limit of detection (LOD) and limit of quantification (LOQ).

It has to be noted that, in the case of the in-house validated methods, the information provided by Member States' experts is reported as it was received, as usually the SOPs were not available.

Table 4.1: Questionnaire sent to national experts to collect information about available test methods to enforce the CoE ResAP(2008)1 provisions.

			International standard method	National standard method	In-house validated test method	Test method described in literature
aromatic amines (see separate file)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				
colorants (see separate file)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				
inorganic impurities, metals and their salts (see separate file)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				
organic impurities and PAH (see separate file)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				
solvent residues (e.g. ethylacetate, acetone, n-butanol, methanol, ethanol, hexane, dichloromethane, methyl ethyl ketone, propan-2-ol)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				
banned substances, listed in Annex II to Regulation (EC) No 1223/2009 (e.g. quaternary ammonium salts, phenols, benzoic acids, chlorohydrocarbons, nitrosamines, phthalates, nitroaromatics, etc.)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				
substances which appear in part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogenic, mutagenic, or toxic to reproduction in categories 1A, 1B, or 2 (Table 3.1) or category 1, 2 or 3 (Table 3.2)	1	title and reference				
	2	scope and field of application				
	3	principle				
	4	description of the test method				
	5	type of instrumental analysis				
	6	LOD, LOQ				
	7	repeatability and reproducibility				

4.2.1. Primary aromatic amines

Primary aromatic amines are used in the synthesis of azo colorants, which can be ingredients of tattoo and PMU inks. Azo colorants are synthetised starting from primary aromatic amines which are first diazotised and then coupled with other aromatic compounds to form the azo group which is characteristic of this class of colorants. Under certain conditions, azo colorants can be converted back to their initial reagents by reductive cleavage. In addition, aromatic amines can be present as impurities in azo colorants.

The CoE ResAP(2008)1, in its Table 1 (Annex I, Table 1), presents a list of 27 primary aromatic amines that should be neither present nor released from azo colorants in tattoo and PMU products, due to their carcinogenic, mutagenic, toxic for reproduction and sensitising properties.

As reported in Table 4.2, 25 out of the 27 primary aromatic amines listed in Table 1 of the CoE ResAP(2008)1 are classified as carcinogenic, mutagenic and reprotoxic (CMR) in categories 1A, 1B or 2 in Table 3.1 under the EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP regulation). Their classification related to CMR properties, as well as to skin irritation/corrosion, serious eye damage/irritation and skin sensitisation properties, is reported. Moreover, 19 primary aromatic amines are also listed in Annex II of the EC Regulation 1223/2009 on cosmetics.

According to REACH Regulation (EC Reg. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals), azo colorants which by reductive cleavage of one or more azo groups may release one or more of the 22 aromatic amines, listed in Appendix 8 to entry 43 in Annex XVII, in concentrations above 30 mg/kg, shall not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity. These 22 aromatic amines are all listed in Table 1 of the CoE ResAP(2008)1.

Table 4.2: Primary aromatic amines listed in Table 1 of the CoE ResAP(2008)1, with indications if present in Annex II of EC Regulation 1223/2009 and/or Table 3.1 of EC Regulation 1272/2008.

		CoE ResAP (2008)1	EC Reg 1223/2009		EC Reg 1272/2008		
Substances	CAS number	Table 1	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
4-Aminoazobenzene	60-09-3	x	x	990	x	611-008-00-4	Carc. 1B
2,6-Xylidine	87-62-7	x			x	612-161-00-X	Carc. 2, Skin Irrit. 2
o-Anisidine	90-04-0	x	x	708	x	612-035-00-4	Carc. 1B, Muta. 2
2-Naphtylamine	91-59-8	x	x	242	x	612-022-00-3	Carc. 1A
3,3'-Dichlorobenzidine	91-94-1	x	x	712	x	612-068-00-4	Carc. 1B, Skin. Sens. 1
Biphenyl-4-ylamine	92-67-1	x	x	726	x	612-072-00-6	Carc. 1A
Benzidine	92-87-5	x	x	26	x	612-042-00-2	Carc. 1A
o-Toluidine	95-53-4	x			x	612-091-00-X	Carc. 1B, Eye Irrit. 2
2,4-Xylidine	95-68-1	x					
4-Chloro-o-toluidine	95-69-2	x			x	612-196-00-0	Carc. 1B, Muta. 2
4-Methyl-m-phenylenediamine	95-80-7	x	x	364	x	612-099-00-3	Carc. 1B, Muta. 2, Repr. 2, Skin Sens. 1
o-Aminoazotoluene	97-56-3	x	x	989	x	611-006-00-3	Carc. 1B, Skin. Sens. 1
5-Nitro-o-toluidine	99-55-8	x	x	1195	x	612-210-00-5	Carc. 2
4,4'-Methylenebis(2-chloroaniline)	101-14-4	x			x	612-078-00-9	Carc. 1B
4,4'-Methylenedianiline	101-77-9	x	x	705	x	612-051-00-1	Carc. 1B, Muta. 2, Skin Sens. 1
4,4'-Oxydianiline	101-80-4	x	x	1160	x	612-199-00-7	Carc. 1B, Muta. 1B, Repr. 2
4-Chloroaniline	106-47-8	x			x	612-137-00-9	Carc. 1B, Skin. Sens. 1
Para-phenylenediamine	106-50-3	x			x	612-028-00-6	Eye Irrit. 2, Skin Sens. 1
3,3'-Dimethoxybenzidine	119-90-4	x	x	709	x	612-036-00-X	Carc. 1B
3,3'-Dimethylbenzidine	119-93-7	x	x	721	x	612-041-00-7	Carc. 1B
6-Methoxy-m-toluidine	120-71-8	x	x	1162	x	612-209-00-X	Carc. 1B
2,4,5-Trimethylaniline	137-17-7	x	x	1158	x	612-197-00-6	Carc. 1B
4,4'-Thiodianiline	139-65-1	x	x	1159	x	612-198-00-1	Carc. 1B
4-Amino-3-fluorophenol	399-95-1	x	x	1242	x	604-028-00-X	Carc. 1B, Skin. Sens. 1
4-Methoxy-m-phenylenediamine	615-05-4	x	x	376	x	612-200-00-0	Carc. 1B, Muta. 2
4,4'-Methylenedi-o-toluidine	838-88-0	x	x	707	x	612-085-00-7	Carc. 1B, Skin. Sens. 1
2-Amino-6-ethoxynaphthalene	293733-21-8	x					

The CoE ResAP(2008)1 recommends that tattoos and PMU inks, do not contain substances, listed in Annex II to the cosmetic regulation and the substances classified as CMRs in the CLP regulation. These lists contain additional primary aromatic amines that, for completeness reason, were identified and are reported in Annex II of this document (Table A). With the exception of CMRs classified in categories 1A, 1B and 2 with index numbers comprised between 648-001-00-0 and 649-550-00-9, which mainly consist in distillates, extract residues, tar oils, fuels, gases from petroleum, etc., as they were not considered relevant for tattoo and PMU inks.

International standard methods

No international standard methods are available for the analysis of aromatic amines in tattoo and PMU products. Some exist to analyse these compounds in textiles, toys and leather products and are summarised in Annex IV.

Swedish and Slovenian experts use a modified version of EN 14362 to analyse tattoo and PMU inks. The modified protocol adopted by Slovenian experts is described at the end of the correspondent standard method. The same is true for EN ISO 17234, which is used, with some modifications, by Italian experts for the analysis of tattoo and PMU inks.

1. EN 14362-1:2012 Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres

2. EN 14362-3:2012 Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene
3. ISO 24362-1:2014 Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres (this method corresponds to EN 14362-1:2012)
4. ISO 24362-3:2014 Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 3: Detection of the use of certain azo colorants which may release 4-amminoazobenzene (this method corresponds to EN 14362-3:2012)
5. EN 71-7:2014 Safety of toys Part 7: Finger Paints requirements and test methods
6. EN 71-11:2005 Safety of toys Part 11: organic chemical compounds-method of analysis
7. EN ISO 17234-1:2010 Leather - Chemical tests for the determination of certain azo colorants in dyed leathers - Part 1: Determination of certain aromatic amines derived from azo colorants
8. EN ISO 17234-2:2011 Leather - Chemical tests for the determination of certain azo colorants in dyed leathers - Part 2: Determination of 4-aminoazobenzene.

ISO 24362-1:2014 and ISO 24362-3:2014 correspond to EN 14362-1:2012 and EN 14362-3:2012, respectively; therefore only the EN standards are described in Annex IV.

With the exception of EN 71-11:2005, the standards listed are meant to detect the use of azo-dyes that may release, by reductive cleavage, harmful aromatic amines. The azo group(s) of the colorant(s) contained in samples is/are broken down and the released aromatic amines determined. On the contrary, EN 71-11:2005 is based on the extraction of aromatic amines from samples followed by their quantification.

The analytical methods based on the reductive cleavage of the colorants were developed to test the aromatic amines that can be released by azo-dyes. Azo-dyes are soluble and can be completely converted into their original reagents under the method conditions; vice versa azo-pigments are insoluble and the formation of the primary aromatic amines, derived from the break of the azo bond, is not complete and depends very much on the experimental conditions of the test methods. This makes difficult to get reproducible results.

National standard methods

Only Swedish experts mentioned one of their national standard method, 64§ LFGB[6] 82-02-2 for the analysis of aromatic amines. This method is equivalent to EN 14362-1 and for this reason is not described in Annex IV.

In-house validated methods

A short description of the following in-house validated methods for the analysis of aromatic amines was provided by experts from Member States and is reported in Annex IV.

1. MDHS 75 (United Kingdom);

[6] Lebensmittel- und Futtermittelgesetzbuch (German Food and Feed Code)

2. Determination of primary aromatic amines in acidic migration solutions by LC-MS/MS (Austria);
3. In-house HPLC/MS method based on: "Determination of carcinogenic aromatic amines in dyes, cosmetics, finger paints and inks for pens and tattoos with LC/MS" (U. Hauri; Mitt. Lebnsm. Hyg. 2005, 96, 321-335), (France);
4. Determination of free carcinogenic aromatic amines in tattoo inks by HPLC/MS/MS (Switzerland);
5. Determination of carcinogenic aromatic amines in tattoo inks by HPLC/MS/MS after reductive cleavage according to EN 14362 (Switzerland);
6. Determination of Aromatic Amines in tattoo inks (Slovenia);
7. CHE01-WV494 Determination of aromatic amines in tattoo ink, permanent make up and textile using GC-MS (The Netherlands);
8. GC/MS analysis for primary aromatic amines (PAA) liberated from azo colorants and free PAA (Denmark);
9. GC/MS analysis for p-phenylendiamine (PPD) and free PAA (Denmark).

Methods 3-9 were validated for the analysis of tattoo and PMU inks.

Test methods 1, 2, 4 and 9 determine only free aromatic amines, whereas the others detect both free aromatic amines and those released by azo-colorants by reductive cleavage.

Method 1 is used for the determination of aromatic amines in air and English experts commented that it could be adapted for the analysis of bulk solutions. The second one is a method developed for the determination of aromatic amines in migration solutions from food contact materials.

Methods described in literature

A not exhaustive list of test methods published in the literature and used for the analysis of aromatic amines includes:

1. Specific determination of 20 primary aromatic amines (PAA) in aqueous food simulants by liquid chromatography-electrospray ionization-tandem mass spectrometry (Mortensen, Trier, Foverskov, Jens, J. Chromatography A, 2005, 1-2 (1091) ,40-50);
2. Determination and Quantification of Primary Aromatic Amine in Printer Inks (Margraf, Marlen, Borslel, LCGC Chromatography online. 2012);
3. Chemical Substances in Tattoo Ink. Survey of chemical substances in consumer products, 116 (The Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8).

The first two methods are meant to determine free aromatic amines, while the two described in the survey by the Danish EPA can detect both the free aromatic amines and the mixture of free and released (by reductive cleavage) aromatic amines (numbers 9 and 8 under in-house validated methods). It has to be highlighted that the Danish methods were applied to the analysis of tattoo inks.

A short description of these methods is reported in Annex IV.

4.2.2. Colorants

Tattoo and PMU inks are mixtures of colorants in a liquid, made of binder(s) and solvent(s), together with additives which improve the product's application properties, e.g. stability. Pigments (insoluble colorants) are usually the main ingredients of these inks.

A world-wide recognised classification of colorants is reported in the Colour Index (CI), published by the Society of Dyers and Colourists (SDC) and American Association of Textile Chemists and Colourists (AATCC). The Colour Index lists the essential colorants, defined as dyes or pigments responsible for the color of the product in the absence of additives.

The Colour Index is based on a dual classification system: on the one hand the Colour Index Generic Name (CIGN) and, on the other hand, the Colour Index Constitution Number (CICN), which is related to the chemical structure of colorants.

The C.I. Generic Name describes a commercial product by means of its recognised usage class (e.g. Pigment, Acid, Direct, Solvent, etc), its colour and a serial number, which refers to the chronological order in which related colorant types have been registered with the Colour Index. In certain cases, the same essential colorant is present in a number of application categories. For instance, a disperse dye can often be applied as a solvent dye, and a vat dye can sometimes be used as a pigment.

The C.I. Constitution Number is a five or more recently six-figure which refers to the chemical structure of the colorant. For this reason, dyes and pigments that belong to different application classes, but are chemically related, can have similar C.I. Constitution Numbers. For example, all monoazo and anthraquinone colorants show a CICN in the range 11000 – 19999 and 58000 – 72999, respectively.

The main chemical categories used to classify colorants in the Colour Index are: nitroso, nitro, monoazo, diazo, triazo, polyazo, azoic, stilbene, carotenoid, diphenylmethane, triarylmethane, xanthene, indamine, indophenol, azine, oxazine, thiazine, sulphur, lactone, aminoketone, hydroxyketone, anthraquinone, indigoid, phthalocyanone.

In case dyes or pigments differ only in the metal or acid used for salt formation, the CICN show an additional number after a colon. For instance, C.I. 15865 corresponds to the sodium salt of C.I. Pigment Red 48 and C.I. 15865:1 to its barium salt. Also CIGN may contain colon numbers; however, they do not necessarily coincide with those attached to the corresponding constitution numbers. Also, colon numbers associated with a particular structure may relate to quite different generic names.

Table 2 of the CoE ResAP(2008)1 reports a non-exhaustive list of 35 colorants that should not be present in tattoo and PMU products, due to their carcinogenic, mutagenic, toxic for reproduction and sensitising properties (Annex I, Table 2).

As reported in Table 4.3, 7 out of the 35 colorants listed in Table 2 of the CoE ResAP(2008)1 are classified as CMRs in categories 1A, 1B or 2 in the EC Regulation 1272/2008. Their classification related to CMR properties, as well as to skin irritation/corrosion, serious eye damage/irritation and skin sensitisation properties, is reported. In addition, 13 of them are listed in Annex II of the cosmetic regulation; whereas, none of them is listed in Annex IV to the same regulation with colorants allowed in cosmetics.

The CoE ResAP(2008)1 recommends that colorants listed in Annex II of the cosmetic regulation and/or classified as CMRs in the CLP regulation are not present in tattoo and PMU inks. For the sake of completeness such colorants, not included in the non-exhaustive table 2 of the ResAP (2008)1, have been listed in Annex II of this document (Table B). CMRs classified in categories 1A, 1B and 2 with index numbers comprised between 648-001-00-0 and 649-550-00-9, which mainly consist in distillates, extract residues, tar oils, fuels, gases from petroleum, etc., were not considered as not relevant for tattoo/PMU inks.

Table 4.3: Colorants listed in Table 2 of the CoE ResAP(2008)1, with indications if present in Annex II of EC Regulation 1223/2009 and/or Table 3.1 of EC Regulation 1272/2008.

				CoE ResAP (2008) 1	EC Reg 1223/2009		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Table 2	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Acid Green 16	44025	12768-78-4	triarylmethane dyes	x					
Acid Red 26	16150	3761-53-3	monoazo dyes	x					
Acid Violet 17	42650	4129-84-4	triarylmethane dyes	x					
Acid Violet 49	42640	1694-09-3	triarylmethane dyes	x	x	386	x	650-010-00-X	Carc. 2
Acid Yellow 36	13065	587-98-4	monoazo dyes	x	x	387			
Basic Blue 7	42595	2390-60-5	triarylmethane dyes	x	x	1328			
Basic Green 1	42040	633-03-4	triarylmethane dyes	x					
Basic Red 1	45160	989-38-8	xanthene	x					
Basic Red 9	42500	569-61-9	triarylmethane dyes	x	x	706	x	611-031-00-X	Carc. 1B
Basic Violet 1	42535	8004-87-3	triarylmethane dyes	x	x	388			
Basic Violet 3	42555	548-62-9	triarylmethane dyes	x	x	380	x	612-204-00-2	Carc. 2, Eye Dam. 1
Basic Violet 10	45170	81-88-9	xanthene	x	x	398			
Disperse Blue 1	64500	2475-45-8	anthraquinone dyes	x	x	700	x	611-032-00-5	Carc. 1B, Skin Irr. 2, Eye Dam. 1, Skin Sens. 1
Disperse Blue 3	61505	2475-46-9	anthraquinone dyes	x	x	1300			
Disperse Blue 35		12222-75-2	anthraquinone dyes	x					
Disperse Blue 106		12223-01-7	monoazo dyes	x					
Disperse Blue 124		61951-51-7	monoazo dyes	x					
Disperse Orange 3	11005	730-40-5	monoazo dyes	x	x	1281			
Disperse Orange 37		12223-33-5	monoazo dyes	x					
Disperse Red 1	11110	2872-52-8	monoazo dyes	x					
Disperse Red 17	11210	3179-89-3	monoazo dyes	x					
Disperse Yellow 3	11855	2832-40-8	monoazo dyes	x	x	1055	x	611-055-00-0	Carc. 2, Skin Sens. 1
Disperse Yellow 9	10375	6373-73-5	nitro	x					
Pigment Orange 5	12075	3468-63-1	monoazo dyes	x					
Pigment Red 53	15585	2092-56-0	monoazo dyes	x					
Pigment Violet 3	42535:2	1325-82-2	triarylmethane dyes	x					
Pigment Violet 39	42555:2	64070-98-0	triarylmethane dyes	x					
Solvent Blue 35	61554	17354-14-2	anthraquinone dyes	x					
Solvent Orange 7	12140	3118-97-6	monoazo dyes	x					
Solvent Red 24	26105	85-83-6	diazo dyes	x					
Solvent Red 49	45170:1	509-34-2	xanthene	x					
Solvent Violet 9	42555:1	467-63-0	triarylmethane dyes	x					
Solvent Yellow 1	11000	60-09-3	monoazo dyes	x	x	990	x	611-008-00-4	Carc. 1B
Solvent Yellow 2	11020	60-11-7	monoazo dyes	x					
Solvent Yellow 3	11160	97-56-3	monoazo dyes	x	x	989	x	611-006-00-3	Carc. 1B, Skin Sens. 1

International standard methods

No international standard methods are available for the analysis of colorants in tattoo and PMU products or in cosmetics; however, some exist to analyse these compounds in textiles and toys and are summarised in Annex V.

1. EN ISO 16373-2:2014 Textiles - Dyestuffs - Part 2: General method for the determination of extractable dyestuffs including allergenic and carcinogenic dyestuffs (method using pyridine-water);
2. EN ISO 16373-3:2014 Textiles - Dyestuffs - Part 3: Method for determination of certain carcinogenic dyestuffs (method using triethylamine/methanol);
3. EN 71-11:2005 Safety of toys Part 11: organic chemical compounds-method of analysis.

These methods are based on the extraction of colorants from solid samples using either pyridine-water, or triethylamine/methanol or ethanol, respectively, followed by analysis and

quantification. In order to extend the field of application of these methods to tattoo and PMU inks, it could be necessary to modify the sample preparation and extraction.

National standard methods

No national standard methods were mentioned by experts from Member States.

In-house validated methods

The following in-house validated methods for the analysis of colorants were mentioned by experts from Member States and their short description is reported in Annex V, when available.

1. Determination of Acid Red 1 (Slovakia);
2. SOP 1201: Intern metod för analys av färgämnen i hårfärgsprodukter med LC-MS (Internal method for analysis of colorants in hair colours by LC-MS) (Sweden);
3. Identification of colorants in tattoo inks with MALDI/TOF (Switzerland);
4. Identification of colorants in tattoo inks with colorimetry (Switzerland).

Methods 3 and 4 were developed for the analysis of tattoo inks in Switzerland, whereas method 2 is a Swedish one applicable to hair colours. Only the information about the title was provided for method 1.

Methods described in literature

A not exhaustive list of test methods published in the literature and used for the analysis of colorants includes:

1. In situ chemical analysis of modern organic tattooing inks and pigments by micro-Raman spectroscopy (Poon K.W.C., Dadour J.R., McKibley J., J. Raman Spectrosc., 2008, 39, 1227-1237);
2. Non-destructive analysis of paintings using Fourier transform Raman spectroscopy with fibre optics (Vandenabeele P., Verpoort F., Moens L., J. Raman Spectrosc., 2001, 32, 263–269);
3. In vitro quantitative chemical analysis of tattoo pigments (Timko A.L., Miller C.H., Johnson F.B., Arch Dermatol, 2001, 137, 143–147);
4. Q-Switch laser and tattoo pigments: first results of the chemical and photophysical analysis of 41 compounds (Bäumler W., Eibler E.T., Hohenleutner U., Sens B., Sauer J., Landthaler M., Lasers Surg. Med., 2000, 26, 13–21);
5. Analysis of the chemical composition of red pigments and inks for the characterization and differentiation of contemporary prints (Vila A., Garcia F.J., Anal. Lett., 2012, 45, 1274–1285);
6. Pigment classification of synthetic organic pigments by multivariate data analysis of FTIR spectra (Schäning A., Varmuza K., Schreiner M., e-PS 2009, 6, 75–80);
7. The use of a diamond cell for the FTIR characterization of paints and varnishes available to twentieth century artists (Learner T., Postprints: IRUG2 Meeting, 7-20. Available at http://www.getty.edu/conservation/our_projects/science/modpaints/1Learner.pdf);
8. FTIR Analysis of Paints, Tapes, and Polymers (FBI Laboratory Chemistry Unit, FBI Laboratory Chemistry Unit SOP Manual PPSU 200–0.doc, 2006, pp 1–12);

9. Photodecomposition of Pigment Yellow 74, a pigment used in tattoo inks (Cui Y., Spann A.P., Couch L.H., Gopee N.V., Evans F.E., Churchwell M.I., Williams L.D., Doerge D.R., Howard P.C., Photochem. Photobiol., 2004, 80, 175–184);
10. Establishment of an extraction method for the recovery of tattoo pigments from human skin using HPLC diode array detector technology (Engel E., Santarelli F., et al., Anal. Chem., 2006, 15, 78, 6440–6470);
11. Tattoo pigments are cleaved by laser light- the chemical analysis in vitro provide evidence for hazardous compounds (Vasold R., Naarmann N., Ulrich H., Fisher D., König B., Landthaler M., Bäumler W., Photochem. Photobiol., 2004, 80, 185–190);
12. Inks for tattoos and PMU (permanent make-up)/organic pigments, preservatives and impurities such as primary aromatic amines and nitrosamines (Hauri U., State Laboratory of the Canton Basel City, 2011. Available from: www.kantonslabor-bs.ch/files/berichte/6729_111012_JB_Tattoo_PMU_2011_EN.pdf);
13. Analysis of organic pigments using a direct exposure probe on JMS-T100GC 'AccuTOF GC' Jeol MS Data Sheet no 085, 2006;
14. The use of HPTLC and Direct Analysis in Real Time-Of-Flight Mass Spectrometry (DART-TOF-MS) for rapid analysis of degradation by oxidation and sonication of an azo dye (Djelal H., Cornée C., Tartivel R., Lavastre O., Abdeltif A., Arabian J. Chem., 2013. http://dx.doi.org/10.1016/j.arabjc.2013.06.003);
15. Determination of EU-Banned Disperse Dyes by LC/MSD TOF (Fang Y., Li P., Zumwalt M., Agilent Technologies, 2005. Available at: http://www.chem.agilent.com/Library/applications/5989-3859EN.pdf);
16. Chemical Substances in Tattoo Ink. Survey of chemical substances in consumer products, 116 (The Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8);
17. Characterization of coal tattoos by Raman Spectroscopy (Cinotti E., Labeille B., Boukenter A., Ouerdane Y., Cambazard F., Perrot J.L., Skin Res. Technol., 2015, 0, 1-2. Available at: http://onlinelibrary.wiley.com/doi/10.1111/srt.12221/epdf).

Methods 1, 3-5, 9-12, 16 and 17 were used for the analysis of pigments in tattoo and/or permanent make-up inks. Methods 1, 4-8 are based on Fourier Transform Infrared Spectroscopy, whereas methods 9-11 use High-Pressure Liquid Chromatography for the analysis. Raman spectroscopy is used by methods 1, 2 and 17 and Different Time-of-Flight Mass Spectrometry by methods 12-15. The report, mentioned in point 16 above, describes TGA-analysis for carbon black and the qualitative ASTM D 3256-86 analysis for phthalocyanine blue and green.

4.2.3. Elements

A number of impurities can be present in tattoo and permanent make-up inks. For instance, inorganic pigments may contain metals, such as nickel, and carbon black may contain polycyclic aromatic hydrocarbons (PAHs) that could be of concern for human health.

Table 3 of the CoE ResAP(2008)1 lists the maximum concentrations of impurities recommended in products for tattoos and PMU (Annex I, Table 3). Among the fifteen limit values established, 13 apply to elements and 2 to organic compounds. The resolution specifies that soluble copper should be determined after extraction to an aqueous solution with pH 5.5. In addition, it establishes that the presence of traces of chromium (VI) or nickel in products for tattoos and PMU should be mentioned on the package together with a warning, like "Contains chromium or nickel. Can cause allergic reactions."

As reported in Table 4.4, cadmium, mercury and nickel are classified as CMRs in categories 1A, 1B or 2. Arsenic, cadmium, chromium, mercury, nickel, lead and selenium are listed in Annex II of the cosmetic regulation. The classification related to CMR properties, as well as to skin irritation/corrosion, serious eye damage/irritation and skin sensitisation properties, is also reported.

Some elements and their salts are also listed in Annex II to the EC Regulation 1223/2009 on cosmetics and/or are classified as carcinogenic, mutagenic and reprotoxic (CMR) substances classified in Table 3.1 in categories 1A, 1B and 2 under the EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures. According to the CoE ResAP (2008)1, these elements should not be contained in tattoo and PMU inks.

For completeness reasons, such elements and their inorganic salts, not listed in Table 3 of the CoE ResAP (2008)1, were identified and are reported in Annex II of this document (Table C). For this work, CMRs classified in categories 1A, 1B and 2 with index numbers comprised between 648-001-00-0 and 649-550-00-9, which mainly consist in distillates, extract residues, tar oils, fuels, gases from petroleum, etc., were not considered as not relevant for tattoo/PMU inks.

Table 4.4: Elements listed in Table 3 of the CoE ResAP(2008)1, with indications if present in Annex II of EC Regulation 1223/2009 and/or Table 3.1 of EC Regulation 1272/2008.

		CoE ResAP (2008) 1		EC Reg 1223/2009		EC Reg 1272/2008		
Elements	CAS number	Table 3	Limit (ppm)	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Arsenic (As)	7440-38-2	x	2	x	43			
Barium (Ba)	7440-39-3	x	50					
Cadmium (Cd)	7440-43-9	x	0.2	x	68	x	048-011-00-X	Carc. 1B, Muta. 2, Repr. 2
Cobalt (Co)	7440-48-4	x	25					
Chromium (Cr) (VI)	7440-47-3	x	0.2	x	97			
Copper (Cu) soluble	7440-50-8	x	25					
Mercury (Hg)	7439-97-6	x	0.2	x	221	x	080-001-00-0	Repr. 2
Nickel (Ni)	7440-02-0	x	as low as technically achievable	x	1093	x	028-002-00-7	Carc. 2, Skin Sens. 1
Lead (Pb)	7439-92-1	x	2	x	289			
Selenium (Se)	7782-49-2	x	2	x	297			
Antimony (Sb)	7440-36-0	x	2					
Tin (Sn)	7440-31-5	x	50					
Zinc (Zn)	7440-66-6	x	50					

International standard methods

No international standard methods are available for the analysis of elements in tattoo and PMU products; however, several exist to analyse these compounds in cosmetics, toys, food, leather products and other matrices.

The underlined methods, the majority of which is used with modifications in some Member State to analyse tattoo and PMU products, are shortly described in Annex VI.

1. EN 71-3:2013+A1:2014 (see also ISO 8124-3:2010) Safety of toys - Part 3: migration of certain elements;
2. EN 13806:2002 Foodstuffs - Determination of trace elements - Determination of mercury by cold-vapour atomic absorption spectrometry (CVAAS) after pressure digestion;
3. EN 14083:2003 Foodstuffs - Determination of trace elements - Determination of lead, cadmium, chromium and molybdenum by graphite furnace atomic absorption spectrometry (GFAAS) after pressure digestion;
4. EN 15763:2009 Foodstuffs - Determination of trace elements - Determination of arsenic, cadmium, mercury and lead in foodstuffs by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion;
5. EN ISO 17072-1:2011 Leather - Chemical determination of metal content - Part 1: Extractable metals;
6. EN ISO 17072-2:2011 Leather - Chemical determination of metal content - Part 2: Total metal content;
7. ISO/TR 17276:2014 Analytical Approach for screening and quantification methods for HM in cosmetics;
8. EN 15111:2007 Foodstuffs - Determination of trace elements - Determination of iodine by ICP-MS (inductively coupled plasma mass spectrometry;
9. EN 14082:2003 Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper, iron and chromium by atomic absorption spectrometry (AAS) after dry ashing;
10. EN 14084:2003 Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper and iron by atomic absorption spectrometry (AAS) after microwave digestion;
11. EN 14546:2005 Foodstuffs - Determination of trace elements - Determination of total arsenic by hydride generation atomic absorption spectrometry (HGAAS) after dry ashing;
12. EN 14627:2005 Foodstuffs - Determination of trace elements - Determination of total arsenic and selenium by hydride generation atomic absorption spectrometry (HGAAS) after pressure digestion;
13. EN 15764:2009 Foodstuffs - Determination of trace elements - Determination of tin by flame and graphite furnace atomic absorption spectrometry (FAAS and GFAAS) after pressure digestion;
14. EN 15765:2009 Foodstuffs - Determination of trace elements - Determination of tin by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion;
15. EN 15517:2008 Foodstuffs - Determination of trace elements - Determination of inorganic arsenic in seaweed by hydride generation atomic absorption spectrometry (HGAAS) after acid extraction;
16. EN 15505:2008 Foodstuffs - Determination of trace elements - Determination of sodium and magnesium by flame atomic absorption spectrometry (AAS) after microwave digestion;

17. EN 14332:2004 Foodstuffs - Determination of trace elements - Determination of arsenic in seafood by graphite furnace atomic absorption spectrometry (GFAAS) after microwave digestion;
18. EN ISO 5398-1:2007 Leather - Chemical determination of chromic oxide content - Part 1: Quantification by titration;
19. EN ISO 5398-2:2009 Leather - Chemical determination of chromic oxide content - Part 2: Quantification by colorimetric determination;
20. EN ISO 5398-3:2007 Leather - Chemical determination of chromic oxide content - Part 3: Quantification by atomic absorption spectrometry;
21. EN ISO 5398-4:2007 Leather - Chemical determination of chromic oxide content - Part 4: Quantification by inductively coupled plasma - optical emission spectrometer (ICP-OES);
22. EN ISO 17075:2007 Leather - Chemical tests - Determination of chromium(VI) content;
23. EPA 3051A (and EPA 3051) Microwave assisted acid digestion of sediments, sludges, soils, and oils;
24. EPA 3052 Microwave assisted acid digestion of siliceous and organically based matrices;
25. EPA 3060A Alkaline digestion for hexavalent chromium;
26. EPA 218.7 Determination of hexavalent chromium in drinking water by ion chromatography with post-column derivatisation and UV-Visible spectroscopic detection;
27. EN ISO 17294-2 Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) Determination of 62 elements;
28. EN ISO 11885 Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES);
29. EN ISO 12846:2012 Water quality determination of mercury – method using atomic absorption spectroscopy (AAS) with and without enrichment.

With some modifications, Italian experts use the following methods for the analysis of elements in tattoo and PMU products: EN ISO 17072-1 based on the migration of elements in an artificial perspiration solution; EPA 3051A and EPA 3052 based on microwave digestion; EPA 3060A and EPA 218.7 for the determination of chromium VI.

German experts apply EN 13806 and EN 14083 to analyse mercury and other elements, respectively, in tattoo and PMU inks. They apply a German official method for cosmetic products (§ 64 LFGB K 84.00-29) for the extraction and microwave digestion of the tattoo or PMU sample. Austrian experts make use of EN 15763, Austrians and Slovenians use EN ISO 17294-2 and Swedish apply EN ISO 11885.

Some of the above mentioned analytical methods are used to determine to content of soluble elements, e.g. methods 1 and 5 with which the elements are extracted in a simulant of gastric juices or artificial perspiration solution at pH 5.5, respectively. The majority of the listed methods are useful to determine the total content of elements.

National standard methods

The following national standard methods for the analysis of elements were mentioned by experts from Member States. The first two methods are equivalent to other international

standard methods described in Annex VI, while for the last one the description was not available.

1. DIN EN ISO 11885 (this method is equivalent to EN ISO 11885) (Germany);
2. DIN EN 1483 (Hg) (this method was superseded by DIN EN ISO 12846:2012) (Germany);
3. K 84.00-29 (nach § 64 LFGB): Untersuchung von kosmetischen Mitteln - Druckaufschluss zur Bestimmung von Elementen in kosmetischen Mitteln (Austria and Germany).

In-house validated methods

The following in-house validated methods for the analysis of elements were mentioned by experts from Member States and their short description is reported in Annex VI, if available.

1. Determination of heavy metals (Cd, Pb, Ni) in cosmetics and food contact materials (Slovakia);
2. Determination of mercury in cosmetics and food contact materials (Slovakia);
3. Determination of heavy metals (Hg, Zn, Cu, Cr (VI), Co, Sb) in cosmetics and food contact materials (Slovakia);
4. ICP-MS (in-house method) (France);
5. MI-08 Determinazione degli elementi in cosmetici - Accredia Rev. 5, 2014 (Determination of elements in cosmetics) (Italy);
6. Metals and other elements in tattoo inks (Slovenia);
7. CHE01-WV495: Determination of certain elements in tattoo inks using ICP-MS (The Netherlands);
8. ICP/MS screening analysis for metals and other elements (Denmark).

Test methods 1, 4-8 are able to quantify the total content of elements.

Methods described in literature

A not exhaustive list of test methods published in the literature and used for the analysis of elements includes:

1. Market survey on toxic metals contained in tattoo inks (Forte G, Petrucci F, Cristaudo A, Bocca B., Science of the Total Environment, 2009, 407, 5997-6002);
2. Quantification of para-phenylenediamine and heavy metals in henna dye (Kang I-J, Lee M-H., Contact Dermatitis, 2006, 55(1), 26–29);
3. Survey of Selected Samples of Tattoo Inks for the Presence of Heavy Metals (Ministry of Health, 2013, Wellington);
4. Determination of hexavalent chromium in cosmetic products by ion chromatography and post-column derivatisation (Kang et al., Contact Dermatitis, 2006, 54, 244–248);
5. Determination of heavy metals in tattoo inks (Eghbali K, Mousavi Z, Ziarati P., Bioscience Biotechnology Research Asia, 2014, 11(2), 941-946);
6. Chemical Substances in Tattoo Ink. Survey of chemical substances in consumer products, 116 (Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8).

The majority of the listed methods are useful to determine the total content of elements. A short description is reported in Annex VI.

4.2.4. Polycyclic aromatic hydrocarbons (PAH)

The manufacturing of black inks usually involves the thermal combustion of feedstock oil, consequently compounds such as polycyclic aromatic hydrocarbons and carbon black can be found as impurities in tattoo and PMU inks.
PAHs are hydrocarbons composed of multiple aromatic rings and a number of them are classified as carcinogenic and/or mutagenic and/or toxic to reproduction.

As already mentioned, Table 3 of the CoE ResAP(2008)1 lists the maximum concentrations of impurities recommended in products for tattoos and PMU (Annex I, Table 3). Two out of the fifteen limit values established apply to organic compounds (sum of PAHs and benzo[a]pyrene).

As reported in Table 4.5, benzo[a]pyrene has a limit value of 5 ppb, it is classified as carcinogen (category 1B), mutagenic (category 1B), toxic for reproduction (category 1B) and skin sensitizer (category 1) and it is also listed in Annex II of the cosmetic regulation.

The CoE ResAP(2008)1 recommends that tattoos and PMU inks, do not contain substances, listed in Annex II to the cosmetic regulation and the substances classified as CMRs in the CLP regulation. These lists contain additional PAHs that, for completeness reasons, were identified and are reported in Annex II of this document (Table D). With the exception of CMRs classified in categories 1A, 1B and 2 with index numbers comprised between 648-001-00-0 and 649-550-00-9, which mainly consist in distillates, extract residues, tar oils, fuels, gases from petroleum, etc., as they were not considered relevant for tattoo and PMU inks.

Table 4.5: Polycyclic aromatic hydrocarbons listed in Table 3 of the CoE ResAP(2008)1, with indications if present in Annex II of EC Regulation 1223/2009 and/or Table 3.1 of EC Regulation 1272/2008.

		CoE ResAP (2008)		EC Reg 1223/2009		EC Reg 1272/2008		
Substances	CAS number	Table 3	Limit (ppm)	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
PAH		x	0.5					
Benzo[def]chrysene (benzo[a]pyrene)	50-32-8	x	0.005	x	612	x	601-032-00-3	Carc. 1B, Muta. 1B, Repr. 1B, Skin Sens. 1

International standard methods

No international standard methods are available for the analysis of PAHs in tattoo and PMU products; however, some exist to analyse these compounds in toys and food and are shortly described in Annex VII.

1. EN 71-7:2014 Safety of toys Part 7: Finger Paints requirements and test methods;
2. CEN/TS 16621:2014 Food analysis - Determination of benzo[a]pyrene, benz[a]anthracene, chrysene and benzo[b]fluoranthene in foodstuffs by high performance liquid chromatography with fluorescence detection (HPLC-FD).

These methods are based on solvent extraction of PAHs from samples followed by determination carried out either with GC-MS or HPLC-FD techniques.

National standard methods

Only Swedish experts mentioned one of their national standard methods applicable to polymer samples and based on solvent extraction followed by GC-MS analysis. The method is briefly described in Annex VII.

1. ZEK[7] 01.2-08 (superseded by ZEK 01.4-08): Testing and validation of Polycyclic Aromatic Hydrocarbons (PAH) in the course of GS[8]-Mark certification (Sweden).

In-house validated methods

The following three in-house validated methods for the analysis of polycyclic aromatic hydrocarbons in tattoo inks were cited by experts from Member States and their short description is reported in Annex VII.

1. Determination of PAHs in tattoo inks with GC/MS (Italy);
2. PAHs in tattoo inks by HPLC/UV/FLD after microwave assisted extraction with toluene (Switzerland);
3. CHE01-WV405 Determination of polycyclic aromatic hydrocarbons (PAH's) in tattoo ink and rubber using a GC-MS system (The Netherlands).

Samples are extracted by means of solvent(s), using ultrasonic apparatus (method 1) or microwave oven (method 2).

Methods described in literature

A not exhaustive list of test methods published in the literature and used for the analysis of polycyclic aromatic hydrocarbons includes:

1. Chemical Substances in Tattoo Ink. Survey of chemical substances in consumer products, 116 (Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8);
2. Tattoo inks contain polycyclic aromatic hydrocarbons that additionally generate deleterious singlet oxygen (Regensburger et al., Experimental Dermatology, 2010, 8 (19), 275-281).

Both methods are applicable to tattoo and PMU inks and are based on solvent extraction in ultrasonic bath.

[7] Zentraler Erfahrungsaustauschkreis ("Central Committee on Experience Exchange")
[8] Geprüfte Sicherheit ("Tested Safety")

4.2.5. Other hazardous chemicals

4.2.5.1. Phthalates

Some phthalates, e.g. DBP, were detected in tattoo and PMU products by Høgsberg T. et al. (2013, Experimental Dermatology, 2013, 22, 464–469) and Lehner K. et al. (2011, Contact Dermatitis, 65, 231–238).

Benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and di-(2-ethylhexyl) phthalate (DEHP) are classified as toxic for reproduction category 1B in Table 3.1 under the CLP regulation. Therefore the CoE ResAP(2008)1 recommends that such chemicals are not present in tattoo and PMU products.

DBP, DEHP and di-(2-methoxyexthyl) phthalate (DMEP) are listed in Annex II of the cosmetic regulation, consequently they also fall under the provisions of the CoE ResAP(2008)1.

International standard methods

No international standard methods are available for the analysis of phthalates in tattoo and PMU products; however, some exist to analyse these compounds in cosmetic, toy and textile products. The underlined ones are shortly described in Annex VIII.

1. EN 16521:2014 Cosmetics. Analytical methods. GC/MS method for the identification and assay of 12 phthalates in cosmetic samples ready for analytical injection;
2. EN ISO 14389:2014 Textiles - Determination of the phthalate content - Tetrahydrofuran method;
3. ISO 8124-6:2014 Safety of toys - Part 6: Certain phthalate esters in toys and children's products.

National standard methods

No national standard methods were mentioned by experts from Member States.

In-house validated methods

Austrian and Slovakian experts cited the following two in-house validated methods for the analysis of phthalates in cosmetic products (details in Annex VIII).

1. Determination of phthalates in cosmetics by GC-MS (Austria);
2. Determination of phthalate esters in cosmetics (Slovakia).

The first method use GC-MS analysis, while the second HPLC.

4.2.5.2. Nitrosamines

Some nitrosamines, e.g. NDELA and nitrosodimethylamine, were detected in tattoo and PMU products by Hauri U. (2014, Tinten für Tattoos und Permanent Make-Up / Pigmente,

Konservierungsstoffe, Aromatische Amine, Polyaromatische Kohlenwasserstoffe und Nitrosamine).

Dimethylnitrosoamine, nitrosodipropylamine and N-Nitrosodiethanolamine (NDELA), also called 2,2'-nitrosoimino)bisethanol, are classified as carcinogen category 1B in Table 3.1 under the CLP regulation and are listed in Annex II of the cosmetic regulation. Therefore the CoE ResAP(2008)1 recommends that such chemicals are not present in tattoo and PMU products.

International standard methods

No international standard methods are available for the analysis of nitrosamines in tattoo and PMU products. The three listed hereafter are applicable to toys or cosmetics (details for the underlined one in Annex IX).

1. EN 71-12:2013 Safety of toys. N-Nitrosamines and N-nitrosatable substances;
2. ISO 15819:2014 Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS;
3. ISO 10130:2009 Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization.

National standard methods

No national standard methods were mentioned by experts from Member States.

In-house validated methods

Swiss experts cited the following in-house validated method for the analysis of nitrosamine in cosmetics, finger paints and tattoo inks (see Annex IX).

1. Nitrosamines in cosmetics, finger paints and tattoo inks by LC/MS/MS (Switzerland).

4.3. Regulatory review: Country reports

The following chapter describes the different regulatory frameworks, laws, guidelines, etc. (in place or in draft), relating to tattoos and PMU products and services across the EU Member States, EFTA (Iceland, Liechtenstein, Norway, Switzerland) and some third countries. The review is updated until November 2014.

The information was collected via a standard questionnaire (Table 4.6), sent to all EU and EFTA Competent Authorities, as well as through the direct analysis of the background documents mentioned by those Authorities (Annex X). Furthermore we gathered additional material related to some other jurisdiction via an international webinar on tattoos held on 24th April 2014, and scrutinised other web available information as well.

The questionnaire has been structured in line with the CoE ResAP(2008)1 criteria, i.e. chemical, hygienic, labelling and packaging and information requirements, as well as provisions on risk assessment, tattoo processes and studio's.

Accordingly, each national legislation and/or guideline has been reviewed following the above mentioned criteria.

In total, out of the 32 EU/EFTA countries we received 28 replies, among which 22 completed questionnaires (19 Member States, plus Liechtenstein, Norway and Switzerland). We did not receive any reply from: Hungary, Lithuania, the UK and Iceland.

Table 4.6: Template of questionnaire sent to EU/EFTA Competent Authorities to collect information about their current legislative framework on tattoos and PMU.

			legislation/ proposal/ guideline 1	legislation/ proposal/ guideline 2
legislation/ draft proposals/ guideline	1	title and reference		
	2	based on		
	3	in force since		
	4	scope and field of application		
	5	definitions		
chemical requirements	1	banned aromatic amines (27 in ResAP (2008) 1)		
	2	banned colourants (35 in ResAP (2008) 1)		
	3	limits for impurities (15 in ResAP (2008) 1)		
	4	minimum requirements for further organic impurities for colorants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC		
	5	banned substances, listed in Directive 76/768/EEC (Annex II)		
	6	banned substances, specified in Directive 76/768/EEC (Annex IV, columns 2 to 4)		
	7	banned carcinogenic, mutagenic and reprotoxic substances of categories 1, 2 or 3 which are classified under Directive 67/548/EEC		
	8	preservatives (allowed, not allowed, under which conditions)		
	9	positive list of pigments		
	10	positive list of preservatives		
	11	guidance values for technically unavoidable amounts		
	12	other requirements (specify)		
hygienic requirements	1	products shall be sterile and supplied in a container which maintains the sterility of the product until application		
	2	requirements for tattoo studios		
	3	treatment and maintenance of the instruments, in particular sterilisation and disinfection – must be carried out by the tattooist in conformity with the hygiene regulations laid down by national public health services (specify which ones)		
	4	tattooists's obligations		
	5	other requirements (specify)		
packaging requirements	1	single use container		
	2	Multi-use containers (their design should ensure that the contents will not be contaminated during the period of use)		
	3	other requirements (specify)		
labelling requirements	1	name and address of manufacturer		
	2	date of minimum durability		
	3	PAO (period after opening)		
	4	conditions of use and warnings		
	5	batch number		
	6	list of ingredients according to IUPAC name, CAS number or colour index number		
	7	guarantee of sterility		
	8	other requirements (specify)		
requirements for tattooing processes and tattooists	1	compulsory training for tattooist		
	2	authorisation to open a tattoo studio		
	3	the tattooist should necessarily provide the consumer with complete, reliable and comprehensible information on the risks entailed by those practices, including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications		
	4	register of authorised tattoo studios and/or tattoo artists		
	5	other requirements (specify)		
requirements for risk assessment	1	to be done by		
	2	before placing the product on the market		
	3	based on recent toxicological data		
	4	file available to competent authorities		
	5	to be done on ingredients		
	6	to be done on final products		
	7	animal testing (allowed, prohibited, for ingredients or final products)		
	8	safety data required for the assessment		
	9	other requirements (specify)		
other requirements	1	age limits		
	2	banned positions for tattoos (e.g.head)		
	3	notification obbligation for tattoo products		
	4	tattoo vigilance system		
	5	reporting system on undesirable health effects		
	6	mass information campaigns		
	7	other requirements (specify)		

4.3.1. EU Member States

Some Member States already have specific legislation on tattoo/PMU in place, based fully or partially, on the CoE Resolutions. Others are considering to adopt such a legislation, but still have it on a draft form, while some others implement general safety requirements on consumer products (GPSD) or on chemicals (REACH and CLP). For a certain number of countries specific legislation is not available.

The outcome of this work, i.e. a description and analysis of each single national legislation/guideline, is presented hereafter, in an alphabetic order, as a state of play of the legal situation in the EU.

AUSTRIA

AT.1. Tätowiermittelverordnung 2014

(Regulation on tattoo products)

The "Regulation on tattoo products" of 2014 is a draft regulation based on the Product Safety Act 2004, equivalent to the General Product Safety Directive (GPSD). This draft Regulation was notified to the European Commission, in compliance with the provisions of Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, last amended by Directive 2006/96/EC.

Its field of application includes tattoo and permanent make-up products. The definitions are similar to those given in the CoE ResAP(2008)1.

Chemical requirements

This draft law considers the same 27 aromatic amines and 35 colorants included in the negative lists of the CoE ResAP(2008)1 and the same 15 limits for impurities. In addition, the same minimal requirements for further organic impurities for colorants used in foodstuffs, set out in Directive 95/45/EEC, should apply. Finally, the substances listed in Annex II of Regulation (EC) 1223/2009 on cosmetics and the ones restricted to an area of application, as stated in column g of Annex IV of the same Regulation should be prohibited, as well as the substances classified as CMR in categories 1A, 1B or 2 pursuant to part 3 table 3.1 in Annex VI to Regulation (EC) 1272/2008 on classification, labelling and packaging.

AT:2. Verordnung des Bundesministers für Wirtschaft und Arbeit über Ausübungsregeln für das Piercen und Tätowieren durch Kosmetik (Schönheitspflege)-Gewerbetreibende

(Regulation of the Minister of Economy and Labor on rules of exercise for piercing and tattooing by cosmetics professionals)

This Regulation, 141/2003, last amended in 2008, is based on the Industrial Code (*Gewerbeordnung*) of 1994, and sets out some obligations on the part of the tattooists, in particular as regards the customer, together with a definition of tattooing activities.

Requirements for processes and tattooists

The tattooist must get written approval by the customer before any treatment is carried out. He shall explain him by written aftercare treatment and possible risks (like allergy). Contraindications have to be noted. In case of complications, the tattooist should advise the customer to go to a doctor. The tattooist must keep a record of all the written consent from each client, together with a description as to how the operation was carried out, including the

list of products and inks which have been injected into the client's skin. This documentation should be kept for a 10 years period. A photocopy of the said documents shall be issued to the customer.

Other requirements
Tattooing is prohibited on people under 16. In addition, for persons between 16 and 18 years of age, the approval of parents or guardians is required.

AT.3. Verordnung des Bundesministers für Wirtschaft und Arbeit über Ausübungsregeln für Fußpflege, Kosmetik und Massage durch Gewerbetreibende

(Regulation of the Minister of Economy and Labour on rules of exercise for pedicure, cosmetics and massage professionals)
This Regulation, 262/2008, is based on the Industrial Code (*Gewerbeordnung*) of 1994, and sets out some requirements applicable to tattooists, mostly hygienic, with regard to working area, staff, tattooing tools and inks.

Chemical requirements
There are no detailed requirements for tattoo dyes, only general safety obligations apply, such as the absence of adverse health effects. The tattooing devices and inks may only be supplied by companies that are entitled to market them.

Hygienic requirements
Products shall be sterile and supplied in a container which maintains the sterility of the product until application. There are hygienic requirements for tattoo studios and the staff involved. Treatment and maintenance of the instruments, in particular concerning sterilisation and disinfection must be carried out by the tattooist in conformity with the hygiene prescriptions laid down in Annex 1 to the Regulation. Disinfectants may be used only if approved by the "Austrian Society for Microbiology and Preventive Medicine" (ÖGHMP) or the "Association for Applied Hygiene" (VAH). The working premises must undergo a yearly check by an accredited body which delivers a safety certificate. The tattooist shall be vaccinated against Hepatitis B. Tattoo shop employees dealing with customers have to attest in writing they are exempt of certain infectious diseases, and they must report without delay symptoms of certain diseases (as listed in Annex 3). The tattooist has to keep all documentation pertaining to the yearly external check, and of instruction to staff with regard to their physical condition available for a period of ten years. First-aid equipment is mandatory.

Requirements for processes and tattooists
The tattooists need specific training and authorisation to open a tattoo studio.

AT.4. Verordnung des Bundesministers für Wirtschaft und Arbeit über Zugangsvoraussetzungen für das reglementiere Gewerbe der Kosmetik

(Regulation of the Minister of Economy and Labour on admission requirements for the exercise of cosmetics professions)
This Regulation, 139/2003, last amended in 2008, is based on the Industrial Code (*Gewerbeordnung*) of 1994, and sets out the professional requirements and personal qualifications needed for practising various professions, *inter alia* tattooists.

Requirements for processes and tattooists

The authorisation to open a tattoo studio and to practice tattooing is given only to persons who have taken theoretical and practical courses, and passed the corresponding exams.

BELGIUM

BE.1. Arrêté Royal (A.R.) 25/11/2005 réglementant les tatouages et les piercings

(Royal Order providing rules for tattoos and piercing)

In force since 1/1/2006, it sets out requirements for the acts of tattooing and piercing with regard to tattoo products, material, equipment, hygiene and formation.

Chemical requirements

For the tattoo inks' composition, Annex I point 4 refers to the provisions of the CoE ResAP(2003)2.

Hygienic requirements

They are reported in Annex I. The skin or mucous membrane on which the treatment has to be carried out must be intact and cleaned and disinfected before any treatment is carried out. The use of disposable CE marked gloves for medical applications, preferably sterile, is compulsory when making tattoos and piercings. The gloves must be changed for every new client and after each septic action. Hands shall be disinfected before putting on gloves.

The materials that can penetrate skin or can enter into contact with the client's skin or mucous shall be sterile and disposable. If disposable materials are not available on the market, they shall be sterilised. All other materials shall be cleaned with a detergent/disinfectant.

The cleaning of materials should be preferably done automatically by thermal disinfection. If the cleaning is done manually, then a disinfectant solution shall be used. The sterilisation of thermo-resistant materials shall be carried out via autoclave (process using humid heat) according to the manufacturer's guidelines. The disinfection of thermo-sensible materials shall be done using a disinfectant product in accordance with the manufacturer's guidelines.

Tattoo and piercing studios shall contain at least the following distinct spaces: waiting area, working area, decontamination/sterilisation area, area to stock wastes and dirty linen.

The working area shall include at least a sink, a liquid soap distributor and a disposable towel distributor. The working and decontamination/sterilisation areas shall contain coating non porous, smooth surfaces, which can be treated with disinfectants.

Packaging requirements

Products shall be sterile and supplied in a container which maintains the sterility of the product until application.

Labelling requirements

The date of minimum durability shall be indicated on labels for tattoo ink. As guarantee of sterility, the batch number and the date of minimum durability shall be reported.

Requirements for processes and tattooists

Only people authorised by the Minister for Health can practice tattooing and piercing (art. 4) and they need to be registered. In order to be able to exercise their profession, tattooists and piercers shall follow a compulsory training of at least 20 hours with an exam at the end (art. 12). Topics of training shall include: basic principles of infection risks, toxicology of pigments, transmittable diseases, first aid, disinfection, hygiene, sterilisation, waste, spaces and linen management.

Tattoos and piercing cannot be carried out on people under the influence of drugs or alcohol (art. 7). Before applying tattoos and piercing, some time to reflect must be given to the client. A written agreement must be signed in duplicate, the document shall describe risks, cases in which a doctor must be consulted before tattooing or piercing, treatments needed to help skin recovery, contraindications and complications. In addition, information about the type of treatment, date, brand name and batch number of the tattoo inks used must be also included in the signed document.
Professionals have the obligation to inform clients orally and provide written advice about risks, etc. in the studio.
Checks are performed by hygiene inspectors of the Federal Public Service of public health, safety of food chain and environment.

Other requirements
A document signed by parents or a guardian is needed for young people under 18.

BE.2. Avis du Conseil Supérieur de la Santé (CSS) N° 8631 - 2 February 2011 - Maquillage semi-permanent et tatouage
(Recommendation of the Health Council on semi-permanent make-up and tattoos)

Chemical requirements
In the opinion of the Health Council, a national law on chemical and hygienic requirements is advisable.

Hygienic requirements
The same minimum hygienic conditions are established for tattoos, permanent and semi-permanent make-up.

Requirements for processes and tattooists
In order to be allowed to carry out a permanent or semi-permanent make-up (PMU or SPMU), the person must have being trained as a beautician plus taken a specific training on PMU and SPMU regarding products used, hygiene and risks of infections.

Other requirements
The laser required to get rid of tattoos must be used by a doctor, who must have followed a specific training course. The doctor may supervise another person carrying out the process, but he remains responsible for this act.
The same inspections are foreseen for tattoos, PMU and SPMU, including used products, infrastructure, compulsory training and written acceptance by clients.

BE.3. Avis du Conseil Supérieur de la Santé (CSS) N° 8719 – 5 September 2012 - Recommandations relatives à la maîtrise des infections lors de la pose de maquillage semi-permanent et permanent, de tatouages et de piercings
(Recommendations on the mastering of infections while laying semi-permanent and permanent make-up, tattoo and piercings)
It provides hygienic requirements to be fulfilled.

Hygienic requirements
The Health Council recommends:

- using systematic prevention measures (sterility) as in the context of health care;
- respecting personal hygiene including hands, hair, beard, nose;
- using glasses or a mask, appropriate clothes, gloves;
- getting vaccinated;
- maintaining a clear environment, with clear separation and organisation among different areas (clean, for wastes and warehouse);
- taking care of the maintenance of reusable materials and instruments and making use as much as possible of disposable materials;
- avoiding contamination by clients by disinfecting the cutaneous and mucous areas to be treated.

BE.4. Avis du Conseil Supérieur de la Santé (CSS) N° 8893 – 7 January 2015
Produits de tatouage et de maquillage permanent et semi-permanent - avis intermédiaire visant à limiter les complications et à accroître la sécurité des produits et techniques de tatouage et de maquillage permanent et semi-permanent en attendant une liste positive de produits pour ceux-ci
(Tattoo and PMU products – recommendations aimed at reducing the complications and at increasing the safety of the products and the techniques of tattooing and of permanent and semi-permanent make-up)

The Health Council recommends better enforcement of the CoE ResAP(2008)1 provisions in terms of infrastructure hygiene, sterility and labelling of ink containers, chemical composition of inks, and information campaigns. It further suggests enhancing controls related to single-use tools (i.e. nickel content), products traceability, and tattooists training. A body art EC label has been also proposed.

BULGARIA
No specific legislation is available.

CROATIA
HR.1. Act on objects of common use (NN 39/2013, 47/14)
Source of the act:
http://www.poslovni-savjetnik.com/propisi/zdravstvo-zdravstvena-ispravnost-i-zdravstveni-nadzor-nad-namirnicama-i-predmetima-opce-up-7
It is in force since 01.07.2013.
Article 3 of the act defines certain objects and appliances which may come into contact with the skin and/or mucous membrane, including also decorating items for face and the body (e.g. tattoo, piercing, and permanent make-up).

Chemical requirements
Article 7, point 1 states: Object of common use (defined also in art. 3) may contain additives as regulated by EU 2023/2006 (European legislation on good manufacturing practice for materials and articles intended to come into contact with food).
Article 7, point 2: Additives must be declared, in terms of type and amount as requested by legislation.

Object is considered non-compliant if contains compounds not allowed in objects for common use or if the content of them is higher than allowed.
Object is non-compliant if contains natural toxic compounds, in amounts harmful to humans.
Object is non-compliant if contains toxic substances above permissible limits.
Object is non-compliant if contains radionuclides.

Hygienic requirements
Part II, article 4: it is forbidden to place on the market objects that do not satisfy general requirements on safety and microbiological safety where needed, and must not cause harm to user.

Packaging requirements
Article 3, point 3: packaging is considered under definition of object of common use, therefore covered by this Act.

Labelling requirements
Object of common use is considered non-compliant if it is out of date or if there is no "use by" date. In addition, object of common use is considered non-compliant if its composition does not comply with what is declared on the label.

Other requirements
Object of common use is non-compliant if its composition and sensory characteristics have changed due to physical, chemical or microbiological processes, so much that it is not suitable for use anymore.
Object of common use is non-compliant if there is any other issue, not covered by point 1-10 of Article 5 of this Act, but for which there is a based suspicion that it can cause harm to humans.

HR.2. Ordinance (regulation) on health safety of objects of common use (NN 125/09, 23/13)
Part A: General conditions, Article 3 Point 7: This Regulation includes objects of common use that come into close contact with skin and mucous tissue.
These objects include also jewellery and other products that are aimed at decoration of some parts of the body, products for intimate adult amusement and other (Part VII, art. 59).

Chemical requirements
Objects that contain nickel, and during use come into contact with skin over longer periods, must not release nickel in amount higher than 0.5 $\mu g/cm^2$/week.

Hygienic requirements
In products meant for use on mucous tissues, the number of aerobic mesophilic bacteria, yeasts and mould may not be higher than 102 cfu/g or ml.
There should be no presence of Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Candida albicans in 0.5 g or ml of the product.

Labelling requirements
Art. 5 establishes that objects of common use that are being placed on the market must contain a readable, permanent, and comprehensive label. Label must be written in Croatian Latin letters. The declaration should contain details related to trade mark, brand name, name

and address of producer and/or legal or physical person that is placing product on the market, name and address of importer, and country of origin, relevant toxicological and ecological data, handling manual when necessary and other relevant information.

HR.3. Act on protection of population from infectious diseases (OG 79/07, 113/08, 43/09)
This Act defines the obligations and general measures for facilities that are subject to sanitary surveillance, premises, devices and equipment. It aims at ensuring the health and safety of sanitary-technical and hygienic conditions of production and trade.

CYPRUS
No specific legislation is available. The implementation of the EU Regulation 1907/2006 (REACH) and 1272/2008 for the classification, labelling, and packaging of chemical substances and mixtures (CLP) was mentioned.

CZECH REPUBLIC
CZ.1. Act No 258/2000 Coll., on the protection of public health
In force since 2001, this Act prescribes some hygienic requirements for i.a. tattoo studios.

Hygienic requirements
The public health authority will require the studio owner to submit the operational rules setting out the conditions for the activity, use of machinery, instruments and other equipment, prevention of contagious diseases, disinfection and sterilisation, principles of personal hygiene of the employees and protection of health to customers, and cleaning of the premises. At the commencement of activities, the studio owner shall display the approved operational rules in the premises.
A first-aid box is mandatory. Prior to commencement of the activities, the tattooist must be in a sufficiently healthy condition to carry out such activities, confirmed by a medical certificate.

Requirements for processes and tattooists
The tattooist must have the necessary knowledge for protection of public health, verified by the relevant competent body. He shall ensure that customers' health is not endangered by a contagious disease or otherwise damaged during such activities.

Other requirements
Tattooist may not carry out operations on diseased skin, or manipulate scars or birth-marks. Operations on mucous membranes, eye conjunctivas and corneas are ruled out.

CZ.2. Decree 137/2004 Coll., on hygienic requirements for food services and the principles of personal and operational hygiene which carry out epidemiologically important activities
In force since 1st April 2004, this Decree mainly sets out, in § 51 article (1) and (2), hygienic requirements for tattoo studios.

Hygienic requirements

§ 51 describes hygienic rules for cleaning and disinfection of working place and instruments, waste management, ventilation of the studio, which should be a separated, non-smoking area, forbidden to unauthorized persons and items not related with the activity.
§ 52 describes rules for personal hygiene in workspace, such as hand washing, or wearing of working clothes and protective gloves.
Sterilisation methods are detailed in Annex n. 6 to the decree.

Other requirements
Some body parts cannot be tattooed.

CZ.3. Decree No. 490/2000, Coll., on the scope of knowledge and other conditions to acquire professional competence in some fields of public health protection
In force since 1st of January 2001, this Decree imposes, in its § 10 and Annex 3, some knowledge and other professional competences to be acquired by tattoo studio owners for public health protection purposes.

CZ.4. Act No 102/2001 Coll. on general product safety
In force since 1st of July 2001, this Act sets out general safety rules.

Labelling requirements
Manufacturer shall label the marketed products, with the batch number, and provide a warning about any potential safety risk. He will supply information, in Czech language, about risk assessment connected with specific use of product or any information related to safety of products.

Requirements for risk assessment
Manufacturers may only market safe products. To that end they must take samples of marketed products and test them for safety. If a manufacturer has marketed an unsafe product, he must notify the competent authority.

CZ.5. Act No 634/1992 Coll., on the protection of consumers (31 December 1992)
This Act contains general consumer protection provisions.

Hygienic requirements
Section 17 of the Act provides that products shall be sold in hygienic packaging.

Labelling requirements
The following information shall be included in the label: name and address of manufacturer, batch number, name of the product, weight, quantity, size or dimensions, and any further information necessary for its identification or use.
The manufacturer shall inform consumers in written instructions (in Czech language) attached to products, about properties, how to use and maintenance of products and about possible danger caused by specific or inappropriate use.

Requirements for processes and tattooists
Sellers shall provide consumers with instructions for use.

CZ.6. Trade Licensing Act (law n. 455/1991 in actual version) for "Activities by which the integrity of human skin is disturbed"

Requirements for processes and tattooists

The tattooist needs to hold a trade licence and shall meet criteria listed in Annex 2 to § 23 and 24 of the present law. Generally, the person shall be medical doctor or dentist or general nurse, midwife, paramedic or health assistant or secondary educated or retrained in cosmetics. More info on: http://www.businessinfo.cz/en/articles/activitiy-integrity-human-skin-disturbed-8382.html

DENMARK

DK.1. Recommendation from the Danish EPA on the safety of tattoo inks

http://mst.dk/media/mst/9347058/danish_epa_recommendation_for_tattoo_ink.pdf

This Recommendation, drafted in 2014, provides technical guidelines for safety assessment of tattoo inks, and sets out various requirements.

Chemical requirements

It is recommended not to use tattoo inks which may release the nine aromatic amines listed in Table 1, n° 1-9 in excess of the threshold values stated (10 ppm), except aniline (5 ppm). Eight of them are part of the 27 listed in the ResAP(2008)1; whereas the ninth one, aniline, is not.

Recommended limit values apply to the following impurities: benzo(a)pyrene (0.2 ppm), other PAH's expressed as total (2 ppm), lead (10 ppm).

For the safety assessment all known impurities of the tattoo ink must be identified . It is recommended not to use ink with CMR Cat 1A or 1B substances according to CLP Reg. (EC) 1272/2008, or CMR Cat.1, 2 according to the DK-Order on CLP.

Hygienic requirements

Products shall be sterile and supplied in a container which maintains the sterility of the product until application. Inks must comply with the sterility test according to the European Pharmacopoeia. Sterilization method may be e.g. ionizing radiation, ISO 11137.

Labelling requirements

Ink labels shall include, in Danish or English, name and address of manufacturer, date of minimum durability (with a clear expiry date), batch number, nominal content, list of ingredients (if >1%, or allergens, regardless of the concentration), preferably according to INCI, EINECS or ELINCS, otherwise with ISO or IUPAC names. Colorants are labelled with their CI number.

Requirements for risk assessment

Before placing the product on the market, a safety assessment, of both ingredients and final product, should be carried out by a competent professional, based on current knowledge available and updated up to the expiry date of the tattoo ink. The data should include: chemical identity of the tattoo ink, and its physico-chemical properties and stability, impurities and information on the container, toxicological profile of ingredients including impurities, exposure to the ink.

The report should conclude on safety issues by calculating a Margin of Safety.

Analytical methods developed for the purpose of chemical analysis of dangerous substances in tattoo ink are referenced to in Chapter 4 of the survey on tattoo inks conducted in 2011 by the Danish EPA (Jacobsen et al 2012). Relevant analytical methods are also given in ResAP(2008)1, standards for toys (EN 71-7:2002) and/or textiles (EN 14362-1). The methodologies might need minor adjustments in order to be suitable for tattoo inks.

DK.2. Act on a voluntary and industry-managed registration system for tattooists and Ministerial order on a voluntary and industry-managed registration system for tattooists

This voluntary and industry-managed registration system for tattooists was established in January 2014 in order to inform and protect consumers on/against risks related to tattoos

Requirements for processes and tattooists

In order to get registered, a tattooist must be trained according to the codes of good practice set up by industry associations. The training programme must include regulations on responsible use of equipment and techniques, rejection of intoxicated customers, tattooing techniques, regulations on tattoo inks, health risks, and hygiene. They must update their professional knowledge, give customers objective information regarding health risks and care, tattoo removal, and about the complaint body.

To be approved by the Danish Health and Medicines Authority the associations for tattooists must have a democratic structure, a board/committee, by-laws, training requirements and codes of good practice for tattooists, and a complaints body for customers. "Registered tattooist" is a protected title. When a tattooist has been registered he must follow the regulations set by the association.

DK.3. Law on tattoos

This law is in force since 15 June 1966. It requires a minimum age for tattoos, i.e. 18 years old, and forbids certain part of the body, such as head, neck and hands.

Requirements for processes and tattooists cf supra

DK.4. DRAFT for the Order on tattoo inks

The scope of this draft legislation is the import, sale and use of tattoo inks, much in line with the Guidelines described above (under **1.**). It defines notions such as ingredient, expiry date, tattooing, tattoo ink, and tattoo ink container.

Chemical requirements

It bans 9 aromatic amines listed in Annex 2 of the Draft Order, n° 1-9.

The limits for 3 impurities are stated in Annex 2, n° 10-12.

It bans all CMRs classified in Cat.1A, 1B and 2 according to EC Regulation 1272/2008 and those classified in Cat.1, 2 or 3, according to the DK-Order on CLP.

Hygienic requirements

Products shall be sterile and supplied in a container which maintains the sterility of the product until application. Inks must comply with the sterility test according to the European Pharmacopoeia. (cf 1. supra). Tattoo inks are forbidden if their expiry date has passed.

Labelling requirements
The label shall include, in Danish or English, the name and address of manufacturer, batch n°, container's nominal amount (nominal mass or volume), date of minimum durability (with a clear expiry date), list of ingredients, preferably according to INCI, EINECS or ELINCS nomenclature, otherwise with ISO or IUPAC names. Dyes are labelled with their Colour Index number.

Requirements for risk assessment
Tattoo inks are forbidden if they constitute a risk to human health.
Before placing a product on the market, a safety assessment report based on recent toxicological data must be submitted in Danish or English, and can be replaced by a REACH dossier.

Other requirements
Law enforcement is subject to inspections by the DK-EPA

ESTONIA
No specific legislation is available.

FINLAND
FI.1. CLP Regulation (EC) No 1272/2008
This EU Regulation, dealing with classification and labelling of chemical substances, is already in force, but will include mixtures from 1 June 2015 on.

Chemical requirements
Classification of substances.

Packaging requirements
For chemical packaging see Article 35 of CLP.

Labelling requirements
For chemical labels, see Article 17 of CLP.

Other requirements
Classification and labelling notification to the European Chemicals Agency on substances (see Article 40 of the CLP).
Obligations on advertising of hazardous mixtures are dealt with in Article 48 of CLP.

FI.2. REACH Regulation (EU) No 1907/2006 (in force since 1 June 2007)

Chemical requirements
Restricted chemicals are listed in Annex XVII of REACH Regulation, while substances subject to authorisation are included in Annex XIV of REACH.

Requirements for risk assessment
The risk assessment on ingredients is done by the manufacturer/importer before the product is placed on the market, and based on recent toxicological data, in conformity with REACH

requirements and testing methods. Safety data sheet should be provided to the supplier or downstream user at least on request, according to Article 31 of REACH.

FI.3. Ministry of Social Affairs and Health Decree on chemical classification and labelling principles (807/2001)

This law is in force since 1 October 2001 and is based on the Dangerous preparation directive 1999/45/EC (DPD). It regulates the classification of mixtures until 1.6.2015. After this date, it will be repealed by the CLP Regulation (EC) No 1272/2008.

Chemical requirements
Classification of mixtures valid until 01.06.2015.

Packaging requirements
For chemical packaging, see Article 9 of the DPD.

Labelling requirements
For chemical labels, see Article 10 of the DPD.

FI.4. Chemicals Act (599/2013)

In force since 1st of September 2013, the objective of this Act is to protect health and the environment from the hazards and harm caused by chemicals

Chemical requirements
The law obliges the operators to be aware of the effects of the chemical on human health and the environment and of the requirements related to the sales of the chemical. An operator who places a hazardous chemical on the market must provide information to the Finnish Safety and Chemicals Agency, and notify the national chemical product register of dangerous chemicals of the product(s).
A chemical must not be made available through retail if it may entail particular health risks.
The recipient of a chemical hazardous to health must provide the supplier with necessary information about the recipient and user of the chemical and the purpose for which the chemical is being used.

Labelling requirements
In addition to the CLP provisions of the EU chemicals legislation, the marketing of chemicals may not refer to a chemical in a way that is misleading or untruthful as concerns the risks posed by the chemical to human health or the environment.

Requirements for risk assessment
Safety data sheets, under Article 31 of the REACH Regulation, must be provided for the recipient of the chemical either in Finnish or in Swedish or in both of these languages.
The study on the health and environmental impacts of chemicals submitted to authorities and required by the EU chemicals legislation must be conducted in a laboratory which complies with the requirements laid down in Directive 2004/10/EC on good laboratory practice.

FI.5. Health Protection Act (763/1994 in the Finnish Statute Book)

In force since 1st of September 2013, this Act requires that service providers, in relation to activities that may cause health hazards, to submit a written notification to the municipal

surveillance authorities 30 days prior to the commencement of the use of premises located in a residential building or area.

Hygienic requirements
Treatment and maintenance of the instruments, in particular sterilisation and disinfection – must be carried out by the tattooist in conformity with the hygiene regulations laid down by national public health services.

Requirements for processes and tattooists
See above.

FI.6. Decree of the Ministry of Social Affairs and Health (167/2003 in the Finnish Statute Book)

Hygienic requirements
Treatment and maintenance of the instruments, in particular sterilisation and disinfection – must be carried out by the tattooist in conformity with the hygiene regulations laid down by national public health services.

FI.7. Consumer Safety Act (920/2011, in the Finnish Statute Book)
In force since 1.1.2012, this Act represents the national implementation of the GPSD.
The Consumer Safety Act stipulates a general safety requirement that consumer products or services may not involve risk to health or to anyone's property.

Requirements for processes and tattooists
Tattoo parlour owners must submit a notification to the municipal surveillance authorities before the commencement of their activity. This, however, does not constitute a permit procedure. In addition, tattooists must draw up a written safety document. Further provisions on the contents of the safety document are issued under a Government Decree on the safety document concerning certain consumer services (1110/2011).
The service provider shall clearly inform consumers about possible risks involved in consumer goods and services. Operators must report to authorities if a consumer product or service involves risk. Surveillance authorities shall have access to any area, premises or other space where it is necessary to carry out inspections.

FI.8. Upcoming guidelines from the National Supervisory Authority for Welfare and Health
This guidance will provide details on hygienic requirements of service providers' premises.

FI.9. Government Decree on the safety document concerning certain consumer services (1110/2011).
This Decree issues further provisions on the contents of the safety document mentioned under the Consumer Safety Act (see 7 above).

FRANCE

FR.1. Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique, article 149

(Law n° 2004-806 of 9 August 2004 on public health policy, article 149: article L.513-10-1 to L.513-10-4)

The article L.513-10-1 defines tattoo products as any substance or preparation intended for colouring, by cutaneous penetration, creating a mark on the external parts of the human body with the exception of products which are medical devices within the meaning of article L.5211-1.

Only the provisions that are in addition to those described in the law 2014-201 of 24 February 2014 adapting various provisions in line with the European Union in the field of health are reported hereafter.

Requirements for risk assessment

It is forbidden to put tattoo products on the market whose final composition or ingredients (or mixture of ingredients) have been tested on animals by a method which is not an alternative one. In exceptional circumstances, when serious doubts exist on the safety of an ingredient of a tattoo product, the French agency of health products safety can ask the European Commission a derogation to the before mentioned provisions.

FR.2. Loi 2014-201 du 24 février 2014 portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la santé

(Law 2014-201 of 24 February 2014 adapting various provisions in line with the European Union legislation in the field of health) - articles L.513-10-2 to L.513-10-10 and L.5437-2 to L.5437-5

The tattoo products available on the market shall not endanger human health when they are applied under foreseeable conditions of use.

Labelling requirements

The following information shall be reported on the labelling: name and address of manufacturer, date of minimum durability, conditions of use and warnings, batch number, list of ingredients according to IUPAC name, CAS number or colour index number (in decreasing order of weigh), mention of sterility.

Requirements for risk assessment

The risk assessment of tattoo products shall be performed, before their introduction on the market, by the person responsible for placing them on the market according to good laboratory practice (GLP). GLP principles are published by the national agency for drugs and health products safety (ANSM), as well as the rules applicable to their inspections.

The person responsible for placing tattoo products on the market shall keep and make accessible to authorities a dossier including all information about qualitative and quantitative composition of products, as well as their physical-chemical and microbiological specifications, conditions of manufacturing and quality control, health risk assessment and adverse effects. The detailed implementation of the risk assessment is not described in regulatory text.

Other requirements

The opening and establishment of production plants, packaging or importation premises of tattoo products, as well as the extension of activity, are subject to notification to the national

agency for drugs and health products safety (ANSM). The person responsible for putting the products on the market shall prepare the notification. Any following modification shall be transmitted to the agency. The person responsible for putting the product on the market shall select one or more qualified people responsible for the manufacturing, packaging, import, quality control, health risk assessment, control of stocks of raw materials and finished products. These people must have appropriate scientific knowledge proved by certificates determined by law.
The release on the market of tattoo products is subordinated to the transmission to poison control centres of appropriate information concerning the substances contained in the products. The list of information required is determined by law.
The person responsible for putting tattoo products on the market shall make their composition and adverse effects available to the public.
The person responsible for putting tattoo products on the market shall declare to the national agency for drugs and health products safety (ANSM) the serious adverse effects that could result from the use of these products. The same shall be done by health care professionals and tattoo artists, who shall specify if the serious adverse effect was the result of a non-correct use of the product and describe the conditions in which the tattoo was carried out. Also consumers can declare to ANSM adverse effects of tattoo products.
In case of serious doubt about the safety of one or more components of tattoo products, the person responsible for putting them on the market, upon motivated request of the director general of ANSM, shall provide the list of its tattoo products containing one or more of these substances, as well as their quantity in the products. The ANSM will treat this information as confidential.

FR.3. Décret 2008-210 du 3 mars 2008 fixant les règles de fabrication, de conditionnement et d'importation des produits de tatouage, instituant un système national de vigilance et modifiant le code de la santé publique (dispositions réglementaires)

(Order 2008-210 of 3 March 2008 concerning rules of manufacturing, packaging, import of tattoo products, establishing a national vigilance system and modifying the code of public health)
This law further specifies provisions established in law 2004-806 and reaffirmed in the law 2014-201.

Chemical requirements
The Health Minister establishes:

1. the list of forbidden substances in tattoo products;
2. the list of substances that can be present in tattoo products with some restrictions.

Packaging requirements
Tattoo products shall be sterilised by appropriate methods. They shall be provided in a container that maintains the sterility until use. Multi-dose containers are allowed provided that their design ensures that the contents will not be contaminated during the period of use and the delivery of each dose does not compromise the sterility of the product remaining in the container. A dose is defined as the amount of product used for one person during a single session. The quality of containers and substances in tattoo inks, apart from tattoo colorants, shall be in accordance with the European Pharmacopeia.

Labelling requirements

The labelling of tattoo products shall contain:

1. product name;
2. nominal content expressed in mass or volume;
3. maximum durability, with the indication “use before”;
4. batch number;
5. sterility;
6. name and address of manufacturer or person responsible for placing them on the market;
7. use precautions;
8. list of ingredients in descending order by weight (impurities in raw materials are not considered ingredients, as well as substances not present in the final product);
9. if necessary, phone number or URL address where the information to public is available.

Requirements for risk assessment

The dossier that the person responsible for placing tattoo products on the market must keep available for the authorities shall contain:

1. qualitative and quantitative composition of products;
2. physico-chemical and microbiological specifications of raw materials and tattoo products;
3. description of production process and quality control of products;
4. conservation period and method used to determine it;
5. health risk assessment of products;
6. name and address of the qualified person responsible for health risk assessment, as well as his/her level of professional qualification;
7. data available on adverse health effects that can result from use of products;
8. evidence of transmission to poison control centres of appropriate information concerning the substances contained in products.

Other requirements

The notification to the national agency for drugs and health products safety (ANSM) of the opening and establishment of production plants, packaging or importation premises of tattoo products shall contain:

1. name and address of the company;
2. address of the French plant and activities foreseen;
3. name, address of subcontractors and activities outsourced;
4. use of products put on the market;
5. name, function and professional qualification of the responsible for the activities mentioned in the fourth indent of article L. 5131-2.

The national vigilance system about risks of adverse effects of tattoo products includes:

1. French agency for health safety of healthcare products, which is responsible for the system;
2. administrative authorities;
3. expert group on risk evaluation for tattoo products;
4. healthcare professionals;
5. producers, responsible for placing on the market, distributors;
6. tattoo artists.

The national vigilance system implies:

1. notification of adverse effects to the French agency for health safety of healthcare products, specifying if adverse effects are due to misuse of products;

2. data evaluation in view of preventive actions;
3. study on safe use of tattoo products;
4. corrective actions.

Upon motivated request by the agency, the producer or person responsible for placing the tattoo products on the market shall provide the following information:

1. commercial name;
2. name and address of producer or responsible for placing on the market;
3. concentration of the substance suspected to be dangerous;
4. appearance and capacity of commercialized packaging.

The transmitted information is kept confidential.

The following information shall be available to the public:

1. qualitative product composition in terms of list of ingredients;
2. indication of quantity express as percentage or maximum concentration for dangerous substances;
3. adverse effects specifying nature and occurrence;

Consumers that want to access this information shall request it by mail, fax or email specifying product name, brand name and colour. The producer or person responsible for placing them on the market shall reply within a three week deadline and shall keep all questions and answers for a period of five years.

FR.4. Décret 2008-149 du 19 février 2008 fixant les conditions d'hygiène et de salubrité relatives aux pratiques du tatouage avec effraction cutanée et du perçage, et modifiant le code de la santé publique (dispositions réglementaires)

(Order 2008-149 of 19 February 2008 establishing hygiene requirements for tattooing and piercing processes, modifying the public health code)

The described requirements apply to tattooing, permanent make-up and piercing processes, with the exclusion of piercing of ears and nose when carried out via an ear piercing gun.

Hygienic requirements

The following hygienic requirements are established:

1. equipment coming into contact with client skin or mucous membrane and their direct supports shall be either disposable and sterile or sterilised before each use;
2. premises include a room exclusively dedicated to tattooing.

Wastes are treated as those resulting from care treatments with infection risk.

Labelling requirements

The hermetic packaging of each unit which includes the jewel and its support shall be labelled with the following information:

- product name;
- maximum durability with the indication "use before";
- batch number;
- sterile materials.

Requirements for processes and tattooists

People carrying out tattoos, piercing and permanent make-up shall notify their activity to the prefect of the department where the activity takes place. A notification shall be transmitted to the same authority in case of cessation of the activity.

Professionals shall take and complete training courses on hygiene and health requirements.

Tattooists, piercers and people practicing permanent make-up shall inform customers before any practice about the risks to which they are exposed and precautions to be followed after the realisation of tattooing or piercing (information displayed in the studio and delivered in writing to customers).

Other requirements

It is forbidden to practice tattooing, piercing or permanent make-up on a minor without the written consent of a holder of parental authority or guardian. The persons carrying out these practices on a minor must be able to present evidence of consent to competent authority over a 3 year period.

FR.5. Arrêté du 6 mars 2013 fixant la liste des substances qui ne peuvent pas entrer dans la composition des produits de tatouage

(Order of 6 March 2013 establishing the list of substances prohibited in tattoo products)

Chemical requirements

The following substances shall not be present in tattoo products:

1. substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) categories 1A, 1B, 2 and sensitisers category 1 in EC Regulation 1272/2008 (Annex VI, Tables 3.1 and 3.2);
2. substances that cannot be used as ingredients in cosmetic products (listed in the order of 6 February 2001 on cosmetic products);
3. substances considered sentitisers by the scientific committee for consumer safety in hair dyes, listed in an Annex of the order of 6 February 2001 outside the restrictions and conditions established in this list;
4. colorants reported in columns 2-4 in the Annex of order of 6 February 2001;
5. CMR substances and sensitisers of the Annex in the chapter "criteria regarding processes and chemical substances" (point 22 regarding prohibited dyes that are carcinogenic, mutagenic or toxic to reproduction and point 23 concerning dyes potentially sensitisers) in the Decision 2002/371/EC establishing the ecological criteria for the award of the Community eco-label to textile products and amending Decision 1999/178/EC;
6. colorants listed in Tables 1 (carcinogenic colorants) and 2 (carcinogenic aromatic amines) of the recommendation of the scientific committee for consumer safety (SCCNFP/0495/01 final), adopted on 27th February 2002;
7. substances listed in Tables 1 (CMR and sensitiser aromatic amines that shall not be present or released by azo dyes in products for tattooing and permanent make-up) and 2 (non-exhaustive list of CMR and/or sensitiser substances that shall not be present in products for tattooing and permanent make-up) of the CoE ResAP(2008)1.

FR.6. Arrêté du 15 septembre 2010 pris pour l'application de l'article L. 513-10-3 du code de la santé publique relatif aux bonnes pratiques de fabrication des produits de tatouage

(Order of 15 September 2010 for the application of art. L. 513-10-3 of public health code on good manufacturing practices for tattoo products)

This order describes good manufacturing practices (GMP) for tattoo products.

FR.7. Arrêté du 23 juin 2011 pris pour l'application de l'article L.513-10-3 du code de la santé publique relatif aux bonnes pratiques de laboratoire des produits de tatouage, aux règles générales relatives aux modalités d'inspection et de vérification des bonnes pratiques de laboratoire ainsi qu'à la délivrance de documents attestant de leur respect

(Order of 23 June 2011 for the application of art. L. 513-10-3 of public health code on good laboratory practices for tattoo products, general rules on inspection of GLP)

This order describes good laboratory practices (GLP) for tattoo products, the general rules for inspection and verification procedures of good laboratory practices and the delivery of documents to prove their compliance.

GERMANY

DE.1. Tätowiermittel-Verordnung

(Order on Tattooing Products, OTP)

The "Order on tattooing products" of 2008 (last amended in July 2014), is in force since 1st of May 2009, and based on the CoE Resolution ResAP(2003)2 on tattoos and permanent make-up. It clarifies notions such as "tattooing products", "date of minimum durability", and "date of usability following opening".

Chemical requirements

Tattooing products have to comply with the principles of good manufacturing practices, and may not contain any substance:

1. listed in Annex II of Regulation (EC) 1223/2009 on cosmetics, hence including all CMR's classified before 1 December 2010.
2. that according to column g of Annex IV of Reg. 1223/2009 may only be used in rinse-off products, not be used in eye products or in products applied on mucous membranes.

In addition to 26 aromatic amines contemplated by the CoE ResAP(2003)2, the OTP bans also para-phenylenediamine (Annex 1). To the 35 colorants listed in the ResAP, the German OTP adds Solvent Yellow 14 in its Annex 2.

Labelling requirements

Manufacturers must label containers with the date of minimum durability and the period of usage following opening, mentioning also specific conditions of storage, if applicable. Labelling has to be clearly visible and indelible, in German language for most of the information. In addition to the date of minimum durability and PAO (period after opening), the label must show the batch number, name and address of manufacturer, along with the conditions of use and warnings. The list of ingredients according to INCI (preferably) or other common nomenclature, should be available. For colorants the colour index number has to be given.

Other requirements

Notification obligations: before placing the product on the market the manufacturer/importer shall provide the competent authority with the trade name and composition of the substances employed. This information is to be stored separately from other documents and may only be used for health treatment purposes.

DE.2. Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch [LFGB]

(German Food and Feed Code)

This law was enacted on 1st of September 2005, and last amended in 2012. Its main objective is to ensure the general safety of food, cosmetic and tattooing products from the human health perspective, while also protecting consumers against misleading information.

Hygienic requirements
The products have to comply with general microbiological quality requirements

Labelling requirements
The label has to contain the composition of the product and the list of ingredients. Misleading labelling of tattooing products is forbidden

Requirements for risk assessment
Tattooing products may only be placed on the market when they are safe for the human health.

DE.3. [*Landes*] Verordnung zur Verhütung übertragbarer Krankheiten bei bestimmten gewerblichen Tätigkeiten - Infektionsverhütungs-Verordnung

(Ordinance [of the Federal Länder] on the prevention of communicable diseases in certain professional activities).

These regional regulations, based on the "Infektionsschutzgesetz" (Protection against Infection Act) govern the hygiene and infection protection i.a. in tattoo studio's since the nineties.

Hygienic requirements
The tattooing instruments shall be sterile and supplied in a container which maintains the sterility of the product until application. The Ordinances set out requirements about personal hygiene, disinfection of skin (by using at least 80 % alcohol), wearing of disposable gloves, sterilization of instruments, garbage disposal, etc. Disinfection should be performed with effective means approved by Robert Koch-Institut, by the Association for Applied Hygiene, the German Society for Hygiene and Microbiology, or by the Federal Health Office; sterilization has to be carried out with steam or hot air. Sterilizers are to be checked at least semi-annually and in any case following each repair.

DE.4. Anforderungen an Tätowiermittel, Stellungnahme Nr. 013/2013 des BfR vom 28. August 2012

(Requirements for tattoo inks, opinion n° 013/2013 of the BfR, 28.08.2012)

This opinion of the Federal Institute for Risk Assessment includes recommendations on specifications for the active ingredients of tattoo inks, recommendations on exposure and safety assessment of tattoo inks, information about tattoo-related health risks, including during tattoo removal.

Chemical requirements
The BfR recommends drawing up a positive list of substances allowed in tattoo products.

Hygienic requirements
The BfR recommends products to be sterile and supplied in a container that maintains the sterility of the product until application.

Packaging requirements
Disposable packaging is favoured.

Requirements for risk assessment
The manufacturer or importer should conduct a safety assessment on tattoo inks ingredients based on recent toxicological data. The dossiers should be available to competent authorities and contain the safety data specified in the opinion, according to predefined testing methods for each endpoint. Dossiers for the assessment of tattoo inks should use as guidelines the specifications for cosmetic products (SCCS Notes of Guidance 2010).

DE.5. Suggestions for future legislation on tattoo inks

In order to ensure a high level of consumer health protection, and reflecting on their experience with the enforcement of German legislation on tattoo products, Germany suggested including the following points in any future legislation on tattoo inks.

Chemical requirements
Along the lines of CoE's ResAP(2008)1, the proposal suggests to ban 27 aromatic amines, 35 colorants, the substances listed in Annex II and Annex IV, columns 2 to 4, of Directive 76/768/EEC on cosmetics (now substituted by the EC Regulation 1223/2009), together carcinogenic, mutagenic and reprotoxic substances of categories 1, 2 or 3 which are classified under CLP Directive 67/548/EEC (now substituted by the EC Regulation 1272/2008). It also provides limits for the same 15 impurities as mentioned in ResAP(2008)1, and minimum requirements for further organic impurities of colorants used in foodstuffs and cosmetics, as set out in Directive 95/45/EEC, while setting guidance values for technically unavoidable amounts.
The development of a positive list of pigments and preservatives is encouraged, as the best way to ensure consumer health protection.

Hygienic requirements
Germany requests products to be sterile and supplied in a container that maintains the sterility of the product until application.

Packaging requirements
Germany favours one time use containers or multi use containers with a design that ensures that the contents will not be contaminated during the period of use.

Labelling requirements
According to Germany, the label should contain: batch n°, name and address of manufacturer, date of minimum durability, PAO (period after opening), conditions of use and warnings, and guarantee of sterility.

Requirements for risk assessment
Reference to the currently ongoing work on the toxicological risk assessment of tattoo chemicals and inks at the Council of Europe is recommended.
The manufacturer or importer should be responsible for providing the safety assessment report before placing the product on the market. The safety assessment should be done by a qualified person based on recent toxicological data.
The safety of the finished product should be assessed by taking all available and necessary information on each ingredient into account, including their potential interactions.

GREECE

No specific legislation is available. The implementation of the EU Regulation 1907/2006 (REACH) and 1272/2008 for the classification, labelling, and packaging of chemical substances and mixtures (CLP) was mentioned.

HUNGARY

No information was received.

IRELAND

There are currently no specific regulations enacted in Ireland for tattoo businesses in Ireland.

There are no registration requirements, no minimum structural or operational standards to be attained before opening such a business, no basic training requirements for staff and no age of consent/ medical history requirements for those availing of such services. Consequently these premises are not included in any inspection programme by Environmental Health Officers and receive no regular or routine visits from any statutory inspectorate.

However Environmental Health Officers do follow up and investigate confirmed cases of infectious disease which may have originated in such premises.

The Competition and Consumer Protection Commission (formerly the National Consumer Agency) is the authority responsible for the enforcement of the regulations which transposed the EC General Product Safety Directive into Irish legislation (General Product Safety Regulations) 2004 [SI. 199 of 2004]. Chemical safety is outside the legislative remit of the Competition and Consumer Protection Commission.

The Competition and Consumer Protection Commission as the national co-ordinator for RAPEX is responsible for ensuring that any relevant RAPEX reactions for Ireland are submitted to the European Commission.

In Ireland, the Health and Safety Authority (HSA) is the lead Competent and Enforcement Authority for REACH Regulation (EC) No 1907/2006 and CLP Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures.

ITALY

IT.1. Circolare 05.02.1998 n.2.9/156 – Linee guida del Ministero della Sanità per l'esecuzione di procedure di tatuaggio e piercing in condizioni di sicurezza

(Order of the Health Ministry 05/02/1998 no. 2.9/156 - Guidelines for the implementation of safety procedures for tattooing and piercing)

IT.1a. Circolare del Ministero della Sanità del 16.07.1998 n.2.8/633 – Chiarimenti forniti dal Consiglio Superiore della Sanità

(Order of the Health Ministry 16/07/1998 n. 2.8/633 – Clarifications of the High Council of Healthcare)

Hygienic requirements

The following hygienic requirements are compulsory:

- rooms where tattooing procedures are carried out must be separated from waiting, cleaning and sterilisation areas. In addition, there must be a clear separation between the areas intended for dirty materials and those where materials clean and sterile materials are stored. The dirty area shall contain a bath tub with hot and cold water for washing;
- wall coatings shall be waterproof and easy to clean;
- operators shall wear sterile disposable gloves and lab coat (not necessarily sterile) in all phases of the procedure, as well as mask. Use of protective glasses is suggested but not compulsory.
- tattooing and piercing shall not be made on damaged skin or mucous membranes of in case of burns,
- disposable materials shall be eliminated correctly in order to avoid accidental exposure;
- disinfection and sterilisation procedures shall be accurately performed.
- before and after each procedure, hands shall be washed accurately with an antiseptic product.

Instruments must be sterilised by heat, or alternatively, by chemical disinfection. Steam or dry heat sterilisation (121°C for minimum 20 minutes or 170°C for 2 hours, respectively) are the methods of choice for reusable instruments. Only when the above mentioned procedures are not applicable, chemical disinfection must be carried out (e.g., sodium hypochlorite 5000 ppm, or 2% glutaraldehyde). Instruments must be thoroughly cleaned before any kind of sterilisation or disinfection; in case of disinfection they shall be properly washed and dried afterwards.

Blood shall be removed and the contaminated area chemically disinfected. In case of consistent bloodshed, the contaminated area shall be covered by solid dichloroisocyanurate before cleaning and further chemical disinfection. Gloves shall be worn during these procedures.

Needles and sharp instruments shall be disposable. In the cases of instruments, such as electric tattoogun, with multiple needles the following requirements apply:

- the part on which needles are mounted shall be sterilised by humid heat;
- needles shall be disposable;
- pigments shall be non-toxic, sterile and certified by foreign or national healthcare authority; temporarily, until Istituto Superiore di Sanità (ISS) drafts a procedure for certification of non-toxicity, an auto-certification by the producer is considered sufficient.
- containers for pigments shall be small, disposable, one time use and shall be eliminated after use with one client;
- the circuit where pigments pass through shall be disposable and changed after each client.

Dirty contaminated linen shall be washed with hot water (temperature higher than 71 °C for 25 minutes) with an appropriate detergent.

Public conventions must be held in appropriate rooms, with floor and surfaces covered by easy to clean and waterproof materials. They must be authorised by the competent authority. Safety and hygienic requirements must be guaranteed. As for tattoo studios, rooms where the procedures of tattooing are carried out must be separated from waiting, cleaning and sterilization rooms. In addition, there must be a clear separation between the areas intended

for soiled materials and those where materials are kept clean and sterile. Transparent walls can be used to show tattooing activities.

Packaging requirements
In the case of instruments, such as electric tattoogun, containers for pigments shall be small, disposable, single use and shall be eliminated after use with each client.

Requirements for processes and tattooists
Tattooists and piercers shall request authorisation from the local healthcare public utility (ASL) that shall verify the existence of appropriate hygienic requirements.
Operators shall follow appropriate training on anatomy and histology of skin, ways of infection transmissions, hygiene, disinfection and sterilisation.
Clients shall be informed about the risk of infectious diseases linked to tattooing and piercing. They shall sign to give their consent.
Tattooists and piercers shall have attended school for at least 10 years and hold a certificate of participation in a regional training course for tattooists.

Other requirements
Healthcare educational campaigns, on the risks linked to tattooing and piercing, shall be organised (not yet implemented).

IT.2. Dlgs 206/2005, Codice del consumo

(Decree n 206 of 06.09.2005 "Consumer Code")
Article 105 of Dlgs 206/2005, declares that in absence of specific EU law, a product is considered safe when it complies with the national law of the country in which the product is commercialised.
Moreover, the same article states that a product is safe when it complies with the national transposition of EU law whose references have been published by the European Commission in the Official Journal.
When the aforementioned conditions are not applicable, "the safety of a product is assessed on the basis of voluntary national standards transposing European standards, European Commission recommendations, etc."
Based upon this understanding, provisions listed in the CoE ResAP(2008)1 of 20.02.2008 have been embodied as far as the chemical and hygienic requirements are concerned.

Labelling requirements

- Article 6 of Decree 206/2005 states that label should clearly indicate, in the Italian language, the following information:
  - Name of the product
  - Name and address of the manufacturer
  - Country of origin, if outside EU
  - Possible occurrence of materials or substances that may cause damage to humans or environment
  - Materials and ingredients employed for the preparation
  - Instruction and precaution for use
- CoE ResAP(2008)1 recommends to indicate the date of minimum durability, batch number and guarantee of sterility.

Other requirements (tattoo vigilance system)

Art. 107 of Decree n. 206/2005 (as well as Circ. Min. Salute n. 21911 of 2009) states that the surveillance/monitoring activities to assess the compliance with regulations and hygienic/sanitary guidelines are performed:

- on a local level by Local Health Authorities (ASL) and by Regional Environmental Protection Agencies (ARPA)
- on a national level by Carabinieri NAS (Carabinieri Healthcare Command) and by USMAF (Border Health Offices) that carry out health and hygiene controls on imported products arriving at Italian customs.

IT.3. Pronunciamento del Consiglio Superiore di Sanità (CSS) del 19 Novembre 2003

(Decision by the High Council for Health, 19th November 2003)

Other Requirements (safety requirement of instruments used for tattoo and permanent make-up)

The use of CE-marked needles and sharp instruments is preferred. If this is not possible, disposable needles and sharp accessories must be used. They have to comply with the requirements specified in the "Circolare SISIST del 17 giugno 2003 (Misure per aghi, taglienti, strumenti e sostanze d'uso per tatuaggi e piercing)". The following information should be clearly indicated on the label:

- expiry date;
- name of the manufacturer;
- sterilisation method.

IT.4. Proposals

Chemical requirements

The use of the following aromatic amines, in addition to the 27 aromatic amines listed in the CoE ResAP(2008)1, should be avoided:

N-isopropil-N'-phenylparaphenylen-diamine (IPPD, EC 202-966-7; CAS 101-72-4)
Aniline (EC 200-539-3; CAS 62-53-3)
4-ethoxyaniline (EC: 205-855-5; CAS 156-43-4)

The use of the following colorants, in addition to the 35 listed in the CoE ResAP(2008)1, should be avoided:

Pigment Violet 1 (CI: 45170:2; CAS: 1326-03-0)
Pigment Yellow 74 (CI 11741; CAS 6358-31-2)
Pigment Red 17 (CI: 12390; CAS 6655-84-1)
Pigment Red 181 (CI: 73360; CAS: 2379-74-0)
Pigment Blue 15 (CI: 74160; CAS: 147-14-8)
Pigment Green 7 (CI: 74260; CAS: 1328-53-6)
Pigment Red 5 (CI: 12490; CAS: 6410-41-9)
Pigment Yellow 1 (CI: 11680; CAS 2512-29-0)

In relation to the CoE ResAP(2008)1 recommendations, the concentration limits for metal impurities could be amended as follows:

As: 0.2 ppm; Co: 5.0 ppm (labelling: 'Contains cobalt; may cause an allergic reaction'); Pb: 1.0 ppm; Sb: 1.0 ppm; Ni: 0.5 ppm.

Candidate metals to be considered as impurities (in addition to the elements listed in ResAP(2008)1): Al (50 ppm) and Mn (1.0 ppm).

Guidance values for technically unavoidable amounts: Ni: 0.5 ppm.

Preservatives should be allowed at lowest effective concentrations, after having being proved safe by risk assessment.
The use of nanomaterial should be labelled, as established in the cosmetic Regulation 1223/2009.

Requirements for risk assessment
Risk assessment should be systematically provided before placing any product on the market, and not only upon request. Manufacturers should clearly state that only safe ingredients, based on safety data, have been used. The introduction of alternative methods to animal testing is desirable, as specified by guidelines (e.g. OECD). Risk assessment for nanomaterial should be taken into consideration.

IT.5. Legislation at a regional level
Most of the Italian regions have simply enforced the 1998 Guidelines of the Ministry of Health (refer to "IT.1."). A few of them have issued specific regional laws.

Requirements for processes and tattooists
Depending on regional laws, duration of training ranges from 14 hours to 600 hours.

Other requirement: age limits
In some regions (e.g. Tuscany) performing tattoos under the age of 14 is forbidden.

In the absence of specific legislation, the business of tattooist is disciplined by the following administrative procedure and craftsmanship joint regulations:
IT.6. Law August 7, 1990, no. 241: New rules for administrative procedure and the right of access to administrative documents (art. 19, as amended by Law 30 July 2010, no. 122 Urgent measures for financial stabilization and economic competitiveness)

IT.7. Law February 14, 1963 no. 161 Discipline for the business of barber, hairdresser and similar

IT.8. Law January 4, 1990 no. 1 Discipline for the business of beautician

Hygienic requirements
The tattoo parlours must comply with:

- D.Lgs.81/2008 (as amended by D.Lgs. 03/08/2009, No. 106) Protection of health and safety in the workplace;
- D.Lgs. 152/2006 of 03/04/2006 No. 152 Environmental Regulations (for sanitary waste);
- D.M. 28/09/1990 "Standards of protection from professional HIV infection in public and private health care facilities";
- D.M. no. 37 of 22/01/2008 "Regulation of reorganization provisions on activities regarding installation of the equipment inside the building".

Requirements for processes and tattooists
Authorisation to open a tattoo studio: the business of tattooing is subject to SCIA (Segnalazione certificata di inizio attività: auto-report of starting a business) by which compliance with regional and municipal laws and regulations is guaranteed. Tattoo parlours

should comply with the minimum structural and sanitary regional and municipal regulations. The SCIA application is presented to the municipality where the parlour is located. ASL (Local Health Unit), responsible for the area, carries out an inspection to verify and evaluate the respect of the hygiene requirements, suitability of the site of the tattoo parlour and compliance with the building regulations (environmental requirements, equipment, tools, procedures, product labeling). The municipality also assesses the professional requirements.

Other requirement: age limits

No regulation about age limits nationwide. According to art. 2 and 316 of the Civil Code (principle of legal capacity to act connected to the coming of age), it is forbidden to perform tattoos to customers under the age of eighteen without the informed consent of the parents or guardian.

LATVIA

LV1. DRAFT regulation on the hygiene requirements for the provision of tattooing and piercing services and special requirements for tattoo inks

This draft legislation is based on Article 38 of the Epidemiological safety law, on Article 21 of the Consumer rights protection law and on Article 8 of the Law on the safety of goods and services. It covers hygiene requirements for tattooing process, and sets out the special requirements for tattoo inks.

Chemical requirements

Based on the recommendations of the CoE Resolution ResAP(2008)1, this Regulation bans the same 27 aromatic amines, 35 colorants and puts limits for 15 impurities. It also bans substances specified in Annex II and Annex IV (column g) of EU Cosmetic Regulation 1223/2009, together with the CMR's listed in Annex VI, Table 3.1 of CLP Regulation (EC) No 1272/2008. However, tattoo inks may contain an admixture of the banned substances by this regulation if, in compliance with good manufacturing practice, this admixture cannot be avoided.

Hygienic requirements

Tattoo inks must be sterile. If they are placed in a reusable container, it must be ensured that the ink is not contaminated during use.

The service provider shall prepare a plan for the maintenance, disinfection and sterilisation of premises, equipment and tools. He will keep records on the disinfection and sterilisation of reusable tools, also carrying out quality checks. The microclimate, ventilation, lighting, auxiliary rooms for the staff shall meet the requirements of the regulations on health and safety at work. Premises shall have

1. a customer area separated from the place where the Service is delivered;
2. a room equipped with hand-washing facilities where tools and equipment are disinfected and sterilised;
3. an household sewage system;
4. a first aid kit.

Premises shall be cleaned at least once a day. The toilet shall be cleaned using appropriately marked equipment. Surfaces which come in touch with blood shall be disinfected after each customer use.

The service provider shall maintain personal hygiene and wear appropriate work clothes. Before the procedure, he shall disinfect customer's skin. He will disinfect his hands before

and after the service delivery. If contact with damaged skin, blood or other bio fluids cannot be avoided, disposable gloves shall be worn.
The couch or chair shall be covered with a disposable sheet. For each customer, an individual set of disposable towels and sterile needles shall be used. Reusable tools shall be cleaned and disinfected, and if they come into contact with the internal tissues of the body, blood or other bio fluids (high infection risks), they shall be appropriately sterilised, ensuring the removal of viruses (hepatitis B, C, HIV) and bacteria (e.g. tuberculosis). The disinfected and sterilised tools shall be kept separately from the used tools. There shall be at least two sets of tools ready for work.
Waste is collected in accordance with the regulations on waste management. Used linen and disposable tools which have come into contact with blood, or body tissues shall be collected and stored in a closed waste bin. Used disposable sharps shall be discarded after use in a special container.

Labelling requirements
Tattoos inks containers shall indicate batch number, name and address of manufacturer or importer, expiry date (with appropriate storage conditions), instructions and precautions of use, list of ingredients according to usual name (IUPAC, INCI, CI,…).

Requirements for processes and tattooists
Tattooist is a regulated profession subject to recognition by a training certificate, to be renewed every 5 years.
The service provider shall inform the customer on the tattoo inks, wound care, healing times and potential complications, for example, allergic reactions, inflammation, bacterial or viral infections, and possibilities of removing tattoos. Before treatment, the information on the tattoo inks shall be issued in written to the customer, who will fill in a questionnaire. Tattooing damaged skin is allowed only if the customer produces a medical certificate. Parental consent is mandatory for clients under 18.

LITHUANIA
No information was received.

LUXEMBOURG
There are currently no specific regulations.

LU.1. Règlement grand-ducal du 1er décembre 2011
(Grand Duchy Regulation)
The scope of this regulation is to specify necessary criteria for practising some liberal professions. A diploma for hairdresser, beautician or manicurist is required to open a tattoo studio.

Requirements for processes and tattooists
See above (diploma).

MALTA
MT.1. Control of tattooing act (CAP. 270)

In force since 1976, and amended in 1983, this Act states the requirements to be met by tattooists.

Requirements for processes and tattooists
An annually renewed licence is compulsory for tattooing (or possession of any tattooing instrument and colouring material). The premises are subject to inspection.

Other requirements
A tattoo may be placed only on people above the age of 18.

MT.2. Tattoo Studios and Tattooing (Conditions) Regulations, L.N. of 2011
Based on Article 8 of Control of Tattooing Act (Cap. 270), these Health Ministry regulations of 2011 bring more details on the requirements the tattooists have to comply with.

Chemical requirements
Colors are to be bought from reputable suppliers and shall be traceable at all times.

Hygienic requirements
The premises shall conform with sanitary and safety laws, clean and disinfected between each customer. The tattooing area must include: hot and cold running water with foot/elbow operated taps, soap, disposable paper towels or hot air dryer. Sharp and other waste items are to be disposed of by means of a waste collector registered with the competent authority.
The tattooist must prevent the risk of transmission of any infection by strictly observing the basic rules of hygiene. He must be vaccinated against Hepatitis B, and free from any infectious disease. Should he have a cut or abrasion or any type of skin infection, this must be completely covered with a water proof adhesive bandage. For each customer, he shall use new disposable surgical-type gloves, needles and sharps, fresh colours and disposable pigment containers. Skin must be washed and disinfected before the procedure. If some cream is used it should be applied out of a tube or a fresh pot for each customer using a disposable spatula. All other not disposable instruments must be sterilised by Type B vacuum autoclave exclusively. No instrument should be autoclaved if coated with ointment. Once tattooing is complete, the wound is to be disinfected and covered with a sterile dressing.

Packaging requirements
One-time use container is mandatory.

Requirements for processes and tattooists
The tattooist shall attend any training organised by the Health authorities. If the tattooist wishes to train an individual, he shall obtain prior approval from the Health authorities. The Authorities will publish the list of licensed tattooists' studios. The licensee shall provide the Authorities with all information about the staff he employs. For each client, the tattooist must keep a confidential record pertaining to all patient's medical details, and a brief description of the applied tattoo. These data are open to inspection by the authorised officer

Other requirements
No tattooing is allowed on the face, palms and back of hands. The tattooist must ensure that the client is of sound mind and is not under the influence of alcohol or any drugs. He shall give him written after-care guidelines.

POLAND

No specific legislation is available. An act implementing the General Product Safety Directive can be applied concerning labelling requirement.

PORTUGAL

No specific legislation is available.

ROMANIA

RO.1. Order n° 1136/2007 on the hygiene standards for the cabinets of body beauty, (OJ of Romania n°484/2007);

This Order states the requirements to be met by tattooists.

Hygienic requirements

Pigments for use are put into sterile disposable plastic or rubber caps for each client. Remaining non utilized pigments and opened caps are thrown away after the procedure.

The tattooing premises should access only to the operator, the customer and health professionals, and must have separate enclosures, as follows:

a) in the reception area, all licenses necessary to conduct tattoo business Order 1136/2007 of the Minister of Public Health dermal implant, information and warnings must be visibly displayed;
b) working space for tattooing activities must have a minimum area of 6 m² by working module. Working modules must be separated by partition panels. There should be a minimum of 22 °C and enough lighting necessary to carry out the work under optimal conditions, air conditioning and fan; module for conducting the tattooing activity shall include: sofa-bed for client, work table for pigments and compartments for tattooing materials, operator chair, specific instruments and materials for this activity, boxes, and disinfectant for used instruments ,unit for biting and cutting materials, hazardous waste container;
c) space for sterilization of tools, and related activities (washing, decontamination, packaging and storage) must comply with the provisions of Order No. 1338/2007 of the Ministry of public health for the approval of medical and dental offices, and provisions of Order no. 261/2007 of the Ministry of public health for the approval of Technical Norms on cleaning, disinfection and sterilization in hospitals;
d) space for storing equipment and materials used for cleaning.

Work surfaces must be cleaned and disinfected according to legal provisions respecting times and concentrations recommended by the manufacturer

Labelling requirements

Pigments and dyes containers' label shall identify manufacturers, importers or distributors, pigment brand, code and colour name, batch number, date of manufacture and expiry date, plus test reports issued by accredited laboratories. It shall include conformity certificates as regards the chemical composition, quality certificates issued by the manufacturer, and the following warning: "Some people may experience allergic reactions to this product".

Requirements for processes and tattooists

A sanitary tattoo license is mandatory following an evaluation procedure in accordance with the Order 1030/2009

Before treatment, the operator must fill-in the self-declaration, and inform the client both verbally and in writing on after treatment personal hygiene, skin care and prophylaxis to reduce the risk of infection. He should warn the customer to contact the operator and a medical professional at the first sign of inflammation, bleeding or possible infection;
Tattoo removal by the operators is prohibited; tattoo removal will be done only by qualified medical personnel, in medical units.

Other requirements
Tattooing is forbidden on persons less than 18 years. Between 16 and 18 years tattooing is allowed if the accompanying parent or guardian approves in writing.
It is forbidden to perform tattooing on people suffering from diabetes, haemophilia, heart disease, skin diseases, skin lesions or skin sensitivity to soaps, disinfectants and other cosmetics, allergic reactions to pigments, dyes or other skin sensitizers, lipothymic states, epilepsy, stroke, narcolepsy, immune deficiencies, keloid scars, mentally disabled, hepatitis, seropositive (AIDS), blind (even if accompanied), pregnancy, breastfeeding.
Warnings shall be visibly displayed.
Cabinet holders shall report by written to public health authority in case of allergies or infections, communicable diseases, accidents, hospitalization of a client as a result of services provided by the operator.

RO.2. Annex 2 : Hygiene standards for services in piercing and tattoo offices
is based on Health Ministry Order n° 1136/2007, and provides further details on tattooist's requirements.

Hygienic requirements
Before carrying out a tattoo, an allergy test for the dye to be used is mandatory. The skin shall be shaved with a disposable razor, cleaned and disinfected with a biocidal product using a sterile swab. Patterns of paper, and other devices and substances applied to the skin of the customer in order to transfer the design of the mold must be disposed after each client;
The operator must use instruments and work equipment, which are clean and disinfected or disposable, caps that completely cover the hair, face and eye. The operator must use surgical sterile gloves. Cotton towels are not allowed for use as protective equipment. Cleaning, disinfection and sterilization of reusable instruments shall be performed only by trained personnel, in a different place than the working room.

Requirements for processes and tattooists
Operators must provide proof of graduation from basic notions of hygiene, first aid and specialized course, except for health professionals. Organization of professional training and certification of persons, deals with knowledge of hygiene, body care services and first aid.
Before starting tattooing procedure, the client is informed of the possible risks arising from the procedure, on hygiene measures to be taken after the procedure and on other technical details about treatment. Written warning obliges the client to inform the operator who performed the tattoo, and a medical professional, of the first signs of abnormal inflammation, bleeding, delayed healing or possible infection.
Each applicant for tattoo operation must sign a self-declaration. The self-declarations for tattooing procedures and records related to customers, and details regarding the procedure, including a photo of the tattoo and unpleasant consequences, are kept by the operator for 2 years, in conformity with Law no. 677/2001 on the protection of personal data.

If the tattooing requires a period longer than 4 hours, it will be done over several sessions and it will continue until the old wound is healed.

SLOVAKIA

SK.1. Act N° 355/2007 Coll. from 21 June 2007 on Protection, Support and Development of Public Health

This Act is enforced since September 2007.

Chemical requirements

Slovak Health Authority checks tattoo inks according to Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up when these products are notified through RAPEX.

Hygienic requirements

Basic requirements on tattoo studios include requirements of a building-technical design, layout, equipment and internal arrangements. An entrepreneur who operates facilities for human body care is obliged to use such working procedures, instruments, working tools, devices and preparations to prevent a threat or damage to health when providing the service. He should have a first-aid kit at disposal and inform the customer on the risks connected with the service provided.

Requirements for processes and tattooists

Tattoo studio owner can start to operate only after assessment by respective regional public health authority (Assessment activity) and approval of the operational instructions he submitted. There is no national register of authorised tattoo studios, but regional public health authorities have a list of tattoo studios which were opened in their respective region.

Other requirements

The operator of a facility of human body care and his employees are not allowed to carry out operations on scars, birthmarks, eye conjunctiva and cornea, or ears.

SK.2. Ordinance of Ministry of Health No. 554/2007 Coll. on requirements on facilities of human body care

Hygienic requirements

Detailed requirements on tattoo studios are mentioned in this Ministry Ordinance of 2007, such as requirements for construction-technical solution, layout of premises, equipment and internal division of facilities, requirements for working procedures, devices, working tools, requirements for operation of a facility and in terms of equipment operation. Basic hygiene requirements imply the facility must be a closed entity, separated from other premises not related with facility operation; there must be secured day lighting, artificial lighting, heating and ventilation; supply of drinking and hot water. Floors must be easily washable, smooth, non-slip and without cracks.

Other requirements include waste disposal, wet mechanical cleansing and disinfection of working surfaces. Areas of facilities coming into direct contact with the body of customer must be washed and disinfected after each customer.

Disinfection may be performed only with registered biocides, according to manufacturer instructions. In a facility only disposable working tools can be used or multiple use working

tools which can be easily washed, disinfected and sterilized. Working tools for multiple use must be washed with hot water and detergent after each customer, and dried off. Working tools which harm the skin must be disinfected and sterilized. Kind of sterilized tools, sterilization parameters and date of sterilization must be recorded into the sterilization diary. In customers suffering from skin diseases, working tools must be thoroughly disinfected after use. Customer must be warned about possible contraindications and health risks, and he must be provided with corresponding health protection means.

SK.3.Ordinance of Ministry of Health No. 585/2008 Coll. on prevention and control of communicable diseases

Requirements for processes and tattooists

Workers providing tattoo services must be certified as professionally competent by regional public health authority, possess competence in health matters, proved by certification issued by a physician.

SLOVENIA

SI.1. Rules on minimum sanitary and health requirements for hygiene care and other similar establishments

(References: Official Gazette of the Republic of Slovenia, No.104/2009, http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV5449)

In force since January 2010, this rules are based on Act on technical requirements for products and conformity assessment (OG No. 99/04), General product safety act (OG No. 101/03), and Communicable diseases act (OG No. 33/0&). They set minimum sanitary and health requirements for i.a. tattoo and piercing establishments. Article 30 states that tattoo products must be safe for consumers.

Chemical requirements

They are the same as in in ResAP (2008)1. Preservatives are allowed only after appropriate safety assessment and in the lowest effective concentration.

Hygienic requirements

Products shall be sterile and supplied in a container which maintains the sterility of the product until application. Hygienic requirements applying to tattoo studios are the same as those for all care establishments. Sterilisation of the instruments and skin disinfection must be carried out by the tattooist in conformity with the hygiene regulations laid down by the Ministry for health and good hygiene practices. There are provisions for cleaning, use of gloves, hygiene training of staff, waste handling, …

Packaging requirements

The design of multi-use containers should ensure that the contents will not be contaminated during the period of use.

Labelling requirements

The following information shall be written on the label: batch number, name and address of manufacturer, date of minimum durability, guarantee of sterility, conditions of use and warnings, list of ingredients according to IUPAC name, CAS or CI number.

Requirements for processes and tattooists

Tattooists need to register their business (but anyone can apply). The tattooist must provide the consumer with complete and comprehensible information on the risks entailed by those practices, including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications.

Requirements for risk assessment

Before placing tattoo products on the market the producer/importer must carry out a human health safety evaluation of the final product, based on recent toxicological and safety data, and make the file available to competent authorities.

Other requirements

Parents' or guardian's permission is required for children under 15 years.

SPAIN

ES.1. Real Decreto 1599/1997 sobre productos cosméticos

(Royal Decree 1599/1997 on cosmetic products)

The Royal Decree collects all the regulations on cosmetics existing in Spain and at the same time transposes Directive 93/35/EEC (6th amendment of the Council Directive 76/768/EEC) related to cosmetic products, as well as Commission Directives 95/17/EC on the inclusion of one or more ingredients for the labelling of cosmetic products, and 97/18/EC.

ES.2. Real Decreto 2131/2004 (por el que se modifica el RD 1599/1997) sobre productos cosméticos

(Royal Decree 2131/2004 (amending Royal Decree 1599/1997) on cosmetic products)

This amendment of the Royal Decree 1599/1997, transposing the provisions of Directive 2003/15/EC, regulates the term of use of cosmetics after opening with the introduction of a symbol indicating the durability of cosmetic products.

This Royal Decree has been in force since 2004.

Labelling requirements

For cosmetic products, a date will indicate a period of time after the opening of the product in which it can be used without any risk to the consumer. This information shall be indicated by a symbol showing the durability of cosmetics products after the opening date given in Annex VIII bis and followed by the period in months and/or years.

ES.3. Real Decreto 209/2005 (por el que se modifica el RD 1599/1997) sobre productos cosméticos

(Royal Decree 209/2005 (amending Royal Decree 1599/1997) on cosmetic products)

In this Decree, enforced since 2005, tattoo inks and permanent make–up are explicitly mentioned and after entry into force of this amendment of RD 1599/1997, the products used for tattooing and PMU are to be considered under the Spanish legislation 'personal hygiene products' and consequently regulated by the already mentioned Royal Decree and its amendments.

Labelling requirements

The label shall contain the list of active ingredients with the indication of their respective quantity, together with the registration number of the product. The Spanish Agency for Medicines and Medical Devices (AEMPS) may require labelling indications for correct product use and risk prevention.

Other requirements

The products shall be authorised by the AEMPS for a period of five years, renewable. This Agency may require testing results, data or evidence to toxicologically evaluate the product safety in relation to human health.

ES.4. Consejo Interterritorial del Sistema Nacional de Salud 2003 and regulación of regiones autónomas sobre las condiciones higiénico-sanitarias de los establecimientos de tatuaje y piercing

(Inter-regional Council of the National Health System 2003 and regulations of autonomous regions, establishing the hygienic requirements of tattoo and piercing parlours)

This document describes the technical requirements and sanitary conditions of tattoo and piercing shops.

Hygienic requirements

All products used in the tattoo shops have to be sterile and disposable. There are hygienic requirements for tattoo studios and staff. Sterilisation and disinfection of the instruments must be carried out by the tattooist in conformity with the procedures described in Annex I.

Tattooists have to use disposable medical gloves and specific clothes. Moreover it is recommended that the tattooists are vaccinated for Hepatitis B and tetanus.

The sanitary controls are performed by the municipalities.

Annex I describes the sterilization methods for all the materials used in the tattooing process.

Requirements for processes and tattooists

The waste products management shall be conducted according to the requirements of the national legislation.

Other requirements

A minimum age for having a tattoo is not always indicated as 18 and in some regions the parents' permission in the case of minors or disabled people is necessary.

ES.5. Real Decreto 944/2010 (por el que se modifica el RD 1599/1997) sobre productos cosméticos

(Royal Decree 944/2010 (amending Royal Decree 1599/1997) on cosmetic products)

This law, in force since 2010, adapts the cosmetic products legal provisions to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Chemical requirements

Substances classified as carcinogenic, mutagenic or toxic for reproduction belonging to the categories 1A, 1B and 2, are forbidden in cosmetic, tattoo and PMU products. Nevertheless, a substance classified in category 2 may be used in cosmetics if, after being evaluated by the Scientific Committee on Consumer Safety (SCCS), it is considered acceptable for use in cosmetic products.

ES.6. AEMPS (Agencia Española de medicamentos y productos sanitarios). Solicitud de autorización de comercialización para productos de higiene personal (instrucciones y formularios)

(AEMPS (Spanish agency of medicines and medical devices). Application for marketing authorization for personal hygiene products (instructions and forms)
This recommendation is based on the CoE ResAP(2008)1.

Chemical requirements
Products for permanent make-up and tattoos must be provided with a certificate of compliance with the specifications detailed in paragraph 3 of the CoE ResAP(2008)1 and consequently according to this document the same chemical requirements of the above mentioned resolution apply.

Packaging requirements
All the containers for permanent make-up and tattoo inks shall be single use.

Labelling requirements
Labels for PMU and tattoo inks, should contain warnings and information, such as sterile product, for professional use only, single use (disposable) product. Furthermore, an allergy test has to be performed before the utilisation of the product.

SWEDEN

SE.1. Regulation on tattoo ink (Government SFS 2012:503)

In force since 1st of August 2012, this Regulation is based on the CoE ResAP(2008)1 and on the Swedish Environmental Code. It refers to concepts such as tattoo ink, or sterility.
Manufacturers, importers or professionals selling tattoo ink must notify the Medical Products Agency, and instantly if new data show CMR concerns. The Agency will hold a national products register.

Hygienic requirements
Products shall be sterile and supplied in a container which maintains the sterility of the product until application.
The tattooist must inform (also in writing) customers of the inks used on them.

Labelling requirements
The professional who puts a tattoo ink on the market shall ensure that all information on safety matters necessary to protect human health and environment is easily legible on the packaging and container.

SE.2. Ordinance on tattoo ink (Medical Products Agency LVFS 2012:25)

In force since 1st of February 2013, this Ordinance is based on Regulation (SFS 2012:503), setting out the requirements for tattoo inks used in Sweden, and defining the concept of "Manufacturer".

Chemical requirements
This Ordinance bans the same 27 aromatic amines and 35 colorants as those listed in the CoE ResAP(2008)1, and sets out limits for the same 15 impurities. There are also minimum

requirements for further organic impurities in colorants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC, while impurities which are technically unavoidable are allowed if the ink is considered safe. The Ordinance further bans substances listed in Annex II to Cosmetics Regulation (EC) No 1223/2009, and those listed with restrictions in column g of Annex IV of the same EC Regulation. It also bans CMR's in categories 1 or 2 according to Annex VI to CLP Reg. (EC) No 1272/2008.
Preservatives can only be used following a safety assessment and only in the lowest effective concentration to ensure safe use after opening but not to compensate for poor hygienic conditions.

Hygienic requirements
Products shall be sterile and supplied in a container which maintains the sterility of the product until application. Inks shall meet the sterility requirements of the European Pharmacopoeia.

Labelling requirements
A tattoo ink shall bear the instructions for safe use and the information necessary to protect health and environment, in particular: the batch n°, the name and address of Swedish manufacturer or importer to Sweden, date of minimum durability, PAO (period after opening), warnings (at least those linked to limits of impurities, such as Nickel), list of ingredients according to IUPAC name, CAS number or colour index number, guarantee of sterility. Labelling provisions on tattoo inks have to be transmitted in writing by the tattooist to the customers (including the inks' properties), and are also available in the Swedish National Chemicals Inspectorate (KEMI) regulations and in CLP Regulation (EC) No 1272/2008. Certain labelling information must be in Swedish or English.

Requirements for risk assessment
If preservatives are used, a safety assessment of this use shall be done.

Other requirements
Notification to the products register shall be made, at the latest, one month after the tattoo ink is placed on the Swedish market.

SE.3. Ordinance (AFS 2005:1) on microbiological work risks, contamination, toxic effects and sensibilisation (Swedish Work Environment Authority)

In force since 1st of June 2005, this Ordinance deals with activities where contaminants or other biological agents might cause health issues or microbiological work risks by lack of sterility.

Hygienic requirements
Risk assessment of microbiologic concerns shall be made at the workplace.
Precautionary measures in terms of area, interior decoration and equipment used, must be adopted to avoid contamination. The tattoo studio owner shall ensure that every employee has proper training and knowledge about biological agents, and on how to handle sharp objects and contaminated materials.

Requirements for processes and tattooists
Special training is needed for those exposed to human body liquids.

SE.4. The Swedish Environmental Code Ds 2000:61

The Environmental Code is a major piece of legislation dating from 1999. The Code contains 33 chapters comprising almost 500 sections. However, only fundamental environmental rules are included in the Environmental Code, while more detailed provisions are laid down in Government ordinances.

Chemical requirements

Chapt. 2 provides for risk reduction in general, requiring the choice of less hazardous products.

Chapt.14 states that chemical products that are manufactured in or imported into Sweden shall be listed in a product register.

Hygienic requirements

Chapters 2, 9, and 26 provide for general precautionary measures to be adopted by the company operator in order to prevent harming human health.

Labelling requirements

Chapter 14 requires manufacturers or importers of chemical products to label their products in order to protect human health or the environment. (Law 2000:119)

Requirements for processes and tattooists

According to the precautionary principle (Chapt. 2), all business owners must have proper knowledge of what is required to protect human health and environment.

Requirements for risk assessment

Chapter 14 imposes that professional users and importers of chemical products supply authorities with any information about the products and their handling in order to assess the associated health risks.

SE.5. General guidance on professional hygienic activities (from the National Board of Health and Welfare) SOFS 2006:4

This guidance is intended to professionals performing hygienic public activities such as tattooing.

Hygienic requirements

Products shall be sterile. The guidance establishes rules for working hygienically in tattoo studios, in particular regarding the design of the working area, the appropriate disinfection of instruments, etc.

Packaging requirements

The Guidance lays down general principles to avoid microbial contamination of products.

Requirements for processes and tattooists

The tattooist should provide the consumer with all information on the risks entailed by these practices, including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications

SE.6. Ordinance (1998:899) concerning Environmentally Hazardous Activities and the Protection of Public Health (Government)

Based on the Swedish Environmental Code, in particular its chapter 9 on the need to protect public health, this 1999 law (revised in 2002) contemplates all activities in relation to environmental hazards.

Requirements for processes and tattooists

6 weeks prior to commencing operation, anyone who intends to offer hygienic treatment to the general public shall notify the municipal board

SE.7. Regulation (SFS 1998:901) on the control issued by the activity holder

This 1999 regulation sets out requirements for all professional activities that need to notify prior to commencing operation.

Chemical requirements

A list of all chemicals used within the activity shall be established

Hygienic requirements

The Regulation states general hygienic requirements for studios, tools, personal hygiene, etc.

Labelling requirements

The person operating an activity shall list all chemicals handled that could constitute a risk for the health or the environment, with the following data: 1, The product name, 2, The amount used, 3, Data on the environmental and health risks of the product, 4, the classification of the product concerning health and/or the environment.

Requirements for processes and tattooists

The tattooist should provide the consumer with all written information on the risks entailed by those practices, including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications.

THE NETHERLANDS

NL.1. Warenwet

(Commodities Act), article 24

In force since 1935, the Commodities Act states the requirements to be met for preventing food and consumer products to endanger the health or safety of consumers. Since 2007 the Act contains further requirements concerning hygienic standards, monitoring and age-limits for placing a tattoo or piercing.

Hygienic requirements

A Dutch monitoring system (CESES, Consumer Exposure Skin Effects and Surveillance) registers all undesirable reactions as well as other allergic reactions caused by cosmetics.

Requirements for processes and tattooists

A licence is compulsory for using tattooing instruments in commercial activities. A public website (www.veiligtatoeërenenpiercen.nl) lists all Dutch licensed studios, with additional information about the risks, aftercare treatment/instructions of tattoos, age limits, etc.

Other requirements
A tattoo may be placed only on people above the age of 16, and is strictly forbidden to children younger than 12. Between the age of 12 and 16 years, tattooing is only allowed with permission and presence of a parent or legal guardian during the sitting in the tattoo shop.

NL.2. Commodities Act Decree on tattooing and piercing
Based on the Commodities Act, this Decree of 21 March 2007 defines some concepts such as tattooing, or entrepreneur, and a hygiene guideline for the safe use of tattooing materials (Safety code.). It does not apply in cases where tattoo materials are used by a medical doctor.

Hygienic requirements
An entrepreneur holding a license from the Minister must comply with the hygiene measures of the Safety code. He ensures that tattoo materials are used without putting people's safety or health at risk in terms of room condition and staff hygiene. Such activity is forbidden if the client has undergone an injury or skin diseases.

Requirements for processes and tattooists
The licence delivered by the municipal health service upon inspection of the tattoo studio, is valid for 3 years. Written information about the possible consequences of applying a tattoo has to be provided to the customer, together with after care instructions.

Other requirements
People younger than16 years may not be tattooed on the head, neck, wrist or hands.

NL.3. Ministry Regulation on the use of tattooing/piercing materials (23.05.07, n° VGP/PSL 2770998)
Based on the Commodities Act Decree on Tattooing & Piercing, this regulation is in force since 1st of June 2007, and defines concepts like Municipal health service (GGD) or license.

Requirements for processes and tattooists
This regulation explains the application procedure for getting a license to tattoo. A public website lists all registered entrepreneurs. Before the materials are used, the studio owner provides the client (or his legal guardian) with written information on possibilities of infection and other complications, aftercare wounds and risks of using these materials when there are already underlined health problems.

NL.4. Commodities Act Decree relating to Tattooing Dyes
Based on the Commodities Act, this Decree of 14/08/2003 is in force since September 2003. It contemplates tattooing dyes & pigments, and defines concepts like "sterility" or "holder".

Chemical requirements
Only tattoo products that do not pose a risk to human health or safety may be traded, according to chemical and microbiological testing methods to be specified.

The 22 aromatic amines listed in Annex I and the 36 colorants listed in Annex II of this Act Decree are banned from tattoo inks. The substances, specified in Annexes II and IV (column g) of the Cosmetics Regulation 1223/2009/EC, are banned as well. In conformity to the CoE ResAP(2003)2, the Dutch legislation does not mention limits for impurities. CMRs of categories 1A, 1B or 2, listed in Table 3.1 of Annex VI of Regulation (EC) no. 1272/2008, are banned; so are the preservatives.

Hygienic requirements
The Decree provides the tattooing products shall be sterile according to analytical methods MIC01-WV154; MIC01-WV121; MIC01-WV124; MIC01-WV155

Labelling requirements
The label must contain the batch n°, the name and address of manufacturer/importer, the best-before date, list of ingredients, and instructions for use and warnings.

NL.5. Tattoo hygiene guidelines

These guidelines enforced since June 2014 were developed by the National Centre for Hygiene & Safety (LCHV).

Hygienic requirements
They include general hygiene measures that an entrepreneur must take before, during and immediately after placing a tattoo, such as sufficient hand hygiene and personal protective equipment, e.g. protective gloves that meet standards EN 420, 455 and 374. Hand disinfectants should be approved by the Board for the Authorization of Plant Protection Products and Biocides (CTGB).
The guidelines set out the principles for safe practice regarding cleaning instruments, inks and needles; sterile packaging before and during tattooing; the safe disposal of contaminated materials and sharps; and providing instructions for safe aftercare. All sterile products in stock in a studio must be labelled with a date.
A special chapter covers the cleaning, disinfection and sterilization of surfaces and materials with a dedicated, registered product. Sterilizing used needles is not permitted, they should be collected in a UN approved needle container, categorized as ‘hospital waste’, and as such to be disposed at approved collectors. Sterilizing instruments by steam (autoclave) requires the tattooist to hold a special license, otherwise he must use disposable materials or outsource the sterilization process.
A third chapter is dedicated to building, equipment and furnishings of the working space.
The treatment room has to be smoke-free. No animals are allowed in. No alcohol or drug consumption before or during the procedure. Do not eat or drink in the treatment room or during the tattooing. Do not tattoo the same area within six weeks. Ensure there is always someone present in the studio that has a First Aid certificate. Vaccination against hepatitis B is strongly recommended.
The tattooist should determine whether the customer has allergies, skin infections or swellings. A tattoo can be placed on a birthmark, mole or damaged skin only after permission from a physician. Using aftercare cream to treat the wound can only be done with a cream listed in the positive list of the LCHV.

Requirements for processes and tattooists
Do not tattoo a customer if they are pregnant or under the influence of alcohol or drugs. Before placing a tattoo, written information about the risks of infection and aftercare

instructions about the tattoo wound are to be handed out to customers, which shall be advised to seek medical assistance in case of a complication.
The customer, or his legal guardian for children younger than 16, has to sign the consent form. A copy of it is to be kept confidentially for at least two years. Local anaesthetic cannot be imported or sold by the tattooist.

UNITED KINGDOM

No information was received from the National Competent Authority. What is reported hereafter is based on:

- a comparison of guidelines and regulatory frameworks for personal services establishments performed in different countries (USA, Canada, UK) in July 2010;
- "Tattooing and body piercing guidance toolkit", issued by the Health and Safety Laboratory (HSE) in 2013.

a) Regulatory Authority and Guidelines

- Public Health Laboratory Service (PHLS) Communicable Disease Surveillance Centre / London School of Hygiene and Tropical Medicine (Dr. Norman Noah).
- Local Government Act 1982, Part VIII Acupuncture, Tattooing, Ear-Piercing.
- Local Government Act 2003 (Section 120 and Schedule 6). Byelaws are for use by local authority environmental health officers (EHOs) to aid enforcement.
- Tattooing of Minors Act 1969.
- Tattooing and body piercing guidance Toolkit (The Health and Safety Laboratory 2013).
- Public Health (Control of Disease) Act 1984 (as amended) together with the Health Protection (Local Authority Powers) Regulations 2010 and the associated provisions.
- Under the Health and Safety at Work Act (1974), employers should ensure that all their employees are appropriately trained in the procedures necessary for working safely. They must also pay for protective measures such as immunisation.
- Employers are also required by the Control of Substances Hazardous to Health Regulations 2002, known as COSHH, to review every procedure carried out by their employees which involves contact with a substance hazardous to health, including pathogenic micro-organisms. Specific guidance is available from the Department of Health (Department of Health, 1998).
- Regulation 3 of the Management of Health and Safety at Work Regulations 1999 (Health and Safety Executive, 2008) requires every employer to make a suitable assessment of risks to the health and safety of their employees.
- The Control of Substances Hazardous to Health Regulations 2002 requires that a specific risk assessment is carried out by employers or self-employed persons who work with substances hazardous to health, including biological agents which can cause communicable diseases. Therefore a specific risk assessment in respect of infection control is necessary for all persons undertaking tattooing activities. Businesses employing less than 5 people do not have to record the findings of this risk assessment, however they still have to satisfy regulatory officers that their risk assessment is suitable.
- In 2012 the Department of Health published the “Safe Management of Healthcare Waste” to put English waste legislation in line with Europe.

b) Enforcement, Training & Licensing

- There are no nationally recognised training courses, standards for practice, agreed knowledge and skills frameworks or arrangements for monitoring professional competence.
- All who practice tattooing must register with health and local authorities.
- Local Authorities have power to make bylaws (e.g. sanitation, facilities, operators) and regulate registrants.
- The tattoo premises owners have a duty to ensure that persons working on their premises are competent and that they carry out their work in a safe manner. The only way they can do this is to assess the practitioners and monitor their activities to ensure they have carried out their own risk assessment, as they are required to do by law, and that they are following control measures they have identified. The business owner has the ultimate power to remove the risk, by stopping particular contractors working at their premises.
- Everyone providing treatments to clients should carry out standard principles for infection prevention and control (National Institute for Health and Care Excellence 2012). To that end they should have received training in: hand hygiene and skin care, the use of personal protective equipment (PPE), sharps management and management of exposure to blood and body fluids, safe handling, storage and disposal of waste materials, and cleaning and disinfection of the environment.
- Amendments of Local Government Act 2003 give powers to local authorities in England (outside London) and Wales, allowing them to require businesses providing tattoo services to register with the local authorities and observe bylaws.

c) Specifics and Highlights

- Minimum age of consent for tattoos is 18 years.
- The practitioner has to make sure that a fully 'informed consent' procedure is adopted, by gathering information from the client about their health and suitability for the treatment, and giving the client enough information about the possible complications that could arise from the treatment for them to make their own decision.
- Operators should be trained in giving aftercare advice.
- Those at risk of blood/body fluid exposure through sharps or splashes should have a full course of hepatitis B vaccine.
- Hand rubs should conform to the standard BS EN 1500.
- Reusable stainless needles must be cleaned with ultrasonic, then autoclaved; chromium plate needles are single use only.
- Used needles should be disinfected before discarding, with flame, autoclave, boiling, or hypochlorite solution soaked for 30 min.
- All non-sharp waste (paper towels, tissue, ink capsules) should be sealed in plastic and autoclaved or incinerated.
- All gloves used for direct client care must conform to current EU legislation (CE marked as for single use) plus EN 374 -1:2003 or EN 374-2. Only PPE meeting the basic health and safety requirements of the EC Personal Protective Equipment Directive requirements is entitled to carry a CE mark.
- Gloves should be changed when punctured or contaminated.
- Ultrasonic equipment should be used with lid to prevent formation of aerosol and requires periodic functional testing.
- Bleach used for disinfection should state chlorine activity on label.

- Hot ovens, water boilers, UV light, or glass bead sterilisers must not be used for sterilisation.
- Standards for sterile packaging (BS EN 868-4:1999), and indicators (ISO 11140 part 1).
- All 'sharps' must be handled and disposed safely and with extreme care. After use they should be placed immediately into yellow sharps containers, compliant with UN3291 and BS7320 standards.
- Ink products should be sterile and inert at first use.

d) Gaps and Potential Hazards
- Gloves are not required for tattooing.
- Re-sterilisable tattoo needles are permitted.
- Use of unpackaged items in bench top steam sterilisers present risk of post-sterilisation contamination.
- Use of pens for marking skin is a risk for cross-contamination.

Summary

The situation varies broadly across the EU Member States.

1. Belgium, France, Germany and The Netherlands have a specific legislation in place, based on the CoE ResAP(2003)2, whereas Spain, Slovenia, and Sweden adopted the principles of the CoE ResAP(2008)1.
2. Austria, Denmark and Latvia have a draft legislation based on the CoE ResAP(2008)1 recommendations (currently on hold).
3. Italy, Malta, Romania, and to some extent, Czech Republic, Finland and Slovakia do only regulate tattooing practices and premises safety, i.e. to ensure that health and hygienic requirements are met, but they did not transpose the CoE ResAP into their national legislative scheme. In Slovakia and Italy, the Public Health Authorities perform market surveillance of tattoo and PMU inks, in the frame of the RAPEX system, according to the recommendations and limits established by the ResAP(2008)1.
4. Croatia, Cyprus, Greece, Ireland, and Poland do not have specific legal texts on tattooing activity, but they refer to REACH, CLP and GPSD.
5. Bulgaria, Estonia, Portugal and Luxembourg do not have specific legislation. In addition, Luxembourg is about to adopt hygiene requirements in tattoo studios, inspired by the French legislation on this matter.

We did not get any reply from Hungary, Lithuania and the UK. However, for the latter, information on Local Authorities' bylaws has been added on the basis of a web search.

More specifically:

- in 2013 France updated its list of prohibited substances in line with CoE ResAP(2008)1 recommendations by banning CMR and sensitising dyes.
- Those countries who have incorporated the CoE ResAP(2003)2 provisions into their legislation , i.e. Belgium, France, Germany and The Netherlands, do not apply limits for impurities in tattoo and PMU inks, while those having embodied the CoE ResAP(2008)1, (Slovenia, Spain and Sweden), do have such limits.

- Minimum hygienic requirements for tattoo studio's and age limits for client are in place in most of the EU MS. Provisions frequently require ink sterility and single use of material and products.
- Before placing a tattoo or PMU product on the market, the manufacturer/importer has to notify the Competent Authorities on possible adverse health effects, and further submit a safety assessment report in some countries, e.g. Czech Republic, Slovenia, France (ANSM), Spain (AEMPS). Animal testing is explicitly prohibited by the French legislation.
- Labelling requirements for tattoo and PMU inks are present in nearly all the considered legislations. In addition, in Germany and Sweden, the label has to mention a period after opening (PAO).
- While France has established a national vigilance system for tattoos, Germany and Italy are performing surveillance/monitoring activities to assess the compliance with regulations and hygienic/sanitary guidelines. A reporting system of undesirable effects is also present in e.g. Austria, France, Romania, the Netherlands.
- A written consent from the customer, or from his legal guardian, is mandatory in almost all consulted MS.
- Authorisation to carry out tattoo activities is compulsory in Belgium, Czech Republic, Italy, the Netherlands, Malta, Romania, Slovenia and Slovakia. Specific training is mandatory for tattoo artists in Belgium, Czech Republic, France, Italy, Romania and Sweden. Both of these two requirements are also foreseen in the Austrian, Latvian and Danish draft legislation.

4.3.2. EFTA countries

The available information received from three national authorities (no reply from Iceland) shows that these EFTA countries have embodied in their legal scheme, provisions of the Council of Europe Resolution on tattooing. It has to be noted that in this field, Liechtenstein has adopted legislation similar to the Swiss one.

ICELAND

No information was received.

LIECHTENSTEIN

LI.1 Verordnung vom 6. April 2010 über die Anforderungen beim Anbringen von Tätowierungen, Permanent-Make-up und Piercing (LR 811.011.2)

(Regulation of 6.04.2010 on the requirements for applying tattoos)

In force since 12/04/2010, this legislation on hygienic and other requirements in applying Tattoos, Permanent-Make-up and Piercing, was based on the Swiss Ordinance on objects that come into human contact (regulation SR 817.023.41). The manufacturer and supplier of tattooing colours and pigments must certify that the products comply with the Swiss SR 817.023.41 provisions on inks composition, hygiene and labelling, and with regard to tools sterility.

Chemical requirements

This law regulates the same 27 aromatic amines and 35 colorants included in the negative lists of the CoE ResAP(2008)1 and the same 15 limits for impurities. It also bans substances specified in Annex II and Annex IV (columns 2 to 4) of the old Cosmetic Directive 76/768/EEC (now substituted by the EC Regulation 1223/2009), together with the CMRs of categories 1, 2 or 3 classified under the old Classification and Labelling Directive 67/548/EEC (now substituted by the EC Regulation 1272/2008). The tattoo inks may only contain preservatives which are allowed for cosmetics (Swiss positive list), only one in each ink, just as in the Swiss law on cosmetics. Flavoring agents and perfumes are forbidden.

Hygienic requirements

Tattoo inks shall be sterile and supplied in a container which maintains the sterility of the product until application. Tattoo tools coming into contact with the human body have to be kept sterile. The regulation specifies some technical rules on sterilisation and disinfection of the instruments. Hygiene rules enforcement has to be documented by a health plan indicating the type and frequency of the cleaning and disinfection of rooms, facilities and materials. Hands disinfection, as well as use of gloves and of disposable working tools for each treatment is mandatory. Reusable tools should be appropriately disinfected, without using alcohol or aldehyde, and sterilised before re-use. Every sterilisation process must be documented with a protocol mentioning date, temperature and duration. Staff must be informed on precautions for prevention of infections occurring from blood contact. The tattooist may not suffer from an acute transmissible disease, and must comply with hands-, body and dresses hygiene requirements. The tattooist should in particular tie longer hair or wear adequate headgear that covers the surrounding hair, shave and disinfect the patient's skin, and treat the fresh wound with an antiseptic. Studios are subject to checks and inspection by Authorities.

Packaging requirements

The design of multi-use containers should ensure that the contents will not be contaminated during the period of use.

Labelling requirements
Tattoo inks containers shall indicate batch number, name and address of manufacturer, importer or seller, date of minimum durability (with storage conditions), instructions and precautions of use, list of ingredients according to usual name (IUPAC, CAS or CI n.).

Requirements for processes and tattooists
Authorisation to open a tattoo studio and training for tattooist are indirectly compulsory, as a licence is needed to carry on a trade, and a register of authorised tattoo studios and/or tattoo artists is established. The tattooist must provide the consumer with complete and comprehensible information on the risks entailed by tattooing, including the potential sensitisation, and the advice of consulting a physician in case of medical complications.
Contraindications of treatment are in particular pregnancy and breast-feeding, heart/circulatory problems, birthmarks in the treatment area or other skin deformations, chronic skin diseases and certain blood-transmitted infectious diseases. He should inform the customer about after care, reversibility and removal of tattoos.

Requirements for risk assessment
Conformity with legislation should be checked before placing the product on the market.

Other requirements
The client (or his parents if under 18 years old) must give his written consent to treatment.

NORWAY

NO.1. Regulation of production, import, sale, etc. of tattoo products and other products for cutaneous injection for cosmetic purposes. Reference: FOR-2008-11-03-1189
In force since 2009, this Regulation ensures tattoo products are safe for human health.

Chemical requirements
This Regulation bans the same 26 aromatic amines and 35 colorants as those listed in the CoE ResAP(2003)2. It further bans substances, classified as carcinogenic, mutagenic and reprotoxic of categories 1, 2 or 3 under CLP Directive 67/548/EEC (now substituted by the EC Regulation 1272/2008), and those specified in Annex II and Annex IV, columns 2 to 4 to the Cosmetics Directive 76/768/EEC (now substituted by the EC Regulation 1223/2009) . While some preservatives are allowed (positive list) with several restrictions (i.e. max. concentrations and labelling), medicines are not.

Hygienic requirements
Products shall be sterile and supplied in a container which maintains the sterility of the product until application.

Labelling requirements
Pigments label shall include, in Norwegian or closely related languages, the name and address of manufacturers (in Norway), batch n°, weight and volume, date of minimum durability, PAO (period after opening), guarantee of sterility, list of ingredients according to IUPAC name, CAS or colour index number, conditions of use and warnings. Misleading

marketing is forbidden. Producers and importers of tattoo inks must be registered, their premises are subject to inspection.

Requirements for risk assessment

Before placing the product on the market, manufacturer or importer should submit to national authorities (in either Norwegian or English) safety data, including sterilisation methods and a risk assessment of both ingredients and final products. Dossier shall include information on qualitative and quantitative composition of the product, physical-chemical properties of the ingredients and the finished product, production method in accordance to GMP, safety, persons responsible for documentation, side effects, experimental data. Animal testing is prohibited. Persons responsible for the documentation must demonstrate expertise in toxicology or similar areas.

Other requirements

Tattoo products must be notified. There is a tattoo vigilance system and a reporting system on undesirable health effects. Mass information campaigns are foreseen.

NO.2. Regulation on the obligation of health professionals to notify suspected adverse reactions cosmetics and body care products (including tattoo products). Ref.: FOR-2008-02-27-219

This regulation obliges health professionals to report to the Norwegian Institute of Public Health undesirable health effects, providing consent by the patient.

NO.3. Regulation on hygienic conditions for tattooing & piercing studios, hair dressers, etc.. Reference: FOR-1998-05-06-581

This regulation ensures satisfactory hygienic conditions for prevention of disease transmission in tattoo studios.

Hygienic requirements

Products shall be sterile and supplied in a container which maintains the sterility of the product until application.

Practice shall only take place in facilities authorized by the Local Council, who will register them, though there is no national register. The owner or operator is responsible for internal review and control systems which must be able to be documented to the supervising authority (the Local Council).

The facilities may only be used for the purpose of which it is authorized for (i.e. tattoo studio), and must be designed, furnished and equipped in such a way that cleaning, disinfection and sterilization can be "hygienically satisfactory" All equipment must be sterile, incl. needles and liquids. Containers used for mixing of such liquids must be sterile, and changed with each customer. Equipment must be disposed of in special closed containers.

The tattooist must possess a satisfactory personal hygienic practices and workwear. By using disposable gloves, for instance, he will prevent transmission of diseases, according to regulations issued by the Ministry of Health. He shall identify any medical conditions of the customer that may require extra hygienic precautions and inform him of possible health risks. Where risk of infection is especially high, e.g. on damaged skin or in case of rash or eczema, tattooing shall not be performed.

Packaging requirements

Single use or sterile multi-use containers are recommended, if applicable, by a guideline to this regulation.

Requirements for processes and tattooists
The tattooist must provide the consumer with information on the risks entailed by those practices, including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications.

SWITZERLAND

CH.1. Ordinance on objects intended to be in contact with the human body (SR 817.023.41)

In force since 1/1/2006, defines tattooing and sterility, and sets out the requirements for tattooing inks and tools.

Chemical requirements
This law regulates the same 27 aromatic amines and 35 colorants included in the negative lists of the CoE ResAP(2008)1 and the same limits for impurities, except for nickel and antimony. It also bans substances specified in Annex II and Annex IV (columns 2 to 4) of Cosmetics Directive 76/768/EEC (now substituted by the EC Regulation 1223/2009), together with the CMRs of categories 1, 2 or 3 classified under C&L Directive 67/548/EEC (now substituted by the EC Regulation 1272/2008). The tattoo inks may only contain preservatives which are allowed for cosmetics (listed in Annex 3 of ordinance on cosmetics, OCos, RS 817.023.31) with the same maximal concentrations. A mixture of different preservatives is forbidden, as are flavoring and fragrances.

Hygienic requirements
Tattoo inks shall be prepared and supplied in a container which maintains the sterility of the product until the first application. All tattoo equipment that comes into contact with the human body has to be sterile.

Labelling requirements
Tattoos inks containers shall indicate batch number, name and address of manufacturer, importer or seller, date of minimum durability (with storage conditions), instructions and precautions of use, list of ingredients according to usual name (IUPAC, CAS or CI n.). This data must be available to consumers upon request.

CH.2. Guidance on good practices of working and hygiene

This Guidance is addressed to professional tattooists, piercing and permanent make-up artists.

Hygienic requirements
This Guidance sets out precise hygiene requisites for sterilising tattooing instruments, and keeping clean working areas. It forbids any alcohol/drug consumption by staff during working hours.

Requirements for processes and tattooists

Tattooists should be older than 18 years, and vaccinated for Hepatitis B. Recommended training for tattooist includes one basic course on general hygiene plus one specific professional course on hygiene and a first aid course.
Clients shall be informed about the treatment applied to the wound and possible risks. They will be instructed to refer any infections or complications to the tattoo studio and to consult a doctor immediately.

CH.3. Federal law on Food and common items (LDAl ; RS 817.0)
Provides in its Art. 23, al. 1, a self-assessment obligation for tattoo colours' manufacturers, importers or sellers. This information was published in June 2009 by the Cantonal Laboratory of Base, and includes a checklist concerning the tattoo inks.

Chemical requirements
Suppliers should provide test certificates (no older than 2 years) showing their products do not contain in particular aromatic amines (according to Annex 1a of RS 817.023.41), nor N-nitrosamines. Only preservatives listed in Annex 3 of the Swiss cosmetics law, with "antimicrobial activity" mentioned in column b, are allowed. Each colour may contain only one preservative. Perfumes and preservatives such as benzisothiazolinone, octylisothiazolinone (octhilinone) or phenol, may not be used.

Summary

The legislations in place in Liechtenstein and Switzerland are based on the CoE ResAP(2008)1, whereas the one in force in Norway is based on the CoE ResAP(2003)2. This is the reason why the Norwegian law does not include limits for impurities and does not ban paraphenylenediamine.

All three countries have established positive lists of preservatives, with the specification of quantitative limits and conditions of use. All of them lay down minimum hygienic standards for tattoo studios and sterility of inks.

Norway has labelling requirements similar to those applying to cosmetic products. It forbids animal testing.

4.3.3. Other jurisdictions

As a matter of comparison, we have gathered some information from various third countries (Australia, Canada, Japan, New Zealand and the United States of America), where the legal framework on tattooing activities is very heterogeneous. In fact, it concerns jurisdictions which are not only very different from the European picture, but which also vary a lot amongst each other.

AUSTRALIA

On the Australian territory the public health department of the government of each jurisdiction is responsible of issuing the "Public Health Act" which normally contains a section dedicated to the body art industry. Moreover, all the jurisdictions in Australia regulate invasive Body Art procedures in some form to minimise the risk of blood borne infections, with particular attention to hygienic conditions and requirements of premises.
The following section contains information on each jurisdiction.

Capital territory

Body art industry is cited in the following documents:

- Infection Control for office practices and other community based services, Code of practice, 2002 and amended version 2005, 2006.
- Section 338 of the ACT Children and Young People Act 1999: "A person must not in any manner tattoo a part of the body of a child or young person unless the person has first obtained the written permission of a parent of the child or young person to tattoo the child or young person in that manner on that part of the child's or young person's body"

The "Code of practice" covers many infection control practices including:

- provision of written "after care" advice;
- use of single use and reusable equipment;
- premises construction;
- handling and disposal of sharps and clinical wastes;
- personal protective equipment and immunisation;
- aseptic technique and skin disinfectants;
- environmental cleaning including dealing with blood and body substance spills

New South Wales

Infection Control in the Body Art Industry is ruled by the "Tattooing and other body art - hygiene standards" factsheet published by the health department of NSW government: This document summarises sections of Public Health (Skin Penetration) Regulation of 2012 and Public Health Act 2010, as well as sections of Children and Young Persons (Care and Protection) Act 1998 related to tattooing and piercing.

Premises - registration, construction and materials

- All tattooist and other body art practitioners who carry out skin penetration procedures, must be registered with the local council
- The construction of the premises should meet with local council requirements
- The finish on all surfaces within the premises should be made of materials that are easily cleaned
- The floor should be non-slip
- Adequate lighting and good ventilation should be provided

- Premises must be properly equipped with:
  1. A hand wash basin that has a supply of clean, warm, potable water. (The hand wash basin should be located in the treatment area)
  2. A separate sink that has a supply of clean, warm water for cleaning equipment. (A cleaning area should be provided and the dirty area(s) should be separated from the clean area)
  3. Liquid soap (or an alcohol based hand cleaner)
  4. Single-use towels or an automatic hand dryer
  5. Disposable gloves, clean linen and gowns or aprons that are appropriate for the skin procedures carried out at the premises
  6. A waste disposal bin

Equipment

- Any equipment at the premises must be in good working order, be cleaned and dried after use and be kept in a clean and dry condition
- If reusable articles are sterilised on site, they must be sterilised using a bench-top steriliser which complies with AS 2182-1998 Sterilisers - Steam - Benchtop.
- Equipment must be thoroughly cleaned (i.e. via scrubbing, using an instrument washer, and/or ultra-sonic cleaner) before processing through a bench-top steriliser
- All instruments must be wrapped and packaged prior to processing through a bench-top steriliser. This will maintain sterility and permit aseptic removal of the contents of the pack at the time of use. An exception to this requirement is if items are used immediately after processing through a bench-top steriliser
- The bench-top steriliser must have a printout facility to record the cycle parameters (i.e. temp, pressure, time), otherwise a Class 4, 5 or 6 chemical indicator must be placed in one insturment pack (in every load) or there must be direct observation and recording of cycle parameters
- Where on-site technical support is not available to achieve calibration or validation, a Class 5 or 6 indicator must be placed in every instrument package (in every load) or a process challenge device must be used in every load
- Equipment that is difficult to clean and sterilise, should only be used once and then thrown away (single-use only)
- If needles are used in any skin penetration procedure, they must be single use and disposed into an appropriate sharps container which complies with AS/NZS 4261:1994 Reusable containers for the collection of sharp items used in human and animal medical applications, or AS 4031 - 1992 Non-reusable containers for the collection of sharp medical items used in health care areas
- Articles that are used in a skin penetration procedure but do not penetrate the skin must be cleaned and kept in a clean condition
- Towels or other types of linen used for covering or protection during the procedure must be clean at the start of each treatment. Linen should be washed in detergent and hot water

Hygiene procedures

- The premises must be kept in a clean and hygienic condition at all time
- Treatment areas such as benches should be cleaned between each client and/or a clean covering placed over the treatment surface
- To prevent cross contamination, all liquids, creams, inks and pigments must be decanted into single use containers, and a single use applicator must be used for each person undergoing the procedure (no double dipping)

- Sterile packaging should be opened just prior to starting the treatment
- Sterile parts of the equipment that will penetrate the skin should not be handled. (If handling sterile equipment is necessary, a sterile insertion tube, a pre-packed sterile alcohol swab, a sterile dry swab, or sterile single use gloves should be used)
- The area to be tattooed should be cleaned with a skin antiseptic

Personal hygiene for tattooists

- A clean gown or apron and single use gloves must be worn by the tattooist and other body art practitioner during a skin penetration procedure
- Hands should be washed i) before and after attending a client; ii) before and after a procedure; iii) after exposure to a body substance; iv) after touching a clients surroundings and v) after the removal of gloves
- Cuts or wounds should be covered with a sealed waterproof bandage

Other requirements

- Sterilisation records must be kept for 12 months showing (a) the time and date when each article was sterilised and (b) the length of time that the article was sterilised and the temperature and pressure levels of the bench-top steriliser
- In circumstances where a topical anaesthetic preparation is required or desired, there is no objection to the client purchasing the product from a local pharmacy and bringing it to the tattoo parlour. This product may then only be applied or used for that patron. The tattoo parlour cannot under any circumstances supply a topical anaesthetic cream (such as Lignocaine, Emla cream, Medijel, and Xylocaine)
- Tattoo premises and tattoo artist must comply with the requirements of the Tattoo Parlour Act 2012 and be registered.
- Tattoo and body art practitioners must comply with the Children and Young Persons (Care and Protection) Act 1998.

Northern territory

The Northern Territory has no legislation specific to infection control in the Body Art industry. However, it has a "Standards for commercial skin penetration hairdressing, and beauty and natural therapy" which defines the following points:

Operator hygiene

- Hands must be washed thoroughly with water and soap or an antibacterial cleanser and dried with disposable paper towels before treating every client and after any activity which may contaminate the hands.
- Operators should always wear clean outer clothing or a clean over-garment when attending a client.
- Other protective attire that should be worn includes:
  Disposable gloves when conducting skin penetration practices.
  Aprons and gloves when mixing chemicals.
  Protective footwear when using sharps such as razors, scissors, clippers and needles and chemicals.
  Protective eye wear when conducting any skin penetration practice.
- Operators should not smoke when attending a client.

Additional hygiene measures

- Laundry: Only clean linen, towels and other clothing or cloths should be placed on clients. Clean items should be stored in an area that protects them from being soiled through hair, dust etc. Dirty linen should be placed into a suitable receptacle after use. All linen should be washed in hot water (> 70oC) with an appropriate detergent. Operators should immediately dispose of any blood-stained linen.
- Waste Disposal General waste, such as paper, hair and food scraps, should be disposed of in a refuse receptacle with plastic lining and a close-fitting lid. All sharps, including razors, old scissors, glass, cosmetic lancers and needles, should be placed in a sharps container and disposed of in accordance with the direction of an Environmental Health Officer.

Cleaning and Sterilising skin penetration Instruments

All needles or sharps that penetrate the skin, as well as any items that holds the needle (such as the tattooing gun needle bar or nozzle) should be in a sterile condition immediately prior to use.

Dry Heat Sterilisers should not be used for sterilising equipment as their application is limited

due to the relatively long sterilisation times and the likelihood of materials being damaged by the 160°C-180°C temperatures usually used. There is also a long warm up period and limited control over temperature within the chamber space.

Pressure Cookers *are not sterilisers* and *should not* be used.

Ultra-sonic cleansers can be used during tattooing to clean ink off needles; however they are not sterilisers, and needles are still required to be cleaned and sterilised between clients. The use of ultra-sonic cleansers shall be in accordance with Australian Standard 1487-1994.

Handling skin penetration instruments

Needles and other penetrating devices should not be handled in a manner that can lead to their contamination. Single-use disposable gloves should be worn when conducting skin penetration operations.

- Dyes for Tattooing / Semi-permanent Make up
  It is possible for pigment dyes to be contaminated from viruses (such as Hepatitis B and C) in blood and serum. To avoid these contaminated dyes from being the source of transmission to other clients, pigments in new or sterile containers or "caps" should be used for each client. Dyes should be administered from "collapsible" tubes, or by another appropriate manner, so as to reduce the chance of contamination.
- Pads, Swabs, Cloths, Tissues, Cotton Wool
  Some skin penetration procedures require the skin to be wiped down during the process to remove ink, sweat, plasma and blood. Any swabs, cloths, paper or cotton gauze used during skin penetration should be single-use and should be disposed of immediately after use in a water-proof bag. These bags should then be sealed and disposed of in a bin with a close fitting lid after each client.

Premises structure

Skin penetration premises should be constructed and fitted-out with materials that can be easily cleaned and disinfected.

This may include:

- All surfaces and fittings should be constructed of smooth, impervious, durable and preferably light coloured material
- Separate hand washing facilities, dispensing hot and cold water from a single outlet, should be provided in the room of operation or in a central location.

- Soap or a suitable anti-bacterial lotion, and disposable paper towels or a hot air drier, should be provided at the hand washing facilities
- A separate staff sink and laundry facilities should be considered in the design of the premises

Quuensland

In Queensland, the following legislation relates to Infection Control in the Body Art Industry:

- Health Regulation 1996 – Part 15 – Skin Penetration.
- NCP report health act 1937 (hairdressing & skin penetration) and following version, 2009.

Moreover, tattoo industry is regulated by the "Tattoo parlours act 2013", which passed into law on 15 October 2013.

It set up a licensing system for tattoo operators and tattooists

South Australia

In South Australia, the following legislation relates to Body Art industry:

- Public and environmental health act 1987 (and following version 2011).
- Guidelines on the safe and hygienic practice of skin penetration (revised version 2004).

The latter covers:

- septic or "non-touch" procedures;
- cleaning disinfection & sterilisation of equipment;
- disinfectants;
- hand washing and personal hygiene;
- skin preparation;
- needle stick injuries and cleaning of wounds;
- general hygiene;
- waste disposal;
- disposal of sharps; and
- storage & safe handling of chemicals.

Tasmania

In Tasmania, the following legislation relates to the Body Art Industry:

- Public Health Act 1997.

Victoria

The following Victorian legislation relates to Infection Control in the Body Art Industry:

- Part 19 of the Health Act 1958;
- Part 5 of the Health (Infectious Diseases) Regulations 2001;
- Health (Exempt Businesses) Regulations 2000; and
- Health (Registration of Premises) Regulations 1992.

Health guidelines for personal care and body art industries, has been issued by Victorian Department of Health and human services, established by Government to integrate health and human services policies.

This latter document covers:

- Specific and general requirements of premises
- Occupational health and safety aspects
- Cleaning and disinfection of reusable instruments and equipment
- Sterilisation of reusable instruments and equipment

Moreover a specific section (Industry-specific requirements) dedicated to " Body art tattooing and piercing" is included in the second part of the document. It specifies:

- preparation of work area and equipment for body piercing and tattooing ,
- management of bleeding,
- dispensing (pigments, creams, jelly etc.)
- cleaning and disinfection
- disposal

Western Australia

In Western Australia the following legislation relates to Body Art Industry:

- Skin Penetration Code of Practice, issued by department of health which sets rules in the field of safety of work environment, standards for premises, special requirement for tattooing and piercing, standard precaution to be adopted as well as management of needlestick and blood accidents.
- Section 138A of the Child Welfare Act 1947: " Except where the Director-General, with the consent of the parents or guardians of the child given by reason of long standing cultural or religious belief, otherwise authorizes, a person over the age of 18 years who for gain or reward tattoos, or otherwise makes a permanent mark or design resembling a tattoo on the skin of, any child or causes any such tattoo, mark or design to be made commits an offence".

CANADA

There is no specific legislation on tattooing in Canada.
Personal services establishments (PSEs) are governed by provincial level authority.

There are a lot of gaps and conflicting information regarding public health issues associated with PSEs. Guidelines and regulations are often vague or impractical. In general, there is a lack of training and licensing of both practitioners and business owners within the personal services industry. The level of public health guidance for PSEs varies in comprehensiveness across jurisdictions within Canada. Risk assessment procedures for infection prevention and control (IPAC) in the personal services industry should be developed, as well as tools to assess risk from failure of IPAC procedures in any personal services setting. As invasive body modification grows in popularity and range of procedures, there is an increasing need to clarify when a procedure falls under the auspices of invasive surgery and whether it should be regulated as such.
The following non-exhaustive summary of the Canadian regulatory frameworks has been compiled in July 2010 by the National Collaborating Centre for Environmental Health, comparing the state of play in different jurisdictions, and highlighting gaps from existing guidelines/regulations.

Canada (federal)

a) Regulatory Authority and Guidelines
   Health Canada Infection Prevention and Control Practices for Personal Services: Tattooing & Piercing
   Note**:** the document has been retracted.

b) Enforcement, Training and Licensing

Enforcement is implemented at provincial level. It is recommended to train staff on infection control via local public health units.

c) Specifics and Highlights
Detailed instructions are provided regarding sterilization methods, and environment and instrument cleaning. Machines should be foot operated. After each client is treated, the office equipment should be disinfected and gloves changed. Skin antiseptics should not be sprayed directly onto skin.

d) Gaps and Potential Hazards
Removal of needles and reuse of needle bars permitted in tattooing.

Alberta

a) Regulatory Authority and Guidelines
Provincial legislation is old and is expected to change in the near future.
- Alberta Regulation 20/2003, Public Health Act, Personal Services Regulation (2003)
- Health Standards and Guidelines for Tattooing (2002)

A new Departmental Standard Operating Procedure, Personal Service Establishment Inspection Protocol, has been tested since July 2010.

b) Enforcement, Training and Licensing
Annual inspection by public health inspector of high risk personal service establishments. This is set out in provincial Blue Book (A Common Reference System and Operational Standards for Alberta); actual practice differs by region.
Operators are not required to have specific knowledge or demonstrate a level of competency.
No permit or licence required; studios may open without health approval.

c) Specifics and Highlights
- sharps container required
- disposal in accordance with regional health authority
- Recommendation for informed consent and minimum age of 18 years.

d) Gaps and Potential Hazards
- Legislation is weak. The word *should* is used when many items require *shall*. For example, operators *should* ensure that all critical instruments are sterile. Disposable blades "recommended" but not required.
- No legislative requirements for physical, chemical, or biological monitoring of sterilizers.
- Use of spray bottles (vs squirt bottles or pumps) for disinfectants presents risk of aerosol formation of disinfectant and possibly contaminated debris.
- Removal of needles and reuse of needle bars permitted.
- Reusable marking pens permitted for marking skin present risk for cross-contamination.

British Columbia

a) Regulatory Authority and Guidelines
Cosmetology industry was deregulated in 2003.

Health Act – Personal Services Establishments Regulation, BC Reg 202/83 - OC 912/83.9

Note**:** The Regulation pertains to water supply and facilities and prevention of health hazards; it is brief and open to interpretation.
Specific Guidelines for Tattooing are also available.

b) Enforcement, Training and Licensing
- Education and graduated warning system.
- Annual inspection by environmental health officer, with closure of establishment if there is any evidence of a health hazard.
- Business licence and approval by health inspector required, but no specific training or licensing required for operators or establishments
- Cosmetology Industry Association of BC (CIABC) is planning to offer a voluntary training/certification program called BeautySafe.

c) Specifics and Highlights
- Informed consent required; parental consent recommended for minors.
- Deodorant sticks for tattoo stencils should be used with disposable applicator.
- Needles, tubes, and bars should be sterilized prior to use; needles should be single use only.

d) Gaps and Potential Hazards
- Difficult to classify some instruments as critical, semi-critical, etc.
- Reusable marking pens permitted for marking skin presents risk for cross-contamination.
- Rinsing of tattoo needles in ultrasonic between colours presents risk of aerosolization and contamination.
- Practicality of disinfection options for different equipment (e.g., equipment compatibility) not considered.
- No minimum age for tattooing or piercing procedures.
- No risk assessment framework for infection prevention and control (IPAC) in regulations or guidelines.

Ontario

a) Regulatory Authority and Guidelines
- Ontario Public Health Standards
- *Infection Prevention and Control Best Practices for Personal Services Settings*, January 2009 (named under Ontario Public Health Standards, 2008, requirement no. 10)
- *Infection Prevention and Control in Personal Services Settings Protocol*, 2008

Note**:** Provides minimum expectations for service
- CIPHI Ontario fact sheets on Tattoo and Micropigmentation

b) Enforcement, Training and Licensing
Authority by Boards of Health. Inspection at least annually and in response to complaint or non-compliance; by MOH or designate

c) Specifics and Highlights
- Detailed tattoo set-up instructions provided.
- Needles should be rinsed in tap water between colours, using disposable cups

d) Gaps and Potential Hazards
- Lack of detail on frequency and timing of glove changes.
- Reusable skin marking pens permitted; presents risk for cross-contamination
- Gloves may be put on after cleaning clients' skin

JAPAN

Japan prohibits or highly restricts marketing or use of hazardous chemical substances under multiple regulations: Chemical Substance Control Law (CSCL), Industrial Safety and Health Law (ISHL), Poisonous and Deleterious Substance Control Law (PDSCL) and Household Products Containing Harmful Substance Control Law (HPCHSCL). These regulations cover both industrial and consumer products but to the best of our knowledge none of them refers specifically to tattoo inks.
As far as we know the tattoo establishments in Japan are not regulated or inspected under Japanese law.

NEW ZEALAND

NZ.1. Tattoo and Permanent Makeup Substances Group Standard 2011

Under the Hazardous Substances and New Organisms (HSNO) Act all hazardous substances require an approval. The Environmental Protection Agency (EPA) pursuant section 96B(1) of the Hazardous substances and new organisms (HSNO) Act of 1996 established the Tattoo and Permanent Makeup Substances Group Standard to manage the chemical risks associated with tattoo and permanent makeup substances with a notice in the New Zealand Gazette no 147 of 29 September 2011. This group standard applies to any substance imported or manufactured for use as tattoo or permanent make up substance

Other requirements

Substances must not trigger any hazard classification apart from the following: a) acute toxicity HSNO 6.1 D or 6.1E (substances that may be harmful to people if they are exposed to significant amounts of the substance), b) skin irritancy, HSNO 6.3A or 6.3B (substances that may cause irritation to the skin), c) eye irritancy, HSNO 6.4 (substances that may cause irritation to the eye), d) Eye corrosivity, HSNO 8.3A (substances that may cause permanent damage to the eye), e) ecotoxicity, HSNO 9 (substances that may cause damage to the environment if discharged to the air, land or water

NZ.2. EPA Guidelines for tattoo and permanent makeup substances

The guidelines are not mandatory but represent best practice guidance from the Council of Europe and the EPA recommends their use to help prevent adverse effects. They include a set of tables listing substances that tattoo inks should not contain.

Chemical requirements

These guidelines contemplate the same chemical provisions as those listed in the CoE ResAP(2008)1. Recommendations regard in particular the same 27 aromatic amines and 35

colorants, as those listed in table 1 and 2 of appendix 1. Equally the same 15 limits for impurities do apply, as listed in table 3 and 4 of appendix 2.

Labelling requirements
Traces of Cr (VI) and/or Ni should be indicated with a warning such as "contains chromium and/or Ni. Can cause allergic reactions".

UNITED STATES OF AMERICA

When analysing the US system, one ought to distinguish between the federal, state and local levels.

1. Current U.S. Federal Regulatory Approach

While state and local authorities oversee, in a widely varying manner, the practice of tattooing, ink and ink colourings (pigments) used in tattoos are subject to Food and Drug Administration (FDA) regulation as cosmetics and colour additives.
However, because of other public health priorities and a previous lack of evidence of safety concerns, FDA has not traditionally regulated tattoo inks or the pigments used in them.
Recent reports associated with permanent make-up inks have prompted FDA to study tattoo ink safety, but more information is needed on:

- Tattoo ink ingredients and contaminants
  – FDA is in the process of sampling and testing tattoo inks to learn more about ingredients and develop better tools to assess human health risks. The current Ingredient Data stem from Ingredient lists on labeling or from Material Safety Data Sheets (MSDS's) online or shipped with product. The methods to characterize inks are not fully developed, pigment standards are not always available.
- Processing methods
  – FDA is planning to inspect more manufacturers to learn more about prevailing practices

2. Federal Legal Authorities

- Cosmetics Regulatory Authority in the Food Drug & Cosmetic Act (FD&CA) : does not authorize pre-market review for safety
- Color Additive Regulatory Authority in the FD&CA

3. Perspectives

FDA is reconsidering its Regulatory Position on Tattoo Ink:

- Single vs. multiple use?
- Preservation requirements?
- Sterilization treatment options?
  Required labelling statements?

It further considers changing the colour additive enforcement policy, which encompasses:

- A pre-market petition submitted to the FDA to establish safety.
- Only approved and Code of Federal Regulations (CFR) listed colour additives may be used in FDA-regulated products (food, drugs, cosmetics, and medical devices) marketed in the U.S. FDA's colour certification Program is FDA's oldest user fee program, now there is an online certification system.

- All colour additives must comply with the requirements in their listing regulations, including purity requirements. Adulteration and misbranding are prohibited
- Colour additives must be used appropriately: manufacturers must consult the listing regulation, and are responsible for compliance with CFR specifications.
- Batch-certified material must be used in products when required.
- Regulations list specific approved uses, i.e., for injection. Currently, no color additives are specifically listed for use in injection.

3. US. States Regulatory State of play

No clear guidance existed for states developing tattoo regulations until The National Environmental Health Association (NEHA) published in 1999 "Body Art: A Comprehensive Guidebook and Model Code". The model code provided detailed guidelines and recommended regulations on sanitation and infection control. Artist training was addressed by NEHA by specifying that artists should have training in sterilisation procedures, anatomy, and infection control.

Body art industry regulation varies substantially on a state-by-state basis. According to an analysis led by V. P. Carlson et al., published on the Journal of Environmental Health, vol.75, 3, 2012, 41 states have at least one state statute regulating tattooing practice; 36 states regulated sanitation; 15 states regulated training and 26 states regulated infection control effectively. Fourteen states met the criteria for regulating all three categories effectively. According to more recent data collected by Haugh I. M. et al.[9], there were only four completely unregulated states as of September 2014, namely Arizona, Idaho, Utah and Wyoming. Nevertheless, also in unregulated states, townships and municipalities may set their own laws regarding the performance of body modification. In the case of an unregulated state, it is the responsibility of the customer to select a clean, knowledgeable shop.

Tattoo parlor requirements

Tattoo parlor requirements vary on a state-by-state basis, as there are no federal laws that cover body art or cosmetic tattoos. Each state is responsible for its own legislation. While each state may have different requirements, certain elements are common among them, including the licensing of artists, health standards, records and identification, file keeping and age laws. Most states require tattoo parlors to be licensed by the board of health, which is responsible for enforcing the laws regarding tattoo parlors.

Health Standards: sanitation and infection control

This branch of Body Art industry is the most regulated. Strict health standards are required in almost every state, in a tattoo studio.

Sanitation:

Comprehensive sanitation regulation, which apply almost everywhere on the US territory includes regularly scheduled inspections.

Almost everywhere, laws outline the type of tools that can be used to tattoo; how those tools should be cleaned and how the studio itself must be cleaned and maintained. Studios may be required to have an autoclave sterilizer on hand for reusable materials and hazardous waste collection receptacles for those that are disposable.

[9] 2015, Haugh I. M. et al, Regulation of tattoo ink production the tattoo business in the US, in Serup J et al. Eds., Tattooed Skin and Health. Curr. Probl. Dermatol. Basel, Karger, vol. 48, pp 248-252.

Training and Licensing

While strict health standards are required in most states, training is the less consistently regulated chapter in the body art industry. Certain states require no training at all before licensing a tattoo artist while some other states require prove of apprenticeship under a licensed practitioner.

In most regulated states, tattoo artist license is mandatory. Artist must be licensed to operate in 32 states while in 34 states facilities must be also licensed. The requirements varies state by state and is issued by the state department of health services; in most cases (especially where the training is compulsory) this includes certification demonstrating knowledge of aseptic tattooing technique, completion of a blood-borne pathogen safety class, first aid certification and, in some states, an apprenticeship where required. Some states do not regulate their artists; as the industry expands, it is becoming increasingly common. States may require that an artist be licensed by either the state, or county or city.

Restrictions on age and banned position for tattoo

In many states, it is illegal for a tattoo parlor to tattoo a minor, even if parental consent is granted. Each state or municipality regulates the age of a tattoo parlor's customers individually. In all jurisdictions individual tattooists may choose to set age restrictions for their business. The artist may also choose to place additional restrictions based on his or her own moral feelings, such as refusing any clients under a specific age even with parental consent, or limiting the type and/or location of where they are willing to tattoo a minor.

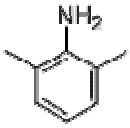
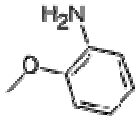
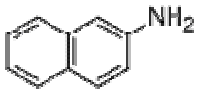
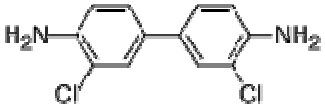
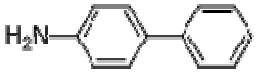
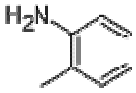
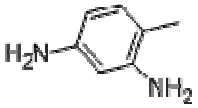
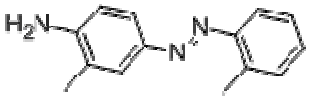
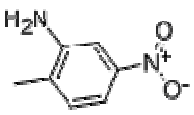
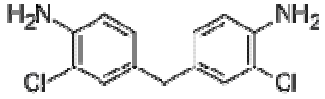
Summary

In summary, the regulatory framework and practices vary dramatically not only from one country to another (Australia, Canada, Japan, New Zealand, United States of America), but also within each national jurisdiction, as most of these countries have a federal structure and the responsible entities are usually the local ones, e.g. states, provinces, etc.. It principally takes into consideration tattoo processes and hygiene conditions, without focusing on the chemical composition of tattoo and PMU inks, with the noticeable exception of New Zealand.

Annex I

List of substances that tattoo and PMU products should not contain as recommended by the CoE ResAP(2008)1

Table 1: Aromatic amines, which should neither be present in tattoos and PMU products nor released from azo-colorants (CoE ResAP(2008)1 - Table 1).

CAS number	EC-number	Substances	Structure
60-09-3	200-453-6	4-aminoazobenzene	
87-62-7	201-758-7	2,6-xylidine	
90-04-0	201-963-1	o-anisidine	
91-59-8	202-080-4	2-naphtylamine	
91-94-1	202-109-0	3,3'-d-dichlorobenzidine	
92-67-1	202-177-1	biphenyl-4-ylamine	
92-87-5	202-199-1	benzidine	
95-53-4	202-429-0	o-toluidine	
95-68-1	202-440-0	2,4-xylidine	
95-69-2	202-411-6	4-chloro-o-toluidine	
95-80-7	202-453-1	4-methyl-m-phenylenediamine	
97-56-3	202-591-2	o-aminoazotoluene	
99-55-8	202-765-8	5-nitro-o-toluidine	
101-14-4	202-918-9	4,4'-methylenebis(2-chloroaniline)	

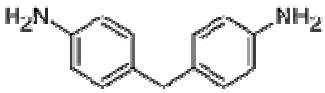
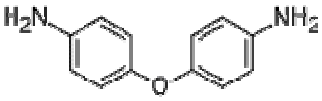
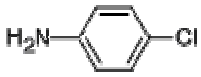
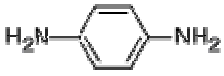
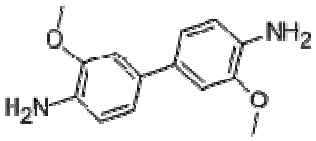
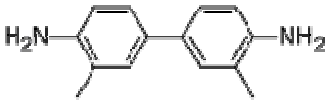
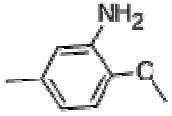
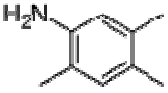
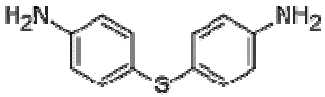
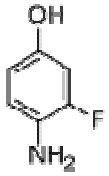
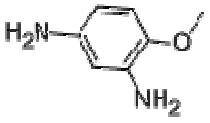
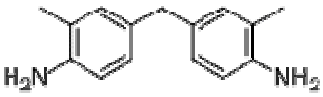
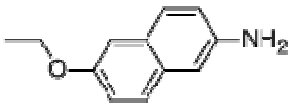
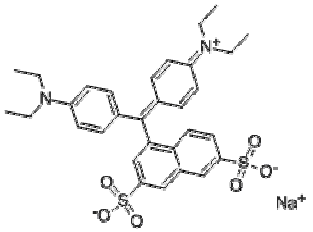
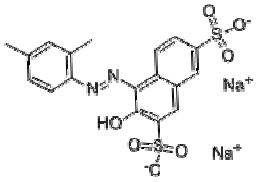
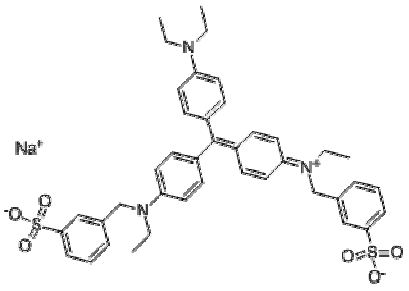
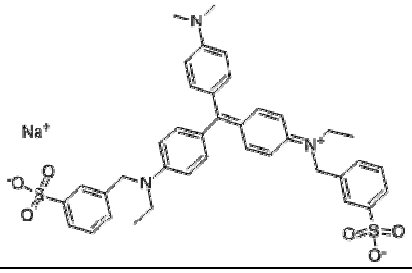
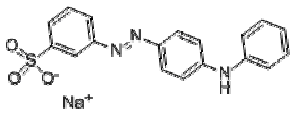
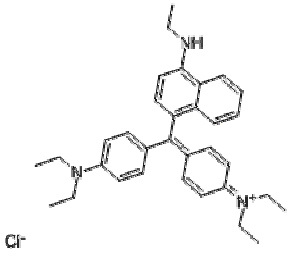
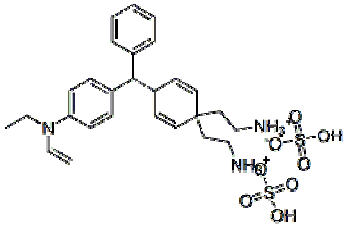
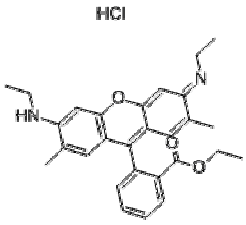
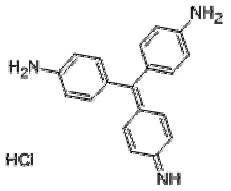
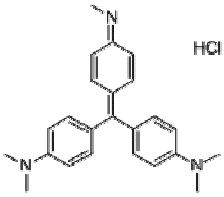
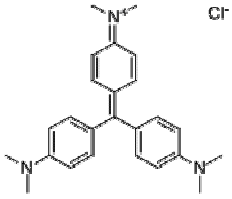
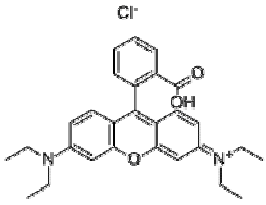
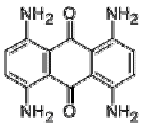
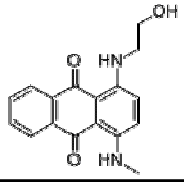
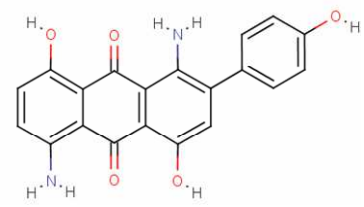
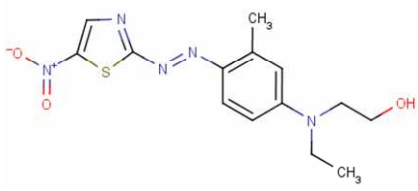
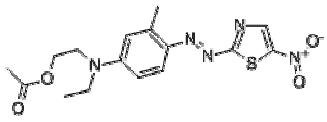
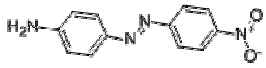
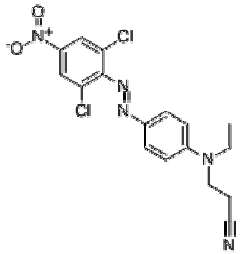
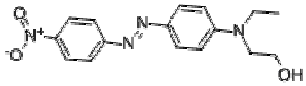
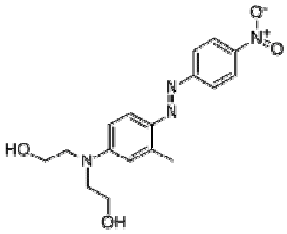
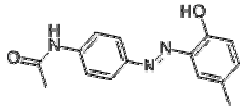
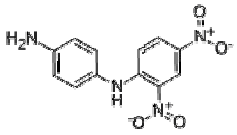
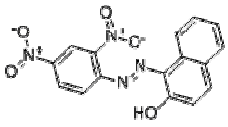
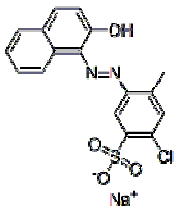
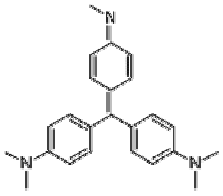
CAS number	EC-number	Substances	Structure
101-77-9	202-974-4	4,4'-methylenedianiline	
101-80-4	202-977-0	4,4'-oxydianiline	
106-47-8	203-401-0	4-chloroaniline	
106-50-3	2003-404-7	para-phenylenediamine	
119-90-4	204-355-4	3,3'-dimethoxybenzidine	
119-93-7	204-358-0	3,3'-dimethylbenzidine	
120-71-8	204-419-1	6-methoxy-m-toluidine	
137-17-7	205-282-0	2,4,5-trimethylaniline	
139-65-1	205-370-9	4,4'-thiodianiline	
399-95-1	402-230-0	4-amino-3-fluorophenol	
615-05-4	210-406-1	4-methoxy-m-phenylenediamine	
838-88-0	212-658-8	4,4'-methylenedi-o-toluidine	
293733-21-8	-	2-amino-6-ethoxynaphthalene	

Table 2: List of colorants, particularly with regard to their carcinogenic, mutagenic, reprotoxic and/or sensitising properties, which tattoo and PMU products should not contain (CoE ResAP(2008)1 - Table 2).

CAS number	CI Number	CI Name	Structure	Molecular formula	Dye class
12768-78-4	44025	Acid Green 16		C27H25N2NaO6S2	triarylmethane dyes
3761-53-3	16150	Acid Red 26		C18H14N2Na2O7S2	monoazo dyes
4129-84-4	42650	Acid Violet 17		C41H44N3NaO6S2	triarylmethane dyes
1694-09-3	42640	Acid Violet 49		C39H40N3NaO6S2	triarylmethane dyes
587-98-4	13065	Acid Yellow 36		C18H16N3NaO3S	monoazo dyes
2390-60-5	42595	Basic Blue 7		C33H40N3.Cl	triarylmethane dyes
633-03-4	42040	Basic Green 1		C27H34N2O4S	triarylmethane dyes

CAS number	CI Number	CI Name	Structure	Molecular formula	Dye class
989-38-8	45160	Basic Red 1		C27H29ClN2O3	xanthene class
569-61-9	42500	Basic Red 9		C19H17N3.ClH	triarylmethane dyes
8004-87-3	42535	Basic Violet 1		C24H28ClN3	triarylmethane dyes
548-62-9	42555	Basic Violet 3		C25H30ClN3	triarylmethane dyes
81-88-9	45170	Basic Violet 10		C28H31ClN2O3	xanthene class
2475-45-8	64500	Disperse Blue 1		C14H12N4O2	antraquinone dyes
2475-46-9	61505	Disperse Blue 3		C17H16N2O3	antraquinone dyes
12222-75-2		Disperse Blue 35		C20H14N2O5	
12223-01-7		Disperse Blue 106		C14H17N5O3S	

CAS number	CI Number	CI Name	Structure	Molecular formula	Dye class
61951-51-7		Disperse Blue 124		C16H19N5O4S	
730-40-5	11005	Disperse Orange 3		C12H10N4O2	monoazo dyes
12223-33-5		Disperse Orange 37		C17H15Cl2N5O2	
2872-52-8	11110	Disperse Red 1		C16H18N4O3	monoazo dyes
3179-89-3	11210	Disperse Red 17		C17H20N4O4	monoazo dyes
2832-40-8	11855	Disperse Yellow 3		C15H15N3O2	monoazo dyes
6373-73-5	10375	Disperse Yellow 9		C12H10N4O4	nitro class
3468-63-1	12075	Pigment Orange 5		C16H10N4O5	monoazo dyes
2092-56-0	15585	Pigment Red 53		C17H12Cl2NaO4S	monoazo dyes
1325-82-2	42535:2	Pigment Violet 3		C24H27N3	triarylmethane dyes

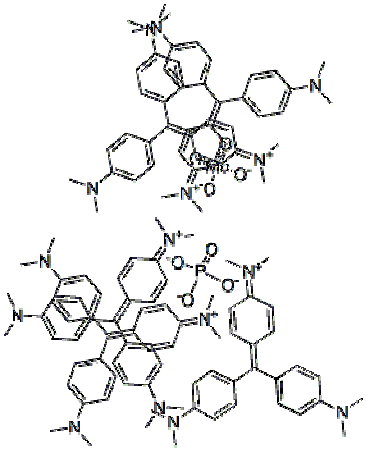
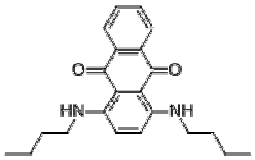
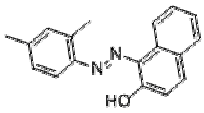
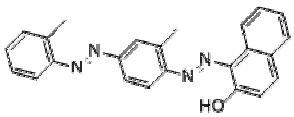
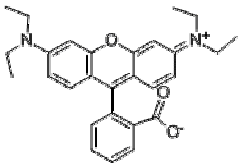
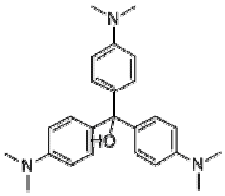
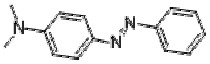
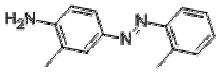
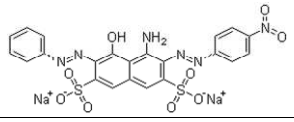
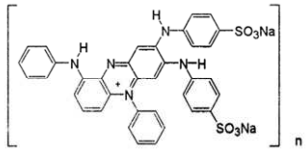
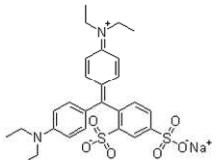
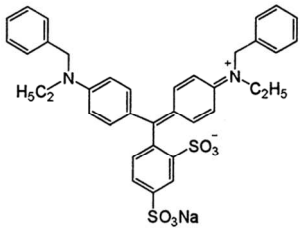
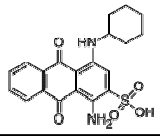
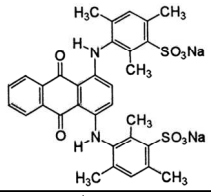
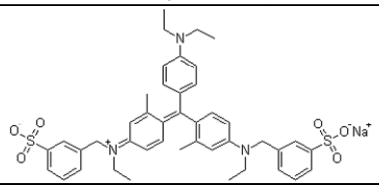
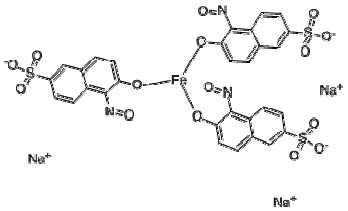
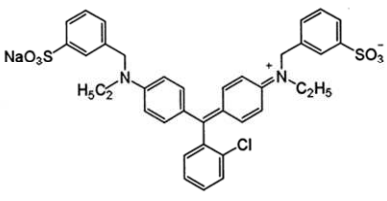
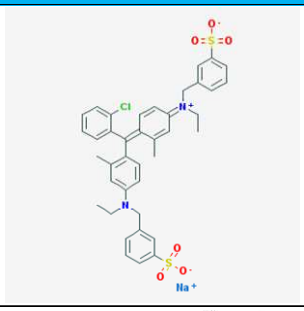
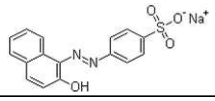
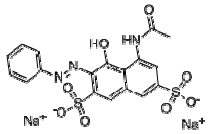
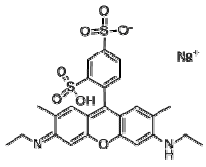
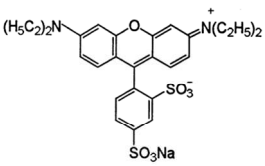
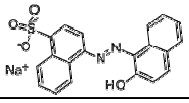
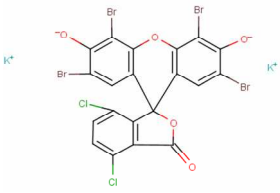
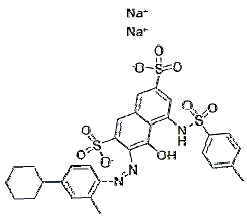
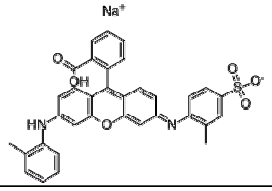
CAS number	CI Number	CI Name	Structure	Molecular formula	Dye class
64070-98-0	42555:2	Pigment Violet 39		C25H30N3.x	triarylmethane dyes
17354-14-2	61554	Solvent Blue 35		C22H26N2O2	
3118-97-6	12140	Solvent Orange 7		C18H16N2O	monoazo dyes
85-83-6	26105	Solvent Red 24		C24H20N4O	diazo dyes
509-34-2	45170:1	Solvent Red 49		C28H30N2O3	xanthene class
467-63-0	42555:1	Solvent Violet 9		C25H31N3O	triarylmethane dyes
60-09-3	11000	Solvent Yellow 1		C12H11N3	monoazo dyes
60-11-7	11020	Solvent Yellow 2		C14H15N3	monoazo dyes
97-56-3	11160	Solvent Yellow 3		C14H15N3	monoazo dyes

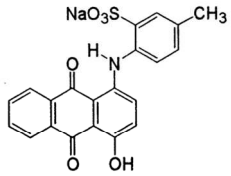
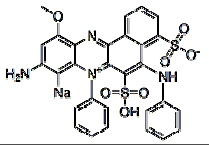
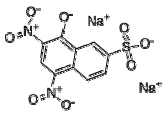
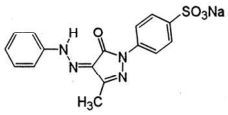
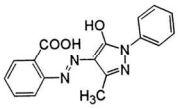
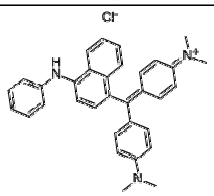
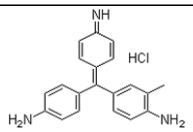
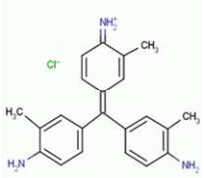
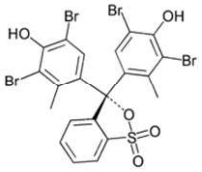
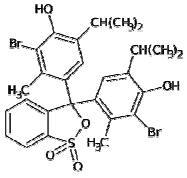
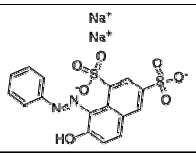
Table 3: Maximum recommended concentrations of impurities in products for tattoos and PMU (CoE ResAP(2008)1 - Table 3).

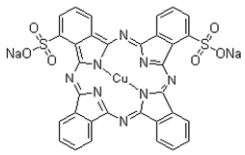
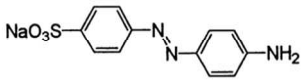
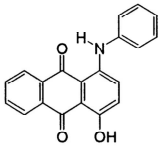
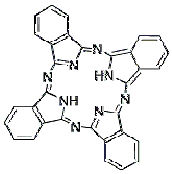
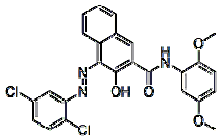
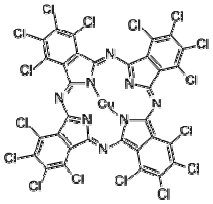
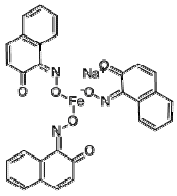
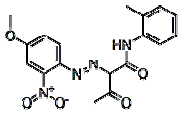
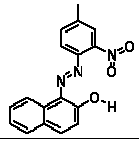
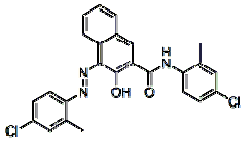
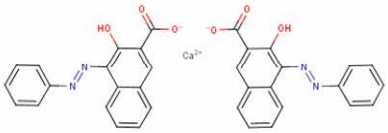
Substance or impurity	Maximum allowed concentrations	Labelling
Arsenic (As)	2 ppm	
Barium (Ba)	50 ppm	
Cadmium (Cd)	0.2 ppm	
Cobalt (Co)	25 ppm	
Chromium (Cr) (VI)	0.2 ppm	The presence of traces of chromium (VI) in products for tattoos and PMU should be mentioned on the package together with a warning (for example, “Contains chromium. Can cause allergic reactions.")
Copper (Cu) soluble	25 ppm	Soluble copper should be determined after extraction to an aqueous solution with pH 5.5
Mercury (Hg)	0.2 ppm	
Nickel (Ni)	As low as technically achievable	The presence of traces of nickel in products for tattoos and PMU should be mentioned on the package together with a warning (for example, “Contains nickel. Can cause allergic reactions.”).
Lead (Pb)	2 ppm	
Selenium (Se)	2 ppm	
Antimony (Sb)	2 ppm	
Tin (Sn)	50 ppm	
Zinc (Zn)	50 ppm	
Policyclic aromatic hydrocarbons (PAH)	0.5 ppm	
Benzene-a-pyrene (BaP)	5 ppb	

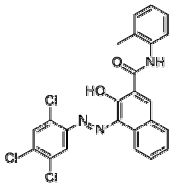
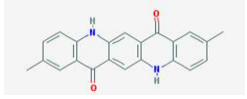
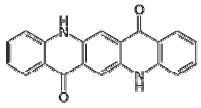
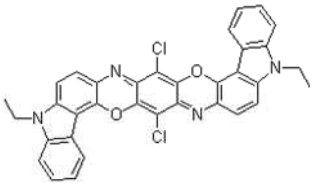
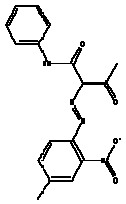
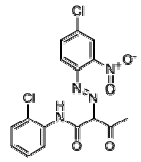
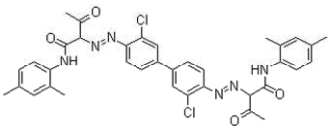
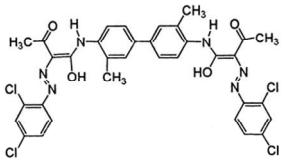
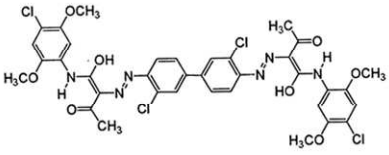
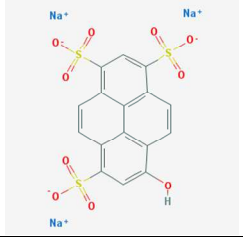
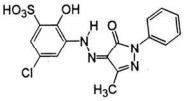
Table 4: List of colorants with restrictions in column g of Annex IV to EC Regulation 1223/2009, and recommended not to be present in tattoo and PMU products by the CoE ResAP(2008)1.

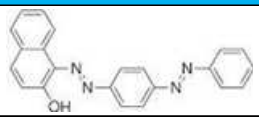
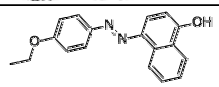
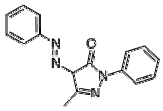
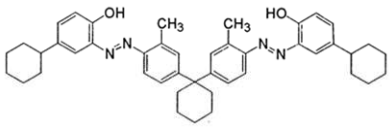
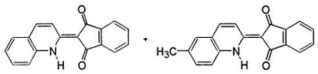
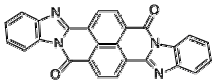
Reference number	CI name	CI number	CAS number	EC number	Structure	Molecular formula	Dye class
46	Acid Black 1	20470	1064-48-8	213-903-1		C22H14N6Na2O9S2	diazo dyes
84	Acid Black 2	50420	8005-03-6	309-930-4		C22H14N6Na2O9S2	azin dyes
59	Acid blue 1	42045	129-17-9	204-934-1		C27H31N2NaO6S2	triarylmethane dyes
62	Acid Blue 7	42080	3486-30-4	222-476-0		C37H35N2NaO6S2	triarylmethane dyes
94	Acid Blue 62	62045	4368-56-3	224-460-9		C20H20N2O5S	antraquinone dyes
93	Acid Blue 80	61585	4474-24-2	224-748-4		C32H28N2Na2O8S2	antraquinone dyes
68	Acid Blue 104	42735	6505-30-2	229-390-2		C43H48N3NaO6S2	triarylmethane class
2	Acid Green 1	10020	19381-50-1	243-010-2		C30H15FeN3Na3O15S3	nitroso compounds
64	Acid green 9	42100	4857-81-2	225-458-0		C37H34ClN2NaO6S2	triarylmethane class

Reference number	CI name	CI number	CAS number	EC number	Structure	Molecular formula	Dye class
65	Acid Green 22	42170	5863-51-4	227-513-4		C39H38ClN2NaO6S2	triarylmethane class
21	Acid Orange 7	15510	633-96-5	211-199-0		C16H11N2NaO4S	monoazo dyes
38	Acid red 1	18050	3734-67-6	223-098-9		C18H13N3Na2O8S2	monoazo dyes
73	Acid red 50	45220	5873-16-5	227-528-6		C25H25N2NaO7S2	xanthene class
71	Acid Red 52	45100	3520-42-1	222-529-8		C27H29N2NaO7S2	xanthene class
24	Acid Red 88	15620	1658-56-6	216-760-3		C20H13N2NaO4S	monoazo dyes
78	Acid Red 98	45405	6441-77-6	228-767-9		C20H4Br4Cl2K2O5	xanthene class
39	Acid red 155	18130	8004-53-3	---		C30H29N3Na2O9S3	monoazo dyes
50	Acid Red 163	24790	13421-53-9	236-531-1		C44H34N4Na2O12S3	diazo dyes
153	Acid red 195		12220-24-5	-			
72	Acid Violet 9	45190	6252-76-2	228-377-9		C34H25N2NaO6S,	xanthene class

Reference number	CI name	CI number	CAS number	EC number	Structure	Molecular formula	Dye class
90	Acid Violet 43	60730	4430-18-6	224-618-7		C21H14NO6S, Na	antraquinone dyes
83	Acid Violet 50	50325	6837-46-3	229-951-1		$C_{29}H_{22}N_4O_7S_2$. Na	azin dyes
3	Acid yellow 1	10316	846-70-8	212-690-2		C10H4N2Na2O8S	nitro compound
42	Acid Yellow 11	18820	6359-82-6			C16H13N4NaO4S	monoazo dyes
40	Acid yellow 59	18690	12220-52-9			C17H14N4O3	monoazo dyes
69	Basic Blue 26	44045	2580-56-5	219-943-6		C33H32N3.Cl	triarylmethane class
66	Basic Violet 14	42510	632-99-5	211-189-6		C20H20ClN3	triarylmethane class
67	Basic Violet 2	42520	3248-91-7	221-831-7		C26H27ClKN3O2	triarylmethane class
152	Bromocresol green		76-60-8	200-972-8		C21H14Br4O5S	
151	Bromothymol blue		76-59-5	200-971-2		C27H28Br2O5S	
34	C.I. Orange G	16230	1936-15-8	217-705-6		C16H10N2Na2O7S2	monoazo dyes

Reference number	CI name	CI number	CAS number	EC number	Structure	Molecular formula	Dye class
106	Direct blue 86	74180	1330-38-7	215-537-8		C32H14CuN8Na2O6S2	phtalocyanines dyes
54	Direct Orange 39	40215	1325-54-8			C12H10N3NaO3S	
88	Disperse Violet 23	60724	19286-75-0	242-939-0		C20H13NO3	antraquinone dyes
104	Pigment blue 16	74100	574-93-6	209-378-3		C32H18N8	phtalocyanines dyes
13	Pigment brown 1	12480	6410-40-8	229-106-7		C25H19Cl2N3O4	monoazo dyes
107	Pigment green 7	74260	1328-53-6	215-524-7		C32Cl16CuN8	phtalocyanines dyes
1	Pigment Green 8	10006	16143-80-9	240-299-7		C20H12FeN2O4.C10H6NO2.Na	nitroso compounds
6	Pigment Orange 1	11725	6371-96-6	228-901-6		C18H18N4O5	monoazo dyes
10	Pigment Red 3	12120	2425-85-6	219-372-2		C17H13N3O3	monoazo dyes
12	Pigment red 7	12420	6471-51-8	229-315-3		C25H19Cl2N3O2	monoazo dyes
26	Pigment Red 64:1; C.I. Pigment Red 64, calcium salt; C.I. Pigment Red 64, calcium salt (2:1) (8CI);	15800	6371-76-2	228-899-7		C34H22CaN4O6	monoazo dyes

Reference number	CI name	CI number	CAS number	EC number	Structure	Molecular formula	Dye class
11	Pigment Red 112	12370	6535-46-2	229-440-3		C24H16Cl3N3O2	monoazo dyes
103	Pigment red 122	73915	980-26-7			C22H16N2O2	quinacridone
102	Pigment Violet 19	73900	1047-16-1	213-879-2		C20H12N2O2	quinacridone
85	Pigment Violet 23	51319	6358-30-1			C34H22Cl2N4O2	oxazine dyes
4	Pigment Yellow 1	11680	2512-29-0	219-730-8		C17H16N4O4	monoazo dyes
5	Pigment Yellow 3	11710	6486-23-3	229-355-1		C16H12Cl2N4O4	monoazo dyes
47	Pigment Yellow 13	21100	5102-83-0	225-822-9		C36H34Cl2N6O4	diazo dyes
45	Pigment Yellow 16	20040	5979-28-2	227-783-3		C34H28Cl4N6O4	diazo dyes
48	Pigment yellow 83	21108	5567-15-7	226-939-8		C36H32Cl4N6O8	diazo dyes
87	Solvent green 7	59040	6358-69-6	228-783-6		C16H7Na3O10S3	antraquinone dyes
41	Solvent Orange 6	18736	10127-28-3			C16H13ClN4O5S	monoazo dyes

Reference number	CI name	CI number	CAS number	EC number	Structure	Molecular formula	Dye class
51	Solvent Red 23	26100	85-86-9	201-638-4		C22H16N4O	diazo dyes
8	Solvent Red 3	12010	6535-42-8	229-439-8		C18H16N2O2	monoazo dyes
15	Solvent Yellow 16	12700	4314-14-1	224-330-1		C16H14N4O	monoazo dyes
49	Solvent Yellow 29	21230	6706-82-7	229-754-0		C44H52N4O2	diazo dyes
81	Solvent Yellow 33	47000	8003-22-3	232-318-2		C18H11NO2	quinoline
97	Vat Orange 7	71105	4424-06-0	224-597-4		C26H12N4O2	antraquinone dyes

Annex II

Aromatic amines, colorants, elements and polycyclic aromatic hydrocarbons that tattoo and PMU products should not contain as recommended by the CoE ResAP(2008)1, but not listed in its Tables 1-3

Table A: Primary aromatic amines classified as CMR in categories 1A, 1B or 2 in Table 3.1 under the EC Regulation 1272/2008 and/or listed in Annex II of the EC Regulation 1223/2009 (not listed in Table 1 of the CoE ResAP(2008)1).

		EC Reg 1223/2009		EC Reg 1272/2008		
Substances	**CAS number**	**Annex II**	**Reference number**	**Table 3.1**	**Index number**	**Classification (CMR, Skin/Eye Irrir./Sens.)**
Zoxazolamine (INN)	61-80-3	x	24			
amitrole (ISO); 1,2,4-triazol-3-ylamine	61-82-5			x	613-011-00-6	Repr. 2
Aniline, its salts and its halogenated and sulphonated derivatives	62-53-3	x	22	x	612-008-00-7	Carc. 2, Muta. 2, Eye Dam. 1, Skin Sens. 1
4-Aminosalicylic acid and its salts	65-49-6	x	31			
Biphenyl-2-ylamine	90-41-5	x	1116	x	612-142-00-6	Carc. 2
2-Nitroanisole	91-23-6	x	685	x	609-047-00-7	Carc. 1B
N,N-Diethyl-m-Aminophenol, when used as a substance in hair dye products	91-68-9 / 68239-84-9	x	1223			
N,N-Diethyl-p-phenylenediamine and its salts, when used as a substance in hair dye products	93-05-0 / 6065-27-6 / 6283-63-2	x	1311			
o-Phenylenediamine and its salts	95-54-5	x	363	x	612-145-00-2	Carc. 2, Muta. 2, Eye Irrit. 2, Skin Sens. 1
2-Aminophenol (o-Aminophenol; CI 76520) and its salts	95-55-6 / 67845-79-8 / 51-19-4	x	1372	x	612-033-00-3	Muta. 2
4-Chloro-2-Aminophenol, when used as a substance in hair dye products	95-85-2	x	1219			
1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) and its dihydrochloride salts (2,4-Diaminophenol HCl) when used as a substance in hair dye products	95-86-3 / 137-09-7 (HCl)	x	1338			
2-Amino-4-nitrophenol	99-57-0	x	383			
N,N-Dimethyl-p-phenylenediamine and its salts, when used as a substance in hair dye products	99-98-9 / 6219-73-4	x	1312			
N,N,N′,N′-Tetramethyl-4,4′-methylenedianiline	101-61-1	x	1161	x	612-201-00-6	Carc. 1B
p-toluidine; 4-aminotoluene	106-49-0			x	612-160-00-4	Carc. 2, Eye Irrit. 2, Skin Sens. 1
m-Phenylenediamine and its salts	108-45-2	x	1204	x	612-147-00-3	Muta. 2, Eye Irrit. 2, Skin Sens. 1
4-Amino-2-nitrophenol	119-34-6	x	412			
4-Aminobenzenesulfonic acid (Sulfanilic acid) and its salts, when used as a substance in hair dye products	121-57-3 / 515-74-2	x	1257	x	612-014-00-X	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1
2-Amino-5-nitrophenol	121-88-0	x	384			
4-aminophenol	123-30-8			x	612-128-00-X	Muta. 2
1-and 2-Naphthylamines and their salts	134-32-7 / 91-59-8	x	242			
2,4-Diaminodiphenylamine, when used as a substance in hair dye products	136-17-4	x	1214			
4-Diethylamino-o-toluidine and its salts, when used as a substance in hair dye products	148-71-0 / 24828-38-4 / 2051-79-8	x	1310			
4-ethoxyaniline; p-phenetidine	156-43-4			x	612-207-00-9	Muta. 2, Eye Irrit. 2, Skin Sens. 1
Phenazinium, 3,7-diamino-2,8-dimethyl-5-phenyl-, and its salts, when used as a substance in hair dye products	477-73-6	x	1322			
m-Phenylenediamine, 4-(phenylazo)-, and its salts, when used as a substance in hair dye products	495-54-5	x	1293	x	611-151-00-2	Muta. 2, Skin Irrit. 2
Toluene-3,4-Diamine and its salts, when used as a substance in hair dye products	496-72-0	x	1313			
Benzidine dihydrochloride	531-85-1	x	713	x	612-070-00-5	Carc. 1A
salts of benzidine	531-86-2			x	612-070-00-5	Carc. 1A
chrysoidine monohydrochloride; 4-phenylazophenylene-1,3- diamine monohydrochloride; [1] chrysoidine monoacetate; 4-(phenylazo)benzene-1,3-diamine monoacetate; [2] chrysoidine acetate; 4-(phenylazo)benzene-1,3- diamine acetate; [3] chrysoidine-p-dodecylbenzenesulfonate; dodecylbenzenesulfonic acid, compound with 4-(phenylazo)benzene-1,3-diamine (1:1); [4] chrysoidine dihydrochloride; 4-(phenylazo)benzene-1,3-diamine dihydrochloride; [5] chrysoidine sulfate; bis[4-(phenylazo)benzene-1,3-diamine] sulfate [6]	532-82-1 [1] 75660-25-2 [2] 79234-33-6 [3] 63681-54-9 [4] 83968-67-6 [5] 84196-22-5 [6]			x	611-152-00-8	Muta. 2, Eye Dam. 1, Skin Irrit. 2
4,4'-Diaminodiphenylamine and its salts, when used as a substance in hair dye products	537-65-5	x	1309			
Toluidinium chloride	540-23-8	x	1069	x	612-160-00-4	Carc. 2, Eye Irrit. 2, Skin Sens. 1
Toluidine sulphate (1:1)	540-25-0	x	1070	x	612-160-00-4	Carc. 2, Eye Irrit. 2, Skin Sens. 1

Substances	CAS number	EC Reg 1223/2009		EC Reg 1272/2008		
		Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
m-phenylenediamine dihydrochloride	541-69-5			x	612-148-00-9	Muta. 2, Eye Irrit. 2, Skin Sens. 1
salts of 2-naphthylamine	553-00-4 612-52-2			x	612-071-00-0	Carc. 1A
4,4′-(4-Iminocyclohexa-2,5-dienylidenemethylene) dianiline hydrochloride	569-61-9	x	706	x	611-031-00-X	Carc. 1B
6-Nitro-o-Toluidine	570-24-1	x	1235			
Disodium 3,3′-[[1,1′-biphenyl]-4,4′-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate)	573-58-0	x	986	x	611-027-00-8	Carc. 1B, Repr. 2
2-Amino-3-nitrophenol and its salts, when used as a substance in hair dye products	603-85-0	x	1317			
4,4′-Bi-o-toluidine dihydrochloride	612-82-8	x	722	x	612-081-00-5	Carc. 1B
3,3′-Dichlorobenzidine dihydrochloride	612-83-9	x	715			
o-phenylenediamine dihydrochloride	615-28-1			x	612-146-00-8	Carc. 2, Muta. 2, Eye Irrit. 2, Skin Sens. 1
3,4-Diaminobenzoic acid, when used as a substance in hair dye products	619-05-6	x	1229			
2-Methyl-m-phenylenediamine (Toluene-2,6-diamine)	823-40-5	x	413	x	612-111-00-7	Muta. 2, Skin Sens. 1
1-Amino-4-(methylamino)-9,10-anthracenedione (Disperse Violet 4) and its salts, when used as a substance in hair dye products	1220-94-6	x	1283			
ethidium bromide; 3,8-diamino-1-ethyl-6-phenylphenantridinium bromide	1239-45-8			x	612-278-00-6	Muta. 2
Xylidines, their isomers, salts and halogenated and sulphonated derivatives	1300-73-8	x	33			
Disodium 4-amino-3-[[4′-[(2,4-diaminophenyl)azo] [1,1′-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate	1937-37-7	x	987	x	611-025-00-7	Carc. 1B, Repr. 2
Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate (Food Black 2; CI 27755) when used as a substance in hair dye products	2118-39-0	x	1354			
1,5-naphthylenediamine	2243-62-1			x	612-089-00-9	Carc. 2
1,4,5,8-Tetraaminoanthraquinone (Disperse Blue 1)	2475-45-8	x	700	x	611-032-00-5	Carc. 1B, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1
Tetrasodium 3,3′-[[1,1′-biphenyl]-4,4′-diylbis(azo)]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate]	2602-46-2	x	988	x	611-026-00-2	Carc. 1B, Repr. 2
1,4-Diamino-2-methoxy-9,10-anthracenedione (Disperse Red 11) and its salts, when used as a substance in hair dye products	2872-48-2	x	1301			
N-Methyl-3-nitro-p-phenylenediamine and its salts, when used as a substance in hair dye products	2973-21-9	x	1284			
4-[(4-Aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine and its hydrochloride salt (Basic Violet 14; CI 42510) when used as a substance in hair dye products	3248-93-9 / 632-99-5 (HCl)	x	1329			
2-methoxy-4-nitrophenol (4-Nitroguaiacol) and its salts, when used as a substance in hair dye products	3251-56-7	x	1251			
3(or5)-[[4-[(7-amino-1-hydroxy-3-sulphonato-2-naphthyl)azo]-1-naphthyl]azo]salicylic acid and its salts, when used as a substance in hair dye products	3442-21-5 / 34977-63-4	x	1266			
1,3-Benzenediamine, 4-methyl-6-(phenylazo)- and its salts, when used as a substance in hair dye products	4438-16-8	x	1294			
4,4'-[(4-Methyl-1,3-phenylene)bis(azo)]bis[6-methyl-1, 3-benzenediamine] (Basic Brown 4) and its salts, when used as a substance in hair dye products	4482-25-1	x	1296			
4-Nitro-m-phenylenediamine and its salts, when used as a substance in hair dye products	5131-58-8	x	1282			
1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and its salts	5307-02-8	x	377			
2-Nitro-p-phenylenediamine and its salts, when used as a substance in hair dye products	5307-14-2 / 18266-52-9	x	1319			
4-Ethoxy-m-phenylenediamine and its salts	5862-77-1	x	406			
4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)	5909-04-6	x	81			
3,4-Methylenedioxyaniline and its salts, when used as a substance in hair dye products	14268-66-7	x	1248			
2,4-Diaminophenylethanol and its salts	14572-93-1	x	407			
6-Amino-o-cresol and its salts, when used as a substance in hair dye products	17672-22-9	x	1315			
4,4′-Methylenebis(2-ethylaniline)	19900-65-3	x	1038	x	612-141-00-0	Carc. 2
4,5-Diamino-1-Methylpyrazole and its HCl salt, when used as a substance in hair dye products	20055-01-0 / 21616-59-1	x	1217			
Benzidine sulphate	21136-70-9	x	716	x	612-070-00-5	Carc. 1A
Diaminotoluene, technical product -mixture of [4-methyl-m-phenylenediamine] (4) and [2-methyl-m-phenylenediamine] (5)	25376-45-8	x	1144	x	612-151-00-5	Carc. 1B, Muta. 2, Repr. 2, Eye Irrit. 2, Skin Sens. 1

Substances	CAS number	EC Reg 1223/2009		EC Reg 1272/2008		
		Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Toluidines, their isomers, salts and halogenated and sulphonated derivatives	26915-12-8	x	32			
Benzidine acetate	36341-27-2	x	717	x	612-070-00-5	Carc. 1A
6-(Piperidinyl)-2,4-pyrimidinediamine 3-oxide (Minoxidil (INN)) and its salts	38304-91-5	x	372			
2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine and its salts, when used as a substance in hair dye products	50610-28-1	x	1318			
3-Nitro-4-aminophenoxyethanol and its salts, when used as a substance in hair dye products	50982-74-6	x	1250			
5-Nitro-o-toluidine hydrochloride	51085-52-0	x	1195	x	612-210-00-5	Carc. 2
4-Methoxytoluene-2,5-Diamine and its HCl salt, when used as a substance in hair dye products	56496-88-9	x	1221			
N1-(2-Hydroxyethyl)-4-nitro-o-phenylenediamine (HC Yellow No. 5) and its salts, when used as a substance in hair dye products	56932-44-6	x	1285			
N1-(Tris(hydroxymethyl))methyl-4-nitro-1,2-phenylenediamine (HC Yellow No. 3) and its salts, when used as a substance in hair dye products	56932-45-7	x	1286			
3,3′-Dichlorobenzidine dihydrogen bis(sulphate)	64969-34-2	x	718			
[3,3′-Dimethyl[1,1′-biphenyl]-4,4′-diyl]diammonium bis(hydrogen sulphate)	64969-36-4	x	723	x	612-081-00-5	Carc. 1B
toluene-2,4-diammonium sulphate; 4-methyl-m-phenylenediamine sulfate	65321-67-7			x	612-126-00-9	Carc. 1B, Eye Irrit. 2, Skin Sens. 1
1-Amino-4-[[4-[(dimethylamino)methyl]phenyl]amino]anthraquinone and its salts, when used as a substance in hair dye products	67905-56-0 / 12217-43-5	x	1278			
Ethanol, 2,2'-iminobis-, reaction products with epichlorohydrin and 2-nitro-1,4-benzenediamine (HC Blue No. 5) and its salts, when used as a substance in hair dye products	68478-64-8 / 158571-58-5	x	1255			
6-Nitro-2,5-pyridinediamine and its salts, when used as a substance in hair dye products	69825-83-8	x	1321			
(8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-2-naphthyl) trimethylammonium and its salts, except Basic Red 118 (CAS 71134-97-9) as impurity in Basic Brown 17, when used as a substance in hair dye products	71134-97-9	x	1291			
N-(2-Methoxyethyl)-p-phenylenediamine and its HCl salt, when used as a substance in hair dye products	72584-59-9 / 66566-48-1	x	1226			
4-[(4-Nitrophenyl)azo]aniline (Disperse Orange 3) and its salts, when used as a substance in hair dye products	730-40-5 / 70170-61-5	x	1281			
3,3′-Dichlorobenzidine sulphate	74332-73-3	x	719			
4,4′-Bi-o-toluidine sulphate	74753-18-7	x	724	x	612-081-00-5	Carc. 1B
2-Aminomethyl-p-aminophenol and its HCl salt, when used as a substance in hair dye products	79352-72-0	x	1230			
Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-1-naphthalenyl]azo]-N,N,N-trimethyl-, and its salts, when used as a substance in hair dye products	83803-98-9	x	1298			
Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-2-methylphenyl]azo]-N,N,N-trimethyl-, and its salts, when used as a substance in hair dye products	83803-99-0	x	1297			
chrysoidine C 10-14-alkyl derivatives; benzenesulfonic acid, mono-C 10- 14-alkyl derivatives, compounds with 4-(phenylazo)-1,3-benzenediamine; [1] chrysoidine compound with dibutylnaphthalene sulfonic acid; dibutylnaphthalenesulfonic acid, compound with 4-(phenylazo)benzene-1,3-diamine (1:1) [2]	85407-90-5 [1] 94247-67-3 [2]			x	611-153-00-3	Muta. 2, Eye Dam. 1, Skin Irrit. 2
4,6-Bis(2-Hydroxyethoxy)-m-Phenylenediamine and its salts, when used as a substance in hair dye products	94082-85-6	x	1307			
6-Methoxy-2,3-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	94166-62-8	x	1212			
5-Amino-2,6-Dimethoxy-3-Hydroxypyridine and its salts, when used as a substance in hair dye products	104333-03-1	x	1308			
N-Cyclopentyl-m-Aminophenol, when used as a substance in hair dye products	104903-49-3	x	1225			
Hydroxyethylaminomethyl-p-aminophenol and its salts, when used as a substance in hair dye products	110952-46-0 / 135043-63-9	x	1316			
2,4-Diamino-5-methylphenetol and its HCl salt, when used as a substance in hair dye products	113715-25-6	x	1227			
2,6-Bis(2-Hydroxyethoxy)-3,5-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	117907-42-3	x	1215			
2-Methoxymethyl-p-Aminophenol and its HCl salt, when used as a substance in hair dye products	135043-65-1 / 29785-47-5	x	1216			
2,4-Diamino-5-methylphenoxyethanol and its salts, when used as a substance in hair dye products	141614-05-3 / 113715-27-8	x	1314			
N-Methyl-1,4-diaminoanthraquinone, reaction products with epichlorohydrin and monoethanolamine (HC Blue No. 4) and its salts, when used as a substance in hair dye products	158571-57-4	x	1256			

Substances	CAS number	EC Reg 1223/2009		EC Reg 1272/2008		
		Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
N-(2-Nitro-4-aminophenyl)-allylamine (HC Red No 16) and its salts	160219-76-1	x	1373			
4-[(3-chlorophenyl)(1H- imidazol-1-yl)methyl]-1,2-benzenediamine dihydrochloride	159939-85-2			x	612-249-00-8	Repr. 2, Skin Sens. 1
4,5-Diamino-1-((4-Chlorophenyl)Methyl)-1H-Pyrazole Sulfate, when used as a substance in hair dye products	163183-00-4	x	1218			
5-Amino-4-Fluoro-2-Methylphenol Sulfate, when used as a substance in hair dye products	163183-01-5	x	1222			
reaction mass of: 5-[(4-[(7- amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo]benzoic acid; 5-[(4-[(7-amino-1-hydroxy-3- sulfo-2-naphthyl)azo]-2,5- diethoxyphenyl)azo]-3-[(3-phosphonophenyl)azo]benzoic acid	163879-69-4			x	611-129-00-2	
3-chloro-4-(3-fluorobenzyloxy)aniline	202197-26-0			x	612-266-00-0	Muta. 2
1-(2-amino-5-chlorophenyl)- 2,2,2-trifluoro-1,1-ethanediol, hydrochloride; [containing ≥ 0,1 % 4-chloroaniline (EC No 203-401-0)]	214353-17-0			x	603-221-01-3	Carc. 1B
Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Annex VI	—	x	167			
methyl-phenylene diamine; diaminotoluene [technical product - reaction mass of 4-methyl-m-phenylene diamine (EC No 202-453-1) and 2-methyl-m-phenylene diamine (EC No 212-513-9)]	—			x	612-151-00-5	Carc. 1B, Muta. 2, Repr. 2, Eye Irrit. 2, Skin Sens. 1
N,N-Dimethyl-2,6-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	—	x	1224			
salts of aniline	—			x	612-009-00-2	Carc. 2, Muta. 2, Eye Dam. 1, Skin Sens. 1
salts of 3,3'-dichlorobenzidine; salts of 3,3'-dichlorobiphenyl- 4,4'-ylenediamine	—			x	612-069-00-X	Carc. 1B, Skin Sens. 1
salts of biphenyl-4-ylamine; salts of xenylamine; salts of 4-aminobiphenyl	—			x	612-073-00-1	Carc. 1A
diammonium 1-hydroxy-2-(4-(4- carboxyphenylazo)-2,5-dimethoxyphenylazo)-7-amino-3-naphthalenesulfonate	—			x	607-504-00-5	Repr. 2
reaction mass of: triammonium 6-amino-3-((2,5-diethoxy-4-(3- phosphonophenyl)azo)phenyl)azo-4-hydroxy-2-naphthalenesulfonate; diammonium 3-((4-((7-amino-1-hydroxy-3-sulfo-naphthalen-2- yl)azo)-2,5-diethoxyphenyl)azo)benzoate	—			x	611-172-00-7	Repr. 2
salts of 3,3'-dimethoxybenzidine; salts of o-dianisidine	—			x	612-037-00-5	Carc. 1B
salts of 2,2'-dichloro-4,4'- methylenedianiline; salts of 4,4'-methylenebis(2- chloroaniline)	—			x	612-079-00-4	Carc. 1B

Table B: Colorants classified as CMR in categories 1A, 1B or 2 in Table 3.1 under the EC Regulation 1272/2008 and/or listed in Annex II or IV (with restrictions in column g) of the EC Regulation 1223/2009 (not listed in Table 2 of the CoE ResAP(2008)1).

				EC Reg 1223/2009		Cosmetic Regulation		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Annex IV	Reference number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Acid Black 1	20470	1064-48-8	diazo dyes	x	46					
Acid Black 2	50420	101357-32-8	azin dyes	x	84					
Acid Black 2 (Nigrosine), when used as a substance in hair dye products	50420	8005-03-6	azin dyes			x	1359			
Acid Black 52 and its salts, when used as a substance in hair dye products	15711	16279-54-2/ 5610-64-0	monoazo dyes			x	1323			
Acid Black 131 and its salts, when used as a substance in hair dye products		12219-01-1				x	1252			
Acid Blue 1	42045	129-17-9	triarylmethane dyes	x	59	x	1355			
Acid Blue 3, when used as a substance in hair dye products	42051	3536-49-0	triarylmethane dyes			x	1356			
Acid Blue 7	42080	3486-30-4	triarylmethane dyes	x	62					
Acid Blue 62	62045	4368-56-3	Antraquinone dyes	x	94					
Acid Blue 80	61585	4474-24-2	Antraquinone dyes	x	93					
Acid Blue 104	42735	6505-30-2	triarylmethane dyes	x	68					
Acid Green 1	10020	19381-50-1	nitroso	x	2	x	1342			
Acid Green 9	42100	4857-81-2	triarylmethane dyes	x	64					
Acid Green 22	42170	5863-51-4	triarylmethane dyes	x	65					
Acid Orange 3 and its salts, when used as a substance in hair dye products	10385	6373-74-6/ 15347-52-1	nitro dyes			x	1280			
Acid Orange 6 and its sodium salt, when used as substance in hair dye products	14270 13015	2050-34-2 / 547-57-9 (Na)	monoazo dyes			x	1330			
Acid Orange 7	15510	633-96-5	monoazo dyes	x	21					
Acid Orange 24, when used as a substance in hair dye products	20170	1320-07-6	diazo dyes			x	1232			
Acid Red 1	18050	3734-67-6	monoazo dyes	x	38					
Acid Red 27, when used as a substance in hair dye products	16185	915-67-3	monoazo dyes			x	1350			
Acid Red 35 and its salts, when used as a substance in hair dye	18065	6441-93-6	monoazo dyes			x	1295			
Acid Red 50	45220	5873-16-5	xanthene	x	73					
Acid Red 52	45100	3520-42-1	xanthene	x	71					
Acid Red 73, when used as a substance in hair dye products	27290	5413-75-2	diazo dyes			x	1233			
Acid Red 88	15620	1658-56-6	monoazo dyes	x	24					
Acid Red 98	45405	6441-77-6	xanthene	x	78					
Acid Red 155	18130	8004-53-3	monoazo dyes	x	39					
Acid Red 163	24790	13421-53-9	diazo dyes	x	50					
Acid Red 195		12220-24-5		x	153					
Acid Violet 9	45190	6252-76-2	xanthene	x	72	x	1335			
Acid Violet 43	60730	4430-18-6	antraquinone dyes	x	90					
Acid Violet 50	50325	6837-46-3	azin dyes	x	83					
Acid Yellow 1	10316	846-70-8	nitro	x	3					
Acid Yellow 11	18820	6359-82-6	monoazo dyes	x	42					
Acid Yellow 59	18690	12220-52-9	monoazo dyes	x	40					
Acid Yellow 73 and its sodium salt (Fluorescein), when used as a substance in hair dye products	45350	2321-07-5 / 518-47-8 (Na)	triarylmethane dyes			x	1332			

				EC Reg 1223/2009		Cosmetic Regulation		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Annex IV	Reference number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
(8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-2-naphthyl) trimethylammonium and its salts, except Basic Red 118 (CAS 71134-97-9) as impurity in Basic Brown 17, when used as a substance in hair dye products	12251:1	71134-97-9	monoazo dyes			x	1291			
2-Aminophenol (o-Aminophenol) and its salts	76520	95-55-6 / 67845-79-8 / 51-19-4	natural dyes			x	1372	x	612-033-00-3	Muta. 2
Azobenzene		103-33-3	monoazo dyes			x	727	x	611-001-00-6	Carc. 1B, Muta. 2
Basic Blue 3 and its salts, when used as a substance in hair dye products	51004	47367-75-9/ 33203-82-6	Oxazin dyes			x	1275			
Basic Blue 9 (Methylene Blue) and its salts, when used as a substance in hair dye products	52015	61-73-4	thiazin dyes			x	1306			
Basic Blue 26	44045	2580-56-5	triarylmethane dyes	x	69	x	1340			
Basic Blue 41 and its salts, when used as a substance in hair dye	11105	12270-13-2	monoazo dyes			x	1261			
Basic Blue 47and its salts, when used as a substance in hair dye products	61111	67905-56-0/ 12217-43-5	antraquinone dyes			x	1278			
Basic Brown 4 and its salts, when used as a substance in hair dye	21010	4482-25-1	diazo dyes			x	1296			
Basic Green 1 (Brilliant Green) and its salts, when used as a substance in hair dye products	42040	633-03-4	Triarylmethane dyes			x	1299			
Basic Orange 1 (Chrysoidine R) and its salts, when used as a substance in hair dye products	11320	4438-16-8	monoazo dyes			x	1294			
Basic Red 2, and its salts when used as a substance in hair dye	50240	477-73-6	azin dyes			x	1322			
Basic Red 22 and its salts, when used as a substance in hair dye	11055	12221-52-2	monoazo dyes			x	1292			
Basic Red 46 and its salts, when used as a substance in hair dye products	110825	89959-98-8/ 12221-69-1	monoazo dyes			x	1259			
Basic Violet 2	42520	3248-91-7	triarylmethane dyes	x	67					
Basic Violet 4 and its salts, when used as a substance in hair dye	42600	2390-59-2	triarylmethane dyes			x	1271			
Basic Violet 14	42510	632-99-5	triarylmethane dyes	x	66					
Basic Violet 14 (Solvent Red 41 found ?) and its hydrochloride salt (Fuchsin Basic), when used as a substance in hair dye products	42510	3248-93-9 / 632-99-5 (HCl)	triarylmethane dyes			x	1329			
Basic Yellow 11 and its salts, when used as a substance in hair dye products	48055	4208-80-4	methine/indolium based dyes			x	1273			
Basic Yellow 28 and its salts, when used as a substance in hair dye products	48054	54060-92-3	methine/indolium based dyes			x	1272			
Benzidine based azo dyes						x	720			
Bromocresol green		76-60-8		x	152					
Bromothymol blue		76-59-5		x	151					
4-[4-(1,3-Dihydroxyprop-2-yl)phenylamino]-1,8-dihydroxy-5-nitroanthraquinone		114565-66-1				x	1002	x	603-121-00-2	Carc. 2, Skin Sens. 1
Direct Black 38	30235	1937-37-7	triazo dyes			x	987	x	611-025-00-7	Carc. 1B, Repr. 2
Direct Black 51 and its salts, when used as a substance in hair dye products	27720	3442-21-5/ 34977-63-4	diazo dyes			x	1266			
Direct Blue 6	22610	2602-46-2	diazo dyes			x	988	x	611-026-00-2	Carc. 1B, Repr. 2
Direct Blue 86	74180	1330-38-7	phtalocyanines dyes	x	106	x	1368			
Direct Brown 95	30145	16071-86-6	triazo dyes			x	991	x	611-005-00-8	Carc. 1B
Direct Orange 39	40215	1325-54-8	stilbene	x	54					
Direct Red 23 and its salts, when used as a substance in hair dye	29160	3441-14-3	diazo dyes			x	1269			
Direct Red 28	22120	573-58-0	diazo dyes			x	986	x	611-027-00-8	Carc. 1B, Repr. 2

				EC Reg 1223/2009		Cosmetic Regulation		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Annex IV	Reference number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Direct Red 80 and its salts, when used as a substance in hair dye products	35780	2610-10-8/ 25188-41-4	diazo dyes			x	1270			
Direct Red 81 and its salts, when used as a substance in hair dye products	28160	2610-11-9	diazo dyes			x	1267			
Direct Violet 48 and its salts, when used as a substance in hair dye products	29125	37279-54-2	diazo dyes			x	1268			
Direct Yellow 12 and its salts, when used as a substance in hair dye products	24895	2870-32-8	diazo dyes			x	1264			
Disperse Blue 7 and its salts, when used as a substance in hair dye	62500	3179-90-6	antraquinone dyes			x	1302			
Disperse Brown 1 and its salts, when used as a substance in hair dye products	11152	23355-64-8	monoazo dyes			x	1260			
Disperse Red 11 and its salts, when used as a substance in hair dye products	62015	2872-48-2	antraquinone dyes			x	1301			
Disperse Red 15 (Solvent Red 53), except as impurity in Disperse Violet	60710	116-85-8	antraquinone dyes			x	1241			
Disperse Violet 4 and its salts, when used as a substance in hair dye products	61105	1220-94-6	antraquinone dyes			x	1283			
Disperse Violet 23	60724	19286-75-0	antraquinone dyes	x	88					
Food Black 2, when used as a substance in hair dye products	27755	2118-39-0	diazo dyes			x	1354			
Food Green 3 (Fast Green FCF), when used as a substance in hair dye products	42053	2353-45-9	triarylmethane dyes			x	1357			
HC Blue No. 4 and its salts, when used as a substance in hair dye products		158571-57-4				x	1256			
HC Blue No. 5 and its salts, when used as a substance in hair dye products		68478-64-8 / 158571-58-5				x	1255			
HC Blue 10 and its salts, when used as a substance in hair dye products		173994-75-7/ 102767-27-1				x	1326			
HC Blue 8 and its salts, when used as a substance in hair dye products		22366-99-0	antraquinone dyes			x	1303			
HC Blue 9 and its salts, when used as a substance in hair dye products		114087-41-1/ 114087-42-2				x	1327			
HC Brown 1 and its salts, when used as a substance in hair dye products		83803-98-9				x	1298			
HC Brown 2 and its salts, when used as a substance in hair dye products		83803-99-0				x	1297			
HC Green No 1		52136-25-1				x	1238			
HC Orange No 3		81612-54-6				x	1237			
HC Red No 8 and its salts		13556-29-1/ 97404-14-3	antraquinone dyes			x	1239			
HC Red No. 9 and its salts, when used as a substance in hair dye		56330-88-2				x	1305			
HC Red No 16 and its salts		160219-76-1				x	1373			
HC Yellow No. 3 and its salts, when used as a substance in hair dye products		56932-45-7				x	1286			
HC Yellow No. 5 and its salts, when used as a substance in hair dye products		56932-44-6				x	1285			
HC Yellow No. 6 and its salts, when used as a substance in hair dye products		104333-00-8				x	1324			
HC Yellow No. 8 and its salts, when used as a substance in hair dye products		66612-11-1				x	1304			

				EC Reg 1223/2009		Cosmetic Regulation		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Annex IV	Reference number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
HC Yellow No 11		73388-54-2				x	1236			
HC Yellow No. 12 and its salts, when used as a substance in hair dye products		59320-13-7				x	1325			
2-[2-Hydroxy-3-(2-chlorophenyl)carbamoyl-1-naphthylazo] -7-[2-hydroxy-3-(3-methylphenyl)carbamoyl-1-naphthylazo] fluoren-9-one						x	1156			
Mendola Blue and its salts, when used as a substance in hair dye products	51175	7057-57-0/ 966-62-1	Oxazin dyes			x	1276			
1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole) and its salts	76050	615-05-4	natural dyes			x	376	x	612-200-00-0	Carc. 1B, Muta. 2
(Methylenebis(4,1-phenylenazo(1-(3-(dimethylamino)propyl)-1, 2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diyl))) -1,1′-dipyridinium dichloride dihydrochloride						x	1155			
Natural Red 25 and its salts, when used as a substance in hair dye products	75450	60687-93-6	natural dyes			x	1279			
o-Dianisidine based azo dyes						x	711			
Orange G	16230	1936-15-8	monoazo dyes	x	34					
o-Tolidine based dyes						x	725			
Pigment Blue 15, when used as a substance in hair dye products	74160	147-14-8	phtalocyanines dyes			x	1367			
Pigment Blue 16	74100	574-93-6	phtalocyanines dyes	x	104					
Pigment Brown 1	12480	6410-40-8	monoazo dyes	x	13					
Pigment Green 7	74260	1328-53-6	phtalocyanines dyes	x	107	x	1369			
Pigment Green 8	10006	16143-80-9	nitroso	x	1					
Pigment Orange 1	11725	6371-96-6	monoazo dyes	x	6					
Pigment Orange 5	12075	3468-63-1	monoazo dyes			x	397			
Pigment Red 3	12120	2425-85-6	monoazo dyes	x	10					
Pigment Red 4 and its salts when used as a substance in hair dye	12085	2814-77-9	monoazo dyes			x	1345			
Pigment Red 5 and its salts when used as a substance in hair dye	12490	6410-41-9	monoazo dyes			x	1347			
Pigment Red 7	12420	6471-51-8	monoazo dyes	x	12					
Pigment Red 48 when used as a substance in hair dye products	15865	3564-21-4	monoazo dyes			x	1348			
Pigment Red 53:1	15585	5160-02-1 2092-56-0	monoazo dyes			x	401			
Pigment Red 63:1, when used as a substance in hair dye products	15880	6417-83-0	monoazo dyes			x	1349			
Pigment Red 64, calcium salt	15800	6371-76-2	monoazo dyes	x	26	x	1331			
Pigment Red 83, when used as a substance in hair dye products	58000	72-48-0	antraquinone dyes			x	1361			
Pigment Red 112	12370	6535-46-2	monoazo dyes	x	11	x	1346			
Pigment Red 122	73915	980-26-7	quinacridone/indigoid	x	103					
Pigment Violet 19	73900	1047-16-1	quinacridone/indigoid	x	102	x	1366			
Pigment Violet 23	51319	6358-30-1	oxazin dyes	x	85	x	1360			
Pigment Yellow 1	11680	2512-29-0	monoazo dyes	x	4					
Pigment Yellow 3	11710	6486-23-3	monoazo dyes	x	5					
Pigment Yellow 12 and its salts, when used as a substance in hair dye products	21090	6358-85-6	diazo dyes			x	1263			
Pigment Yellow 13	21100	5102-83-0	diazo dyes	x	47	x	1351			
Pigment Yellow 16	20040	5979-28-2	diazo dyes	x	45					
Pigment Yellow 73 and its salts, when used as a substance in hair dye products	11738	13515-40-7	monoazo dyes			x	1262			
Pigment Yellow 83	21108	5567-15-7	diazo dyes	x	48					
Ponceau SX, when used as a substance in hair dye products	14700	4548-53-2	monoazo dyes			x	1341			
Solvent Black 3 and its salts, when used as a substance in hair dye products	26150	4197-25-5	diazo dyes			x	1265			

				EC Reg 1223/2009		Cosmetic Regulation		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Annex IV	Reference number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Solvent Black 5, when used as a substance in hair dye products	50415	11099-03-9	Azin dyes			x	1274			
Solvent Blue 35	61554	17354-14-2	antraquinone dyes			x	389			
Solvent Green 3, when used as a substance in hair dye products	61565	128-80-3	antraquinone dyes			x	1364			
Solvent Green 7	59040	6358-69-6	antraquinone dyes	x	87	x	1362			
Solvent Orange 1 and its salts when used as a substance in hair dye products	11920	2051-85-6	monoazo dyes			x	1343			
Solvent Orange 3 and its salts, when used as a substance in hair dye products	11270	495-54-5	monoazo dyes			x	1293	x	611-151-00-2	Muta. 2, Skin Irrit. 2
Solvent Orange 6	18736	10127-28-3	monoazo dyes	x	41					
Solvent Orange 7	12140	3118-97-6	monoazo dyes			x	378			
Solvent Red 1, when used as a substance in hair dye products	12150	1229-55-6	monoazo dyes			x	1231			
Solvent Red 3	12010	6535-42-8	monoazo dyes	x	8	x	1344			
Solvent Red 23	26100	85-86-9	diazo dyes	x	51	x	1353			
Solvent Red 24	26105	85-83-6	diazo dyes			x	379			
Solvent Red 43, its disodium salt (Acid Red 87; CI 45380) and its aluminium salt (Pigment Red 90:1 Aluminium lake), when used as a substance in hair dye products	45380	15086-94-9 / 17372-87-1 (Na) / 15876-39-8 (Al)	xanthene			x	1334			
Solvent Red 72 and its disodium salt, when used as a substance in hair dye products	45370	596-03-2 / 4372-02-5 (Na)	xanthene			x	1333			
Solvent Red 73 and its sodium salt (Acid Red 95; CI) when used as a substance in hair dye products	45425	38577-97-8 / 33239-19-9	xanthene			x	1336			
Solvent Violet 13, when used as a substance in hair dye products	60725	81-48-1	antraquinone dyes			x	1363			
Solvent Yellow 14	12055	842-07-9	monoazo dyes			x	1107	x	611-056-00-6	Carc. 2, Muta. 2, Skin Sens. 1
Solvent Yellow 16	12700	4314-14-1	monoazo dyes	x	15					
Solvent Yellow 29	21230	6706-82-7	diazo dyes	x	49	x	1352			
Solvent Yellow 33	47000	8003-22-3	quinoline dyes	x	81	x	1358			
Solvent Yellow 44 (Disperse Yellow 11 and Solvent Yellow 85 found) and its salts, when used as a substance in hair dye products	56200	2478-20-8	aminoketone based dyes			x	1277			
2′,4′,5′,7′-Tetraiodofluorescein, its disodium salt (Acid Red 51; CI 45430) and its aluminium salt (Pigment Red 172 Aluminium lake) when used as a substance in hair dye products	45430	15905-32-5 / 16423-68-0 (Na) / 12227-78-0 (Al)	xanthene			x	1337			
Trisodium bis(7-acetamido-2-(4-nitro-2-oxidophenylazo)-3-sulfonato-1-naphtholato)chromate(1-)						x	1131			
Vat Orange 7	71105	4424-06-0	antraquinone dyes	x	97					
VAT Red 1 (Oralith Brilliant Pink R), when used as a substance in hair dye products	73360	2379-74-0	indigoid based dyes			x	1365			
A 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl)resorcinol-4-yl-tris (6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) and 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl)resorcinolbis (6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)		140698-96-0				x	1186	x	016-093-00-6	Carc. 2

				EC Reg 1223/2009		Cosmetic Regulation		EC Reg 1272/2008		
CI Name	CI Number	CAS number	dye category/structure	Annex IV	Reference number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
A mixture of: 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo]benzoic acid and 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]-2,5-diethoxyphenyl)azo]-3-[(3-phosphonophenyl)azo]benzoic acid		163879-69-4				x	1193	x	611-129-00-2	Repr. 2, Skin Sens. 1
A mixture of: reaction product of 4,4′-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxo-naphthalenesulfonate (1:2) and reaction product of 4,4′-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:3)						x	1187			

Table C: Elements and their inorganic salts classified as CMR in categories 1A, 1B or 2 in Table 3.1 under the EC Regulation 1272/2008 and/or listed in Annex II of the EC Regulation 1223/2009 (not listed in Table 3 of the CoE ResAP(2008)1).

		EC Reg 1223/2009		EC Reg 1272/2008		
Elements	**CAS number**	**Annex II**	**Reference number**	**Table 3.1**	**Index number**	**Classification (CMR, Skin/Eye Irrir./Sens.)**
Antimony trioxide	1309-64-4			x	051-005-00-X	Carc. 2
Diarsenic trioxide; Arsenic trioxide	1327-53-3			x	033-003-00-0	Carc. 1A, Skin Corr. 1B
Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide	1303-28-2			x	033-004-00-6	Carc. 1A
Arsenic acid and its salts	2139-59-4			x	033-005-00-1	Carc. 1A
Barium salts, with the exception of barium sulphide under the conditions laid down in Annex III, and of barium sulfate, lakes, salts and pigments prepared from colouring agents when listed in Annex IV		x	46			
Beryllium and its compounds	7440-41-7	x	54	x	004-001-00-7	Carc. 1B, Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1
Beryllium compounds with the exception of aluminium beryllium silicates, and with those specified elsewhere in this Annex				x	004-002-00-2	Carc. 1B, Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1
Beryllium oxide	1304-56-9			x	004-003-00-8	Carc. 1B, Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1
Cadmium (non-pyrophoric); [1] Cadmium oxide (non-pyrophoric) [2]	7440-43-9 [1] 1306-19-0 [2]			x	048-002-00-0	Carc. 1B, Muta. 2, Repr. 2
Cadmium cyanide	542-83-6			x	048-004-00-1	Carc. 2
Cadmiumhexafluorosilicate(2-); Cadmium fluorosilica	17010-21-8			x	048-005-00-7	Carc. 2
Cadmium fluoride	7790-79-6			x	048-006-00-2	Carc. 1B, Muta. 1B, Repr. 1B
Cadmium iodide	7790-80-9			x	048-007-00-8	Carc. 2
Cadmium chloride	10108-64-2			x	048-008-00-3	Carc. 1B, Muta. 1B, Repr. 1B
Cadmium sulphate	10124-36-4			x	048-009-00-9	Carc. 1B, Muta. 1B, Repr. 1B
Cadmium sulphide	1306-23-6			x	048-010-00-4	Carc. 1B, Muta. 2, Repr. 2
Chromium (VI) trioxide	1333-82-0			x	024-001-00-0	Carc. 1A, Muta. 1B, Repr. 2, Skin Corr. 1A, Skin Sens. 1
Chromium (VI) compounds, with the exception of Barium chromate and of compounds specified elsewhere in this Annex				x	024-017-00-8	Carc. 1B, Skin Sens. 1
Dichromium tris(chromate); Chromium III chromate; Chromic chromate	24613-89-6			x	024-010-00-X	Carc. 1B, Skin Corr. 1A, Skin Sens. 1
Chromyl dichloride; Chromic oxychloride	14977-61-8			x	024-005-00-2	Carc. 1B, Muta. 1B,Skin Corr. 1A, Skin Sens. 1
Potassium dichromate	7778-50-9			x	024-002-00-6	Carc. 1B, Muta. 1B, Repr. 1B, Skin Corr. 1B, Skin Sens. 1
Ammonium dichromate	2151-16-3			x	024-003-00-1	Carc. 1B, Muta. 1B, Repr. 1B, Skin Corr. 1B, Skin Sens. 1
Sodium dichromate anhydrate	10588-01-9			x	024-004-00-7	Carc. 1B, Muta. 1B, Repr. 1B, Skin Corr. 1B, Skin Sens. 1
Sodium dichromate, dihydrate	7789-12-0			x	024-004-01-4	
Potassium chromate	7789-00-6			x	024-006-00-8	Carc. 1B, Muta. 1B, Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1
Calcium chromate	13765-19-0			x	024-008-00-9	Carc. 1B
Strontium chromate	2151-06-8			x	024-009-00-4	Carc. 1B

		EC Reg 1223/2009		EC Reg 1272/2008		
Elements	CAS number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Sodium chromate	2146-10-8			x	024-018-00-3	Carc. 1B, Muta. 1B, Repr. 1B, Skin Corr. 1B, Skin Sens. 1
Cobalt dichloride	7646-79-9			x	027-004-00-5	Carc. 1B, Muta. 2, Repr. 1B, Skin Sens. 1
Cobalt dinitrate	10141-05-6			x	027-009-00-2	Carc. 1B, Muta. 2, Repr. 1B, Skin Sens. 1
Cobalt lithium nickel oxide				x	028-058-00-2	Carc. 1A, Skin Sens. 1
Copper chloride; Copper (I) chloride; Cuprous chlorid	7758-89-6			x	029-001-00-4e	
Dicopper oxide; Copper (I) oxide	1317-39-1			x	029-002-00-X	
Cobalt sulphate	10124-43-3	x	454	x	027-005-00-0	Carc. 1B, Muta. 2, Repr. 1B, Skin Sens. 1
Lead chromate	7758-97-6			x	082-004-00-2	Carc. 1B, Repr. 1A
Lead hexafluorosilicate	25808-74-6			x	009-014-00-1	Repr. 1A
Lead compounds with the exception of those specified elsewhere in this Annex				x	082-001-00-6	Repr. 1A
Lead diazide;Lead azide	13424-46-9			x	082-003-00-7	Repr. 1A
Lead diazide; Lead azide [≥ 20 % phlegmatiser]	13424-46-9			x	082-003-01-4	Repr. 1A
Trilead bis(orthophosphate)	7446-27-7			x	082-006-00-3	Repr. 1A
Lead chromate molybdate sulfate red; C.I. Pigment Red 104; [This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77605.]	12656-85-8			x	082-010-00-5	Carc. 1B, Repr. 1A
Lead hydrogen arsenate	7784-40-9			x	082-011-00-0	Carc. 1A, Repr. 1A
Mercury dichloride; Mercuric chloride	7487-94-7			x	080-010-00-X	Muta. 2, Repr. 2, Skin Corr. 1B
Molybdenum trioxide	1313-27-5			x	042-001-00-9	Carc. 1B
Nickel monoxide	1313-99-1	x	455	x	028-003-00-2	Carc. 1A
Dinickel trioxide	1314-06-3	x	456	x	028-005-00-3	Carc. 1A, Skin Sens. 1
Nickel dioxide	12035-36-8	x	457	x	028-004-00-8	Carc. 1A, Skin Sens. 1
Trinickel disulphide	12035-72-2	x	458	x	028-007-00-4	Carc. 1A, Muta. 2, Skin Sens. 1
Nickel sulphide	16812-54-7	x	460	x	028-006-00-9	Carc. 1A, Muta. 2, Skin Sens. 2
Nickel dihydroxide	12054-48-7	x	1006	x	028-008-00-X	Carc. 1A, Muta. 2, Repr. 1B, Skin Irrit. 2, Skin Sens. 1
Nickel sulphate	7786-81-4	x	1100	x	028-009-00-5	Carc. 1A, Muta. 2, Repr. 1B, Skin Irrit. 2, Skin Sens. 1
Nickel sulfate	7786-81-4			x	028-009-00-5	Carc. 1A, Muta. 2, Repr. 1B, Skin Irrit. 2, Skin Sens. 1
Nickel matte	69012-50-6			x	028-013-00-7	Carc. 1A, Skin Sens. 1
Nickel powder; [particle diameter < 1 mm]	7440-02-0			x	028-002-01-4	Carc. 2, Skin Sens. 1
Nickel monoxide	1313-99-1			x	028-003-00-2	Carc. 1A, Skin Sens. 1
Nickel dioxide	12035-36-8			x	028-004-00-8	Carc. 1A, Skin Sens. 1
Dinickel trioxide	1314-06-3			x	028-005-00-3	Carc. 1A, Skin Sens. 1
Nickel sulphide	16812-54-7			x	028-006-00-9	Carc. 1A, Muta. 2, Skin Sens. 1
Nickel subsulphide;Trinickel disulphide	12035-72-2			x	028-007-00-4	Carc. 1A, Muta. 2, Skin Sens. 2
Nickel dihydroxide; [1] Nickel hydroxide [2]	12054-48-7 [1] 11113-74-9 [2]			x	028-008-00-X	Carc. 1A, Muta. 2, Repr. 1B, Skin Irrit. 2, Skin Sens. 1
Nickel dichloride	7718-54-9			x	028-011-00-6	Carc. 1A, Muta. 2, Repr. 1B, Skin Irrit. 2, Skin Sens. 1
Nickel dinitrate; [1] Nitric acid, nickel salt [2]	13138-45-9 [1] 14216-75-2 [2]			x	028-012-00-1	Carc. 1A, Muta. 2, Repr. 1B, Eye Dam. 1, Skin Irrit. 2, Skin Sens. 1

Elements	CAS number	EC Reg 1223/2009		EC Reg 1272/2008		
		Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Nickel diperchlorate; Perchloric acid, nickel(II) salt	13637-71-3			x	028-016-00-3	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel dipotassium bis(sulfate); [1] Diammonium nickel bis(sulfate) [2]	13842-46-1 [1] 15699-18-0 [2]			x	028-017-00-9	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel bis(sulfamidate); Nickel sulfamate	13770-89-3			x	028-018-00-4	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel bis(tetrafluoroborate)	14708-14-6			x	028-019-00-X	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel difluoride; [1] Nickel dibromide; [2] Nickel diiodide; [3] Nickel potassium fluoride [4]	10028-18-9 [1] 13462-88-9 [2] 13462-90-3 [3] 11132-10-8 [4]			x	028-029-00-4	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel hexafluorosilicate	26043-11-8			x	028-030-00-X	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel selenate	15060-62-5			x	028-031-00-5	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel hydrogen phosphate; [1] Nickel bis(dihydrogen phosphate); [2] Trinickel bis(orthophosphate); [3] Dinickel diphosphate; [4] Nickel bis(phosphinate); [5] Nickel phosphinate; [6] Phosphoric acid, calcium nickel salt; [7] Diphosphoric acid, nickel(II) salt [8]	14332-34-4 [1] 18718-11-1 [2] 10381-36-9 [3] 14448-18-1 [4] 14507-36-9 [5] 36026-88-7 [6] 17169-61-8 [7] 19372-20-4 [8]			x	028-032-00-0	Carc. 1A, Skin Sens. 1
Diammonium nickel hexacyanoferrate	74195-78-1			x	028-033-00-6	Carc. 1A, Skin Sens. 1
Nickel dicyanide	557-19-7			x	028-034-00-1	Carc. 1A, Skin Sens. 1
Nickel chromate	14721-18-7			x	028-035-00-7	Carc. 1A, Skin Sens. 1
Nickel(II) silicate; [1] Dinickel orthosilicate; [2] Nickel silicate (3:4); [3] Silicic acid, nickel salt; [4] Trihydrogen hydroxybis[orthosilicato(4-)]trinickelate(3-) [5]	21784-78-1[1] 13775-54-7 [2] 31748-25-1 [3] 37321-15-6 [4] 12519-85-6 [5]			x	028-036-00-2	Carc. 1A, Skin Sens. 1
Dinickel hexacyanoferrate	14874-78-3			x	028-037-00-8	Carc. 1A, Skin Sens. 1
Trinickel bis(arsenate); Nickel(II) arsenate	13477-70-8			x	028-038-00-3	Carc. 1A, Skin Sens. 1
Nickel telluride	12142-88-0			x	028-040-00-4	Carc. 1A, Skin Sens. 1
Trinickel tetrasulfide	12137-12-1			x	028-041-00-X	Carc. 1A, Skin Sens. 1
Trinickel bis(arsenite)	74646-29-0			x	028-042-00-5	Carc. 1A, Skin Sens. 1
Cobalt nickel gray periclase; C.I. Pigment Black 25; C.I. 77332; [1] Cobalt nickel dioxide; [2] Cobalt nickel oxide [3]	68186-89-0 [1] 58591-45-0 [2] 12737-30-3 [3]			x	028-043-00-0	Carc. 1A, Skin Sens. 1
Nickel tin trioxide; Nickel stannate	12035-38-0			x	028-044-00-6	Carc. 1A, Skin Sens. 1
Nickel triuranium decaoxide	15780-33-3			x	028-045-00-1	Carc. 1A, Skin Sens. 1
Nickel dichromate	15586-38-6			x	028-047-00-2	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel(II) selenite	10101-96-9			x	028-048-00-8	Carc. 1A, Skin Sens. 1
Nickel selenide	1314-05-2			x	028-049-00-3	Carc. 1A, Skin Sens. 1
Silicic acid, lead nickel salt	68130-19-8			x	028-050-00-9	Carc. 1A, Repr. 1A, Skin Sens. 1

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Elements	**CAS number**	**Annex II**	**Reference number**	**Table 3.1**	**Index number**	**Classification (CMR, Skin/Eye Irrir./Sens.)**
Nickel diarsenide; [1] Nickel arsenide [2]	12068-61-0 [1] 27016-75-7 [2]			x	028-051-00-4	Carc. 1A, Skin Sens. 1
Nickel dichlorate; [1] Nickel dibromate; [2] Ethyl hydrogen sulfate, nickel(II) salt [3]	67952-43-6 [1] 14550-87-9 [2] 71720-48-4 [3]			x	028-053-00-5	Carc. 1A, Muta. 2, Repr. 1B, Skin Sens. 1
Nickel(II) sulfite; [1] Nickel tellurium trioxide; [2] Nickel tellurium tetraoxide; [3] Molybdenum nickel hydroxide oxide phosphate [4]	7757-95-1 [1] 15851-52-2 [2] 15852-21-8 [3] 68130-36-9 [4]			x	028-055-00-6	Carc. 1A, Skin Sens. 1
Nickel boride (NiB); [1] Dinickel boride; [2] Trinickel boride; [3] Nickel boride; [4] Dinickel silicide; [5] Nickel disilicide; [6] Dinickel phosphide; [7] Nickel boron phosphide [8]	12007-00-0 [1] 12007-01-1 [2] 12007-02-2 [3] 12619-90-8 [4] 12059-14-2 [5] 12201-89-7 [6] 12035-64-2 [7] 65229-23-4 [8]			x	028-056-00-1	Carc. 1A, Skin Sens. 1
Dialuminium nickel tetraoxide; [1] Nickel titanium trioxide; [2] Nickel titanium oxide; [3] Nickel Divanadium hexaoxide; [4] Cobalt dimolybdenum nickel octaoxide; [5] Nickel zirkonium trioxide; [6] Molybdenum Nickel tetraoxide; [7] Nickel tungsten tetraoxide; [8] Olivine, nickel green; [9] Lithium nickel dioxide; [10] Molybdenum nickel oxide; [11]	12004-35-2 [1] 12035-39-1 [2] 12653-76-8 [3] 52502-12-2 [4] 68016-03-5 [5] 70692-93-2 [6] 14177-55-0 [7] 14177-51-6 [8] 68515-84-4 [9] 12031-65-1 [10] 12673-58-4 [11]			x	028-057-00-7	Carc. 1A, Skin Sens. 1
Potassium bromate	231-829-8			x	035-003-00-6	Carc. 2, Eye Irrit. 2
Strontium nitrate	10042-76-9	x	403			
Tellurium and its compounds	13494-80-9	x	312			
Potassium titanium oxide (K2Ti6O13)	12056-51-8			x	022-004-00-1	Carc. 2
Divanadium pentaoxide; Vanadium pentoxide	1314-62-1			x	023-001-00-8	Muta. 2, Repr. 2
Zinc chromates including Zinc potassium chromate				x	024-007-00-3	Carc. 1A, Skin Sens. 1
Zirconium and its compounds, with the exception of the substances listed under reference number 50 in Annex III, and the zirconium lakes, pigments or salts of the colouring agents when listed in Annex IV	7440-67-7	x	391			

Table D: Polycyclic aromatic hydrocarbons classified as CMR in categories 1A, 1B or 2 in Table 3.1 under the EC Regulation 1272/2008 and/or listed in Annex II of the EC Regulation 1223/2009 (not listed in Table 3 of the CoE ResAP(2008)1).

		EC Reg 1223/2009		EC Reg 1272/2008		
Substances	CAS number	Annex II	Reference number	Table 3.1	Index number	Classification (CMR, Skin/Eye Irrir./Sens.)
Dibenz[a,h]anthracene	53-70-3	x	637	x	601-041-00-2	Carc. 1B
Benz[a]anthracene	56-55-3	x	638	x	601-033-00-9	Carc. 1B
Benzo[e]pyrene	192-97-2	x	639	x	601-049-00-6	Carc. 1B
Benzo[j]fluoranthene	205-82-3	x	640	x	601-035-00-X	Carc. 1B
Benz(e)acephenanthrylene	205-99-2	x	641	x	601-034-00-4	Carc. 1B
Benzo(k)fluoranthene	207-08-9	x	642	x	601-036-00-5	Carc. 1B
Chrysene	218-01-9	x	643	x	601-048-00-0	Carc. 1B, Muta. 2

Annex III

Meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (11 November 2014)

Minutes of the meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (Ispra – Italy, 11 November 2014)

The agenda and list of participants are reported in Tables A and B, respectively.

1. Welcome and adoption of the agenda

The chairperson Mrs Paola Piccinini, from the Chemical Assessment and Testing Unit (EC DG JRC I.1), opened the meeting by welcoming the experts and thanking them for their participation. She briefly introduced the DG JRC ISPRA site and after providing practical information, a short tour de table was made. The agenda of the meeting was approved without any modification.

2. Adoption of the minutes of the CSN (sub-group tattoos and permanent make-up) meeting of 23.06.2014

The minutes of the meeting of 23.06.2014 were adopted without comments.

3. Objectives of the meeting and of the working group

The objectives of the meeting and working group were presented under point 4.

4. Project on tattoos and permanent make-up towards a European legislation (Paola PICCININI – EC DG JRC)

There is a large consensus among the Consumer Safety Network (CSN) members that an initiative should be proposed at European level for the safety of tattoo inks and permanent make-up. The actual situation in Europe is nowadays uneven with some Member States that already have legislation in place.

DG JRC will provide scientific and technical support to DG SANCO for the preparation of a future EU legislation on the requirements of tattoo inks. In its work, DG JRC will strictly collaborate with the CSN sub-group tattoos and permanent make-up (CSN-STPM). The project execution needs the active involvement of the experts of the subgroup that will be asked to provide info, share their knowledge and experience, draft contributions, revise reports, etc.

The objectives of the project are the establishment of the state of the play, the assessment and update of the Council of Europe (CoE) resolution (ResAP) (2008)1 and the conclusions. Information about, for example, percentage of tattooed persons, ink market, chemicals present in tattoo inks, health effects of tattooing and removal processes and available legislation will be gathered. The list of restricted chemicals and limits present in the CoE ResAP(2008)1 will be evaluated, as well as the proposed analytical methods. Consideration will be devoted to the requirements on labelling, safety assessment, hygiene and sterility. Data gaps and research needs will be identified and risk communication strategies adopted by Member States will be considered. The conclusions would identify the elements to be addressed by the European action on the safety of tattoos.

The project started at the end of September and will last eighteen months (March 2016). The work is divided into four packages, which will not include experimental work. For each work package one meeting of the CSN-STPM will be organised and a report with all the information collected will be prepared. The timeframe for all the packages is very strict and exchange of knowledge among the members of the CSN-STPM will have to be very rapid.

<u>Work Package 1 - Preparatory work</u>

The deliverable for this work package (WP) is due by the end of 2014 and foresees to carry out:

- a regulatory review on national legislations in place or in draft and/or guidelines on requirements for tattoo inks, hygiene, market surveillance, authorisation of tattoo studios, recommended or compulsory training for tattoo artists, etc.;
- a review of test methods potentially useful to enforce the restrictions of the CoE ResAP(2008)1.

Experts of CSN-STPM will be asked to provide legislative documents in the national language, with an English translation. They will also be asked to provide information about international, national, in–house validated test methods, as well as methods published in the literature to quantify substances (such as aromatic amines, dyes, heavy metals, polycyclic aromatic hydrocarbon, carcinogenic, mutagenic and toxic for reproduction substances) in tattoo inks or other similar matrices. The European Network of Official Cosmetics Control Laboratories will also be contacted.

Work Package 2 - State of play

WP 2 will be finalised by the end of June 2015. In this part of the project the actual quantitative situation in terms of national statistics on tattoo related data will be evaluated and a survey on used inks, chemicals and preservatives will be conducted with the help of a questionnaire to be circulated among associations of producers, distributors, tattoo artists and dermatologists.

Work Package 3: Assessment and update ResAP(2008)1

The deadline for this part of the project is end 2015. The tasks consist in preparing overviews on the health effects and risks linked to tattooing and removal processes, on national information campaigns organised in Member states, on data gaps and research needs related to analytical test methods and on recommendation for safety assessment requirements.

Work Package 4: Conclusions

A workshop to present the activities concluded and foreseen will be organised and experts from all Member States will be invited. The final report, to be delivered by March 2016, will focus on best practices, lessons learnt from the implementation of the envisage GPSD article 13 and on the conclusions of the project.

5. Measure on the safety of tattoo ink under article 13 GPSD (Ana Maria BLASS RICO – EC DG JUST)

Mrs Blass explained that some Member States have national legislation on the safety of tattoos and others not. An urgent EU action is needed to ensure a consistent high level of protection for all European citizens and to avoid problems of free circulation of products on the market. This is justified by the increasing number of tattoos and reported RAPEX notifications. She updated experts on what had been discussed in the last meetings in Brussels.

In the meeting of CSN-STPM in June, experts discussed the requirements to be included in an emergency measure according to art. 13 of the General Product Safety Directive (GPSD) 2001/95/EC. Among them, preservatives, limit for nickel, single or multiple packaging, period after opening labelling, sterility and strict aseptic practices were considered, as well as suggestions for inclusion of some chemicals in the list of prohibited substances. Experts were in favour of including requirements about chemical substances that are injected for tattoo removing.

A draft text of the elements to be included in an emergency measure was presented in the CSN meeting in October.

The draft legislation is currently under inter-service consultation (ISC) and the effects of this measure in other existing legislation (e.g. REACH and cosmetics legislation) are being discussed. Independently of the outcome of this consultation, the work of the CSN-STPM is needed especially if a stand-alone legislation is to be envisaged. In this case an impact assessment, considering cost of industry, impact on manufacturer, health effect costs, sanity and health service, etc., will be needed.
Mrs Blass explained that article 13 of GPSD does not provide the possibility of including in the emergency measure requirements for tattoo artists and most probably also for labelling.
She also mentioned the work of CEN/TC 435 "Project Committee - Tattooing services" on hygienic requirements that will complement the work done in the frame of the project lead by the Directorate General Joint Research Centre.

6. Analytical control of metal impurities in tattoo inks: state of the art and future needs (Beatrice BOCCA – Italian National Institute for Health)

According to the CoE ResAP(2008)1, metals should comply with the maximum allowed concentrations of impurities listed in Table 3, however no methods are suggested in this document. In addition, it is not clear if the limits in Table 3 are valid for the bioavailable fraction (soluble metals) or for the total amount quantifiable after sample decomposition. On the one hand, some metals in pigments can be not readily soluble in aqueous solutions, but on the other hand the determination of the total amount could overestimate the biologically relevant exposure to metals from tattoos. Failing to provide appropriate and harmonised analytical methods for the determination metals leads to questionable results.
Nowadays, no standard methods are available for the quantification of metals in tattoo inks, consequently methods applicable to other matrices should be considered and modified.
The following test methods can be considered, after modification, for the detection of metal impurities in tattoo inks:

- ISO/TR 17276:2014 Cosmetics - Analytical approach for screening and quantification methods for heavy metals in cosmetics;
- ISO 12787:2011 Cosmetics - Analytical methods-Validation criteria for analytical results using chromatographic techniques;
- EPA 3050B, EPA 3051, EPA 3051A (acid extraction/dissolution of the samples) and EPA 3052 (total sample decomposition);
- ISO 11885 Water quality - Determination of 33 selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES);
- ISO 17294-2 Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of 62 elements;
- ISO 15586 Water quality - Determination of trace elements (Ag, Al, As, Cd, Co, Cr, Cu, Fe, Mn, Mo, Ni, Pb, Sb, Se, Tl, V, and Zn) using atomic absorption spectrometry with graphite furnace (GF) AAS.

Regarding the determination of soluble copper, the methods commonly applied are:

- ISO 105-E04 Textiles – Tests for colour fastness - Part E04: Colour fastness to perspiration;
- ISO 17072-1 Leather - Chemical determination of metal content - Part 1: Extractable metals;
- EN 16711-2 Textiles – Determination of metal content - Part 2: Determination of metals extracted by acidic artificial perspiration solution.

The quantification of chromium hexavalent can be carried out using:

- EPA 3060A - Alkaline digestion for hexavalent chromium determination in soil, sludge, sediment, and similar waste materials;

- EPA 218.7 - Determination of hexavalent chromium in drinking water by Ion Chromatography with post-column derivatisation and UV-VIS spectroscopic detection;
- ISO 17075 Leather – Chemical tests - Determination of Cr (VI) content.

Some in-house methods were developed and validated according to EN ISO 17025 by various laboratories in Italy and are reported hereafter:

- determination of elements in cosmetics by ICP-MS after microwave digestion (ISS, Rome, extension of application field to tattoo inks);
- -determination of metals in tattoo inks by ICP-MS after microwave digestion (ISS, Rome);
- determination of As, Sb, Ba, Cd, Co, Ni and Pb in tattoo samples by ICP-MS after under-pressure digestion (ARPA, Alto Adige);
- determination of Cr (VI) in cosmetic products using Ion Chromatography with Dynamic Reaction Cell ICP-MS (ISS, Rome);
- determination of Cr (VI) in tattoo inks by Ion Chromatography and Dynamic Reaction Cell ICP-MS (ISS, Rome);

Other in-house methods were validated for the detection of heavy metals in tattoo inks in New Zealand, Denmark, Slovenia, Germany and France.

As the EU Regulation 1223/2009 on cosmetic takes into account the presence safety of nanoparticles, the last part of the presentation considered this issue and an in-house validated method for the detection of nanoparticles in tattoo inks based on a combination of analytical techniques (Dynamic Light Scattering, Field Flow Fractionation, Multi Angle Light Scattering and ICP-MS) was presented.

In conclusion, considering the toxicological properties of certain metals, such as As, Cd, Cr VI (carcinogenic) and Hg, Pb (neurotoxic), there is strong need to harmonise test methods for their determination in tattoo inks. Metals like Al, Ti and Mn should probably be checked as well. Moreover, a safety assessment for nanoparticles would be desirable.

7. Analysing target compounds in tattoo inks in light of legal restrictions- strategies and their application (Christopher HOHL – Swiss Kantonales Laboratorium)

In Switzerland, the first studies on tattoo inks were made on 2004 and since 2008 over 650 tattoo inks have been analysed. The "Swiss Kantonales laboratorium" focusses on the analysis of pigments, aromatic amines, preservatives, nitrosamines, PAHs (polyaromatic hydrocarbons), microbiological contamination, and studies on photodegradation by laser and sunlight.

Aromatic amines (AA) are present in inks as impurities of colorants belonging to several classes. The screening and quantitative determinations are carried out using one method covering about 30 amines. Since there is no harmonised method for the detection of AA in tattoo inks, the method that foresees the reductive cleavage of azodyes in textiles is used. The determination of the aromatic amines thus released is indirect proof that forbidden colorants (produced using carcinogenic AA) are present in the ink. However, it has to be noted that pigments are not soluble and the most important risk linked to them derives from their photodegradation and not from their reductive cleavage. There is evidence that when exposed to the sun and/or laser light, pigments degrade into AA.

In Switzerland there is a negative list regarding organic pigments, based on toys and cosmetics, and a positive list for preservatives. This led to the fact that many tattoo inks on the Swiss market legally contain pigments not allowed in cosmetics (as they are neither in the positive list of colorants for cosmetics nor on the negative list for tattoo inks).

Reference materials are needed to improve the efficiency of market surveillance. In the last few years more and more falsified labelling was detected. Forbidden colorants are often disguised and labelled as allowed colorants.
Concerning analytical methods, colorimetry and LC/MS are supporting methods, for which expertise is required. MALDI TOF (Matrix-assisted laser desorption/ionization Time of Flight) is the best technique to identify pigments, even though colorimetry can still represent a good help.
There is the need of developing an harmonised extraction and detection method for PAHs, nitrosamines and preservatives. In addition, further research on the phototoxicity and photodegration of pigments under solar and laser irradiation is essential.

8. Discussion

Mr. Serup noted that the bioavailability of tattoo inks needs to be considered, when assessing the toxicity, as pigments are in principle insoluble.
The Dutch experts explained that in the Netherlands tattoo removal, both made with laser and chemicals, is considered medical treatment; for this reasons they were not in favour of the inclusion of such substances in the emergency measure.
On the contrary, Mr Renzoni was in favour; he confirmed that in Italy two products used for tattoo removal (one of which based on lactic acid) are banned, but this is not the case in other countries.
Mr Serup explained that in the past, tattoo removal was carried out using many substances (tannic acid among them), whereas nowadays lactic acid is used (20-40 %, pH 1-3).
The possibility to establish a positive list of allowed substances (colorants and preservatives) was discussed and considered an interesting approach for the future, even though it was acknowledged that there would be no time within the current project. Mr Fiala noted in Switzerland only substances approved for cosmetics can be used for the production of tattoo inks.
Answering a question, Mrs Piccinini explained that limits for aromatic amines could be discussed in WP 3, when the restrictions of CoE will be evaluated. Mrs Blass underlined the necessity to have a risk assessment for tattoo inks to avoid the risk that inks produced for other purposes and with no risk assessment could be used for tattooing. The burden of the risk assessment should fall on the manufacturer who shall prove that the final product, including preservatives, is safe.
Concerning impurities, it was noted that it is not possible to implement too low limits.

9. Report on analytical methods to enforce the restrictions of the Council of Europe ResAP(2008)1. Distribution of tasks

The chairman explained that to prepare the review of test methods potentially useful to enforce the restrictions of the CoE ResAP(2008)1, information should be collected from Member States and asked the availability of participants to share their knowledge with the group. She explained that a template with the required information will be prepared and circulated in the next weeks.
The following experts volunteered: Mrs Bocca (IT), Mr Hohl (CH), Mr Njboer (NL), Mr Dirks, plus experts to be identified in Germany, United Kingdom and Denmark. The European Network of Official Cosmetics Control Laboratories (OCCL) will be contacted through the Council of Europe.

10. The Italian experience in controlling the safety of tattoos: current situation and legislative framework (Alberto RENZONI – Italian National Institute for Health)

There is a growing trend in the development of tattoo related activities and the number of tattoo shops has increased in the last few years.
In Italy tattooing and PMU are not covered by a specific national law, but there is an articulated regulatory framework that guarantees the protection of consumers through a set of rules and regulatory acts. The CoE ResAP(2008)1 is not formally mandatory in Italy, but the Italian Decree n. 206/2005, based on the "EU General Product Safety Directive (GPSD) 2001/95/CE", confers it a binding nature, so tattoo inks placed on the market shall comply with this Resolution.
Consequently, Italian Authorities developed a well-functioning surveillance system to assess the compliance with regulations and hygienic/sanitary guidelines which is carried out at local and national level. Checks are carried out on tattoo products available on commercial distribution, on imported products at customs, in tattooing parlours and during tattoo conventions. Sampling campaigns and analytical controls are undertaken on the basis of RAPEX warnings, individual complaints, routine controls and sampling campaigns requested by the Ministry of Health. If tattoo inks/products do not comply with the CoE ResAP(2008)1 and the other regulatory requirements, the National Authority can ban the importation/sale and can order the requisition of unsafe tattoo products. In this case, an immediate notification to all EU countries is sent through the RAPEX system. Results of checks showed that, considering the chemical requirements, 43% and 41% of the analysed tattoo inks were non-compliant for heavy metals and aromatic amines, respectively.
Sterilisation is a crucial aspect for tattoo inks. A preliminary study showed that more than 80% of unopened packages, out of the 34 investigated, were contaminated by micro-organisms.
To open a tattoo parlour, authorisation shall be requested at the municipality, which in turns asks for a technical opinion from the Local Health Authority which verifies compliance with requirements.
Tattooing should be an informed choice, for this reason information campaigns should be organised at national level. In Italy, a few campaigns have been realised only locally, for high schools.
In Italy, there is an urgent need for harmonisation as, due to the lack of regulatory uniformity between regions, the level of health protection varies across the country and issues such as the non-recognition of training courses taken in other regions exist. There is the need to ensure uniform criteria for the definition of the professional requirements for operators and to set up a public registrar of qualified tattoo artists to avoid the phenomenon of illegal tattooists. In addition, there is the additional problem of recognition of qualifications of tattoo artists from foreign countries.

11. Tattoos: national legislations (Paola PICCININI – EC DG JRC)
In 2003, before the enlargement of the European Union, the JRC prepared an overview of specific provisions covered in the national regulations, projects and guidelines. This overview needs to be updated and integrated with information coming from the new Member States.
A preliminary comparison among the chemical requirements established in the CoE ResAP(2008)1 and those established in the national legislations in place or available in draft in Germany, the Netherlands, Sweden, France, Denmark and Austria was illustrated. The comparison focussed on the following substances that shall not be present in tattoo and permanent make-up products: aromatic amines (as such or released from azo-colorants); colorants; inorganic and organic impurities; substances listed in Annex II of the EU Reg. 1223/2009 on cosmetics; colorants listed in Annex IV of the EC Reg. 1223/2009, with restrictions in column g; organic impurities for colorants used in foodstuffs as set out in the Commission Directive 95/45/EC; carcinogenic, mutagenic and reprotoxic substances

classified in categories 1A, 1B or 2 under EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures.

12. Regulatory review. Distribution of tasks

The chairman explained that in order to prepare the regulatory review, information should be collected from Member States and asked about for the availability of participants in sharing their knowledge with the group. She explained that a template with the requested information will be prepared and circulated in the next week and requested, if possible, to send unofficial translations of the legislative documents in case they are not written in English, French, Italian and Spanish.

The following experts volunteered: Mr Renzoni (IT), Mr Pinchen (UK), Mrs Meisner (DE), Mrs Nohrstedt (SE), Mrs Andersen (NO), Mrs Hrzenjak (SI), Mrs Jaltai (HU), Mrs Lerche (DK), Mrs Verdier (FR), Mrs van Gerwen (NL), Mr Medwed (AT), Mr Meuwly (CH).

13. Work packages 2, 3 and 4. Preliminary distribution of tasks

Producers and experts working in laboratories will be invited to participate in the meeting concerning tattoo inks available on the market and their ingredients (planned for March 2015). Mrs Piccinini would like to collect as much information as possible before March, in order to have a fruitful and effective discussion during the meeting and asked those presents to provide documentation and contact details of experts to be involved. Mrs Kemner, Mr Dirks and Mr Hohl volunteered and German, Dutch and English experts agreed to communicate contacts. Mr Serup will provide the contact details of an expert on tattoo ink ingredients.

Italy, Germany and the Netherlands have guidelines for hygienic conditions and Mr Renzoni suggested drafting a template based on the new and updated Dutch guidelines.

The third meeting, regarding WP3, is foreseen in the second half of 2015 and it will focus on negative health effects related to tattoos. The meeting concerning WP4 will be the final one and is planned for March 2016.

14-15. Discussion, conclusion and follow-up

The presentations will be distributed among participants.

The chairman kindly asked the participants to provide the information related to legislation and test methods, needed for the deliverables of WP1, in due time even if the time schedule is very strict. Mrs Piccinini closed the meeting by thanking the experts for their precious collaboration.

Table A: Agenda of the meeting of the CSN-STPM held on 11 November 2014 at the DG JRC in Ispra (VA), Italy.

AGENDA

	Time estimates	Subject
1.	9:00 – 9:10	**Welcome and adoption of the agenda**
2.	9:10 – 9:15	**Adoption of the minutes of the CSN (sub-group tattoos and permanent make-up) meeting of 23.06.2014**
3.	9:15 – 9:30	**Objectives of the meeting and of the working group**
4.	9:30 – 10:00	**Project on tattoos and permanent make-up** **Towards an European legislation** Paola PICCININI (EC DG JRC)
5.	10:00 – 10:30	**Measure on the safety of tattoo inks under article 13 GPSD** Ana Maria BLASS RICO (EC DG JUST)
6.	10:30 – 11:00	**Analytical control of metal impurities in tattoo inks: state of the art and future needs** Beatrice BOCCA (Italian National Institute for Health)
	11:00 – 11:15	**Coffee break**
7.	11:15 – 11:45	**Analyzing target compounds in tattoo inks in light of legal restrictions - Strategies and their application** Christopher HOHL (Swiss Kantonales Laboratorium)
8.	11:45 – 12:30	**Discussion**
	12:30-13:30	**Working lunch**
9.	13:30 – 14:00	**Report on analytical methods to enforce the restrictions of the Council of Europe ResAP (2008)** **Distribution of tasks**
10.	14:00 – 14:30	**The Italian experience in controlling the safety of tattoos: current situation and legislative framework** Alberto RENZONI (Italian National Institute for Health)
11.	14:30 – 15:00	**Tattoos: national legislations** Paola PICCININI
12.	15:00 – 15:30	**Regulatory review** **Distribution of tasks**
	15:30 – 15:45	**Coffee break**
13.	15:45 – 16:15	**Work packages 2, 3 and 4** **Preliminary distribution of tasks**
14.	16:15 – 16:45	**Discussion**
15.	16:45 – 17:00	**Conclusions and follow-up**
	17:00	**END**

Table B: List of participants (meeting of the CSN-STPM on 11 November 2014).

Country	National Expert	Affiliation
Austria	ÖZELT Gregor	AGES
Denmark	BJERREGAARD LERCHE Dorte PALUDAN Elisabeth	Danish Environmental Protection Agency
France	VERDIER Cécile	ANSM - Agence nationale de sécurité du médicament et des produits de santé
Germany	BLUME Annegret MEISNER Anke	BfR - Bundesinstitut für Risikobewertung Federal Ministry of Food and Agriculture
Hungary	JALTAI Judit	National Institute of Chemical Safety
Italy	ALIMONTI Alessandro BOCCA Beatrice RENZONI Alberto	Istituto Superiore di Sanità
The Netherlands	HARTOG Peter JANSSEN Paul NIJBOER Lucas	Ministry of Health- Welfare and Sport RIVM - National Institute for Public Health and the Envionment NVWA - Netherlands Food and Consumer Product Safety Authority
Slovakia	KISACOVA Janka	Public Health Authority of the Slovak Republic
Slovenia	HRŽENJAK Vesna	National laboratory of health, environment and food
Sweden	NOHRSTEDT Lena	Medical Product Agency
United Kingdom	PINCHEN Robert	Royal Borough of Greenwich
Norway	STAVENES ANDERSEN Ingrid	Norwegian Food Safety Authority
Switzerland	HOHL Christopher	Kantonales Laboratoirum Basel-Stadt
	Stakeholders	**Affiliation**
	DIRKS Michael	H-A-N-Haus der Angewandten Naturwissenschaften-Gesellschaft mbH
	KEMNER Sina	TIME - Tattoo Ink Manufacturers of Europe
	FIALA Franz	ASI CC - Austrian Standards Institute Consumer Council
	SERUP Jorgen	ESTP - European Society of Tattooo and Pigment Research
European Commission	**Directorate General**	**Institute/Directorate and Unit**
PICCININI Paola BARRERO Josefa SENALDI Chiara	Joint Research Centre	Institute for Health and Consumer Protection, Chemical Assessment and Testing Unit
BLASS RICO Ana Maria	Justice and Consumers	Directore E Consumers Consumers, Product and Service Safety Unit

Annex IV

Analytical methods for aromatic amines

International standard methods

1. EN 14362-1:2012

This standard, partly modified, is used by Swedish and Slovenian experts for the analysis of tattoo inks. The Slovenian protocol is reported at the end of this section.

Scope and field of application

In the field of textiles, this European Standard describes a procedure to detect the use of certain azo colorants that release, by reductive cleavage of azo group(s), one or more harmful aromatic amines (listed hereafter) and therefore may not be used in the manufacture or treatment of certain products made of textile fibres.

Substance	CAS number
o-anisidine	90-04-1
2-naphthylamine	91-59-8
3,3'-dichlorobenzidine	91-94-1
benzidine	92-87-5
o-toluidine	95-53-3
4-chloro-o-toluidine	95-69-2
4-methyl-m-phenylenediamine	95-80-9
o-aminoazotoluene	97-56-3
5-nitro-o-toluidine	99-55-8
4,4'-methylene-bis-(2-chloro-aniline)	101-14-6
4,4'-methylenedianiline	101-77-9
4,4'-oxydianiline	101-80-4
4-chloroaniline	106-47-8
3,3'-dimethoxybenzidine	119-90-5
3,3'-dimethylbenzidine	119-93-8
6-methoxy-m-toluidine	120-71-9
2,4,5-trimethylaniline	137-17-7
4,4'-thiodianiline	139-65-1
biphenyl-4-ylamine	192-67-1
4-methoxy-m-phenylenediamine	615-05-4
4,4'-methylenedi-o-toluidine	838-88-1

Principle

The method entails the reductive cleavage of the azo group(s) present in the azo dyes (extracted from the specimen according to the method of colorant extraction for disperse dyes and/or the method of direct reduction for the other classes of dyes) and the subsequent detection and quantification of the released aromatic amine(s) by chromatography.

Description of test method

The method includes the following steps: (extraction), reduction, liquid-liquid extraction, concentration and chromatographic detection and quantification of the aromatic amines.

In the case of disperse dyes, colorants are extracted from the test specimen using boiling chlorobenzene (35 min), while for the other classes of dyes the reduction is carried out without extraction. The extract or the test specimen reacts with the reducing reagent (sodium dithionite in a citrate buffered aqueous solution (pH = 6) at 70 °C for 30 min). The aromatic amines thus formed are transferred to a t-butyl methyl ether phase by means of liquid-liquid extraction using diatomaceous earth columns. The t-butyl methyl ether extract is then

concentrated, and the residue is taken up in a solvent appropriate for detection and determination of the amines by chromatography.

Type of instrument analysis
Any of the following chromatographic techniques:

- High Performance Thin Layer Chromatography (HPTLC);
- High Performance Liquid Chromatography with diode array or mass selective detector (HPLC-DAD or HPLC-MS);
- Gas Chromatography with flame ionisation or mass selective detector (GC-FID or GC-MS);
- Capillary Electrophoresis with diode array detector (CE-DAD).

Repeatability (r) and Reproducibility (R)
Values are given for 3,3'-dimethylbenzidine, 3,3'-dimethoxybenzidine, benzidine and 4,4'-methylenedianiline. The Relative Standard Deviation of the Reproducibility (RSD_R) ranges between 35.1% and 61.1%, while the Relative Standard Deviation of the repeatability (RSD_r) ranges between 12.9% and 19.5% for several textile samples (wool, cotton, viscose).

Slovenian National Experts adapted this standard to the analysis of tattoo inks modifying the method as reported hereafter.

Slovenian Standard Operating Procedure
17 ml of citrate buffer is added to a subsample of the tattoo ink (approximately 0.5 g accurately weighed) and heated to 70 °C for 30 minutes under regular shaking. 3 ml dithionite solution is added (20 % dithionite water solution, freshly prepared), and the solution is heated at 70 °C for additional 30 min. under regular shaking. The reaction solution is cooled down to room temperature and decanted on diatomaceous earth column and allowed to be absorbed by the column for 15 min. The reaction solution is extracted with 2 x 10 ml and 1 x 20 ml t-butyl methyl ether and added on column. Amines are eluted from column with t-butyl methyl ether. The extract is concentrated, and the residue is taken up in N,N-dimethylformamide and mobile phase mixture. Amines are determined by HPLC.

2. EN 14362-3:2012

This standard is used by Swedish experts for the analysis of tattoo inks.

Scope and field of application
In the field of textiles, this European Standard describes a procedure to detect the use of certain azo colorants that may specifically release 4-aminoazobenzene (CAS 60-09-3), by reductive cleavage of azo group(s). This part of EN 14362 is supplementary to Part 1.

Principle
As already described for EN 14362-1, the method entails the reductive cleavage of the azo group(s) present in the azo dyes and the subsequent detection and quantification of the released 4-aminoazobenzene by means of chromatography.

Description of test method
The method includes the following steps: (extraction), reduction, liquid-liquid extraction, concentration and chromatographic detection and quantification of the aromatic amines.

In the case of disperse dyes, colorants are extracted from the test specimen using boiling chlorobenzene (35 min), while for the other classes of dyes the reduction is carried out without extraction. The extract or the test specimen is treated with sodium dithionite in an alkaline solution at 40 °C in a closed vessel. 4-aminoazobenzene, which is released in the process, is transferred to a t-butyl methyl ether phase by means of liquid-liquid extraction. An aliquot of the t-butyl methyl ether phase is used for analysis. The detection and quantification of 4-aminoazobenzene is performed using chromatography techniques.

Type of instrument analysis

Any of the following chromatographic techniques:

- High Performance Thin Layer Chromatography (HPTLC);
- High Performance Liquid Chromatography with diode array or mass selective detector (HPLC-DAD or HPLC-MS);
- Gas Chromatography with mass selective detector (GC-MS);
- Capillary Electrophoresis with diode array detector (CE-DAD).

Repeatability (r) and Reproducibility (R)

The detection of 4-aminoazobenzene in silk shows RSD_r and RSD_R equal to 13.9% and 64.8%, respectively, when determined by HPLC and equal to 29.2% and 70.8%, respectively, when determined by GC/MS. When measured in polyester, 4-aminoazobenzene shows RSD_r and RSD_R of 18.9% and 91.4%, respectively, when determined by HPLC and of 45.8% and 76.4%, respectively, when determined by GC/MS.

5. EN 71-7:2014

Scope and field of application

In the framework of safety of toys, this European Standard specifies requirements for the substances and materials in finger paints. It also gives methods for detection of certain azo colorants (through the determination of the aromatic amines release by reductive cleavage), as well as for the determination of "free" primary aromatic amines (reported in the following).

Substance	CAS number
p-Aminoazobenzene	60-09-4
2-Naphthylamine	91-59-9
3,3'-Dichlorobenzidine	91-94-3
4-Aminobiphenyl	92-67-2
Benzidine	92-87-5
o-Toluidine	95-53-4
4-Chloro-o-toluidine	95-69-3
4-Methyl-m-phenylendiamine	95-80-10
o-Aminoazotoluene	97-56-3
5-Nitro-o-toluidine	99-55-9
2,2-Dichloro-4,4-methylenedianiline	101-14-7
4,4-Methylenedianiline	101-77-11
4,4'-Oxydianiline	101-80-5
4-Methoxy aniline	104-94-10
4-Chloroaniline	106-47-9
3,3-Dimethoxybenzidine	119-90-6
3,3-Dimethylbenzidine	119-93-9
6-Methoxy-m-toluidine	120-71-10
2,4,5-Trimethylaniline	137-17-9
4,4'-Thiodianiline	139-65-1
4-Methoxy-m-phenylenediamine	615-05-7
4,4-Methylenedi-o-toluidine	838-88-2

Principles

For the detection of the use of certain azo-colorants the sample is treated with sodium dithionite (reductive cleavage). The same method can be applied for the detection and quantification of "free" amines; in this case the reductive cleavage is not carried out.
In both cases, after solid phase extraction and concentration, the amines are detected and determined either by high performance liquid chromatography with a diode-array detector (HPLC/DAD) or by capillary gas chromatography with mass-selective detector (GC-MS).

Description of test method

The weighed sample is added to a preheated (70 ± 2) °C citrate/sodium hydroxide buffer and the conical flask is tightly closed. After vigorous shaking (to achieve complete homogenisation of the content) the heating is prolonged for (30 ± 2) min.
Reductive cleavage is achieved by reaction with sodium dithionite solution; after the addition of the reactant, the conical flask is immediately tightly sealed, thoroughly shaken and kept again at (70 ± 2) °C for another (30 ± 2) min, and then cooled to ambient temperature within 2 min. In the case of free aromatic amines, reductive cleavage step is not necessary. In this case, preheated (37 ± 2 °C) citrate/sodium hydroxide buffer is added to the sample. The conical flask is tightly closed and after brief vigorous shaking to homogenize the contents is kept at (37 ± 2) °C about 30 min.
Last step entails the solid phase extraction and concentration of amines. The solution containing the extract of amines is poured onto a SPE column without rinsing the conical flask with water or buffer. The aqueous phase is allowed to absorb onto the column for 30 minutes. The amines are then extracted twice with methyl tert-butyl ether (MTBE).
The MTBE extract is carefully concentrated at a maximum temperature of 25 °C using a rotary evaporator to about 1 ml and the residue is diluted with acetonitrile.
The quantification of the amines is conducted using HPLC/DAD or GC-MS. If using GC-MS, internal standards shall be used.

Type of instrument analysis

Any of the following chromatographic techniques:

- High Performance Liquid Chromatography with diode array detector (HPLC-DAD);
- Gas Chromatography with mass selective detector (GC-MS).

LOD, LOQ
By GC/MS**:** (0.01<LOQ<0.05) mg/l; (0.2<LOQ<1.0) mg/l.
By LC/DAD**:** LOQ = 1.0 mg/l; LOQ = 2.0 mg/l.

6. EN 71-11:2005

Scope and field of application
In the framework of toy safety, this Part 11 of the European Standard EN 71 specifies analytical methods for the detection and quantification of several groups of organic chemicals, among which are primary aromatic amines (see the following list).

Substance	CAS number
Aniline	62-53-3
2-Methoxyaniline	90-04-1
2-Naphthylamine	91-59-7
3,3'-Dichlorobenzidine	91-94-1
Benzidine	92-87-3
o-Toluidine	95-53-2
4-Chloroaniline	106-47-7
3,3'-Dimethoxybenzidine	119-90-4
3,3'-Dimethylbenzidine	119-93-7

Principle
Aromatic amines are determined in extracts of toy materials by gas chromatography with mass spectrometry detection (GC-MS) using the external standard method of calibration.

Type of instrument analysis
GC/MS

Repeatability (r) and Reproducibility (R)
RSD_r measured at 5 mg/l (equivalent to 5 mg/kg in sample) ranges between 1.9 and 5.0 %.

7. EN ISO 17234-1:2010

This standard, partly modified, is used by Italian experts for the analysis of tattoo inks. The adapted Standard Operating Procedure is reported at the end of this section.

Scope and field of application
This European Standard applies to the field of leather products and, as for EN 14362-1:2012 (textiles), it describes a procedure to detect the use of certain azo colorants that may release one or more harmful aromatic amines (refer to the following list), by reductive cleavage of azo group(s).

Substance	CAS number
o-anisidine	90-04-1
2-naphthylamine	91-59-8
3,3'-dichlorobenzidine	91-94-1
benzidine	92-87-4
o-toluidine	95-53-3
4-chloro-o-toluidine	95-69-2
4-methyl-m-phenylenediamine	95-80-9
o-aminoazotoluene	97-56-3
5-nitro-o-toluidine	99-55-8
4,4'-methylene-bis-(2-chloro-aniline)	101-14-6
4,4'-methylenedianiline	101-77-10
4,4'-oxydianiline	101-80-4
4-chloroaniline	106-47-8
3,3'-dimethoxybenzidine	119-90-5
3,3'-dimethylbenzidine	119-93-8
6-methoxy-m-toluidine	120-71-9
2,4,5-trimethylaniline	137-17-7
4,4'-thiodianiline	139-65-1
biphenyl-4-ylamine	192-67-1
4-methoxy-m-phenylenediamine	615-05-6
4,4'-methylenedi-o-toluidine	838-88-1

Principles and description of the test method

The same principle as already described for textiles (EN 14362-1:2012) applies. Aromatic amines are released via treatment with sodium dithionite in an aqueous buffer solution (pH 6) at 70 °C in a closed vessel (reductive cleavage), then transferred to a *t*-butyl methyl ether phase by means of liquid-liquid extraction. The *t*-butyl methyl ether extract is concentrated and the residue is dissolved in a suitable solvent, depending on the method used to determine the amines.

Type of instrument analysis

Chromatographic analyses for quantitative and qualitative detection:

- High-performance liquid chromatography (HPLC-DAD)

Chromatographic analyses for qualitative detection

- Capillary gas chromatography (GC-FID and or GC-MS);
- Capillary electrophoresis (HPCE-DAD);
- Thin layer chromatography (TLC, HPTLC).

The modified procedure used by **Italian National Experts**, to analyse tattoo inks is described hereafter.

Italian Standard Operating Procedure

Weigh 1 g of tattoo ink sample and add 17 ml of buffer solution (citrate buffer solution) pre-heated at 70 ± 5 °C. Keep the solution in a warm bath for 25 ± 5 min at 70 ± 2 °C. Add 1.5 ml of aqueous sodium dithionite solution (200 mg/ml) and keep the solution at 70 °C for 10 min. Repeat the same procedure and then allow the solution to cool to room temperature.

Transfer the reaction solution in a glass beaker and add Extrelut NT 20 until complete absorption of the solution. Transfer in a glass column and elute the amines with t-butyl methyl ether (MTBE). Flush the column twice with 40 ml of MTBE and collect the eluate in a conical flask. Concentrate the MBTE to approximately 1 ml in a rotary vacuum evaporator and then evaporate to dryness under a gentle flow of inert gas (e.g. nitrogen).

Add 1 ml of methanol with deuterated naphtalene (naphthalene D8) as Internal Standard and proceed to the instrumental analysis.

Type of instrument analysis
GC/MS

LOQ
1.5 mg/kg

Repeatability (r) and Reproducibility (R)
For each aromatic amines $RSD_r < 20\%$ and $RSD_R < 40\%$.

8. EN ISO 17234-2:2011

Scope and field of application
This European Standard applies to the field of dyed leather products and it is supplementary to ISO 17234-1. In particular, it describes a procedure to detect the use of both azo colorants which may specifically release 4-aminoazobenzene and "free" (without reducing pre-treatment) 4-aminoazobenzene (Solvent Yellow 1).

Principles and description of the test method
After reductive cleavage (treatment with sodium dithionite in an alkaline solution at 40 °C in a closed vessel), the released 4-aminoazobenzene is transferred to a *t*-butyl methyl ether phase by means of liquid-liquid extraction. An aliquot of concentrated tert-butyl methyl ether phase is used for analysis.
The detection of 4-aminoazobenzene can be performed using any of the following techniques: GC/MS; HPLC/DAD or HPLC/MS; TLC or HPTLC; CE/DAD.
The quantification of 4-aminoazobenzene is performed by means of HPLC/DAD or GC/MS; if gas chromatography is used, appropriate internal standards shall be employed.

Type of instrument analysis
Quantitative procedures are described for HPLC/DAD, HPLC/DAD/MS and CE/DAD; qualitative procedure is described for TLC and HPTLC.

Repeatability (r) and Reproducibility (R)
$RSD_r = 29.7\%$ and $RSD_R = 39.4\%$ for HPLC; $RSD_r = 26.1\%$ and $RSD_R = 39.7\%$ for GC/MS.

In-house validated methods

1. MDHS 75 (United Kingdom)

Scope and field of application

The scope is the determination of aromatic amines in air and identification of amine contamination on surfaces. The method is applicable to a range of aromatic amines including:

Substance	CAS number
Aniline (Phenylamine)	62-53-2
o-chloroaniline (2-chloroaniline, OCA)	95-51-3
o-toluidine (2-methylanailine)	95-53-4
2,2'-dichloro - 4,4'-methylene dianiline (MbOCA)	101-14-6
4,4'methylene dianiline (MDA)	101-77-9

Principles

The aromatic amines are trapped on acid coated filters and, after neutralisation, analysed by HPLC.

Type of instrument analysis

HPLC-UV.

Description of the test method

A measured volume of air is drawn through an acid-coated glass fibre filter to trap aromatic amines. After sampling, the filters are desorbed in sodium hydroxide solution and the resultant solutions are analysed by HPLC with UV detection. Surface contamination can be estimated using wipes moistened with methanol. The wipes are subsequently desorbed in methanol and analysed by HPLC.

LOD, LOQ

For the extraction from samples the typical LOD is 40 ng/sample.

Repeatability (r) and Reproducibility (R)

For extraction of samples, the typical Coefficient of Variation (CV) is 5-10%.

Comments

It is an air monitoring method that could be adapted for bulk solutions.

2. Determination of primary aromatic amines in acidic migration solutions by LC-MS/MS (Austria)

Scope and field of application

The method is applicable to eight primary aromatic amines in migration solutions from food contact materials.

Description of the test method

Migration from food contact material is achieved with 3% acetic acid solution. The resulting solution is measured by LC-MS/MS.

Type of instrument analysis

LC-MS/MS

LOQ
0.5-4 µg/kg

Repeatability (r) and Reproducibility (R)
RSD_r < 7.5%

3. In-house HPLC/MS method based on: "Determination of carcinogenic aromatic amines in dyes, cosmetics, finger paints and inks for pens and tattoos with LC/MS" *(U. Hauri; Mitt. Lebnsm. Hyg. 2005, 96, 321-335)* (France)

Scope and field of application
This method can determine about 40 substances.

Principle
Determination of aromatic amines by LC-MS after reductive cleavage of azo dyes

Type of instrument analysis
Agilent Technologies: LC-MS QQQ 6460 Triple Quad - RRLC 1290 Infinity

Description of the test method
Gradient elution HPLC method with positive mode APCI/MS detection

LOQ
1 ppm

Repeatability (r) and Reproducibility (R)
Typical repeatability on standard: CV = 10 % (n=6)

4. Determination of free carcinogenic aromatic amines in tattoo inks by HPLC/MS/MS (Switzerland)

Scope and field of application
Determination of free aromatic amines in tattoo inks

Description of the test method
Dilution of the samples with methanol. Extraction by shaking and sonication for 15 minutes. Filtration over HPLC-membrane filters. Separation and quantification by LC/MS/MS. Formic acid eluents for all substances except 2,4-diaminotoluene and 2,4-diaminoanisole; ammonium formiate eluent is used for the latter two substances.

Type of instrument analysis
LC/MS/MS

LOD, LOQ
LOQ's are 1 mg/kg if the appropriate method is chosen (formic acid or ammonium formiate see above).

Repeatability (r) and Reproducibility (R)

Depending on the analyte, RSD_r ranged between 2.7 and 23 % for tattoo inks spiked with 20 mg/kg of aromatic amines.

Comment
Out of more than 20 banned aromatic amines, after analysing more than 600 tattoo ink samples, Swiss experts only found the following seven compounds: o-anisidine, o-toluidine, 2,4-diaminotoluene, 2,4-diaminoanisole, 3,3'-dichloroaniline, 4-chloro-aniline, 5-nitro-o-toluidine (and aniline).

5. Determination of carcinogenic aromatic amines in tattoo inks by HPLC/MS/MS after reductive cleavage according to EN 14362 (Switzerland)

Scope and field of application
Indirect determination of forbidden colorants in tattoo inks by means of the determination of possible carcinogenic breakdown products.

Type of instrument analysis
LC/MS/MS

Description of the test method
Reductive cleavage of tattoo inks according to EN 14362 (azo colorants in textiles), as requested by Swiss legislation. Dilution of the extracts with ethanol, in order to precipitate salts and solubilise non polar aromatic amines. Filtration. Determination by LC/MS/MS. Formic acid eluents for all substances except 2,4-diaminotoluene and 2,4-diaminoanisole; ammonium formiate eluent for the latter two substances.

LOD, LOQ
LOQ's are 1 mg/kg if the appropriate method is chosen.

Repeatability (r) and Reproducibility (R)
Often free amines are measured! These measurements show good reproducibility. For the original task - detecting forbidden colorants that may be released in the body – repeatability and reproducibility is limited for pigments as the problem is the very low solubility of these substances in the reaction medium. Repeatability values derived from spiked samples are not to be trusted.

Comment
The analysis of several hundreds of tattoo inks showed that, out of more than 20 banned aromatic amines, only o-anisidine, o-toluidine, 2,4-diaminotoluene, 2,4-diaminoanisole, 3,3'-dichloroaniline, 4-chloro-aniline, 5-nitro-o-toluidine and aniline were detected.

6. Determination of Aromatic Amines in tattoo inks (Slovenia)

Scope and field of application:
Determination of PAA as the sum of PAA liberated from azo colorants and content of PAA from other sources e.g. residue or PAA added as colour (called ʿfree PAAʿ).

Description of the test method
17 ml of citrate buffer is added to a subsample of the tattoo ink (app. 0.5 g accurately weighed) and heated at 70 °C for 30 min under regular shaking. Then, 3 ml dithionite

solution is added (20 % dithionite water solution, freshly prepared), and additional heating at 70 °C for 30 min under regular shaking is carried out. The reaction solution is cooled down to room temperature and decanted on diatomaceous earth column and allowed to be absorbed by the column for 15 min. The reaction solution is extracted with 2 x 10 ml and 1 x 20 ml MTBE and added on column. Amines are eluted from column with MTBE (as described in DS/EN 14362-1). The extract is concentrated and the residue is taken up in N,N-dimethylformamide and mobile phase mixture. AA are determined by HPLC.

Type of instrument analysis
HPLC/DAD

Comment
The method is based on methods described in Resolution CoE ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up, which is a modified method of EN 14362-1.

7. CHE01-WV494 Determination of aromatic amines in tattoo ink, permanent make up and textile using GC-MS (The Netherlands)

Scope and field of application
This procedure describes a method for determination of aromatic amines in tattoo and permanent make up (PMU). The method can be used as screening for aromatic amines in textiles. For quantification of aromatic amines in textiles EN 14362-1 or EN 14362-2 shall be used.

Principle
Azo dyes, based on carcinogenic aromatic amines, are reduced to the free primary aromatic amine using sodium dithionite. The aromatic amine is extracted with methyl tert-butyl ether and analysed with GC-MS.

Description of the test method
Tattoo inks and permanent make up products should be homogenised by shaking or mixing with a spatula. In order to extract the aromatic amines, weigh 500 mg sample in a tube. Add for tattoo inks and PMU 5 ml dithionite solution (5%) in phosphate buffer. Mix with a vortex mixer during 20 seconds. Place the tubes in a water bath of 70 °C for 90 minutes. After 30 minutes, mix the solution again with a vortex mixer. Cool the solution to room temperature. Add 5 ml internal standard solution. Mix the extract for 20 seconds with a vortex mixer. Place the tube in a centrifuge and rotate at 1000 g for 15 minutes. Filtrate the upper layer using a micro filter and put the extract in a vial. Proceed with the gas chromatographic analysis.

Type of instrument analysis
GC/MS

LOD, LOD
(0.9< LOD <2.5) mg/kg; (1,8< LOQ <5) mg/kg

Repeatability (r) and Reproducibility (R)
1.3% <RSD_r< 10.4%

8. GC/MS analysis for primary aromatic amines (PAA) liberated from azo colorants and free PAA (Denmark)

Scope and field of application

This method applies to the tattoo ink analysis by quantitatively determining the primary aromatic amines (PAA) as the sum of PAA liberated from azo colorants and content of PAA from other sources e.g. residue or PAA added as colour (called ”free PAA”). The method is based on methods described in the Resolution (2008)1 of the Council of Europe on requirements and criteria for the safety of tattoos and permanent make-up, which is a modified method of ”DS/EN 14362-1, Methods for determination of certain aromatic amines liberated from azo colorants and pigments”. The following amines are determined:

Substance	CAS number
Aniline	62-53-2
o-Anisidine	90-04-1
2-Naphthylamine	91-59-8
3,3'-Dichlorobenzidine	91-94-1
4-Aminobiphenyl	92-67-1
Benzidine	92-87-4
o-Toluidine	95-53-3
2,4-Xylidine/2,6-xylidine	95-68-1/87-62-8
4-Chloro-o-toluidine	95-69-2
4-Methyl-mphenylenediamine	95-80-7
5-Nitro-o-toluidine	99-55-8
4,4,'-Methylenebis(2-chloroaniline)	101-14-6
4,4'-methylenedianiline	101-77-9
4,4'-Oxydianiline	101-80-4
p-Chloroaniline	106-47-8
3,3'-Dimethoxybenzidine	119-90-5
3,3'-Dimethylbenzidine	119-93-7
6-Methoxy-m-toluidine (p-Cresidine)	120-71-11
2,4-5-Trimethylaniline	137-17-8
4,4'-Thiodianiline	139-65-1
4-Methoxy-mphenylenediamine	615-05-4
3,3'-Dimethylenedianiline	838-88-1

Description of the test method

5 ml of 5 % dithionite solution in citrate buffer is added to a subsample of the tattoo ink* (app. 0.5 g accurately weighed), it is shaken mechanically for 30 min and heated at 70 °C for 90 min under regular shaking. The solution is extracted with 2 x 5 ml of MTBE (which contains aniline-d5 and naphthalene-d8 as internal standards) under mechanical shaking for 10 min. Analysis in duplicate has to be carried out. The extracts are analysed by means of capillary gas chromatography combined with mass spectrometry (GC/MS).

* All tattoo inks are shaken thoroughly immediately before extraction of subsample for analysis in order to obtain a sample that is as homogeneous as possible. In connection with sampling, weight is used rather than volume because for some tattoo inks it is impossible to remove a known volume due to high viscosity (thick-flowing).

9. GC/MS analysis for p-phenylendiamine (PPD) and free PAA (Denmark)

Scope and field of application

This analysis quantitatively determines p-phenylendiamine and primary aromatic amines that are not liberated from azo colorants, but added by other means e.g. as part of the colour, as

residue or a break-down product (called ”free PAA”). The method differs from the method previously described as dithionite solution is not added and therefore the azo colorants are not decomposed. The following amines are determined:

Substance	CAS number
Aniline	62-53-2
o-Anisidine	90-04-1
2-Naphthylamine	91-59-8
3,3'-Dichlorobenzidine	91-94-1
4-Aminobiphenyl	92-67-1
Benzidine	92-87-4
o-Toluidine	95-53-3
2,4-Xylidine/2,6-xylidine	95-68-1/87-62-8
4-Chloro-o-toluidine	95-69-2
4-Methyl-mphenylenediamine	95-80-7
5-Nitro-o-toluidine	99-55-8
4,4,'-Methylenebis(2-chloroaniline)	101-14-6
4,4'-methylenedianiline	101-77-9
4,4'-Oxydianiline	101-80-4
p-Chloroaniline	106-47-8
3,3'-Dimethoxybenzidine	119-90-5
3,3'-Dimethylbenzidine	119-93-7
6-Methoxy-m-toluidine (p-Cresidine)	120-71-11
2,4-5-Trimethylaniline	137-17-8
4,4'-Thiodianiline	139-65-1
4-Methoxy-mphenylenediamine	615-05-4
3,3'-Dimethylenedianiline	838-88-1

Description of the test method

5 ml citrate buffer is added to the subsample of the tattoo ink* (app. 0.5 g accurately weighed). Ultrasound extraction is carried out for 60 min. The solution is extracted with 2 x 5 ml MTBE (which contains aniline-d5 and naphthalene-d8 as internal standards) and exposed to mechanical shaking for 10 min. Analysis in duplicate has to be carried out. The extracts are analysed by means of capillary gas chromatography combined with mass spectrometry (GC/MS).

*: All tattoo inks are shaken thoroughly immediately before extraction of subsample for analysis in order to obtain a sample that is as homogeneous as possible. In connection with sampling, weight is used rather than volume because for some tattoo inks it is impossible to remove a known volume due to high viscosity (thick-flowing).

Methods described in literature

1. Specific determination of 20 primary aromatic amines (PAA) in aqueous food simulants by liquid chromatography-electrospray ionization-tandem mass spectrometry
Mortensen, Trier, Foverskov, Jens, J. Chromatography A, 2005, 1-2 (1091), 40-50.

Scope and field of application
Description of a multi-analyte method for the determination of 20 primary aromatic amines (PAA) associated with polyurethane (PUR) products or azo-colours. It does not foresee any pre-treatment steps and it uses reversed-phase liquid chromatography-electrospray ionization-tandem mass spectrometry (LC-ESI-MS/MS). The method is applicable to samples that are put in contact with aqueous food simulants.

Principle
The PAA migrate from the samples to the aqueous food simulant and the direct analysis of this solution is performed by HPLC.

Description of test method
Laminate samples or nylon cooking utensils are put in contact with the food simulant (3% acetic acid solution) for a given period at a given temperature. Afterwards the food simulant is directly analysed by HPLC.

Type of instrumental analysis
HPLC-ESI-MS/MS

LOD
Detection limits range from 0.27 to 3 µg amine/l food simulants.

Repeatability (r) and Reproducibility (R)
RSD_r values at 2 µg PAA/l level ranged from 3.9 to 19%.

Comments
LC-MS/MS would be the method of choice for this type of analysis, especially for a more complex matrix such as tattoo ink.

2. Determination and Quantification of Primary Aromatic Amine in Printer Inks
Margraf, Marlen, Borslel, LCGC Chromatography online. 2012.

Scope and field of application
Determination of aromatic amines in dyes like printer ink. Five primary aromatic amines (PAAs) (aniline, 2-anisidine, 3-chloro-4-methoxyanline, 2,4-dimethylaniline, o-toluidine) were chosen for this demonstration.

Principle
The aromatic amines are extracted from the printer inks and the solution is analysed by HPLC.

Description of test method
Samples are prepared as cold water extracts according to EN 645:1993 from printed paper and then analysed by HPLC.

Type of instrumental analysis
uHPLC-MS.

LOD, LOQ
The LOD was in the range between 1 to 5 µg/l.

Comments
uHPLC may not be a common instrument at present but could substituted by HPLC.

3. Chemical Substances in Tattoo Ink
Survey of chemical substances in consumer products, 116
The Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8.

Scope and field of application
Determination of primary aromatic amines (PAA) as the sum of PAA liberated from azo colorants and content of PAA from other sources e.g. residue or PAA added as colour (called "free PAA").

Principle
Subsample of tattoo ink is reduced, extracted and analysed by gas chromatography combined with mass spectrometry (GC/MS).

Description of test method
Five ml of 5 % dithionite solution in citrate buffer is added to about 0.5 g tattoo ink; it is shaken mechanically and heated to 70 °C during regular shaking. The solution is extracted with 2 x 5 ml MTBE with added internal standards. The extracts were analysed by capillary gas chromatography combined with mass spectrometry (GC/MS).

Type of instrumental analysis
GC/MS

LOD, LOQ
The limit of detection was in the range of between 0.5 and 10 µg/g.

Annex V

Analytical methods for colorants

International standard methods

1. EN ISO 16373-2:2014

Scope and field of application

In the framework of textile products, this international standard specifies the analyses used to detect extractable dyestuffs. The allergenic and carcinogenic dyestuffs, which can be analysed using this method, are listed hereafter.

Carcinogenic Dyestuffs

Substance	CI number	CAS number
Acid Red 26	16150	3761-53-3
Acid Red 114	23635	6459-94-5
Basic Red 9	42500	569-61-9
Basic Violet 14	42510	632-99-5
Direct Black 38	30235	1937-37-1
Direct Blue 6	22610	2602-46-2
Direct Red 28	22120	573-58-0
Disperse Blue 1	64500	2475-45-8
Disperse Orange 11	60700	82-28-0
Disperse Yellow 3	11855	2832-40-8
Solvent Yellow 1	11000	60-09-4
Solvent Yellow 2	11020	60-11-7
Solvent Yellow 3	11160	95-56-3

Allergenic Dyestuffs

Substance	CI number	CAS number
Disperse Blue 1	64500	2475-45-8
Disperse Blue 102	11945	12222-97-8
Disperse Blue 106	111935	12223-01-7
Disperse Blue 124	111938	61951-51-7
Disperse Blue 3	61505	2475-46-9
Disperse Blue 7	62500	3179-90-6
Disperse Blue 26	63305	3860-63-7
Disperse Blue 35	-----	56524-76-6
Disperse Blue 35	-----	56524-77-7
Disperse Brown 1	11152	23355-64-8
Disperse Orange 1	11080	2581-69-3
Disperse Orange 3	11005	730-40-5
Disperse Orange 37/76/59	11132	13301-61-6
Disperse Red 1	11110	2872-52-8
Disperse Red 11	62015	2872-48-2
Disperse Red 17	11210	3179-89-3
Disperse Yellow 1	10345	119-15-3
Disperse Yellow 3	11855	2832-40-8
Disperse Yellow 9	10375	6373-73-5
Disperse Yellow 39	480095	12236-29-2
Disperse Yellow 49	-----	54824-37-2

Other Dyestuffs

Substance	CI number	CAS number
Disperse Orange 61	111355	55281-26-0
Disperse Orange 149	-----	85136-74-9
Disperse Yellow 23	26070	6250-22-3
Navy Blue 018112	-----	118685-33-9

Principle
The coloured test specimen is extracted with pyridine/water mixture at 100 °C and analysed by LC/MS or LC/DAD.

Description of test method
After preparation of the test specimen by accurately determining its mass (that shall not exceed 1.0 g), proceed with the extraction, in a closed vial, by heating pyridine/water mixture up to 100 °C for 35 ± 5 min. Transfer small aliquots (1 ml volume) into smaller vials for further analysis. The detection of dyestuff is achieved either by LC/DAD or LC/MS, the quantification by LC/MS/DAD.

Type of instrument analysis
LC/DAD or LC/MS

LOD, LOQ
Direct Blue 6 was chosen to determine LOD and LOQ as it shows the lowest signal intensity. For Direct Blue 6, LOD=1.7 mg/ml and LOQ=2.5 mg/l.

Repeatability (r) and Reproducibility (R)
Repeatability of the method resulted in a RSD of 7% for the whole process consisting of sample preparation and determination with a mass spectrometer.

2. EN ISO 16373-3:2014

Scope and field of application
In the framework of textile products, this international standard specifies a method for the detection and quantification of carcinogenic dyestuff (refer to the following list) in dyed, printed and coated samples.

Substance	CI number	CAS number
Acid Red 26	16150	3761-53-3
Acid Red 114	23635	6459-94-5
Basic Red 9	42500	569-61-9
Basic Violet 14	42510	632-99-5
Direct Black 38	30235	1937-37-1
Direct Blue 6	22610	2602-46-2
Direct Brown 45	30145	17061-86-6
Direct Red 28	22120	573-58-0
Disperse Blue 1	64500	2475-45-8
Disperse Orange 11	60700	82-28-0
Disperse Yellow 3	11855	2832-40-8

Principle
After extraction by means of a solvent and ultrasonic bath, the extract is analysed either by HPLC/DAD or HPLC/MS.

Description of test method
After preparation of the test specimen by accurately determining its mass (that shall not exceed 1.0 g), proceed with the extraction by means of a 0.25 % solution of trietanolamine (TEA) in methanol is used as the extracting mixture. The test specimen is placed in a closed vial in the presence of the extracting mixture and the vial is heated in an ultrasonic bath at 50

°C for 3 hours. The extract is concentrated under vacuum. The residue is re-dissolved in methanol, filtered through a 0.45 µm PTFE filter and analysed either by HPLC/DAD or HPLC/MS. When a large amount of foreign substances is present, LC/MS is recommended for quantification.

Type of instrument analysis
LC/DAD or LC/MS

Repeatability (r) and Reproducibility (R)
The coefficient of variation of repeatability (CV_r) ranges between 5.9 and 13.2 % and the coefficient of variation of reproducibility (CV_R) between 18.5 and 74.4 %. Data were determined for Acid red 114, Acid red 26 and Disperse yellow 3, in different textile matrices (wool and polyammide).

3. EN 71-11:2005

Scope and field of application
In the framework of safety of toys, this international standard specifies the analytical methods for the detection and quantification of several chemicals. A specific section is dedicated to colorants (refer to the following list) which are identified and semi-quantified.

Substance	CI number	CAS number
Acid Red 26	16150	3761-53-3
Acid Violet 49	42640	1694-09-3
Basic Red 9	42500	569-61-9
Basic Violet 1	42535	8004-87-3
Basic Violet 3	42555	548-62-9
Disperse Blue 1	64500	2475-45-8
Disperse Blue 3	61505	2475-46-9
Disperse Blue 106	111935	12223-01-7
Disperse Blue 124	111938	61951-51-7
Disperse Orange 3	11005	730-40-5
Disperse Orange 37	11132	13301-61-6
Disperse Red 1	11110	2872-52-8
Disperse Yellow 3	11855	2832-40-8
Solvent Yellow 1	11000	60-09-4
Solvent Yellow 2	11020	60-11-7
Solvent Yellow 3	11160	95-56-3

Principle
Colorants are identified and semi-quantified by HPLC/DAD following extraction from toys (Process described in EN 71-10). If a positive identification is achieved using Diode Array Detector, confirmation can be achieved using mass spectrometry detection.

Description of test method
Extraction is performed by weighing approximately 0,5 g of the test portion into a 40-ml amber glass vial with a PTFE liner screw cap in the presence of 10 ml ethanol. Place the vial in an ultrasonic bath for 15 min then concentrate the extract to about 1 ml under a stream of air or nitrogen. Filter the extract and proceed with the detection of dyestuff either by LC/DAD or LC/MS: quantification of dyestuff by LC/MS/DAD

Type of instrument analysis

LC/DAD, LC/MS

LOD, LOQ

Direct Blue 6 was chosen to determine LOD and LOQ as it shows the lowest signal intensity. For Direct Blue 6, LOD=1.7 mg/l and LOQ=2.5 mg/l

Repeatability (r) and Reproducibility (R)

For LC/DAD, at 5 mg/l (equivalent to 10 mg/kg in a sample) RSD_r ranges between 0.3 and 4.9 % for Disperse Yellow 3 and Disperse Blue 3, respectively.

In-house validated methods

1. Determination of Acid Red 1 (Slovakia)

2. SOP 1201: Intern metod för analys av färgämnen i hårfärgsprodukter med LC-MS (Sweden) *(Internal method for analysis of colorants in hair colours by LC-MS)*

Scope and field of application
Hair colour products. It is a screening method.

Description of test method
Extraction of the colorants in acetonitrile/0.5 % sodium ascorbate (60:40, v/v). Analysis carried out with LC-MS (SIR). Standard addition method.

Type of instrument analysis
LC/MS

LOD, LOQ
LOD expressed in w/w %: 3-aminophenol (2.4), resorcinol (10), p-phenylenediamine (4), 5-amino-2-methylphenol and 5-amino-o-cresol (3), toluene-2,5-diamine sulfate (8, as free base).

3. Identification of colorants in tattoo inks with MALDI/TOF (Switzerland)

Scope and field of application
Almost all colorants in tattoo inks, depending on the spectra database

Description of test method
Dilution of the ink with ethanol to ensure better application. Recording of high resolution mass spectra with MALDI/TOF. Comparison of spectra against spectra of the colorant references in a library.

Type of instrument analysis
MALDI/TOF

LOD, LOQ
Depend heavily on substance and sample.

Repeatability (r) and Reproducibility (R)
At the moment, only qualitative repeatability and reproducibility are available.

4. Identification of colorants in tattoo inks with colorimetry (Switzerland)

Scope and field of application
Main colorants in tattoo ink, especially the forbidden substances and possible replacement substances C.I. 51319, 73900, 73907, 73915, 74160, 74260, 74265

Principle
Colorimetry

Description of test method
Dilution/Extraction of the samples with concentrated sulfuric acid and/or chloronaphthalene. Recording of UV/VIS spectra. Comparison of recorded UV/VIS spectra against spectra of the references in a library.

Type of instrument analysis
UV/VIS spectroscopy

LOD, LOQ
Only for main components

Repeatability (r) and Reproducibility (R)
At the moment, only qualitative repeatability and reproducibility are available.

Annex VI

Analytical methods for elements

International standard methods

1. EN 71-3:2013+A1:2014

Scope and field of application

In the field of toys safety, this European Standard describes test methods for the migration of specific elements (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin and zinc) from parts of toys.

Principles and description of method

Extraction of soluble elements from toy materials is performed under conditions which simulate the material remaining in contact with gastric juices for a period of time after swallowing. Sample preparation depends on toy material. Their concentration is then determined quantitatively by three different methods, according to the element:

- method for determining general elements: aluminium, antimony, arsenic, barium, boron, cadmium, chromium, cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin and zinc;
- method for determining chromium (III) and chromium (VI);
- method for determining organic tin.

For all types of sample preparation, the final extract is analysed for the presence of elements by ICP-MS, ICP-OES, CVAAS, GC-MS or other suitable techniques.

Type of instrument analysis

ICP-MS, ICP-OES, CVAAS, GC-MS

LOD, LOQ

When using ICP-MS for determining general elements:

Element	LOD mg/kg	LOQ mg/kg
Aluminium	0.073	0.146
Antimony	0.014	0.029
Arsenic	0.027	0.055
Barium	0.027	0.054
Boron	0.039	0.078
Cadmium	0.059	0.118
Chromium (total)	0.023	0.046
Cobalt	0.019	0.039
Copper	0.010	0.020
Lead	0.061	0.122
Manganese	0.050	0.099
Mercury	0.010	0.021
Nickel	0.042	0.083
Selenium	0.147	0.294
Strontium	0.067	0.134
Tin	0.110	0.221
Zinc	0.097	0.197

When using LC-ICP-MS for quantifying chromium:

Element	LOD mg/kg	LOQ mg/kg
Chromium (III)	0.064	0.128
Chromium (VI)	0.026	0.053

When using GC-MS for determining organic tin:

Element	LOD mg/kg	LOQ mg/kg
Methyltin	0.06	0.12
Butyltin	0.08	0.16
Tributyltin	0.12	0.24
Monooctyltin	0.37	0.74
Dioctyltin	0.17	0.35
Dibutyltin	0.08	0.16
Dipropyltin	0.26	0.52
Tetrabutyltin	0.12	0.24
Diphenyltin	0.54	1.08
Triphenyltin	0.15	0.29

2. EN 13806:2002

This standard, partly modified, is used by German experts for the analysis of tattoo inks.

Scope and field of application

In the framework of foodstuff, this European Standard specifies the method for the determination of mercury. Detailed description of cold-vapour atomic absorption spectrometry (CVAAS) is given. On the contrary, sample preparation and pressure digestion are defined in EN 13804 and EN 13805 respectively.

Principles

Determination of mercury in the test solution by cold-vapour atomic absorption spectrometry (CVAAS) following pressure digestion

Description of test method

Germany applies a German official method (§ 64 LFGB K 84.00-29) for the extraction and microwave digestion for cosmetic products. Analysis by cold-vapour atomic absorption spectrometry (CVAAS) is then carried out to quantify the metal content.

Type of instrument analysis

CVAAS

Repeatability (r) and Reproducibility (R)

It is specifically reported for several food matrices. RSD_r% ranges between 5.7 and 12.9 %, while RSD_R% between 12.3 and 51 %.

3. EN 14083:2003

This standard, partly modified, is used by German experts for the analysis of tattoo inks.

Scope and field of application

This European Standard can be applied in the field of foodstuffs and describes a method for the determination of lead, cadmium, chromium and molybdenum by graphite furnace atomic absorption spectrometry (GFAAS) following pressure digestion.

Principle
Following pressure digestion, elements in food samples are determined by graphite furnace atomic absorption spectrometry (GFAAS).

Description of test method
Sample preparation entails extraction and digestion of the test sample. For the extraction, Germany laboratories use a German official method for cosmetic products (method according to § 64 LFGB K 84.00-29). The method carries out microwave digestion of the samples, by means of a chloridric/nitric acid mixture. Elements are then quantified by GFAAS.

Type of instrument analysis
GFAAS

LOQ
The atomic absorption spectrometer shall be capable of determining the following concentrations at an injection volume of 20 µl of the measuring solution (specific for foodstuffs):
Pb 0.004 mg/ml
Cd 0.0004 mg/ml
Cr 0.004 mg/ml
Mo 0.004 mg/ml

Repeatability (r) and Reproducibility (R)
RSD_r and RSD_R, measured on six different food matrices, fall within the following ranges:

Element	RSDr %	RSDR %
Pb	12-40	42-70
Cd	10-29	31-58
Cr	18-55	53-100
Mo	15-33	35-60

4. EN 15763:2009
This standard, partly modified, is used by Austrian experts for the analysis of tattoo inks.

Scope and field of application
In the field of foodstuff, this European Standard describes a method for the determination of arsenic, cadmium, mercury and lead by inductively coupled plasma mass spectrometry (ICP-MS).

Principle
Following pressure digestion of the test samples, the ICP/MS analysis is carried out to identify and quantify arsenic, cadmium, mercury and lead.

Type of instrument analysis
ICP/MS

LOD, LOQ
Austrian experts report order of magnitude between 0.0001 and 0.01 µg/l.

Repeatability (r) and Reproducibility (R)
Repeatability (r) and Reproducibility (R) are specifically reported for eight different food matrices and fall within the following ranges:

Element	r mg/kg	R mg/kg
As	0.012 - 1.8	0.052 - 7.1
Cd	0.006 - 4.0	0.028 - 10.0
Hg	0.022 - 0.13	0.041 - 0.31
Pb	0.009 - 0.9	0.018 - 1.1

5. EN ISO 17072-1:2011

This standard, partly modified, is used by Italian experts for the analysis of tattoo inks.

Scope and field of application
In the field of leather products, this part of ISO 17072 describes a method for the determination of extractable metals using an acid artificial-perspiration solution followed by analysis with inductively coupled plasma/optical emission spectrometry (ICP-OES), or inductively coupled plasma/atomic emission spectrometry (ICP/AES), or inductively coupled plasma/mass spectrometry (ICP/MS), or atomic absorption spectrometry (AAS) or spectrometry of atomic fluorescence (SFA).
This method is especially suitable for determining the extractable chromium, but is also applicable for the determination of other extractable metals, including:

Aluminium (Al)	Magnesium (Mg)
Antimony (Sb)	Manganese (Mn)
Arsenic (As)	Mercury (Hg)
Barium (Ba)	Molybdenum (Mo)
Cadmium (Cd)	Nickel (Ni)
Calcium (Ca)	Potassium (K)
Chromium (Cr)	Selenium (Se)
Cobalt (Co)	Tin (Sn)
Copper (Cu)	Titanium (Ti)
Iron (Fe)	Zinc (Zn)
Lead (Pb)	Zirconium (Zr)

Principle
Extraction of metals is performed at 37 °C ± 2 °C for 4 h ± 5 min in an acid artificial-perspiration solution. The extract solution is filtered, acidified and analysed by ICP, or SFA or AAS.

Description of test method
2 g of leather sample is extracted at pH 5.5 by means of an acid artificial-perspiration solution (L-histidine monohydrochloride monohydrate, sodium chloride, sodium dihydrogen orthophosphate dehydrate) at 37± 2 °C for 4 h ± 5 min.

The extract is passed through a filter paper, and then further filtered through a membrane filter. The elements are then directly measured (ICP, AAS and SFA), taking a suitable amount of extract for analysis and adding 5 % (by volume) of nitric acid.

NOTE: In case the solution is not clear after filtration and acidification, perform the digestion procedure described in ISO 17072-2:2011.

Type of instrument analysis
ICP, AAS and SFA

6. EN ISO 17072-2:2011

Scope and field of application

In the field of leather products, this international standard describes a method for the determination of the total metal content in leather by digestion of the leather and subsequent determination with inductively coupled plasma/optical emission spectrometry (ICP/OES), or inductively coupled plasma/mass spectrometry (ICP/MS), or atomic absorption spectrometry (AAS) or spectrometry of atomic fluorescence (SFA).
This method is suitable to determine the total metal content and can be used for the following metals:

Aluminium (Al)	Copper (Cu)	Potassium (K)
Antimony (Sb)	Iron (Fe)	Selenium (Se)
Arsenic (As)	Lead (Pb)	Silicon (Si)
Barium (Ba)	Magnesium (Mg)	Sodium (Na)
Cadmium (Cd)	Manganese (Mn)	Tin (Sn)
Calcium (Ca)	Mercury (Hg)	Titanium (Ti)
Molybdenum (Mo)	Cobalt (Co)	Nickel (Ni)
Zinc (Zn)	Zirconium (Zr)	Chromium (Cr) (except chromium-tanned leathers)

Principle

Following digestion of the sample of ground leather until complete mineralization (carried out either by using a ternary acid mixture or a microwave) the residue is re-dissolved with water and analysed by AAS or ICP.

Description of test method

Acid digestion: It entails the use of a ternary mixture of nitric acid, sulphuric acid and perchloric acid in a ratio of 3:1:1. The leather sample in the presence of acidic mixture is then heated to boiling point until the digestion is complete and the red vapours of nitrogen dioxide have disappeared.
Allow to cool, re-dissolve with distilled water, filter if necessary, dilute, and proceed to direct measurement of the elements (ICP, AAS and SFA).
As an alternative to the acidic digestion, microwave assisted digestion can be done.

Type of instrument analysis
ICP, AAS and SFA

23. EPA 3051A

This standard, partly modified, is used by Italian experts for the analysis of tattoo inks.

Scope and field of application
Microwave extraction using HNO_3, or HNO_3 and HCl; applicable to sediments, soils, and oils for the analysis of Al, Sb, As, Ba, Be, B, Cd, Ca, Cr, Co, Cu, Fe, Pb, Mg, Mn, Hg, Mo, Ni, K, Se, Ag, Na, Sr, Tl, V, Zn by FLAAS, GFAA, ICP-AES, ICP-MS.

Principles
A representative sample is extracted/dissolved in HNO_3, or HNO_3 and HCl using microwave oven. The vessel is heated for a specific time period. After cooling, the vessel contents may be filtered, centrifuged or allowed to settle, then diluted and analysed by the appropriate determinative method.

Description of test method
Weight no more than 0.5 g of sample in PFA, TFM or quartz vessels, add 10 (± 0.1) ml HNO_3, or 9 (± 0.1) ml HNO_3 + 3 (± 0.1) ml HCl. Temperature should rise to 175 (± 5) °C in 5.5 min and remain at 175 °C for 4.5 min. At the end of the microwave programme, allow the vessels to cool for 5 min, and if the digest contains particulates, it may be centrifuged, allowed to settle or filtered.

Type of instrument analysis
FLAA (EPA 7000), GFAA (EPA 7010), ICP-AES (EPA 6010), ICP-MS (EPA 6020), As by AA (EPA 7061), As and Sb by AA (EPA 7062), As by ASV (EPA 7063), Hg by CV (EPA 7470, EPA 7471), Hg by ASV (EPA 7472), Se by AA (EPA 7741, EPA 7742).

24. EPA 3052
This standard, partly modified, is used by Italian experts for the analysis of tattoo inks.

Scope and field of application
Microwave assisted acid digestion for the total decomposition of samples; applicable to ashes, biological tissues, oils, oil contaminated soils, sediments, sludges, and soils for the analysis of Al, Sb, As, B, Ba, Be, Cd, Ca, Cr, Co, Cu, Fe, Pb, Mg, Mn, Hg, Mo, Ni, K, Se, Ag, Na, Sr, Tl, V, Zn by FLAA, CVAA, GFAA, ICP-AES, ICP-MS.

Principle
A representative sample is digested in HNO_3 and HF for 15 min using microwave oven. After cooling, the vessel contents may be filtered, centrifuged or allowed to settle, then diluted and analysed by the appropriate SW-846 method.

Description of test method
Weight no more than 0.5 g of sample in PFA or TFM vessels, add 9 ml of HNO_3 and 3 ml of HF. Temperature should rise to 180 °C (± 5) in 5.5 min and remain at 180 °C for 9.5 min. The addition of 2 + 2 ml HCl is appropriate for Ag, Ba, Sb, Fe and Al. Centrifugation or filtering, if necessary.

Type of instrument analysis
SW-846 Test Methods for Evaluating Solid Waste, Physical/Chemical Methods.

25. EPA 3060A
This standard, partly modified, is used by Italian experts for the analysis of tattoo inks.

Scope and field of application
Alkaline digestion procedure for extracting Cr (VI) from soluble, adsorbed, and precipitated forms of Cr compounds in soils, sludges, sediments, and similar waste materials. Quantification can be performed by Method 7196 (colorimetrically by UV-VIS spectrophotometry) or Method 7199 (colorimetrically by Ion Chromatography). Ion Chromatography with ICP-MS detection, HPLC-ICP-MS or CE-ICP-MS can also be used.

Principles
Sample is digested with 0.28 M Na_2CO_3/0.5 M NaOH solution and heated at 90-95 °C for 60 min.

Description of test method
Place 2.5 (± 0.1) g of sample in 250 ml of digestion vessel, add 50 (± 1) ml of digestion solution, heat at 90-95 °C for 60 min. Filter the resulting solution (0.45 µm).
.
Type of instrument analysis
EPA 7196 (colorimetrically by UV-VIS spectrophotometry), EPA 7199 (colorimetrically by Ion Chromatography). Ion Chromatography with ICP-MS detection, HPLC-ICP-MS or CE-ICP-MS can also be used.

26. EPA 218.7
This standard, partly modified, is used by Italian experts for the analysis of tattoo inks.

Scope and field of application
Determination of Cr (VI) as the chromate anion CrO_4^{2-} in treated drinking water using ion chromatography. Samples are analysed by direct injection.

Principle
Samples are preserved with a combined buffer/dechlorating reagent which complexes free chlorine and increases pH > 8. 1 ml of sample is introduced into an ion chromatography with an anion exchange column. CrO_4^{2-} is derivatised with 1,5-diphenylcarbazide in a post-column reactor and is detected at a wavelength of 530 nm. Cr (VI) is qualitatively identified via retention time, and the concentration of CrO_4^{2-} is calculated using the integrated peak area and the external standard technique.

Type of instrument analysis
Ion chromatography with an anion exchange column, post-column derivatisation with 2 mM 1,5-diphenylcarbazide and detection at 530 nm.

LOD, LOQ
LOD for Cr (VI) fortified into reagent water ranged from 0.0044 to 0.015 µg/l.

Repeatability (r) and Reproducibility (R)
Single lab precision: using $NH_4OH/(NH_4)_2SO_4$ as preservative: 4.2 % (at 0.020 µg/l) with ammonium hydroxide/ammonium sulphate as eluent and 8.0 % (at 0.0625 µg/l) with carbonate/bicarbonate as eluent.

27. EN ISO 17294-2

This standard, partly modified, is used by Austrian and Slovenian experts for the analysis of tattoo inks.

Scope and field of application

In the field of water quality (drinking water, surface water, groundwater, wastewater and eluates), this international standard specifies a method for the determination of the following elements: aluminium, antimony, arsenic, barium, beryllium, bismuth, boron, cadmium, caesium, calcium, cerium, chromium, cobalt, copper, dysprosium, erbium, europium, gadolinium, gallium, germanium, gold, hafnium, holmium, indium, iridium, lanthanum, lead, lithium, lutetium, magnesium, manganese, molybdenum, neodymium, nickel, palladium, phosphorus, platinum, potassium, praseodymium, rubidium, rhenium, rhodium, ruthenium, samarium, scandium, selenium, silver, sodium, strontium, terbium, tellurium, thorium, thallium, thulium, tin, tungsten, uranium, vanadium, yttrium, ytterbium, zinc, and zirconium.

Principle

Multi-element determination of 62 elements by inductively coupled plasma mass spectrometry (ICP-MS)

Description of test method

For tattoo ink analysis, Slovenian experts report the following procedure. The tattoo ink is homogenised and then digested in a microwave oven in the presence of a H_2O_2/HNO_3/HF mixture. Quantification is carried out by ICP-MS.

Type of instrument analysis

ICP-MS

LOD, LOQ

Austria reports order of magnitude between 0.0001 and 0.01 µg/l.

Repeatability (r) and Reproducibility (R)

For the matrix surface water, CV_r, ranged between 2.5 and 13.2 % and CV_R between 6.4 and 20.3 %, depending on the element.

28. EN ISO 11885

This standard is used by Swedish experts for the analysis of tattoo inks.

Scope and field of application

In the field of water quality, this International Standard specifies a method for the determination of dissolved elements, elements bound to particles and total content of elements in different types of water. The method can be applied to the quantification of the following: aluminium, antimony, arsenic, barium, beryllium, bismuth, boron, cadmium, calcium, chromium, cobalt, copper, gallium, indium, iron, lead, lithium, magnesium, manganese, molybdenum, nickel, phosphorus, potassium, selenium, silicon, silver, sodium, strontium, sulphur, tin, titanium, tungsten, vanadium, zinc and zirconium.

Principle

Measurement of light emission by an optical spectroscopic technique coupled with an inductively coupled plasma. The recommended wavelength is indicated for each element.

Description of test method

In the case of particulate elements, a measured volume sample is filtered through a 0.45 μm membrane filter after collection. The membrane filter containing the insoluble material is transferred to a digestion vessel and microwave digested in the presence of nitric acid and hydrogen peroxide. The digested sample is evaporated to near dryness and cooled. Then a hydrochloric acid solution is added. The vessel is heated in order to dissolve any precipitated or residue material. After cooling, the sample is filtered to remove insoluble material. The volume is adjusted according to the element to be detected and the expected concentration and the sample is then analysed by ICP-OES.

For the determination of total elements, the digestion procedure can be omitted and the sample is directly acidified with nitric acid to reach pH 2.

Type of instrument analysis

ICP/OES

LOQ:

Element	Wavelenght	Radial viewing LOQ µg/l	Axial viewing LOQ µg/l
Pb	220.353	14	5
	283.305	70	20
S	180.669	13	33
	181.975	39	17
Sb	206.834	100	4
	217.582	100	18
Se	196.089	100	7
	203.984	100	7
Si	212.412	3	13
	251.611	20	10
	288.158	30	24
Sn	189.988	100	60
	235.485	100	200
	283.998	—	120
Sr	407.771	2.6	0.6
	421.552	0.1	0.1
	460.733	10	3
Ti	334.941	5	2
	336.123	10	1
	337.280	10	—
	368.521	10	—
V	290.881	10	—
	292.402	10	3
	310.229	10	0.7
	311.071	10	1
W	202.998	60	--
	207.912	30	10
	209.860	60	20
	222.589	60	30
	239.711	60	—
Zn	202.548	—	3
	206.200	13	5
	213.857	3.3	1
Zr	339.197	—	2
	343.823	10	0.3
	354.262	50	1

Repeatability (r) and Reproducibility (R)
CV_R: minimum 2.6 %; maximum 15.8 %.
CV_r: minimum 1.2 %; maximum 8.2 %.

29. EN ISO 12846:2012 (Supersedes DIN EN 1483)
Scope and field of application
In the field of water quality, this International Standard specifies two different methods (with or without enrichment) for the determination of mercury in drinking, surface, ground, rain and waste water after pre-digestion. The choice of the method depends on the equipment available.

Principle

Organo mercury, mono- and divalent mercury compounds are oxidised to divalent mercury by reaction with $KBrO_3$-KBr then reduced to the elemental form by tin (II) chloride in an acidic medium. After stripping of elemental mercury with an inert gas (or mercury free air) the sample is analysed by AAS.
When the enrichment step is applied, the stream of inert gas is used to transport the mercury (in the form of atomic vapour) to a quartz tube containing a suitable adsorbent on which mercury is adsorbed.

Type of instrument analysis
AAS

LOQ
Method with enrichment has a working range from 0.01 to 1 µg/l and a LOQ = 0.008 µg/l.
Method without enrichment has a working range starting from 0.05 µg/l and a LOQ=0.024 µg/l.

Repeatability (r) and Reproducibility (R)
Method with enrichment shows CV_r ranging from 1.7 to 6.3 % and CV_R from 4.8 to 14.4 %.
Method without enrichment shows CV_r ranging from 0.8 to 4.1% and CV_R from 3.6 to 10.6 %.

In-house validated methods

1. Determination of heavy metals (Cd, Pb, Ni) in cosmetics and food contact materials (Slovakia)

Scope and field of application
Determination of Cd, Pb, Ni in cosmetics, food contact materials.

Principle
Graphite Furnace Atomic Absorption Spectrometry (GFAAS).

Description of test method
Sample preparation entails microwave mineralization (0.4g of the sample).

Type of instrument analysis
ETA-AAS (GFAAS)

LOD, LOQ

	LOD mg/kg	LOQ mg/kg
Cd	0.002	0.006
Pb	0.008	0.026
Ni	0.016	0.054

Repeatability (r) and Reproducibility (R)

	RSDr %
Cd	≤ 10
Pb	≤ 20
Ni	≤ 25

2. Determination of mercury in cosmetics and food contact materials (Slovakia)

Scope and field of application
Determination of Hg in cosmetics and food contact materials.

Principle
Direct analysis method

Type of instrument analysis
AAS/AMA-direct mercury analyser

LOD, LOQ
LOD = 0.09 mg/kg; LOQ = 0.3 mg/kg

3. Determination of heavy metals (Hg, Zn, Cu, Cr (VI), Co, Sb) in cosmetics and food contact materials (Slovakia)

Scope and field of application
Determination of Hg, Zn, Cu, Cr (VI), Co, Sb in cosmetics and food contact materials.

4. ICP-MS (in-house method) (France)

Scope and field of application

ICP-MS: Elements of the CoE resolution (As, Ba, Cd, Co, Cr, Cu, Hg, Ni, Pb, Se, Sb, Sn, Zn) and others elements of ICH-Q3D Guideline (V, Tl, Au, Pd, Ir, Os, Rh, Ru, Ag, Pt, Li, Mo)
X-RF: Elements between Na and U

Principle

Quantitative determination of elemental impurities by ICP-MS after mineralization of sample in high acid conditions
Screening and semi-quantitative determination of elements between Na and U, usually without sample preparation, by means of X-RF

Type of instrument analysis

ICP-MS
EDXRF Analyser

LOQ

ICP-MS: Depending on sample preparation. Usually 0.1-0.2 ppm, except for Cu (2.5 ppm), Zn (1.0 ppm) and Mo (0.5 ppm).
X-RF: Depending on the elements (between 10 and 100 ppm).

Repeatability (r) and Reproducibility (R)

ICP-MS: Typical repeatability measured on standard: CV_r = 3 % (n = 6)
The test method was never applied to tattoo inks.
XRF: only used for screening and semi-quantitative determinations.

ITALY

5. MI-08 Determinazione degli elementi in cosmetici - Accredia Rev. 5, 2014 (Italy) (Determination of elements in cosmetics)

Scope and field of application

In-house validated method for the determination of Cd, Co, Cr, Ni, Pb in cosmetics by ICP-MS after microwave digestion with HNO_3, HF and H_2O_2.

Principle

A representative sample is digested in microwave oven for 30 min with HNO_3/HF/H_2O_2 mixture. After cooling, the vessel contents are diluted and analysed by using the appropriate ICP-MS method.

Description of test method

Weight 0.1 (± 0.02) g of sample in TFM vessels, add 4 ml of HNO_3 (67-69 %), 2 ml of H_2O_2 (30 %), 0.5 ml of HF (47-51 %). Microwave programme: 10 min at 250 W, 10 min at 400 W, 10 min at 600 W, 10 min of cooling.

Type of instrument analysis

High Resolution (HR)-ICP-MS; masses: ^{111}Cd, ^{114}Cd, ^{206}Pb, ^{208}Pb in Low Resolution; ^{59}Co, ^{52}Cr, ^{60}Ni in Medium Resolution; internal standardisation by ^{103}Rh. Quantification by addition calibration in matrix.

LOD

	LOD mg/kg
Cd	0.007
Co	0.15
Cr	1.26

Repeatability (r) and Reproducibility (R)

	RSDr %
Cd	9.6
Co	8.3
Cr	7.6
Ni	7.2
Pb	10

6. Metals and other elements in tattoo inks (Slovenia)

Scope and field of application

Tattoo inks.

Description of test method

The tattoo ink specimen is homogenised and then digested in the presence of a H_2O_2/HNO_3/HF mixture in a microwave oven. Quantification is carried out by ICP-MS analysis.

Type of instrument analysis

ICP-MS

LOQ

The limit of quantification depends on the element and ranges from 0.01 to 10 mg/kg.

Comments

Analysis is carried out according to SIST EN ISO 17294-2 with modification (external calibration, Rh internal standard).

7. CHE01-WV495: Determination of certain elements in tattoo inks using ICP-MS (The Netherlands)

Scope and field of application

The procedure describes the quantitative analysis of certain heavy metals in tattoo inks using Inductively Coupled Plasma with mass selective detection (ICP-MS). The method is validated for the analysis of antimony, arsenic, barium, cadmium, chromium, cobalt, copper, lead, mercury, nickel, selenium and tin. The method is not validated for the analysis of zinc.

Principle

After microwave-assisted destruction of the tattoo ink, using a mixture of nitric acid and hydrogen peroxide, the final solution is analysed by using Inductively Coupled Plasma in combination with mass selective detection.

Description of test method
The homogenisation of the tattoo ink specimen is followed by microwave-assisted digestion using a mixture of nitric acid and hydrogen peroxide. Quantification of elements is achieved by ICP-MS analysis.

Type of instrument analysis
ICP/MS

LOD, LOQ
(0.004 < LOD < 1.46) mg/kg
(0.008 < LOQ < 2.93) mg/kg

Repeatability (r) and Reproducibility (R)
2.3 % < RSD_r < 25 %

8. ICP/MS screening analysis for metals and other elements (Denmark)

Scope and field of application
For the quantitative determination of metals and other elements, a sample preparation was carried out with acid and subsequent ICP/MS screening analysis. The expert programme TotalQuantIII was applied. It quantifies the content on the basis of an instrument response curve of the elements from mass 6 (Li) to mass 238 (U).

Description of test method
The weighed subsamples* are heated with concentrated nitric acid by means of microwaves in a quartz autoclave. Subsequently, the sample is filtered and diluted. Blank specimens are treated in the same way.

*: All tattoo inks were shaken thoroughly right before extraction of the subsample to be analysed in order to obtain a sample that was as homogeneous as possible. In connection with sampling, weight was used rather than volume because in connection with some tattoo inks, it proved impossible to remove a known volume due to high viscosity (thick-flowing).

Type of instrument analysis
ICP/MS

Methods described in literature

1. Market survey on toxic metals contained in tattoo inks
Forte G, Petrucci F, Cristaudo A, Bocca B., Science of the Total Environment, 2009, 407, 5997-6002.

Scope and field of application
Microwave digestion of tattoo inks by HNO_3, HF and H_2O_2 and analysis of Al, Ba, Cd, Co, Cr, Cu, Fe, Hg, Mn, Ni, Pb, Sb, Sr, V by ICP-MS.

Principle
A representative sample is digested in HNO_3, HF and H_2O_2 for 20 min using a microwave oven. After cooling, the vessel contents are diluted and analysed by the appropriate ICP-MS method.

Description of test method
Weight about 0.25 g of sample in vessels, add 4 ml of HNO_3 (67-69 %), 1 ml of H_2O_2 (30 %), 1 ml of HF (47-51 %). Microwave programme: 5 min at 250 W, 5 min at 400 W, 10 min at 600 W. After digestion, the solutions are diluted with high purity deionised water and analysed by ICP-MS.

Type of instrumental analysis
High Resolution (HR)-ICP-MS. Quantification by addition calibration in matrix.

LOD, LOQ
The limit of detection ranged from 0.02 (Cd) to 3 ng/ml (Al, Fe). The LOQ varied from 0.07 (Cd) to 10 ng/ml (Al, Fe).

Repeatability (r) and Reproducibility (R)
The between-day RSD_r ranged from 1.58 % (Co) to 5.33 % (Cu), while the within-day RSD_r varied between 2.67 % (Co) and 7.05 % (Cu).

2. Quantification of para-phenylenediamine and heavy metals in henna dye
Kang I-J, Lee M-H., Contact Dermatitis, 2006, 55(1), 26–29.

Scope and field of application
Determination of Co and Ni in henna dyes by AAS

Principle
Dissolution of henna dyes in water and analysis of Co and Ni by AAS

Description of test method
A 0.4 g sample was added to a 15-ml Falcon tube with pure water to make 10 ml of solution. The solution was heated in an 80 – 90 C water bath for 30 min. After cooling, it was treated with ultrasounds for 15 min and filtered in order to make the test solution.

Type of instrumental analysis

AAS was performed at a wavelength of 232.0 nm and a lamp current of 4 mA for Ni and at a wavelength of 240.7 nm and a lamp current of 7 mA for Co.

LOD, LOQ
The detection limits for Co and Ni were found as 0.05 µg/ml and 0.1 µg/ml respectively.

3. Survey of Selected Samples of Tattoo Inks for the Presence of Heavy Metals
Ministry of Health, 2013, Wellington.

Scope and field of application
Determination of As, Ba, Cd, Co, Cr (VI), Cu soluble, Hg, Ni, Pb, Se, Sb, Zn by ICP-MS in tattoo inks.

Principle
MW digestion of tattoo inks with acid, dilution and analysis of heavy metals by ICP-MS.

Description of test method
MW digestion of tattoo inks with acid, dilution and analysis of As, Ba, Cd, Co, Hg, Ni, Pb, Se, Sb, Zn by ICP-MS. Buffered extraction solution (pH 5.5), dilution and analysis of soluble Cu by ICP-MS. Analysis of Cr (VI) using a modified version of the EPA method 218.7 by ion chromatography with post-column derivatisation and UV-VIS spectroscopic detection.

Type of instrumental analysis
ICP-MS and Ion Chromatography

4. Determination of hexavalent chromium in cosmetic products by ion chromatography and post-column derivatisation
Kang et al., Contact Dermatitis, 2006, 54, 244–248.

Scope and field of application
Determination of Cr(VI) in eye shadows by ion chromatography and post column derivatisation.

Principle
Dissolution of cosmetic and subsequent ion chromatography with post column detection by 1,5-diphenilcarbazide.

Description of test method
Eye shadow samples are weighted (0.1 g) and placed in 15-ml polypropylene centrifuge tubes with 10 ml of ethanol-hexane (1:1 v/v) solution. The mixtures are sonicated for 15 min, followed by centrifuge for 20 min at 450 g. After the solution is removed, this process is repeated. The samples are dried at 60 °C for 12 h. Dried sample with 10 ml of eluent solution are heated at 90 °C water bath for 30 min. After cooling, the solution is filtered (0.45 mm) and then analysed by IC.

Type of instrumental analysis
Ion chromatography with 1,5-diphenilcarbazide as post-column reagent.

LOD, LOQ
The limit of quantification for Cr (VI) is 1.0 µg/l.

Repeatability (r) and Reproducibility (R)
RSD_r at 1.0 µg/l was calculated as 0.978 %.

ITALY and UNITED KINGDOM

5. Determination of heavy metals in tattoo inks

Eghbali K, Mousavi Z, Ziarati P., Bioscience Biotechnology Research Asia, 2014, 11(2), 941-946.

Scope and field of application
Determination of Cd, Zn and Pb in tattoo inks by Flame Emission Spectrophotometry.

Principle
Wet digestion of a sample with a mixture of acids and analysis by Flame Emission Spectrophotometry

Description of test method
For heavy metal analyses, 2 g of each sample was weighed. The samples were analysed according to standardized international protocols (not referenced) by wet digestion method, using HNO_3 (65 %), conc. $HClO_4$ and H_2SO_4 and H_2O_2 (30 %) in the ratios 3:2:1:1 and analysed by Flame Emission Spectrophotometer.

Type of instrumental analysis
Flame Emission Spectrophotometry using an air-acetylene flame

Comments
UK: Flame Emission may lack required sensitivity.

6. Chemical Substances in Tattoo Ink - Survey of chemical substances in consumer products, 116

Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8.

Scope and field of application
Quantitative analysis of metals and other elements in tattoo inks. The method reports for 66 elements but covers mass 6 (Li) to mass 238 (U).

Principle
Micro wave acid digestion of samples followed by ICP-MS

Description of test method
Samples are weighted, heated with concentrated HNO_3 (sub boiling quality) by means of microwave in a quartz autoclave, and then filtered and diluted. Metals are determined by ICP-MS.

Type of instrumental analysis

ICP-MS

LOD, LOQ
The detection limits, depending on the heavy metal, ranged from 0.01 to 1 µg/g.

Comments
UK: ICP-MS is more of a specialist instrument but offers the sensitivity and range required.

Annex VII

Analytical methods for the polycyclic aromatic hydrocarbons

International standard methods

1. EN 71-7:2014

Scope and field of application

In the framework of safety of toys, this European Standard specifies requirements for substances and materials in finger-paint. In particular "Annex E" provides a method for the determination of benzo[α]pyrene (CAS n 50-32-8).

Principle

Solvent extractable benzo[α]pyrene (B[α]P) is determined in finger-paints by mixing with anhydrous sodium sulphate and extracting with 2:1 mixture of toluene and acetone for B[α]P by means of a Soxhlet extractor. The extract is cleaned up and concentrated prior to analysis using gas chromatography with a mass spectrometric detection (GC-MS) using the internal standard method of calibration.

Description of test method

Sample preparation is specific for finger paint and requires the vigorous mixing of the specimen with anhydrous sodium sulphate until a homogeneous mixture is obtained. The mixture should consist of particles no larger than 1 mm to 5 mm (a rod can be used to break larger particles). The mixture obtained as described before is transferred into an extraction microfibre glass thimble and a Soxhlet extraction is carried out with a toluene/acetone mixture, under gentle reflux to extract soluble B[α]P.

The extract is then transferred onto a column containing Kieselguhr and left standing for approximately 1 h. Then it is eluted with toluene and concentrated. After re-dilution with 2,2,4-trimethylpentane an aliquot is transferred to a sample vial and the B[α]P internal standard solution added for quantitative determination by GC-MS.

Type of instrument analysis

GC/MS

LOD, LOQ

LOD = 0.002 mg/ml; LOQ = 0.05 mg/ml

Repeatability (r) and Reproducibility (R)

B[α]P (0.050 mg/kg): Lab 1 (0.037 ± 0.002) mg/kg, Lab 2 (0.039 ± 0.001) mg/kg

2. CEN/TS 16621:2014

Scope and field of application

This Technical Specification applies to several food matrices and describes a method for the determination of benzo[*a*]pyrene (BaP), benz[*a*]anthracene (BaA), benzo[*b*]fluoranthene (BbF) and chrysene (CHR). In addition, the method was tested in-house and shown to be applicable also for the quantification of other 12 PAHs: benzo[*c*]fluorene (BcL), benzo[*j*]fluoranthene (BjF), benzo[*k*]fluoranthene (BkF), cyclopenta[*cd*]pyrene (CPP), dibenz[*a,h*]anthracene (DhA), dibenzo[*a,e*]pyrene (DeP), benzo[*ghi*]perylene (BgP), dibenzo[*a,h*]pyrene (DhP), dibenzo[*a,i*]pyrene (DiP), dibenzo[*a,l*]pyrene (DlP), indeno[1,2,3-*cd*]pyrene (IcP), 5-methylchrysene (5MC).

Principle

The PAHs are extracted (or simply dispersed, when possible) with dichloromethane then purified by SEC. The final extracts are analysed by HPLC with programmable fluorescence detection.

Description of test method

The extraction/dispersion is carried out with dichloromethane. SEC clean-up is performed, after equilibration with dichloromethane, eluting the PAHs by passing dichloromethane at a flow rate of 5 ml/min. The fraction(s) corresponding to the elution time of PAHs are collected. Fraction(s) are evaporated to dryness, re-dissolved in acetonitrile and analysed by HPLC-FD.

LOQ

0.41 - 0.51 µg/kg

Repeatability (r) and Reproducibility (R)

RSD_R ranges between 3.1 and 16.2 % and it is strongly dependent on the matrix.

National standard methods

1. ZEK 01.2-08 (superseded by ZEK 01.4-08): Testing and validation of Polycyclic Aromatic Hydrocarbons (PAH) in the course of GS-Mark certification (Sweden)
ZEK (Zentraler Erfahrungsaustauschkreis "Central Committee on Experience Exchange")
GS (Geprüfte Sicherheit "Tested Safety")

Scope and field of application

This document substantiates the national requirements (mentioned in e.g. §§ 30 and 31 of the LFGB and the § 3 of the ProdSG) regarding PAH by describing test procedures for detection of PAH in polymer samples (benzo[a]pyrene and sum of 18 PAHs in mg/kg).

Substance	CAS number
Benzo[a]pyrene	50-32-8
Dibenz[a,h]anthracene	53-70-3
Benz[a]anthracene	56-55-3
Acenaphthene	83-32-9
Phenanthrene	85-01-8
Fluorene	86-73-7
Naphthalene	91-20-3
Anthracene	120-12-7
Pyrene	129-00-0
Benzo[g,h,i]perylene	191-24-2
Benzo[e]pyrene	192-97-2
Indeno[1,2,3-cd]pyrene	193-39-5
Benzo[j]fluoranthene	205-82-3
Benzo[b]Fluoranthene	205-99-2
Fluoranthene	206-44-0
Benzo[k]fluoranthene	207-08-9
Acenaphthylene	208-96-8
Chrysene	218-01-9

Principle

Extraction followed by GC/MS analysis.

Description of test method

A representative sample from the material is mixed with toluene (already containing the internal standards). Extraction is achieved by ultrasonic irradiation for 1h at a constant temperature of 60 °C. Directly proceed with GC/MS analysis.

LOQ

0.2 mg/kg

In-house validated methods

1. Determination of PAHs in tattoo inks with GC/MS (Italy)

Scope and field of application

This method describes a procedure for the extraction, purification, identification and quantification of PAH (refer to the following list) in tattoo inks.

Substance	CAS number
Benzo[a]pyrene	50-32-8
Dibenz[a,h]anthracene	53-70-3
Benz[a]anthracene	56-55-3
Acenaphthene	83-32-9
Phenanthrene	85-01-8
Fluorene	86-73-7
Naphthalene	91-20-3
Anthracene	120-12-7
Pyrene	129-00-0
Dibenzo[a,h]pyrene	189-64-0
Benzo[g,h,i]perylene	191-24-2
Dibenzo[a,l]pyrene	191-30-0
Dibenzo[a,i]pyrene	192-55-9
Dibenzo[a,e]pyrene	192-65-4
Benzo[e]pyrene	192-97-2
Indeno[1,2,3-cd]pyrene	193-39-5
Benzo[j]fluoranthene	205-82-3
Benzo[b]Fluoranthene	205-99-2
Fluoranthene	206-44-0
Benzo[k]fluoranthene	207-08-9
Acenaphthylene	208-96-8
Chrysene	218-01-9
Cyclopenta(c,d)pyrene	27208-37-3

Principle

1 g of sample is dissolved in a 2:1 mixture of benzene:acetone and sonicated for 1 hour at 60 (± 10) °C. After cooling at room temperature the solution is centrifuged and the supernatant is collected and purified with silica gel.

The determination of the PAHs is performed by GC/MSD (Gas Chromatography / Mass Spectrometer Detector).

Description of test method

Weigh 1 g of sample and add 20 ml of a solution benzene:acetone (2:1) and 1 ml of mix B(a)P D12, B(a)A D12, B(b)F D12, Cri D12 - amount about 100 µg/kg in cyclohexane (deuterated process standards). Put it in an ultrasonic bath for 1 hour at a constant temperature (60 °C) for extraction. After cooling at room temperature, put it in a centrifuge at 5000 g for 10 min. Collect the supernatant and evaporate it at about 1 ml using a rotary vacuum evaporator.

Purification is carried out by means of a clean-up column with fiberglass, 4 g of silica gel and 1 cm of sodium sulphate. The silica gel is first dehydrated in an oven at 120°C for 24 hours and then deactivated by the addition of 10% of water. The conditioning of the packed column is done with 20 ml of petroleum ether.

After conditioning, the sample is put into the column and the elution is done with 50 ml of petroleum ether. These 50 ml are collected and evaporated using a rotary vacuum evaporator

at about 1 ml. Perform the complete evaporation of the ether with a gentle flow of N_2 or other inert gas. Add 1 ml of cyclohexane with Internal Standard (naphtalene D8) and proceed to the determination with GC/MSD.

Type of instrument analysis
GC/MS

LOQ
1 µg/kg (same for each PAH)

Repeatability (r) and Reproducibility (R)
$HORRAT_r \leq 2$
$HORRAT_R \leq 2$

2. PAHs in tattoo inks by HPLC/UV/FLD after microwave assisted extraction with toluene (Switzerland)

Scope and field of application
PAH in tattoo inks: 5-methylchrysene, acenaphthene, acenaphthylene*, anthracene, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene, benzo(ghi)perylene, benzo(j)fluoranthene*, benzo(k)fluoranthene, chrysene, cyclopenta(c,d)pyrene*, dibenzo(a,e)pyrene, dibenzo(a,h)anthracene, dibenzo(a,h)pyrene**, dibenzo(a,i)pyrene**, dibenzo(a,l)pyrene, fluoranthene, fluorene, indeno(1,2,3-c,d)pyrene, naphthalene, phenanthrene, pyrene.
* with limited sensitivity;
** in most samples with very low recoveries.

Description of test method
Samples are extracted with toluene in a pressurized microwave oven at 120 °C for 40 minutes. Polar analytes like naphthalene, acenaphthene and acenaphthylene are preferably extracted with 2-butanone/tetrahydrofurane at 80 °C in an ultrasonic bath to improve detection limits. After filtration of the sample over HPLC membrane filters. Sample solutions are analysed by HPLC/UV/FLD.

Type of instrument analysis
HPLC/UV/FLD

LOD, LOQ
LOD's and LOQ's are strongly dependent on analytes and on the presence and type of carbon black; for naphthalene, the extraction should be performed with MEK/THF to drastically improve LOQ.

Repeatability (r) and Reproducibility (R)
Depend on analyte and matrix. Average precision in terms of RSD_R on five samples containing PAH's ranges from 6.0 to 19.1 %

3. CHE01-WV405 Determination of polycyclic aromatic hydrocarbons (PAH's) in tattoo ink and rubber using a GC-MS system (The Netherlands)

Scope and field of application

This method describes the identification and quantification of 18 Polycyclic Aromatic Hydrocarbon (refer to the following list) in tattoo inks and in rubber using a GC-MS system.

Substance	CAS number
Benzo(a)pyrene	50-32-8
Dibenzo(a,h)anthracene	53-70-3
Benzo(a)antracene	56-55-3
Acenaphthene	83-32-9
Phenanthrene	85-01-8
Fluorene	86-73-7
Naphthalene	91-20-3
Antracene	120-12-7
Benzo(g,h,i)perylene	191-24-2
Benz(e)pyrene	192-97-2
Indeno(1,2,3-cd)pyrene	193-39-5
Benzo(j)fluoranthene	205-82-3
Benzo(b)fluoranthene	205-99-2
Fluoranthene	206-44-0
Benzo(k)fluoranthene	207-08-9
Acenaphthylene	208-96-8
Chrysene	218-01-9
Pyrene	1718-52-1

Principle
The PAH's are extracted from the tattoo ink with toluene/acetone

Description of test method
1. Homogenisation of the tattoo inks by shaking or mixing with a spatula
2. Extraction of the tattoo ink with a toluene/acetone mixture
3. Gas chromatographic analysis

Type of instrument analysis
GC/MS

Repeatability (r) and Reproducibility (R)
RSD_r ranged from 5 to 21 %.

Methods described in literature

1. Chemical Substances in Tattoo Ink
Survey of chemical substances in consumer products, 116
Danish Environmental Protection Agency, 2012, ISBN 978-87-92779-87-8.

Scope and field of application
This method determines the content of polycyclic aromatic hydrocarbons (PAH) in tattoo inks. The analysis is quantitative.

Principle
A prepared sample is analysed by gas chromatography combined with mass spectrometry (GC/MS).

Description of test method
A subsample of the tattoo ink (about 1 g) is mixed with 1 ml acetone. 100 µl internal standards and 2 ml benzene is added. It is heated in an ultrasonic bath for 60 min. at 60 °C and centrifuged at 3000 rpm for 10 min. The supernatant is saved. Extraction is repeated two more times and the supernatants combined. Sample evaporated to about 1 ml, filtered if required, then diluted 1:10 with dichloromethane. Analysis is by capillary gas chromatography combined with mass spectrometry (GC/MS).

Type of instrumental analysis
GC/MS

LOD, LOQ
The limit of detection ranges from 0.15 to 0.5 µg/g depending on the substance.

Comments
Standard approach to this analysis.

2. Tattoo inks contain polycyclic aromatic hydrocarbons that additionally generate deleterious singlet oxygen
Regensburger et al., Experimental Dermatology, 2010, 8 (19), 275-281.

Scope and field of application
Quantitative analysis of the content of polycyclic aromatic hydrocarbons (PAH) in tattoo inks

Substance	CAS number
Benz(a)pyrene	50-32-8
Dibenz(ah)anthracene	53-70-3
Benz(a)anthracene/chrysene	56-55-3/218-01-9
Acenaphtene	83-32-9
Phenanthrene/Anthracene	85-01-8/120-12-7
Fluorene	86-73-7
Naphthalene	91-20-3
Pyrene	129-00-0
Benz(ghi)perylene	191-24-2
Indeno(123)pyrene	193-39-5
Benz(b)fluoranthene	205-99-2
Fluoranthene	206-44-0
Benz(k)flouranthene	207-08-9
Acenaphthylene	208-96-8

Description of test method

A subsample of the tattoo ink* (app. 1 g accurately weighed) is mixed with 1 ml acetone on a whirley mixer. 100 µl internal standard (naphthalene-d8, antracene-d10, pyrene-d10 and benz(a)pyrene-d12) and 2 ml benzene is added, which are mixed on the whirley mixer. It is heated in an ultrasonic bath for 60 min. at 60 °C and centrifuged at 3000 rpm for 10 min. The supernatant is transferred to a new glass and saved. Extraction is repeated two more times with 1 ml acetone and 2 ml benzene. The supernatant is pooled with the previous supernatants. Evaporation takes place till app. 1 ml and filtration takes place if the sample is unclear. The sample is then diluted 1:10 with dichloromethane and analysed by means of capillary gas chromatography combined with mass spectrometry (GC/MS).

*: All tattoo inks were shaken thoroughly right before extraction of subsample for analysis in order to obtain a sample that was as homogeneous as possible. In connection with sampling, weight was used rather than volume because in connection with some tattoo inks it was impossible to remove a known volume due to high viscosity (thick-flowing).

LOD

0.15 - 0.5 µg/g

Annex VIII

Analytical methods for phthalates

International standard methods

1. EN 16521:2014

Scope and field of application

This international standard applies to the field of ready-to-inject cosmetics products and describes a GC/MS method for the assay the following phthalates (amongst which the 8 phthalates regulated by the European cosmetic regulation 1223/2009 hereby indicated with an asterisk):

Substance	CAS number
DCHP (dicyclohexyl phthalate)	84–61–7
DEP (diethyl phthalate)	84–66–2
DiBP * (diisobutyl phthalate)	84–69–5
DBP * (dibutyl phthalate)	84–74–2
BBP * (butylbenzyl phthalate)	85–68–7
DEHP * (diethylhexyl phthalate)	117–81–7
DMEP * (di(2-methoxyethyl) phthalate)	117–82–8
DnOP (di-n-octyl phthalate)	117–84–0
DMP (dimethyl phthalate)	131–11–3
DnPP * (di-n-pentyl phthalate)	131–18–0
DiPP * (diisopentyl phthalate)	605–50–5
DPP * (n-pentyl isopentyl phthalate)	84777–06–0

Description of test method

Sample preparation is specifically described for cosmetic samples ready for analytical injection. To a solution of the cosmetic sample ready for analytical injection in ethanol, the internal standard stock solution (SM-ISTD) is added. This solution is injected. In case of excessive concentration of phthalates, an appropriate previous dilution of the sample is performed. Analysis is carried out by means of gas chromatography.

LOQ

The limit of quantification applying the sample preparation described in the standard was set at 5 ppm.

2. EN ISO 14389:2014

Scope and field of application

In the field of textile products, this standard specifies a method for the determination of the following list of phthalates) by GC/MS.

Substance	CAS number
DCHP (dicyclohexyl phthalate)	84–61–7
DiBP (diisobutyl phthalate)	84–69–5
DBP (dibutyl phthalate)	84–74–2
BBP (butylbenzyl phthalate)	85–68–7
DEHP (diethylhexyl phthalate)	117–81–7
DMEP (di(2-methoxyethyl) phthalate)	117–82–8
DnOP (di-n-octyl phthalate)	117–84–0
DIDP (diisodecyl phthalate)	26761-40-0
DIHP (diisoheptyl phthalate)	41451-28-9, 71888-89-6 (C6-C8 ester)
DINP (di-iso-nonyl phtalate)	68515-48-0
DPP (n-pentyl isopentyl phthalate)	84777–06–0

Principle
Phthalates are extracted from the textile sample by means of sonication in the presence of tetrahydrofurane. The extraction is followed by selective precipitation of dissolved polymer (acetonitrile, n-hexane). The extract is then centrifuged and diluted to volume. GC/MS analysis is then run to identify and quantitate individual phthalates.

Type of instrument analysis
GC/MS

LOD
Ranges from 40 to 200 µg/g

Repeatability (r) and Reproducibility (R)
CV_r ranges from 3.0 to 23.5 %
CV_R ranges from 31.5 to 165.9 %

In-house validated methods

1. Determination of phthalates in cosmetics by GC-MS (Austria)

Scope and field of application
12 phthalates, cosmetics (nail polish etc.)

Description of test method
Dispersion of sample in ethyl acetate, dilution, measurement by GC-MS

Type of instrument analysis
GC-MS

LOQ
LOQ = 0.01 %

Repeatability (r) and Reproducibility (R)
$RSD_r \leq 11$ %

2. Determination of phthalate esters in cosmetics (Slovakia)

Scope and field of application
In the field of cosmetics, food contact materials.

Principles
Rapid extraction and HPLC analysis of 15 phthalic esters

Description of test method
1-5 g sample extracted using ethanol/water 9:1 (25-50 ml)

Type of instrument analysis
HPLC/DAD

LOD, LOQ
LOD = 2.2-4.5 mg/kg; LOQ = 3 x LOD

Repeatability (r) and Reproducibility (R)
$RSD_r \leq 7$ %

Annex IX

Analytical methods for nitrosamines

International standard methods

1. EN 71-12:2013

Scope and field of application

This method, in the field of toys safety, applies to toys and parts of toys, made from elastomers and finger paints, and describes a method for the determination of N-nitrosamines and N-nitrosatable substances (refer to the following list).

Substance	CAS number
N-nitroso-N-ethyl-N-phenylamine6 (NEPhA)	12-64-6
N-nitrosodiethylamine (NDEA)	55-18-5
N-nitrosomorpholine (NMOR)	59-89-2
N-nitrosodimethylamine (NDMA)	62-75-9
N-nitrosopiperidine (NPIP)	100-75-4
N-nitrosodiisopropylamine (NDiPA)	601-77-4
N-nitroso-N-methyl-N-phenylamine (NMPhA)	614-00-6
N-nitrosodipropylamine (NDPA)	621-64-7
N-nitrosodibutylamine (NDBA)	924-16-3
N-nitrosodiisobutylamine (NDiBA)	997-95-5
N-nitrosodiethanolamine (NDELA)	1116-54-7
N-nitrosodibenzylamine (NDBzA)	5336-53-8
N-nitrosodiisononylamine (NDiNA)	1207995-62-7

Principle

N-nitrosamines and N-nitrosatable substances migrate into a test solution (water in the case of N-nitrosamines in finger paints and saliva test solution in the case of N-nitrosatable substances in finger paints and for N-nitrosamines and N-nitrosatable substances in elastomers). N-nitrosatable substances are then converted to N-nitrosamines by acidification. The final test solutions are analysed for N-nitrosamines by HPLC/MS.

Description of test method

Sample preparation from "Finger paint" is hereby described.

N-nitrosamines. Homogenise the "Finger paints" test sample and weigh about 1.0 g of the sample into a sample tube, add 0.20 ml of d8-NDELA working solution and 18.8 ml water. Vortex for about 1 min and shake continuously for approximately 15 min. Centrifuge the sample solution at approximately 4000 g for about 15 min. Transfer a portion of the supernatant into a second sample tube and centrifuge at approximately 20000 g for about 15 min. If necessary, filter the supernatant through a membrane filter which will not retain analytes.

N-nitrosatable substances. Homogenise the "Finger paints" test sample and weigh about 0.4 g of the sample into a sample tube and add saliva test solution until the total weight is 20 g. Vortex for about 1 min and shake continuously for approximately 15 min on a shaking machine. Transfer 5.0 ml of the test solution in an amber vial and add 0.5 ml of 1 mol/l hydrochloric acid solution. Cap the vial, shake to mix and allow the solution to stand for 30 (± 1) min at 40 (± 2) °C. Add 1.0 ml of 1 mol/l sodium hydroxide solution and shake to mix. Transfer the solution into a centrifugation tube and centrifuge the sample solution at 20000 g for 15 min. If necessary, filter the supernatant through a membrane filter.

This test solution may be used for N-nitrosamines analysis or nitrosated and analysed for N-nitrosatable compounds.

Type of instrument analysis
HPLC/MS.

LOQ:
For NDELA in water 1 μg/l
For each N-nitrosamine in saliva test solution 1 μg/l

Repeatability (r) and Reproducibility (R)
NDELA in finger paint shows RSD_r = 16 % and RSD_R = 25 % (9 results, 0.026 mg/kg average amount).
N-nitrosamines and N-nitrosatable substances in elastomers show RSD_r ranging from 6.1 to 16 % and RSD_R ranging from 31 to 59 % depending on the type of elastomer (balloon or sheets of rubber).

In-house validated methods

1. Nitrosamines in cosmetics, finger paints and tattoo inks by LC/MS/MS (Switzerland)

Scope and field of application

N-nitrosodiethanolamine (NDELA), N-nitrosodimethylamine, N-nitrosodiethylamine, N-nitrosodipropylamine, N-nitrosodiisobutylamine, N-nitrosodibutylamine, N-nitrosomorpholine, N-nitrosopiperidine, N-nitrosopyrimidine, N-nitrosomethylethylamine in cosmetics, finger paints and tattoo inks.

Description of test method

Extraction of nitrosamines with water for 15 minutes in an ultrasonic bath followed by centrifugation, filtration over 0.1 µm PVDF membrane filters and LC/MS/MS analysis. For quantitative extraction of the non-polar nitrosamines (like N-nitrosodibutylamine), extraction has to be performed with methanol or a methanol/water mixture.

Type of instrument analysis

LC/MS/MS

LOD, LOQ

As with every multi LC/MS/MS method LOD's and LOQ's strongly depend on the analyte and the matrix! LOQ: between 10 µg/kg (NDELA, Ni-nitrosomorpholine, N-nitrosodiethylamin, N-nitrosoethylmethylamine), 20 µg/kg (N-nitrosodibutylamine, N-nitrosodiisobutylamine, N-nitrosodimethylamine and 100 µg/kg (N-nitrosopyrrolidine)

Repeatability (r) and Reproducibility (R)

Reproducibility heavily depends on analyte and sample. The average RSD_R for NDELA (determined in 52 samples with contents higher than 20 µg/kg) was 9.3 % (0.3-31.4 %). For N-nitrosomorpholine, the average RSD_R on 7 samples with contents higher than 20 µg/kg was 12.6 % (1.4-37.6 %). For nitrosodibutylamine, the RSD_R on 5 samples with contents higher than 10 µg/kg was 4.5 % (2.4-9.6 %).Up to now, no other nitrosamines were found in tattoo inks or permanent-make up.

Annex X

List of background documents (laws/guidelines) related to tattoo and permanent make-up products and processes in EU/EFTA countries, and other consulted data supporting this report

Country	Piece of legislation/guidance/proposal
EU Member States	
AUSTRIA	
AT.1.	Tätowiermittelverordnung 2014
AT:2.	Verordnung des Bundesministers für Wirtschaft und Arbeit über Ausübungsregeln für das Piercen und Tätowieren durch Kosmetik (Schönheitspflege)-Gewerbetreibende
AT.3.	Verordnung des Bundesministers für Wirtschaft und Arbeit über Ausübungsregeln für Fußpflege, Kosmetik und Massage durch Gewerbetreibende
AT.4.	Verordnung des Bundesministers für Wirtschaft und Arbeit über Zugangsvoraussetzungen für das reglementiere Gewerbe der Kosmetik
BELGIUM	
BE.1.	Arrêté Royal (A.R.) 25/11/2005 réglementant les tatouages et les piercings
BE.2.	Avis du Conseil Supérieur de la Santé (CSS) N° 8631 - 2 February 2011 - Maquillage semi-permanent et tatouage
BE.3.	Avis du Conseil Supérieur de la Santé (CSS) N° 8719 – 5 September 2012 - Recommandations relatives à la maîtrise des infections lors de la pose de maquillage semi-permanent et permanent, de tatouages et de piercings
CROATIA	
HR.1.	Act on objects of common use (NN 39/2013, 47/14),
HR.2.	Ordinance (regulation) on health safety of objects of common use (NN 125/09, 23/13)
HR.3.	Act on protection of population from infectious diseases (OG 79/07, 113/08, 43/09)
CZECH REPUBLIC	
CZ.1.	Act No 258/2000 Coll., on the protection of public health
CZ.2.	Decree 137/2004 Coll., on hygienic requirements for food services and the principles of personal and operational hygiene which carry out epidemiologically important activities
CZ.3.	Decree No. 490/2000, Coll., on the scope of knowledge and other conditions to acquire professional competence in some fields of public health protection
CZ.4.	Act No 102/2001 Coll. on general product safety
CZ.5.	Act No 634/1992 Coll., on the protection of consumers (31 December 1992)
CZ.6.	Trade Licensing Act (law n. 455/1991 in actual version) for "Activities by which the integrity of human skin is disturbed"
DENMARK	

DK.1.	Recommendation from the Danish EPA on the safety of tattoo inks
DK.2.	Act on a voluntary and industry-managed registration system for tattooists and Ministerial order on a voluntary and industry-managed registration system for tattooists
DK.3.	Law on tattoos
DK.4.	DRAFT for the Order on tattoo inks
FINLAND	
FI.1.	CLP Regulation (EC) No 1272/2008
FI.2.	REACH Regulation (EU) No 1907/2006 (in force since 1 June 2007)
FI.3.	Ministry of Social Affairs and Health Decree on chemical classification and labelling principles (807/2001)
FI.4.	Chemicals Act (599/2013)
FI.5.	Health Protection Act (763/1994 in the Finnish Statute Book)
FI.6.	Decree of the Ministry of Social Affairs and Health (167/2003 in the Finnish Statute Book)
FI.7.	Consumer Safety Act (920/2011, in the Finnish Statute Book)
FI.8.	Upcoming guidelines from the National Supervisory Authority for Welfare and Health
FI.9.	Government Decree on the safety document concerning certain consumer services (1110/2011).
FRANCE	
FR.1.	Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique, article 149
FR.2.	Loi 2014-201 du 24 février 2014 portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la santé - articles L.513-10-2 à L.513-10-10 et L.5437-2 à L.5437-5
FR.3.	Décret 2008-210 du 3 mars 2008 fixant les règles de fabrication, de conditionnement et d'importation des produits de tatouage, instituant un système national de vigilance et modifiant le code de la santé publique (dispositions réglementaires)
FR.4.	Décret 2008-149 du 19 février 2008 fixant les conditions d'hygiène et de salubrité relatives aux pratiques du tatouage avec effraction cutanée et du perçage, et modifiant le code de la santé publique (dispositions réglementaires)
FR.5.	Arrêté du 6 mars 2013 fixant la liste des substances qui ne peuvent pas entrer dans la composition des produits de tatouage
FR.6.	Arrêté du 15 septembre 2010 pris pour l'application de l'article L. 513-10-3 du code de la santé publique relatif aux bonnes pratiques de fabrication des produits de tatouage
FR.7.	Arrêté du 23 juin 2011 pris pour l'application de l'article

	L.513-10-3 du code de la santé publique relatif aux bonnes pratiques de laboratoire des produits de tatouage, aux règles générales relatives aux modalités d'inspection et de vérification des bonnes pratiques de laboratoire ainsi qu'à la délivrance de documents attestant de leur respect
GERMANY	
DE.1.	Tätowiermittel-Verordnung (Order on Tattooing Products, OTP)
DE.2.	Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch [LFGB]
DE.3.	[*Landes*] Verordnung zur Verhütung übertragbarer Krankheiten bei bestimmten gewerblichen Tätigkeiten - Infektionsverhütungs-Verordnung
DE.4.	Anforderungen an Tätowiermittel, Stellungnahme Nr. 013/2013 des BfR vom 28. August 2012
DE.5.	Suggestions for future legislation on tattoo inks.
ITALY	
IT.1.	Circolare 05.02.1998 n.2.9/156 – Linee guida del Ministero della Sanità per l'esecuzione di procedure di tatuaggio e piercing in condizioni di sicurezza
IT.1a.	Circolare del Ministero della Sanità del 16.07.1998 n.2.8/633 – Chiarimenti forniti dal Consiglio Superiore della Sanità
IT.2.	Dlgs 206/2005, Codice del consumo (Decree n 206 of 06.09.2005 "Consumer Code")
IT.3.	Pronunciamento del Consiglio Superiore di Sanità (CSS) del 19 Novembre 2003
IT.4.	Proposals
IT.5.	Legislation at a regional level
IT.6.	Law August 7, 1990, no. 241: New rules for administrative procedure and the right of access to administrative documents (art. 19, as amended by Law 30 July 2010, no. 122 Urgent measures for financial stabilization and economic competitiveness);
IT.7.	Law February 14, 1963 no. 161 Discipline for the business of barber, hairdresser and similar;
IT.8.	Law January 4, 1990 no. 1 Discipline for the business of beautician
LATVIA	
LV.1.	Regulation on the hygiene requirements for the provision of tattooing and piercing services and special requirements for tattoo inks
LUXEMBOURG	
LU.1.	Règlement grand-ducal du 1er décembre 2011
MALTA	
MT.1.	Control of tattoing act (CAP. 270);
MT.2.	Tattoo Studios and Tattooing (Conditions) Regulations, L.N. of 2011

ROMANIA	
RO.1.	Order n° 1136/2007 on the hygiene standards for the cabinets of body beauty, (OJ of Romania n°484/2007);
RO.2.	Annex 2 : HYGIENE STANDARDS for services in piercing and tattoo offices
SLOVAKIA	
SK.1.	Act N° 355/2007 Coll. from 21 June 2007 on Protection, Support and Development of Public Health
SK.2.	Ordinance of Ministry of Health No. 554/2007 Coll. on requirements on facilities of human body care
SK.3.	Ordinance of Ministry of Health No. 585/2008 Coll. on prevention and control of communicable diseases
SLOVENIA	
SI.1.	Rules on minimum sanitary and health requirements for hygiene care and other similar establishments
SPAIN	
ES.1.	Real Decreto 1599/1997 sobre productos cosméticos
ES.2.	Real Decreto 2131/2004 (por el que se modifica el RD 1599/1997) sobre productos cosméticos
ES.3.	Real Decreto 209/2005 (por el que se modifica el RD 1599/1997) sobre productos cosméticos
ES.4.	Consejo Interterritorial del Sistema Nacional de Salud 2003 and regulación of regiones autónomas sobre las condiciones higiénico-sanitarias de los establecimientos de tatuaje y piercing
ES.5.	Real Decreto 944/2010 (por el que se modifica el RD 1599/1997) sobre productos cosméticos
ES.6.	AEMPS (Agencia Española de medicamentos y productos sanitarios). Solicitud de autorización de comercialización para productos de higiene personal (instrucciones y formularios)
SWEDEN	
SE.1.	Regulation on tattoo ink (Government SFS 2012:503)
SE.2.	Ordinance on tattoo ink (Medical Products Agency LVFS 2012:25)
SE.3.	Ordinance (AFS 2005:1) on microbiological work risks, contamination, toxic effects and sensibilisation (Swedish Work Environment Authority)
SE.4.	The Swedish Environmental Code Ds 2000:61
SE.5.	General guidance on professional hygienic activities (from the National Board of Health and Welfare) SOFS 2006:4
SE.6.	Ordinance (1998:899) concerning Environmentally Hazardous Activities and the Protection of Public Health (Government)
SE.7.	Regulation (SFS 1998:901) on the control issued by the activity holder
THE NETHERLANDS	

NL.1.	Warenwet (Commodities Act), article 24
NL.2.	Commodities Act Decree on tattooing and piercing
NL.3.	Ministry Regulation on the use of tattooing/piercing materials (23.05.07, n° VGP/PSL 2770998)
NL.4.	Commodities Act Decree relating to Tattooing Dyes
NL.5.	Tattoo hygiene guidelines
UNITED KINGDOM	
UK.1.	"Tattooing and body piercing guidance toolkit", issued by the Health and Safety Laboratory (HSE) in 2013
EFTA Countries	
LIECHTENSTEIN	
LI.1.	Verordnung vom 6. April 2010 über die Anforderungen beim Anbringen von Tätowierungen, Permanent-Make-up und Piercing (LR 811.011.2)
NORWAY	
NO.1.	Regulation of production, import, sale, etc. of tattoo products and other products for cutaneous injection for cosmetic purposes. Reference: FOR-2008-11-03-1189
NO.2.	Regulation on the obligation of health professionals to notify suspected adverse reactions cosmetics and body care products (including tattoo products). Ref.: FOR-2008-02-27-219
NO.3.	Regulation on hygienic conditions for tattooing & piercing studios, hair dressers, etc.. Reference: FOR-1998-05-06-581
SWITZERLAND	
CH.1.	Ordinance on objects intended to be in contact with the human body (SR 817.023.41)
CH.2.	Guidance on good practices of working and hygiene
CH.3.	Federal law on Food and common items (LDAl ; RS 817.0)
Other jurisdictions	
CANADA	
CA.1.	"Comparison of Guidelines and Regulatory Frameworks for Personal Services Establishments" Author: Karen Rideout (National Collaborating Centre for Environmental Health), July 2010
NEW ZEALAND	
NZ.1.	Tattoo and Permanent Makeup Substances Group Standard 2011
NZ.2.	EPA Guidelines for tattoo and permanent makeup substances
UNITED STATES OF AMERICA	
US.1.	"Body Art: A Comprehensive Guidebook and Model Code".1999, The National Environmental Health Association (NEHA)
US.2.	"Tattooing Regulations in U.S. States, 2011", V. P. Carlson et al., Journal of Environmental Health, 75,

	3, 30-37
US.3.	Haugh I.M. et al., Regulation of Tattoo Ink Production and the Tattoo Business in the US, in Serup J, et al. Eds., Tattooed Skin and Health. Curr Probl Dermatol. Basel, Karger, 2015, vol 48, pp 248–252
US.4.	"Tattoo Inks in the United States" Presentation of L. Katz, from US FDA at the International Symposium for ICPSC and OECD on Tattoo Safety, April 24, 2014

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