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Safety of tattoos and permanent make-up
State of play and trends in tattoo practices

Report on Work Package 2
Administrative Arrangement N. 2014-33617
Analysis conducted on behalf of DG JUST

Paola Piccinini, Laura Contor, Sazan Pakalin, Tim Raemaekers, Chiara Senaldi

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Abstract

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

The report on work package 1 (2015, Piccinini P. et al.) is available at http://bookshop.europa.eu/en/safety-of-tattoos-and-permanent-make-up-compilation-of-information-on-legislative-framework-and-analytical-methods-pbLBNA27394/

The present report is the outcome of the work package 2 which aims to describe the status of tattoo and PMU practices like tattoo prevalence in the population, including the removal processes, details on service providers and ink manufacturers, tattoo and PMU market, inks' chemical composition, RAPEX notifications and national market surveillance.

The information was gathered through questionnaires sent to 32 national authorities (all EU MS and EFTA countries), plus OECD Secretariat, 38 ink manufacturers/distributors/private labels and 23 tattooists/PMU professionals' associations. Replies were collected from 24 EU/EFTA national authorities, 4 non-EU/EFTA countries, 7 ink manufacturers/ distributors/private labels and 10 associations.

In addition, we reviewed thoroughly data available from other sources like scientific literature, RAPEX (Rapid Alert System for dangerous non-food products) notifications and national surveillance reports, as of May 2015.

The main findings show that:

Tattoo and PMU inks are complex chemical mixtures containing several ingredients. The main ingredients are the colorants, pigments in particular; more than 100 of them have been identified in tattoo and PMU inks. These pigments are not produced specifically for such application and a risk assessment taking into account their injection and permanence into the human body is not carried out. An additional identified risk is the presence of impurities; in fact tattoo and PMU inks' purity is on average around 70-90 %. Azo pigments, group to which most of the organic colorants in use belong, are proved to release potentially carcinogenic aromatic amines when exposed to solar, UV or laser irradiation.

It is estimated that around 12 % of the whole European population, all ages comprised, are tattooed (estimation based on available data from 14 Member States) and more than 20 % in the United States. Higher tattoo prevalence was reported in young population, including adolescents. While traditionally men were more tattooed than women, figures show that this trend in Europe, Australia and North America is changing. Nowadays in a number of cases the tattoo prevalence in women is higher than in men, particularly in young generations.

Most of the tattoo inks used in Europe are imported from the United States, while PMU inks are mostly produced in Europe. The European manufacturers are mainly based in the United Kingdom, Germany, Italy and Spain.

With regards to the tattoo artists performing the tattoos, the number of "non-professional tattooists" might represent up to 10 times the number of "registered/professionals" ones.

Around 95 % of the 126 RAPEX alerts notified for tattoo/PMU during the last decade related to chemical risks: hazardous chemicals and/or impurities (such as carcinogenic aromatic amines, polycyclic aromatic hydrocarbons, sensitizers, preservatives and heavy

[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.

metals). The remaining 5% concerned microbiological risks, which are mainly due to the lack of sterility of the inks before opening and from the use of tap water for their dilution. Two thirds of the RAPEX notifications pertain to products imported, with the highest percentages from the United States.

1. Introduction

With the substantial increase in use of tattoos and permanent make up during the last years, concerns have been growing about the potential health problems they might cause, due to the possible presence of hazardous chemicals in their ingredients, or to the lack of strict hygiene conditions during their application.

In 2003, the Directorate General Joint Research Centre (DG JRC) of the European Commission was asked by the DG Health and Consumers (SANCO) to gather and scrutinise all available data needed for considering the need for a coordinated initiative on tattoo/PMU inks at EU level. These recommendations for EU regulatory action on the safety of tattoos, body piercing and related practices in the EU were published in 2003 (Papameletiou D. et al).

The 2003 JRC report presented a prevalence of 5-10 % of tattoo and piercing in the EU general population, with higher rates among the young. It also contained an extensive survey of the chemical composition of products applied for tattooing purposes, identifying some 60 colorants used in tattoo inks, among which many that could release carcinogenic aromatic amines. It further stressed the high microbiological load of the inks. One of the notable conclusions of that report was that the colorants in question were the same as those being used for industrial purposes like paints, printing inks, coatings, plastics coloration, car lacquers, etc. and that purity requirements were needed for tattoo inks.

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. A number of European countries included in their national legislation the recommendations of the CoE ResAPs and prohibited the use of certain substances in tattoos and PMU inks.

Since the 2003 JRC report, an update of the situation was necessary, considering the following changes:

- the increasing prevalence of tattooed population;
- the regulatory measures taken in some EU/EFTA countries following the CoE ResAP recommendations of 2003 and 2008;
- the enlargement of the EU from 15 Member States (MS) in 2003 to 28 in 2014;
- the wider availability of inks via internet.

2. Tattoos and Permanent Make-up Project

In April 2014, DG SANCO established the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (CSN-STPM) as a subgroup of the Consumer Safety Network (CSN), now under the umbrella of DG Justice and Consumers (JUST).

The kick off meeting was hosted by DG SANCO on 23th June 2014 with representatives from 14 EU/EFTA national authorities, involving also other stakeholders such as tattooists' and ink manufacturers' associations, consumers' groups, medical professionals, the Council of Europe, etc. As a follow up, in September 2014, DG SANCO entrusted DG JRC with an 18-month project "Tattoos - Permanent Make-up" aimed at collecting data about the current legislative framework of tattoo practices in Europe and beyond, together with a state of play of the use trends, the ingredients, the EU market and the potential adverse health effects associated to tattoo and PMU inks[2].

The overall objective of the project is to collect all available data on issues related to the safety and hygiene of tattoo and PMU inks and processes, including statistics and health risks arising from chemical, physical, and biological agents potentially present in such products.

This project is divided into 4 Work Packages:

1) **preparatory work**: on regulatory framework and testing methods (2015, Piccinini P. et al.)
2) **state of play**: on current trends in tattoo practices, prevalence, data on inks market and composition of tattoo/PMU inks, RAPEX surveys (present report)
3) **assessment and suggestions for update of the CoE ResAP(2008)1**: including adverse health effects, risk communication, data gaps
4) **conclusions**.

The present report presents the outcome of work package 2 of the Tattoos and PMU project, covering:

1. the compilation of statistical data on tattoo and PMU practices, such as prevalence, number and size of tattoos, removal frequency, etc.;
2. data on tattoo studios and artists;
3. data on ink market, manufacturers, importers and distributors;
4. chemical composition of tattoo and PMU inks with identification of the different ingredients, additives and impurities present, considering also their fate;
5. RAPEX notifications and market surveillance issues.

[2] 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.

3. Methodology

The data contained in the present document have been collected and discussed at the CSN-STPM meeting on 20th April 2015 (Annex I), where experts provided feedback, shared their knowledge and experience, and from the sources listed hereunder:

1. replies from national authorities, tattooists' associations and manufacturers to various questionnaires prepared by DG JRC (Annexes II, III and IV);
2. internet search (statistical data, ink ingredients, ink market share, brands, manufacturers, importers, distributors);
3. RAPEX notifications;
4. national studies and surveys;
5. literature;
6. presentations held during the meeting on 20th April 2015.

The overall information stemming from the various sources has then been processed and aggregated in different tables (Annexes V to VIII) and summarised in chapter 4.

3.1. Questionnaires

Two types of questionnaires were established (see Annex II), either with open questions on statistical data or as a list of ingredients to be filled in.

For each type of questionnaire, three different versions adapted to the recipients have been sent to:

a. 28 EU MS + 4 EFTA countries' authorities, plus other countries (via the OECD Secretariat);

b. 23 tattooist and PMU professional associations (Table 3.1);

c. 38 tattoo and/or PMU ink manufacturers/importers/private labels (Table 3.2).

The **questions to the national authorities** were the following: percentages of tattooed or PMU population, age of first tattoo/PMU, number of tattoos per person, tattoo or PMU per year in the country, % of tattooed population who regrets, tattoo removal per year, registered tattoo studios and artists, non-registered tattoo studios and artists, national tattooist associations, tattoo/PMU ink manufacturers/importers, origin of tattoo/PMU inks imported, volume of sales and purchases of tattoo/PMU inks, market surveillance actions, main problems, list of ink ingredients, register of complains or vigilance system and comments.

The **questions to tattooist associations** were: number of members, registered and non-registered tattoo/PMU studios, registered and non-registered tattoo/PMU artists, suppliers of inks, yearly volume of purchased inks, existence of composition label, list of ink ingredients, single vs multiple ink containers, suppliers of equipment and needles, tattoos/PMU performed per year in the country, customers per year and customers per year below 18 years old, main problems and comments.

The **questions to ink manufacturers** were: origin of ingredients and raw materials, purity certificate for raw materials, volumes of tattoo/PMU ink produced per year, % of products sold on the EU market, composition label, other information on labelling, list of ink ingredients, single vs multiple use containers, average sale price per ml of tattoo/PMU ink, products risk assessment and notification to competent authorities, Good Manufacturing Practices (GMP), contacts with clients after sale, feedback on adverse effects, safety of EU manufactured inks and of inks produced elsewhere, main problems and comments.

Replies on statistical data (Annex III) were received from:

a. 24 EU/EFTA national authorities (AT, BE, BG, CH/LI joint reply, CY, CZ, DE, DK, ES, FI, FR, HU, IC, IT, LU, NL, NO, PL, RO, SE, SI, SK, UK) and from 4 non-EU/EFTA countries (CA, MX, NZ and US);

b. 10 tattooist and/or PMU professional associations (ART, ATEC, BVT, CNA, DTL, NTU, SRT, UETA, UNTAP, VST) from DE, ES, IT, SE plus CH and NO;

c. 7 tattoo/PMU ink manufacturers/importers/private labels: ABC Ink, Biotek, Clinita, Deep Colours, HAN, MT-Derm, and WEFA.

Replies on ink ingredients (Annex IV) were received from:

a. 13 EU/EFTA national authorities (BG, CH/LI, DE, DK, ES, FR, IT, LU, NL, NO, SE, SI) plus two non-EU/EFTA countries (CA and US);

b. 6 tattooist and/or PMU professional associations (ART, BVT, CNA, DTL, NTU, UETA);

c. 7 tattoo/PMU ink manufacturers/importers/private labels: ABC Ink, Biotek, Clinita, Deep Colours, HAN, MT-Derm, and WEFA.

Table 3.1: List of tattooist and/or PMU professional associations consulted.

Country	Tattooist and/or PMU professional associations	Acronym
CH	Verband Schweizerischer Berufstätowierer	VST
DE	Bundesverband Tattoo	BVT
DE	United European Tattoo Artists	UETA
DK	Dansk Tatovør Laug	DTL
ES	Spanish National Union of Professional Tattooists	UNTAP
IT	Associazionetatuatori.it	ART
IT	Confederazione Nazionale Artigianato	CNA
IT	Associazione Tatuaggio Estetico Correttivo	ATEC
NO	Norwegian Tattoo Union	NTU
SE	Sveriges Registrerade Tatuerare	SRT
DE	Deutsche Organisierte Tätowierer e.V.	DOT
DK	Danish Professional Tattooist Association	DPTA
FI	Finnish Tattoo Artist Association	FTAA
FR	Syndicat National des Artistes Tatoueurs	SNAT
FR	Association Tatouage et Partage	ATP
HU	Tetoválók Szakmai és Érdekvédelmi Szervezete	TSZEE
IT	Associazione Piercers e Tatuatori Professionisti Italiani	APTPI
IT	Associazione tatuatori italiani riuniti	ATIR
NL	Belangenbehartiging voor Tatoeëerders en Piercers	BVTP
RO	Uniunea Tatuatorilor Romani	UTR
UK	British tattoo artists' Federation	BTTF
UK	Tattoo Club of Great Britain	TCGB
UK	Tattoo and Piercing Union	TPU
UK	Tattooing and Piercing Industry Union	TPIU

Note: the associations indicated in red did not respond to the questionnaire.

Table 3.2: List of manufacturers/importers/private labels consulted.

company	country
ABC Ink	IT
Biotek srl	IT
Clinita	IT
DC-TP Europe GmbH	DE
H-A-N Haus der Angewandten Naturwissenschaften-Gesellschaft GmbH	DE
MT Derm GmbH	DE
WEFA colors Jo Weinbach	DE
Atomic Tattoo Ink	DE
Bloodline	US
Cheyenne ink	DE
Color Lab	IT
Danny's Tattoo Supplies Ltd	UK
Eternal Ink	US
Euro Permanent Cosmetics S.L	ES
Fusion inks	US
Goldeneye	UK
Guangzhou Baiyun Jingtai Qiaoli Business Firm	CN
Guangzhou Zixuan Tattoo and Permanent Makeup Co. Ltd (Goochie)	CN
I MAX International	IT
Inspiration sp. z o.o.	PL
Intenze Ink	US
Kuro Sumi	US
Laboratoires Biotic Phocea	FR
Laurendor S.L.	ES
LCN / Wilde Cosmetics	DE
LONG-TIME-LINER® Conture® Make-up GmbH	DE
Magic Cosmetic	IL
Micky Sharp Supplies Limited - MICKY SHARP INK	UK
Nuova EUROCOLORI SRL	IT
Polystone-Chemical GmbH	DE
Professional Body Supply	IT
Purebeau New Cosmetics GmbH	DE
Riso Cooperation GmbH	DE
Schwan Stabilo Cosmetics GmbH and CO	US
Starbrite Colors	US
Sunskin Tattoo Equipment SRL	IT
von Berg pharma GmbH	DE
Yakuza Ink	IT

Note: the manufacturers, importers, private labels indicated in red did not respond to the questionnaire.

3.2. Web search

A snapshot on tattoo/PMU market situation in terms of brands, market share, manufacturers, importers and distributors was also based on the outcome of a JRC web-based research.

While tattoo inks are produced in both EU and third countries, most of PMU inks are manufactured in the EU. Ninety brands of tattoo and PMU inks were identified and a brief on-line search allowed retrieving a number of suppliers selling a specific brand. In addition, ingredients used in some of the brands, such as Intenze, Kuro Sumi and Starbrite inks, were found on the internet.

3.3. RAPEX notifications

The Rapid Alert System for non-food dangerous products (RAPEX) was established by Directive 2001/95/EC of the European Parliament and Council on general product safety (GPSD). It allows the rapid communication between EU/EFTA countries and the Commission on actions taken by each Member State whenever a product presents a

serious risk to the health and safety of consumers. Pharmaceuticals, medical devices, food and feed are excluded from the scope of RAPEX.

The European Commission's Directorate General Justice and Consumers publishes every Friday the list of RAPEX notifications on dangerous products representing a serious risk, as reported by the national authorities.

The search on RAPEX database was done with the searching tool of the RAPEX system using the key word "tattoo", years "2005-2015" (until week 15), risk types "chemical" and "microbiological" and the product category "chemical products". 126 entries matched the searching criteria.

The list of these notifications is presented in Annex VIII. The production country, the chemicals and the microbiological agents involved, the geographical production area, the brand name and type of product were indicated to describe in detail all the alerts on tattoo and PMU products. In addition for each alert the following data were mentioned: year, week of the notification, legal basis according to which the product was considered to pose an identified risk, and action taken by national authorities or 'voluntarily' by producers and distributors.

3.4. National studies and surveys

The information was also gathered through market surveillance studies conducted by different national authorities.

Italy performed between 2009 and 2014 a survey on control of hazardous substances in tattoo and PMU inks. Germany conducted various market surveillance activities in 2010, 2013 and 2014.

Slovenia also carried out a couple of surveys from 2009 to 2014. A Swiss study on the presence of harmful chemicals in inks was published in 2014. In addition, in recent years some Member States, such as The Netherlands, Denmark, Sweden and Belgium published different surveillance campaigns on tattooing issues.

New Zealand and Canada conducted surveys in 2013 and 2011, respectively.

3.5. Literature

A literature search was carried out with Scifinder using the following keywords: tattoo population, tattoo prevalence, tattoo presence, tattoo (ink) exposure, tattoo number per year, tattoo age, tattoo ink containers, tattoo ink, tattoo colorants, tattoo ink composition, tattoo pigments, tattoo dyes, tattoo ingredients and tattoo ink market.

The list of consulted literature is presented in Chapter 6.

3.6. Presentations

Material was gathered from presentations made during the meeting of the Consumer Safety Network Sub-Group Tattoos and Permanent Make-Up, held in Ispra on 20.04.2015 (see the full list in Chapter 6).

4. Work Package 2: state of play

4.1. Meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (20th April 2015)

Following the meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (CSN-STPM), held at Ispra in November 2014 addressing the topics of work package 1, DG JRC organised a second meeting of this working group on 20th April 2015 to discuss the issues related to work package 2.

There were 23 participants including delegates from 8 EU Member States, plus Switzerland, and stakeholders, such as dermatologists, representatives from universities, tattoo artists' associations, ink manufacturers, and consumers' associations.

The meeting aimed at:

1. defining tasks and planning the future work within the project;
2. preparing the second report of the project, work package 2 (state of play) including:
    a. collection of facts and statistics on tattoo and PMU practices, and on inks' market;
    b. data on used ingredients and additives and their fate;
    c. RAPEX and market surveillance activities.

DG JRC presented the data gathered through the replies to the questionnaires and other sources of information on statistical data and ink composition. Italy, Germany and Slovenia shared the results of market surveillance activities and two stakeholders presented information on ink ingredients. A discussion followed.

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

4.2. Statistics about tattoo and PMU practices

4.2.1. Introduction

4.2.1.1. Definition and uses

According to the CoE ResAP(2008)1, "Tattooing is a practice whereby a permanent skin marking or design (a "tattoo") is administered by intradermal injection of products consisting of colorants and auxiliary ingredients" and "A permanent make-up (PMU) consists of colorants and auxiliary ingredients which are injected intradermal for the purposes of enhancing the contours of the face".

Permanent make-up is also used to hide pathological skin conditions, finalising the aesthetics of plastic and reconstructive surgeries and masking scars (2015, De Cuyper).

Good results of PMU could show a more natural and realistic effect than conventional make-up. Medical applications are undertaken after breast cancer surgery, to camouflage scars, birth marks, vitiligo and alopecia.

4.2.1.2. Tattoo as an art

Since thousands of years, tattooing has been part of a cultural heritage that aimed at communicating sociocultural and psychosocial concepts including, cultural identity, status and position, medicine, and supernatural protection (2015, Krutak). More recently, tattoos were associated to some population subgroups like bikers, sailors and criminals. Today, this perception has changed and tattoos are considered fashionable and even expressions of art. In some cases performing a tattoo is like purchasing art and many professional and famous tattooists are artists recognised in the tattoo world.

4.2.2. Prevalence of tattoos and PMU

4.2.2.1. General population

Over the last years, with advances in fine art skills within the tattooist community and as a consequence of publicity made by "celebrities" (sport or music idols), tattooing has gained popularity in Western countries (Kluger, 2015) .The increased presence of tattoos in particular in young population can easily and consistently be seen all around the EU, however it is difficult to get an accurate estimation of the percentage of population having tattoos as there is no official registration system whatsoever in the EU.

For Europe, the results presented in this chapter are based on the answers to the questionnaires received from 13 national authorities (Austria, Bulgaria, Cyprus, Germany, Denmark, Finland, France, Hungary, Italy, Luxembourg, The Netherlands, Poland and Sweden) who provided information related to the percentage of general population having tattoos in their country. In addition, data available in the literature and in national reports were also taken into consideration (2015, Conseil Supérieur de la Santé; 2015, Kluger; 2012a, Danish EPA; 2012, BfR; 2010, Fourquet; 2010, Laumann; 2006, Stirn). Luxembourg (60 %), Hungary (50 %) and Cyprus (30 %) reported the highest values, whereas in the rest of the countries the values ranged from 7 to 19 % (Fig. 4.1 and Table 4.1).

The prevalence of general population having at least one tattoo in Europe is estimated at 12.0 %, considering the tattoo prevalence in the countries and the number of people living there [3] (reference Eurostat Demographic Balance available at http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Demographic_balance,_2014_(thousand)_YB15_II.png), as reported in Table 4.2. As the data provided by national authorities and other sources were in very good agreement, this estimate is based on the data reported in the questionnaires for 13 countries, plus the value reported in the literature for the United Kingdom. This percentage (12 %) corresponds to more than 44 million tattooed people in the 14 considered countries that have a global population of about 373 million and to over 60 million people in the EU-28.

The high prevalence reported by Luxembourg, which is based on information provided by the organiser of the national tattoo convention, and Cyprus practically do not have an impact on the estimation of the average prevalence in Europe; in fact this value would be 11.8 % without considering these data. On the contrary, the high value reported by Hungary has a more significant impact on the estimated average tattoo prevalence in Europe, which would be equal to 10.7 % if this country would not be considered in the calculation.

The Bulgarian competent authority informed that the data reported in the questionnaire were obtained from population surveys that included young people, as well as from tattoo studios, beauty salons offering the service permanent make up and inspections, conducted by Regional Health Inspectorates. The French estimate is based on a national survey performed in 2010 on 958 persons aged 18 years-old and more (2010, Fourquet). The Finnish value is an estimation made by a specialist on general population. The Swedish answer is based on data from Swedish stakeholder organisation (Sveriges Registrerade Tatuerare). The Italian competent authority informed that the data reported in the questionnaire were obtained from a national survey performed by the National Health Institute "Istituto Superiore di Sanità", Rome Italy, in 2014-2015 on 7608 persons aged 12-75+ years-old. The Danish data were based on an internet survey with 4327 respondents (age range 15-74 years old) conducted in 2013. In the other cases the national authorities did not specify the data sources.

[3] For the purpose of estimating the tattoo prevalence in Europe, the tattoo prevalence in each considered country has been multiplied by the number of people living there (including everyone, e.g. children), thus obtaining the number of tattooed people in that country. The total number of tattooed people in the 14 countries considered was then used to calculate the tattoo prevalence in the EU-28. This might have led to a slight overestimation of this parameter.

Figure 4.1: Tattoo prevalence among the general population.

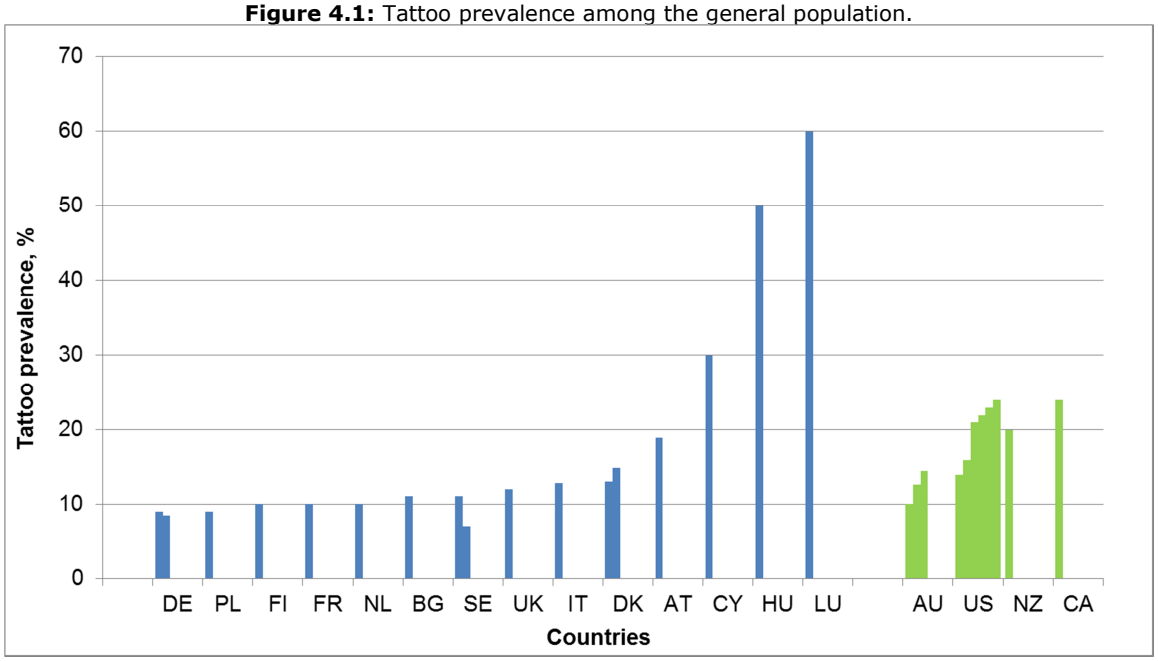


Table 4.1: Tattoo prevalence among the general population.

Country	Tattoo prevalence (%)	Age range (Years)	References	Country	Tattoo prevalence (%)	Age range (Years)	References
AT	19	16-50+	Questionnaire	AU	14.5	16-64	2012, Heywood
BG	10-12		Questionnaire		12.6	16-59	2003, Grulich
CY	30		Questionnaire		10	14+	2001, Makkai
DE	9		Questionnaire; 2015, Conseil Supérieur de la Santé; 2012, BfR	CA	24		Questionnaire (data from 2013)
	8.5	14-93	2006, Stirn; 2010, Laumann	NZ	20		Questionnaire; 2013, New Zealander Ministry of Health
DK	15		Questionnaire				based on 2009, Forte
	13	15-74	2012a, Danish EPA				
FI	10		Questionnaire	US	21		Questionnaire
FR	10	18-65+	Questionnaire; 2010, Fourquet; 2015, Kluger		24	18-50	2015, Conseil Supérieur de la Santé
HU	50		Questionnaire		22	18+	2014, Shanon-Missal
IT	12.8	12-75+	Questionnaire		14		2013, Pew Research Centre
LU	60		Questionnaire		21	18-65+	2012, Braverman
NL	10	12-60+	Questionnaire		23	18-65+	2010, Taylor
PL	9	15-50	Questionnaire		14	18-65+	2008, Corso
SE	11		Questionnaire		24	18-64	2007, Pew Research Centre
	7		2015, Conseil Supérieur de la Santé		24	18-50	2006, Laumann
UK	12		2015, Conseil Supérieur de la Santé		16	18-65+	2003, Sever

In 2003 Papameletiou et al. reported prevalence in Europe comprised between 5 and 10%, which however included tattooed, pierced, as well as tattooed/pierced people, thus representing an overestimation of the tattooed population. Assuming that 20 % of the tattooed/pierced population was only pierced, the estimate of the tattoo prevalence in 2003 would be lowered to the range 4-8%. Despite all the uncertainties and the limited number of data available, the current estimate of the tattoo prevalence in the general population in Europe seems to indicate an increase over time. Such an increase can be considered significant thinking that only 12 years have passed and that the prevalence in the general population is an average calculated on a large age range. Assuming that over the last decade the trend in the young generations was to get more tattooed, this would only slightly modify the general prevalence in one decade. If this trend continues or at least keeps constant, a larger influence on the general prevalence will become evident within the next decades.

According to the replies to the questionnaires, the average of tattooed people in the United States, Canada and New Zealand is higher than in Europe and reaches 21, 24 and

20 %, respectively (Fig. 4.1). These data are in line with the information available in the literature. On the contrary, the situation in Australia seems to be similar to the European one and the most recent publication (2012, Heywood) reports a prevalence on general population of 14.5 % (Fig. 4.1 and Table 4.1).

Only 3 national authorities (Bulgaria, Cyprus and Italy) reported data on the prevalence of PMU in the general population, respectively, less than 8 %, 20 % and 3 %. No data were available for countries outside Europe.

The full set of collected data on tattoo and PMU prevalence are reported in Annex III, Table A and Annex VI, Table A.

Table 4.2: Number of tattooed people in various countries.

Country	Tattoo prevalence (%)	Population 01/2014	Nb of tattooed people
AT	19	8506900	1616311
BG	11	7245700	797027
CY	30	858000	257400
DE	9	80767500	7269075
DK	15	5617300	842595
FI	10	5451300	545130
FR	10	65835600	6583560
HU	50	9877400	4938700
IT	12.8	60782700	7780186
LU	60	549700	329820
NL	10.0	15829300	1582930
PL	9	38017900	3421611
SE	11.0	9644900	1060939
UK	12	64351200	7722144
TOTAL		**373335400**	**44747428**

4.2.2.2. Influence of age and gender

The tattoo prevalence in different age groups in nine European countries (Austria, Germany, Denmark, Finland, France, Iceland, Italy, The Netherland and Norway) was indicated by national authorities in the questionnaires and additional information was found in the literature published in the last decade (for instance 2010, Laumann and 2015, Kluger).

In some cases tattoo prevalence seems to follow a Gaussian curve, such as for French, Italian and Dutch data, whereas in other cases the trend shows a decrease with the increasing age of the population, like for Austrian, German and Danish digits (Fig. 4.2 and Table 4.3). The red horizontal lines represent, if known, the prevalence in the general population.

The data for the various countries were not available in the same age ranges and in the absence of the raw data they could not be aggregated in a different way, this made difficult a comparison. However, in general in each country the prevalence in the young generations is higher than the one in the general population and in certain cases it reaches almost the double or more, such as for example in Germany, Finland, France, Italy and The Netherlands (for people 16-29, 25-29, 25-34, 18-44, 20-49 years old respectively). Data usually show prevalence of 20 % or more in at least one young age group. If this trend will continue, in the next decades we will assist to a significant increase in the prevalence related to the general population.

Figure 4.2: Tattoo prevalence among various age groups in European countries.

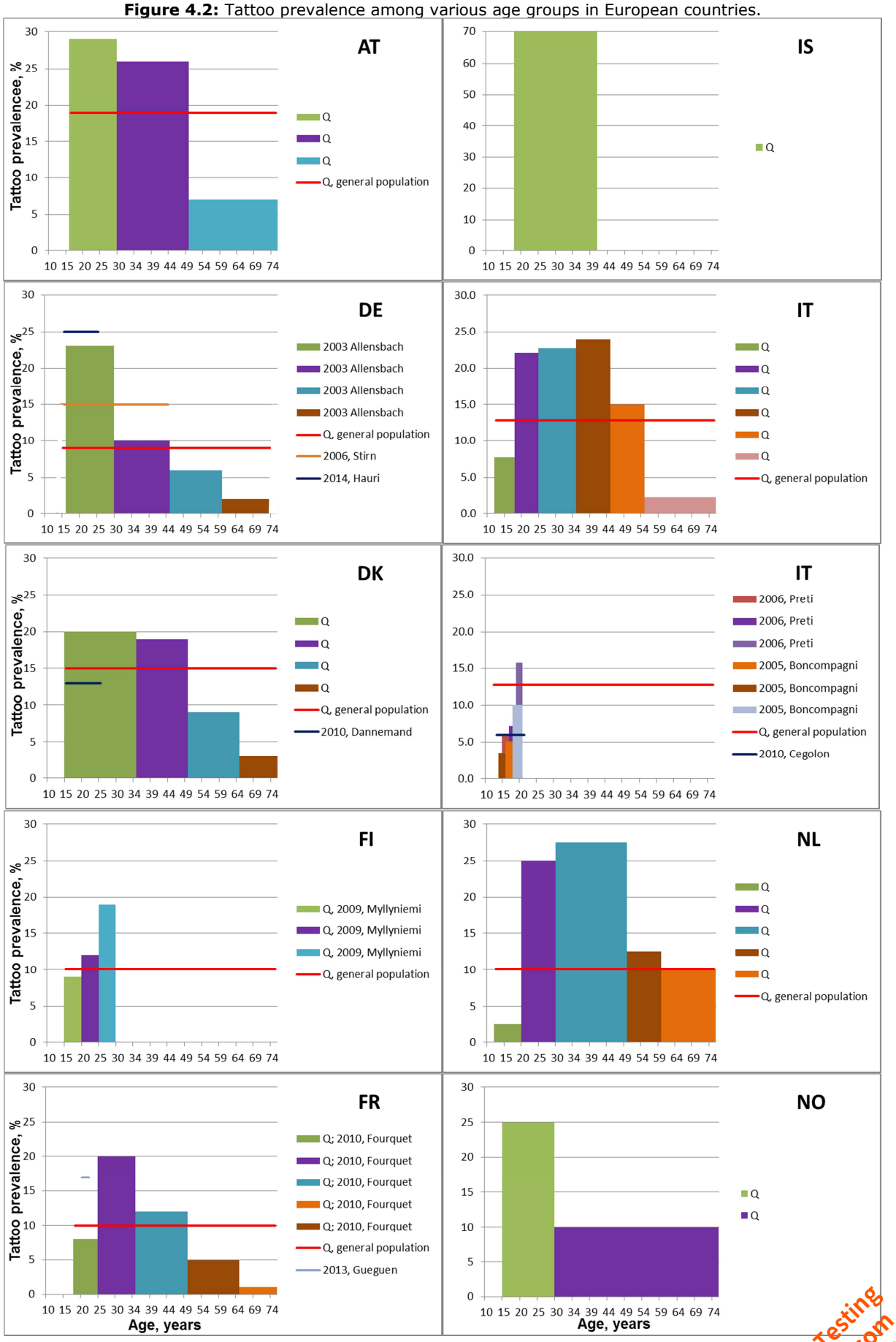


Table 4.3: Tattoo prevalence among various age groups in European countries.

Country	Tattoo prevalence (%)	Age range (Years)	References	Country	Tattoo prevalence (%)	Age range (Years)	References
AT	29	16 – 29	Questionnaires	IT	7.7	12 - 17	Questionnaires
	26	30 – 49			22.1	18 - 24	
	7	50+			22.7	25 - 34	
DE	23	16 - 29	Questionnaires; 2003, Allensbach		23.9	35 - 44	
	10	30-44	2003, Allensbach		15	45 - 54	
	6	45 - 59			2.2	54+	
	2	60+			9.6	[20.1]	2011, Quaranta
	15	14 - 44	2006, Stirn		11.3	[16.1]	2011, Gallè
	25	15 - 25	2014, Hauri		24	[21.6]	
DK	13	15 - 25	2010, Dannemand		6	13 - 21	2010, Cegolon
	20	15 - 34	Questionnaires		6	15 - 16	2006, Preti
	19	35 - 49			7.2	17 - 18	
	9	50 - 64			15.8	19+	
	3	65 - 74			3.5	14 - 16	2005, Boncompagni
FI	9	15 - 19	Questionnaires; 2009, Myllyniemi		5.1	16 - 17	
	12	20 - 24			10	18 - 20	
	19	25 - 29		NL	2-3	12 - 19	Questionnaires
FR	17	20 - 22	2013, Gueguen		20-30	20 - 29	
	8	18 - 24	Questionnaires; 2010, Fourquet		25-30	30 - 39	
	20	25 - 34			25-30	40 - 49	
	12	35 - 49			10-15	50 - 59	
	5	50 - 64			10	60+	
	1	64+		NO	25	<30	Questionnaires
IS	70	18 - 40	Questionnaires		10	>30	

In the literature, data were available on tattoo prevalence in different age groups for Canada and the US. In addition, US authorities provided data via the questionnaire.

The tattoo prevalence shows either a Gaussian shape or a decrease with the increasing age of groups. The situation is similar to the one observed in Europe, the young generations generally show prevalence higher than the one in the general population (reported as horizontal red line), up to almost the double (Fig. 4.3 and Table 4.4). A tattoo prevalence of 38 % in the United States was reported for the age groups 30-39 and 16-29 by Braverman (2012) and Taylor (2010), respectively. In 2007, Pew Research Centre estimated a tattoo prevalence of 40 % in American people aged 26-40.

While traditionally men were more tattooed than women, figures show that this trend is changing. Nowadays this gap is becoming smaller and smaller and in certain cases the tattoo prevalence in women is higher than in men, particularly in young generations. This trend can be observed in Europe, Australia and North America (Table 4.5), as reported by several sources (DK, questionnaire; IT, questionnaire; US, questionnaire; 2013, Guéguen; 2011, Gallè; 2011, Quaranta; 2012, Heywood; 2012, Braverman; 2012, Karagas; 2006a and b, Deschesnes; 2005, Boncompagni; 2002, Mayers). The highest differences in tattoo prevalence among young male and female, with significant predominance of women, were estimated by Guéguen (2013) in France in the group 20-22 years old (24 % F and 11.5 % M) and Karagas (2012) in the United States for people 18-49 years old (29 % F and 18 % M).

Figure 4.3: Tattoo prevalence among various age groups in non-European countries.

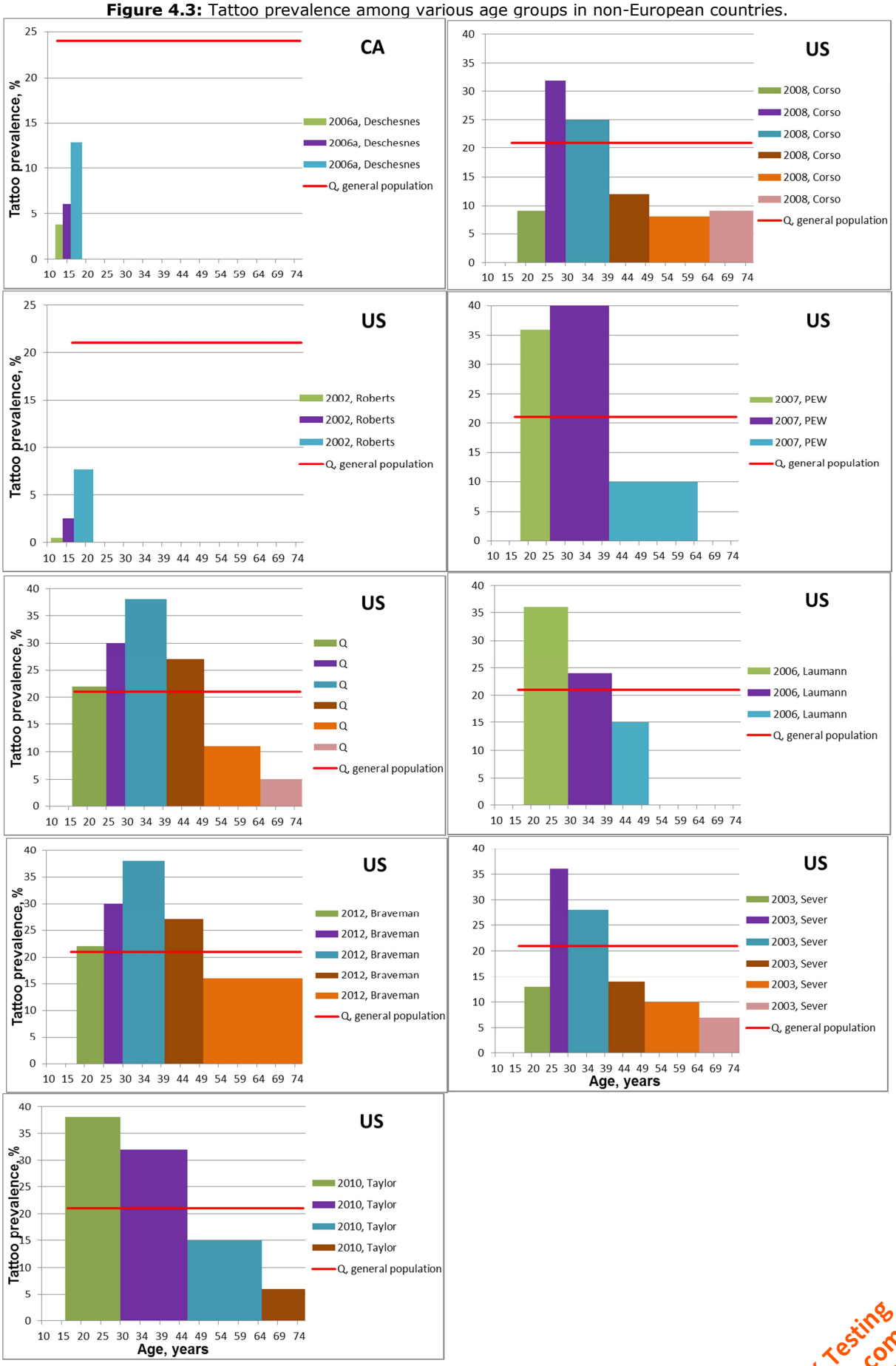


Table 4.4: Tattoo prevalence among various age groups in non-European countries.

Country	Tattoo prevalence (%)	Age range (Years)	References
CA	7.7	12 - 18	2006a, Deschesnes
	3.8	12 - 13	
	6.1	14 - 15	
	12.9	16 - 18	
US	22	16 -24	Questionnaire
	30	25 - 29	
	38	30 - 39	
	27	40 - 49	
	11	50 - 64	
	5	65+	
	22	18 - 24	2012, Braveman
	30	25 - 29	
	38	30 - 39	
	27	40 - 49	
	16	50 - 65+	
	38	16 - 29	2010, Taylor
	32	30 - 45	
	15	46 - 64	
	6	65+	
US	9	18 - 24	2008, Corso
	32	25 - 29	
	25	30 - 39	
	12	40 - 49	
	8	50 - 64	
	9	65+	
	36	18 - 25	2007, PEW
	40	26 - 40	
	10	41 - 64	
	36	18 - 29	2006, Laumann
	24	30 - 40	
	15	41 - 50	
	13	18 - 24	2003, Sever
	36	25 - 29	
	28	30 - 39	
	14	40 - 49	
	10	50 - 64	
	7	65+	
	4.6	11 - 21	2002, Roberts
	0.5	11 - 13	
	2.6	14 - 16	
	7.6	17 - 21	

Table 4.5: Tattoo prevalence according to age and gender.

Country	Tattoo prevalence Male (%)	Tattoo prevalence Female (%)	Age range (Years)	References
In Europe				
DK	14	15	15 – 74	Questionnaires
FR	11	9	18 – 64+	Questionnaires; 2010, Fourquet
	11.5	24	20 - 22	2013, Guéguen
IT	11.7	13.8	12 - 54+	Questionnaires
	9	9.8	20.1	2011, Quaranta
	15.1	20.7	21.6	2011, Gallè
	11.7	10.9	16.1	2011, Gallè
	14.5	5.4	15 - 19+	2006, Preti
	3	6	14 - 20	2005, Boncompagni
	7.2	5.7	12 - 18	2002, Eurispes

Country	Tattoo prevalence Male (%)	Tattoo prevalence Female (%)	Age range (Years)	References
Outside Europe				
AU	15.4	13.6	16 - 64	2012, Heywood
	5..4	6.9	16 - 19	
	22.3	29.4	20 - 29	
	23.2	22.3	30 - 39	
	16.3	9.8	40 - 49	
	8.7	3.3	50+	
	14.5	10.6	16 - 59	2003, Grulich
	11.9	8.5	14+	2001, Makkai
CA	26	22		Questionnaires
	5.8	9.8	12 - 18	2006b, Deschesnes
	5.6	9.8	12 - 18	2006a, Deschesnes
US	19	23		Questionnaires
	18	29	18 - 49	2012, Karagas
	16	7	50 - 69	
	19	23	18 - 65+	2012, Braverman
	15	13	18 - 65+	2008, Corso
	23	21	21	2008, Mayers
	26	22	18 - 50	2006, Laumann
	16	15	18 - 65+	2003, Sever
	4.8	4.2	11 - 21	2002, Roberts
	22	24	16 - 26	2002, Mayers

Figures underlined = average

4.2.2.3. Age of getting the first tattoo/PMU

Among the 17 European countries that replied to the question concerning at which age people usually get their first tattoo, Spain and United Kingdom informed that in their territory a tattoo cannot be legally carried out on clients younger than 18 years old. Some authorities provided the average age of the first tattoo, others age ranges, while for Germany, Denmark and France data were available, in questionnaires or in the literature, including percentages (Table 4.6 and Fig 4.4). It has to be noted that even in countries where legally only people at least 18 years old can be tattooed, e.g. Denmark, adolescents still get tattooed. Information was also available for three jurisdictions outside Europe, Canada, New Zealand and the United States.

Data clearly show that people tend to get the first tattoo done when they are young. Ten European countries reported that the first tattoo is made before 22 years old, among which Iceland and The Netherland referred to an age as low as 16. Poland, Norway, Italy

and Hungary mentioned an age of 25 or lower and Austria reported an age range of 16-30.

From the literature or questionnaires, it is known that adolescents below 18 get tattooed in several countries, such as for example Austria, Denmark, Germany, Finland, Iceland, Italy and The Netherlands. A similar situation also applies to Canada and the United States.

Overall, among the tattooed population in each country, the following percentages get their first tattoo below the age indicated in parenthesis: 94.6 % of Germans (< 36), 86% of Danishes (< 35), 84.8 % of Frenchs (< 30), 60 % of Canadians (< 43), 16 % of Americans (< 18) and 65 % (< 24).

Only little information was collected with regards to the age of getting the first PMU and it seems that, in general, this age is higher than the one for tattoos. Apart from Spain and United Kingdom, in which legally the minimum age is 18, Belgium and The Netherlands indicated 16 years old, Austria, Bulgaria and Cyprus 25 years old and the United States higher than 35.

Figure 4.4: Age of first tattoo in various countries in and outside Europe.

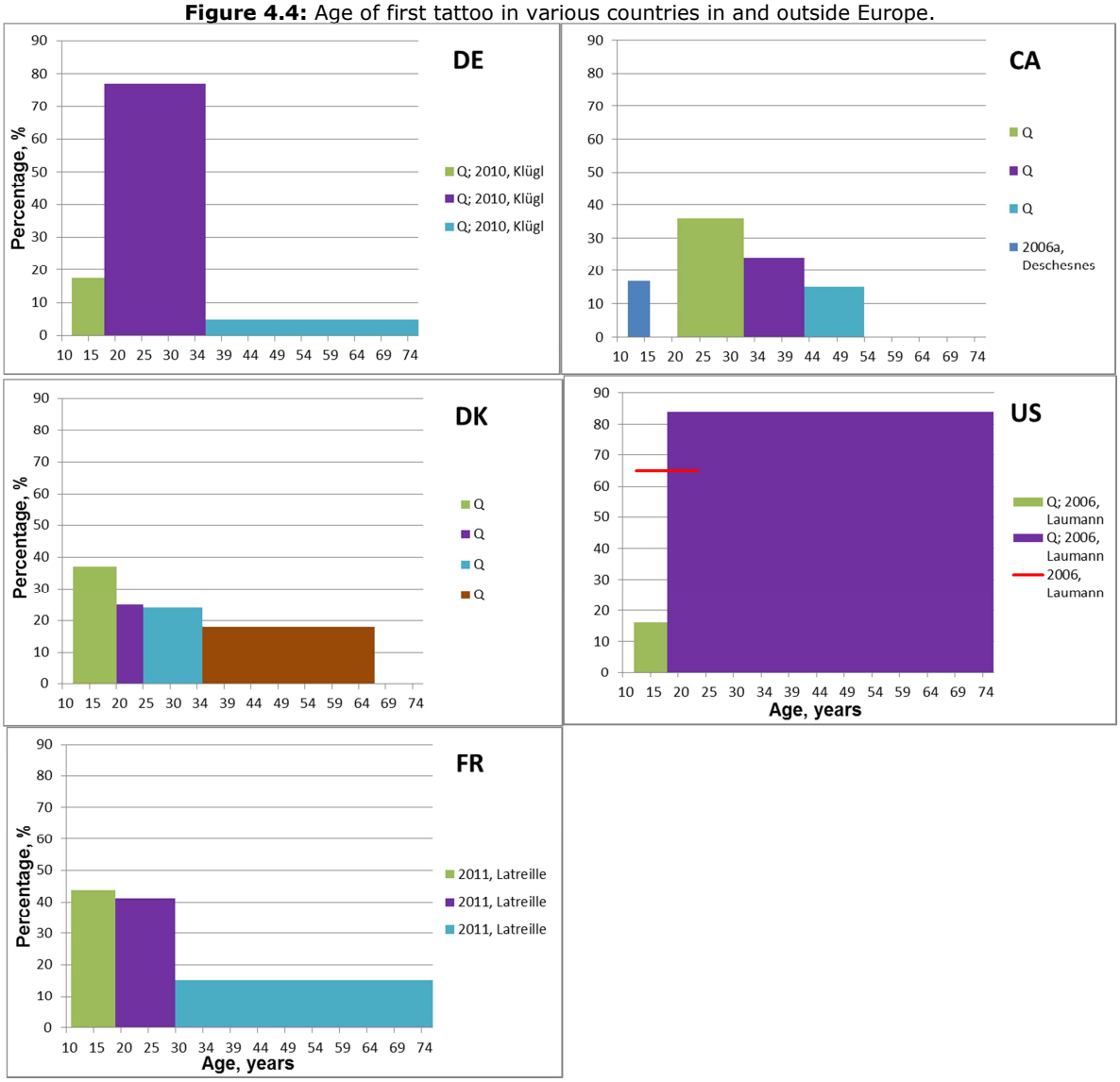


Table 4.6: Age of first tattoo or PMU in various countries in and outside Europe.

Country	Age for 1st tattoo (years)	Age for 1st PMU (years)	References	Country	Age for 1st tattoo (years)	Age or 1st PMU (years)	References
	In Europe				In Europe		
AT	16 – 30	25	Questionnaires	**IT**	25		Questionnaires
BE	>18	>16	Questionnaires	**LU**	18 – 21		Questionnaires
BG	18	25	Questionnaires	**NL**	16	16	Questionnaires
CY	18-20	25	Questionnaires	**NO**	25		Questionnaires
DE	≤18 (17.6%) 18-35 (77%) ≥35 (4.8%)		Questionnaires; 2010, Klügl	**PL**	<25		Questionnaires
				SE	18-22		Questionnaires
				UK	legally min 18	legally min 18	Questionnaires
DK	<20 (37%) 20-24 (25%) 25-34 (24%) 35-66 (18%)		Questionnaires		Outside Europe		
				CA	21-31 (36%) 32-42 (24%) 43-53 (15%) <15 (32.1%) <12 (16.9% M)		Questionnaires 2006a, Deschesnes
ES	legally min 18	legally min 18					
FR	22 11-18 (43.7%) 19-29 (41.1%) ≥30 (15.2)		Questionnaires 2011, Latreille	**NZ**	<30 (33%)		
				US	<18 (16%) >18 (84%)	>35	Questionnaires; 2006, Laumann
HU	18-25		Questionnaires		<24 (65%)		2006, Laumann
IS	16-18		Questionnaires				

4.2.3. Exposure

Engel et al. in 2008 evaluated the concentration of pigment (Pigment Red 22) in the skin directly after tattooing. The experiments were conducted both on pig and human skin and the study proved that pigment concentration found in the skin was between 0.6 and 9.42 mg/cm², with a mean value of 2.53 mg/cm². The values depended on factors, such as who carried out the tattoo (experienced or not experienced tattooist) and the method used (different instrumental set-up). Considering that an average tattoo has an area of around 400 cm² the quantity of pigment soon after tattooing would correspond to approximately 1 g. The same mean value (2.53 mg/cm²) was cited by many other authors, for example BfR (2012) and Danish EPA (2012a and 2014).

Data regarding skin exposure are reported in Annex VI, Table F, while the fate of pigments in the body is described in chapter 4 (4.3.4).

4.2.3.1. Tattoo size, location and gender

The size of a tattoo is described in the literature using different units: percentage of body skin, hand palm and square centimetres. Høgsberg et al. (2013b) considered that 1% of the body surface area is equal to the sum of the palm and fingers' areas. The Danish EPA (2012a) reported that 1 % of the body skin surface corresponds to the area of one palm. Considering an average standard body surface area of 1.81 m^2 (1.69 m^2 for women and 1.94 m^2 for men), the average area of one palm would correspond to 182 cm^2.

On the basis of the available data, the size of a tattoo can be sorted into three categories (Table 4.7):

Small ≤ 30 cm^2

Medium = 30 – 300 cm^2

Large ≥ 300 cm^2

When comparing gender trends, women have a general tendency of having smaller tattoos than men whether in Europe or in the United States. An American survey showed that women have tattoos that are smaller than the palm of the hand (80 %) and that men with this tattoo size only represent 56 % (2006, Laumann). Another example, a German study showed that the prevalence of tattoo sizes smaller than 300 cm² was 48 % with women (compared to 27 % with men), while 73 % men (compared to 52 % women) had tattoos larger than 300 cm² (Klügl et al., 2010). When considering the data in Table 4.7, it has to be highlighted that the study of Latreille (2011) is a survey on laser tattoo removal.

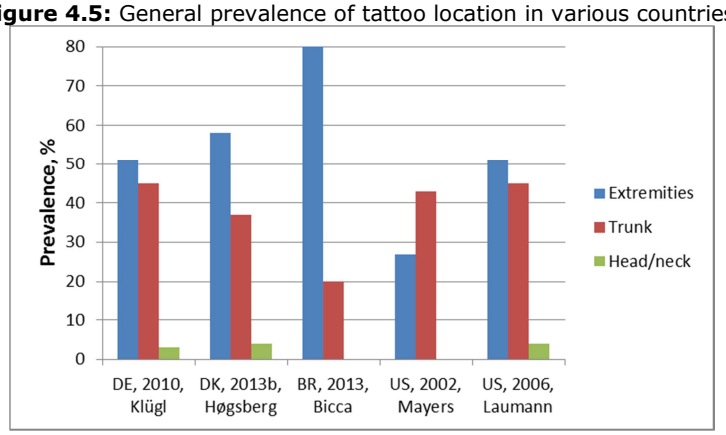
Table 4.7: Tattoo prevalence related to tattoo size.

Country	Size of tattoos (cm^2)	Tattoo prevalence (%)	Tattoo prevalence Male (%)	Tattoo prevalence Female (%)	References
In Europe					
DE	< 300	39	27	48	2010, Klügl
	≥ 300	61	73	52	cited by 2012, BfR
	25	8			
	>900	16			
DK	454 - 1090				2012a, Danish EPA
	≤ 1% body surface area	70	56	88	2013b, Høgsberg
	> 1% body surface area	30	44	12	
	900				2014, Danish EPA
FR	< 30		45	74	2011, Latreille
	≥ 30		54	26	
Outside Europe					
BR	≤ 10 cm	51	51		2013, Bicca
	11 - 20 cm	35	35		
	> 20 cm	14	14		
US	≤ 1 palm	67	56	80	2006, Laumann
	> 1 palm	33	44	20	

Table 4.8: Tattoo location in various countries.

Country	Tattoo localisation	General prevalence (%)	Prevalence Male (%)	Prevalence Female (%)	References
In Europe					
DE	extremities	51	64	41	2010, Klügl
	trunk	45	32	54	
	head/neck	3	2	3	
DK	extremities	58	67	48	2013b, Høgsberg
	trunk	37	29	48	
	head/neck	4	5	4	
FR	arms		75	25	2011, Latreille
	hands		13	3	
	lower back		0	12	
IT	shoulder		54.6	28.7	2005, Boncompagni
	ankles		7.8	27.1	
	arms and wrists		7.8		
	lower back			11.4	
Outside Europe					
BR	extremities	80	80		2013, Bicca
	trunk	20	20		
US	extremities	51	61	35	2006, Laumann
	trunk	45	35	60	
	head/neck	4	4	5	
	extremities	27	35	18	2002, Mayers
	trunk	43	33	53	

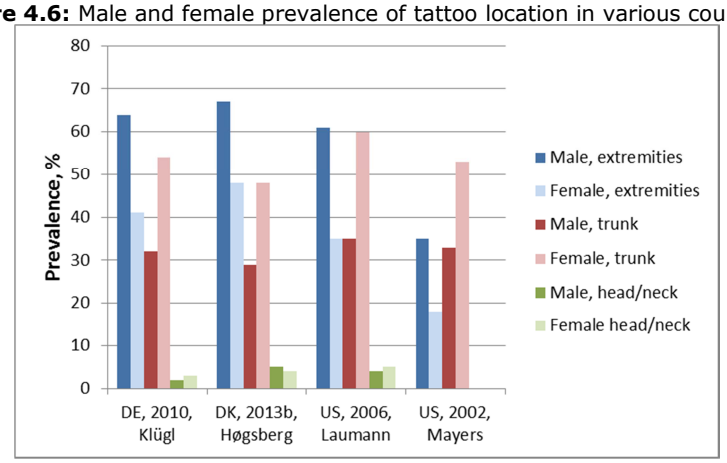
Figure 4.5: General prevalence of tattoo location in various countries.



Considering the prevalence of the tattoo location in the general tattooed population of Germany, Denmark, Brazil and the United States, usually the extremities (arms, hands, wrists, legs, feet and ankles) and the trunk (including also the lower back) are favoured and both together count for more than 70 %, while the head/neck is by far less popular, maximum 5 % (Table 4.8 and Fig. 4.5).

In Germany, Denmark and the United States, more women tend to have tattoos located on the trunk, while more men have tattoos located on the extremities (2010, Klügl; 2013b, Høgsberg; 2006, Laumann; 2002, Mayers). In Italy, shoulders are predominantly preferred by men, ankles come next and are preferred by woman (Table 4.8 and Figure 4.6) (2005, Boncompagni).

Figure 4.6: Male and female prevalence of tattoo location in various countries.



Data regarding size, location and gender are reported in Annex VI, Table D.

4.2.3.2. Tattoo number and gender

According to the replies to the questionnaires, at least 50 % of individuals have more than one tattoo (Fig. 4.7 and Table 4.9) and a similar situation emerges from the data available in the literature (Fig. 4.8). There are only few exceptions, France, Italy, the United States (for people in the age range 46-64) and Brazil (study performed on military recruits 18 years old). The tendency seems to be that, once people have one tattoo, a majority decides to have more than one. Data from the United States suggest that this trend is more pronounced in the young generations.

A comment from New Zealand mentioned that tattoos culturally based 'tell a story', are built up over a number of tattooing sessions and are interlinked. Thus it is not possible to differentiate between individual tattoos. Hungary also reported 'So called collectors' that are having continuously bigger tattoos.

Two papers (2010, Klügl et al.; 2013b, Høgsberg et al.) report the prevalence of one or more tattoos in the general, male and female population in Germany and Denmark. In Germany women show higher prevalence than men up to 3 tattoos; an inverted tendency can be observed for 4 or more tattoos, with a difference becoming more and more important with the increasing number of tattoos. However, in Denmark women prevalence dominate the men one in the case of 2-5 tattoos. In conclusion, no clear trend related to gender can be derived from these data.

Data regarding tattoo number and gender are reported in Annex III, Table D and Annex VI, Table G.

Figure 4.7: Number of tattoos/person (questionnaires).

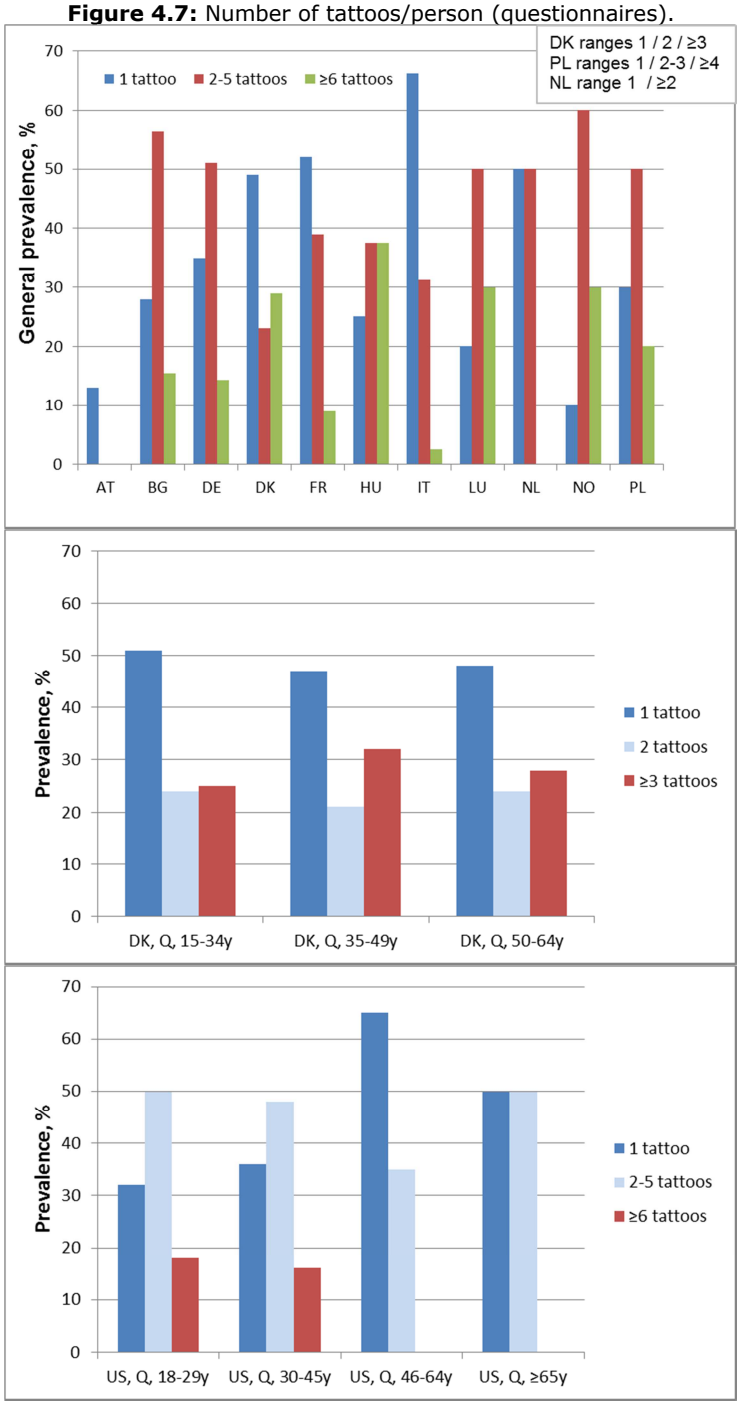
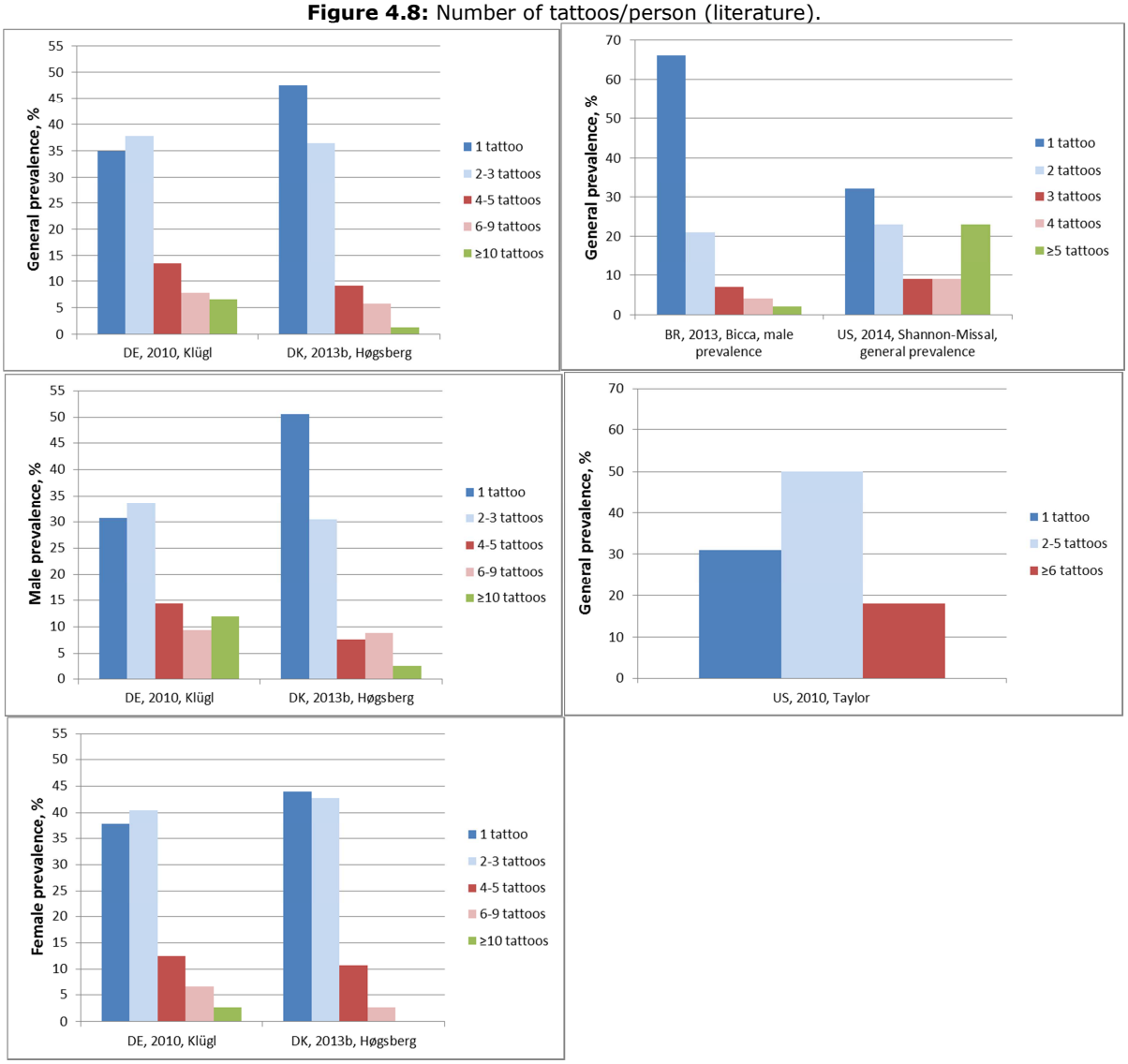


Table 4.9: Number of tattoos/person (questionnaires).

Country	Prevalence 1 tattoo (%)	Prevalence 2-5 tattoos (%)	Prevalence ≥ 6 tattoos (%)	Country	Prevalence 1 tattoo (%)	Prevalence 2-5 tattoos (%)	Prevalence ≥ 6 tattoos (%)
In Europe				Outside Europe			
AT	13	≥ 6		CA	21 (≥1)		
BG	28	56.5	15.5	US	32 (18-29y)	50 (18-29y)	18 (18-29y)
DE	34.9	51	14.3		36 (30-45y)	48 (30-45y)	16 (30-45y)
DK	49 (F 52/M 45)	23 (2) (F 23/M 22)	29 (≥3) (F 25/M 32)		65 (46-64y)	35 (46-64y)	0 (46-64y)
	51 (15-34y)	24 (15-34y)	25 (15-34y)		50 (>65y)	50 (>65y)	0 (>65y)
	47 (35-49y)	21 (35-49y)	32 (35-49y)				
	48 (50-64y)	24 (50-64y)	28 (50-64y)				
FR	52	39	9				
HU	20-30	30-40	30-40				
IT	60.2	31.3	2.5				
LU	20	50					
NL	50	50 (>1)					
NO	10	60	30				
PL	30	30 (2), 20 (3)	20 (≥4)				

Figure 4.8: Number of tattoos/person (literature).



4.2.3.3. Tattoo colours

The information gathered in the literature includes German, Danish and Brazilian data on the colours used (Annex VI, Table E). The results show that typically tattoos are of a single colour, predominantly black. A German study (2010, Klügl et al.) showed that 59 % of tattoos are black (40 % were of mixed colours). Of the most recent tattoo acquired, 50 % were black, 63% was of a single colour, while for example 14 % existed of two colours or were red. After black, red is the most popular colour (14-15 %), followed by blue (10 %), green (9-11 %), yellow (8-10 %) and white (2-7 %) (2010, Klügl et al.; 2013b, Høgsberg et al.). The Danish Competent Authority informed that among the Danish tattooed population, the following colours were most used in the tattoos: black (91 %), red (29 %), green (22 %), blue (21 %) and yellow (17 %).

4.2.4. Tattoo regrets and removals

Reasons for removing tattoos include regrets and a wish to improve self-image. A common technique nowadays used for tattoo removal is based on Q-switched lasers, which by photo selective thermolysis induces the fragmentation of tattoo pigments in the skin. If correctly applied, usually satisfactory results can be obtained. The wavelength should be well absorbed by the target chemicals and the pulse width should be equal or shorter than the target's thermal relaxation time. In order to obtain good results, it is then very important to know the absorption spectra of the pigments that have to be removed. The use of colour mixtures, especially by professional tattooists, poses sometimes a challenge for the selection of the right wavelength. The following Q-switched lasers with specific wavelength are mainly employed for the removal of tattoos containing the colours in parenthesis: Nd:YAG laser (532 nm for red and orange), ruby laser (694 nm for black, blue and green), alexandrite laser (755 nm for black, blue and green) and Nd:YAG laser (1064 nm for black and blue) (2015, Eklund et al.).

According to Bäumler et al. (2000), possible production and release of toxic or carcinogenic compounds following a laser removal needs to be investigated.

In the US and Canada between 14-17 % of the tattooed individuals regret having placed a tattoo and consider removing it (2003, Sever; 2006, Laumann et al.; 2008, Corso; 2012, Braverman,) (Table 4.10). In Europe, this percentage is in line with data reported for Denmark, Belgium, Bulgaria, Italy and Poland, while Germany, France, Hungary and Iceland indicate a percentage lower than 10 % (DE: 2010, Klügl et al.; IT: 2005, Boncompagni et al.). Among tattooed people, only a small part undertakes the process of removal: in Denmark and the Unites States for instance only 5 % and 11 % of removals are reported, respectively.

Interestingly a German study showed that 33 % of individuals that underwent laser tattoo removal were unsatisfied with the result, and in only 38 % of cases there was complete pigment removal (2014, Klein et al.). Scarring was seen in 32 % of the cases, of which 8 % was defined as important. Currently, the long-term safety of laser treatments used for tattoo removal is unclear, particularly due to the laser-induced photodecomposition products of inks.

Data related to tattoo regrets and removals are reported in Annex III, Table B and Annex VI, Table B.

Table 4.10: Amount of procedures, regrets and removals (questionnaires and literature).

Country	Tattoo procedures (number/year)	Tattooed population with regrets (%)	Removal procedures (%)	Reference
		In Europe		
BE	300000-500000	20	10-20	2015, BE CSS; Q.MS
BG	9000	12 10 (PMU)		Q.MS
CH	810000			Q.TAT (VST)
DE		5		Q.MS
DK	600000	18 13.6 (youth)	5	2012a, DK EPA; Q.MS 2013b, Høgsberg
ES	2000000			Q.TAT (UNTAP)
FR			1 (35-49 y)	Q.MS
HU	250000	5-10		Q.MS
IS		5-10		Q.MS
IT	1060000	17.2 4.3 (youth)	4.3	Q.TAT (ATEC); Q.MS 2005, Boncompagni
NO	360750			Q.TAT (NTU)
PL		12		Q.MS
SE	1000/day			Q.MS; Q.TAT (SRT)
		Outside Europe		
CA		17		Q.MS
US		17 17 16 14 4 (youth)	11 96000 in 2013	2013, Harris Poll Global Omn. Q.MS 2008, Corso 2012, Braveman 2002, Mayers

Q.MS = Questionnaire Member States
Q.TAT = Questionnaire Tattooist Associations

4.2.5. Tattoo market

4.2.5.1. Tattoo studios and artists

The size of the market of registered or official tattooist studios is very wide and the number of studios largely depends on the size of the country, from less than 50 in Cyprus, Iceland, Lichtenstein, Luxembourg and Slovenia up to more than 8000 in Germany to 15000 in the United States. The number of nonregistered studios performing tattoos was estimated by national authorities, tattooists' associations or found in the literature and varied between less than 100 (Cyprus and Iceland) up to 5000 (Spain). Considering these figures, the monitoring of all the existing premises is a gigantic task.

According to various sources, both questionnaires for authorities and tattooists' associations and the literature, the estimated number of professional and non-official tattooists in various European countries and in Canada are reported in Table 4.11. In particular the information regarding the number of professional tattooists per 30000 inhabitants comes from Kluger (2015). The presence of this professional activity shows a tendency of being higher in the Nordic countries, such as Sweden (up to 9.4 professional tattooists/30000 habitants), Norway and Denmark, and lower when heading South. In the case of Italy, the estimate of the number of professional and non-official artists were provided by different sources and varied quite a lot; the data communicated by the Italian competent authority are 2500-4000 and 4000-10000, respectively.

Table 4.11: Number of professional and non-registered tattooists/country.

Country	Professional tattooists Number	Number of professional tattooists/ inhabitants	Non registered tattooists Number	Reference
In Europe				
CH	550-900	1/13000	1000	2015, Kluger; Q.TAT (VST)
DE	6000	1/13000	6000-20000	2015, Kluger; Q.TAT (UETA)
DK	500	1/11200	1000-1200	2015, Kluger; Q.TAT (DTL)
ES	3000-3500		2000-5000	Q.TAT (UNTAP)
FR	2000-4000	1/22600		2015, Kluger; Q.MS
IS	8-10	1/30000	16-70	2015, Kluger; Q.MS
IT	1200-10000	1/20000	4000-30000	2015, Kluger; Q.TAT (ART); Q.MS
NO	400-650	1/10000	3000-5000	2015, Kluger; Q.TAT (NTU)
SE	2000-3000	1/3200	3000-20000	2015, Kluger; Q.TAT (SRT)
Outside Europe				
CA	150			Q.MS

Q.MS = Questionnaire Member States
Q.TAT = Questionnaire Tattooist Associations

In Sweden, it is estimated that approximately as much as 15000 start kits (kit containing needles, ink and a collection of suggestions) could be on the home market, based on the number of web shops selling to private persons. There is no estimate as to how many of these kits are used in official tattoo studios.

The number of tattooists per studio indicates that the standard is to have 1 artist per studio and only in some cases 2 or more, indicating that tattooists operate rather more individually than in groups on the same premises.

Data related to tattoo studios and artists are reported in Annex III, Tables E and F and Annex VI, Table H.

4.2.5.2. Tattooist associations

The data represented in this section come from the responses to the questionnaires (Annex III, Table G) and a search on the internet.

The existence of tattooist associations shows that some structure is in place for grouping and coordinating tattoo studios and artists. 52 tattooist and PMU professional associations (Table 4.12 and Figures 4.9 and 4.10) were identified, but the list is probably not exhaustive. According to this data, Germany, Italy and the United Kingdom are the countries gathering a majority of associations (1/2 of all European associations). Canada, New Zealand and the United States form together as many associations as all the European countries together.

In most nations, the number of members within an association represents a minority of the existing tattooists (Table 4.13). Indeed, although countries do have associations relevant for the tattooing world, it seems that they only cover a small percentage (less than 20 %) of the tattooists present in each country. Only little information was gathered related to the number of customers per year. However, it is worth noticing that among the clients, 2, 10 and 10-15% of them were reported to be less than 18 years-old from Swiss, Spanish and Norwegian associations, respectively.

According to the above mentioned associations the place where inks are purchased depends on the country examined and often this is done online. In Switzerland, Norway and Sweden only 1-4 brand names were reported to be used. While in Germany, Spain and Italy, up to 37 different brands were cited. The equipment used is often purchased by the same suppliers as the inks. Regarding volumes of ink purchased, it is estimated to reach between 1-3 litres yearly per tattooist.

Table 4.12: List of tattooist and/or PMU professional associations.

Country	Tattooist and/or PMU professional associations	Acronym
	In Europe	
AT	Association within the Chamber of Commerce	WKO
CH	Swiss Association of Tattoo Artists	VST
DE	German Tattoo Organisation	DOT
	German Federal Association for tattooing	BVT
	Pro Tattoo e.V.	PT
	United European Tattoo Artists	UETA
DK	Dansk Tatovør Laug	DTL
	Danish Professional Tattoo Organisation	DPTA
ES	Spanish National Union of Professional Tattooists	UNTAP
FI	Finnish Tattoo Artist Association	FTAA
FR	Association Tatouage et Partage	ATP
	Syndicat National des Artistes Tatoueurs	SNAT
HU	Association of Hungarian Tattoo Artists	MTSZ
	Professional and Interest Association of Tattoo Artists	TSZEE
IT	Associazione.it	ART
	Italian Association of Professional Piercers and Tattooists	APTPI
	Association of Corrective Aesthetic Tattoos	ATEC
	Association of united tattoo artists	ATIR
	National Artwork Confederation	CNA
NL	Advocacy for Tattoo artists and Piercers	BVTP
NO	Norwegian Tattoo Union	NTU
RO	Roman Tattoo union	UTR
	Asociatia Tattoo & Piercing Romania	ATPR
SE	SRT Swedish Registered Tattoo Artists Association	SRT
UK	Tattoo and Piercing Union	TPU
	Tattoo Club of Great Britain	TCGB
	Tattooing and Piercing Industry Union	TPIU
	British Tattoo Artists Federation	BTAF
	Outside Europe	
CA	Allied Beauty Association	ABA
	Canadian Institute of Public Health Inspectors	CIPHI
	Canadian Network of Make-up Artists	CNMA
	Cosmetology Association of New Brunswick	CANB
	Cosmetology Association of Nova Scotia	CANS
	Cosmetology Industry Association of British Columbia	CIABC
	Cosmetology Industry Association of Ontario	CIAO
	Esthetique SPA International	ESAPI
	International Spa Association	ISA
	Leading Spas of Canada	LSC
NZ	Tattoo Artist Association of New Zealand	TAANZ
US	Alliance of Professional Tattooists	APT
	American Academy of Dermatology	AAD
	American Academy of Micropigmentation	AAM
	Association of Professional Tattoo Artists	APTA
	Conventional and Cosmetic Tattoo Association	CCTA
	Florida Professional Tattoo Artist Guild	FPTAG
	Idaho Tattoo Association	ITA
	National Tattoo Association	NTA
	New York Tattoo Society	NYTS
	Permanent Makeup Society	PMS
	Permanent Makeup Society International	PMSI
	Society of Permanent Cosmetic Professionals	SPCP
	Tattoo Directory	TD

Data collected from questionnaires related to tattooist and/or PMU professional associations are reported in Annex III, Tables F-H.

Figure 4.9: Tattooist and/or PMU professional associations per European country.

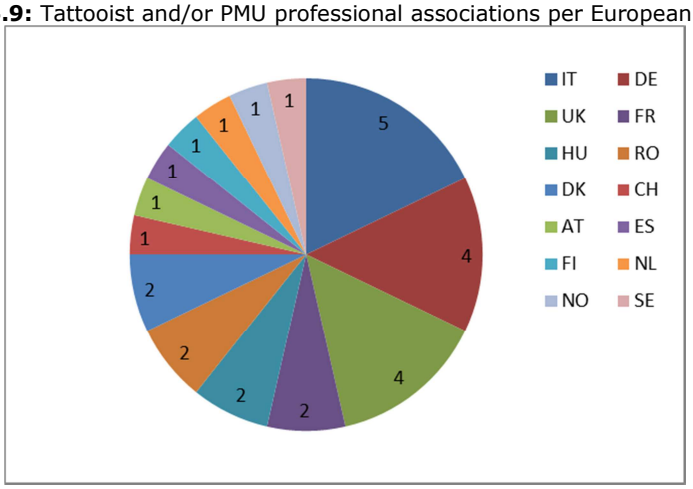


Figure 4.10: Tattooist and/or PMU professional associations in Europe versus CA, NZ and US.

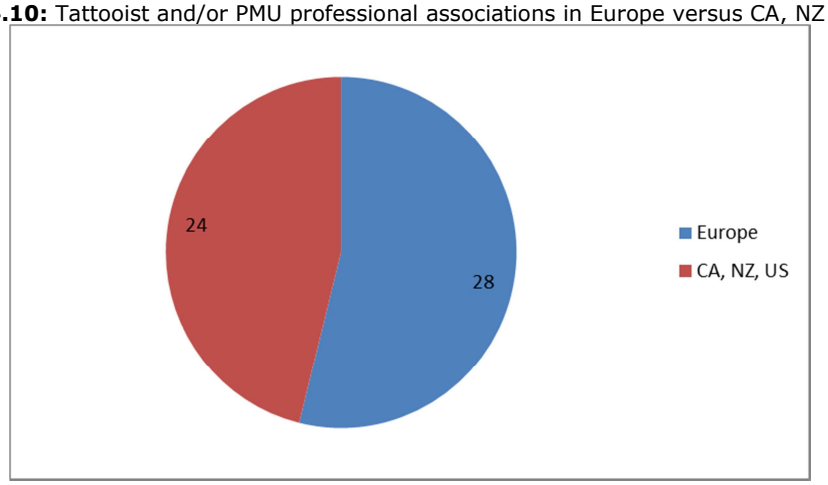


Table 4.13: Number of members according to the tattooist and/or PMU professional associations.

MS	Acronym	Number of members in association	No. professional tattoists/country
CH	VST	34	900
DE	UETA BVT	120 800	8000
ES	UNTAP	480	3000 - 3500
IT	ART ATEC	100 100	10000
NO	NTU	59	600-650
SE	SRT	110	

4.2.5.3. Ink production and imports

Tables I and J in Annex III report the ink importers and the production countries mentioned by the respondents of the questionnaires.

According to the replies, the majority of the tattoo inks imported in the European countries come from the United States, which largely dominates the EU market (Table 4.14), followed by Germany and the United Kingdom, with half of the Member States reporting them as manufacturers of the inks in their markets. Other countries mentioned

to be producers are China, Japan, Brazil, Mexico, Italy, Spain and Poland. Regarding PMU (Table 4.14), Germany is the main country producing PMU inks (5 Member States out of 9 responses).

Table 4.14: Tattoo and PMU ink production countries (in columns), as reported by various countries (in rows).

	Tattoo inks							PMU inks						
Country	**US**	**CN**	**DE**	**UK**	**IT**	**JP**	**Others**	**US**	**CN**	**DE**	**UK**	**IT**	**JP**	**Others**
In Europe								In Europe						
AT	X		X											
BE	X									X				
BG	X		X	X		X				X				ES, IL
DE	X			X	X	X	MX, BR	X						
ES	X	X	X	X	X									
FR	X	X	X	X										
HU	X		X						X					
IS	X						Europe							
IT	X		X	X			ES, BR	X		X				FR
LI			X							X				
LU	X	X												
NL	X	X												Europe, NL
NO	X	X	X	X			ES, BR			X				NL, AT
SI	X					X		X						
SK	X					X	PL		X					
UK	X			X			Asia, Europe							
Total	**15**	**5**	**8**	**7**	**2**	**4**		**3**	**2**	**5**				
Outside Europe								Outside Europe						
CA	X	X	X		X			X	X	X		X		
NZ	X	X												
US	X	X												
Total	**3**	**3**	**1**		**1**			**1**	**1**	**1**		**1**		

This information is in agreement with what reported by Michel (2015), who wrote that 70-80 % of the tattoo inks used in Europe are manufactured outside the EU, with US products mainly being used by professional tattooists and Chinese one by non-professionals. The same author mentioned that 70-80 % of the PMU inks on the EU market are manufactured within Europe, with only few products imported from America and China.

Table 4.15 presents the non-exhaustive list of manufacturers/importers/private labels collected through the questionnaires (Annex III, Tables I and K) and identified with a web based search. The situation is complex and it is not easy to understand who is producing what. In fact, on the one hand, the same manufacturer may produce more than one brand of products and, on the other hand, in the market there are the so called "private labels", meaning that some manufacturers produce for other companies that put their brand name on the final products.

Table 4.15: List of manufacturers/importers/private labels by country.

Country	Tattoos	PMU
	In Europe	
AT		MS Gaube Kosmetik GmbH
BG	Hibiskus Group Ltd Velev Tattoo Ltd Radoev 23 Ltd	Capital - East Ltd Fashion Cosmetics Ltd
DE	Tattoo Goods Tattoo Ink Manufacturers of Europe DC-TP Europe GmbH Diabolo genesis H-A-N GmbH Magic Moon MT.Derm GmbH Schwan Stabilo Cosmetics GmbH Tattoo Tools GmbH Tribal Jewelry GmbH WEFA Colors Jo Weinbach	DC-TP Europe GmbH H-A-N GmbH LONG-TIME-LINER® Conture® Make-up GmbH MaBea Stammhaus MT.Derm GmbH Polystone-Chemical GmbH Purebeau New Cosmetics GmbH Riso Cooperation GmbH von Berg pharma GmbH
ES	AM Tattoo and Piercing Supplies Alkimia Technology and Stetic American Cosmetics- Lola Samy Electric Ink NTS Europe Euro Permanent Cosmetics Goldeneye S.L. Madrid Laurendor S.L. Micropigmentación Corporación Española Starlight- Estetica Especializada Tevian	AM Tattoo and Piercing Supplies Alkimia Technology and Stetic American Cosmetics- Lola Samy Electric Ink NTS Europe Euro Permanent Cosmetics Goldeneye S.L. Madrid Laurendor S.L. Micropigmentación Corporación Española Starlight- Estetica Especializada Tevian
FR	French Touch Colors	Laboratoires Biotic Phocea
HU	Radical shop	
IL	Sebi Tattoo Supplies Magic Cosmetic	Magic Cosmetic
IT	ABC INK Atomic Ink Biokolor Italia Srl Color Lab Colour Waves Supply I Max International Incredibile Tattoo Supply Ink Karma Tattoo Intenzit SRL Nuova EUROCOLORI Panthera ink Professional Body Supply RCS Company Skin energy Sunskin Tattoo Equipment Sunskin Tattoo Equipment Srl Yakuza Ink	Biotek Clinita RCS Company Srl
LU	ITC Tattoo et Piercing Magic Moon Tattooing	
NL	B.S. Trading BV Baloe Coldskin La Coresse Tattworks TS Trading BV	Ecuri Cosmetics B.V. Nouveau Contour
PL		Inspiration sp. z o.o.
SK	Tattoo Supply Slovakia Euro tattoo supply professional	
UK	Danny's Tattoo Supplies Ltd Dr Sailor Company - Sailor Ink Easyflow Superior Fusion Ink, Inc. Micky Sharp Supplies Limited - Micky Sharp Ink Star Brite Color	Goldeneye

Outside Europe		
BR	Electric Ink	
CA	Badger Air Brush co. Cam's Tattoo Supply Demco Evanesco Cream Papillon Supply & Mfg. Stencil Stuff Products	
CN	E-M Medical Treatment And Electron (Suzhou) Co. Guangzhou Baiyun Jingtai Qiaoli Business Firm Guangzhou Zixuan Tattoo & PMU Co., Ltd Shenzhen Elijah Technology Co., Ltd	E-M Medical Treatment And Electron (Suzhou) Co. Guangzhou Baiyun Jingtai Qiaoli Business Firm Guangzhou Zixuan Tattoo & PMU Co., Ltd Shenzhen Elijah Technology Co., Ltd
US	Alla Prima Bloodline Dynamic Color Co. Electric Ink USA Eternal Ink, Inc. Fantasia Art Supply Formula 51 Supply Fusion Ink, Inc. Intenze Products Kuro Sumi Millennium Colors, Inc. Radiant Colors Silverback Ink Silverback Ink Corp. Skin Candy Tattoo Supply SOF TAP Cosmetics Solid Ink-Ferroni Starbrite Colors Tattoo Goo Tommy's Supply	

A non-exhaustive list of tattoo and PMU ink brand names gathered thanks to a web based search is reported in Table 4.16. In total seventy two tattoo ink brands were identified, while for PMU inks the number of brands found was twenty two. As shown in Table 4.17, some brands can be purchased on many web sites, whereas others are seldom offered. A ranking of the most 'popular' brand names (Table 4.18) according to their presence 'on-line' shows a similar trend as the ranking of a well-known specialised web site (http://info.painfulpleasures.com). The number of suppliers ranges from 3 – 28 for the 20 most popular inks and the top 10 inks are sold by at least 10 suppliers.

In contrast, PMU ink brands are much less widespread and only five brands were found to be sold by one or two suppliers (Table 4.19).

Table 4.16: Brand names of tattoo/PMU inks and the number of their web suppliers.

Brand	Tattoo Ink	PMU Ink	Web Supplier	Brand	Tattoo Ink	PMU Ink	Web Suppliers
Alla Prima Ink	X		8	Kabuki Tattoo Ink	X		1
Amiea		X		Kashoku	X		1
Arcane Tattoo Ink	X		2	Killer Black	X		
Atomic Ink	X		6	Kokkai Sumi Tattoo Ink	X		2
Azayaka Colours	X		2	Kuro Sumi Tattoo Ink	X		16
Bella Pigment		X	1	Laurendor		X	
Biotek		X		LONG-TIME-LINER® Conture® Make-up		X	
Biotic		X		Lushcolor	X	X	
Black Budda	X		1	MaBea		X	
Black Mamba	X		2	Makkuro Sumi Tattoo Ink	X		5
Black Scorpion	X			Maube		X	1
Bloodline & Skin Candy Tattoo Ink	X		7	Micky Sharpz	X		1
Bullets	X		2	Mom's Ink	X		10
Cheyenne Colors	X		12	M'S Tattoo Color	X		
Classic Ink	X			Nocturnal Tattoo Ink	X		1
Cosmetic Partner		X	2	Nouveau Contour		X	
Dermagalo	X		1	One	X		2
Diabolo Genesis Plus	X			Painful Pleasures	X		
Dragonhawk	X		1	Panthera Ink	X		19
Dynamic Tattoo Ink	X		12	Pelikan Drawing Ink	X		
Easyflow Superior	X			Petrify Ink	X		
Ecuri		X		Platinum Ink 2	X		1
Electra-Pro Ink	X		1	Polinesian Ink	X		3
Electric Ink	X		3	Precision	X		
Eternal Ink	X		28	Pure Colours		X	2
Euro Permanent		X		Purebeau		X	
Evil Ink	X		1	Quantum Tattoo Pigments	X		1
Fantasia Tattoo Ink	X		2	Radiant Colors Tattoo Ink	X		2
Formula 51 Tattoo Ink	X		2	Ri-soft lining		X	
France Jet Black Ink	X		1	Rocket Fuel	X		2
Fusion Ink	X		10	Ron Meyers	X		1
Futura Ink	X		4	Sacred Color Tattoo Ink	X		7
Gaube		X		Saylor Jerry	X		
Glam Colours		X	1	Scream	X		2
Gold	X			Scream 2 Tattoo Ink	X		
Golden Rose	X	X		Silverback Ink	X		13
Goldeneye		X		Solid Ink	X		2
Goochie	X	X		StarBrite Color Ink	X		14
Hautcutuer	X	X		Starlight	X		
Immortal2 Tattoo Ink	X		2	Sunskin Tattoo Ink	X		2
Imperial Ink	X			Talens Ink	X		6
Infinity Pro	X		1	Tattoo Goo	X		
Intenze Tattoo Ink	X		22	Viking Ink	X		1
Iron Butterfly	X		2	WEFA colors	X		
Joker Tattoo Ink	X		1	World Famous Tattoo Ink	X		1

Table 4.17: Tattoo ink web suppliers.

Web-Suppliers	Number of brands sold	Web-Suppliers	Number of brands sold
ebay.com	almost all	onlinetattoowholesale.com	6
paintfulpleasures.com	18	tattoo-supplies.com	6
killerinktattoo.it	17	bmdtattoosupply.it	5
thetattooshop.co.uk	17	skincandy.net	5
worldwidetattoo.com	15	tattooshop.sk	5
protatsupplies.com.au	14	skinenergy.it	4
tattoosupplies.eu	14	colourwavesupply.com	3
camtattoo.net	13	gekotattoo.com	3
sebitattoosupplies.hu	11	tattoowarehouse.co.nz	3
needlesupply.com	10	underworldtattoosupplies.com.au	3
radicalshop.hu	10	lauropaolini.net	2
imaxshop.com	9	passiontattoosupply.com	2
tattoo-supply.cz	9	sunskintattoo.com	2
barberdts.co.uk	8	eternaltattooink.eu	1
jokertattoo.net	7	eternaltattoosupply.com	1
monstersteel.com	7	intenzeproducts.eu	1
toppiercing.sk	7	karmatattoosupply.com	1
calaveratattoosupply.com	6	maxsignorello.it	1
italiantattoosupply.com	6	tattoolatina.com	1
magic-moon-shop.com	6		

Table 4.18: Top tattoo ink brands sold on-line (ordered by presence on web-sites).

Brand name	Suppliers Nr	Price €/ml	Capacity ml
Eternal Inks	28	0.35	30, 60, 120
Intenze Tattoo Inks	22	0.35	30, 60, 90
Panthera Tattoo Inks	19	0.20	150
Kuro Sumi Tattoo Inks	16	0.15	180
Starbrite Colors Inks	14	0.35	15, 30, 60, 90
Silverback Inks	13	0.30	120
Cheyenne Inks	12	0.35	50
Dynamic Tattoo Inks	12	0.15	240
Fusion Inks	10	0.35	60
Mom's Inks	10	0.15	15, 30
Alla Prima Inks	8	0.35	30
Sacred Color Tattoo Inks	7	0.60	15, 30
Bloodline & Skin Candy Tattoo Inks	7	0.35	30, 60
Atomic Inks	6	0.65	30
Talens Inks	6	0.10	490
Makkuro Sumi Inks	5	0.15	120, 360
Fusion Inks	4	0.70	15, 30
Electric Inks	3	0.30	30, 60
Polynesian Inks	3	0.10	200

In red top brands mentioned in http://info.painfulpleasures.com

Table 4.19: Top PMU ink brands sold on-line (ordered by presence on web-sites).

Brand name	Suppliers Nr	Price €/ml	Capacity ml
Cosmetic Partner	2	3.8	15
Pure Colours	2	3.2	15
Bella Pigment	1	2.5	15
Glam Colours	1	4.3	2, 15
Maube	1	2.6	15

Few producers replied to the question: "what is the yearly total volume of tattoo/PMU inks produced by your company?", only 4 and 6 manufacturers of tattoo and PMU inks, respectively. In the case of tattoo inks, this parameter varies between 2 and 10 m^3/year, with an average price ranging from 0.1 to 0.5 €/ml; whereas for PMU inks, the annual production for each manufacturer amounts to 0.05 - 1.15 m^3/year with a reported price range of 0.45-5.9 €/ml (Annex III, Table L). PMU inks show on average a much higher price than tattoo inks and a bigger price variation among various producers. The respondents declared that they sell at least 90 % and 60 % of tattoo and PMU inks in Europe.

Manufacturers did mention that they are in contact with their clients after sale and do receive feed-back from them. One manufacturer highlighted a strong relation to teach and train customers in using its colours. For one company whose clients put their name/brand on the label, there is a continuous feedback for business development to ensure client and final user satisfaction and product evolution. Collection of client feed-back through Facebook was also cited. It was also mentioned that some clients report if they are satisfied or if they experienced problems, such as allergic reaction or infections, lack of brightness or not enough darkness for colours. Other communication between manufacturers and clients covers topics such as general support, adjustment of recipes, troubleshooting services, recommendations for clients with allergic background (Annex III, Table P).

4.2.5.4. Quality measures

Manufacturers were asked to describe the measures they undertook to ensure the quality of their products (Annex III, Table M). Most of them request a purity certificate

and/or undertake a risk assessment of manufactured products and ingredients before putting them on the market. The goal is to detect impurities/unwanted contaminants and check if the limits of each raw material are well below the recommendations reported in the CoE ResAP(2008)1. One producer mentioned the use of tissue tests like cytotoxicity and UV-toxicity or physico-chemical-testing for detecting contaminants like PAH, AA and heavy metals for the pigments. Another producer reported the elaboration of a Product Information File (similar to the one for cosmetic products). All manufacturers responded using Good Manufacturers Practices (GMP) for the production of their products but only some of them have a notification system to the country Competent Authorities.

In general, the European producers who responded to the questionnaires were of the opinion that tattoo/PMU inks manufactured in Europe are safer than those coming from abroad. Rationale included: the existence of the CoE ResAP(2008)1 that forced manufacturer to change the formulation of their products (e.g. replacement of pigment yellow 74), controls in Europe are considered stricter than elsewhere, better education of personnel and the lack of safety guidelines for tattoo/PMU inks in the United States.

4.2.5.5. Labelling

All respondent producers have a common set of items that appear on the label of their products (Annex III, Table N):

- List of ingredients (INCI, CI and IUPAC numbers in decreasing order of concentration)
- Manufacturer name and address
- Date of minimum durability
- Conditions of use and warnings
- Batch number
- Guarantee of sterility of the contents

Other information is sometimes added:

- Type of product: tattoo colour / permanent make-up ink
- Basic ingredients (distilled water, thickener, preservative, alcohol)
- Date of production
- Method of packing and sterilization
- Conditions of storage
- Durability after opening (e.g. use after opening within x days)
- Address of distributor/ origin of the product
- Warnings such as 'Product or ingredients can cause allergic reactions'.

4.2.5.6. Ink containers

When asked for the type of container used for tattoo inks' packaging, the response from the tattooists associations did not totally match the one from the manufacturers (Annex III, Table O). While the associations reported mainly single use containers (6/9 answers), the majority of the manufacturers cited multiple use containers.

The reasons mentioned for the use of multiple use packaging included the following:

- single use containers do not respect the way tattoo artists work in general and the market does not accept it;
- no single use containers sold, single use containers are considered unsuitable for tattoo inks;
- although the first choice would be single use, 10-30-50-150 ml bottles are requested by the customers.

Looking at the data found on web-sites, the volume of the ink bottles sold range from 15 to 490 ml (Tables 4.18 and 4.19). According to Jacobsen (2012) and the Danish EPA (2014), 1 ml of tattoo ink covers about 121 cm^2 of skin, considering an average tattooed

area of around 454 cm^2, a bit less than 4 ml of ink per tattoo would be needed, plus the losses and excess used for the process. This data would lead to conclude that the multi dose containers are the norm.

Manufacturers producing only PMU inks report single use containers, but they do point out that it is not a good solution for half of the cosmeticians that normally mix their inks for working. As shown in Table 4.19, the volume of PMU ink bottles is usually 15 ml.

4.2.6 Additional comments provided by the respondents to the questionnaires

The results presented in this section originate from the replies to the open question concerning additional comments or information respondents wanted to provide. The responses were provided by national authorities, tattooist and PMU professional associations and manufacturers and were classified in three categories:

1. General issues;
2. Regulatory issues;
3. Market surveillance.

4.2.6.1. General issues

Data are reported in Annex III, Table Q.

Safety improvements needed

A total of 5 respondents reported the need of:

- a system for the registration of side effects;
- a compulsory safety assessment;
- guidelines for risk assessment;
- GMP for tattoo/PMU inks (a draft version prepared by TIME exists);
- stopping "home tattooists" and sales of "start-kit";
- mandatory hygiene and ink-control training;
- public web-site with list of authorised studios.

Improve trade

Nine respondents pointed out the following problems:

- uncertain situations with pigment suppliers;
- suppliers do not follow existing legislation;
- exact quantitative labelling difficult to find from market operators;
- fake CE marking, counterfeit products on the EU market;
- obligations of chemical legislation not well known by market operators;
- compliance with legislation and CoE ResAP recommendations avoids problems but leads to higher prices for the final products than the ones of competitors (mainly from outside EU);
- need for more control on web sales (as inks are mainly bought online, illegal inks are sold – surveillance difficult);
- lack of training and knowledge of proper health and hygiene practices;
- need for correction of work done with no knowledge of the installations, colour changes and migration of pigments (PMU)
- questionable information (e.g. false indication of sterility of needles).

Need for clear composition labelling

The report of respondents includes the hereunder problems:

- unlabelled containers with mixed or diluted inks;
- labels poorly glued;
- incomplete labelling of colours, list of ingredients;
- manufacturer's list of ingredients inconsistent with importer's one;
- confusion with cosmetic products on labelling;
- sterility of inks is not controlled;
- life date after opening is not always provided;
- no indication of durability, of use and of warnings;
- undefined substances are mentioned;
- lack of best before and batch number;
- unauthorized pigments, Ni and Cu present and not mentioned on the labels;
- mandatory information incomplete or absent;
- lack of manufacturer information;
- lack of composition certificates.

Analytical methods

Among the problems related to analytical methods, Germany mentioned the lack of a quantitative method for the soluble fraction of barium and The Netherlands considered as a high priority the need for harmonisation of test methods (e.g. for PAA and PAH). Manufacturers highlighted the lack standard methods for tests (e.g. quantification of soluble copper, heavy metals).

Inks

Regarding inks, a Spanish tattooist association mentioned the poor quality of tattoo ink authorised in Spain, stating that better quality in terms of colour properties like brightness and durability is found among the non-authorised ones; while a Swedish association reported poor quality of inks, especially from China, in terms of impurities. A couple of manufacturers pointed out that despite microbiological and chemical problems, tattooists continue using multi dose containers. The use of expired tattoo inks was also spotted.

4.2.6.2. Regulatory issues

Data are reported in Annex III, Tables R and S.

Non-compliance

Belgium reported that the CoE ResAP recommendations are not always fulfilled. A number of countries (Germany, Italy, Liechtenstein, Spain, Switzerland and The Netherlands) and tattooist association mentioned the presence of banned pigments, preservatives, heavy metals, PAA, PAH, microbiological contamination, incorrect or missing composition labelling (e.g. lack of compulsory warnings for Ni, batch number, sterility indication, identification of responsible person). Finland highlighted that "backyard tattoo shops" are out of authorities' surveillance and that obligations stipulated in health protection and consumer safety legislation are not well known by tattoo service providers in general. Finally, Spain reported the presence of tattoo inks not authorised by AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) on the Spanish market.

Overseas, the United States stated that the pigments listed on the material safety data sheet do not reflect the actual composition of inks.

Regulation required

In the opinion of the respondents, there is a need for:

- an EU harmonised legislation;
- a positive list of colorants;
- a single negative or positive list, instead of referencing various lists in different legislations;
- CEN hygiene standards;
- a system to report undesirable health effects;
- training and regulation of the profession;
- guidance values for technically unavoidable amounts of impurities;
- prevention of illegal studios and artists.

Problems were experienced due to:

- different laws and requirements in MS;
- poor collaboration between manufacturers and national authorities;
- lack of sterility

Register of complaints/vigilance system

Only five European countries (Spain, France, The Netherlands, Norway and Romania), out of the 24 who responded, have a register of complaints or vigilance system on tattoo issues. For example, in The Netherlands an online website where consumers can register complaints after using cosmetic products is available.

Regarding overseas systems, the American authority mentioned MedWatch (for adverse events) and US Federal and Drug Administration (for consumer complaints). Canada reported the Consumer Product Safety Program that tracks trends in complaints and incidents with cosmetics. Both consumers and industry may submit incident reports on a voluntary basis.

4.2.6.3. Market surveillance

Data are reported in Annex III, Table T.

Out of 24 countries, only 6 report not having performed any market surveillance. Various entities depending on the country undertake market surveillance on tattoo products: Health Council or Protection Department, Regional Health Inspectorates, Health and Safety Laboratory, Chemicals Agency, Medical Products Agency, Food and Drug Administration, Luxembourg Institute of standardization, accreditation, security and quality of products and services (ILNAS) or Trade Inspection.

A detailed description of the analytical results obtained during market surveillance activities is included in the sub-chapter 4.4.

4.3. Ingredients of tattoo and PMU inks and their fate

The aim of this part of the work was to gather an overview of the ingredients currently used in tattoo and PMU ink formulations, considered as a first step towards the evaluation of possible problems linked to toxicity, adverse health effects, infections and allergies to be taken into consideration in the next phase of this project (Work Package 3).

To this end, several sources were taken into consideration:

1. knowledge of experts in European countries and some other jurisdictions, tattooists' and PMU professionals' associations and manufacturers,/distributors/private labels, collected through a questionnaire prepared by DG JRC (Annex II, Table B);
2. composition declarations available on internet for some tattoo products;
3. literature search to derive the state-of-the-art of the available knowledge about the fate of ink ingredients, in particular pigments, in the body and/or under light irradiation.

Stakeholders were requested to indicate ingredients found in the composition of tattoo and PMU inks, with quantitative information where available. They were also asked to add additional pigments and/or additives if they were aware of them.

The questionnaires for ingredients were sent to the 28 Member States, plus the four EFTA countries, through the Consumer Safety Network under the responsibility of the Directorate General Justice and Consumers, and to two other countries (via the OECD Secretariat). Thirteen replies were received from European countries (Bulgaria, Denmark, France, Germany, Italy, Luxembourg, the Netherlands, Spain, Slovenia, Sweden, Liechtenstein, Norway and Switzerland) and two from non-European countries (Canada and the United States). Liechtenstein and Switzerland provided a joint answer.

The questionnaire on ingredients was also sent to 23 European tattooist and/or PMU professional associations and 38 manufacturers/importers/private labels, which were identified thanks to the replies received by the Member States and to a search on the web. More associations and manufacturers were identified, but they were not involved in the survey as it was impossible to find their contact details. Tables 3.1 and 3.2 report the list of the contacted associations and manufacturers/importers/private labels; the ones that did not reply are indicated in red. A total of 6 replies were received from tattooist and/or PMU professional associations and 7 from manufacturers/importers/private labels.

4.3.1. Introduction

Tattoo and PMU inks are mixtures of insoluble pigments in a liquid made of binder(s) and solvent(s) that have been stabilised using additives, Preservatives are also often added to avoid microbiological contamination (2015, Dirks M.).

Colorants absorb visible light, are responsible for the ink colour and are major ingredients of tattoo and PMU inks. Their concentration can reach almost 60% by weight. They can be classified into two groups, namely pigments and dyes, on the basis of their solubility properties. **Pigments** are insoluble in the vehicle in which they are incorporated and they are the preferred choice for tattoo and PMU applications, also because of their high photo stability and chemical resistance. On the contrary, **dyes** due to their solubility and fast biodegradability after application are generally not suitable for such use. In case dyes are used, more often in PMU than in tattoo inks, they are in the form of the so-called "lakes", which are produced by precipitating dyes onto an insoluble base or stratum made by insoluble inorganic compounds, such as barium sulphate and aluminium hydroxide making them more stable to light and other chemicals.

From a chemical perspective, pigments can be inorganic or organic substances. In general, **inorganic pigments** are more frequently used for PMU than for tattoo applications, due to their dull and non-brilliant hue compared to organic ones. They include iron oxides, titanium dioxide and chromium oxide green.

Organic pigments cover a much wider range of colours compared to inorganic ones, show more brilliant colours and higher colour strength when mixed with white barium sulphate and titanium dioxide. For these characteristics, they are mainly used in tattoo inks. On the other hand, compared to inorganic pigments they also show the drawback of having poorer dispersability properties. These properties are important to obtain a good dispersion of the inks, which are suspensions.

The Colour Index, a world-wide recognised classification of colorants published by the Society of Dyers and Colourists (SDC) and American Association of Textile Chemists and Colourists (AATCC), classifies organic colorants in the following main **chemical categories**: nitroso, nitro, monoazo, diazo, triazo, polyazo, azoic, stilbene, carotenoid, diphenylmethane, triarylmethane, xanthene, indamine, indophenol, azine, oxazine, thiazine, sulphur, lactone, aminoketone, hydroxyketone, anthraquinone, indigoid and phthalocyanine. Of these classifications, azo pigments are characterised by the azo group (–N=N–), while the majority of the other categories consist of polycyclic pigments, having aromatic rings in their structure. One exception is represented by the triarylmethane category.

Ink manufacturers formulate tattoo and PMU inks starting from different chemical substances, but they do not synthesize them. One important problem highlighted by several authors in the literature (2015, Blume A. et al.; 2015, Hauri U. et al.; 2015, Petersen et al.; 2015, Jacobsen et al.) and by many stakeholders, such as TIME (tattoo ink manufacturers' of Europe, a manufacturers' association), is that the **pigments used in the formulation of tattoo and PMU inks are not produced for such a purpose** and do not undergo any risk assessment that takes into account their injection and permanence into the human body. The pigments incorporated in tattoo and PMU inks are usually produced by the chemical industry for outdoor applications in products like textiles, paints for cars and plastics, because they show good light fastness properties (resistant to fading when exposed to light). In addition, their purity is not very high (it has been reported to be between 70 and maximum 90%, depending on the source). Results from test analysis of colorants show the presence of **impurities** such as chromium VI in chromium oxides, nickel, chromium, copper and cobalt in iron oxides, aromatic amines in azo-colorants and polycyclic aromatic hydrocarbons in carbon black.

Additives are used to modify certain characteristics and are usually added in a concentration lower than 5% by weight. In tattoo and PMU inks, additives include surfactants, thickening agents and preservatives. **Surfactants** are employed to adjust surface tension thereby promoting dispersion and stabilisation of pigments. Pigment dispersions tend to agglomerate to reach the smallest possible surface in a given volume, and surface-active substances help to reduce or avoid this phenomenon by facilitating the wetting of pigments by binder solution. In order to inhibit the sedimentation of pigment dispersions during long term storage, **thixotropic agents**, e.g. silica, are part of the formulation of inks. They increase the viscosity and thixotropy of the product. The growth of microbiological organisms in inks is possible due to the high quantity of water present in the formulation. Already in 2003, the first version of the CoE ResAP recommended that inks should be sterile until opening. The current CoE ResAP(2008)1 allows the use of **preservatives** to ensure the preservation of the product after opening. Reducing the water content can be an alternative way to prevent the proliferation of microorganisms in tattoo inks.

Binding agents are non-volatile compounds, whose function is to bind pigment particles to each other and to the tattooing needle with the aim to facilitate the injection of tattoo and PMU ink in the skin. As reported by Dirks M. (2015), the binders most frequently used in tattoo inks consist of polyethers, polyvinylpyrrolidone, block copolymer and

Shellac. They are of high molecular mass (generally in the range of thousands of g/mol), which limits their bio-availability.

As **solvent**, tattoo and PMU inks principally contain water that can solubilise and solvate binder(s). Alcohols, for instance ethanol and isopropyl alcohol, can be used to modify the drying properties, viscosity and dispersability of inks. Their concentration should be limited to avoid skin irritation. Glycerine can be added as an ingredient as it acts as humectant and helps increasing viscosity, while propylene glycol can be used as humectant and to increase dispersability.

Inks can contain **fillers**, usually inorganic substances, which influence dispersability properties promoting re-dispersion of pigments after long term storage. Silica and barium sulphate are mainly employed for this aim. Barium sulphate is used in the flocculation of organic pigments to optimise their dispersability.

4.3.2. Colorants

On the basis of the survey carried out among experts and stakeholders and the information gathered from the literature and on the internet, a total of 113 and 100 colorants respectively were identified as being ingredients of tattoo and PMU inks,. Among them, a large majority consists of organic colorants (92 and 84 corresponding to 81 % and 84 %) and the chemical class of azo pigments represents the most numerous one (60 and 54, corresponding to 65 % and 64 % of the organic class).

Tables 4.20 and 4.21 provide an overview of the colorants identified, in terms of number per different hue, subdivision in inorganic and organic pigments and the percentage of azo colorants per hue. Red, yellow, orange, blue, green, violet, brown, black and white were taken into consideration.

Table 4.20: Overview of colorants used in tattoo and PMU inks.

	Tattoos					PMU				
		organic colorants		inorganic colorants			organic colorants		inorganic colorants	
Colour	n. of colorants	n.	%	n.	%	n. of colorants	n.	%	n.	%
Red	44	41	93	2	5	42	40	95	2	5
Yellow	27	25	93	2	7	25	24	96	1	4
Orange	10	10	100	0	0	8	8	100	0	0
Blue	7	5	71	2	29	5	3	60	2	40
Green	4	3	75	1	25	5	3	60	2	40
Violet	9	7	78	2	22	6	5	83	1	17
Brown	3	1	33	1	33	2	1	50	1	50
Black	6	0	0	5	83	4	0	0	4	100
White	3	0	0	3	100	3	0	0	3	100
	113	**92**				**100**	**84**			

Table 4.21: Percentage of azo colorants among the pigments used in tattoo and PMU inks.

	Tattoos			PMU		
		azo colorants			azo colorants	
Colour	n. of colorants	n.	%	n. of colorants	n.	%
Red	44	30	68	42	27	64
Yellow	27	21	78	25	20	80
Orange	10	7	70	8	6	75
Blue	8	1	13	5	0	0
Green	5	0	0	5	0	0
Violet	9	0	0	6	0	0
Brown	3	1	33	2	1	50
Black	6	0	0	4	0	0
White	4	0	0	3	0	0

As reported also by Bäumler et al. in 2003, our collection of information confirmed that nowadays the organic colorants are more often used than the inorganic pigments. The situation about 20-30 years ago was the opposite and the reason for this shift is

probably due to some favourable properties of the organic colorants, such as their brilliant colours. Inorganic pigments are used more often for the production of PMU inks, compared to tattoo inks, as they provide more natural colours.

No inorganic pigments were identified for orange colorants. In tattoo inks inorganic pigments are predominant in the case of black and white hue (83 and 75 %) and represent 33 % of the brown colours, while their percentage is maximum 25 % for the other colours. In PMU inks they represent 100 % of the black and white hues, 50 % of the brown, and 40 % of the blue and green colours.

Many colorants reported by stakeholders as being ingredients of tattoo and PMU products, were also found in market surveillance campaigns organised at Member States' level.

Only few indications were collected in regard to the quantity of colorants present in inks, this information was provided by Canada and some manufactures. Colorants were reported to be in concentration lower than 60 %, more frequently in the range 20-45 %.

On the basis of the collected information it is not possible to determine with accuracy the frequency of use of the various colorants. However, a very rough idea of the most common colorants used as ingredients in tattoo and/or PMU products could be based on the observation of how many sources (e.g. paper, questionnaire, etc.) cited a particular colorant. This observation, together with the discussion of results, is reported in the following sections divided by colours.

4.3.2.1. Red colorants

In total 51 red colorants were identified in this survey (Table 4.22; Annex IV, Tables A and B) and their structures are reported in Annex IX, Table A. Comparing this result with what was reported by Bäumler et al. in 2003, it can be highlighted that all the 25 red colorants cited in 2003, with the exception of pigment red 14, are still reported to be in use in our survey. In total, 44 and 42 red colorants find application in tattoo and PMU inks, respectively. A huge majority are organic substances and only approximately 5 % of these colorants consist of inorganic pigments both in tattoo and PMU inks. 66 % and 60 % of all red colorants in use in tattoo and PMU inks, respectively, belong to the class of monoazo colorants (Figure 4.11), the other classes being diazo, indigoid, xanthene, antraquinone, aminoketone, heterocycle and natural dyes. The chemical structure of colorants within these classes is shown in Figure 4.12.

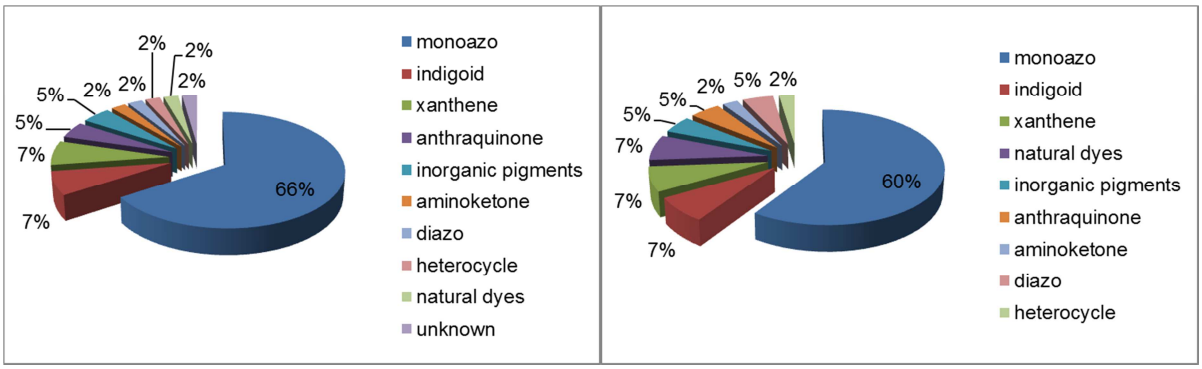
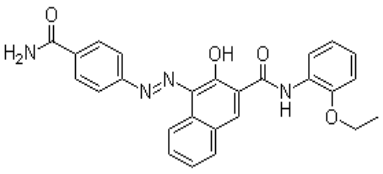
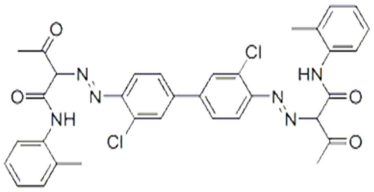


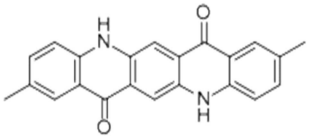
Figure 4.11: Chemical class of red colorants used in tattoo (left) and PMU (right) inks.



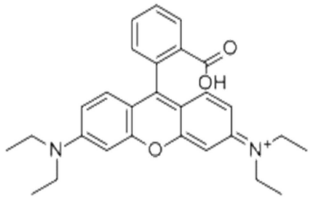
Monoazo *(Pigment red 170)*



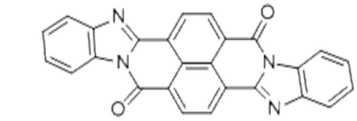
Diazo *(Pigment yellow 14)*



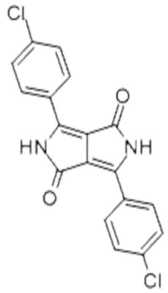
Indigoid *(Pigment red 122)*



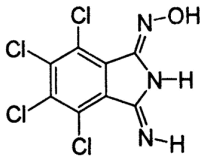
Xanthene *(Basic violet 10)*



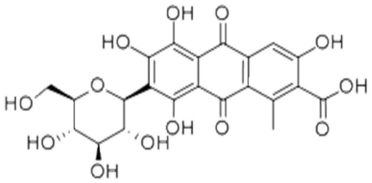
Anthraquinone *(Pigment orange 43)*



Aminoketone *(Pigment red 254)*



Heterocycle *(Pigment red 257)*



Natural dyes *(Natural red 4)*

Figure 4.12: Chemical structure of the described colorant classes (the names of the colorants shown as examples are indicated in italics).

Azo pigments, characterised by the azo group (–N=N–), are often included in ink formulations. Usually, only compounds containing one or two azo groups are used for such application. The production of these pigments usually foresees the diazotisation of primary aromatic amines followed by the coupling with other aromatic compounds to form the azo bond. Impurities of primary aromatic amines may be found in azo pigments, moreover these pigments may degrade, for example under solar or laser irradiation, into the original primary aromatic amines or other decomposition products (Engel et al., 2006, 2008, 2009; Vasold et al., 2004, 2008). It should be noted that a number of these products are classified as CMR (Carcinogenic, Mutagenic and Reprotoxic substances) in Table 3.1 of the EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP regulation).

Table 4.22: List of red colorants used in tattoo and PMU inks.

Negative list in CoE ResAP(2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y	Acid red 14, Food red 3 (Carmoisine lake)	14720	3567-69-9	monoazo		X
	Y	Acid red 18	16255	2611-82-7	monoazo	X	X
	Y	Acid red 51	45430	568-63-8	xanthene	X	X
	Y	Acid red 87	45380	548-26-5	xanthene	X	X
Table 2	N	Basic red 1	45160	989-38-8	xanthene	X	X
	N	Cinnabar (HgS)		23333-45-1	inorganic pigments	X	X
	N	Direct Red 53 Oxamine B	22095	6375-58-2	diazo	X	X
	Y, restricted with max conc. in HC (CI 16035)	Food red 17:1 (Allura red AC, FD&C Red 40 Al lake, E129)	16035:1	68583-95-9	monoazo	X	X
	Y	Natural red 4 (E180) Carmine (E 120)	75470	1343-78-8 1390-65-4 1260-17-9	natural dyes	X	X
	N	Natural red 22 (red sandalwood)	75510	98225-55-9	natural dyes		X
	N	Natural red 23 (Rhubarb root)	75510	6771-96-6	natural dyes		X
	N	Pigment red 2	12310	6041-94-7	monoazo	X	X
Annex IV cosmetics	Y (only rinse-off products)	Pigment red 3	12120	2425-85-6	monoazo	X	X
Annex II cosmetics in HC	Y	Pigment red 4	12085	2814-77-9	monoazo	X	X
Annex II cosmetics in HC	Y	Pigment red 5	12490	6410-41-9	monoazo	X	X
Annex IV cosmetics	Y (only rinse-off products)	Pigment red 7	12420	6471-51-8	monoazo		X
	N	Pigment red 9	12460	6410-38-4	monoazo	X	X
	N	Pigment red 12	12385	6410-32-8	monoazo	X	X
	N	Pigment red 14	12380	6471-50-7	monoazo		
	N	Pigment red 15	12465	6410-39-5	monoazo	X	
	N	Pigment red 17	12390	6655-84-1	monoazo	X	
	N	Pigment red 22	12315	6448-95-9	monoazo	X	X
	N	Pigment red 23	12355	6471-49-4	monoazo	X	
Annex II cosmetics in HC	N	Pigment red 48:1	15865:1	7585-41-3	monoazo	X	
	Y	Pigment red 49	15630	1103-38-4	monoazo	X	X
	N	Pigment red 49:2	15630:2	1103-39-5	monoazo	X	
	Y	Pigment red 51	15580	5850-87-3	monoazo	X	X
Table 2 - Annex II cosmetics	N	Pigment red 53:1	15585	5160-02-1	monoazo	X	X
	Y (CI 15850)	Pigment red 57:1	15850:1	5281-04-9	monoazo	X	X
	Y (CI 15850)	Pigment red 57:2	15850:2	17852-98-1	monoazo	X	X
	N	Pigment red 60	16105	1325-16-2	monoazo	X	
Annex II cosmetics in HC	Y	Pigment red 63:1	15880	6417-83-0	monoazo	X	X
	Y	Pigment red 101 and 102	77491	1309-37-1	inorganic pigments	X	X
Annexes II in HC and IV cosmetics	Y (only rinse-off products)	Pigment red 112	12370	6535-46-2	monoazo	X	X
	N	Pigment Red 120	12474	2786-76-7	monoazo	X	X
Annex IV cosmetics	Y (only rinse-off products)	Pigment red 122	73915	980-26-7	indigoid (quinacridone)	X	X
	N	Pigment red 146	12485	5280-68-2	monoazo	X	X
	N	Pigment red 170	12475	2786-76-7	monoazo	X	X
	N	Pigment red 177	65300	4051-63-2	anthraquinone	X	X
	N	Pigment red 179	71130	5521-31-3	anthraquinone	X	X
	Y	Pigment red 181	73360	2379-74-0	indigoid	X	X
	N	Pigment red 202	73907	3089-17-6	indigoid (quinacridone)	X	X
	N	Pigment red 210	12477	61932-63-6	monoazo	X	X
	N	Pigment red 222	123665	71872-63-4	monoazo	X	
	N	Pigment red 242	20067	52238-92-3	diazo		X
	N	Pigment red 254	56110	84632-65-5	aminoketone	X	X
	N	Pigment red 257	562700	117989-29-4	heterocycle	X	X
	N	Pigment red 266	12474	2786-76-7	monoazo	X	X
	N	Pigment red 269	12466	67990-05-0	monoazo	X	X
		Pigment red 340				X	
Annex II cosmetics in HC	N	Solvent red 1	12150	1229-55-6	monoazo		X

As mentioned in Table 4.22, two red colorants currently in use in tattoo and PMU inks are actually listed in Table 2 of the CoE ResAP(2008)1: **basic red 1** (xanthene) and **pigment red 53:1** (monoazo); pigment red 53:1 is also listed in Annex II of the EC Regulation 1223/2009 on cosmetics that contains the substances prohibited in cosmetic products. In addition, **pigments red 4, 5, 48:1, 63:1, 112** and **solvent red 1** (all monoazo) are prohibited in Annex II of cosmetics regulation for the use as hair colours; **pigments red 3, 7, 112** (both monoazo) and **122** (indigoid) are listed with restrictions

in Annex IV of the cosmetics regulation, that enumerates the colorants allowed in cosmetic products, and can be used only in rinse-off products.

As additional information, Table 4.22 highlights the presence or absence of the listed red colorants in Annex IV of the cosmetic regulation, which corresponds to the permission with restrictions, or prohibition to use such colorants in cosmetic products. This information was considered relevant, as the selection of the colorants included in Annex IV of such regulation was based on a safety assessment of their use as cosmetic ingredients, carried out by the EU Scientific Committee on Cosmetics (SCC) before 1997 and by the EU Scientific Committee on Cosmetics and Non-food Consumer Products (SCCNFP), from 1997 on. For pigment red 340 this information is missing as it was impossible to find the corresponding Colour Index Constitution Number (CICN). The analysis showed that, among the remaining 50 listed red colours, the majority, 31 of them corresponding to 62 %, are prohibited in cosmetic products, whereas 14 are allowed with no restrictions and 5 are permitted with restrictions.

Among the identified red colorants, the four most cited are mentioned hereafter with the indication of their chemical structure and number of citations in parenthesis: **pigment red 170** (monoazo, 40), **pigment red 122** (indigoid, 38), **pigment red 101** and **102** (inorganic pigments, 36) and **pigment red 210** (monoazo, 30). As mentioned before, pigment red 122 is listed with restrictions in Annex IV of the cosmetics regulation and can be used only in rinse-off products; in addition pigments red 170 and 210 are not allowed as colorants in cosmetic products.

As reported by Blume A. et al (2015), apparently pigment red 202 has replaced the restricted pigment violet 19 and pigment red 122. The comparison of their chemical structures (Annex IX, Table A) show that 2 hydrogen atoms or methyl groups, have been substituted by 2 chlorine atoms in pigment red 202. The doubt remains if the resulting structure of pigment red 202 actually shows a better toxicological profile compared to the restricted colorants.

4.3.2.2. Yellow colorants

In 2003, Bäumler et al. listed 12 yellow colorants. In this survey we collected information on these and other ones, in total 30 colorants (Table 4.23; Annex IV, Tables A and B). According to the gathered information, acid yellow 9 and pigment yellow 36 seem to be no longer in use. As in the case of red colorants, the large majority of colorants are organic substances. In fact, out of the 27 and 25 yellow colorants identified as ingredients of tattoo and PMU inks, only 7 % and 4 % of them are inorganic pigments, respectively (Figure 4.13). Among the organic colorants, most of them are monoazo compounds (at least 45 %), followed by diazo, aminoketone and quinoline structures (Figures 4.12 and 4.14).

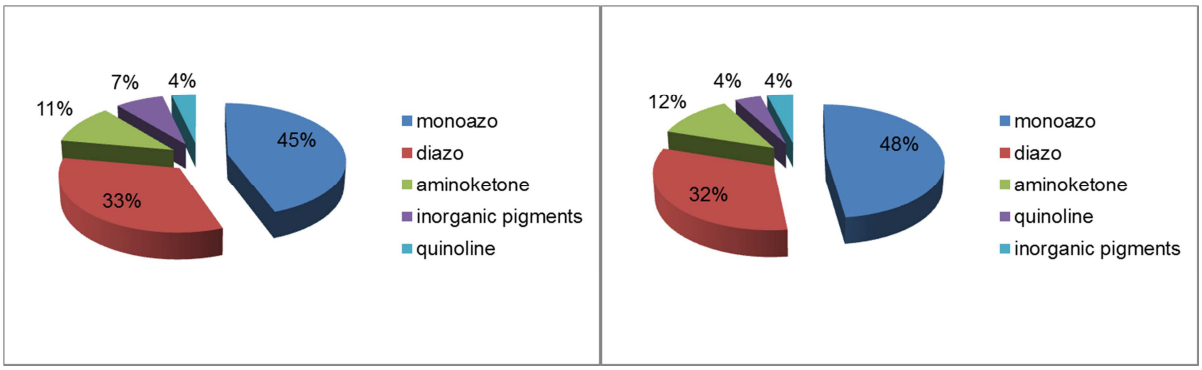


Figure 4.13: Chemical class of yellow colorants used in tattoo (left) and PMU (right) inks.

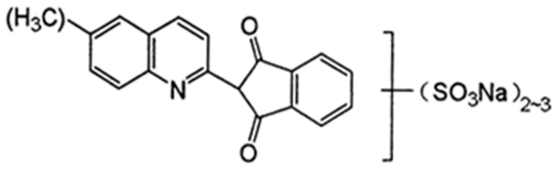


Figure 4.14: Chemical structure of the quinoline class (shown: Acid yellow 3).

Table 4.23: List of yellow colorants used in tattoo and PMU inks.

Negative list in CoE ResAP (2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y	Acid yellow 3	47005	8004-92-0	quinoline	X	X
	Y	Acid yellow 9	13015	2706-28-7	monoazo		
	Y	Acid yellow 23	19140	1934-21-0	monoazo	X	X
	Y (CI 15985)	Acid yellow 104 aluminium lake (FD&C Yellow 6 Al lake)	15985:1	12227-60-0	monoazo	X	X
		Diarylide yellow			diazo	X	X
		Arylide yellow			monoazo	X	X
	Y	Food yellow 3 (Sunset yellow, E110)	15985	2783-94-0	monoazo	X	X
Annex IV cosmetics	Y (no in products applied on mucous membranes)	Pigment yellow 1	11680	2512-29-0	monoazo	X	X
Annex IV cosmetics	Y (no in products applied on mucous membranes)	Pigment yellow 3	11710	6486-23-3	monoazo	X	X
Annex II cosmetics in HC	N	Pigment yellow 12	21090	6358-85-6 (15541-56-7)	diazo	X	X
	N	Pigment yellow 14	21095	5468-75-7	diazo	X	X
	N	Pigment yellow 36	77955	37300-23-5	inorganic pigments		
	Y	Pigment yellow 42 and 43	77492	51274-00-1	inorganic pigments	X	X
	N	Pigment yellow 55	21096	6358-37-8	diazo	X	X
	N	Pigment yellow 65	11740	6528-34-3	monoazo	X	X
	N	Pigment yellow 74	11741	6358-31-2	monoazo	X	X
Annex IV cosmetics	Y (only rinse-off products)	Pigment yellow 83	21108	5567-15-7	diazo	X	X
	N	Pigment yellow 87	21107:1	14110-84-6	diazo	X	X
	N	Pigment yellow 93	20710	5580-57-4	diazo	X	X
	N	Pigment yellow 97	11767	12225-18-2	monoazo	X	X
	Y (CI 19140)	Pigment yellow 100 (Food yellow 4:1)	19140:1	12225-21-7	monoazo		X
	N	Pigment yellow 110	56280	5590-18-1	aminoketone	X	X
	N	Pigment yellow 119	77496	68187-51-9	inorganic pigments	X	
	N	Pigment yellow 138	56300	30125-47-4	aminoketone	X	X
	N	Pigment yellow 139	56298	36888-99-0	aminoketone	X	X
	N	Pigment yellow 151	13980	31837-42-0	monoazo	X	X
	N	Pigment yellow 154	11781	68134-22-5	monoazo	X	X
	N	Pigment yellow 155	200310	68516-73-4 77465-46-4	diazo	X	
	N	Pigment yellow 180	21290	77804-81-0	diazo	X	X
	N	Pigment yellow 194	11785	82199-12-0	monoazo	X	

As shown in Table 4.23, the CoE ResAP(2008)1 recommends not to use some yellow colorants that were reported to be currently utilised in tattoo and/or PMU inks: **pigment yellow 12** (diazo) because it is part of Annex II of the EC Regulation 1223/2009 on cosmetics and it is prohibited in hair colorants; **pigments yellow 1, 3** (monoazo) and **83** (diazo) as they are listed in Annex IV of the cosmetics regulation with restrictions for the use in products applied on mucous membranes or can be used only in rinse-off products.

No Colour Index Constitution Numbers were associated with arylide and diarylide yellow, as they represent more a family of pigments rather than a particular one. For the remaining pigments: 18 (64 %) are prohibited as ingredients in cosmetic products, 7 (25 %) are allowed for all uses and 3 (11 %) are permitted with restrictions for certain uses in such products.

Among the identified yellow colorants, the four most cited are mentioned hereafter with the indication of their chemical structure and number of citations in parenthesis: **pigment yellow 74** (monoazo, 35), **pigment yellow 83** (diazo, 29), **pigments yellow 42** and **43** (inorganic pigments, 27) and **pigment yellow 14** (diazo, 26). As

just mentioned, the CoE ResAP(2008)1 recommends not to use pigment yellow 83; in addition pigments yellow 14 and 74 are not allowed as colorants in cosmetic products.

4.3.2.3. Blue colorants

In the survey, 8 blue colorants were identified. All of them seem to be in use, 7 and 5 in tattoo and PMU inks, respectively (Table 4.24; Annex IV, Tables A and B). Among them, only one diazo compound is present, while the other pigments belong to the phthalocyanine, triarylmethane, antraquinone and inorganic classes (Figures 4.15, 4.12 and 4.16).

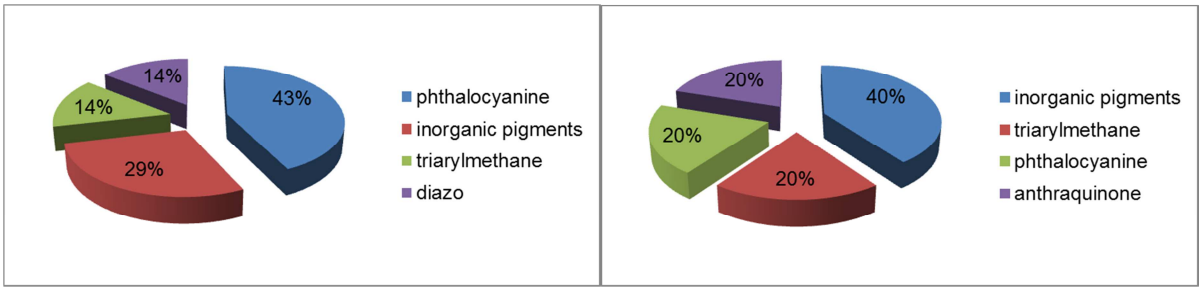
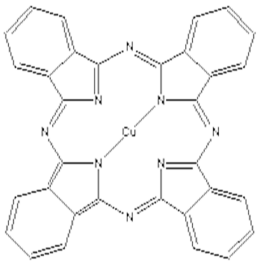


Figure 4.15: Chemical class of blue colorants used in tattoo (left) and PMU (right) inks.

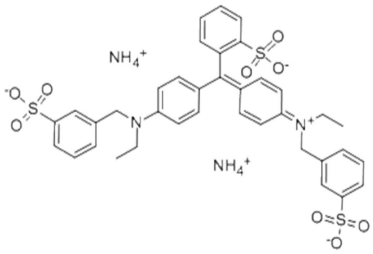
Phthalocyanines are macrocyclic compounds, having four pyrrole-like subunits linked to form a 16-membered ring in their structure, intensely blue-green-coloured. They form deeply coloured coordination complexes with several metals, such as copper.

Triarylmethane colorants have in common their triphenylmethane structure that can show different substitutes.

Antraquinone pigments are aromatic compounds having in common the basic structure of the 9,10-antraquinone variously substituted.



Phthalocyanine *(Pigment blue 15)*



Triarylmethane *(Acid blue 9)*

Figure 4.16: Chemical structure of the described classes (the names of the colorants shown as examples are indicated in italics).

Table 4.24: List of blue colorants used in tattoo and PMU inks.

Negative list in CoE ResAP (2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y	Acid blue 9	42090	2650-18-2	triarylmethane	X	X
Annexes II in HC and IV cosmetics	Y (only rinse-off products)	Direct blue 86	74180	1330-38-7	phthalocyanine	X	
Annex II cosmetics in HC	Y	Pigment blue 15	74160	147-14-8	phthalocyanine	X	X
	Y (only rinse-off products)	Pigment blue 17	74180 74200	71799-04-7 153640-87-0	phthalocyanine	X	
	N	Pigment blue 25	21180	10127-03-4	diazo	X	
	Y	Pigment blue 27 (Prussian blue)	77510	12240-15-2	inorganic pigments	X	X
	Y	Pigment blue 29 (Ultramarine blue)	77007	57455-37-5	inorganic pigments	X	X
	Y	Pigment blue 60	69800	81-77-6	anthraquinone		X

Among the blue colorants in use, **direct blue 86** is listed in Annex II of the cosmetic regulation (prohibited when used in hair dye products), as well as not listed as allowed colorant in cosmetic products, except in rinse-off products (Annex IV).

Pigment blue 15 is, on the one hand, allowed in all cosmetics (Annex IV of the cosmetic regulation) and, on the other hand, prohibited in hair colours (Annex II of the same regulation).

The CoE ResAP(2008)1 recommends not to use the chemicals listed in Annex II of the cosmetic regulation, however it is important to note that according to industry there is no better alternative to pigment blue 15.

Pigment blue 25 cannot be used in cosmetic products as it is not included in Annex IV. For pigment blue 17 it was not possible to find a unique Colour Index Constitution Number, as sometimes it was referred to with the same number as the one for direct blue 86 (CI 74180) as other times with a different one (CI 74200), the restriction reported in Table 4.29 refers to the first CI number. The other 5 blue colorants are all permitted as ingredients in cosmetic products.

The four most cited blue colorants, with an indication of chemical structure and number of citations in parenthesis, are: **pigment blue 15** (phthalocyanine, 54), **pigment blue 29** (inorganic pigment, 17), **acid blue 9** (triarylmethane, 13) and **pigment blue 27** (inorganic pigment, 4).

4.3.2.4. Orange colorants

10 orange colorants were reported as ingredients in tattoo inks and 8 in PMU inks (Table 4.25; Annex IV, Tables A and B). All of them are organic compounds and the azo pigments, either mono or diazo, represent more than 70 % (Figure 4.17). The other colorants belong to the chemical class of natural dyes, antraquinone and pyrrole ketone (Figures 4.12 and 4.18).

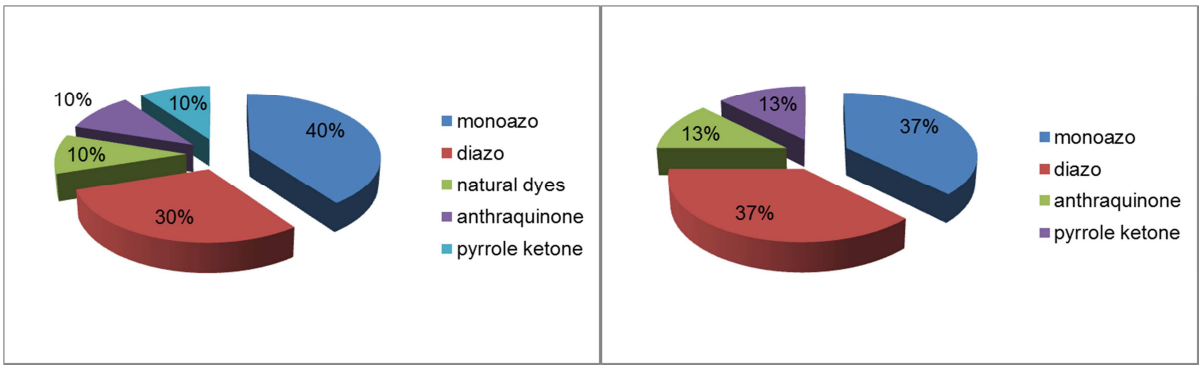


Figure 4.17: Chemical class of orange colorants used in tattoo (left) and PMU (right) inks.

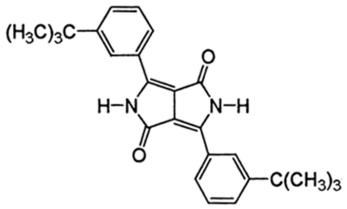


Figure 4.18: Chemical structure of the pyrrole ketone class (shown: Pigment orange 73).

Table 4.25: List of orange colorants used in tattoo and PMU inks.

Negative lists in CoE ResAP(2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	N	Lawsone (2-hydroxyl-1,4-naphtoquinone; HNQ)	75480	83-72-7	natural dyes	X	
Table 2 - Annex II cosmetics	N	Pigment orange 5	12075	3468-63-1	monoazo	X	X
	N	Pigment orange 13	21110	3520-72-7	diazo	X	X
	N	Pigment orange 16	21160	6505-28-8	diazo	X	X
	N	Pigment orange 22	12470	6358-48-1	monoazo	X	X
	N	Pigment orange 34	21115	15793-73-4	diazo	X	X
	N	Pigment orange 36	11780	12236-62-3	monoazo	X	X
Annex IV cosmetics	Y (no in products applied on mucous membranes)	Pigment orange 43	71105	4424-06-0	anthraquinone	X	X
	N	Pigment orange 73	561170	84632-59-7	pyrrole ketone	X	X
		Pigment orange 74		85776-14-3	monoazo	X	

The CoE ResAP(2008)1 recommends not to use **pigment orange 5** and **pigment orange 43**, as the first is listed in its Table 2 and the second in Annex IV of the cosmetic regulation with restrictions for products applied to the mucous membranes.

Basically all the identified orange colorants are not allowed as ingredients in cosmetic products, with the exception of pigment 43 in products other than the ones applied to the mucous membranes. No information was available for pigment orange 74, as it was not possible to find its Colour Index Constitution Number.

The four most cited orange colorants, with an indication of chemical structure and number of citations in parenthesis, are: **pigment orange 13** (diazo, 30), **pigment orange 16** (diazo, 27), **pigment orange 73** (pyrrole ketone, 21) and **pigment orange 43** (antraquinone, 20). As mentioned before, the CoE ResAP(2008)1 recommends not to use pigment orange 43.

4.3.2.5. Violet colorants

The number of colorants mentioned as being used in tattoo and PMU inks are 9 and 6, respectively (Table 4.26; Annex IV, Tables A and B). Pigments violet 15 and 16 are inorganic, lazurite and ammonium manganese (III) diphosphate respectively. The other colorants are organic compounds, including chemical class like xanthene, oxazine, indigoid and antraquinone (Figures 4.12 and 4.20).

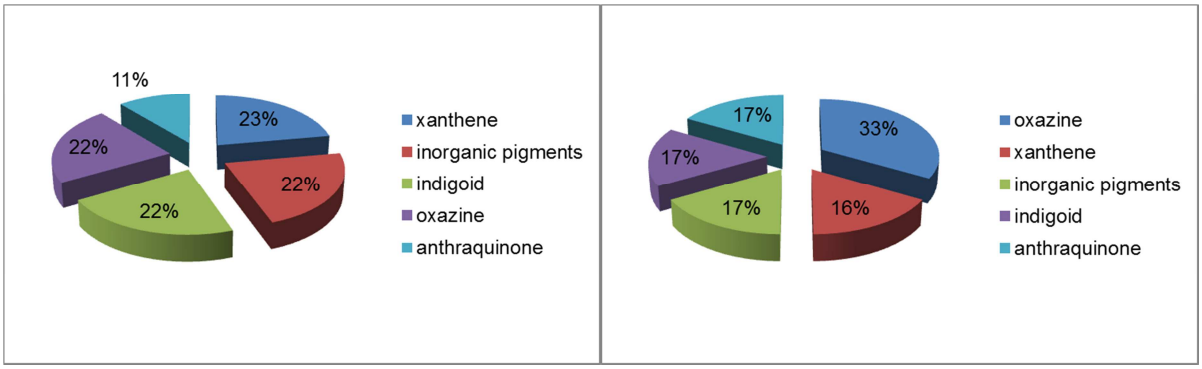


Figure 4.19: Chemical class of violet colorants used in tattoo (left) and PMU (right) inks.

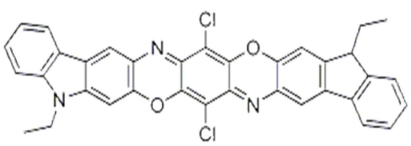


Figure 4.20: Chemical structure of the oxazine class (shown: Pigment violet 23).

Table 4.26: List of violet colorants used in tattoo and PMU inks.

Negative list in CoE ResAP (2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
Table 2 - Annex II cosmetics	N	**Basic violet 10**	45170	81-88-9	xanthene	X	X
	N	**Pigment violet 1**	45170:2	1326-03-0	xanthene	X	
	N	**Pigment violet 12**	58050	81-64-1	anthraquinone	X	X
	Y	**Pigment violet 15 (Sodium aluminosilicate violet)**	77007	12769-96-9	inorganic pigments	X	
	Y	**Pigment violet 16 (Manganese violet)**	77742	10101-66-3	inorganic pigments	X	X
Annexes II in HC and IV cosmetics	Y (only rinse-off products)	**Pigment violet 19**	73900	1047-16-1	indigoid	X	X
Annexes II in HC and IV cosmetics	Y (only rinse-off products)	**Pigment violet 23**	51319	6358-30-1	oxazine	X	X
	N	**Pigment violet 37**	51345	57971-98-5 17741-63-8	oxazine	X	X
	Y	**Vat violet 2**	73385	5462-29-3	indigoid	X	

The CoE ResAP(2008)1 recommends not to use **basic violet 10, pigments violet 19** and **23**: the first is both listed in Table 2 of the resolution and in Annex II of the cosmetic regulation; the other two are both listed in Annex II, with restrictions for the use in hair colours, and in Annex IV of the cosmetic regulation, with restrictions for all cosmetic products, except rinse-off ones.

In addition, four colorants (basic violet 10, pigments violet 1, 12 and 37) are not allowed as ingredients in cosmetic products, whereas pigments violet 15, 16 and vat violet 2 are.

Among the identified violet colorants, the four most cited, with an indication of their chemical structure and the number of citations in parenthesis, are: **pigment violet 23** (oxazine, 28), **pigment violet 19** (indigoid, 25), **pigments violet 16** (inorganic pigments, 17) and **pigment violet 37** (oxazine, 15). As just mentioned, the CoE ResAP(2008)1 recommends not to use pigments violet 19 and 23, frequently mentioned as ingredients of tattoo and PMU products; in addition pigment violet 37 is not allowed as colorants in cosmetic products.

4.3.2.6. Brown colorants

Only three colorants were identified for the brown hue: one inorganic, one monoazo and one pigment with unknown structure (Table 4.27; Annex IV, Tables A and B). The CoE ResAP(2008)1 does not include any recommendations for these colorants. Pigment brown 25 is not allowed in cosmetic products, while pigments brown 6 and 7 are.

Iron oxides may show hues that vary from yellow to red and brown colours and they show high opacity. They are suitable for PMU, but in general not widely used in tattoo inks. Yellow and brown iron oxides are not heat stable and with time tend to be transformed in the red heat-stable haematite. The brown colour is obtained by mixing red, yellow and black iron oxides. The major problem related to iron oxides is the presence of hazardous impurities, in particular heavy metals, such as nickel, chromium, copper and cobalt.

Among the brown colorants, **pigments brown 6** and **7** (inorganic pigments) were by far the most cited by various sources (36), followed by **pigment brown 25** (monoazo) mentioned by 17 sources.

Table 4.27: List of brown colorants used in tattoo and PMU inks.

Negative lists in CoE ResAP(2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y (red) Y (yellow) Y (black)	**Pigment brown 6 and 7**	77491 77492 77499	52357-70-7 1345-27-3	inorganic pigments	X	X
	N	**Pigment brown 25**	12510	6992-11-6	monoazo	X	X
		Pigment brown 175				X	X

4.3.2.7. Green colorants

Five green colorants were reported as ingredients in PMU inks and four in the tattoo ones (Table 4.28; Annex IV, Tables A and B). Two of them are inorganic pigments; the other three are organic compounds belonging to the chemical classes: antraquinone and phthalocyanine (Figures 4.12 and 4.16).

The CoE ResAP(2008)1 recommends not to use **pigment green 7**, which is listed both in Annex II (relatively to the use in hair colours) and Annex IV (restriction for eye products) of the cosmetic regulation. Pigment green 36 is the only one not permitted as ingredient in cosmetic products.

The most cited green colorants, with their chemical structure and number of citations in parenthesis, are: **pigment green 7** (phthalocyanine, 39), which is not recommended by the CoE ResAP(2008)1, followed by **pigment green 36** (phthalocyanine, 28) and **pigment green 17** (inorganic pigment, 13).

As reported by Blume A. et al (2015), pigment green 36 has been used on the market to substitute the not recommended pigment green 7. The chemical structures of those colorants (Annex IX, Table A) are very similar, the only difference being the substitution of 6 chlorine atoms with 5 bromine ones. It seems reasonable that both compounds show similar toxicological properties.

According to Dirks M. (2015), the green chromium oxide pigments, both chromium oxide (Cr_2O_3) and chromium oxide hydrate ($Cr_2O_3 \bullet 3H_2O$), can usually only be found in PMU inks. These pigments should be carefully analysed for the presence of chromium VI (whose limit in the CoE ResAP(2008)1 is 0.2 ppm).

Table 4.28: List of green colorants used in tattoo and PMU inks.

Negative lists in CoE ResAP(2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y	Acid green 25	61570	4403-90-1	anthraquinone	X	X
Annexes II in HC and IV cosmetics	Y (no in eye products)	Pigment green 7	74260	1328-53-6	phthalocyanine	X	X
	Y	Pigment green 17	77288	58591-12-1 1333-82-0	inorganic pigments	X	X
	Y	Pigment green 18 (Chromium Hydroxide Green, Viridian 3B)	77289	12001-99-9	inorganic pigments		X
	N	Pigment green 36	74265	14302-13-7	phthalocyanine	X	X

4.3.2.8. Black colorants

Six black pigments were identified during the survey. Apart from pigment black 2, for which it was not possible to find its structure, they are all inorganic pigments (Table 4.29; Annex IV, Tables A and B). Ferrous oxide black and pigment black 11 are based on iron oxides, pigment black 15 on copper oxide, pigment black 6 and 7 on carbon black and pigment black 9 on bone charcoal.

These colorants are not mentioned in the CoE ResAP(2008)1. In addition, CI numbers 77489, 77266, 77267 and 77499 are allowed as ingredients in cosmetic products, whereas CI numbers 77265 and 77403 are not.

By large, the most used colour for tattoos is black, and carbon black (pigment black 6 and 7) is the most used pigment (cited by 55 different sources). Pigment black 11 and ferrous oxide black were reported by 24 and 19 sources, respectively.

Carbon black can be produced through different processes that influence the size and dispersability properties of the resulting pigment. As described by Dirks M. (2015), production processes start with primary particles or nodules of about 15-300 nm that are melted to form particle aggregates (85-500 nm), which in turn form agglomerates of size in the range 1-100 µm thanks to electric forces. Depending on the production

process, carbon black may contain Polycyclic Aromatic Hydrocarbons (PAHs) as impurities.

Table 4.29: List of black colorants used in tattoo and PMU inks.

Negative lists in CoE ResAP(2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y (orange)	**(Ferous oxide , black)**	77489		inorganic pigments	X	X
		Pigment black 2				X	
	Y N	**Pigment black 6 and 7 (graphite)**	77266 77265	1333-86-4 98615-67-9	inorganic pigments	X	X
	Y	**Pigment black 9**	77267	8021-99-6	inorganic pigments	X	X
	Y	**Pigment black 11**	77499	12227-89-3	inorganic pigments	X	X
	N	**Pigment black 15**	77403	1317-38-0	inorganic pigments	X	

4.3.2.9. White colorants

The survey identified four white colorants, all being inorganic pigments (Table 4.30; Annex IV, Tables A and B). Similarly to titanium dioxide, barium sulphate is used not only as a white colour, but also because of its lightening effect and adjustment of colour strength. In addition, it is also employed in the production of lakes and as filler. Pigment white 4 is zinc oxide and pigment white 6 is titanium dioxide.

Due to their high scattering power, titanium dioxide pigments reflect almost completely white light. Because of their high refractive index they are used to lighten colours. As described by Dirks M. (2015), titanium dioxide consists of three crystallisation forms: Brookit, Anatas and Rutil. Among them, Rutil is widely used in inks, as it is chemically inert and shows low photochemical activity. On the contrary, Anatas has a limited use, due to its strong photocatalytic activity that can initiate the photochemical degradation of pigments in the presence of UV light, and Brookit is not employed at all in the production of tattoo and PMU inks.

Pigment white 6 (titanium dioxide) was the most reported white colorant (55 citations) followed by barium sulphate (4).

These pigments are not mentioned in the CoE ResAP(2008)1. With the exception of pigment white 4, they can all be ingredients of cosmetic products.

Table 4.30: List of white colorants used in tattoo and PMU inks.

Negative lists in CoE ResAP(2008)1	Permitted by cosmetic regulation (Annex IV)	Colour Index Generic Name	Colour index Constitution Number	CAS number	Chemical class	tattoo	PMU
	Y	**Aluminium Silicate (bentonite, White)**	77004	1302-78-9 1327-36-2 1332-58-7	inorganic pigments		X
	Y	**Barium sulphate**	77120	7727-43-7	inorganic pigments	X	X
	N	**Pigment white 4**	77941	1314-13-2	inorganic pigments	X	
	Y	**Pigment white 6 (titanium dioxide)**	77891	13463-67-7	inorganic pigments	X	X

4.3.3. Ingredients other than colorants

As previously mentioned, additives include substances which are used to modify certain characteristics of the inks, such as surfactants and thickening agents, as well as preservatives to avoid the growth of microorganisms in the product after opening. In the list reported hereafter (Table 4.31), solvents and binders were also considered.

The questionnaire sent to stakeholders included 15 auxiliaries and 4 preservatives. The information collected through the replies to the questionnaire and from other sources, such as national studies, papers in the literature and search on the internet, resulted in a list of 100 auxiliaries and 48 preservatives. 99 and 70 auxiliaries and 47 and 30 preservatives were reported to be used in tattoo and PMU inks, respectively (for detailed information look at Annex IV, Tables C and D).

Table 4.31: List of additives (auxiliaries and preservatives) used in tattoo and PMU inks.

Auxiliaries	CAS number	tattoo inks	PMU inks
Acrylates copolymer		x	x
Acrylic polymer		x	
Acrylic Resin TSRN00195201005-5100P		x	
Acrylic Resin TSRN00195201005-5102P		x	
Aloe barbadensis	85507-69-3 94349-62-9	x	x
Aluminum hydroxide	21645-51-2	x	x
Aminomethyl propanediol	115-69-5	x	x
Ammonia	7664-41-7	x	x
Ammonium acrylates copolymer	63744-68-3	x	x
Amorphous silica (Silicon dioxide)	7631-86-9	x	x
Anionic surfactant		x	
Barium sulphate	7727-43-7	x	x
beta-Naphthol ethoxylate	35545-57-4	x	x
Block copolymer		x	
Borax	71377-02-1	x	x
Butanamid	541-35-5		
Calcium natrium phosphosilicate		x	x
Calcium sodium phoshosilicate		x	x
Calendula extract	84776-23-8	x	x
Caprylil glycol (1,3-octadienol)	1117-86-8	x	x
Carboxylated acrylic copolymer		x	x
Carbomer	9007-20-9 9003-01-4 76050-42-5 9062-04-8 9007-16-3 9007-17-4	x	x
5-Chloro-2methyl-2H-isothiazol-3-one/2-Methyl-2H-isothiazol-3 one mixture (CMIT/MIT mixture) antimicrobial	55965-84-9	x	
Citric acid	77-92-9 5949-29-1	x	x
Detergents		x	
Dibutyl phthalate	84-74-2	x	
Diethyleneglycol	111-46-6	x	x
Dimethicone	9006-65-9	x	
7-Diethylamino-4-methylcoumarin	91-44-1	x	
Dipropylene glycol	110-98-5	x	x
Disodium cocoyl glutamate	68187-30-4	x	x
Emulsifier		x	x
Ethanol	64-17-5	x	x
Ethylene glycol	107-21-1	x	
Ethylhexyl glycerine	70445-33-9	x	x
Essential oils		x	
Gelatine	9000-70-8	x	x
Glycerol (Glycerine)	56-81-5 8043-29-6	x	x
Glyceryl caprylate/caprate	26402-26-6 27214-36-4	x	x
Glyceryl stearate	31566-31-1	x	x
Gum	11138-66-2	x	x
Hamamelis virginiana (leaf extract)/ Witch hazel extract	84696-19-5	x	x
Hamamelis virginiana extract	68916-39-2	x	x
Hydrochloric acid	7647-01-0	x	x

Auxiliaries	CAS number	tattoo inks	PMU inks
Hydroxypropylmethylcellulose	9004-64-2 9004-65-3 8063-82-9	x	x
Hydroxymethyl aminoethanol	65184-12-5	x	x
Humectants		x	
iso-Octylphenolethoxylate, Octoxynol	92046-34-9	x	x
Isopropanol	67-63-0	x	x
Kaolin	1332-58-7	x	
Lactic acid	50-21-5	x	x
Lecithin	8002-43-5 8030-76-0 (soybean)	x	x
Menthol	2216-51-5	x	x
Methanol	67-56-1	x	
Methyl ethyl keton	78-93-3	x	x
Methylpropanediol	2163-42-0	x	x
Modified organo polysiloxanes		x	
Neodecanoic acid	26896-20-8		
N-vinyl-2-pyrrolidone	94800-10-9	x	
Nonylphenolethoxylate, Nonoxynol		x	x
Non-ionic surfactant		x	
C9-11 Pareth-6	68439-46-3	x	x
PEG-8	5117-19-1 25322-68-3 (generic)	x	x
PEG-200	25322-68-3	x	x
PEG-400	25322-68-3	x	x
PEG-600		x	x
PEG Isooctyl phenyl ether		x	x
Phenylpropanol	1335-12-2	x	x
Poloxamer 188	9003-11-6	x	x
Poloxamer 407	9003-11-6	x	x
Poly alchilen glycol ether		x	
Polyethylenglycol	25322-68-3	x	
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-, branched, phosphates	68412-53-3	x	
Polysorbate 20 (Tween 20)	9005-64-5	x	x
Polysorbate 80 (Tween 80)	9005-65-6	x	x
Polyvinylpyrrolidone (PVP) (Polyvidone, Povidone)	9003-39-8	x	x
Proprietary resin		x	x
Polypropilene	9003-07-0	x	
Propanediol	26264-14-2	x	
Propylene glycol	57-55-6	x	x
Poly(propylene glycol)	25322-69-47	x	
Ricin Oil	8001-79-4	x	x
Rosa canina	84603-93-0	x	x
Rosa Centifolia	84604-12-6	x	x
Rosa damascena extract	90106-38-0	x	x
Rosin	8050-09-7	x	x
Shellac	9000-59-3	x	x
Silica	112945-52-5	x	
Silica dimethyl silylate	271-893-4	x	x
Simethicone	8050-81-5	x	x
Sodium cocoyl glutamate	68187-32-6	x	x
Sodium hydroxide	1310-73-2	x	x
Sorbitol	50-70-4 8201-93-5	x	x
Tetramethyl decynediol (Surfonyl®104, TMDD)	126-86-3	x	x
Thymol	89-83-8	x	

Auxiliaries	CAS number	tattoo inks	PMU inks
Trimethylolpropane triisostearate	68541-50-4	x	x
Vodka		x	
VP/VA Copolymer	25086-89-9	x	x
Water	7732-18-5	x	x
Witch hazel		x	

Preservatives	CAS number	tattoo inks	PMU inks
Aldehydes (like glutaraldehyde)		x	
2-Amino-2-methylpropanol	124-68-5	x	x
Benzoates		x	
Benzophenone	119-61-9	x	
Benzoic acid	65-85-0	x	x
Benzoisothiazolinone (BIT)	2634-33-5	x	x
2-Bromo-2-nitropropane-1,3-diol	52-51-7	x	x
Buthylparaben	94-26-8	x	
Chlorhexidine	55-56-1	x	x
4-Chloro-3,5-dimethylphenol (Chloroxylenol)	88-04-0	x	x
Dehydroacetic acid	520-45-6 771-03-9 16807-48-0	x	x
Dibenzofuran	132-64-9	x	
1,2-Dibromo-2,4-dicyanobutane	35691-65-7	x	
2-4 Dichlorobenzylalcohol	1777-82-8	x	
DMDM Hydantoin	6440-58-0	x	x
Ethylparaben	120-47-8	x	x
9-Fluoenone	486-25-9	x	
Formaldehyde	50-00-0	x	x
Glyoxal	107-22-2	x	x
Hexachlorobutadiene	87-68-3	x	
Hexamethylenetetramine	100-97-0	x	
p-Hydroxy benzoate	456-23-5	x	x

Preservatives	CAS number	tattoo inks	PMU inks
Hydroxymethylamino ethanol		x	
Iodopropynyl butylcarbamate	55406-53-6	x	x
Isobuthylparaben	4247-02-3	x	x
Isopropylparaben	4191-73-5	x	
Isothiazolon (Kathon CG)	96118-96-6	x	
Listerine (mouth wash) for thinning of traditional inks - this contains thymol, eucalyptol, menthol, methyl-salicylate, benzoic acid, sodium benzoate, water, alcahol, poloxamer		x	
Melamine	108-78-1	x	
Methylchloroisothiazolinone	26172-55-4	x	x
Methyldibromo glutaronitrile	35691-65-7	x	x
Methylisothiazolinone (2-methyl-4-isothiazolinone)	2682-20-4	x	x
Methylparaben	99-76-3	x	x
MI/MCI	26172-55-4 2682-20-4	x	x
Octylisothiazolinon	26530-20-1	x	x
o-Phenylphenol	90-43-7	x	x
Phenol	108-95-2	x	x
Phenoxyethanol	122-99-6	x	x
Polyaminopropyl biguanide	32289-58-0 133029-32-0	x	x
Preservative		x	x
Propylparaben	94-13-3	x	x
Salicylic acid	69-72-7	x	x
Sodium Borat	1330-43-4 1303-96-4	x	
Sodium Chloride	7647-14-5		x
Sorbic acid	110-44-1	x	x
Thymol	89-83-8	x	x
Triclosan Irgasan	9012-63-9	x	
Toluenesulfonamide resin		x	

Only limited information was collected concerning the quantity of substances used as additives in the formulation of inks. For example, ethanol seems to be used in high percentages (Germany reported a concentration of 48 % while a concentration range of 10-30 % was described by Canada). A similar situation was reported for isopropanol: Germany reported in a market surveillance campaign a concentration of 19 %, while Canada mentioned it being used in a concentration range of 10-30 %, and one manufacturer stated to use it in formulations at a level between 5 and 20 %. For glycerol the indicated concentration ranges were 10-30 % (Canada), 1-5 % in tattoo inks and 10-15 % in PMU products (from one manufacturer). According to one manufacturer, propylene glycol accounted for 10-15 % and 10-20 % in the formulation of tattoo and PMU products, respectively. Finally, nonylphenolethoxylate was quantified by test analysis by Switzerland and Liechtenstein in the range 0.03-3.9 %.

Concerning preservatives, quantitative data were provided only by some Member States and EFTA countries (Germany, Switzerland and Liechtenstein), which carried out test analysis on products available on the market. Depending on the compound, the concentration of these substances was reported to be in the range 0.0003 - 1.5 %, (for detailed information see Annex IV, Tables C and D).

4.3.4. Fate of colorants

Free azo dyes may undergo metabolic reductive cleavage into aromatic amines upon oral intake either in the lumen of the gastric tract or in the liver after uptake from the intestine. According to Platzek T. et al. (1999), such cleavage may occur even on the

skin due to influence of the skin bacteria. Cui Y. et al. (2005) showed that pigment yellow 74 can be metabolised in vitro by microsomal proteins in rats and humans to form metabolites consisting in hydrolylated and demethylated compounds.

Even though the azo colorants used in tattoo and PMU inks are either pigments or lakes, both being considered insoluble in water and deposited in the derma as microcrystalline grains, equilibrium may exist between the solid phase and small amount of colorants dissolved in the fluid constantly circulating in the body. Therefore, it cannot be excluded that to a certain degree the azo compounds may be metabolically reductively cleaved into aromatic amines when situated in the viable skin layers – or in the liver upon release into the bloodstream.

Table 4.32 presents the list of colorants in use in commercial tattoo and PMU inks that by reductive cleavage of the azo bond can release primary aromatic amines that the CoE ResAP(2008)1 recommends not to use, because they are listed in its Table 1, or in Annex II of the cosmetic regulation or in Table 3.1 of the Classification, Labelling and Packaging (CLP) regulation. In the case of substances classified as Carcinogenic, Mutagenic and Reprotoxic (CMR) in the CLP regulation, their CMR classification is specified together with their classification related to skin sensitisation, eye irritation and eye damages.

In total, 22 % of the azo colorants in use both in tattoo inks (13 out of 60) and in PMU products (12 out of 54), contain and might release, by simple reductive cleavage of the azo bond, aromatic amines listed in Table 1 of the CoE ResAP(2008)1 also classified as CMR: o-anisidine, 3,3-dichlorobenzidine, benzidine, 4-chloro-o-toluidine, 5-nitro-o-toluidine, 3,3'-dimethoxybenzidine.

Other azo colorants may form aromatic amines classified as CMR deriving from either a further conversion of the aromatic amines formed after cleavage of the azo bond or by cleavage of a different type of bond (e.g amide bond). Examples of these azo-colorants, with the derived aromatic amines in parenthesis, are: pigment yellow 14 (o-toluidine), pigment yellow 74 (o-anisidine) and pigment red 112 (o-toluidine).

Table 4.32: List of colorants in use that may release by reductive cleavage primary aromatic amines present in some negative lists mentioned in the CoE ResAP(2008)1.

			CoE ResAP (2008)1	EC Reg 1223/2009	EC Reg 1272/2008	Used in tattoos/PMU
Colorant	**Primary aromatic amine**	**CAS**	**Table 1**	**Annex II**	**Table 3.1**	**T/P**
Solvent red 1	o-anisidine	90-04-0	X	X	X	P
Pigment yellow 194					Carc. 1B, Muta. 2	T
Pigment yellow 12	3,3'-dichlorobenzidine	91-94-1	X	X	X	T/P
Pigment yellow 14					Carc. 1B, Skin Sens. 1	T/P
Pigment yellow 55						T/P
Pigment yellow 83						T/P
Pigment yellow 87						T/P
Pigment orange 13						T/P
Pigment orange 34						T/P
Direct red 53	benzidine	92-87-5	X	X	X	T/P
					Carc. 1A	
Pigment red 7	4-chloro-o-toluidine	95-69-2	X		X	P
					Carc. 1B, Muta 2	
Pigment red 17	5-nitro-o-toluidine	99-55-8	X	X	X	T
Pigment red 22					Carc. 2	T/P
Pigment orange 16	3,3'-dimethoxybenzidine	119-90-4	X	X	X	T/P
Pigment blue 25					Carc. 1B	T

The cleavage of azo colorants into aromatic amines may also occur under either solar, or UV or laser radiation, which is the preferred technique for tattoo removal. This has been demonstrated by a number of studies (2015, Hauri U. et al.; 2014, Hauri U.; 2010a, KEMI Swedish Chemical Agency; 2009, Engel E. et al.; 2008, Vasold R. et al.; 2006, Engel E. et al.; 2004, Vasold R. et al.).

Studies were conducted to evaluate the fate of colorants under irradiation both in vitro and in vivo, for instance by extracting the skin after laser treatment for removal processes. A summary of the information available in the literature on this issue is reported in Annex IX Table B, including the references.

Tables 4.33 and 4.34 present the list of decomposition compounds identified from a variety of colorants under irradiation with different light sources (e.g. sunlight and UV light) and laser radiation, respectively. The same tables also identify the Primary Aromatic Amines (PAA) that are formed and include the references to the CoE ResAP(2008)1.

Table 4.33: List of decomposition products identified from colorants under irradiation with different light sources, with the indication of the recommendations deriving from the CoE ResAP(2008)1.

CI Generic Name	Irradiation with different light sources	CAS	PAA	CoE ResAP (2008)1 Table 1	EC Reg 1223/2009 Annex II	EC Reg 1272/2008 Table 3.1
PY 14	2-methylformanilide	94-69-9	N			
	2-methyl-acetanilide	120-66-1	N			
	3,3'-dichlorodiphenyl	2050-67-1	N			
	3,3'-dichlorobenzidine	91-94-1	Y	X	X	X (Carc. 1B, Skin Sens. 1)
	o-toluidine	95-53-4	Y	X		X (Carc. 1B, Eye Irrit. 2)
PY 74*	2-methoxyacetanilide	93-26-5	N			
	In vitro decomposition product after simulated solar light:	92-15-9	N			
	o-acetoacetanisidide		N			
	2-(hydroxylamine)-N-(2-methoxyphenyl)-3-oxobutanamide	1226-63-7	N			
	o-anisidine	90-04-0	Y	X	X	X (Carc. 1B, Muta. 2)
PO 13	3,3'-dichlorobenzidine	91-94-1	Y	X	X	X (Carc. 1B, Skin Sens. 1)
	3,3'-dichlorodiphenyl	2050-67-1	N			
PO 16	formanilide	103-70-8	N			
	acetanilide	103-84-4	N			
	3,3'-dimethoxydiphenyl	6161-50-8	N			
	o-dianisidine	119-90-4	Y	X	X	X (Carc. 1B)
PO 34	3,3'-dichlorobenzidine	91-94-1	Y	X	X	X (Carc. 1B, Skin Sens. 1)
PR	2-amino-4-nitroanisole	99-59-2	Y			
PR 22	In vitro decomposition products (UVB, natural sunlight):					
	5-nitro-o-toluidine	99-55-8	Y	X	X	X (Carc.2)
	4-nitrotoluene	99-99-0	N			
PR 112	o-toluidine	95-53-4	Y	X		X (Carc. 1B, Eye Irrit. 2)
	2,4,5-trichloroaniline	636-30-6	Y			
	2-methylformanilide	94-69-9	N			
	2-methylacetanilide	120-66-1	N			
PR 170	benzamide	55-21-0	N			
	4-hydroxybenzamide	619-57-8	N			
	4-aminobenzamide	2835-68-9	Y			
PR 202	4-chloroaniline	106-47-8	Y	X		X (Carc. 1B, Skin Sens. 1)
PW 6	UVA radiation combined with visible light: in vitro test for cytotoxicity and photocytotoxicity; 0% cytotoxic but 80% are photocytotxic (10 inks analysed)					

*In vitro using microsomal proteins metabolised into 2 metabolites:
2-((2-methoxy-4-nitrophenyl)azo)-N-(2-methoxy-4-hydroxyphenyl)-3-oxobutanamide (2005, Cui)
2-((2-hydroxy-4-nitrophenyl)azo)-N-(2-methoxy-4-hydroxyphenyl)-3-oxobutanamide (2005, Cui)

In general, experimental results both confirmed the cleavage of the azo bond and proved that the decomposition of colorants under irradiation continues further on, for example with the loss of amino or nitro groups, with the formation of other substances some of which show CMR properties. Considering this, it would be extremely important to take the full decomposition pathway, also under irradiation, in consideration when carrying out the risk assessment of a colorant for tattoo and PMU applications.

Papers in the literature pointed out that the initial quantity of ink injected in human skin during tattooing processes decreases over time. For instance, Engel et al. (2009) carried out animal experiments (with SKH-1 mice) that proved that one third of this quantity disappears from skin within six weeks after tattooing. In addition, in the same model they also proved a 60 % decrease in pigment concentration after 32 days of solar radiation and 51 % decrease after laser irradiation. The photodecomposition of pigment red 22 was confirmed by the identification of some decomposition products after extraction of the skin. However, the transport of pigment to other places in the body, for example via the lymphatic system, cannot be excluded and needs to be further studied to see whether it contributed to sharp decrease in pigment concentration. Recently, Lehner K. et al. (2011b) showed that red tattoo colorants are transported away from skin in the months and years after tattooing. They analysed nine human tattooed skin specimens and estimated a decrease in concentration in the range of 87-99 %.

Ferguson J. et al. (1997) showed that pigment particles are found in the cytoplasm of cells in secondary lysosomes (membrane-bound structures). Also macrophages may contain pigment particles. Cui Y. et al. (2005) suggested that the mechanisms for tattoo fading may include: 1) the dispersion of pigments in the skin; 2) their phagocytosis and consequent removal; 3) the occurrence of their metabolism in the skin; 4) the photochemical degradation of pigments, as reported by Vasold et al. (2004) for pigment yellow 74. According to Bäumler W. (2015), the concentration of pigments initially deposited into the derma may be reduced by three major mechanisms. 1) the bleeding occurring during or immediately after the tattooing process; 2) the transportation through the lymphatic or blood vessel systems; 3) the photodecomposition of colorants due to sunlight, UV or laser radiation.

Even though insoluble pigments are injected as solid particles and are meant to stay in the derma, a number of studies pointed out that a fraction of them actually may be removed from the skin through the lymphatic and/or the blood vessel systems. However, until now only the transport of tattoo colorants to the lymph nodes have been proved. In particular, experimental results showed that tattoo colorants can be found in lymph nodes near the tattoo area (2014, Lehner et al.; 2014, Soran A. et al.; 2013, Balasubramanian I. et al.; 2013, Yactor A. R. et al.; 2008, Peterson S. et al; 2009, Jaigirdar, A. et al.; 2008, Dominguez E. et al.; 2004, Honegger M. et al.; 2001, Moehrle M. et al.).

Hypothetically, pigments in the form of large particles should not be able to be transferred to the lymph nodes and therefore should remain in the derma. However, some processes, like light-induced decomposition, could be able to decrease the size of particles and could therefore help their mobilisation in the body. Enzymatic processes and activation of macrophages could also contribute to the transport of pigments.

Finally, it should not be neglected the fact that not only colorants but also impurities, by-products and additives could be transported away from the skin. In this view, the fate of toxic substances, such as polycyclic aromatic hydrocarbons, primary aromatic amines and heavy metals is of course a concern.

What ultimately happens *in vivo* and the extent to which degradation products are produced and transported in the body will depend on the type of exposure the tattoo undergoes. Whereas tattoo exposure to sunlight irradiation is likely to lead to continuous, low-level production of degradation compounds (possibly comparable to degradation by enzymes), tattoo laser irradiation is likely to release a momentary, high-level spike (probably comparable to concentration spikes of pigment impurities when a tattoo ink is injected into the body). Independent of the irradiation source to which the tattoo is being exposed, it is likely that some degradation products and their *in vivo* effects are produced (2015, Hauri et al.).

Table 4.34: List of decomposition products identified from colorants under laser irradiation, with the indication of the recommendations deriving from the CoE ResAP(2008)1.

CI Generic Name	Irradiation with laser	CAS	PAA	CoE ResAP (2008)1 Table 1	EC Reg 1223/2009 Annex II	EC Reg 1272/2008 Table 3.1
PY 14	3,3'-dichlorobenzidine	91-94-1	Y	X	X	X (Carc. 1B, Skin Sens. 1)
PY 83	3,3'-dichlorobenzidine	91-94-1	Y	X	X	X (Carc. 1B, Skin Sens. 1)
PY 97	aniline	62-53-3	Y		X	X (Carc. 2, Muta. 2, Eye Dam. 1, Skin Sens. 1)
PO 13	3,3'-dichlorobenzidine aniline	91-94-1 62-53-3	Y Y	X	X X	X (Carc. 1B, Skin Sens. 1) X (Carc. 2, Muta. 2, Eye Dam. 1, Skin Sens. 1)
PR 9	In vitro decomposition products: 2,5-dichloroaniline 1,4-dichlorobenzene methoxy-naphthol AS Extraction from skin after laser treatment: 2,5-dichloroaniline 1,4-dichlorobenzene	 95-82-9 106-46-7 95-82-9 106-46-7	 Y N N Y N		 X X	 X (Carc. 2, Eye Irrit. 2) X (Carc. 2, Eye Irrit. 2)
PR 22	In vitro decomposition products: 5-nitro-o-toluidine 4-nitrotoluene naphthol AS Extraction from skin after laser treatment: 2-methyl-5-nitroaniline 4-nitrotoluene	 99-55-8 99-99-0 92-77-3 99-55-8 99-99-0	 Y N N Y N	 X X	 X X	 X (Carc. 2) X (Carc. 2)

4.4. RAPEX notifications and market surveillance

4.4.1. RAPEX notifications related to tattoo and PMU products

RAPEX (Rapid alert system for dangerous non-food products) is a rapid alert system that enables quick exchange of information among 31 European countries and the European Commission about dangerous non-food products posing a risk to health and safety of consumers. During the last ten years 126 RAPEX notifications related to tattoo and PMU inks were identified according to the searching criteria already described in chapter 3.

As shown in Figure 4.21, 120 notifications referred to products posing a chemical risk: 109 were related to tattoo and 11 to PMU inks. Six products (all of them tattoo inks) were found to be potentially dangerous as they entailed a microbiological risk. Many of the 126 notifications referred to inks containing two or more dangerous substances for a total of 188 single compound related alerts. All the microbiological notifications referred to only one potentially dangerous agent.

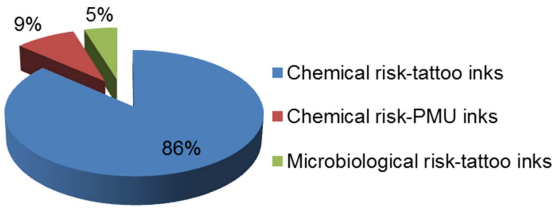


Figure 4.21: Notifications by category of product and type of risk.

Figures 4.22 and 4.23 show the notifications divided respectively by countries and years. The majority of notifications were done after 2012 and the most active countries in notifying dangerous products on the market are Germany and Italy.

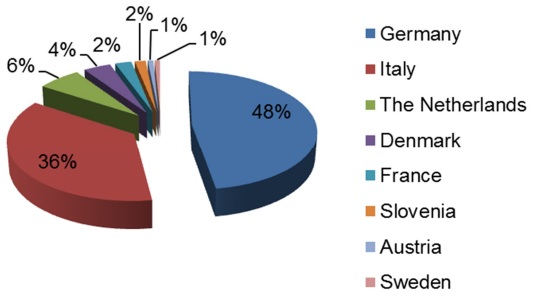


Figure 4.22: Notifications by notification country.

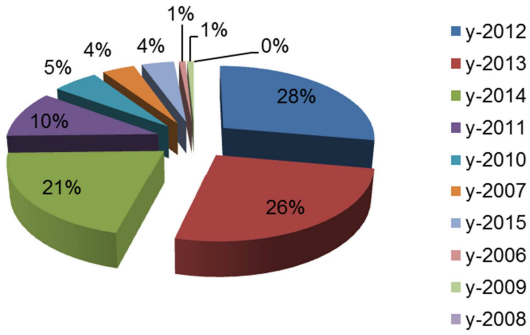


Figure 4.23: Notifications by year.

Figures 4.24 and 4.25 describe the notifications ordered by country of production and brand names. 67 % of the products identified in RAPEX notifications were produced in the United States and this is consistent with the fact that the majority of the dangerous inks mentioned in RAPEX system were US products, such as for example Intenze (35 %), Eternal ink (21 %) and Starbrite 2 (8 %).

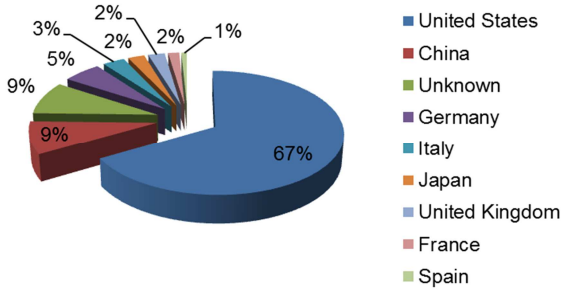


Figure 4.24: Notifications by product country of origin.

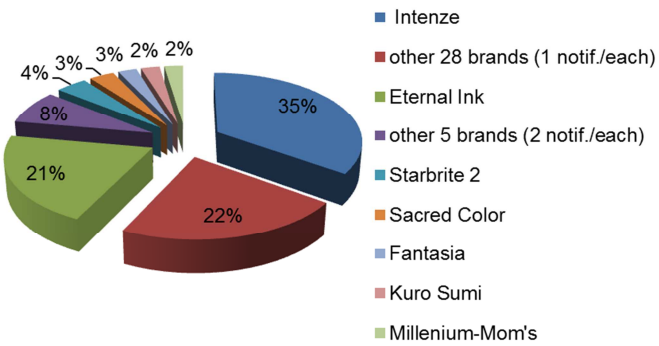


Figure 4.25: Notifications by brand names.

As it can be seen in Figure 4.26, the alerts were classified also according to the measures taken in each country after the identification of the dangerous product. Different typologies of actions were taken, ranging from the voluntary recall from the market by the importer to the destruction of the product ordered by the authorities. Withdraw from the market was the most common measure taken (35 %) followed by the ban on the marketing of the product (29 %).

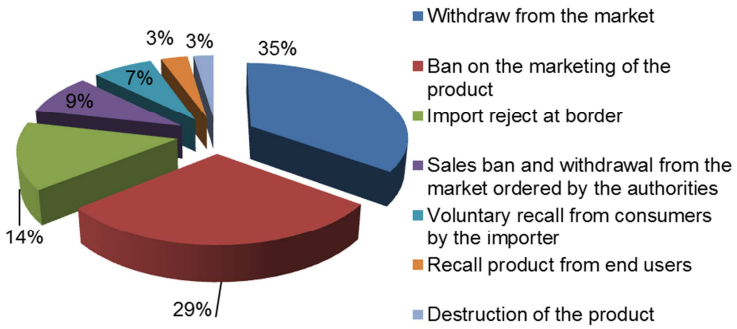


Figure 4.26: Notifications by measure/action taken.

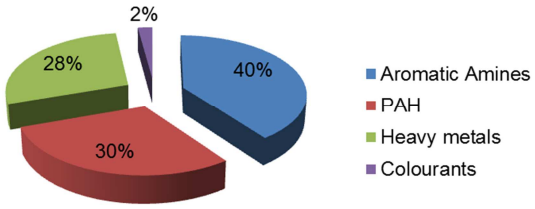


Figure 4.27: Notifications by chemical class.

Table 4.35: Summary of RAPEX chemical notifications (nr 188).

Substance	Nr. Not.	%	Conc. mg/kg	CoE ResAP limit mg/kg	Notifications/year
PAH (total)	34	18	0.5-96.5	0.5	6 (2011), 7 (2012), 14 (2013), 6 (2014), 1 (2015)
Benzo[a]pyrene	18	10	0.02-0.6	0.005	4 (2011), 1 (2012), 10 (2013), 3 (2014)
Naphthalene	3	2	4.4-4.8	0.5	2 (2013), 1 (2014)
Styrene	1	1		0.5	1 (2012)
PAA (in general)	3	2	-	banned	2 (2007), 1 (2014)
3,3'-Dichlorobenzidine	5	3	710	banned	1 (2010), 3 (2011), 1 (2013)
2-Ethoxyaniline	2	1		-	2 (2012)
4-Methyl-m-phenylendiamine	12	6	3.4-5521	banned	1 (2007), 3 (2013), 7 (2014), 1 (2015)
5-Nitro-o-toluidine	3	2	41	banned	1 (2010), 1 (2013), 1 (2014)
Aniline	5	3	-	banned	5 (2011)
o-Anisidine	33	18	4-1753	banned	1 (2007), 4 (2010), 4 (2011), 20 (2012), 2 (2013), 2 (2014)
o-Toluidine	12	6	8.7-120	banned	4 (2010), 2 (2012), 4 (2013), 2 (2014)
Arsenic (As)	8	4	3.1-123	2	1 (2012), 1 (2013), 5 (2014), 1 (2015)
Barium (Ba)	9	5	72-7800	50	5 (2013), 4 (2014)
Cadmium (Cd)	4	2	0.3-1.7	0.2	3 (2012), 1 (2013)
Chromium (Cr) (VI)	2	1	61-83	0.2	1 (2013), 1 (2014)
Copper (Cu) soluble	2	1	163-4310	25	2 (2014)
Lead (Pb)	7	4	2.4-15.7	2	7 (2014)
Nickel (Ni)	19	10	12.2-9690	-	5 (2012), 4 (2013), 8 (2014), 2 (2015)
Zinc (Zn)	1	1	518	50	1 (2014)
Zirconium (Zr)	1	1	1170	-	1 (2013)
(CI 77260)	1	1	-	-	1 (2014)
Pigment Orange 13 (CI 21110)	1	1	-	-	1 (2014)
Pigment Red 210 (CI 12477)	1	1	-	-	1 (2014)
Pigment Yellow 65 (CI 11740)	1	1	-	-	1 (2014)

With regards to the chemicals, the majority of notifications were related to primary aromatic amines (40 %), followed by polycyclic aromatic hydrocarbons (30 %) and

heavy metals (28 %), as shown by Figure 4.27. Table 4.35 summarises the chemical related notifications: data are presented by chemical class and within them by chemical compound with the indication of number of notifications and percentages. The range of concentration and the limit, if present in CoE ResAP(2008)1, are also indicated. In addition, notifications for each compound were divided by year to highlight possible trends.

According to the CoE ResAP(2008)1, the primary aromatic amines listed in its Table 1 should neither be present nor be released in tattoo and PMU inks. These PAAs can be found in tattoo and PMU inks as impurities, in the form of free primary aromatic amines, or can derive from the reductive cleavage of azo-colorants (see section 4.3.4.). The primary aromatic amines mentioned in Table 1 pose a serious risk to consumers due to their properties as CMR and skin sensitizing substances.

The concentrations measured during market surveillance activities ranged between 3.4 and 5521 mg/kg and the most frequently detected PAA was o-anisidine (33 notifications), followed by 4-methyl-m-phenylendiamine (12) and o-toluidine (12).

PAHs may be present as impurities in black and dark coloured tattoo and PMU inks. PAHs pose serious risk for consumer health and safety as they are classified as carcinogenic compounds and listed in Annex VI Table 3.1 of CLP Regulation. Maximum concentrations for PAHs are set in Table 3 of the CoE ResAP(2008)1: the recommended limit for the sum of PAHs is set at 0.5 mg/kg and for benzo[a]pyrene at 0.005 mg/kg. The measured levels of total PAHs varied between 0.5 and 96.5 mg/kg, while for benzo[a]pyrene between 0.02 to 0.6 mg/kg.

Table 3 of the CoE ResAP(2008)1 lists also the limits of some metals that can be found as impurities in tattoos and PMU inks. In this Table, no threshold is specifically indicated for nickel, instead it is stated that Ni can be present only in levels "as low as technically achievable". Ni may be present in some inorganic pigments (such as iron oxides) mostly used in PMU products, as they give natural nuances to these inks not too bright like organic pigments mostly used in tattooing.

The limit reported for copper is not related to the total content, but to the soluble part at pH 5.5. At this pH, copper contained in green and blue phtalocyanines is stably linked to the pigment and thus not releasable, allowing the use of this class of colorants in inks for tattooing. 28 % of the notifications were related to heavy metals and in particular to As, Ba, Cd, Cr(VI), Cu (soluble), Pb, Ni and Zn found in tattoo or PMU inks. Notifications reported that Ni, Ba and Cu (soluble) concentrations reached 9690, 7800 and 4310 mg/kg, respectively.

Table 4.36 shows the notifications related to microbiological risk; mainly due to the non-sterility of the ink packages before opening. In some samples high levels of some species of Staphylococcus and Pseudomonas were isolated.

Table 4.36: Summary of RAPEX microbiological notifications (nr 6).

Year	Notifying country	Product	Brand	Country of origin	Risk description
2006	FR	Tattoo ink	Intenze	US	Staphylococcus warneri/Moraxella spp
2007	DE	Tattoo ink	Eternal Ink	US	High aerobic mesophile bacteria count
2007	NL	Tattoo ink	Euro Sumi	UK	Pseudomonas spp
2009	NL	Tattoo ink	Eternal Ink	US	Pseudomonas spp
2010	IT	Tattoo ink	Starbrite 2	US	No guarantee of preserving the sterility of the pigment
2015	DE	Tattoo ink	Energy Ink	DE	High aerobic mesophile bacteria count

4.4.2. Market surveillance in Member States and results of test analysis from other sources

DG JRC gathered information from market surveillance actions carried out by some Member States, national studies, peer reviewed articles, books and presentations given

during the meetings of the CSN-STPM. An exhaustive list of all the documents processed for this purpose is available in the list of references. The data included in the mentioned documents are reported in Annex V.

The main problems identified by market surveillance authorities regarding tattoo and PMU inks are, in line with the RAPEX notifications, the presence of impurities such as PAHs, PAAs and heavy metals.

Among the national surveys and market surveillance activities considered, the most significant ones in terms of number of analysed samples were the studies done in the Netherlands, Germany, Switzerland and Italy. The most studied classes of impurities were PAHs, PAA and heavy metals, while preservatives were monitored only in a few campaigns.

In particular, in the Netherlands in the last ten years more than 3000 samples have been analysed for azo-dyes, preservatives and heavy metals (2008, Nederlandse Voedsel en waren autoriteit; 2014, Nederlandse Voedsel en waren autoriteit; 2015, Nederlandse Voedsel en waren autoriteit). PAAs, PAHs, heavy metals, nitrosamines and preservatives were the focus of German campaigns conducted between 2007 and 2014 in about 1000 inks (P 2015, Mildau, Blume; 2013, BVL; 2007, BVL). In Switzerland, between 2009 and 2014, about 600 samples of tattoo and PMU inks were analysed for the presence of PAAs, PAHs, nitrosamines, preservatives and pigments (2014, Hauri). In the market surveillance campaigns conducted in Italy in 2007 - 2014 overall about 300 tattoo and PMU inks were examined for the content of heavy metals, PAAs and PAHs (P 2015, Bocca; P 2015, Fontana).

Tables 4.37-4.40 provide a summary of the test analysis results divided by the different chemical classes and give an overview of the situation on the European market. The Tables report the total number of samples analysed for each substance mentioned in all the considered documents, the number of samples with concentration higher than the recommended one (if available) reported in the Tables as non-compliant, the recommended limit of the CoE ResAP(2008)1 (if present) and the range of concentrations measured.

On the basis of the results of different market surveillances, national studies and peer reviewed articles (2013a, Høgsberg; 2010, Regensbuger), 155 inks corresponding to 43 % of those analysed for PAHs, contained more than 0.5 mg/kg of PAHs expressed as total content. Speaking about benzo[a]pyrene, 24 % of the analysed samples (72 inks) contained this substance in levels higher than the recommended limit of 0.005 mg/kg (Table 4.37). These results show that it is technically possible to produce carbon black based inks that do not contain high levels of PAHs. This is of particular importance considering that among PAHs not only benzo[a]pyrene is classified as CMR substance, according to the EC Regulation 1272/2008, but also others PAHs found in tattoo and PMU inks, such as benzo[a]anthracene, benzo[b]fluorantene, benzo[j]fluorantene, benzo[k]fluorantene, chrysene, dibenzo[a,h]anthracene and naphthalene.

A recent study by Lehner (2014) describes test methods for the *in vivo* detection and quantification of PAHs after their extraction from black tattooed skin and lymph nodes. The level of PAHs found varied from 0.1 to 0.6 mg/cm^2 in the tattooed skin and from 0.1 to 11.8 mg/kg in lymph nodes. The fact that these compounds were detected in lymph nodes after some time after tattooing demonstrates that pigments do not remain in the skin, but can migrate into the body, in particular into lymph nodes.

Table 4.37: PAHs presence in tattoo and PMU inks.

Substance	CAS nr	Number of analysed samples	% non compliant samples	ResAP (2008)1 limit (mg/kg)	Range (min-max) (mg/kg)
PAH (total)		358	43 (155)	0.5	0.5-55000
Benzo[a]pyrene	50-32-8	295	24 (72)	0.005	0.005-6.8
Acenaphthene	83-32-9	46			0.12-0.90
Acenaphthylene	208-96-8	30			0.005-14.5
Anthracene	120-12-7	50			0.001-3.3
Benzo(a)anthracene	56-55-3	30			0.005-1.60
Benzo(b)fluoranthene	205-99-2	46			0.073-4.50
Benzo(ghi)perylene	191-24-2	34			0.008-1.2
Benzo(j)fluoranthene	205-82-3	16			
Benzo(k)fluoranthene	207-08-9	46			0.03-0.40
Chrysene	218-01-9	30			0.006-1.70
Dibenzo(a,h)anthracene	53-70-3	30			0.1-1.1
Fluoranthene	206-44-0	50			0.01-2.80
Fluorene	86-73-7	46			0.006-0.90
Indeno(1,2,3-cd)pyrene	193-39-5	46			1.1
Naphthalene	91-20-3	70			0.005-0.44
Phenanthrene	85-01-8	50			0.005-24.5
Pyrene	129-00-0	50			0.055-202.5

Table 4.38: PAAs presence in tattoo and PMU inks.

Substance	CAS nr	Number of analysed samples	% non compliant samples	ResAP (2008)1 limit (mg/kg)	Range (min-max) (mg/kg)
PAA (total)		3283	14 (468)		0.1-68
4-Aminoazobenzene	60-09-3			0	>0
Aniline	62-53-3			0	5-61
o-Anisidine	90-04-0	3655	10 (347)	0	0.52-2197
Benzidine	92-87-5			0	>0
Biphenyl-4-ylamine	92-67-1			0	>0
4-Chloroaniline	106-47-8	2958	2 (61)	0	1.1-691
4-Chloro-o-toluidine	95-69-2	43	1 (2)	0	5.9-15
3,3'-Dichlorobenzidine	91-94-1	3647	2.4 (91)	0	1.0-4758
3,3'-Dimethoxybenzidine	119-90-4	827	0.5 (2)	0	20-26
3,3'-Dimethylbenzidine	119-93-7	829	0.1 (1)	0	>0
4-Methoxy-m-toluidine	120-71-8			0	>0
4,4'-Methylenbis(2-chloroaniline)	101-14-4			0	>0
4,4'-Methylendianiline	101-77-9			0	>0
4,4'-Methylendi-o-toluidine	838-88-0			0	>0
4-Methyl-m-phenylendiamine	95-80-7	3516	2.5 (85)	0	10-6900
2-Naphthylamine	91-59-8	19	5 (1)	0	2.6
5-Nitro-o-toluidine	99-55-8	2129	1.2 (27)	0	9-285
4,4'-Oxydianiline	101-80-4			0	>0
p-Phenylenediamine	106-50-3	29	3 (1)	0	8
4,4'-Thiodianiline	139-65-1	100	1 (1)	0	>0
o-Toluidine	95-53-4	3675	5 (184)	0	1.1-2197
2,4,5-Trimethylaniline	137-17-7			0	>0
2,4-xylidine	95-68-1	120	1 (1)	0	>0

Data on table 4.38 show that a large number of tattoo/PMU samples were analysed for PAAs content in the last years in surveillance campaigns all over Europe. The measured PAAs, with the exception of aniline, are all listed in Table 1 of the CoE ResAP(2008)1 and therefore should not be present in those articles. Despite this, a significant number of commercially available products contained carcinogenic primary aromatic amines and were then reported as non-compliant in Table 4.38. In particular, the following substances were detected: o-anisidine (10 % out of 3655 samples analysed), 4-chloroaniline (2 % out of 2958), 3,3'-dichlorobenzidine (2.4 % out of 3647), 4-methyl-m-phenylendiamine (2.5 % out of 3516), o-toluidine (5 % out of 3675), 5-nitro-o-toluidine (1.2 % out of 2129). The measured concentrations ranged from 0.1 to 6900 mg/kg.

Table 4.39 summarises the results of elements' analysis. With the exception of soluble copper, the reported concentrations refer to the total content of the element after complete digestion of the samples, as set in the CoE ResAP(2008)1. The data related to

the elements mentioned in Table 3 of the CoE ResAP(2008)1 are reported in the upper part of the table; whereas other elements found during the measurement campaigns are listed in the lower part (from aluminium on).

Table 4.39: Metals present in tattoo and PMU inks.

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

Substance	CAS nr	Number of analysed samples	% samples containing the element	ResAP (2008)1 limit (mg/kg)	Range (min-max) (mg/kg)
Aluminium (Al)	7429-90-5	117			1.8-11000
Chromium (Cr)	7440-47-3	1372			0.01-2038
Copper (Cu)	7440-50-8	227	31 (71)		0.1-49500
Iron (Fe)	7439-89-6	25	100 (25)		1.7-785
Manganese (Mn)	7439-96-5	76			0.02-98.8
Strontium (Sr)	7440-24-6	31	32 (10)		0.174-120
Thallium (Tl)	7440-28-0	172	3 (5)		0.003-0.2
Titanium (Ti)	7440-32-6	56			1-1.5*10^5
Uranium (U)	7440-61-1	168	3 (5)		0.01-0.2
Vanadium (V)	7440-62-2	56			0.01-11

In the case of metals, the percentages of samples showing concentrations higher than the recommended ones were the following: Sb (7% out of 932 samples analysed), As (5% out of 1164), Ba (20% out of 886), Cd (5% out of 1863), Co (4% out of 350), soluble Cu (32% out of 283), Pb (8.5% out of 2175), Hg (2.5% out of 809), Se (17% out of 166), Sn (1.4% out of 277), Zn (21% out of 459).

It was not possible to estimate the percentage of samples containing too high levels of Ni and Cr(VI). The CoE ResAP(2008)1 defines a recommended limit for Cr(VI) but not for the total content of chromium, nevertheless many studies reported the total concentration instead of the one of Cr(VI). Hexavalent chromium can be an impurity of some inorganic pigments, such as chromium oxides, that are produced from the reduction of Cr(VI) to Cr(III), thus a good speciation is crucial to succeed in evaluating the level of Cr(VI).

As already mentioned, according to the EC Regulation 1272/2008, nickel is classified carcinogenic (category 2) and skin sensitizer and it may be present as impurity in tattoo and PMU inks based on iron oxide pigments. The presence of Ni may pose an allergy risk to tattooed people, particularly considering that even low concentrations (below 1 mg/kg) can originate heavy reactions in already sensitised persons. Iron oxide based pigments are mainly used in black, red, yellow and brown inks and a way to avoid potential harmful consequences due to the presence of Ni could be their substitution with organic colorants in the manufacturing process of inks.

Also mercury (classified as reprotoxic category 2 in the CLP Regulation) can be an impurity deriving from inorganic pigments. In the past, mercury sulphide (HgS, cinnabar) was used in the production of red pigments. Lead is neurotoxic even at very low concentrations.

N-nitrosamines, specifically N-Nitrosodiethanolamine and N- Nitrosodimethylamine, were found in some tattoo/PMU products (2014, Hauri). These are impurities coming from raw materials used in the formulation of inks. They are both classified as carcinogenic substances in category 1B (probable human carcinogen) and the CoE ResAP(2008)1 recommends they should not be present in tattoo/PMU inks.

Some phthalates were detected in tattoo/PMU inks (2013, Høgsberg; 2011a, Lehner). They are potentially endocrine disruptors, they are mainly used as plasticizers and might migrate from the container into the product to be used for tattooing.

The CoE ResAP(2008)1 allows the use of preservatives in tattoo/PMU articles only to prevent contamination after the opening of the product package, however this Resolution did not lay down neither a positive nor a negative list of these substances. Some national legislation (i.e Norway and Switzerland) foresee a positive list of preservatives and corresponding limits of concentrations. In The Netherlands the use of any preservative is forbidden. In the Dutch and Swiss studies (2008, Nederlandse Voedsel en waren autoriteit; 2014, Hauri) a large number of tattoo/PMU samples were analysed for the presence of preservatives. As reported in Table 4.40, benzoisothiazolinone was found in 24 % out of 229 analysed samples, methylisothiazolinone in 8 % out of 229 and formaldehyde (7 % out of 229).

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

Chemical class	Substance	CAS nr	Number of analysed samples	% non compliant samples	Range (min-max) (mg/kg)
Preservatives	Preservatives (total)		2060	7 (127)	>0.01%
Preservatives	Benzoic Acid	65-85-0	2289	3 (67)	0.05-0.12%
Preservatives	Benzoisothiazolinone (BIT)	2634-33-5	229	24 (55)	30-424
Preservatives	Dehydroacetic Acid	520-45-6	229	3 (5)	0.038-0.089%
Preservatives	Formaldehyde	50-00-0	229	7 (15)	0.005-0.035%
Preservatives	DMDM hydantoine	6440-58-0	229	3 (7)	not quantified
Preservatives	Ethyl-p-Hydroxybenzoate	120-47-8	556	0.1 (1)	>0.01%
Preservatives	Isobuthyl-p-Hydroxybenzoate	94-26-8	556	0.1 (1)	>0.01%
Preservatives	Methyl-p-Hydroxybenzoate	99-76-3	2060	1.5 (28)	>0.01%
Preservatives	Propyl-p-Hydroxybenzoate	94-13-3	1385	1.6 (23)	>0.01%
Preservatives	p-Hydroxybenzoate	456-23-5	1504	1.4 (22)	>0.01%
Preservatives	Methylchloroisothiazolinone (MCI)	26172-55-4	229	2 (5)	1.1-1.5
Preservatives	Methylisothiazolinone (MI)	2682-20-4	229	8 (18)	0.42-70
Preservatives	Sum MI/MCI	26172-55-	229	2 (5)	2.3-2.7
Preservatives	Phenol	108-95-2	229	3 (6)	0.008-0.47%
Preservatives	2-Phenoxyethanol	122-99-6	2289	2 (46)	0.01-0.80%
Preservatives	o-Phenylphenol	90-43-7	229	1 (2)	0.084-0.11%
Preservatives	Salicylic Acid	69-72-7	829	1 (8)	>0.01%
Preservatives	Sorbic Acid	110-44-1	1058	0.4 (4)	0.05-0.076%
N-nitrosamine	Nitrosodiethanolamine	1116-54-7	229	6 (14)	0.012-66.700
N-nitrosamine	Nitrosodimethylamine	62-75-9	229	0.4 (1)	0.026
Phthalates	Dibutyl phthalate (DBP)	84-74-3	25		0.12-691.2
Phthalates	Di-(2-ethylhexyl) phthalate (DEHP)	117-81-7	11		0.2-19.3

In a recent survey conducted in Switzerland (2014, Hauri), pigment orange 5 (CI 12075) and pigment red 53 (CI 15585) were detected in some samples. These colorants should not be present in tattoo inks, according to Table 2 of the CoE ResAP(2008)1.

The most common issue related to the microbiological risk of tattoo and PMU inks, as already highlighted by RAPEX notifications, is the non-sterility of the product either before the opening or after. In some cases the products were not only contaminated by aerobic mesophilic microorganisms, but also by pathogens for humans as certain species of Pseudomonas, Staphylococcus, Streptococcus and Enterococcus. Out of more than 3800 products analysed (unopened or in use ink bottles), about 11% were contaminated and not sterile as recommended by the CoE ResAP(2008)1 and national laws/guidelines when present. Summary results are shown in Table 4.41.

Table 4.41: Microbiological contamination in tattoo and PMU inks.

Microbiological agent	Number of samples	% Non compliant samples	Limit	Results (cfu/g)	Reference
Contamination	3852	11 (446)	sterility	15-1.5*10^5	
Contamination	145	31 bacterial species (64.5% Gram-positive rods, 25.8% Gram-positive cocci, 9.7% Gram-negative rods)	sterility	10^1 - 10 ^8 cfu/ml	2011, Baumgartner
P.aeruginosa	15	6 (1)	sterility	1.5*10^5	2011 (b), Health Canada
yeasts/moulds	15	12 (2)	sterility	15-1000	2012 (b), Health Canada
Pseudomonas sp. Aeromonas sp. Staphylococcus sp. Enterococcus faecium Streptococcus sanguinis Streptococcus salivarius Acinetobacter sp.	58 (sealed) 6 (opened)	10 (6) 17 (1)	sterility	100-650 bacteria/ml	2013, Høgsberg

It is important to underline that the majority (90 %) of the analyses considered in this report were done on tattoo inks and 10% on permanent make-up inks.

A common problem mentioned by the different studies is the presence of fake inks on the market. These products have counterfeit names and manufacturers, false batch numbers and an incorrect list of ingredients. An inaccurate chemical composition of inks was observed in 33 % of the samples collected in 2010 by the German regional authorities; the same issue was highlighted as well by the Slovenian and Swiss competent authorities. In Italy, campaigns carried out between 2009 and 2014 found that all samples failed to mention the presence of Ni and Cr, as requested by the CoE ResAP(2008)1,even though nickel was present in almost all samples.

Table 4.42: DMEL, DNEL, LOAEL, NOAEL and TDI values calculated by the Danish EPA for some potentially harmful chemicals in tattoo and PMU inks.

Chemical class	Substance	CAS nr	DMEL (ng/kgbw per day)	DNEL (mg/kgbw per day)	LOAEL (mg/kgbw per day)	NOAEL (mg/kgbw per day)	TDI (mg/kgbw per day)
PAH	Benzo[a]pyrene	50-32-8	0.6-5				
PAA	Aniline	62-53-3	20	0.02	7		
PAA	o-Anisidine	90-04-0	40	0.03		16	
PAA	o-Toluidine	95-53-4		0.01	25		
element	Aluminium (Al)	7429-90-5		0.2	50		
element	Barium (Ba)	7440-39-3		0.02		0.21	0.021
element	Cadmium (Cd)	7440-43-9		0.0002	0.0006	1	0.0004
element	Lead (Pb)	7439-92-1		5*10^-5			
element	Nickel (Ni)	7440-02-0		0.0055		1.1	0.0055
Phthalocyanine	Cu-phthalocyanine	147-14-8		2		200	

A qualitative risk assessment for some of the potentially harmful chemicals found in tattoo and PMU inks was performed in Denmark and presented in a study conducted by the Danish Environmental Protection Agency (2012b, Danish EPA). DNEL (Derived No Effect Level)[4], DMEL (Derived Minimal Effect Level) [5], LOAEL (Lowest Observed Adverse Effect Level)[6], NOAEL (No Observed Adverse Effect Level)[7] and TDI (Tolerable Daily Intake)[8] values were calculated according to the method described in this document. The

[4] DNEL is the level of exposure to a substance above which humans should not be exposed.
[5] DMEL represents an exposure level where the likelihood that the identified adverse effect occurs in a population is sufficiently low to be of no concern.
[6] LOAEL is the lowest concentration or amount of a substance that causes an adverse alteration in a target organism.
[7] NOAEL is the level of exposure of an organism at which there is no significant alteration in an organism.
[8] TDI is an estimate of the amount of a substance that can be taken in daily over a lifetime without appreciable health risk.

estimated values for benzo[a]pyrene, aniline, o-anisidine, o-toluidine, aluminium, barium, cadmium, lead, nickel and Cu-phthalocyanine are reported in Table 4.42.

5. Conclusions

The conclusions of the EC project "Tattoos - Permanent Make-up" Work Package 2 is outlined hereunder.

Tattoo and PMU presence and market

- On the basis of the available information and data from 14 Member States the tattoo prevalence in the general population in Europe is estimated at 12 % and at more than 20 % in the United States. Higher prevalence, up to almost the double, was reported in the young population. Moreover, the prevalence in adolescents (younger than 18 years old) is not negligible and for example in Italy it has been estimated at around 8 %. In the past the tattoo prevalence in men was higher than in women, nowadays this is not always the case, especially in young generations.
- The size of tattoos varies (small ≤ 30 cm^2, medium = 30 – 300 cm^2, large ≥ 300 cm^2) and often women's tattoos are smaller than men's ones. In the general population, usually the majority of individuals have more than one tattoo; women mostly between 2 and 3 and men 4 or more. The most frequent tattoos are single black coloured (50-60 %), with an average concentration of pigment used of 2.5 mg/skin cm^2.
- The frequency of persons regretting having made a tattoo varies between 4-20 % and the one of people undergoing removal between 1-20 %. Two thirds of those doing so are satisfied with the results.
- Most of the tattoo inks found on the EU market is imported from the US, while PMU inks are generally manufactured in Europe. Germany, Italy, Spain and the United Kingdom are the main EU manufacturers of tattoo/PMU inks.
- In many European countries, the official tattoo artists have created associations to share good practices and knowledge. However there is a growing phenomenon of illegal "home tattooists" working outside any association or control and tattooing under non-hygienic conditions using unsafe and cheap inks and equipment who might represent up to 10 times the number of registered service providers.

Chemical composition of tattoo/PMU inks

- Tattoo and PMU inks are chemical mixtures containing several ingredients, plus additives and impurities. Colorants are the main ingredients of tattoo and PMU inks (up to 60% of the weight); while additives are usually in concentration lower than 5% by weight, with some exceptions. More than 100 colorants and 100 additives have been reported as being used in tattoo or PMU inks.
- The tattoo ink market is relatively small considering the global production of colorants. Pigments used in tattoo and PMU products are not specifically produced for such purposes (but for textile, car or plastic applications) and they generally lack high purity standards. This problem had already been highlighted by the JRC Report of 2003 and remains unsolved since then. Moreover, companies manufacturing them are generally reluctant to take the responsibility for their products being used as tattoo ink colorants; they may even refuse to sell their products to tattoo ink formulators/manufacturers.
- Organic pigments represent over 80% of the colorants in use, more than 60% of them are azo-pigments. 25% of the azo-colorants in use in tattoo and PMU inks can release carcinogenic PAA via cleavage of azo bond(s), this can also happen after solar exposure and UV or laser irradiation.
- More than half of the tattoo and PMU colorants are not allowed as ingredients in cosmetic products (that is they are not listed in Annex IV of the Cosmetic regulation) and several should not be present according to the CoE ResAP(2008)1.

- By large, carbon black is the most used pigment in tattoo and PMU inks.
- Specific impurities are frequently present in different colorants, for instance: chromium VI in chromium oxides; nickel, chromium, copper and cobalt in iron oxides; aromatic amines in azo-colorants; and polycyclic aromatic hydrocarbons in carbon black.
- The initial quantity of ink injected into human skin during tattooing processes decreases over time through pigment photodecomposition and transport via the lymphatic or blood systems. This proven migration of the chemicals into the body cannot exclude possible systemic undesirable effects by certain CMRs and sensitizers substances such as PAA, PAHs and heavy metals.

RAPEX and market surveillance results

- Products containing e.g. PAA, PAHs and metals not in line with the CoE ResAP(2008)1 recommendations and Member States national legislations have been found in the European market. However, it is technically feasible to produce inks not containing hazardous chemicals as proved by the presence on the market of compliant products.
- Among the 126 RAPEX notifications on tattoo and PMU inks that have been reported in the last decade, 86 % raised concern with regard to chemical risks related to tattoo inks, and 9 % to PMU inks. Microbiological risks were found in 5 % of the notifications.
- Two thirds of the products notified to RAPEX were imports coming from the United States.
- Tattoo market issues include pigment suppliers not complying with labelling and chemical requirements, expired and contaminated (not-sterile) tattoo inks, unknown chemical composition, presence of impurities, counterfeit products and insufficient control on web sales.

6. References

6.1 Literature and national reports

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List of abbreviations

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

AATCC	American Association of Textile Chemists and Colourists
ART	Associazionetatuatori.it
ATEC	Associazione Tatuaggio Estetico e Correttivo (Italy)
BfR	Federal Institute for Risk Assessment (Germany)
BVT	Bundesverband Tattoo e. V. (Germany)
BVL	Federal Office of Consumer Protection and Food Safety, Germany
CEN	European Committee for Standardization
CICN	Colour Index Constitution Number
CLP	Classification, Labelling and Packaging (Regulation (EC) No 1272/2008)
CMR	Carcinogenic, Mutagenic and Reprotoxic substances
CNA	Confederazione Nazionale Artigianato (Italy)
CoE	Council of Europe
CoE ResAP	Council of Europe Resolution
CSN	Consumer Safety Network
CSN-STPM	Consumer Safety Network Subgroup Tattoos and Permanent Make-up
CSS	Consiglio Superiore di Sanità
DG JRC	Directorate General Joint Research Centre
DG JUST	Directorate General Justice and Consumers
DG SANCO	Directorate General Health and Consumers
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EEA	European Economic Area
EFTA	European Free Trade Area
EPA	Environmental Protection Agency (Denmark)
EU	European Union
GMP	Good Manufacturing Practices
GPSD	General Product Safety Directive (Directive 2001/95/EC)
ISO	International Organization for Standardization
KEMI	Swedish National Chemicals Inspectorate
LOAEL	Lowest Observed Adverse Effect Level
MS	Member States
NDELA	N-Nitrosodiethanolamine
NOAEL	No Observed Adverse Effect Level
NTU	Norwegian Tattoo Union
OECD	Organisation for Economic Co-operation and Development

PAA	Primary Aromatic Amine
PAH	Polycyclic Aromatic Hydrocarbon
PMU	Permanent Make-up
ppm	part per million, mg/kg
RAPEX	Rapid Alert System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
SCC	Scientific Committee on Cosmetics
SCCNFP	Scientific Committee on Cosmetics and Non-food Consumer Products
SDC	Society of Dyers and Colourists
SRT	Sveriges Registrerade Tatuerare
TDI	Tolerable Daily Intake
TIME	Tattoo Ink Manufacturers in Europe
TLC	Thin Layer Chromatography
UETA	United European Tattoo Artists
UNTAP	Spanish National Union of Professional Tattooists
VST	Verband Schweizerischer Berufstatowierer (Switzerland)

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Annex I

Meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (20th April 2015)

Minutes of the meeting of the Consumer Safety Network Subgroup Tattoos and Permanent Make-up (Ispra – Italy, 20th April 2015)

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 (PP), 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 JRC-ISPRA site and after giving 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 11.11.2014

The minutes of the meeting of 11.11.2014 were adopted with the following modification suggested by Mr Renzoni of one sentence to point 10: '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'.

3. Update on the European action on the safety of tattoo and permanent make-up inks (Ana Maria BLASS RICO – EC DG JUST)

Mrs Blass Rico explained that the Commission is fully committed to achieving a high level of consumer safety and this includes ensuring the safety of tattoo inks. It was highlighted the importance of this project to collect up to date information and experts' opinion and advice on a comprehensive range of areas related to the tattoo and PMU safety.
The Commission is now considering which action could be appropriate and at which level, an emergency measure under Article 13 of the General Product Safety Directive (GPSD) 2001/95/EC, standalone legislation or even no need for EU action. The high standard rule-making process requires thorough preparation that takes time. The objective is to achieve policy goals in the most efficient way.
In this context, a high level meeting will be held on 6 May to collect the views of Member States and authorities on whether or not there is need for EU level action and how this can be fulfilled, including through the possibility of emergency measure. The German Minister Mr Schmidt and the French authorities have recently written to the Commission expressing their views about the need for EU legislation for tattoo inks. At the high level meeting on 6th of May it is expected that other MS will give their position.
Finally Mrs Blass Rico stressed that the JRC project is independent of the current discussions at political level, but certainly the outcome of this project will further build up the evidence base for the assessment of the possible options to improve the safety of tattoo and PMU inks in the EU.

4. National statistics on tattoos and permanent make-up related data (Paola PICCININI – EC DG JRC)

Mrs Piccinini explained that this meeting was related to the second work package of the project on Tattoo and Permanent Make Up inks. This part of the project aims at collecting data on ingredients of tattoo and PMU inks and to gather information on statistics related to tattoo and PMU products (composition, % of tattooed population, age of first tattoo, number of tattoos/person, tattoo removal %, number of tattoo studies and artists, national tattoo associations, manufacturers, origin of inks volume of sales, market surveillance).
An overview on national statistics on tattoos and permanent make-up related data was presented. Information was collected through questionnaires prepared by the DG JRC (three different ones sent to MS, tattooist and PMU professional associations and manufacturers), a book (Tattooed Skin and Health, 2015, ISBN 978-3-318-02774-7),

national studies, presentations held in previous conferences and papers available in literature.
The questionnaires were developed with open questions (Word-file) and a list of ingredients to be filled in (Excel-file). Manufacturers, tattooist associations, Member States plus CH, IS, LI, NO and other jurisdictions (via OECD) were invited to participate.
The questionnaires were devised to collect information regarding national statistics on tattoos and PMU, national associations and manufacturers, tattoo and PMU inks composition and market of tattoo and PMU products.
Until the meeting, replies to the open questions were received from twenty-two countries (BE, BG, CH, CY, CZ, DE, DK, ES, FR, HU, IS, IT, LI, LU, NL, NO, PL, RO, SE, SI, SK, UK), two jurisdictions (NZ, US), seven tattooist associations (ART, BVT, NTU, SRT, UETA, UNTAP, VST) and two manufacturers (Deep Colours and MT-Derm).

5. Discussion

There was a consensus among participants that the replies to the questionnaires by Member States, manufacturers and tattoo associations were quite representative.
DG JRC invited experts to look at the given list of national studies and to provide as many further documents and information as possible.
In Sweden (but likely in all countries) the majority of tattooist activities are not officially registered and for one registered tattooist there are at least 10 without registration.
Mr Bergstrom reported that in Sweden 98 cases of hepatitis have been recorded since 1997 from not-registered home tattooists and only 2 from regularly registered tattooists.
Mr Baeumler reported that in Germany doctors in general do not state that health problems are linked to tattoos, because in that case their patients would not get any reimbursement from their health insurances. This could influence the statistics on how many adverse health effects are linked to tattoos.
Mr Michel commented that the tattoo inks authorised in Spain are considered of poor quality by the artists due to their inadequate performances and most artists keep using non registered products of better workability available on the European market. He stated that a large number of tattoo inks authorised in Spain are produced by Spanish manufacturers. In his opinion, as a non-resident producer it is nearly impossible to register inks as the registration process is not clear and the requirements are not open to the public. In addition, in the past the authority did ask for animal testing of inks that is not allowed in most countries for this kind of product. According to him, the situation in Spain is an example that certain registration requirements and over regulation could result in the fact that artists keep on working with non-registered products and only keep some registered products on the shelf for control by authorities like it is common use in Spain.

6. Italian experience on control of hazardous substances in tattoo and PMU inks: characterization of heavy metals, aromatic amines and PAH's (Beatrice BOCCA – Italian National Institute for Health and Marco FONTANA-ARPA Piedmont)

Mrs Bocca presented the market surveillance performed in Italy from 2009 on the presence of metals in tattoo and PMU inks.
The analyses have been conducted in Italy by Istituto Superiore di Sanità (ISS, Roma) and Agenzia Provinciale per la Protezione dell'Ambiente (APPA, Bolzano) from 2009 and 2010 respectively. ISS analysed 57 tattoo colours and ARPA 87 tattoo and 17 PMU colours.
In-house developed methods for the determination of metals were used. PMU inks showed to contain lower concentration of metals with respect to tattoo inks. High concentration of Ti, Al, Cu and Ba were found, while Hg and Sb were present in low concentration.
Pb was found in the majority of samples at concentrations many times lower than the CoE ResAP limit, demonstrating that it is feasible for manufacturers to eliminate these impurities from tattoo inks. In general, there was a good consistency between the

ingredients stated in the labels and the elements used in colorants and auxiliary agents found in the sampled inks.
As, Cd, Co, Cr, Mn, Ni, Pb, V and Zn were spread in all the samples and concentrations of Hg and Sb were below the limit of detection in many cases. Ni was found in all samples. Total Cr and Cu were analysed but no comparison was possible because the limits reported in Table 3 refer to Cr (VI) and soluble Cu.
Several clinical dose-response studies state that the level of each allergenic metal should not exceed 1 mg/kg in products that come in contact with the skin, but a large number of samples contained Co, Cr and Ni at concentrations higher than this value.
The results of the market surveillance between 2009 and 2014 show that Ni was present in almost every analysed sample both tattoo and PMU inks.
Tattoo inks containing As, Ba, Cd, Hg, Pb and Sb in concentrations higher than those recommended by the CoE ResAP(2008)1 were found. In PMU products, Ba, Co and Pb were detected in concentration higher than those thresholds.
Regarding labelling, the colorants declared were in accordance with those recommended by the ResAP(2008)1; however the warning flagging the presence of traces of Ni and Cr did not appear on the labels, as recommended by the CoE ResAP(2008)1.
ISS is currently working on the development of a method for Cr (VI) speciation and a method for the detection of metal-nanoparticles.
Mrs Bocca highlighted that there is a need to harmonize testing methods and the expression of results. Moreover she mentioned that it is not clear if the limits of Table 3 in the CoE ResAP(2008)1 refer to total quantity or soluble part of the impurities and if the final data have to be expressed on wet or dry matter content. In her opinion, specific thresholds for PMU should be defined as the amounts of pigments used are usually lower than the ones used for tattoo inks. Furthermore thresholds for impurities should be updated and missing metals and nanomaterials added to the list of Table 3.
Mr Fontana presented the activities of ARPA Piedmont on the surveillance of aromatic amines and PAHs in tattoo and permanent make-up inks. ARPA Piedmont analysed 200 samples of tattoo inks from 2007 to 2013 for the determination of certain aromatic amines deriving from the reduction of azo-colorants. More than 40% of samples contained one or more banned aromatic amines and hence were considered not in line with the recommendations in the CoE ResAP(2008)1.
In the absence of a specific method for tattoo inks, they used the one in place for the determination of certain azo colorants in dyed leathers (EN ISO 17234-1:2010).
In their experience, some colours are more problematic than others. For instance, many yellow, orange and red inks contain o-anisidine and o-toluidine. In some cases the concentration of hazardous aromatic amine was higher than 100 ppm.
Nevertheless it is important to underline that 60% of samples were compliant, showing no release of hazardous aromatic amines. This result confirms that production of inks of good quality is possible.
Concluding Mr Fontana stated that an improvement on sampling modalities would be required to get a clear picture of the real situation, because the sampling was focused on critical samples (suspicious bottles, strange labels, red and orange inks). Furthermore he considered important to include additional dangerous aromatic amines to the list in Table 3 of the CoE ResAP(2008)1, as well as the introduction of limits for AA and single PAHs.
A surveillance activity was performed also for polycyclic aromatic hydrocarbons (PAHs). The majority had low concentrations of carcinogenic PAHs and 10% were non-compliant. It is remarkable that the irregular samples showed concentrations of PAHs much higher those recommended by the CoE ResAP(2008)1. He also pointed out that a harmonisation of analytical methods for surveillance activities is strongly needed at EU level.

7. The contents of ingredients and impurities in tattoo inks (Dorte BJERREGARD LERCHE – Danish Ministry of Environment)

Due to the lack of time, Mrs Lerche volunteered to skip her presentation and agreed to share it with the experts. She briefly mentioned that in Denmark there is a situation similar to the one found in Italy and described in the presentations of Mrs Bocca and Mr Fontana.

Mrs Lerche informed that the Danish Ministry of Environment was preparing a letter for the Commission asking for an Article 13 of the General Product Safety Directive (GPSD) 2001/95/EC regarding emergence measures to be taken to establish legislation on tattoo and PMU products.

8. Tattoos and Permanent Make-up – Market surveillance in Germany (Annegret BLUME – Federal Institute for Risk Assessment)

In 2013 nearly 2000 persons participated in a survey conducted by a market research institute for a German health magazine. From this survey emerged that a strict legislation and surveillance to minimize health risks is urgently needed as tattooing is associated with health risks which could be avoided if a correct legislation is put in place.
In the past years many national and regional market surveillance activities were conducted in Germany particularly on amounts of heavy metals, preservatives, primary aromatic amines (PAA) and microbiological status of tattoo inks.
More than 1000 tattoo inks were sampled and nearly 300 different substances and microbiological organisms were analysed with more than 22000 analytical results.
The presence of heavy metals, AAs, nitrosamines, preservatives, dyes, PAHs, but also organic acids, organic solvents and phthalates were investigated.
The main problems identified by market surveillance authorities regard ingredients: presence of banned colorants or unregulated dyes, preservatives in high concentrations, too high amounts of heavy metals, nickel or aluminium and presence of banned AAs.
Wrong labelling is also very common; in many cases the list of ingredients is incomplete and the manufacturer's list of ingredients is often inconsistent with importer's one.
During the campaign conducted on 2012, 2076 online results were identified for tattoo supplies and 537 for tattoo inks, giving an idea of the importance of the web based market; through internet marketing it is possible to purchase cheap products, to import directly from outside the EU and to buy non-conventional inks.
A -survey identified 65 online distributors located in Germany, and about one third of them were not registered as required.

9. Result of market surveillance in Slovenia concerning tattoo and PMU products from 2009 to 2014 (Vesna HRZENJAK- National laboratory for health, environment and food)

In 2009 a market survey was conducted in Slovenia by the Health Inspectorate. Sixteen tattoo shops and two beauty shops were visited and 34 samples of colorants (31 tattoo inks and 3 PMU inks) were taken for analysis.
The samples were analysed according to the Resolution ResAP(2008)1 for the presence of carcinogenic, mutagenic, reprotoxic substances and sensitising aromatic amines and contaminants, such as polycyclic aromatic hydrocarbons, benzo-a-pyrene and metals (As, Ba, Cd, Co, Cr, Cu, Hg, Ni, Pb, Se, Sb, Sn, Zn) and for the total bacterial count, the presence of moulds, yeasts and pathogenic agents. Two samples (6%) were microbiologically contaminated and several samples (12 samples or 35%) contained metals above maximum allowed recommended concentrations. All samples contained Ni. PAHs and benzo-a-pyrene above maximum allowed concentrations were identified in ten samples (30%). Aromatic amines were identified in 5 samples.
Since the beginning of 2010 the Republic of Slovenia has had a legislation regarding rules on minimum sanitary and health requirements for hygiene care and other similar establishments (Official Gazette of the Republic of Slovenia, No. 104/2009). It concerns hairdressers, cosmetic, body care and tattoo and piercing establishments (Section D, articles 28 to 33).
Another official control by Health Inspectorate was conducted in Slovenia between 2010 and 2014. Thirty five colorants (33 used in tattoo and 2 in PMU inks) were sampled in tattoo and beauty shops.
The samples were analysed according to the Rules on minimum sanitary and health requirements for hygiene care and other similar establishments (Official Gazette of the Republic of Slovenia, No. 104/2009) for the presence of carcinogenic, mutagenic, reprotoxic substances and sensitising aromatic amines and contaminants, such as

polycyclic aromatic hydrocarbons, benzo-a-pyrene and metals (As, Ba, Cd, Co, Cr, Cu, Hg, Ni, Pb, Se, Sb, Sn, Zn). In addition, the samples were examined for the total bacterial count and presence of moulds, yeasts and pathogenic agents.
Only one sample out of the 35 has been found to be microbiologically contaminated while all other samples were sterile. Almost all samples contained metals (As, Ba, Cu, Pb, Zn) above maximum allowed concentrations according to the Slovenian legislation, 16 samples contained nickel and several samples contained more than one metal above maximum allowed concentrations.
PAHs above maximum allowed concentrations were identified in 7 samples (20 %) and two contained also benzo-a-pyrene in quantities exceeding the limit of 5 ppb.
Aromatic amines were identified in 6 samples (2,4-diaminotoluene, 2-methoxyaniline in 3,3'-dichlorobenzidine) and several samples contained more than one aromatic amine.
Moreover the checking regarding labelling requirements showed that a high percentage of products are not compliant: there is no indication of durability, list of ingredients and information are often in English and not in Slovenian.
In conclusion, when applied and used as intended, tattoo and PMU products must not endanger the health or safety of persons or the environment; nevertheless, from the results of the market surveillance and official control it is obvious that tattoos may involve a certain health risk. Since in most Member States tattoos, tattooing and PMU is covered neither by specific national nor by European regulations, it is very difficult to take legal actions in the case of non-compliancy. For this reason an action at European level is strongly needed.

10. Discussion

All the participants agreed that the national surveys outcome presented a realistic overview in accordance with the real situation found nowadays in European countries.

11. An update on the chemistry of tattoo colorants (Wolfgang BAUMLER-University of Regensburg)

Tattoo colorants are complex mixtures as they basically contain: colouring compound, starting materials of chemical synthesis, reaction products, light induced products, solvents, preservatives, impurities and microorganisms.
From a chemical point of view, colorants are classified as either pigments or dyes, but in contrast to dyes, pigments are practically insoluble in the medium in which they are incorporated. Making a persistent tattoo in skin requires the use of water insoluble colorants in form of pigments (inorganic or organic, coloured, white or black). In the past, tattooists used inorganic pigments that contained heavy metals such as mercury, chromium or cadmium: typical colours were yellow (cadmium sulphide), red (mercury sulphide) and green (chromium oxide).
Nowadays tattoo colorants mainly consist of organic pigments like azo or polycyclic pigments; however two important inorganic pigments are still in use (carbon black for black tattoos and titanium dioxide to reduce the colour strength of the pigments).
Carbon black tattoo colorants have nano dimensions, but they form aggregates and in-vivo studies showed that black inks changed from nm-size to µm-size after tattooing.
Due to the low purity of colorants, the presence of high level of admixtures and impurities is not unusual; high concentrations of PAHs, PAA, and heavy metals are frequently found in tattoo and PMU inks. It is not clear yet if adverse reaction after tattooing is specific for coloured tattoos but evidence is that up to now 40 cases were reported of problems with red pigments both in tattoo and PMU inks.
Tattoo colorants interact with light in particular with laser light and UV radiation and it has to be investigated if the decomposition products are responsible for inflammatory reactions.
Break down of carbon black particles was noticed after laser irradiation: the mean diameter of particles passed from 50 to 6 nm after the treatment. PAHs were found to be absorbed onto the nanoparticles surface and some of PAHs are excellent photosensitizers and generate under light exposure singlet oxygen that damages skin cells.

All the substances composing inks could be transported into human body including microorganisms if present. There are evidences of transportation of colorants from skin into the body: colorants were found in axillary lymph nodes proving an effective transfer of pigments from the tattooed part to the lymphatic system.
Some colorants and/or ingredients are potential photosensitizer and decomposition of pigments and/or ingredients occurs by laser light or solar radiation (UV) causing phototoxic and photo allergic reactions. Further research on laser treatment of tattoos and UV-induced decomposition of ink ingredients urges.
There is a need for epidemiologic studies to search for possible systemic health problems as the number of tattooed people clearly increased during the past 20 years and is not yet known the period of latency for any tattoo-related disease (e.g. malignancies).
The in vivo studies conducted until now were done on mice, but we miss studies on large animals as pigs, which have skin and lymphatic system similar to humans. However that kind of research is not allowed anymore in Germany, as tattooing is a voluntary action and as in the case of cosmetics animal experimentation is forbidden (court ruling).
In conclusion the chemistry of tattoo colorants is not new and it follows the chemistry of commercial pigments. Standards for the purity of tattoo colorants are missing and an update on chemistry is almost impossible because too many substances are currently available on the market.

12. Ingredients of tattoo and function of ingredients (Ralf MICHEL-TIME)

Until the eighties the production of tattoo inks followed the traditional manufacturing process; water, alcohol, glycerine and pigments were sufficient to produce a tattoo ink.
In the nineties tattoo inks manufacturing industry started to develop and the composition of inks started to become more and more complex because the market was demanding products with specific properties as the ease of use and colour durability and brightness. Nowadays the general formulation of tattoo inks is water, solvent, pigment, binder, emulsifier, preservative, functional ingredients, surfactant, viscosity controller, thixotropic controller, antifoam controller and sometimes a buffer.
Each ingredient has a specific function: solvents dissolve other substances (mostly the pigments), binders provide cohesion, emulsifiers promote the formation of intimate mixtures of non-miscible liquids, preservatives inhibit primarily the development of micro-organisms (they are listed in the Annex IV of Cosmetic Directive), surfactants lower the surface tension of the product as well as aid the even distribution of the ink when used, antifoaming agents suppress foam during manufacturing or reduce the tendency of finished products to generate foam, viscosity controllers increase or decrease the viscosity of the inks, buffers stabilise the pH of inks, astringents contract the skin after the application of inks and antioxidants inhibit reactions promoted by oxygen, thus avoiding oxidation and rancidity letting colours to stay longer bright after their application. Tattoo inks composition is very complex and it is becoming more and more difficult to accomplish the demand of the market and to find the right formulation to fulfil users' needs.

13. Composition of tattoo inks (Michael DIRKS- H-A-N- Haus der Angewandten Naturwissenschaften-Gesellschaft mbH)

The composition of tattoo inks is very clear and defined: about 33% of a tattoo ink is composed by binders (polyethers, polyvinylpyrrolidone, block-copolymer, shellac, acrylic resins), 33% are pigments (inorganic and organic pigments, carbon black, barium sulphate) and 33% solvents (water, simple alcohols, polyols). The amount of auxiliaries as surfactants, preservatives and thickening agents can reach maximum 5% of the ink.
Due to their high molar masses binders have limited bio-availability and are not considered as acutely hazardous.
Colorants are divided into pigments and dyestuff; pigments are insoluble in their application medium while dyestuffs are generally soluble. Pigments and not dyestuffs are used in tattoo and PMU inks as pigments are not soluble in their solvents otherwise they would be bio-available, posing a risk for the tattooed people health.

Organic pigments are divided into azo and polycyclic pigments; azo pigments in particular conditions could release carcinogenic aromatic amines.
The mostly used inorganic pigments are: titanium oxide that can be found both in tattoo and PMU inks, and iron and chromium oxides that are used in PMU but rarely in tattoo inks.
Titanium dioxide is essential in the fixing of colours; it is used in the rutile form as this particular form has low photochemical activity and thus appropriate for tattooing.
Iron oxides are easily dispersable in water and can be used in black, red, yellow and brown colours; they tend to reach their stable status and for this reason they might change colour towards red if for example irradiated with UV or laser light. Often the iron oxides containing inks are contaminated with heavy metals such as Co and Ni, whose concentration can reach 50 ppm in pigments from cosmetics companies. Chromium oxides are used in green colours, they are easy to disperse and used in PMU inks as red stopper.
Carbon black is used in black coloured inks. The most used fillers are barium sulphate (used as stabilizer) and silica. Silica is a stabilizer with rheological properties and it is used as a thixotropic agent.

14. Composition of tattoo and permanent make-up inks (Paola PICCININI-EC DG JRC)

An overview on the composition of tattoo and permanent make-up inks was presented. Information was collected from questionnaires (sent to MS, tattooist and PMU professional associations and manufacturers), a recently published book (Tattooed Skin and Health, 2015, ISBN 978-3-318-02774-7), RAPEX notifications, national studies, presentations held in previous conferences and papers available in literature.
Until the meeting, replies on ink ingredients were received from 12 countries (DK, LI, LU, NL, NO, SE, SI,CH, ES, BG, IT, DE), 3 countries replied only to the open question questionnaire (BE, IS, PL) and six MS did not have information (CY, CZ, HU, RO, SK, UK), FR only provided information related to prohibited colorants. In addition, one jurisdiction (US), four tattooist associations (ART, BVT, NTU, UETA) and three manufacturers (Deep Colours, HAN, MT-Derm) participated to the enquiry. Ingredients used in some brands as Intenze, Kuro Sumi and Starbrite inks were found in internet.
DG JRC showed all the information received listing the red, yellow, blue, orange, violet, brown, green, black and white colorants present in tattoo and PMU inks.
A list of auxiliaries and preservatives present in tattoo and PMU inks was also presented following the same approach used for pigments.
Since 2006, 123 (117 chemical and 6 microbiological) RAPEX alerts on tattoo and PMU inks have been recorded. Irregular chemical composition was found both in tattoo and PMU inks, but tattoo notifications were the majority of cases. The six microbiological notifications were all related to tattoo inks. A statistic derived from these data was presented: the chemical related notifications were divided by notification country, year, country of production and ink brand.
An overview on tattoo and PMU market, partly based on the outcome of questionnaires and partly on web-based research, was also presented. Thirty four European and fifteen extra-European ink manufacturers were identified, however it has to be highlighted that this is a rough estimation as there are surely a lot of other minor producers.
A tentative to make a connection between brand names and producers was made, even though it was not easy to find this information. Results showed that tattoo inks are mostly produced outside Europe, whereas PMU inks are mostly manufactured in EU. Ninety brands of tattoo and PMU inks were found and a brief on-line search identified the number of suppliers selling a specific brand. The presenter asked the collaboration of producers and experts to refine the search.

15-17. Discussion, Work Packages 3 and 4 preliminary distribution of tasks, conclusion and follow-up

Final considerations as regards to the lack of colorants specifically manufactured to be used in tattoo inks and therefore injected in the human body were highlighted. Colorants

used in tattoo inks are manufactured for applications in textiles, automotive and plastics. Big producers are not interested in manufacturing pigments specifically for tattoo inks due to the relatively small size of the market.
The purity of pigments produced in the EU is around 90%, while for products coming from third countries it is usually between 70 and 80%.
Mr Michel will verify and integrate the information on producers and related brands collected by DG JRC.
The experts acknowledged the huge and impressive work carried out by DG JRC and confirmed that the data presented were realistic.
Participants were asked to provide (if available) more information on national studies and data relevant to the project.
The next meeting of this working group will be held in the autumn and it will be focussed on the third work package related to adverse health effects. Members of the group were invited to contact scientists and dermatologists and to submit available information for the preparation of the next meeting.

Table A: Agenda of the meeting of the CSN-STPM held on 20th April 2015 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 11.11.2014**
3.	9:15 – 9:30	**Update on the European action on the safety of tattoo and permanent make-up inks** Ana Maria BLASS RICO (EC DG JUST)
4.	9:30 – 9:50	**National statistics on tattoo and permanent make-up related data** Paola PICCININI (EC DG JRC)
5.	9:50 – 10:20	**Discussion**
6.	10:20 – 10:40	**Italian experience on control of hazardous substances in tattoo and PMU inks: characterization of heavy metals, aromatic amines and PAH's** Beatrice BOCCA (Italian National Institute for Health) Marco FONTANA (ARPA Piedmont)
7.	10:40 – 11:00	**The content of ingredients and impurities in tattoo inks** Dorte BJERREGARD LERCHE (Danish Ministry of the Environment)
	11:00 – 11:15	**Coffee break**
8.	11:15 – 11:35	**Tattoos and Permanent Make-up – market surveillance in Germany** Annegret BLUME (Federal Institute for Risk Assessment)
9.	11:35 – 11:55	**Results of market surveillance in Slovenia concerning tattoo and PMU products from 2009 to 2014** Vesna HRŽENJAK (National laboratory for health, environment and food)
10.	12:55 – 12:30	**Discussion**
	12:30-13:30	**Working lunch**
11.	13:30 – 14:00	**An update on the chemistry of tattoo colorants** Wolfgang BÄUMLER (University of Regensburg)
12.	14:00 – 14:30	**Ingredients of tattoo and function of ingredients** Ralf MICHEL (TIME)
13.	14:30 – 15:00	**Composition of tattoo inks** Michael DIRKS (H-A-N-Haus der Angewandten Naturwissenschaften-Gesellschaft mbH)

14.	15:00 – 15:30	**Composition of tattoo and permanent make-up inks** Paola PICCININI (EC DG JRC)
	15:30 – 15:45	**Coffee break**
15.	15:45 – 16:15	**Discussion**
16.	16:15 – 16:45	**Work packages 3 and 4** **Preliminary distribution of tasks**
17.	16:45 – 17:00	**Conclusions and follow-up**
	17:00	**END**

Table B: List of participants (meeting of the CSN-STPM on 20th April 2015).

Country	National Expert	Affiliation
France	VERDIER Cécile	ANSM
Denmark	BJERREGAARD LERCHE	Danish Environmental Protection Agency
Germany	BLUME Annegret MEISNER Anke	Bundesinstitut für Risikobewertung Federal Ministry of Food and Agriculture
Italy	AGNELLO Manuela ALIMONTI Alessandro BOCCA Beatrice FONTANA Marco RENZONI Alberto	ARPA Piemonte Istituto Superiore di Sanità Istituto Superiore di Sanità ARPA Piemonte Istituto Superiore di Sanità
The Netherlands	JANSSEN Paul NIJBOER Lucas	RIVM Netherlands Food and Consumer Product Safety Authority
Slovenia	HRŽENJAK Vesna	National laboratory of health-environment and food
Sweden	CRONA Magnus	Medical Product Agency
Switzerland	HOHL Christopher	Kantonales Laboratoirum Basel-Stadt
United Kingdom	PINCHEN Robert	Royal Borough of Greenwich
Country	**Stakeholders**	**Affiliation**
Austria	FIALA Franz	ASI Consumer Council
Denmark	SERUP Jorgen	Bispebjerg University Hospital
Germany	BAUMLER Wolfgang	University of Regensburg
Germany	DIRKS Michael	H-A-N-Haus der Angewandten Naturwissenschaften-Gesellschaft mbH
Germany	KEMNER Sina	TIME
Germany	MICHEL Ralf	TIME
Italy	GIUSEPPIN Eliseo	Associazione tatuatori.it
Italy	ZOPPETTI Marco	Associazione tatuatori.it
Sweden	BERGSTROM JENS	Sweeden Registered Tattoo artists (SRT)
European Commission	**Directorate General**	**Institute and Unit**
PICCININI Paola	Joint Research Centre	Institute for Health and Consumer Protection, Chemical Assessment and Testing Unit (Dir I.1)
SENALDI Chiara	Joint Research Centre	
RAEMAEKERS Tim	Joint Research Centre	
BLASS RICO Ana Maria	Justice and Consumers	Consumers, Product and Service Safety Unit (Dir E.3)

Annex II

Questionnaires

Table A: Questionnaires on statistical data.

MS	Tattooists associations	Manufacturers
1. What is the percentage of population having tattoos and PMU in your country?	1. How many members do belong to your association?	1. What is the origin of the ingredients and raw materials used to manufacture your tattoo/PMU inks?
2. On average, at which age do people get their first tattoo and PMU done?	2. How many tattoos and/or permanent make-up (PMU) studios are officially registered in your country?	2. Do you request purity certificate of raw materials to your providers?
3. Among tattooed people, which is the percentage of population having only one tattoo, between 2-5 tattoos and more than 5 tattoos?	3A. How many NON registered/official tattoo and/or permanent make-up (PMU) studios are estimated in your country?	3. What is the yearly total volume of tattoo/PMU inks produced by your Company? What percentage of this production is sold on the European market?
4. Which is the average number of tattoos and PMU carried out yearly in your country?	3B. How many tattoo and/or PMU artists are officially registered in your country?	4. Do you include in the label of tattoo and PMU inks produced by your Company the list of ingredients?
5. Among tattooed people, which is the percentage of population that regrets to have tattoos and PMU?	4. What is the estimation of the number of NON registered/official tattoo and/or PMU artists which are active in your country?	5. Is there any other information provided in the ink label?
6. Which is the estimated number of tattoo removal executed every year in your country?	5. Where do the members of your Association buy their inks?	6. Please provide the list of ingredients of the tattoo and PMU inks produced by your Company as well as their range of concentration, by filling-in the attached Excel table.
7. Which are the numbers of registered/official tattoo studios and artists active in your country?	6. What is on average the yearly volume of inks purchased by each member of your Association, expressed in litres?	7. Do you package your inks in single or multiple use containers?
8. Which are the estimated numbers of NON registered/official tattoo studios and artists active in your country?	7. Do the inks used by your members have a composition label? If yes, please provide the list of ingredients of the used inks, and fill-in the attached excel table with information about ingredients of tattoo and PMU inks.	8. What is the average sale price/ml of tattoo/PMU inks you produce?
9. Is there one (or more) national association of tattoo artists in your country?	8. Do your members usually utilise single or multiple use ink containers?	9. Do you perform a risk assessment of the products you manufacture and of their ingredients before putting them on the market? Do you have to notify it to the Competent Authorities of your country?
10. Are there tattoo and PMU ink manufacturers/importers in your country?	9. Where do they buy tattoo equipment and needles?	10. Do you apply Good Manufacturing Practices in the production of your products?
11. Where are manufactured the tattoo and PMU inks imported in your country?	10. How many tattoo/PMU procedures are carried out yearly in your country?	11. Do you have any contact with the clients after sale?
12. Which is the volume of sales/purchases of tattoo and PMU inks in your country?	11. What is the total number of customers per year? How many of these customers are below the age of 18?	12. Do clients give you feedback in case of problems with the inks or undesirable effects in tattooed persons as result of the inks?
13. Have any market surveillance actions on tattoo and PMU inks been carried out in your country?	12. What are the main problems encountered by your Association with regard to tattoo and PMU inks, processes, materials, studios?	13. Do you think that EU manufactured inks are safer than those coming from other countries?
14. What are the main problems registered by market surveillance/customs authorities relating to tattoo and PMU inks?	13. Are there any further comments or additional information you wish to provide?	14. What are the main problems encountered by your Company with manufacturing and distribution of tattoo and permanent make-up inks?
15. Please fill-in the attached excel table with information about ingredients of tattoo and PMU inks placed on your market.		15. Are there any further comments or additional information you wish to provide?
16. Is there a register of complains or vigilance system on tattoo issues, e.g. on adverse health effects, available in your country?		
17. Are there any further comments or additional information you wish to provide?		

Table B: Questionnaires on ingredients.

	Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	Used as ingredient in PMU inks	Used as ingredient in tattoo inks	Found in market surveillance activities in PMU inks	Found in market surveillance activities in tattoo inks
Colorants	(Ferous oxide , black)	*77489*				
	Pigment black 6 and 7 (graphite)	*77266*				
	Pigment black 11	*77499*				
	Acid blue 9	*42090*				
	Pigment blue 15	*74160*				
	Pigment blue 27 (Prussian blue)	*77510*				
	Pigment blue 29 (Ultramarine blue)	*77007*				
	Pigment brown 6 and 7	*77491*				
	Pigment brown 6 and 7	*77492*				
	Pigment brown 6 and 7	*77499*				
	Pigment brown 25	*12510*				
	Pigment green 7	*74260*				
	Pigment green 17	*77288*				
	Pigment orange 13	*21110*				
	Pigment orange 16	*21160*				
	Pigment orange 34	*21115*				
	Pigment orange 43	*71105*				
	Pigment orange 74					
	Acid red 18	*16255*				
	Acid red 51	*45430*				
	Acid red 87	*45380*				
	Allura red	*16035*				
	Food red 17	*16035*				
	Natural red 22/23	*75510*				
	Pigment red 5	*12490*				
	Pigment red 7	*12420*				
	Pigment red 9	*12460*				
	Pigment red 12	*12385*				
	Pigment red 14	*12380*				
	Pigment red 15	*77015*				
	Pigment red 22	*12315*				
	Pigment red 23	*12355*				
	Pigment red 49	*15630*				
	Pigment red 57:1	*15850:1*				
	Pigment red 57:2	*15850:2*				
	Pigment red 101 and 102	*77491*				
	Pigment red 112	*12370*				
	Pigment red 122	*73915*				
	Pigment red 146	*12485*				
	Pigment red 170	*12475*				
	Pigment red 181	*73360*				
	Pigment red 210	*12477*				
	Pigment red 266	*12474*				
	Solvent red 1	*12150*				
	Basic violet 10	*45170*				
	Pigment violet 16 (Manganese violet)	*77742*				
	Pigment violet 19	*73900*				
	Pigment violet 23	*51319*				
	Acid yellow 3	*47005*				
	Acid yellow 9	*13015*				
	Acid yellow 23	*19140*				
	Pigment yellow 1	*11680*				
	Pigment yellow 14	*21095*				
	Pigment yellow 36	*11780*				
	Pigment yellow 42 and 43	*77492*				
	Pigment yellow 55	*21096*				
	Pigment yellow 74	*11741*				
	Pigment yellow 83	*21108*				
	Pigment yellow 87	*21107:1*				
	Pigment yellow 97	*11767*				
	Pigment white 4	*77941*				
	Pigment white 6	*77891*				
	Other colorants (please specify C.I. generic name and constitution number number if available)					
	Substance	**CAS number**	**Used as ingredient in PMU inks**	**Used as ingredient in tattoo inks**	**Found in market surveillance activities in PMU inks**	**Found in market surveillance activities in tattoo inks**
Auxiliary ingredients	Aluminum hydroxide	21645-51-2				
	Amorphous silica	7631-86-9				
	Barium sulphate	7727-43-7				
	Butanamid	541-35-5				
	Essential oils					
	Ethanol	64-17-5				
	Glycerol	56-81-5				
	Hydrochloric acid	7647-01-0				
	Isopropanol	67-63-0				
	Kaolin	1332-58-7				
	Neodecanoic acid	26896-20-8				
	Poloxamer 407	9003-11-6				
	Rosa canina	84603-93-0				
	Rosin	8050-09-7				
	Sodium hydroxide	1310-73-2				
	Other auxiliaries (please specify name and CAS number number if available)					
Preservatives	Benzoic acid	65-85-0				
	Methylparaben	99-76-3				
	Methyldibromo glutaronitrile	35691-65-7				
	Phenoxyethanol	122-99-6				
	Other preservatives (please specify name and CAS number number if available)					

Annex III

Replies to questionnaires
Statistical data

Table A: Prevalence of tattoos and PMU inside and outside Europe.

	MS 1A. Population with tattoos (%)			MS 1B. Population with PMU (%)
Country	**General**	**Male**	**Female**	
		In Europe		
AT	19 (16y– 50+) 29 (16 – 29y) 26 (30 – 49y) 7 (>50y)			u
BE	u			u
BG	10-12			<8
CH	u			u
CY	30			20
CZ	u			u
DE	9 23 (16-29y)			u
DK	15 20 (15-34y) 19 (35-49y) 9 (50-64y) 3 (65-74y)	14	15	u
ES	u			u
FI	10 9 (15-19y) 12 (20-24y) 19 (25-29y)			u
FR	10 8 (18-24 y) 20 (25-34 y) 12 (35-49 y) 5 (50-64 y) 1 (> 64 y)	11	9	u
HU	50			u
IS	70 (18-40y)			u
IT	12.8 7.7 (12-17 y) 22.1 (18-24 y) 22.7 (25-34 y) 23.9 (35-44 y) 15.0 (45-54 y) 2.2 (> 54 y)	11.7	13.8	3 0 (12-17 y) 0 (18-24 y) 5.6 (25-34 y) 2.1 (35-44 y) 3.8 (45-54 y)
LI	u			u
LU	60			u
NL	10 (12+) 2-3 (12-19 y) 20-30 (20-29 y) 25-30 (30-39 y) 25-30 (40-49 y) 10-15 (50-59 y) 10 (>60y)			u
NO	25 (<30 y) 10 (>30 y)			u
PL	9 (15-50 y)			u
RO	u			u
SE	11			u
SI	u			u
SK	u			u
UK	u			u
		Outside Europe		
CA	24 (2013)	26 (based on US study)	22 (based on US study)	
US	21 22 (18-24 y) 30 (25-29 y) 38 (30-39 y) 27 (40-49 y) 11 (50-64 y) 5 (>65 y)	19	23	
NZ	20			

MS: Member States Question Number
y: years
Values underlined indicate the general population

Table B: Tattoo procedures, regrets and removals.

Country	Tattoo procedures (number/year)		Tattooed population with regrets (%)	Removal procedures (number/year)
	MS 4	TAT 10	MS 5	MS 6
In Europe				
AT	u		u	u
BE	u		20	u
BG	9 000		12 (10 for PMU)	u
CH	u	810 000 (VST)	u	u
CY	u		u	u
CZ	u		u	u
DE	u	u (UETA & BTV))	5	u
DK	u		Regret: 18 (F 17 and M 19) 13 (15-34y) 9 (35-49y) 40 (50-64y) Consider removal: 11 (F 10 and M 11) 12 (15-34y) 8 (35-49y) 12 (50-64y)	5% (F 4% and M 7%) 6% (15-34y) 5% (35-49y) 5% (50-64y)
ES	u	About 400/y multiplied by 2500 (1/2 of legal studios) = 1 million tattoos. With illegal tattoos --> more than 2 million tattoos (Untap)	u	u
FI	u		u	u
FR	u		u	1 (35-49 y)
HU	250 000		5-10	Low. Laser clinics perform special removals. Professional tattoo artist make special covers.
IS			5-10	
IT	388 (Only 1 studio reported by CNA)	u (ART) PMU: 1500/2000 per 100 000 habitants (ATEC)	17.2	u
LI	u		u	u
LU	u		Very low.	Many people go to Germany (better equipment).
NL	u		u	u
NO	u	650 professional artists make one/day = 152 750 tattoos/y. 4000 non professionals make one/week = 208 000 people/y (NTU)	u	u
PL	u		12	u
RO	u		u	
SE	1000/day (according to SRT)	1000/day (SRT)	u	u
SI	u		u	u
SK	u		u	u
UK	u		u	u
Outside Europe				
CA	u		17	u
US	u		14	96 000 (American Society of Dermatologic Surgeons in 2013)
NZ	u			u

MS: Member States Question Number
TAT: Tattooist Association Question Number
y: years

Table C: Age of individuals for their first tattoo or PMU.

Country	MS 2A. Age of people for 1st tattoo (years)			MS 2B. Age of people for 1st PMU (years)
	General	Male	Female	
In Europe				
AT	16 – 30			25
BE	>18			>16
BG	18 (some 12-16 with parents consent)			25
CH	u			u
CY	18-20			25
CZ	u			u
DE	≤18 (17.6%) 18-35 (77%) ≥ 35 (4.8%)			u
DK	<20 (37%) 20-24 (25%) 25-34 (24%) 35-66 (18%)	<20 (39%) 20-24 (26%) 25-34 (23%) 35-66 (12%)	<20 (35%) 20-24 (23%) 25-34 (25%) 35-66 (18%)	u
ES	Legally min 18 (minors with tutors consent)			Legally min 18 (minors with tutors consent)
FI	u			u
FR	22			u
HU	18-25			u
IS	16-18			
IT	25			u
LI	u			u
LU	18 – 21 (a few years ago)			
NL	16 (12 with parents permission)			16 (12 with parents permission)
NO	25			
PL	<25			u
RO	u			u
SE	18-22			u
SI	u			
SK	u			u
UK	Legally min 18 (Exemption for medical reasons by qualified medical practitioner).			Legally min 18 (local authorities state a minimum age but not consistently applied).
Outside Europe				
CA	21-36 (36%) 32-42 (24%) 43-53 (15%)			u
US	<18 (16%) >18 (84%)			>35
NZ	<30 (33%) No age restrictions			

MS: Member States Question Number

Table D: Number of tattoos/person.

Country	MS 3. Number of tattoos/person (% population)		
	1	**2-5**	**>5**
	In Europe		
AT	13	≥ 6	
BE	u	u	u
BG	28	56.5	15.5
CH	u	u	u
CY	u	u	u
CZ	u	u	u
DE	34.9	51	14.3
DK	49 (F 52/M 45) 51 (15-34y) 47 (35-49y) 48 (50-64y)	23* (F 23/M 22) 24 (15-34y) 21 (35-49y) 24 (50-64y)	29* (F 25/M 32) 25 (15-34y) 32 (35-49y) 28 (50-64y)
ES	u	u	u
FI	u	u	u
FR	52	39	9
HU	20-30	30-40	30-40 (so called collectors are having continuous bigger tattoos)
IS	u	u	u
IT	66.2	31.3	2.5
LI	u	u	u
LU	20	50	
NL		50**	
NO	10	60	30
PL	30	30*** 20***	20***
RO	u	u	u
SE	u	u	u
SI	u		
SK	u	u	u
UK	u	u	u
	Outside Europe		
CN	21****		
US	12 (18-29y) 12 (30-45y) 9 (46-64y) 3 (>65y)	19 (18-29y) 16 (30-45y) 5 (46-64y) 3 (>65y)	7 (18-29y) 5 (30-45y) 0 (46-64y) 0 (>65y)
NZ	Tattoos culturally based 'tell a story' and are built up over a number of tattooing sessions and are interlinked. Thus not possible to differentiate between individual tattoos.		

MS: Member States Question Number
F: Female
M: Male
y: Years
DK*: Ranges 1, 2-3, >4
NL**: Range >2
PL***: Ranges 1, 2-3, ≥5
CN****: Range ≥2

Table E: Number of tattoo artists and studios according to Member States' Authorities.

Country	MS 7A. Number registered/official	MS 7B. Number registered/official	MS 8A. Number NON registered/official	MS 8B. Number NON registered/official
	Tattoo studios	Tattoo artists	Tattoo studios	Tattoo artists
In Europe				
AT	u	u	u	u
BE	691	1 033	u	u
BG	151 (Under the Health Act, Additional Provisions, § 1, point 9 „f" and Ordinance № 9 of 21.03.2005)	200 (Ministry of Health does not performs registration of tattoo artists)	u	u
CH	u	u	u	u
CY	8 (studios + artists)	8 (studios + artists)	40 (studios + artists)	40 (studios + artists)
CZ	u	u	u	u
DE	No obligation to register a tattoo studio.		u	
DK	u	A code for tattoo artist is lacking	u	u
ES	870 (Data provided by 12 out of 17 Regional Authorities)	u	u (Autonomous Communities and local authorities perform inspections to avoid this)	u
FI	250 (No legislation on official tattoo studios)	u (No legislation on official tattoo artists)	u	u
FR		3 500 - 4 000		
HU	150-200	400-500	150-200	400-500
IS	18			50-70
IT	2 055	2 500 - 4 000	u	4 000 - 1 0000
LI	5	6	u	u
LU	28	u	28 (According to registered tattoo artists, as many as the registered tattoo artists/studios)	National tattoo convention believes 10 times more non-registered than registered tattoo artists.
NL	969 (+ 1 027 for PMU)	1 000 – 2 000	500 – 1 000	500 – 1 000
NO	150-200	600	u	
PL	547	587	u	u
RO	146 in 2013	u	u	u
SE	800 - 1 000 (1.7 tattooists/studio)	u	15 000 start kits (on the home market with no estimate for how many of these kits used by official tattoo studios, but normal for a small town of 25-40 000 habitants is 5-10 home scratchers and 1-2 official tattoo studios)	u
SI	44 (studios + artists)	44 (studios + artists)	Number of unregistered tattoo studios and artists > than registered.	Number of unregistered tattoo studios and artists > than registered.
SK	207 (studios + artists)	207 (studios + artists)	u	u
UK	742 (TPIU 2008 for the Health and Safety Laboratory survey)	Hygiene licensing schemes exist only for studios/premises (not tattoo artists or individuals)	Illegal (Environmental Health officers inspection following discovery)	No official registration of tattoo artists
Outside Europe				
CA	885 (salons see Q9) Regulated by the individual provinces/territories	150 according to The Canadian Association of Face & Body Artists (Tattoos + PMU) Regulated by the individual provinces/territories	u	u
NZ	u		u Most cities and towns have commercial tattoo facilities.	
US	15 000			

MS: Member States Question Number

Table F: Number of tattoo artists and studios according to tattooist associations.

Country	Tattooists associations	TAT 2A. Number registered/official	TAT 3.2A. Number registered/official	TAT 3.1A. Number NON registered/official	TAT 4A. Number NON registered/official
		Tattoo studios	Tattoo artists	Tattoo studios	Tattoo artists
CH	VST	600	900	250	1 000
DE	UETA	8 000	u	u	6 000
DE	BVT	8 000	No separate registration process for artists and studios.	Outnumber the registered ones.	Outnumber the registered ones.
DK	DTL	u	0	3-400	1 000-1 200
ES	UNTAP	2200 - 2500	3 000-3 500	2000-5000 (30% - 40% working full time and the rest as complementary work or extra income)	2 000-5 000
IT	ART	1 500	2 500	u	> 30 000
IT	ATEC	10 20-30 (PMU)	u 5 (PMU)	15-20 20-30 (PMU)	u
IT	CNA	528 (2009) (Tattoos and piercings)	10 000	u	20 000
NO	NTU	250 only premises approved by health department	600-650 only premises approved by health department	50 not approved by government	4-5 000 not approved by government
SE	SRT	1 000 (some are registered as a beauty parlour, or other)	No official registration (Registration through health ministry, locally)	u	Home market is 10-1 compared to the legal tattoo artists

Table G: List of tattooist associations.

Country	MS 9. Number national associations of tattoo artists	Acronym	TAT 1. Number of members in association	TAT 11A. Number of customers/ year	TAT 11B. Number of <18y customers/ year
	In Europe				
AT	Association within the Chamber of Commerce	WKO			
BE	YES				
BG	NO				
CH	Swiss Association of Tattoo Artists	VST	34	400 – 450	2%
CY	u				
CZ	u				
DE	United European Tattoo Artists	UETA	120	u	u
	German Federal Association for tattooing	BTV	800	Most customers are ≥18y (artists refuse for their own legal safety)	
	German Tattoo Organisation	DOT			
	Pro Tattoo	PT			
DK	Dansk Tatovør Laug	DTL	72	u	illegal
ES	Spanish National Union of Professional Tattooists	UNTAP	480	400	10-15%
FI	Finnish Tattoo Artist Association	FTAA			
FR	Syndicat National des Artistes Tatoueurs	SNAT			
	Association Tatouage et Partage	ATP			
HU	Professional and Interest Association of Tattoo Artists	TSZEE			
	Association of Hungarian Tattoo Artists	MTSZ			
IS	NO (certified tattoo artists Facebook group share information on dangerous and harmful tattoo inks)				
IT	Italian Association of Professional Piercers and Tattooists	APTPI			
	Association of united tattoo artists	ATIR			
	Tattooists Association	ART	100	u	u
	Association of Corrective Aesthetic Tattoos	ATEC	100	600-700 (PMU)	10-15 (PMU)
	National Artwork Confederation	CNA	23 000 (hairdressers and beauticians)	347 (Only 1 studio)	0 (Only 1 studio)
LI	NO				
LU	NO				
NL	Advocacy for Tattoo artists and Piercers	BVTP			
NO	Norwegian Tattoo Union	NTU	59	100 000	10 000
PL	No				
RO	Roman Tattoo union	UTR			
SE	Swedish Registered Tattoo Artists Association	SRT	110	u	<18y not allowed by members
SI	u				
SK	NO				
UK	Tattooing and Piercing Industry Union	TPIU			
	British Tattoo Artists Federation	BTAF			

MS: Member States Question Number
TAT: Tattooist Association Question Number
y: year

Table G: List of tattooist associations (continued).

Country	MS 9. Number national associations of tattoo artists	Acronym
	Outside Europe	
CA	Allied Beauty Association	ABA
	Canadian Institute of Public Health Inspectors	CIPHI
	Canadian Network of Make-up Artists	CNMA
	Cosmetology Association of New Brunswick	CANB
	Cosmetology Industry Association of British Columbia	CIABC
	Esthetique SPA International	ESAPI
	International Spa Association	ISA
	Leading Spas of Canada	LSC
	The Cosmetology Association of Nova Scotia	CANS
	Cosmetology Industry Association of Ontario	CIAO
NZ	Tattoo Artist Association of New Zealand	TAANZ
US	National Tattoo Association	NTA
	Alliance of Professional Tattooists	APT
	Association of Professional Tattoo Artists	APTA
	American Academy of Dermatology	AAD
	New York Tattoo Society	NYTS
	Tattoo Directory	TD
	Idaho Tattoo Association	ITA
	Society of Permanent Cosmetic Professionals (PMU)	
	Permanent Makeup Society International (PMU)	
	American Academy of Micropigmentation (PMU)	
	Conventional and Cosmetic Tattoo Association (PMU)	

MS: Member States Question Number

Table H: Ink and instrument purchase.

Country	Tattooist associations	Acronym	TAT 5. Where do members buy their ink	TAT 6. Volume of inks purchased yearly/member	TAT 9. Origin of equipment and needles purchase
CH	Swiss Association of Tattoo Artists	VSB	DE Bullets Ink	2 – 3 liters	There are too many to list.
DE	United European Tattoo Artists	UETA	Abstract Silver (UETA, BTV) Fix Ink (UETA, BTV) Magic Moon (UETA, BTV) Premier Products (UETA, BTV) Tattoobedarf (UETA) Tattoo Safe (UETA, BTV) Tattoo Tools (UETA) Wildcat (BTV)	u	
	German Federal Association for tattooing	BTV		Only a fraction of the ink bought reaches a customer's skin. Most of it is wasted.	See TAT 5.
DK	Danish Professional Tattooist Association	DTL	Intenze Eternal Fusion	0.5-1 liters	
ES	Spanish National Union of Professional Tattooists	UNTAP	Only 80-85% of permitted inks is used and comes from the Black Steel Company	2- 3,2 liters (5-8 ml/tattoo)	**China** **Spain:** AM Tattoo Supplies Alkimia Tattoo Akira Body Art NTS Black Steel Supplier Black Stone Pro Arts Sun Tattoo / Micky Sharpz Rufner Primo Tattoo Supplier La Morgue Tattoo Distribution Silvermoon Paratatuar.es tatuajes.com Worldtattoozone.com FamilyArtTattooShop **Europe:** BarberDTS KillerInk Global Tattoo Suppliers LTD Lauro Polini
IT	Tattooists Association	ART	ACME (ART), Aquafirenze (CNA), Biomutazione (ART), Biotek (ART, CNA), BMD sas (ART), BMD Tattoo Supply (CNA), Bodysupply (CNA), Calavera Tattoo Supply (ART), Clarissanails (CNA), Clinita (CNA), Color Lab (ART), Colour Waves Supply (ART), Chriss Supplies (ART), Crazy Tattoo (ART), Dimensione Tatuaggio (ART), GEKO Tattoo Supplies & Equipment (ART), Geko (ART), Goldeneyeitalia (CNA), I MAX (ART, CNA), Incredibile Tattoo Supply (ART), Italian Tatto Supply (ART), Lauropaolini (CNA), MA.PI. (ART), Mar-San Supply (ART), Max Signorello Tattoo Supply (ART), Micromutazioni (ART, CNA), Passion Tattoo Supply (ART), Professional Body Supply (ART), Ripar (CNA), Sfumature (CNA), Skin Energy (ART), Sunskin Tattoo Equipment (ART), Tattoo Art Club (ART), Tattoo Devices (ART), Tattoo Supplies (ART), Tattoo Supply/Al Sole dei Caraibi (ART), Truccopermanente (CNA), Yakuza Ink (ART)	u	See TAT 5.
	National Artwork Confederation	CNA		0.5 liters	See TAT 5.
	Association of Corrective Aesthetic Tattoos	ATEC		1 liters (PMU)	Distributor
NO	Norwegian Tattoo Union	NTU	Mokki Lundberg Tattoo Supply East Street Tattoo Supply Killer Ink Ebay	Depends on how the tattoo looks, its size and who the tattooartist is. More ink is bought than used and left over ink is thrown away.	See TAT 5.
SE	SRT Swedish Registered Tattoo Artists Association	SRT	Lundberg custom supply Eaststreet tattoo supply Killer ink	1.5-2 liters	See TAT 5.

TAT: Tattooist Association Question Number

Table I: Tattoo and PMU ink importers.

	MS 10 Number ink importers in your country	
Country	**Tattoos**	**PMU**
	In Europe	
AT	u	
BE	u	
BG	Hibiskus Group Ltd Radoev 23 Ltd Velev Tattoo Ltd	Capital - East Ltd Fashion Cosmetics Ltd
CH	u	
CY	u	
CZ	u	
DE	H-A-N GmbH Magic Moon MT.Derm GmbH Tattoo Goods, Dresden Tattoo Ink Manufacturers of Europe – TIME Tattoo Tools GmbH Tribal Jewelry GmbH WEFAcolors Jo Weinbach	H-A-N GmbH MT.Derm GmbH
DK	u	
ES	Alkimia Technology and Stetic American Cosmetics- Lola Samy AM Tattoo and Piercing Supplies Ecosmeticos Electric Ink NTS Europe Micropigmentación Corporación Española Starlight- Estetica Especializada Tevian	Alkimia Technology and Stetic American Cosmetics- Lola Samy AM Tattoo and Piercing Supplies Ecosmeticos Electric Ink NTS Europe Micropigmentación Corporación Española Starlight- Estetica Especializada Tevian
FI	u	
FR	French Touch Colors	Laboratoires Biotic Phocea
HU	Radical shop Sebi Tattoo Supplies	
IS	Each artist or studio imports for itself and one store has sold ink.	
IT	Atomik Eternal Eternal/Fusion Tattoo Ink Fusion Tattoo Ink Karma Tattoo Intenzit Srl I Max International Srl Professional Body Supply Starbrite Colors: Colour Waves Supply	
LI	Only for their own studios	
LU	ITC Tattoo et Piercing Magic Moon Tattooing	
NL	Baloe La Coresse Coldskin / B.S. Trading BV TS Trading BV Tattworks	Ecuri Cosmetics B.V. Nouveau Contour

MS: Member States Question Number

Table I: Tattoo and PMU ink importers (continued).

	MS 10 Number ink importers in your country	
Country	**Tattoos**	**PMU**
	In Europe	
NO	Atomic Ink Diabolo genesis Diabolo genesis Plus Dynamic Easyflow Superior Electric Ink Eternal Fusion Ink Intenze Kuro Sumi Lining black Silverback Ink Star Brite Color Starlight Tattoo Goo	Ecuri Gaube Kosmetik Mabea PureBeau
RO	none	
SE	Majority of inks is imported (23 companies notified 1600 tattoo inks)	
SI	Only distributors, two of them provide tattooists, most buy ink online.	
SK	Tattoo Supply Slovakia Tattoo Supply Czech Republic Eternaltattooink Euro Tattoo Supply International	
	Outside Europe	
CA	Badger Air Brush co. Cam's Tattoo Supply Stencil Stuff Products Demco Evanesco Cream Papillon Supply & Mfg. Biokolor Italia SRL Radiant Colors Schwan Stabilo Cosmetics GMBH & CO	
NZ	Ink supplies imported or made very localy (if for cultural reasons).	
US		u

MS: Member States Question Number

Table J: Tattoo and PMU ink production countries (in columns).

	MS 11 Where are manufactured the inks imported in your country	
Country	**Tattoos**	**PMU**
	In Europe	
AT	US, DE importers	u
BE	US	DE
BG	US (Intenze, Eternal, Kuro Sumi, Fusion) DE (HAN Gmbh, brand Bullets) UK (Dr Sailor Company - Sailor Ink, Micky Sharp Supplies Limited - Micky Sharp ink) JP	DE, UK, ES, IL (Magic Cosmetic)
CH	u	u
CY	u	u
CZ	u	u
DE	US, UK, IT, JP, MX, BR	US
DK		u
ES	US, CN, DE, UK, IT	
FI	u	u
FR	US, CN (Imported by IT), DE, UK	u
HU	US, DE	CN
IS	US, Europe	
IT	US, DE, UK, SE	US, DE, FR
LI	DE	DE
LU	US, CN	
NL	US, CN	Europe, NL
NO	US, CN, DE, UK, ES, BR	DE, NL, AT
PL	u	u
RO	u	u
SE	u	u
SI	US JP	US
SK	US, PL, JP	CN
UK	86.7% purchased inks within UK: US (40% manufacturers) UK (32% manufactured) Asian (10% imported) Europe (4% manufacturers)	u
	Outside Europe	
CA	US, CN, DE, IT	US, CN, DE, IT
NZ	US, CN	
US	US, CN	

MS: Member States Question Number

Table K: List of manufacturers according to Member States' Authorities.

	MS 10 Number ink manufacturers	
Country	**Tattoos**	**PMU**
	In Europe	
AT	u	
BE	u	
BG	u	
CH	u	
CY	u	
CZ	u	
DE	H-A-N, Magic Moon, MT.Derm, Tattoo Goods, Tattoo Ink Manufacturers of Europe – TIME, Tattoo Tools, Tribal Jewelry, WEFAcolors Jo Weinbach	H-A-N MT.Derm
DK	u	
ES	Laurendor, Euro Permanent Cosmetics	Laurendor, Euro Permanent Cosmetics
FI	u	
FR	French Touch Colors Laboratoires Biotic Phocea	
HU	Webshops: Radical shop Sebi Tattoo Supplies	
IS	None	
IT	ABC INK, Nuova EUROCOLORI, Sunskin Tattoo Equipment, I Max International, di Max Grassi Incredibile Tattoo Supply, Yakuza Ink	Biotek
LI	Only for their own studios	
LU	None	
NL	None	
NO	None	None
PL	u	
RO	None	
SE	Majority of inks imported	
SI	None	
SK	Toppiercing – Tattoo Supply Slovakia, Eternaltattooink, Tattooshop, Tattoo-supply	
UK	u	
	Outside Europe	
CA	Tattoo ink supplies are either imported or made on a very localised basis	
NZ	u	
US	Badger Air Brush, Cam's Tattoo Supply, Stencil Stuff Products, Demco, Evanesco Cream, Papillon Supply & Mfg., Biokolor Italia, Radiant Colors, Schwan Stabilo Cosmetics Gmbh&co	

MS: Member States Question Number

Table L: Manufacturers production volume.

	MAN 3. Yearly total production volume and European market share				MAN 8. Average sale price of production	
	Tattoo inks		PMU inks			
Manufacturers	**A. Volume produced/ year (m3)**	**B. Volume produced sold on the EU market (%)**	**C. Volume produced/ year (m3)**	**D. Volume produced sold on the EU market (%)**	**A. Tattoo inks (€/ml)**	**B. PMU inks (€/ml)**
A	2.3	90	1.15	66	0.31	5.5
B	10	98	0.05	100	0.15 – 0.50	5.9
C	4	90	0.2	60	0.35	0.45
D					0.4	
E	10	100	1	100	0.12	0.6
F			0.3	100		5
L			0.4	60		5.8

MAN: Manufacturers Question Number

Table M: Manufacturers quality features.

Manufacturers	MAN 1. Origin of the ingredients and raw materials used for manufacturing tattoo or PMU inks	MAN 2. Do you request purity certificate of raw materials to your providers	MAN 9A. Risk assessment of manufactured products and ingredients before putting them on the market.	MAN 9B. Notification to country Competent Authorities.	MAN 10. GMP in production of products	MAN 13. EU manufactured inks are safer than those coming from other countries
A	BASF (DE) Geotech (NL) Univar (DE) Kronox (DE) RoHa (UK) ProVita (ES) Roth (DE) VWR (DE)	NO	On final product and on ingredients	YES	YES	Yes, because EU manufacturer take safety seriously and EU resolution exists.
B	Different European manufacturers/distributors	Best ingredients available and make own tests	Only collection of raw material documents	YES	YES	Yes, restrictions in the past forced the manufacturer to change formulation of their products (e.g. replacement of yellow 74), this did not happen in all MS
C	Commercial secret	MSDS as available, other specifications	Tissue tests like cytotoxicity and UV-toxicity or physic-chemical-testings for contaminants like PAH, AA and heavy metal for the pigments and physic chemical assessment with the complete product	YES	YES	European Standards followed, controls in Europe more strict, better educated personal.
D	European companies	Purity	Ingredients and final product by CTL and other labs	YES	YES	Unknown, no information about their used formulation
E	France (Sensient, through LCM Company) Schülke & Mayr, Italy (FU/PhEur materials through resellers ACEF)	YES. The impurities/unwanted contaminants limits of each raw material MUST be well below the limits reported in RES AP 2008-1	YES. A Product Information File (similar to cosmetic one - Reg. 1223/2009). Evaluation assuming whole product applied is absorbed (tattoo inks bring pigments under the stratum corneum, reaching the derma)	NO (Not mandatory nor requested)	YES	RES AP 2008-1 is a good guideline (avoids problems). No other guidelines exist from USA (though FDA have something similar in study)
F		YES. GMP certificate	NO	NO	YES	
L	Sensient Corp. (US) Sun Chemical (US) Clariant GmbH (DE)	YES. Heavy metal content - Aromanic amines content	YES. On final product	NO	YES	Yes, more control on final product

MAN: Manufacturers Question Number

Table N: Label composition.

	MAN 4.	MAN 5. Other information provided in the ink label					
Manufacturers	**Labelling of list of ingredients on tattoo and PMU inks**	**Manufacturer name and address**	**Date of minimum durability**	**Conditions of use and warnings**	**Batch number**	**Guarantee of sterility of the contents**	**Other information, please specify**
A	INCI Pigments in CI (decreasing order of concentration)	X	X	X	X		
B	INCI CI IUPAC (decreasing order of concentration)	X	X	X	X	X	• Date of production • Conditions of storage • Durability after opening • Type of product: tattoo colour / permanent make-up ink / Pigmentierfarbe • Address of distributor
C	CI (decreasing order of concentration)	X	X	X	X	X	Store in dark, dry and cool place Use product with xxx days after opening Product or ingredients can cause allergic reactions
D	Yes, see ingredients on the label	X	X	X	X	X	Use after opening within 365 days
E	INCI (following COSING) Pigments in CI (decreasing order of concentration)	X	X	X	X	X	Production is under the PRIVATE LABEL (not ABC INK). ABC INK provides all needed data for the own label of the customer.
F		X	X	X	X	X	
L	CI (decreasing order)	X	X	X	X	X	
SRT (SE)	Labelling chemical composition of the colour not required, basic ingredients required (such as # pigment, distilled water, thickener, preservative, alcohol), tapping date, exp date, method of packing and sterilization, exp date after opening, information regarding max temperature of storing, origin of the product batch number required for client of any colour used (if problem, leads the client to full information of content through the registration law that should be followed by anybody who distribute colours in Sweden).						

MAN: Manufacturers Question Number

Table O: Size of ink containers.

Country	Tattooist associations	TAT 8. Single or multiple ink containers
CH	**VST**	**S**
DK	**DTL**	**S**
DE	**UETA**	**M** (bottles multiple, caps single for each customer)
DE	**DOT**	
DE	**BTV**	**M** (no single use containers sold, single use containers are considered unsuitable for tattoo inks)
ES	**UNTAP**	**S** (reusing is minimal, ink is affordable so people do not buy large containers to fill)
IT	**ART**	**M**
IT	**ATEC**	**S**
IT	**CNA**	**S** (Backstage studio) 12-15 ml (members)
NO	**NTU**	**S**
SE	**SRT**	**S**

	MAN 7. Single or multiple ink containers	
Manufacturers	**Tattoo inks: Single or multiple use containers**	**PMU inks: Single or multiple use containers**
A	**M**	**S & M**
B	**M** Single use containers do not respect the way tattoo artists work in general and the market does not accept it.	**M** Single use containers, but it is not a good solution for cosmeticians that mix their inks for working (50%)
C	**M**	**M**
D	**M**	
E	**S** (1st choice monodose) **M** (10-30-50-150- mL bottles requested by customers despite RES AP 2008-1).	**S** (1st choice monodose) **M** (10-30-50-150- mL bottles requested by customers despite RES AP 2008-1).
F		**S**
L		**S & M**

MAN: Manufacturers Question Number
TAT: Tattooist Associations Question Number
S: Single
M: Multiple

Table P: Manufacturers client feed-back.

Manufacturers	MAN 11. Contact with the clients after sale	MAN 12. Client feedback in case of problems with the inks or undesirable effects in tattooed persons as result of the inks
A	Feedback of tattooists	Allergies
B	Some clients to say they are happy or if they have a problem (not often). Collection of feedback using Facebook.	Sometimes, very seldom
C	General support, adjustment of recipes, troubleshooting services, recommendations for clients with allergic background	In case of assumedly allergic reactions or infections caused by the ink
D	Information according statement of facts	No negative results
E	As the client's name/brand is on label, there is a continuous feedback for business development (client & final user satisfaction, product evolution).	Lack of brightness or not dark enough (due to safer pigments who lack colouring power compared to risky ones).
F	Strong relation to teach and train customers in using our colours.	None
L	YES. Customer care and client satisfaction	YES. Normally positive feedback on duration and tint holding in time

MAN: Manufacturers Question Number

Table Q: General issues.

MS14. Problems	MS17. Comments	TAT12. Problems	TAT13. Comments	MAN14. Problems encountered by your Company with manufacturing and distribution of inks	MAN15. Comments
Country	**Safety improvements needed**	**Improve trade**	**Need for clear composition labelling**	**Analytical methods**	**Inks**
AT		Inks bought mainly online – surveillance difficult.			
BE	Need to register side effects				
BG		Mainly via internet	Lack of composition certificates		
CH			Incomplete labelling of colours		
DE	1. Safety assessment should be obligatory 2. Missing guideline for risk assessment (B) 3. Missing GMP for tattoo - draft version of TIME exists (B)	Uncertain situations with pigment suppliers (C)	1. Incomplete list of ingredients 2. Manufacturer's list of ingredients inconsistent with importer's one	1. Missing method for quantification of soluble barium (MS) 2. No uniform rating by the authorities and according to their testing methods (D) 3. Missing standards for tests (B)	
ES		More control on web sales (illegal inks can be bought on the web)			Poor quality of authorised tattoo ink , better quality is available among non authorised ones (UNTAP)
FI		1. Exact chemical composition (including substance concentrations) difficult from market operators 2. Obligations of chemical legislation not well known by market operators			
IT		1. Compliance with regulations/meeting specifications workflow avoids problems (chemical or microbiological, no RAPEX) but leads to higher final product price than current prices (mainly imported products) (E) 2. PMU:correct obscene work with no knowledge of the installation, color changes and migration of pigments (ATEC) 3. Lack of training and knowledge of proper health and hygiene practices (ATEC)	Often confusion with Cosmetic products on labeling (L)	Methods for measuring heavy metals not defined (L)	Despite microbiological and chemical problems, clients continue with multidose sizes (E, F)

MS: Member States Question Number
MAN: Manufacturers Question Number
TAT: Tattooist Associations Question Number

Table Q: General issues (continued).

MS14. Problems	MS17. Comments	TAT12. Problems	TAT13. Comments	MAN14. Problems encountered by your Company with manufacturing and distribution of inks	MAN15. Comments
Country	**Safety improvements needed**	**Improve trade**	**Need for clear composition labelling**	**Analytical methods**	**Inks**
LI			Incomplete labelling of colours		
LU			1. Unlabelled containers with mixed or diluted inks 2. Labels poorly glued		Use of expired tattoo inks
NL				Harmonisation needed with high priority (e.g. PAA and PAH)	
NO	1. Stop hometattooers and sales of "start-kit" 2. Mandatory hygine and ink-control classes 3. Public web-site with list of authorised studios (NTU)	Suppliers do not follow regulation (NTU)			
SE	Stop hometattoers (SRT)	Fake CE marking, questionable info (e.g. sterility of needles when it is not) (SRT)			Poor quality inks in terms of impurities from China (SRT)
SI	Make safety assessment of tattoo inks available to tattoists				
SK	Counterfeit products				

MS: Member States Question Number
MAN: Manufacturers Question Number
TAT: Tattooist Associations Question Number

Table R: Regulatory issues.

Country	Regulation in place	No compliance	Regulation required	Compulsory notification
In Europe				
BE		CoE ResAP	At EU level	
CH	yes	Pigments and preservative difficult to find colours according to ResAP (VST)	Establishing positive list of colorants (VST)	
DE	yes	Banned colorants and preservatives, heavy metals, PAA, PAH, unregulated dyes	1. ≠ laws and requirements in MS (B, C & A) 2. Changing regulations (C) 3. CEN hygiene standard still missing (UETA) 4. Poor collaboration between manufacturers & authorities (C) 5. Guidance values for technically unavoidable impurities amounts 6. Sterility 7. System to report undesirable health effects	1. Place of production in DE or place of import in DE 2. Ingredients
ES	yes	1. Tattoo inks not authorised by AEMPS 2. Incorrect labelling	Better if at EU level (UNTAP)	
FI		"Backyard tattoo shops" out of surveillance authorities powers Obligations stipulated in health protection and consumer safety legislation not well known by tattoo service providers in general	At EU level and CEN standards	
IT	CoE ResAP applies	Sealed tattoo inks microbiologically contaminated, PAA, PAH, heavy metals	1. Lack of a law establishing training and regulation of the profession (CNArt) 2. Regulations not clear (L)	
LI		banned colorants and preservatives		
LU			To prevent illegal studios and artists	
NL	yes	PAA, PAH		
NO	yes	PAA and impurities (NTU)	Single negative or positive list instead of referencing various lists in different legislations	
SE	yes	PAA, PAH, heavy metals, missing compulsory warnings for Ni, composition labels, batch n., sterility indication and SRT		
SK		Heavy metals, missing identification of responsible person (importer)		
Outside Europe				
NZ	Voluntary guidelines	Heavy metals		
US		Pigments listed on MSDS do not reflect the actual ink composition		

Table S: Health problems.

Country	MS 16. Presence of register for adverse effects/Vigilance system	Registered adverse effects - chemical composition	Registered adverse effects - microbiological contamination
In Europe			
AT	no		
BE	no		
BG	no		
CH	no		
CY	no		
CZ	no		
DE	no	1. Extremely rare (allergic reactions to red inks) (BTV) 2. Allergies (A)	Extremely rare (troubles with wound healing) (BTV, see also 2010, Klügl)
DK	no		
ES	National cosmetovigilance system		
FI	no		
FR	yes	Hypersensitivity reactions (eczema, granulomatous, sarcoid, pseudolymphomatous reactions)	Bacterial infections (Mycobacterium chelonae)
HU	no		
IS	no		
IT	no		
LI	no		
LU	no		
NL	Online website where consumers can register complains after using cosmetic products		
NO	yes		
PL	no		
RO	yes		
SE	no	Allergic reaction (SRT)	MRSA, hepathitis, syphilis, infections (SRT)
SI	no		
SK	no		
UK	no		
Outside Europe			
CA	The Consumer Product Safety Program tracks trends in complaints and incidents Both consumers and industry submit incident reports on a voluntary basis. A safety alert was published to warn Canadians about the risks of removal products.		
US	MedWatch (for Adverse Events) FDA (for Consumer Complaints)		

MS: Member States Question Number

Table T: Market surveillance.

Country	MS 13. Market surveillance	Samples	Results	Entity
In Europe				
AT	yes	15 tattoo dyes in 2012	6 Ni excess levels 2 Ba excess levels One 100 times ResAP-limit	Conseil Superieur Sante
BE	yes		Report	Conseil Superieur de la Sante
BG	yes		GRAS-RAPEX	Regional Health Inspectorates
CH	yes		Report 2014	Health Protection Department of the Canton Basel
CY	yes		RAPEX	
CZ	no			Czech Trade Inspection
DE	yes	1 000 since 2010 --> >22 000 results	• Microbiology • Elements amounts • PAA • Preservatives • PAH • Dyes	Market surveillance authority
DK	no			
ES	yes		• Commercialization tattoo inks not authorized by the AEMPS • Incorrect labelling • Microbial contamination due to inadequate manipulation	Autonomous Communities
FI	yes			Based on RAPEX-notifications.
FR	yes	52 in 2012-2013	• Sterility • PAA • Heavy metal	Market control
HU	no			
IS	no			
IT	yes	34 tattoo and 11 PMU brands in 2013-2015	• microbiological contamination • PAA, PAH • Ni, Ba, Sb, Pb, As, Cd (See RAPEX notifications)	
LI	yes			Performed by CH
LU	yes	5 in January-March 2014	Ag,Al, Ba, Co, Cr, Cu, Fe, Ga, Mg, Mn, Mo, Ni, Pb, Sn, Sr, Ti, V, Zn, Zr	Luxembourg Institute of standardization, accreditation, security and quality of products and services (ILNAS)
NL	yes	• 2004 • 2014	PAH	Food and Drug Administration
NO	yes			
PL	no			
RO	no			
SE	yes	• 31 in 2010 • 14 in 2012 • 20 tattoos and 9 PMU in 2014-2015	• impurities • PAA, PAH & benzo-a-pyrene • Sb, As, Ba, Pb, Zn	Swedish Chemicals Agency Swedish Chemicals Agency Medical Products Agency
SI	yes	2013 in 2010-2013	• different metals in different colours • some PAHs • exceptionally PAA • all complied with sterility testing • some non-allowed ingredients	
SK	yes		• Cu 26 737 mg/kg • RAPEX	
UK	yes	12 brands, 143 products in 2008 & 2010	• microbiology • toxic metals	Health and Safety Laboratory
Outside Europe				
CN	no	Done in 2011, testing for heavy metals and microbial contamination		Health Canada
NZ	yes		heavy metals	Ministry of Health

MS: Member States Question Number

Annex IV

Replies to questionnaires
Ink ingredients

Table A: List of colorants in use in tattoo inks and found in market surveillance activities.

		Market surveillance	Used as ingredient in tattoo inks			
Colour Index Generic Name	Colour index Constitution Number	Country	Country	Jurisdictions	tattooist associations	manufacturers
AR 14	14720					
AR 18	16255	BG		CA (>30%)		
AR 51	45430	BG				
AR 87	45380	BG				
BR 1	45160	CH, LI	DE			
Cinnabar (HgS)						
DR 53 Oxamine B	22095	NL	NL			
FR 17:1	16035:1	BG, NL	DE, IT, NL			
NR 4	75470	NL	NL			
NR 22	75510					
NR 23	75510					
PR 2	12310	BG, CH, LI	IT	US		
PR 3	12120	CH, LI				
PR 4	12085	CH, LI, NL	DE, NL			
PR 5	12490	BG, CH, DE, LI, IT[1]	IT		BVT	A (25%), D
PR 7	12420		prohibited in FR			
PR 9	12460					
PR 12	12385	CH, LI				
PR 14	12380					
PR 15	12465			CA (>30%)		
PR 17	12390		IT			
PR 22	12315	BG, CH, DE, LI, IT[2]	IT	CA (>30%), US	DTL, NTU	D, H
PR 23	12355	DE		US		H
PR 48:1	15865:1				NTU	
PR 49	15630	CH, LI				
PR 49:2	15630:2	IT[3]	IT			
PR 51	15580	CH, LI	DE			
PR 53:1	15585	CH, LI	DE			
PR 57:1	15850:1	BG, CH, DE, LI, NL	NL			
PR 57:2	15850:2	BG, CH, LI				
PR 60	16105		IT			
PR 63:1	15880	CH, LI		US		
PR 101 and 102	77491	BG, DE, ES, NL	DK, ES, IT, NL	CA (>30%), US	BVT, DTL, NTU	D (<40%), E, F, H
PR 112	12370	CH, DE, LI, NO	NO, prohibited in FR	CA (>30%)	ART, BVT	D (<40%)
PR 120	12474		DE			
PR 122	73915	BG, CH, DE, LI, NO, SE	DK, IT, NO, SE, prohibited in FR	CA (>30%), US	ART, BVT, DTL, NTU	D (<40%), E, H
PR 146	12485	CH, DE, LI, NL, SE	DK, IT, NL, SE	CA (>30%)	BVT, UETA	D (<40%), I
PR 170	12475	BG, CH, DE, LI, IT[4], NL, NO	DK, IT, NL, NO	US	ART, BVT, NTU, UETA	C, D (<40%), E, F, H, I
PR 177	65300					
PR 179	71130	DE		US		
PR 181	73360	BG, CH, DE, LI	IT			
PR 202	73907	CH, DE, LI, SE	IT, SE		ART	
PR 210	12477	BG, CH, LI, DE, NL, NO, SE	IT, NL, NO, SE	CA (>30%), US	BVT, DTL, NTU	D (<40%), E, F, H
PR 222	123665			US		
PR 242	20067					
PR 254	56110	CH, DE, LI, SE	IT, SE	US	ART, UETA	I
PR 257	56270					
PR 266	12474	CH, DE, LI	DK			
PR 269	12466	BG, NL, NO	IT, NL, NO		ART, NTU	
PR 340		BG				
SR 1	12150					

		Market surveillance	Used as ingredient in tattoo inks			
Colour Index Generic Name	Colour index Constitution Number	Country	Country	Jurisdictions	tattooist associations	manufacturers
AY 3	47005	BG, CH, DE, LI, NL	IT, NL			
AY 9	13015					
AY 23	19140	CH, DE, LI, SE	IT, SE	CA (>30%)		
AY 104	15985:1	DE				
Diarylide Y				US		
Arylide Y				US		
FY 3	15985	ES	ES, IT		UETA	
PY 1	11680	BG, CH, DE, LI, IT[5], NL	DK, prohibited in FR, IT, NL		ART, BVT	C (<40), E (25%)
PY 3	11710	CH, DE, LI, IT[6], NL	IT, NL	US		
PY 12	21090	CH, LI		CA (>30%)		
PY 14	21095	CH, DE, LI, IT[7], NO, SE	IT, NO, SE		BVT, NTU	C (<40), I
PY 36	77955					
PY 42 and	77492	DE	IT, NL	CA (>30%), US	BVT, DTL,	C (<40), G, H, I
PY 55	21096					
PY 65	11740	BG, CH, DE, LI, IT[8],	IT, NO	US	NTU	H
PY 74	11741	BG, CH, DE, LI, IT[9], NL, NO, SE	DK, IT, NL, NO, SE	CA (>30%), US	ART, BVT, DTL, NTU	C (<40), G, I
PY 83	21108	BG, CH, DE, LI, IT[10], NO	prohibited in FR, IT, NO	CA (>30%), US	ART, BVT, DTL, NTU	C (<40), G, H, I
PY 87	21107:1		IT			
PY 93	20710		IT			
PY 97	11767	CH, DE, LI, NL	DK, IT, NL	CA (>30%)	ART, BVT	B, C (<40), H
PY 100	19140:1					
PY 110	56280					B (evaluation)
PY 119	77496			CA (>30%)		
PY 138	56300	CH, DE, LI	IT	US	ART, UETA	A (0-40%), B
PY 139	56298					B (evaluation)
PY 151	13980	CH, LI, DE, NL, NO	IT, NL, NO	CA (>30%), US	ART	
PY 154	11781	CH, LI				
PY 155	200310	DE			UETA	D
PY 180	21290	NL	NL			
PY 194	11785			US		
AB 9	42090	BG, DE, NL	NL	CA (0.1-0.3%)		
DB 86	74180				NTU	
PB 15	74160	BG, CH, DE, LI, ES, NL, NO, SE	DK, ES, IT, NL, NO, SE	CA (>30%), US	ART, BVT, DTL, NTU, UETA	A (0-20%), B, C (x<25), D, E (25%), G, H, I
PB 17	74180 74200				NTU	
PB 25	21180	IT[11]	IT		NTU	
PB 27	77510	BG, ES	ES			
PB 29	77007	BG, DE, NL	NL		BVT	C (x<30)
PB 60	69800					B (evaluation)
Lawsone	75480					
PO 5	12075	CH, DE, LI, NO	NO			G, I
PO 13	21110	BG, CH, DE, LI, NL, NO	IT, NL, NO	CA (>30%), US	ART, BVT, DTL, NTU	C (x<40), H
PO 16	21160	BG, CH, DE, LI, IT[12], NL, NO, SE	IT, NL, NO, SE	CA (>30%), US	ART, BVT, DTL, NTU	C (x<40), G, I
PO 22	12470	NL	NL			
PO 34	21115	CH, DE, LI	IT		ART, NTU	
PO 36	11780		DK			

		Market surveillance	Used as ingredient in tattoo inks			
Colour Index Generic Name	Colour index Constitution Number	Country	Country	Jurisdictions	tattooist associations	manufacturers
PO 43	71105	CH, DE, LI, NL, NO	DK, prohibited in FR, IT, NL, NO			
PO 73	561170	CH, DE, LI, NL, SE	IT, NL, SE		ART, UETA	A (0-15%), B, D
PO 74						
BV 10	45170	BG, DE, CH, LI	prohibited in FR, IT	US	NTU	H
PV 1	45170:2	BG		US		
PV 12	58050			US		
PV 15	77007		IT			
PV 16	77742	DE, NL	IT, NL	US		
PV 19	73900	CH, DE, LI, NL, NO	prohibited in FR, NL, NO	CA (>30%), US	BVT, UETA (prohibited)	C (x<40), G, H, I
PV 23	51319	BG, CH, LI, DE, NL, NO	DK, NO, prohibited in FR, IT, NL	CA (>30%), US	ART, BVT, DTL, NTU, UETA (prohibited)	C (x<40), E (25%), G, H, I
PV 37	51345	CH, DE, LI	IT		ART, UETA	A (0-10%), B, D
VV 2	73385	DE			NTU	
Ferous oxide,black	77489	BG, NL, SE	IT, NL, SE			
PBlack 2				US		
PBlack 6 and 7	77266 77265	BG, DE, ES, NL, NO, SE	DK, ES, IT, NL, NO, SE	CA (>30%)	ART, BVT, DTL, NTU, UETA	A (0-20%), B, C (x<25), D, E (25%), G, H, I
PBlack 9	77267	NL	NL			
PBlack 11	77499	DE, ES, NL	ES, IT, NL			
PBlack 15				US		
PBr 6 and 7	77491 77492 77499	BG, DE, ES, NL, NO, SE	ES, IT, NL, NO, SE	CA (>30%), US	BVT, NTU	C (x<35)
PBr 25	12510	CH, DE, LI, IT[13], NL	DK, IT, NL		ART	
PBr 175		BG				
AG 25	61570	NL	NL			
PG 7	74260	BG, CH, DE, LI, NO	DK, prohibited FR, IT, NO	CA (>30%)	ART, DTL, NTU, UETA (prohibited)	A (0-20%), B (not used but would like), E (25%), G,
PG 17	77288	BG, DE, ES	ES		BVT	C (x<30)
PG 18	77289					
PG 36	74265	BG, CH, DE, LI, NL, NO	IT, NL, NO	US	ART, BVT, NTU	B, C, D
Aluminium Silicate	77004					
Barium sulphate	77120					
PW 4	77941		IT			
PW 6	77891	BG, DE, ES, NL, NO, SE	DK, ES, IT, NL, NO, SE	US	ART, BVT, DTL, NTU, UETA	A (0-45%), B, C (x<60), D, E (25%), G, H, I

IT[1] o-toluidine, 167 mg/Kg; p-chloroaniline, 52 mg/Kg; p-cresidine, 1.0 mg/Kg (as impurities or reductive cleavage products)

IT[2] 2-methyl-5-nitroaniline, 40 mg/Kg; 2,4-diaminotoluene, 400 mg/Kg (as impurities or reductive cleavage products)

IT[3] 3,3'-dichlorobenzidine, 3,3 mg/Kg (as impurity or reductive cleavage product)

IT[4] o-toluidine, 27 mg/Kg; o-anisidine, 1.7 mg/Kg; p-chloroaniline, 23 mg/Kg; 2-methyl-5-nitroaniline, 47 mg/Kg; 2,4-diaminotoluene, 238 mg/Kg (as impurity or reductive cleavage products)

IT[5] o-toluidine, 8.5 mg/Kg (as impurity or reductive cleavage product)

IT[6] o-anisidine, 28 mg/Kg (as impurity or reductive cleavage product)

IT[7] o-toluidine, 100 mg/Kg average (as impurity or reductive cleavage product)

IT[8] o-anisidine, 200 mg/Kg average (as impurity or reductive cleavage product)

IT[9] o-anisidine, 250 mg/Kg average;o-toluidine, 3.0 mg/Kg (as impurities or reductive cleavage products)

IT[10] o-anisidine, 175 mg/Kg (as impurity or reductive cleavage product)

IT[11] o-anisidine, 20 mg/Kg average (as impurity or reductive cleavage product)

IT[12] o-anisidine, 250 mg/Kg (as impurity or reductive cleavage product)

IT[13] o-toluidine, 2.7 mg/Kg; p-chloroaniline, 29 mg/Kg

Table B: List of colorants in use in PMU inks and found in market surveillance activities.

		Market surveillance	Used as ingredient in PMU inks			
Colour Index Generic Name	Colour index Constitution Number	Country	Country	Jurisdictions	tattooist associations	manufacturers
AR 14	14720		IT			
AR 18	16255		IT	CA (>30%)		
AR 51	45430			CA (>30%)		
AR 87	45380	ES	DK, ES			F
BR 1	45160	CH, LI				
Cinnabar (HgS)						
DR 53 Oxamine B	22095					
FR 17:1	16035:1	DE, ES	DK, ES, IT			A (0-30%), F
NR 4	75470	SI	IT			
NR 22	75510	DE				
NR 23	75510	DE				
PR 2	12310	CH, LI				
PR 3	12120	CH, LI				
PR 4	12085	CH, LI	IT			F
PR 5	12490	CH, LI	IT	CA (>30%)	BVT	A (0-30%), E (25%)
PR 7	12420	DE	prohibited in FR			
PR 9	12460					
PR 12	12385	CH, LI				
PR 14	12380					
PR 15	77015					
PR 17	12390					
PR 22	12315	CH, LI				
PR 23	12355					
PR 48:1	15865:1					
PR 49	15630	CH, LI				
PR 49:2	15630:2					
PR 51	15580	CH, LI				
PR 53:1	15585	CH, LI				
PR 57:1	15850:1	CH[1], LI, ES	ES, IT		CNA	F, L (<20%)
PR 57:2	15850:2	CH[2], LI				F
PR 60	16105					
PR 63:1	15880	CH, LI				
PR 101 and 102	77491	DE, ES, SE, SI	DK, ES, IT, SE	CA (>30%)	BVT, CNA	A (0-35%), C (<40)
PR 112	12370	CH, LI	prohibited in FR, IT			
PR 120	12474					
PR 122	73915	CH, LI, ES, SI	ES, prohibited in FR		BVT	C, L (<30%)
PR 146	12485	CH, LI				
PR 170	12475	CH[3], LI, SI			CNA	B
PR 177	65300					
PR 179	71130				CNA	
PR 181	73360	CH, DE, LI, ES, SE, SI	ES, SE	CA (>30%)		A (0-25%), L (<45%)
PR 202	73907	CH, DE, LI, SI				
PR 210	12477	CH, LI, SI				
PR 222	123665					
PR 242	20067					L (<35%)
PR 254	56110	CH, DE, LI, SI			CNA	L (<50%)
PR 257	56270					
PR 266	12474	CH[4], LI				
PR 269	12466					
PR 340						
SR 1	12150	ES	DK, ES			

		Market surveillance	Used as ingredient in PMU inks			
Colour Index Generic Name	Colour index Constitution Number	Country	Country	Jurisdictions	tattooist associations	manufacturers
AY 3	47005	CH, DE, LI	DK, ES, IT	CA (>30%)		
AY 9	13015					
AY 23	19140	CH, DE, LI, ES, SE	ES, IT, SE	CA (>30%)	CNA	F
AY 104	15985:1		IT			
Diarylide Y						
Arylide Y						
FY 3	15985					A (0-20%), F
PY 1	11680	CH, LI	prohibited in FR			E (25%)
PY 3	11710	CH, LI				
PY 12	21090	CH, LI				
PY 14	21095	CH, LI, SI				
PY 36	77955					
PY 42 and 43	77492	DE, ES, SI	DK, ES, IT	CA (>30%)	BVT, CNA	C (x<40)
PY 55	21096					
PY 65	11740	CH, LI, SI				
PY 74	11741	CH, LI				
PY 83	21108	CH, LI	prohibited in FR			
PY 87	21107:1					
PY 93	20710	DE				
PY 97	11767	CH, DE, LI				B
PY 100	19140:1					A (0-10%)
PY 110	56280					B (evaluation)
PY 119	77496					
PY 138	56300	CH, LI				A (0-20%), B
PY 139	56298					B (evaluation)
PY 151	13980	CH, LI				
PY 154	11781	CH, LI			CNA	
PY 155	200310					
PY 180	21290					
PY 194	11785					
AB 9	42090	DE	DK, IT			
DB 86	74180					
PB 15	74160	CH, DE, LI, SI	IT	CA (>30%)	BVT	A (0-15%), B, C (x<35), E (25%)
PB 17	74180 74200					
PB 25	21180					
PB 27	77510		IT			
PB 29	77007	DE, ES, SI	ES, IT	CA (>30%)	BVT	C (x<30), F
PB 60	69800					B (evaluation)
Lawsone	75480					
PO 5	12075	CH, LI				
PO 13	21110	CH, LI, SI				
PO 16	21160	CH, LI				
PO 22	12470					
PO 34	21115	CH, LI				
PO 36	11780					
PO 43	71105	CH, LI	prohibited in FR			
PO 73	561170	CH, LI				B
PO 74						

		Market surveillance	Used as ingredient in PMU inks			
Colour Index Generic Name	Colour index Constitution Number	Country	Country	Jurisdictions	tattooist associations	manufacturers
BV 10	45170	CH, LI	prohibited in FR			
PV 1	45170:2					
PV 12	58050					
PV 15	77007					
PV 16	77742	DE, SE	DK, IT, SE		BVT	C (x<30), F
PV 19	73900	CH, LI	prohibited in FR			L (<25%)
PV 23	51319	CH, LI	prohibited in FR			E (25%)
PV 37	51345	CH, LI				B
VV 2	73385					
Ferous oxide,black	77489	NL, SE, SI	DK, IT, NL, SE		BVT	C (x<40)
PBlack 2						
PBlack 6 and 7	77266 77265	DE, ES, NL, SI	ES, IT, NL	CA (>30%)	CNA, BVT	A (0-20%), B, C (x<25), E (25%), F, L (<55%)
PBlack 9	77367					
PBlack 11	77499	DE, ES, NL, SE, SI	ES, IT, NL, SE		CNA, BVT	A (0-50%), C (x<40), L (<40%)
PBlack 15	77403					
PBr 6 and 7	77491 77492 77499	DE, ES, SE, SI	DK, ES, NL, SE	CA (>30%)	CNA, BVT	A (0-20%), F, C (x<35), L (<60%)
PBr 25	12510	CH, LI				C
PBr 175						
AG 25	61570					
PG 7	74260	CH, LI, SI	prohibited in FR		BVT	B (not used but we would like to use it), E (25%)
PG 17	77288	DE	IT	CA (>30%)	CNA	A (0-35%), C (x<30), F
PG 18	77289	ES	ES, IT			
PG 36	74265	CH, LI			BVT	B, C
Aluminium Silicate (bentonite, White)	77004	DE				
Barium sulphate	77120					
PW 4	77941					
PW 6	77891	DE, ES, SE, SI	DK, ES, IT, SE		BVT, CNA	A (0-50%), B, C (x<60), L (<60%)

CH[1] (not differentiated from free Base or :2)

CH[2] (not differentiated from free Base or :1)

CH[3] 55/637 (29 samples only C.I. 12475; 26 samples in combination with C.I. 12474 as part of pigment C.I. 12477)

CH[4] 26/637 (always in combination with C.I. 12475 as part of pigment C.I. 12477)

Table C: List of additives, both auxiliaries and preservatives, in use in tattoo inks and found in market surveillance activities.

		Market surveillance results	Used as ingredient in tattoo inks			
Auxiliaries	**CAS number**	**Country**	**Jurisdictions**	**Country**	**tattooist associations**	**manufacturers**
Acrylates copolymer						B
Acrylic polymer						A (0-5%)
Acrylic Resin TSRN00195201005-5100P			US		NTU	G, H, I
Acrylic Resin TSRN00195201005-5102P					NTU	H
Aloe barbadensis	85507-69-3 94349-62-9	CH, LI				
Aluminum hydroxide	21645-51-2	CH, LI, DE				
Aminomethyl propanediol	115-69-5	CH, LI				
Ammonia	7664-41-7	NL		NL		B
Ammonium acrylates copolymer	63744-68-3	CH, DE, LI, SE		SE	ART, BVT, UETA	B, C, D
Amorphous silica (Silicon dioxide)	7631-86-9	CH, DE, LI			BVT	B, C
Anionic surfactant						
Barium sulphate	7727-43-7	DE, NL		NL	BVT, UETA	C, D
beta-Naphthol ethoxylate	35545-57-4	CH, LI (1.6-19%)				
Block copolymer		DE				
Borax	71377-02-1	NL		NL		
Butanamid	541-35-5					
Calcium natrium phosphosilicate		CH, LI		DE		B
Calcium sodium phoshosilicate		CH, DE, LI, NL		NL		
Calendula extract	84776-23-8	SE		SE	BVT, NTU	C
Caprylil glycol (1,3-octadienol)	1117-86-8				BVT	B, C
Carboxylated acrylic						B
Carbomer	9007-20-9 9003-01-4 76050-42-5 9062-04-8 9007-16-3 9007-17-4	CH, DE, LI				
5-Chloro-2methyl-2H-isothiazol-3-one/2-Methyl-2H-isothiazol-3 one mixture (CMIT/MIT mixture) antimicrobial	55965-84-9				ART	
Citric acid	77-92-9 5949-29-1	CH, DE, LI				
Detergents						
Dibutyl phthalate	84-74-2					
7-Diethylamino-4-methylcoumarin	91-44-1		US			
Diethyleneglycol	111-46-6	NL		NL		
Dimethicone	9006-65-9				ART	
Dipropylene glycol	110-98-5					B
Disodium cocoyl glutamate	68187-30-4	CH, LI				
Emuisifier		NL		NL		
Ethanol	64-17-5	BG , CH, LI ,DE (48%), ES, NL, SE	CA (10-30%)	ES, IT, NL, SE	ART, BVT, DTL	B, C
Ethylene glycol	107-21-1					
Ethylhexyl glycerine	70445-33-9	CH, DE, LI				
Essential oils		DE				
Gelatine	9000-70-8	NL		NL		
Glycerol (Glycerine)	56-81-5 8043-29-6	BG, CH, LI ,DE, ES, NL, SE	US, CA (10-30%)	ES, IT, NL, SE	ART, BVT, DTL, NTU, UETA	A (1-5%), B, C, D, E, G, H, I
Glyceryl caprylate/caprate	26402-26-6 27214-36-4					B
Glyceryl stearate	31566-31-1	CH, DE, LI			ART	

		Market surveillance results	Used as ingredient in tattoo inks			
Auxiliaries	**CAS number**	**Country**	**Jurisdictions**	**Country**	**tattooist associations**	**manufacturers**
Gum	11138-66-2	NL		NL		
Hamamelis virginiana (leaf extract)/ Whitz hazel extract	84696-19-5	CH, LI, NL, SE		IT, NL, SE	ART, NTU	C
Hamamelis virginiana extract	68916-39-2	DE			ART, BTV	B
Hydrochloric acid	7647-01-0	CH, LI				
Hydroxypropylmethylcellulose	9004-64-2 9004-65-3 8063-82-9	CH, LI				
Hydroymethyl aminoethanol	65184-12-5	CH, LI				
Humectants						
iso-Octylphenolethoxylate, Octoxynol	92046-34-9	CH, LI				
Isopropanol	67-63-0	BG, CH, LI, DE (19%), NL, SE	CA (10-30%)	IT, NL, SE	ART, BVT, DTL, NTU, UETA	A (5-20%), C, D, E, G, H, I
Kaolin	1332-58-7	DE	CA (3-10%)			
Lactic acid	50-21-5	CH, LI				
Lecithin	8002-43-5 8030-76-0 (soybean)	CH, LI	US			
Menthol	2216-51-5	NL		NL		
Methanol	67-56-1					
Methyl ethyl keton	78-93-3	CH, LI				B
Methylpropanediol	2163-42-0				BVT	B, C
Modified organo polysiloxanes						A (0-1%)
Neodecanoic acid	26896-20-8					
N-vinyl-2-pyrrolidone	94800-10-9				ART	
Nonylphenolethoxylate, Nonoxynol		CH, LI (0.03-3.9%)				
Non-ionic surfactant						
C9-11 Pareth-6	68439-46-3	CH, LI				B
PEG-8	5117-19-1 25322-68-3 (generic)	CH, DE, LI, SE		SE	ART, BVT, NTU, UETA	B, C
PEG-200	25322-68-3	CH, DE, LI, SE		IT, SE	ART, NTU	
PEG-400	25322-68-3				BVT	A (0-5%), C
PEG-600		CH, LI	US			
PEG Isooctyl phenyl ether		CH, LI	US			B, G, H
Phenylpropanol	1335-12-2				BVT	C
Poloxamer 188	9003-11-6	CH, DE, LI			UETA	
Poloxamer 407 **Poly alchilen glycol ether**	9003-11-6	CH, LI			BVT UETA	C
Polyethylenglycol	25322-68-3	DE				
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-, branched, phosphates	68412-53-3	DE			ART	
Polysorbate 20 (Tween 20)	9005-64-5	CH, LI			ART, BVT	C
Polysorbate 80 (Tween 80)	9005-65-6					B
Polyvinylpyrrolidone (PVP) (Polyvidone, Povidone)	9003-39-8	CH, DE, LI, NL		NL	BVT, NTU, UETA	B, C, D
Proprietary resin		NL		NL		I
Polypropilene	9003-07-0				ART	
Propanediol	26264-14-2				ART	
Propylene glycol	57-55-6	CH, LI, DE, NO, SE	US	IT, NO, SE	BVT, NTU, UETA	A (10-15%), B, C, D, H, G
Poly(propylene glycol)	25322-69-4				ART	
Ricin Oil	8001-79-4	CH, LI				
Rosa canina	84603-93-0				BVT	C
Rosa Centifolia	84604-12-6	NL		NL		
Rosa damascena extract	90106-38-0	CH, LI				E

		Market surveillance results	Used as ingredient in tattoo inks			
Auxiliaries	**CAS number**	**Country**	**Jurisdictions**	**Country**	**tattooist associations**	**manufacturers**
Rosin	8050-09-7	CH, LI				
Shellac	9000-59-3	CH, DE, LI, NL		NL	ART, BVT, UETA	B, C, D
Silica	112945-52-5				ART, UETA	
Silica dimethyl silylate	271-893-4					B
Simethicone	8050-81-5				BVT	B, C
Sodium cocoyl glutamate	68187-32-6	CH, LI				
Sodium hydroxide	1310-73-2	BG, CH, DE, LI	CA (10-30%)		BVT	C
Sorbitol	50-70-4 98201-93-5	CH, LI				
Tetramethyl decynediol (Surfonyl®104, TMDD)	126-86-3	CH, LI, NO		NO		
Thymol	89-83-8	NL		NL		
Trimethylolpropane triisostearate	68541-50-4	CH, LI				
Vodka						
VP/VA Copolymer	25086-89-9	CH, LI			BVT, NTU	A (0-10%), B, C
Water	7732-18-5	DE, NL, SE	US	NL, SE	BVT, NTU	B, G, H, I,
Witch hazel			US			I

		Market surveillance results	Used as ingredient in tattoo inks			
Preservatives	**CAS number**	**Country**	**Jurisdictions**	**Country**	**tattooist associations**	**manufacturers**
Aldehydes (like glutaraldehyde)						
2-Amino-2-methylpropanol	124-68-5	DE			BVT, UETA	C, D
Benzoates						
Benzophenone	119-61-9					
Benzoic acid	65-85-0	CH, LI (0.004-0.12%), DE (0.04%), NL		NL	BVT	B (not used as preservative) , C
Benzoisothiazolinone (BIT)	2634-33-5	CH, LI (20-420 mg/kg), DE (0.0004%, >100ppm)		IT	UETA	D
2-Bromo-2-nitropropane-1,3-diol	52-51-7	CH, LI (0.02%)			ART	
Buthylparaben	94-26-8					
Chlorhexidine	55-56-1	CH, LI (0.02%)		DE		
4-Chloro-3,5-dimethylphenol (Chloroxylenol)	88-04-0	CH, LI (0.25%)		DE		
Dehydroacetic acid	520-45-6 771-03-9 16807-48-0	CH, LI (0.038-0.089%)				
Dibenzofuran	132-64-9					
1,2-Dibromo-2,4-dicyanobutane	35691-65-7					
2-4 Dichlorobenzylalcohol	1777-82-8					
DMDM Hydantoin	6440-58-0	CH, LI				
Ethylparaben	120-47-8	CH, LI (0.02%)				
9-Fluoenone	486-25-9					
Formaldehyde	50-00-0	CH, LI (0.005-0.23%)	US	DE		
Glyoxal	107-22-2	CH, LI (80-200 mg/kg)		DE		
Hexachlorobutadiene	87-68-3					
Hexamethylenetetramine	100-97-0					
p-Hydroxy benzoate	456-23-5			DE		
Hydroxymethylamino ethanol			US			G, H
Iodopropynyl butylcarbamate	55406-53-6	CH, LI, DE				
Isobuthylparaben	4247-02-3					
Isopropylparaben	4191-73-5					
Isothiazolon (Kathon CG)	96118-96-6					

		Market surveillance results	Used as ingredient in tattoo inks			
Preservatives	**CAS number**	**Country**	**Jurisdictions**	**Country**	**tattooist associations**	**manufacturers**
Listerine (mouth wash) for thinning of traditional inks - this contains thymol, eucalyptol, menthol, methyl-salicylate, benzoic acid, sodium benzoate, water, alcahol, poloxamer						
Melamine	108-78-1		US			
Methylchloroisothiazolinon	26172-55-4	CH, LI				D
Methyldibromo glutaronitrile	35691-65-7	NL	CA (0.1-0.3%)	NL		
Methylisothiazolinone (2-methyl-4-isothiazolinone)	2682-20-4	CH, LI (0.4-70 mg/kg), DE (0.0003%)			UETA	
Methylparaben	99-76-3	CH, LI (0.04, 0.06%), DE (0.04%), NL		NL		
MI/MCI	26172-55-4 2682-20-4			DE		
Octylisothiazolinon	26530-20-1	CH, LI (40-450 mg/kg)		DE	ART	
o-Phenylphenol	90-43-7	CH, LI (0.06-0.11%)		DE		
Phenol	108-95-2	CH, LI (80-4700 mg/kg), NO		DE, NO		
Phenoxyethanol	122-99-6	CH, LI (0.015-1.5%), DE (0.75%), NL		NL	BVT, UETA	B, C
Polyaminopropyl biguanide	32289-58-0 133029-32-0	CH, DE, LI				
Preservative						
Propylparaben	94-13-3	CH, LI (0.01%)				
Salicylic acid	69-72-7	CH, LI (0.02%)				
Sodium Borat	1330-43-4 1303-96-4	DE				
Sodium Chloride	7647-14-5					
Sorbic acid	110-44-1	CH, LI (0.01-0.076%)		DE		
Thymol	89-83-8	NO		NO	UETA	
Triclosan Irgasan	3380-34-5					
Toluenesulfonamide resin			US			

Table D: List of additives, both auxiliaries and preservatives, in use in PMU inks and found in market surveillance activities.

		Market surveillance	Used as ingredient in PMU inks			
Auxiliaries	CAS number	Country	Jurisdictions	Country	tattooist associations	manufacturers
Acrylates copolymer						B
Acrylic polymer						
Acrylic Resin TSRN00195201005-5100P						
Acrylic Resin TSRN00195201005-5102P						
Aloe barbadensis	85507-69-3 94349-62-9	CH, LI				
Aluminum hydroxide	21645-51-2	CH, LI				
Aminomethyl propanediol	115-69-5	CH, LI			BVT	
Ammonia	7664-41-7	SI				B
Ammonium acrylates copolymer	63744-68-3	CH, LI			BVT	B, C
Amorphous silica (Silicon dioxide)	7631-86-9	CH, LI			BVT	B, C
Anionic surfactant						
Barium sulphate	7727-43-7				BVT	B
beta-Naphthol ethoxylate	35545-57-4	CH, LI (1.6-19%)				
Block copolymer						
Borax	71377-02-1					
Butanamid	541-35-5					
Calcium natrium phosphosilicate						B
Calcium sodium		CH, LI, SI				
Calendula extract	84776-23-8				BVT	C
Caprylyl glicol (1,3-octadienol)	1117-86-8				BVT	B, C
Carboxylated acrylic						B
Carbomer	9007-20-9 9003-01-4 76050-42-5 9062-04-8 9007-16-3 9007-17-4	CH, LI				
5-Chloro-2methyl-2H-isothiazol-3-one/2-Methyl-2H-isothiazol-3 one mixture (CMIT/MIT mixture) antimicrobial	55965-84-9					
Citric acid	77-92-9 5949-29-1	CH, LI				
Detergents						
Dibutyl phthalate	84-74-2					
Diethylene glycol	111-46-6					
Dimethicone	9006-65-9					
7-Diethylamino-4-methylcoumarin	91-44-1					
Dipropylene glycol	110-98-5					B
Disodium cocoyl glutamate	68187-30-4	CH, LI				
Emulsifier						
Ethanol	64-17-5	CH, DE, LI, ES, SE, SI		ES, SE	BVT	B, C
Ethylene glycol	107-21-1					
Ethylhexyl glycerine	70445-33-9	CH, LI				
Essential oils						
Gelatine	9000-70-8					
Glycerol	56-81-5	CH, DE, LI, ES, SE, SI		ES, SE	BVT	A (10-15%), B, C, E, F
Glyceril caprylate/caprate						B
Glyceryl stearate	31566-31-1	CH, LI				

		Market surveillance	Used as ingredient in PMU inks			
Auxiliaries	CAS number	Country	Jurisdictions	Country	tattooist associations	manufacturers
Gum	11138-66-2					
Hamamelis virginiana (leaf extract)/ Whitz hazel extract	84696-19-5	CH, LI				
Hamamelis virginiana extract	68916-39-2				BVT	B, C
Hydrochloric acid	7647-01-0	CH, LI				
Hydroxypropylmethylcellulose	9004-64-2 9004-65-3 8063-82-9	CH, LI				
Hydroymethyl aminoethanol	65184-12-5	CH, LI				
Humectants						
iso-Octylphenolethoxylate, Octoxynol	92046-34-9	CH, LI (0.13-1.2%)				
Isopropanol	67-63-0	CH, LI, DE (31%), ES, SE, SI	CA (10-30%)	ES, SE	BVT	A (25-40%), C, E, F
Kaolin	1332-58-7					
Lactic acid	50-21-5	CH, LI				
Lecithin	8002-43-5 8030-76-0 (soybean)	CH, LI				
Menthol	2216-51-5					
Methanol	67-56-1					
Methyl ethyl ketone (Butanone)	78-93-3	CH, LI				B
Methylpropanediol	2163-42-0				BVT	B, C
Modified organo polysiloxanes						
Neodecanoic acid	26896-20-8					
N-vinyl-2-pyrrolidone	94800-10-9					
Nonylphenolethoxylate, Nonoxynol		CH, LI (0.03-3.9%)				
Non-ionic surfactant						
C9-11 Pareth-6	68439-46-3	CH, LI				B
PEG-8	5117-19-1 25322-68-3 (generic)	CH, LI, SI			BVT	B, C
PEG-200	25322-68-3	CH, LI		IT		
PEG-400	25322-98-3				BVT	A (1-5%), C
PEG-600		CH, LI				
PEG Isooctylphenyl ether	9004-87-9					B
Phenylpropanol	1335-12-2				BVT	C
Poloxamer 188	9003-11-6	CH, LI				
Poloxamer 407 Poly alchilen glycol ether	9003-11-6	CH, LI			BVT	C
Polyethylenglycol	25322-68-3					
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-, branched, phosphates	68412-53-3					
Polysorbate 20 (Tween 20)	9005-64-5	CH, LI			BVT	C
Polysorbate 80 (Tween 80)	9005-65-6					B
Polyvinylpyrrolidone (PVP) (Polyvidone, Povidone)	9003-39-8	CH, LI, SI			BVT	B, C
Proprietary resin						
Polypropilene	9003-07-0					
Propanediol	26264-14-2					
Propylene glycol	57-55-6	CH, DE, LI, SE, SI		SE	BVT	A (10-20%), B, C
Poly(propylene glycol)	25322-69-4					
Ricin oil	8001-79-4	CH, LI				
Rosa canina	84603-93-0				BVT	C
Rosa Centifolia	84604-12-6					
Rosa damascena extract	90106-38-0	CH, LI				B

		Market surveillance	Used as ingredient in PMU inks			
Auxiliaries	CAS number	Country	Jurisdictions	Country	tattooist associations	manufacturers
Rosin	8050-09-7	CH, LI				
Shellac	9000-59-3	CH, LI, SI			BVT	B, C
Silica	112945-52-5					
Silica Dimethyl silylate	271-893-4					B
Simethicone	8050-81-5				BVT	B, C
Sodium Cocoyl Glutamate	68187-32-6	CH, LI				
Sodium hydroxide	1310-73-2	CH, LI			BVT	C
Sorbitol	50-70-4 98201-93-5	CH, LI, SE		SE		
Tetramethyl decynediol (Surfonyl®104, TMDD)	126-86-3	CH, LI				
Thymol	89-83-8					
Trimethylolpropane triisostearate	68541-50-4	CH, LI				
Vodka						
VP/VA Copolymer	25086-89-9	CH, LI, SI			BVT	A (0-5%), C
Water	7732-18-5	SE		SE		F, B
Witch hazel						

		Market surveillance	Used as ingredient in PMU inks			
Preservatives	CAS number	Country	Jurisdictions	Country	tattooist associations	manufacturers
Aldehydes (like glutaraldehyde)						
2-Amino-2-methylpropanol	124-68-5					C
Benzoates						
Benzophenone	119-61-9					
Benzoic acid	65-85-0	CH, LI (0.004-0.12%), DE (0.3%)			BVT	B, C
Benzoisothiazolinone (BIT)	2634-33-5	CH, LI (20-420 mg/kg)				
2-Bromo-2-nitropropane-1,3-diol	52-51-7	CH, LI (0.02%)				
Buthylparaben	94-26-8					
Chlorhexidine	55-56-1	CH, LI (0.02%)				
4-Chloro-3,5-dimethylphenol (Chloroxylenol)	88-04-0	CH, LI (0.25%)				
Dehydroacetic acid	520-45-6 771-03-9 16807-48-0	CH, LI (0.038-0.089%)				
Dibenzofuran	132-64-9					
1,2-Dibromo-2,4-dicyanobutane	35691-65-7					
2-4 Dichlorobenzylalcohol	1777-82-8					
DMDM Hydantoin	6440-58-0	CH, LI				
Ethylparaben	120-47-8	CH, LI (0.02%)				
9-Fluoenone	486-25-9					
Formaldehyde	50-00-0	CH, LI (0.005-				
Glyoxal	107-22-2	CH, LI (80-200 mg/kg)				
Hexachlorobutadiene	87-68-3					
Hexamethylenetetramine	100-97-0					
p-Hydroxy benzoate	456-23-5					
Hydroxymethylamino ethanol						
Iodopropynyl	55406-53-6	CH, LI				
Isobuthylparaben	4247-02-3					
Isopropylparaben	4191-73-5					
Isothiazolon (Kathon CG)	96118-96-6					

		Market surveillance	Used as ingredient in PMU inks			
Preservatives	CAS number	Country	Jurisdictions	Country	tattooist associations	manufacturers
Listerine (mouth wash) for thinning of traditional inks - this contains thymol, eucalyptol, menthol, methyl-salicylate, benzoic acid, sodium benzoate, water, alcahol, poloxamer						
Melamine	108-78-1					
Methylchloroisothiazolinon	26172-55-4	CH, LI (0.9-54				
Methyldibromo	35691-65-7					
Methylisothiazolinone (2-methyl-4-isothiazolinone)	2682-20-4	CH, LI (0.4-70 mg/kg)				
Methylparaben	99-76-3	CH, LI (0.04, 0.06%)				
MI/MCI	26172-55-4 2682-20-4					
Octylisothiazolinon	26530-20-1	CH, LI (40-450 mg/kg)				
o-Phenylphenol	90-43-7	CH, LI (0.06-0.11%)				
Phenol	108-95-2	CH, LI (80-4700 mg/kg)				
Phenoxyethanol	122-99-6	CH, LI (0.015-1.5%)			BVT	C
Polyaminopropyl biguanide	32289-58-0 133029-32-0	CH, LI				
Preservative						
Propylparaben	94-13-3	CH, LI (0.010%)				
Salicylic acid	69-72-7	CH, LI (0.02%)				
Sodium Borat	1330-43-4 1303-96-4					
Sodium Chloride	7647-14-5	SE		SE		
Sorbic acid	110-44-1	CH, LI (0.01-0.076%)				
Thymol	89-83-8					
Triclosan Irgasan	3380-34-5					
Toluenesulfonamide resin						

Annex V

Analysis of tattoo and PMU inks
Test results

Table A: Summary of chemical analysis results from all sources.

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
PAH (total)		31	ZEK 01.2-08	13 (4)	national law=ResAP (2008)1	0.5	0.2-270	Classic, Gold 13, Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		14		57 (8)	national law=ResAP (2008)1	0.5	0-34		2012, Swedish Chemical Agency
		29	GC-MS	21 (6)	national law 2013=ResAP (2008)1	0.5	1.1-29	Bloodline, Intenze, Kuro Sumi, Mom's	2015, Swedish Medical Products Agency
		37	GC-MS	41 (15)	ResAP (2008)1	0.5	> 0.5		2015, Nederlandse Voedsel en waren autoriteit
		57 only black and grey inks	HPLC/FLD (toluene extraction)	24 (13)	national law=ResAP (2008)1	0.5	0.5-65.1		2014, Hauri
		19	in house (Acetone, benzene extraction), GC-MS	74 (14)	ResAP(2008)1	0.5	0.53-55056		2012 (a), Danish EPA
		11	GC-MS	91 (10)	national law=ResAP	0.5	0.04-29.4	Eternal Ink, Huck Spaulding, Intenze, Micky Sharpz, Dyynamic Color, Pelikan Ink, National Tattoo, Starbrite, Wefa Color, Gold	2013 (a), Høgsberg
		19	GC-MS	94 (15)	national law=ResAP	0.5	0.14-201	not specified	2010, Regensburger
		16 (skin/lymph)	HPLC-DAD		national law=ResAP	0.5	0.1- 0.6 skin 0.1- 11.8 lymph node		2014, Lehner
		11		91	ResAP(2008)1	0.5	200		(P) 2015, Baeumler, Ispra
		19		74		0.5	PAH > 0.5 µg/g	tattoo inks	(P) 2015, Lerche, Ispra
		34 (2009)		30	ResAP(2008)1	0.5			(P) 2015, Hrzenjak, Ispra
		35 (2014)		20	ResAP(2008)1	0.5	>0.5		(P) 2015, Hrzenjak Ispra
		22 (13 tattoo-9 PMU inks) (2014)					<0.5		(P) 2015, Mildau Blume, Ispra
		20 (2014)	Extraction by a Benzene/Acetone solution	10 (2)	ResAP(2008)1	0.5	0.5-50	tattoo inks	(P) 2015, Fontana, Ispra
Acenaphthene	83-32-9	11	GC-MS				0.12-0.17		2013 (a), Høgsberg
		19	GC-MS				0.9+/- 0.3		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
Acenaphthylene	208-96-8	11	GC-MS				0.005-3.6		2013 (a), Høgsberg
		19	GC-MS				14.5+/- 5.5 (av)		2010, Regensburger

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Acenaphthylene	208-96-8	19	GC-MS				3.3+/- 0.8 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
		4	HPLC-FLD				0.001- 0.4		2004, Bromer
Benzo(a)anthracene	56-55-3	11	GC-MS				0.005-0.31		2013 (a), Høgsberg
		19	GC-MS				1.6+/- 0.2 (av)		2010, Regensburger
Benzo(b)fluoranthene	205-99-2	11	GC-MS				0.073-1.99		2013 (a), Høgsberg
		19	GC-MS				4.5+/- 4.3 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
Benzo(ghi)perylene	191-24-2	11	GC-MS				not analysed		2013 (a), Høgsberg
		19	GC-MS				1.2+/- 1.5 (av)		2010, Regensburger
		4	HPLC-FLD				0.008- 89.7		2004, Bromer
Benzo(j)fluoranthene	205-82-3	16	HPLC-DAD						2014, Lehner
Benzo(k)fluoranthene	207-08-9	11	GC-MS				0.03-1.01		2013 (a), Høgsberg
		19	GC-MS				0.4+/- 0.2 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
Benzo[a]pyrene	50-32-8	29	GC-MS	3 (1)	national law 2013=ResAP (2008)1	0.005	0.6	Mom's	2015, Swedish Medical Products Agency
		37	GC-MS	24 (9)	ResAP (2008)1	0.005	> 0.005		2015, Nederlandse Voedsel en waren autoriteit
		57 only black and grey inks	HPLC/FLD (toluene extraction)	25 (14)	national law=ResAP	0.005	0.085-0.71		2014, Hauri
		19	in house (Acetone, benzene extraction), GC-MS	5 (1)	ResAP (2008)1	0.005	5.3		2012 (a), Danish EPA
		11	GC-MS	100 (11)	national law 2013=ResAP (2008)1	0.005	0.02-1.02	Eternal Ink, Huck Spaulding, Intenze, Micky Sharpz, Dyynamic Color, Pelikan Ink, National Tattoo, Starbrite, Wefa Color, Gold, Talens Black ink	2013 (a), Høgsberg
		19	GC-MS	21 (4)	national law=ResAP	0.005	0.3+/- 0.2 (av)	not specified	2010, Regensburger
		4	HPLC-FLD	75 (3)	national law=ResAP	0.005	0.011-6.8	Sterling V, N330, Lampblack	2004, Bromer
		19	GC-MS						2010, Regensburger
		11		100			0.3		(P) 2015, Baeumler, Ispra
		34 (2009)		9	ResAP(2008)1	0.005			(P) 2015, Hrzenjak, Ispra

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Benzo[a]pyrene	50-32-8	35 (2014)		6	ResAP(2008)1	0.005			(P) 2015, Hrzenjak Ispra
		20 (2014)	Extraction by a Benzene/Acetone solution	10	ResAP(2008)1	0.005	0.0005-0.218	tattoo inks	(P) 2015, Fontana, Ispra
Chrysene	218-01-9	11	GC-MS				0.006-0.41		2013 (a), Høgsberg
		19	GC-MS				1.7+/- 0.8 (av)		2010, Regensburger
Dibenzo(a,h)anthracene	53-70-3	11	GC-MS				not analysed		2013 (a), Høgsberg
		19	GC-MS				0.1+/- 0.1 (av)		2010, Regensburger
Fluoranthene	206-44-0	11	GC-MS				0.23-8.19		2013 (a), Høgsberg
		19	GC-MS				2.8+/- 1.0 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
		4	HPLC-FLD				0.01- 21.5		2004, Bromer
Fluorene	86-73-7	11	GC-MS				0.006-0.01		2013 (a), Høgsberg
		19	GC-MS				0.9+/- 0.2 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
Indeno(1,2,3-cd)pyrene	193-39-5	11	GC-MS				not analysed		2013 (a), Høgsberg
		19	GC-MS				1.1+/- 1.0 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
Naphthalene	91-20-3	11	GC-MS				0.005-0.44		2013 (a), Høgsberg
		19	GC-MS				0.3+/- 0.1 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
							0.3		(P) 2015, Baeumler, Ispra
		34 (2009)		30	ResAP(2008)1	0.5			(P) 2015, Hrzenjak, Ispra
Phenanthrene	85-01-8	11	GC-MS				0.005-12.8		2013 (a), Hogsberg
		19	GC-MS				24.5+/- 6.0(av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
		4	HPLC-FLD				0.039- 8.8		2004, Bromer
Pyrene	129-00-0	11	GC-MS				0.055-4.45		2013 (a), Høgsberg
		19	GC-MS				4.4+/- 0.8 (av)		2010, Regensburger
		16	HPLC-DAD						2014, Lehner
		4	HPLC-FLD				0.065- 202.5		2004, Bromer
PAA (total)		31	EN 14362-1 HPLC /GC-MS	32 (10)	national law 2013=ResAP (2008)1	0	24-68	Classic, Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		829 (2004)		14 (113)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		13 (74)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
PAA (total)		675 (2006)		8 (55)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		454 (2007)		8 (35)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		about 300	derived from EN ISO 17234	> 40			16% <10 , 40% 10<mg/kg<100 and 44% > 100		2015, Agnello
		30 (2012)		67	ResAP(2008)1	0			(P) 2015, Lerche, Ispra
		34 (2009)		15	ResAP(2008)1	0			(P) 2015, Hrzenjak, Ispra
		35 (2014)		17	ResAP(2008)1	0			(P) 2015, Hrzenjak, Ispra
		200 (2007-2013)	DD CEN ISO/TS 17234:2003	42	ResAP(2008)1	0		tattoo and PMU inks	(P) 2015, Fontana, Ispra
o-Aminoazobenzene	97-56-3			x		0			2015, Agnello
4-Aminoazobenzene	60-09-3			x					2015, Agnello
Aniline	62-53-3	29	GC-MS/LC-MS	21 (6)	national law 2013=ResAP (2008)1	0	5-61	Biotouch, Bloodline, Eternal Ink, Tattoo	2015, Swedish Medical Products Agency
		19	EN 14362-1 GC-MS	68 (13)	ResAP(2008)1	0	0.54-300		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without dithionite reduction step) GC-MS	25 (6)	ResAP(2008)1	0	2.3-79		2012 (a), Danish EPA
		200 (2007-2013)	DD CEN ISO/TS 17234:2003	20 (10)	ResAP(2008)1	0		tattoo and PMU inks	(P) 2015, Fontana, Ispra
		120	reductive cleavage	10 (12)	ResAP (2008)1	0	4.43-236		2013, BVL
		22-free		13.6 (3)	ResAP (2008)1	0	1.58-30.9		2013, BVL
o-Anisidine	90-04-0	14		7 (1)	national law 2013=ResAP(2008)1	0			2012, Swedish Chemical Agency
		702	GC-MS	17 (118)	national law	10	10-2197		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		9 (72)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		6 (34)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
o-Anisidine		675 (2006)		4 (29)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		454 (2007)		5 (21)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
	90-04-0	29	GC-MS/LC-MS	7 (2)	national law 2013=ResAP (2008)1	0	5-14	Bloodline, Eternal Ink	2015, Swedish Medical Products Agency
		229	EN 14362-1 LC-MS-MS	14 (23)	national law=ResAP	0	1.4-24		2014, Hauri
		19	EN 14362-1 GC-MS	79 (15)	ResAP(2008)1	0	0.52-1775		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without dithionite reduction step) GC-MS	29 (7)	ResAP(2008)1	0	4.6-34		2012 (a), Danish EPA
				x			3-536		2015, Agnello
		127	reductive cleavage	18.1 (23)	ResAP (2008)1	0	3.04-67		2013, BVL
		23-free		47.8 (11)	ResAP (2008)1	0	5.4-53		2013, BVL
Benzidine	92-87-5			x					2015, Agnello
Biphenyl-4-ylamine	92-67-1			x					2015, Agnello
4-Chloroaniline	106-47-8	29	GC-MS/LC-MS	3 (1)	national law 2013=ResAP (2008)1	0		Tattoo	2015, Swedish Medical Products Agency
		702	GC-MS	3 (20)	national law	10	11-691		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		2.4 (20)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		2 (10)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		0.3 (2)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		19	EN 14362-1 GC-MS	21 (4)	ResAP(2008)1	0	1.1-100		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without dithionite reduction step) GC-MS	8 (2)	ResAP(2008)1	0	2.1-6.3		2012 (a), Danish EPA

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
4-Chloroaniline	106-47-8			x			5-52		2015, Agnello
		127	reductive cleavage	0.8 (1)	ResAP (2008)1	0	0.086-0.40		2013, BVL
		24-free		4.2 (1)	ResAP (2008)1	0	0.017-0.40		2013, BVL
4-Chloro-o-toluidine	95-69-2			x					2015, Agnello
		19	EN 14362-1 GC-MS	5 (1)	ResAP(2008)1	0	15		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without dithionite reduction step) GC-MS	4 (1)	ResAP(2008)1	0	5.9		2012 (a), Danish EPA
3,3'-Dichlorobenzidine	91-94-1	702	GC-MS	3 (19)	national law	10	10-4758		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		3 (23)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		3 (15)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		0.4 (3)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		454 (2007)		0.8 (4)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		229	EN 14362-1 LC-MS-MS	7 (13)	national law=ResAP	0	1.0-11		2014, Hauri
		19	EN 14362-1 GC-MS	21 (4)	ResAP(2008)1	0	2.5-6.2		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without dithionite reduction step) GC-MS	4 (1)	ResAP(2008)1	0	3.7		2012 (a), Danish EPA
				xx			8-22		2015, Agnello
		35 (2014)		3	ResAP(2008)1	0			(P) 2015, Hrzenjak, Ispra
		127	reductive cleavage	4.7 (6)	ResAP (2008)1	0	10.5-710		2013, BVL
		24-free		4.2 (1)	ResAP (2008)1	0	0.294-6.88		2013, BVL

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
3,3'-Dimethoxybenzidine	119-90-4	702	GC-MS	1 (2)	national law	10	20-26		2014, Nederlandse Voedsel en waren autoriteit
				x					2015, Agnello
		127	reductive cleavage	1.6 (2)	ResAP (2008)1	0	0.101-1.9		2013, BVL
3,3'-Dimethylbenzidine	119-93-7	829 (2004)		0.1 (1)	national law	10	not reported		2008, Nederlandse Voedsel en waren autoriteit
				x					2015, Agnello
4-Methoxy-m-phenylendiamine	615-05-4			x					2015, Agnello
		702	GC-MS	1 (3)	national law	10	54-1867		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		0.2 (2)	national law	10	not reported		2008, Nederlandse Voedsel en waren autoriteit
4-Methoxy-m-toluidine	120-71-8			x					2015, Agnello
4,4'-Methylenbis(2-chloroaniline)	101-14-4			x					2015, Agnello
4,4'-Methylendianiline	101-77-9			x					2015, Agnello
4,4'-Methylendi-o-toluidine	838-88-0			x					2015, Agnello
4-Methyl-m-phenylendiamine	95-80-7	29	GC-MS/LC-MS	7 (2)	national law 2013=ResAP (2008)1	0	44-6220	Eternal Ink, Tattoo	2015, Swedish Chemical Agency
		702	GC-MS	5 (36)	national law	10	10-2298		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		1.3 (11)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		0.1 (4)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		0.7 (5)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		454 (2007)		0.4 (2)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		229	EN 14362-1 LC/MS/MS	13 (22)>1 mg/kg, 6 (10) >30 mg/kg	national law=ResAP	0	5.9-6900		2014, Hauri
		19	EN 14362-1 GC-MS	5 (1)	ResAP(2008)1	0	40		2012 (a), Danish EPA

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
4-Methyl-m-phenylendiamine	95-80-7	24 -free	EN 14362-1 (without reduction step) GC-MS	8 (2)	ResAP(2008)1	0	1.8-2.6		2012 (a), Danish EPA
				x			48-240		2015, Agnello
2-Naphthylamine	91-59-8	19	EN 14362-1 GC-MS	5 (1)	ResAP(2008)1	0	2.6		2012 (a), Danish EPA
				x					2015, Agnello
5-Nitro-o-toluidine	99-55-8	702	GC-MS	1 (9)	national law	10	19-285		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		1 (6)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		0.1 (5)	national law	10	>10		2008, Nederlandse Voedsel en waren autoriteit
		19	EN 14362-1 GC-MS	16 (3)	ResAP(2008)1	0	14-400		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without reduction step) GC-MS	16 (4)	ResAP (2008)1	0	6.2-190		2012 (a), Danish EPA
				xx			9-48		2015, Agnello
4,4'-Oxydianiline	101-80-4			x					2015, Agnello
p-Phenylenediamine	106-50-3	29	GC-MS/LC-MS	3 (1)	national law 2013=ResAP 2008	0		Tattoo	2015, Swedish Medical Products Agency
4,4'-Thiodianiline	139-65-1			x					2015, Agnello
		102	reductive cleavage	1 (1)	ResAP (2008)1	0	0.134		2013, BVL
		17-free		5.9 (1)	ResAP (2008)1	0	0.2		2013, BVL
o-Toluidine	95-53-4	29	GC-MS/LC-MS	3 (1)	national law 2013=ResAP (2008)1	0		Eternal Ink	2015, Swedish Medical Products Agency
		702	GC-MS	8 (57)	national law	10	12-2197		2014, Nederlandse Voedsel en waren autoriteit
		829 (2004)		2 (16)	national law	10	> 10		2008, Nederlandse Voedsel en waren autoriteit
		555 (2005)		3 (19)	national law	10	> 10		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		3 (22)	national law	10	> 10		2008, Nederlandse Voedsel en waren autoriteit

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
o-Toluidine	95-53-4	454 (2007)		2 (9)	national law	10	> 10		2008, Nederlandse Voedsel en waren autoriteit
		229	EN 14362-1 LC-MS-MS	13 (21)>1 mg/kg 4 (6) >30 mg/kg	national law=ResAP	0	1.2-129		2014, Hauri
		19	EN 14362-1 GC-	58 (11)	ResAP(2008)1	0	1.1-133		2012 (a), Danish EPA
		24 -free	EN 14362-1 (without dithionite reduction step) GC-MS	25 (6)	ResAP(2008)1	0	1.0-2.9		2012 (a), Danish EPA
				xx			5-710		2015, Agnello
		34 (2009)		12	ResAP(2008)1	0			(P) 2015, Hrzenjak, Ispra
		127	reductive cleavage	3.1 (4)	ResAP (2008)1	0	2.11-206		2013, BVL
		24-free		12.5 (3)	ResAP (2008)1	0	6.92-152		2013, BVL
2,4,5-Trimethylaniline	137-17-7			x					2015, Agnello
2,4-xylidine	95-68-1	121	reductive cleavage	0.8 (1)	ResAP (2008)1	0	0.097-1.27		2013, BVL
		17-free		5.9 (1)	ResAP (2008)1	0	1.36		2013, BVL
Aluminium (Al)	7429-90-5	61	ICP-MS (total content)	100 (61)	positive samples		1.8-11000		2012 (a), Danish EPA
		56	acid digestion/ MW oven				1.59 -5893		2009 (a), Forte
		5		100 (5)	positive samples		23.3-8390	Eternal ink, Yakuza	Questionnaire, LU
Antimony (Sb)	7440-36-0	87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.08 - 0.68		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.50		(P) 2015, Bocca, Ispra
		34 (2009)		0	ResAP(2008)1	2	<0.2		(P) 2015, Hrzenjak, Ispra
		35 (2014)		0	ResAP(2008)1	2	<0.2		(P) 2015, Hrzenjak, Ispra
		280 (2013)		25	ResAP(2008)1	2	< 2		(P) 2015, Mildau Blume, Ispra
		104		18 (19)	ResAP(2008)1	2	0.04-2.7		(P) 2015, Mildau Blume, Ispra
		169	ICP-MS (total content)	11 (18)	EPA Guideline 2012	2	3-147	Alla Prima, Intenze, Kuro Sumi, Tattoo Colour King	2013, Ministry of Health (NZ)

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Antimony (Sb)	7440-36-0	29	ICP-MS (total content)	3 (1)	national law 2013=ResAP (2008)1	2	7.1	Tattoo	2015, Swedish Medical Products Agency
		121		2 (2)	national law 2005	5	>5		2015, Conseil Superior de la Santé (BE)
		56	acid/ MW oven	4 (2)	ResAP (2008)	2	0.004- 4.11	Intenze Prod.: Dark chocolate brown; Diabolo by Deep Colours: Ultramarine Blue	2009 (a), Forte
		189 (coloured)		0.5 (1)	ResAP(2008)1	2	2.83		2013, BVL
Arsenic (As)	7440-38-2	31	DIN EN ISO 11885 ICP-OES (total content)	3 (1)	national law 2013=ResAP (2008)1	2	18	Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		32	ICP-MS (total content)	3 (1)	ResAP (2008)1	2	4.1		2011 (a), Health Canada
		169	ICP-MS (total content)	4 (7)	EPA Guideline 2012	2	3-60	Alla Prima, Intenze, HLC, Tattoo Colour King	2013, Ministry of Health (NZ)
		29	ICP-MS (total content)	3 (1)	national law 2013=ResAP (2008)1	2	49	Magic Cosmetics	2015, Swedish Medical Products Agency
		72	ICP-MS (total content)	4 (3)	national law =ResAP (2008)1	2	2.9-8.9		2014, Nederlandse Voedsel en waren autoriteit
		121		2 (2)	national law 2005	5	>5		2015, Conseil Superior de la Santé (BE)
		87 (tattoo)	ICP-MS after under-pressure digestion	10 (tattoo); 0 (PMU)	ResAP(2008)1	2	<0.16 - 15.8		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.21 - 1.0		(P) 2015, Bocca, Ispra
		34 (2009)		0	ResAP(2008)1	2	<0,2–0,3		(P) 2015, Hrzenjak, Ispra
		35 (2014)		6	ResAP(2008)1	2			(P) 2015, Hrzenjak, Ispra
		190 (coloured)		3.2 (6)	ResAP(2008)1	2	2-30.9		2013, BVL
		98 (black)		1 (1)	ResAP(2008)1	2	2-2.3		2013, BVL

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Barium (Ba)	7440-39-3	31	DIN EN ISO 11885 ICP-OES (total content)	51 (16)	national law 2013=ResAP (2008)1	50	11-9800	Classic, Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		14		35 (5)	national law 2013=ResAP (2008)1	50	0-190		2012, Swedish Chemical Agency
		32	ICP-MS (total content)	9 (3)	ResAP (2008)1	50	600-1500		2011 (a), Health Canada
		169	ICP-MS (total content)	12 (21)	EPA Guideline 2012	50	50-17000	Alla Prima, Eternal Ink, Fusion, Intenze, HLC, Kuro Sumi, Mom's, Tattoo Colour King, Tattoo Tang Dragon, Starbright, Waverly Colour	2013, Ministry of Health (NZ)
		29	ICP-MS (total content)	24 (7)	national law 2013=ResAP (2008)1	50	62-17737	Biotouch, Eternal Ink, Magic Cosmetics, Pure Colours, Purebeau, Tattoo	2015, Swedish Medical Products Agency
		121		13 (16)	national law 2005	5	> 5		2015, Conseil Superior de la Santé (BE)
		61	ICP-MS (total content)	13 (8)	ResAP (2008)1	50	50-1800		2012 (a), Danish EPA
		56	acid/ MW oven	27 (15)	ResAP (2008)1	50	0.058- 1226	Starbrite Colors: Blue (Country & Deep Turquoise), Deep Green, Scarlet Red; Intenze Prod.:Green Grasshopper, Cherry bomb red, Banana cream yellow; Diabolo by Deep Colours: Magic Black, Blue (Blue, Turquoise, Ultramarine), Red (Bordeaux, Port), Violet (Light, Violet)	2009 (a), Forte
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.1 - 8580		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.48 - 562		(P) 2015, Bocca, Ispra
		34 (2009)		15	ResAP(2008)1	50	<5 - 990		(P) 2015, Hrzenjak, Ispra
		35 (2014)		26	ResAP(2008)1	50			(P) 2015, Hrzenjak, Ispra
		200 (2013)		32	ResAP(2008)1				(P) 2015, Mildau Blume, Ispra
		5		20 (1)	positive samples		656	Eternal ink	Questionnaire, LU
		111		14.4 (16)	ResAP(2008)1	50	50-9385		2013, BVL

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Cadmium (Cd)	7440-43-9	39	acid/ MW oven	36 (14)	ResAP (2008)	0.2	0.001- 3.0	Blue (Deep Turquoise, Ice, Baby), Dark chocolate brown, Green (Deep, Grasshopper), Hound Grey, Peach Orange, Violet (Deep, Violent, Grape), White (Brite, Power, Snow Opaque)	2009, Bocca
		13	acid/ MW oven	38 (5)	ResAP (2008)	0.2	0.007- 1.15	Country Blue, Deep Turquoise, Deep Green, Deep Violet, White Brite	2009 (b), Forte
		56	acid/ MW oven	32 (18)	ResAP (2008)	0.2	0.001- 2.98	Starbrite Colors: Blue (Country & Deep Turquoise), Deep Green; Deep Violet, Brite White; Milennium Colorworks Inc: Ice Blue, Hound Grey, Violent Violet; Intenze Prod.: Baby Blue, Dark chocolate brown, Green Grasshopper, Orange peach,Rose Pink, Violet (Grape, Lavender), Banana cream yellow, Snow opaque white	2009 (a), Forte
		32	ICP-MS (total content)	9 (3)	ResAP (2008)1	0.2	0.28-0.4		2011 (a), Health Canada
		169	ICP-MS (total content)	24 (40)	EPA Guideline 2012	0.2	0.21-0.80	Eternal Ink, Fusion, Intenze, Kuro Sumi, Makkuro Sumi, Mom's, Tattoo, Silverback Ink, Starbright, Waverly Colour	2013, Ministry of Health (NZ)
		72	ICP-MS (total content)	1 (1)	national law =ResAP (2008)1	0.2	2.8		2014, Nederlandse Voedsel en waren autoriteit
		787 (2004)		0.1 (1)	national law =ResAP (2008)1	0.2	5		2008, Nederlandse Voedsel en waren autoriteit
		61	ICP-MS (total content)	1 (1)	ResAP (2008)1	0.2	0.27		2012 (a), Danish EPA
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.007 - 7.84		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.50		(P) 2015, Bocca, Ispra

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
		34 (2009)		3	ResAP(2008)1	0.2	<0,02-0,38		(P) 2015, Hrzenjak, Ispra
		35 (2014)		0	ResAP(2008)1	0.2			(P) 2015, Hrzenjak, Ispra
		134		22 (30)	ResAP(2008)1		0.007-5.5		(P) 2015, Mildau Blume, Ispra
		250 (coloured)		9.6 (24)	ResAP(2008)1	0.2	0.2-2.77		2013, BVL
		129 (black)		1.6 (2)	ResAP(2008)1	0.2	0.2-0.77		2013, BVL
Cr (VI)					ResAP (2008)1	0.2	Tattoo:0.3-147 (total); PMU: <0.5 - 2.6 (total)		(P) 2015, Bocca, Ispra
Chromium (tot)	7440-47-3	13	acid/ MW oven		positive samples	1	0.315- 4.7		2009 (b), Forte
		39	acid/ MW oven		positive samples	1	0.31- 147		2009, Bocca
		56	acid/ MW oven		positive samples	1	0.315- 147		2009 (a), Forte
		31	DIN EN ISO 11885 ICP-OES (total content)	35 (11)	positive samples		15-100	Starbrite 2, Intenze	2010(b), Swedish Chemical Agency
		14		35 (5)					2012, Swedish Chemical Agency
		787 (2004)		5 (39)	positive samples		not reported		2008, Nederlandse Voedsel en waren autoriteit
		121		23 (28)	national law 2005	5	>5		2015, Conseil Superior de la Santè (BE)
		61	ICP-MS (total content)	93 (57)	positive samples		up to 31		2012 (a), Danish EPA
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		0.7 - 13.2		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.5 - 2.6		(P) 2015, Bocca, Ispra
		34 (2009)		68	positive samples		<0,2-2,8		(P) 2015, Hrzenjak, Ispra
		35 (2014)		86	positive samples				(P) 2015, Hrzenjak, Ispra
		129		60 (78)	positive samples		0.01-2038		(P) 2015, Mildau Blume, Ispra
		5		80 (4)	positive samples		4.1-12		Questionnaire, LU

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Cobalt (Co)	7440-48-4	121		1 (1)	national law 2005	5	> 5		2015, Conseil Superior de la Santé (BE)
		39	acid/ MW oven	0	ResAP(2008)1	25	0.003- 6.4		2009, Bocca
		13	acid/ MW oven	0	ResAP(2008)1	25	0.003-0.125		2009 (b), Forte
		56	acid/ MW oven	0	ResAP(2008)1	25	0.0028- 6.43		2009 (a), Forte
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.09 - 12.5		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.11 - 25		(P) 2015, Bocca, Ispra
		34 (2009)		0	ResAP(2008)1	25	<1,0 - 1,8		(P) 2015, Hrzenjak, Ispra
		35 (2014)		0	ResAP(2008)1	25			(P) 2015, Hrzenjak, Ispra
		5		40 (2)	positive samples		1.7-3.1	Eternal ink	Questionnaire, LU
Copper (Cu) soluble	7440-50-8	31	DIN EN ISO 11885 ICP-OES	58 (18)	national law 2013=ResAP (2008)1	25	15-45000	Classic, Gold 13, Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		14		14(2)	national law 2013=ResAP (2008)1	25	0-2600		2012, Swedish Chemical Agency
		169	ICP-MS (soluble Cu)	12 (21)	EPA Guideline 2012	25	25-32900	Alla Prima, Eternal Ink, Fusion, Intenze, Kuro Sumi, Mom's, Tattoo Colour King, Starbright	2013, Ministry of Health (NZ)
					ResAP (2008)1	25	Tattoo:0.1-31.3 (total)		(P) 2015, Baeumler, Ispra; (P) 2015, Bocca, Ispra
		34 (2009)		15	ResAP(2008)1	25	<2,5-3400		(P) 2015, Hrzenjak, Ispra
		35 (2014)		34	ResAP(2008)1	25	>25		(P) 2015, Hrzenjak, Ispra
Copper (Cu total)		61	ICP-MS (total content)	3 (2)	positive samples		100-140		2012 (a), Danish EPA
		56	acid/ MW oven		positive samples		0.076- 31.3		2009 (a), Forte
		5		80 (4)	positive samples		1.6-11800	Eternal ink, Yakuza	Questionnaire, LU
		110		64 (71)	positive samples		0.1-49500		(P) 2015, Mildau Blume, Ispra
Iron (Fe)	7439-89-6	56	acid/ MW oven		positive samples		0.717- 88.443		2009 (a), Forte
		25		100 (25)	positive samples		1.7-785		(P) 2015, Mildau Blume, Ispra
		5		100 (5)	positive samples		8.9-1050	Eternal ink, Yakuza	Questionnaire, LU

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Lead (Pb)	7439-92-1	39		5 (2)	ResAP (2008)	2	0.028- 14.8	Dark chocolate brown, Peach Orange	2009, Bocca
		56	acid/ MW oven	4 (2)	ResAP (2008)	2	0.015- 14.79	Intenze Prod.: Dark chocolate brown, Peach Orange	2009 (a), Forte
		14		14 (2)	national law 2013=ResAP (2008)1	2	31-44		2012, Swedish Chemical Agency
		32	ICP-MS (total content)	34 (11)	ResAP (2008)1	2	0.18-2.5		2011 (a), Health Canada
		169	ICP-MS (total content)	22 (38)	EPA Guideline 2012	2	2.1-45	Alla Prima, Intenze, HLC, Kuro Sumi, Makkuro Sumi, Tattoo Colour King, Tattoo	2013, Ministry of Health (NZ)
		29	ICP-MS (total content)	14 (4)	national law 2013=ResAP (2008)1	2	3.3-41	Kuro Sumi, Magic Cosmetics, Tattoo	2015, Swedish Medical Products Agency
		72	ICP-MS (total content)	7 (5)	national law =ResAP (2008)1	2	2.6-401.5		2014, Nederlandse Voedsel en waren autoriteit
		787 (2004)		0.5 (4)	national law =ResAP (2008)1	2	> 2		2008, Nederlandse Voedsel en waren autoriteit
		121		7 (8)	national law 2005	5	> 5		2015, Conseil Superior de la Santé (BE)
		61	ICP-MS (total content)	7 (4)	ResAP (2008)1	2	> 2		2012 (a), Danish EPA
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.08 - 7.73		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.1 - 6.4		(P) 2015, Bocca, Ispra
		34 (2009)		12	ResAP(2008)1	2	<0,2-18		(P) 2015, Hrzenjak, Ispra
		35 (2014)		6	ResAP(2008)1	2			(P) 2015, Hrzenjak, Ispra
		148 (2007)							(P) 2015, Mildau Blume, Ispra
		379 (2013)		42	positive samples		coloured ink : <14 mg/kg; black ink< 23		(P) 2015, Mildau Blume, Ispra
		134		30 (40)	positive samples		0.02-36.5		(P) 2015, Mildau Blume, Ispra
		250 (coloured)		3.2 (8)	ResAP(2008)1	2	2-14.3		2013, BVL
		129 (black)		1.6 (2)	ResAP(2008)1	2	2-23		2013, BVL
Manganese (Mn)		20		65	positive samples		0.02-6.8		(P) 2015, Mildau Blume, Ispra
		56	acid/ MW oven				0.079- 98.8		2009 (a), Forte
		5		60 (3)	positive samples		1.1-4.2	Eternal ink, Yakuza	Questionnaire, LU

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Mercury (Hg)	7439-97-6	169	ICP-MS (total content)	0.6 (1)	EPA Guideline 2012	0.2	0.6	Intenze	2013, Ministry of Health (NZ)
		13	acid/ MW oven	0	ResAP(2008)	0.2	<LoQ - 0.179		2009 (b), Forte
		39	acid/ MW oven	0	ResAP(2008)	0.2	<LoQ - 0.19		2009, Bocca
		56	acid/ MW oven	2 (1)	ResAP(2008)	0.2	<LoQ - 0.253	Diabolo by Deep Colours: Chinese Red	2009 (a), Forte
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.001-0.17		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.005-0.05		(P) 2015, Bocca, Ispra
		34 (2009)		0	ResAP(2008)1	0.2	<0,02		(P) 2015, Hrzenjak, Ispra
		35 (2014)		0	ResAP(2008)1	0.2			(P) 2015, Hrzenjak, Ispra
		305 (2013)		5	positive samples		< 2 (coloured ink); <0.2 (black ink)		(P) 2015, Mildau Blume, Ispra
		106		12 (13)	positive samples		0.001-0.3		(P) 2015, Mildau Blume, Ispra
		209 (coloured)		1.9 (4)	ResAP(2008)1	0.2	0.2-2.8		2013, BVL
Nickel (Ni)	7440-02-0	31	DIN EN ISO 11885 ICP-OES (total content)	3 (1)	national law 2013=ResAP (2008)1	ALTA	not reported	Starbrite 2	2010 (b), Swedish Chemical Agency
		14		14 (2)	national law 2013=ResAP (2008)1	ALTA	0-29		2012, Swedish Chemical Agency
		169	ICP-MS (total content)	79 (133)	EPA Guideline 2012	ALTA	0.30-22.8	All tested brands	2013, Ministry of Health (NZ)
		61	ICP-MS (total content)	100 (61)	ResAP (2008)1	ALTA	up to 18		2012 (a), Danish EPA
		13		2 (2)	possible limit set to 1 ppm	1	0.037- 2.32	Deep Green, Deep Violet	2009 (b), Forte
		39	acid/ MW oven	18 (7)	on the basis of a possible limit set to 1ppm	1	0.067- 9.6	Ultramarine Blue, Dark chocolate brown, Green (Deep, Basic), Hound grey, Violet (Deep, Violet)	2009, Bocca

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
		56	acid/ MW oven	16 (9)	on the basis of a possible limit set to 1ppm	1	0.037- 9.59	Starbrite Colors: Deep green, Deep violet; Milennium Colorworks Inc: Hound grey; Intenze Prod.: Dark chocolate brown; Diabolo by Deep Colours: Ultramarine blue, Green (Basic, Willow), Port Red, Violet violet	2009 (a), Forte
		87 (tattoo)	ICP-MS after under-pressure digestion		positive samples		<0.1 - 64		(P) 2015, Bocca, Ispra
		17 (PMU)	ICP-MS after under-pressure digestion		positive samples		<0.21 - 78		(P) 2015, Bocca, Ispra
		34 (2009)		100	ResAP (2008)1	ALTA	<0,03-3,1		(P) 2015, Hrzenjak, Ispra
		35 (2014)		46	ResAP (2008)1	ALTA			(P) 2015, Hrzenjak, Ispra
		379 (2013)		44	positive samples		coloured ink : <65.1 mg/kg; black ink<60		(P) 2015, Mildau Blume, Ispra
		5		60 (3)	positive samples		1.1-1.8	Eternal ink	Questionnaire, LU
Selenium (Se)	7782-49-2	72	ICP-MS (total content)	5 (4)	EPA Guideline 2012	2	3.0-290		2014, Nederlandse Voedsel en waren autoriteit
	7783-00-8	34 (2009)		0	ResAP(2008)1	2	<0,02-0,85		(P) 2015, Hrzenjak, Ispra
		35 (2014)		0	ResAP(2008)1	2			(P) 2015, Hrzenjak, Ispra
		25		96 (24)	positive samples		0.1-1.3		(P) 2015, Mildau Blume, Ispra
Strontium (Sr)	7440-24-6	31	DIN EN ISO 11885 ICP-OES (total content)	32 (10)			12-120	Classic, Intenze	2010(b), Swedish Chemical Agency
		56	acid/ MW oven				0.174- 36.4		2009 (a), Forte
		5		20 (1)	positive samples		14.9	Eternal ink	Questionnaire, LU
Thallium (Tl)	7440-28-0	148 (2007)							(P) 2015, Mildau Blume, Ispra
		24		21 (5)	positive samples		0.003-0.2		(P) 2015, Mildau Blume, Ispra
Tin (Sn)	7440-31-5	31	DIN EN ISO 11885 ICP-OES (total content)	3 (1)	national law 2013=ResAP (2008)1	50	56	Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		169	ICP-MS (total content)	1.2 (2)	EPA Guideline 2012	50	88-101	Intenze, Kuro Sumi	2013, Ministry of Health (NZ)
		34 (2009)		0	ResAP(2008)1	50	<0,5		(P) 2015, Hrzenjak, Ispra
		35 (2014)		0	ResAP(2008)1	50			(P) 2015, Hrzenjak, Ispra

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
		8		12 (1)	positive samples		3.2		(P) 2015, Mildau Blume, Ispra
		5		40 (2)	positive samples		1.2-4	Eternal ink	Questionnaire, LU
Titanium (Ti)	7440-32-6							Sicotan	(P) 2015, Baeumler, Ispra; (P) 2015, Bocca, Ispra
							median:1-159436		(P) 2015, Bocca, Ispra
		56 (tattoo)	ICP-MS after MW digestion				6597-180893		(P) 2015, Bocca, Ispra
		5		80 (4)	positive samples		2.4-1510	Eternal ink, Yakuza	Questionnaire, LU
Uranium (U)	7440-61-1	148 (2007)							(P) 2015, Mildau Blume, Ispra
		20		25 (5)	positive samples		0.01-0.1		(P) 2015, Mildau Blume, Ispra
Vanadium (V)	7440-62-2	56	acid/ MW oven	100 (56)	positive samples		0.006- 11.05	Diabolo by Deep Colours, Intenze, Millenium, Starbrite	2009 (a), Forte
		5		20 (1)	positive samples		1.9	Eternal ink	Questionnaire, LU
Zinc (Zn)	7440-66-6	31	DIN EN ISO 11885 ICP-OES (total content)	6 (2)	national law 2013=ResAP (2008)1	50	16-95	Starbrite 2, Intenze	2010 (b), Swedish Chemical Agency
		14		43 (6)	national law 2013=ResAP (2008)1	50	0-88		2012, Swedish Chemical Agency
		169	ICP-MS (total content)	35 (60)	EPA Guideline 2012	50	51-1640	Intenze, Kuro Sumi, Mom's, Tang Dragon, Tattoo Colour King, Starbright	2013, Ministry of Health (NZ)
		61	ICP-MS (total content)	1 (1)	ResAP (2008)1	50	53		2012 (a), Danish EPA
		29	ICP-MS (total content)	14 (4)	national law 2013=ResAP (2008)1	50	102-513	Kuro Sumi, Magic Cosmetics, Tattoo	2015, Swedish Medical Product Agency
		56 (tattoo)	ICP-MS after MW digestion		positive samples		0.3 - 48		(P) 2015, Bocca, Ispra
		34 (2009)		0	ResAP(2008)1	50	<5-13		(P) 2015, Hrzenjak, Ispra
		35 (2014)		3	ResAP(2008)1	50			(P) 2015, Hrzenjak, Ispra
		30		76 (23)	positive samples		0.3-195		(P) 2015, Mildau Blume, Ispra
		5		100 (5)	positive samples		7.9-29	Eternal ink, Yakuza	Questionnaire, LU
Preservatives (total)		829 (2004)		12 (103)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		556 (2005)		2 (13)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		2 (11)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Benzoic Acid	65-85-0	829 (2004)		3 (29)	national law	0.05%	>0.05%		2008, Nederlandse Voedsel en waren autoriteit
		556 (2005)		2 (9)	national law	0.05%	>0.05%		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		1 (4)	national law	0.05%	>0.05%		2008, Nederlandse Voedsel en waren autoriteit
		229	MeOH/Phosphoric acid extr., UPLC-DAD	11 (25)	national law		0.010-0.12%		2014, Hauri
		94		5 (5)	positive samples		0.02-54		2007, BVL
Benzoisothiazolinone (BIT)	2634-33-5	229	MeOH/Phosphoric acid extr., UPLC-DAD	24 (55)	national law		30-424		2014, Hauri
		106		35 (37)	positive samples		0.01-170		2007, BVL
Dehydroacetic Acid	520-45-6	229	MeOH/Phosphoric acid extr., UPLC-DAD	3 (5)	national law		0.038-0.089%		2014, Hauri
Formaldehyde	50-00-0	229	Derivat. with DNPH, HPLC-DAD	7 (15)	national law		0.005-0.035%		2014, Hauri
DMDM hydantoine	6440-58-0	229	MeOH/Phosphoric acid extr., UPLC-DAD	3 (7)	national law		not quantified		2014, Hauri
Ethyl-p-Hydroxybenzoate	120-47-8	556 (2005)		0.1 (1)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
Isobuthyl-p-Hydroxybenzoate	94-26-8	556 (2005)		0.1 (1)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
kathon CG		16		25 (4)	positive samples		0.0001-0.001%		2007, BVL
Methyl-p-Hydroxybenzoate	99-76-3	829 (2004)		2 (22)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		556 (2005)		0.1 (1)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		1 (5)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
Propyl-p-Hydroxybenzoate	94-13-3	829 (2004)		2 (22)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		556 (2005)		0.1 (1)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
p-Hydroxybenzoate	456-23-5	829 (2004)		2 (20)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
p-Hydroxybenzoate	456-23-5	675 (2006)		0.3 (2)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		15		6 (1)	positive samples		0.02%		2007, BVL
Methylchloroisothiazolinone (MCI)	26172-55-4	229	Acq. phosphoric acid extraction, HPLC-DAD	2 (5)	national law		1.1-1.5		2014, Hauri
Methylisothiazolinone (MI)	2682-20-4	229	Acq. phosphoric acid extraction, HPLC-DAD	8 (18)	national law		0.42-70		2014, Hauri
		37		5 (2)	positive samples		39-47		2007, BVL
Sum MI/MCI	26172-55-4 2682-20-4	229	MeOH/Phosphoric acid extr., UPLC-DAD	2 (5)	national law		2.3-2.7		2014, Hauri
2-Octyl-2H-isothiazol-3-one	26530-20-1	16		6 (1)	positive samples		19		2007, BVL
Phenol	108-95-2	229	MeOH/Phosphoric acid extr., UPLC-DAD	3 (6)	national law		0.008-0.47%		2014, Hauri
		11	GC-MS				1770-3800		2013, Høgsberg
		19	GC-MS				0.2-385		2010, Regensburger
2-Phenoxyethanol	122-99-6	829 (2004)		3 (32)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		556 (2005)		1 (4)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		675 (2006)		0.3 (2)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
		229	MeOH/Phosphoric acid extr., UPLC-DAD	3 (8)	national law	0.01%	0.015-0.80%		2014, Hauri
		107		2 (2)	positive samples		0.013-0.019		2007, BVL
o-Phenylphenol	90-43-7	229	MeOH/Phosphoric acid extr., UPLC-DAD	1 (2)	national law		0.084-0.11%		2014, Hauri
Salicylic Acid	69-72-7	829 (2004)		1 (8)	national law	0.01%	>0.01%		2008, Nederlandse Voedsel en waren autoriteit
Sorbic Acid	110-44-1	829 (2004)		0.1 (1)	national law	0.05%	>0.05%		2008, Nederlandse Voedsel en waren autoriteit
		229	MeOH/Phosphoric acid extr., UPLC-DAD	1 (3)	national law		0.063-0.076%		2014, Hauri
		38		3 (1)	positive samples		0.01-0.07		2007, BVL

Substance	CAS nr	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	Content/Range (min-max) (mg/kg)	Brand names of non compliant samples	Reference
Trichlorobenzene		11	GC-MS		positive samples		0.01-0.72		2013, Høgsberg
Nitrosodiethanolamine	1116-54-7	229	LC-MS-MS water extraction	6 (14)	national law	0.15	0.012-66.7		2014, Hauri
Nitrosodimethylamine	62-75-9	229	LC-MS-MS water extraction	0.4 (1)	national law	0.15	0.026		2014, Hauri
Dibutyl phthalate (DBP)	84-74-2	11	GC-MS				0.2-5.0		2013, Høgsberg
Dibutyl phthalate (DBP)		14	GC-MS				0.12-691.2		2011, Lehner
Di-(2-ethylhexyl) phthalate (DEHP)	117-81-7	11	GC-MS				0.2-19.3		2013, Høgsberg
Hexachloro-1,3-butadiene	87-68-3	14	GC-MS				0.08- 4.52		2011, Lehner
Metheneamine	74-89-5	14	GC-MS				0.08- 21.64		2011, Lehner
Dibenzofuran	132-64-9	14	GC-MS				0.02-1.62		2011, Lehner
Benzophenone	119-61-9	14	GC-MS				0.26-556.66		2011, Lehner
9-fluorenone	486-25-9	14	GC-MS				0.04-3.04		2011, Lehner
Pigment orange 15 Pigment red 53 Pigment violet 23 Pigment violet 19 Pigment red 122	CI 12075 CI 15585 CI 51319 CI 73900 CI 73915	37 (red inks)	MALDI-TOF/DMF extraction and HPLC	30 (11)	national law	0	> 0		2014, Hauri
Pigment green 7	CI 74260	31 (green inks)	MALDI-TOF/DMF extraction and	52 (16)	national law	0	> 0		2014, Hauri
Pigment yellow 1 Pigment yellow 83 Pigment orange 43	CI 11680 CI 21108 CI 71105	20 (yellow inks)	MALDI-TOF/DMF extraction and	10 (2)	national law	0	> 0		2014, Hauri
Pigment red 53 Pigment violet 23	CI 51319 CI 73900 CI 73914	16 (violet inks)	MALDI-TOF/DMF extraction and HPLC	60 (10)	national law	0	> 0		2014, Hauri
Pigment red 53 Pigment violet 23 Pigment red 122	CI 51319 CI 73900 CI 73915	15 (magenta inks)	MALDI-TOF/DMF extraction and HPLC	40 (6)	national law	0	> 0		2014, Hauri
Pigment orange 15 Pigment red 122	CI 12075 CI 73915	15 (orange inks)	MALDI-TOF/DMF extraction and HPLC	13 (2)	national law	0	> 0		2014, Hauri

Table B: Summary of microbiological analysis results from all documents considered in this WP.

Microbiological agent	Number of analysed samples	Test method used	non compliant samples, % (nr)	Criteria for compliance (national law, CoE ResAP)	limit (mg/kg)	cfu/g	Reference
Contamination	15 (sealed)	ISO 21149 ISO 18415 ISO 18416 ISO 21150 ISO 22717 ISO 22718 ISO 16212	20 (3)	Canada jurisdiction limits for cosmetic products	sterility	15-1.5*10^5	2011 (b), Health Canada
Aerobic mesophilic bacteria	15 (sealed)	ISO 21149	12 (2)	Canada jurisdiction limits for cosmetic products	sterility	200-900	2011 (b), Health Canada
P.aeruginosa	15 (sealed)	ISO 22717	6 (1)		sterility	1.5*10^5	2011 (b), Health Canada
yeasts/moulds	15 (sealed)	ISO 16212	12 (2)		sterility	15-1000	2011 (b), Health Canada
Contamination	698		6 (41)	national law	sterility	not sterile	2014, Nederlandse Voedsel en waren autoriteit
Contamination	829 (2004)		18 (149)	national law	sterility	not sterile	2008, Nederlandse Voedsel en waren autoriteit
Contamination	588 (2005)		12 (73)	national law	sterility	not sterile	2008, Nederlandse Voedsel en waren autoriteit
Contamination	710 (2006)		5 (39)	national law	sterility	not sterile	2008, Nederlandse Voedsel en waren autoriteit
Contamination	553 (2007)		4 (25)	national law	sterility	not sterile	2008, Nederlandse Voedsel en waren autoriteit
Contamination	34		91 (31)	CoE ResAP (2008)1	sterility	not sterile	2013, Bonadonna
Contamination	39 (sealed) 106 (opened)		44 (17) (32)	30	sterility	10^1 - 10 ^8 cfu/ml	2011, Baumgartner
Pseudomonas sp. Aeromonas sp. Staphylococcus sp. Enterococcus faecium Streptococcus sanguinis Streptococcus salivarius Acinetobacter sp.	58 (sealed) 6 (opened)		10 (6) 17 (1)		sterility	100-650 bacteria/ml	2013 (b), Høgsberg
Contamination	216		13 (29)		sterility	not sterile	2007, BVL

Annex VI

Statistical data from literature and national reports

Table A: Prevalence of tattoos inside and outside Europe.
Prevalence of tattoos inside Europe.

Member State	Literature Reference	Survey type	N value	Age (years)	Total (%)	Male (%)	Female (%)
DE	2006, Stirn	general population	2043	**14 - 93** 14 - 44 25 - 34	**8.5** 15	 22	
DK	2010, Dannemand	youth survey	1112	**15 - 25**	**13**		
FI	2009, Myllyniemi	youth barometer	1898	**15 - 29** 15 - 19 20 - 24 25 - 29	**13** 9 12 19		
FR	2010, Fourquet	general population	958	**18 - 65+** 18 - 24 25 - 34 35 - 49 50 - 64 65+	**10** 8 20 12 5 1	11	9
	2013, Gueguen	youth survey	1965	**20 - 22**	**17**	11.5	24
IT	2002, Eurispes	school children	3800	**12 - 18**	**6.6**	7.2	5.7
	2005, Boncompagni	high school students	496	**14 - 20** 14 - 16 16 - 17 18 - 20	**4.8** 3.5 5.1 10	3 3.5 3 0	6 2.4 5.3 20
	2006, Preti	high school students	817	**15 - 19+** 15 - 16 17 - 18 19+	**8.6** 6 7.2 15.8	14.5	5.4
	2010 (a), Cegolon	secondary school students	4277	**13 - 21**	**6**		
	2011, Galle	high school students	9322	**[16.1]**	**11.3**	11.7	10.9
		university students	3610	**[21.6]**	**24**	15.1	20.7
	2011, Quaranta	university students	1598	**20.1**	**9.6**	9	9.8

Note: Bold values indicate totals of the group
[ ]: Mean

Table A: Prevalence of tattoos inside and outside Europe (continued).
Prevalence of tattoos outside Europe.

Country	Literature Reference	Survey type	N value	Age (years)	Total (%)	Male (%)	Female (%)
AU	2001, Makkai	general population	10030	**14+**	**10**	11.9	8.5
	2003, Grulich	general population	19000	**16 - 59**	**12.6**	14.5	10.6
	2012, Heywood	general population	8656	**16 - 64**	**14.5**	15.4	13.6
				16 - 19		5.4	6.9
				20 - 29		22.3	29.4
				30 - 39		23.2	22.3
				40 - 49		16.3	9.8
				> 50		8.7	3.3
BR	2006, Oliveira	adolescents public school	664	**12 - 19**	**3.2**		
	2013, Bicca	military recruits	1968	**18**	**10.8**	10.8	0
CA	2006b, Deschesnes	high school students	2180	**12 - 18**	**7.9**	5.8	9.8
				12 - 13		4	3.5
				14 - 15		4.9	7.6
				16 - 18		8.5	18.1
	2006a, Deschesnes	high school students	2145	**12 - 18**	**7.7**	5.6	9.8
				12 - 13	3.8		
				14 - 15	6.1		
				16 - 18	12.9		
US	2002, Mayers	university undergraduates	454	**16 - 26**	**23**	22	24
	2002, Roberts	school-based survey	5837	**11 - 21**	**4.6**	4.8	4.2
				11 - 13	0.5		
				14 - 16	2.6		
				17 - 21	7.6		
	2003, Sever	general population	2215	**18 - 65+**	**16**	16	15
				18 - 24	13		
				25 - 29	36		
				30 - 39	28		
				40 - 49	14		
				50 - 65+	17		
	2006, Laumann	general population	500	**18 - 50**	**24**	26	22
				18 - 29	36		
				30 - 40	24		
				41 - 50	15		
	2007, PEW	general population	1275	**18 - 64**	**24**		
				18 - 25	36		
				26 - 40	40		
				41 - 64	10		
	2002, Mayers	university undergraduates	661	**[21]**	**21.8**	23	21
	2008, Corso	general population	2302	**18 - 65+**	**14**	15	13
				18 - 24	9		
				25 - 29	32		
				30 - 39	25		
				40 - 49	12		
				50 - 65+	17		
	2010, Taylor	general population	2020	**18 - 65+**	**23**		
				18 - 29	38		
				30 - 45	32		
				46 - 64	15		
				65+	6		
	2012, Braverman	general population	2016	**18 - 65+**	**21**	19	23
				18 - 24	22		
				25 - 29	30		
				30 - 39	38		
				40 - 49	27		
				50 - 65+	16		
	2012, Karagas	general population - internet survey	452	18 - 49		18	29
				50 - 69		16	7
	2014, Shannon-Missal	general population (10major cities)	2102	**≥18**	**22**		

Note: Bold values indicate totals of the group
[ ]: Mean

Table A: Prevalence of tattoos inside and outside Europe (continued). Prevalence of tattoos based on national reports.

Country	National Report Reference	Countries mentioned	Total (%)	Comments	Specific references
BE	2015, Conseil Supérieur de la Santé	Germany United States United Kingdom Sweden Worldwide	9 24 12 7	58% black 40% coloured sum: 120 million	2012, BfR 2009, D'Hollander 2006, Klugl
CH	2014, Hauri	Germany	25	15 - 25 years	2009, Pressemitteilung, Universitat Leipzig: verbreitung von Tatowierungrn, Piercing und Korperhaarentfernung in Deutchland
DE	2012, BfR	Germany	9 23	 16 - 20 years	2003, Allensbacher Reports 2006, Laumann and Derick 2010, Klugl
DK	2012(a), Danish EPA		13	adults (sum: 600000)	
NZ	2013, Ministry of Health		20 33	 < 33 years	2009, Forte
SE	2010(a), Swedish Chemical Agency	EU US	5 - 10 24		2003, Papameletiou
US	2013, Harris Poll Global Omnibus		14 36 40	sum: 45 million 18 - 25 years 26 - 40 years	Pew Research Center

Table B: Regrets, removals and motivations for removal.

Country	Literature Reference	Survey type	N value	Tattoed individuals	Population regrets (% considering removal) Tattoos	Motivations for tattoo removal
DE	2010, Klugl	general population	3411	3399	5	
	2014, Klein	laser tattoo removal survey	157	157	100	esthetic 28%, youthful folly 29% medical problems
DK	2013b, Hogsberg	youth survey	154	154	13.6	
FR	2011, Latreille	laser tattoo removal survey	151	151	100	never been pleased with tattoo (21%) embarassment/ shame (20%) professional reasons (17%) became dissatisfied (12%)
IT	2005, Boncompagni	high school students	496	24	4.3	
US	2002, Mayers	university undergraduates	454	104	4	
	2003, Sever	general population	2215	354	17	
	2006, Laumann	general population	500	118	17	
	2008, Corso	general population	2302	322	16	
	2012, Braverman	general population	2016	423	14	

National reports

Country	National Report Reference	Tattoos placed	Country covered	Population regrets (%)	Removals (%)	Additional comments	Specific references
BE	2015, Conseil Superieur de la Santé	300 000 - 500 000 per year	Belgium		10 - 20		2011, Bfr; 2010, Laumann
SE	2010(a), Swedish Chemical Agency	2000 daily	Sweden				
		600 daily	Stockholm				
US			US	17	11	costs for placing a tattoo: $45 (small) $150/h (large)	2013, Harris Poll Global Omnibus

Table C: Age of individuals for their first tattoo.

	Reference	Survey type	N value	Comment	Age (years)	First tattoo		
						Total (%)	Male (%)	Female (%)
Member State								
DE	2010, Klugl	general population	3400	tattoed individuals	< 18 18 - 35 35+	18 77 5	13 80 7	21 75 3
FR	2011, Latreille	laser tattoo removal survey	152	tattooed individuals	11 - 18 19 - 29 ≥ 30	43.7 41.1 15.2		
Country outside Europe								
BR	2013, Bicca	military recruits	209	tattooed adolescents	12 - 13 14 - 15 16 - 17 18	5 18 58 19		
CA	2006(a), Deschesnes	high school students	166	tattooed students (7.7 % of 2145)	< 15 < 12	32.1	16.9	1
US	2008, Armstrong	dermatology clinics	189	tattoed patients	12 - 15 16 - 18 19 - 23 24+	15 43 29 15	16 41 29 14	16 41 23 16
	2006, Laumann	general population	119	tattoed individuals	< 18 18+ < 24 30+	16 84 65	11	30

Table D: Size and localisation of tattoos.

	Reference	Survey type	N value	Size of tattoos					Localization of tattoos				
				Type	Size (cm2)	Total (%)	Male (%)	Female (%)	Type	Localization	Total (%)	Male (%)	Female (%)
Member State													
DE	2010, Klugl	general population	3411	size of most recent tattoo	< 300 (small) ≥ 300 (large)	39 61	27 73	48 52	localization of most recent tattoo	extremities trunk head/ neck	51 45 3	64 32 2	41 54 3
	2015, Conseil Supérieur de la Santé			size corresponds to localization	800 4 500 16 400					arms back body			
	2012, BfR				25 >900	8 16							
DK	2012a, DK EPA				454 - 1090								
	2013(c), Høgsberg	youth survey	342	size of each tattoo relative to body surface area (where 1% = palm + fingers)	≤ 1% > 1%	70 30	56 44	88 12	localization of each tattoo	extremities trunk head/ neck	58 37 4	67 29 5	48 48 4
	2014, DK EPA				900								
FR	2011, Latreille	laser tattoo removal survey	151	size	< 30 ≥ 30		45 54	74 26		arms hands lower back		75 13 0	25 3 12
IT	2005, Boncompagni	high school students	496							shoulders ankles arms & wrists lower back		54.6 7.8 7.8	28.7 27.1 11.4
Country outside Europe													
BR	2013, Bicca	male military recruits	1968	size	≤ 10 11 - 20 > 20	51 35 14	51 35 14		localization of each tattoo	extremities trunk	80 20	80 20	
US	2006, Lauman	general population	203	size of each tattoo expressed in terms of palm size	≤ palm > palm	67 34	56 45	80 20	localization of each tattoo	extremities trunk head/ neck	51 45 4	61 35 4	35 60 5
	2002, Mayers	university undergraduates								extremities trunk	27 43	35 33	18 53

Table E: Colours of tattoos.

Country	Reference	Survey type	N value	Type	Colour	Total (%)
DE	2010, Klugl	general population	3411	colour of most recent tattoo	black	50
					red	14
					blue	10
					green	9
					yellow	8
					white	2
					violet	1.6
				colours of tattoos in general	black	59
					mixed colours	40
				colour combinations of most recent tattoo	1 colour	63.4
					2 colours	14
					3 colours	9.4
					≥ 4 colours	13.1
DK	2013(b), Hogsberg	youth survey	342	colours of each tattoo	black	96
					red	15
					green	11
					blue	10
					yellow	10
					white	7
BR	2013, Bicca	military recruits	213	colour combinations	monochromatic	75
					dichromatic	12
					trichromatic	5
					≥ 4 colours	8

Table F: Skin exposure.

Member State	Reference	Comment	Skin exposure (mg ink/skin cm2)
DE	2008, Engel	measurements made with Pigment Red 22 directly after tattooing comparing expert tattooists or laboratory researcher and pig or human skin	[2.53] 0.6 - 9.42 [400 cm2]=1 g
	2010, Regensburger extrapolated from 2008, Engel	typical tattoo of 400 cm2 contains 1g black pigment (dry chemical) but because of PAH weight/volume is roughly 50% this implies 2g black ink into skin inks contain: carbon black nanoparticles PAH (0.14 - 201 microg/g) phenols (0.2- 385 microg/g)	2.5
	2011(a), Lehner	presence in inks of dibutyl phthalate (0,12-691,2 microg/g) dibenzofuran (0,02-1,62 microg/g) & other substances	
	2012, BfR Based on2008, Engel	significant differences in the quantity of tattoo ink applied, depending on the experience of the tattooist, thus exposure estimations are unable to give a clear indication of the real situation	0.63 - 2.49 (10% pigment solution) 1.42 - 9.42 (25% pigment solution)
		estimated PAH exposure in tattoo inks based on two scenarios	2.4 - 3.5
	2014, Lehner	presence in human skin of PAH (0,1-0,6 microg/g) and lymph nodes (0,1-11,8microg/g)	
	2015, Conseil Supérieur de la Santé Based on 2012, BfR		2.5 arm=800cm2= 2g back=4 500 cm2=11g body=16 400 cm2=40g
DK	2012(a), DK EPA 2014, DK EPA Based on 2008, Engel		[2.5] 0.6-9.4 [454 cm2] X [2.53] = 1,1 g/person [1 090 cm2] X [9.42 mg/cm2] = 10,3 g/person

[ ]: mean value

Table G: Tattooed individuals and their number of tattoos.

	Reference	N value	Type	Number of tattoos	Total (%)	Male (%)	Female (%)
Member State							
DE	2010, Klugl	3411	tattoed individuals, general population	1	34.9	30.7	37.8
				2 - 3	37.7	33.6	40.5
				4 - 5	13.3	14.4	12.5
				6 - 9	7.8	9.4	6.6
				≥ 10	6.5	11.9	2.7
				single	35	31	38
				multiple	65	69	62
DK	2013(a), Hogsberg	154	tattooed youth	1	47.4	50.6	44
				2 - 3	36.4	30.4	42.7
				4 - 5	9.1	7.6	10.7
				6 - 9	5.8	8.9	2.7
				≥ 10	1.3	2.5	0
FR	2011, Latreille	151	laser tattoo removal survey	single		29	60
				multiple		71	40
IT	2005, Boncompagni	24	tattooed high school students	1	95		
				2	5		
Country outside Europe							
BR	2013, Bicca	213	tattooed male military recruits	1	66	66	
				2	21	21	
				3	7	7	
				4	4	4	
				> 5	2	2	
CA	2006, Deschesnes	165	tattooed high school students	1	79		
				≥ 3	7	11.9	4.1
US	2010, Taylor	768	tattoed individuals: 18 - 29 years old	1	31		
				2 - 5	50		
				≥ 6	18		
		1070	tattoed individuals: 30+ years old	1	47		
				≥ 6	9		
	2014, Shannon-Missal	462	tattooed adults living in ten major cities	1	32		
				2	23		
				3	9		
				4	9		
				≥ 5	23		

Table H: Number of tattooists.

Country	Literature Reference	Population (million)	No. professional tattooists	No. tattoists/ inhabitant	Affiliated tattooists (syndicate)		Estimation unlicensed tattooists
					Number	Name of syndicate	
CH	2015, Kluger	8	550 - 600	1/ 13000	34	VST	
DE		80	6000	1/ 13000	100	DOT	> 20000
DK		5.6	500	1/ 11200	58	DTL	
FR		68	2000 - 3000	1/ 22600	1100	SNAT	
IS		0.3	8 - 10	1/ 30000	0		16 - 20
IT		60.6	1200 - 3000	1/ 20000	98	ART	7000
NO		5	400 - 500	1/ 10000	65	NTU	3000 - 3500
SE		9.6	2000 - 3000	1/ 3200	89	SRT	3000

National reports

Country	National report Reference	Number of professional studios	Affiliated artists	Name of Syndicate
DK	2002, DK EPA		54 tattooists	
			4 PMU	
			40 tattooists	Danish Tattoo Organisation (DPT)
	2012(a), DK EPA		72 tattooists	Danish Tattoo Guild (DTL)
SE	2010(a) Swedish Chemicals Agency	100 PMU studios		Swedish Association of Registered Tattoo Artists (SRT)
US	2013, Harris Poll Global Omnibus	21000 tattoo studios		

Table I: Problems and non-compliances.

Country	Reference	Problems and non-compliances related to labelling
BE	2015, Conseil Superior de la Santè	Sterility of inks is not controlled Life date after opening is not always provided
	2011, Conseil Superior de la Santè	Most manufacturers do not provide a complete list of ingredients. No indication of durability neither manufacturer and indication of use. Often undefined substances are mentioned (Ex. Vodka)
CH	2014, Hauri	lack of contents 4% lack of best before and batch number in 1% of cases 18% of sampled inks (tot 229) contained not authorized pigments, most of them not declared on the package
DK	2012(a), Danish EPA	Ni was found in all 61 samples and none of the labells stated that Ni was present in the product. 2 samples contained Cu (extractable or from phthalocyanines) without declaration on label
NL	2014, Nederlandse Voedsel en waren autoriteit	
	2014	700 samples, 21.7% not compliant: mandatory information were incomplete / absent
	2007	518 samples, 16.4% not compliant: idem
	2006	675 samples, 23.6% not compliant: idem
	2005	514 samples, 55.1% not compliant: idem
	2004	628 samples, 69.4% not compliant: idem
SE	2015, Medical Products Agency	27 out of 29 samples had labelling problems: instructions,warnings, durability and table of ingredients are missing. No batch number and manufacturer mentioned in the label.

Annex VII

Ink ingredients from literature and national reports

Table A: List of colorants in use in tattoo and PMU inks.

Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	tattoo inks	PMU inks
AR 14	14720		
AR 18	16255		
AR 51	45430		
AR 87	45380		2002, Danish EPA
BR 1	45160		
Cinnabar (HgS)		2015, Agnello	
DR 53 Oxamine B	22095	2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
FR 17:1	16035:1	2008, Nederlandse Voedsel en waren autoriteit	2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
NR 4	75470	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
NR 22	75510		
NR 23	75510		
PR 2	12310	2014, Hauri	2014, Hauri
PR 3	12120	2014, Hauri	2014, Hauri
PR 4	12085	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit
PR 5	12490	P 2015, Bäumler (Ispra); 2000, Bäumler; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler
PR 7	12420		
PR 9	12460	P 2015, Bäumler (Ispra), 2000 Bäumler; 2006, Engel; 2008, Vasold; 2011, Lehner	2000, Bäumler
PR 12	12385		
PR 14	12380		
PR 15	77015		
PR 17	12390	2011, Høgsberg; 2012-a, Danish EPA	
PR 22	12315	P 2015, Bäumler (Ispra); 2015, Petersen; 1988, Lehmann; 2000, Bäumler; 2006, Engel ; 2008, Vasold; 2008, Engel (2.53 mg/cm2 from human/ pig skin (ex vivo)); 2011 Lehner (0.04 -0.11 mg/cm2 from human skin (in vivo)); 2009, Engel (mouse skin: 0.186 mg/cm2); 2014, Hauri	2015, Petersen; 2014, Hauri; 2000, Bäumler; 1998, Lehmann
PR 23	12355		
PR 48:1	15865:1	2011, Høgsberg	
PR 49	15630	2014, Hauri	2014, Hauri
PR 49:2	15630:2		
PR 51	15580	2014, Hauri	2014, Hauri
PR 53:1	15585	2014, Hauri	2014, Hauri
PR 57:1	15850:1	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PR 57:2	15850:2		
PR 60	16105		
PR 63:1	15880	2014, Hauri; 2012-a, Danish EPA	2014, Hauri
PR 101 and 102	77491	2015, Petersen; 2010, De Cuyper; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
PR 112	12370	P 2015, Bäumler (Ispra); 2000, Bäumler; 2011, Høgsberg; 2011 Lehner (0.029 - 0.150 mg/cm2 from human skin (in vivo)); 2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler
PR 120	12474	2014, Hauri	2014, Hauri
PR 122	73915	P 2015, Bäumler (Ispra); 2000, Bäumler; 2010, De Cuyper; 2014, Hauri; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler
PR 146	12485	P 2015, Lerche (Ispra); 2010, De Cuyper; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PR 170	12475	P 2015, Bäumler (Ispra); P 2015, Lerche (Ispra); 2000, Bäumler; 2008, Poon; 2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler
PR 177	65300	2015, Petersen	2015, Petersen
PR 179	71130		
PR 181	73360	2010, Wenzel; 2014, Hauri	P 2015, Bäumler (Ispra); 2014, Hauri; 2010,
PR 202	73907	2015, Petersen; 2014, Hauri	2015, Petersen; 2014, Hauri

Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	tattoo inks	PMU inks
PR 210	12477	2015, Petersen; 2011, Høgsberg; 2010, De Cuyper; 2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit
PR 222	123665		
PR 242	20067		
PR 254	56110	2015, Petersen; 2014, Hauri	2015, Petersen; 2014, Hauri
PR 257	56270	P 2015, Bäumler (Ispra)	
PR 266	12474	2002, Danish EPA	
PR 269	12466	2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PR 340			
SR 1	12150		2002, Danish EPA
AY 3	47005	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
AY 9	13015		
AY 23	19140	2014, Hauri	2014, Hauri
AY 104	15985:1		
Diarylide Y			
Arylide Y			
FY 3	15985		
PY 1	11680	2011, Høgsberg; 2010, De Cuyper	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit
PY 3	11710	2011, Høgsberg	2008, Nederlandse Voedsel en waren autoriteit
PY 12	21090		
PY 14	21095	P 2015, Bäumler (Ispra); 2000, Bäumler; 2008, Poon; 2010, De Cuyper; 2014, Hauri ; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler
PY 36	77955		
PY 42 and 43	77492	2015, Petersen; 2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
PY 55	21096	P 2015, Bäumler (Ispra); 2015, Petersen; 2000, Bäumler	2015, Petersen; 2000, Bäumler
PY 65	11740	2015, Petersen; 2011, Høgsberg; 2014, Hauri; 2012-a, Danish EPA	2015, Petersen; 2014, Hauri
PY 74	11741	1988, Lehmann; 2000, Bäumler; 2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit;2000, Bäumler; 1998, Lehmann
PY 83	21108	P 2015, Bäumler (Ispra); 1988, Lehmann; 2000, Bäumler; 2010, De Cuyper; 2014, Hauri; 2012, Danish EPA; 2008, Nederlandse Voedsel en waren	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler; 1988, Lehmann
PY 87	21107:1	P 2015, Bäumler (Ispra), 2000, Bäumler	2000, Bäumler
PY 93	20710		
PY 97	11767	P 2015, Bäumler (Ispra); P 2015, Lerche (Ispra); 2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit
PY 100	19140:1		
PY 110	56280		2014, Hauri
PY 119	77496		
PY 138	56300	2015, Petersen; 2014, Hauri	2015, Petersen
PY 139	56298		2014, Hauri
PY 151	13980	2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit
PY 154	11781	2014, Hauri	
PY 155	200310		
PY 180	21290	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PY 194	11785		
AB 9	42090	2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
DB 86	74180		

Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	tattoo inks	PMU inks
PB 15	74160	P 2015, Bäumler (Ispra); 2015, Petersen; 1988, Lehmann; 2000, Bäumler; 2008, Poon; 2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler; 1998, Lehmann
PB 17	74180		
PB 25	21180		
PB 27	77510		
PB 29	77007	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PB 60	69800		2014, Hauri
Lawsone	75480	2011, Almeida (1-2% -found in 82% of commercial henna preparations)	
PO 5	12075	2014, Hauri ; 2012-a, Danish EPA	2014, Hauri
PO 13	21110	P 2015, Bäumler (Ispra); 2015, Petersen; 2000, Bäumler; 2011, Høgsberg; 2014, Hauri ; 2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler
PO 16	21160	1988, Lehmann; 2014, Hauri ; 2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PO 22	12470	2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PO 34	21115		
PO 36	11780	P 2015, Lerche (Ispra); 2002, Danish EPA	2014, Hauri
PO 43	71105	2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri (CH); 2008, Nederlandse Voedsel en waren autoriteit
PO 73	561170	2015, Petersen; 2014, Hauri; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit
PO 74		2005, Cui	
BV 10	45170		
PV 1	45170:2		
PV 12	58050	2015, Petersen	2015, Petersen
PV 15	77007		
PV 16	77742	2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
PV 19	73900	1988, Lehmann; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit; 1998, Lehmann
PV 23	51319	P 2015, Bäumler (Ispra); 2000, Bäumler; 2010, De Cuyper; 2014, Hauri ; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2000, Bäumler; 2014, Hauri; 2008, Nederlandse Voedsel en waren autoriteit
PV 37	51345	2015, Petersen; 2014, Hauri	2015, Petersen
VV 2	73385		
Ferous oxide,black	77489	2011, Høgsberg; 2008, Nederlandse Voedsel en waren autoriteit	2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
PBlack 2			
PBlack 6 and 7	77266 77265	P 2015, Bäumler (Ispra); P 2015, Dirks (Ispra); 2015, Petersen; Agnello; 2011, Høgsberg; 2008, Poon; 2010, De Cuyper; 2012-a, Danish EPA (5500-330000); 2002, Danish EPA; 2015, Nederlandse Voedsel en waren autoriteit; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit
PBlack 9	77367	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PBlack 11	77499	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit
PBlack 15	77403		
PBr 6 and 7	77491 77492 77499	2011, Høgsberg; 2010, De Cuyper	2010, Wenzel; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit
PBr 25	12510	P 2015, Lerche (Ispra); 2010, De Cuyper; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
PBr 175			
AG 25	61570	2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit
PG 7	74260	P 2015, Bäumler (Ispra); 1988, Lehmann; 2000, Bäumler; 2008, Poon; 2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit; 2000, Bäumler; 1998, Lehmann

Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	tattoo inks	PMU inks
PG 17	77288		
PG 18	77289		P 2015, Lerche (Ispra); 2014, Hauri
PG 36	74265	2015, Petersen; 2011, Høgsberg; 2010, De Cuyper; 2014, Hauri ; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2008, Nederlandse Voedsel en waren autoriteit
Aluminium Silicate (bentonite, White)	77004		
Barium sulphate	77120	2015, Prior; 2015, Olsen	2015, Prior; 2015, Olsen
PW 4	77941		
PW 6	77891	2015, Petersen; 2015, Agnello; 2015, Prior; 2015, Olsen; 2011, Høgsberg; 2008, Poon; 2010, De Cuyper; 2012-a, Danish EPA; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit	2015, Petersen; 2015, Prior; 2010, Wenzel; 2002, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit

Table B: List of additives, both auxiliaries and preservatives, in use in tattoo and PMU inks.

Auxiliaries	CAS number	tattoo inks	PMU inks
Acrylates copolymer			
Acrylic polymer			
Acrylic Resin TSRN00195201005· 5100P			
Acrylic Resin TSRN00195201005· 5102P			
Aloe barbadensis	85507-69-3 94349-62-9		
Aluminum hydroxide	21645-51-2		
Aminomethyl propanediol	115-69-5		
Ammonia	7664-41-7	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Ammonium acrylates copolymer	63744-68-3	P 2015, Michel (Ispra)	
Amorphous silica (Silicon dioxide)	7631-86-9		
Anionic surfactant		2012-a, Danish EPA	
Barium sulphate	7727-43-7	2015, Prior; 2015, Olsen; 2010, De Cuyper	2015, Prior; 2015, Olsen; 2010, De Cuyper
beta-Naphthol ethoxylate	35545-57-4		
Block copolymer		P 2015, Dirks (Ispra)	
Borax	71377-02-1	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Butanamid	541-35-5		
Calcium natrium			
Calcium sodium phoshosilicate		2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Calendula extract	84776-23-8		
Caprylil glycol (1,3-octadienol)	1117-86-8		
Carboxylated acrylic copolymer			
Carbomer	9007-20-9 9003-01-4 76050-42-5 9062-04-8 9007-16-3 9007-17-4		
5-Chloro-2methyl-2H-isothiazol-3-one/2-Methyl-2H-isothiazol-3 one mixture (CMIT/MIT mixture) antimicrobial	55965-84-9	P 2015, Mildau-Blume (Ispra)	
Citric acid	77-92-9 5949-29-1		
Detergents		2010, De Cuyper	
Dibutyl phthalate	84-74-2	2012, Lehner, thesis	
Diethyleneglycol	111-46-6	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Dimethicone	9006-65-9	P 2015, Michel (Ispra)	
7-Diethylamino-4-methylcoumarin	91-44-1		
Dipropylene glycol	110-98-5		
Disodium cocoyl glutamate	68187-30-4		
Emulsifier		2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Ethanol	64-17-5	2012-a, Danish EPA; 2010, De Cuyper, 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Ethylene glycol	107-21-1	2010, De Cuyper	
Ethylhexyl glycerine	70445-33-9		
Essential oils			
Gelatine	9000-70-8	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Glycerol (Glycerine)	56-81-5 8043-29-6	P 2015, Michel (Ispra); 2012-a, Danish EPA; 2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Glyceryl caprylate/caprate	26402-26-6 27214-36-4		
Glyceryl stearate	31566-31-1		
Gum	11138-66-2	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Hamamelis virginiana (leaf extract)/ Witch hazel extract	84696-19-5	2010, De Cuyper	2008, Nederlandse Voedsel en waren autoriteit
Hamamelis virginiana extract	68916-39-2	P 2015, Michel (Ispra)	
Hydrochloric acid	7647-01-0		
Hydroxypropylmethylcellulose	9004-64-2 9004-65-3 8063-82-9		
Hydroymethyl aminoethanol	65184-12-5		
Humectants		2012-a, Danish EPA	
iso-Octylphenolethoxylate, Octoxynol	92046-34-9		
Isopropanol	67-63-0	Bäumler, 2012-a, Danish EPA; 2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Kaolin	1332-58-7		
Lactic acid	50-21-5		

Auxiliaries	CAS number	tattoo inks	PMU inks
Lecithin	8002-43-5 8030-76-0 (soybean)		
Menthol	2216-51-5	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Methanol	67-56-1	2010, De Cuyper	
Methyl ethyl keton	78-93-3		
Methylpropanediol	2163-42-0		
Modified organo polysiloxanes			
Neodecanoic acid	26896-20-8		
N-vinyl-2-pyrrolidone	94800-10-9		
Nonylphenolethoxylate, Nonoxynol			
Non-ionic surfactant		2012-a, Danish EPA	
C9-11 Pareth-6	68439-46-3		
PEG-8	5117-19-1 25322-68-3 (generic)	P 2015, Michel (Ispra)	
PEG-200	25322-68-3		
PEG-400	25322-68-3		
PEG-600			
PEG Isooctyl phenyl ether			
Phenylpropanol	1335-12-2		
Poloxamer 188	9003-11-6		
Poloxamer 407	9003-11-6		
Poly alchilen glycol ether			
Polyethylenglycol	25322-68-3		
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-, branched, phosphates	68412-53-3		
Polysorbate 20 (Tween 20)	9005-64-5		
Polysorbate 80 (Tween 80)	9005-65-6		
Polyvinylpyrrolidone (PVP)	9003-39-8	P 2015, Dirks (Ispra); 2008, Nederlandse	2008, Nederlandse Voedsel en waren autoriteit
Proprietary resin		2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Polypropilene	9003-07-0		
Propanediol	26264-14-2		
Propylene glycol	57-55-6	2010, De Cuyper	
Poly(propylene glycol)	25322-69-47		
Ricin Oil	8001-79-4		
Rosa canina	84603-93-0		
Rosa Centifolia	84604-12-6	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Rosa damascena extract	90106-38-0		
Rosin	8050-09-7		
Shellac	9000-59-3	P 2015, Dirks (Ispra); 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Silica	112945-52-5	P 2015, Michel (Ispra)	
Silica dimethyl silylate	271-893-4	P 2015, Michel (Ispra)	
Simethicone	8050-81-5		
Sodium cocoyl glutamate	68187-32-6		
Sodium hydroxide	1310-73-2		
Sorbitol	50-70-4 8201-93-5		
Tetramethyl decynediol (Surfonyl®104, TMDD)	126-86-3		
Thymol	89-83-8		
Trimethylolpropane triisostearate	68541-50-4		
Vodka		2010, De Cuyper	
VP/VA Copolymer	25086-89-9		
Water	7732-18-5	2015, Bäumler; 2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Witch hazel		2012-a, Danish EPA; 2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit	
Preservatives	**CAS number**	**tattoo inks**	**PMU inks**
Aldehydes (like glutaraldehyde)		2010, De Cuyper	
2-Amino-2-methylpropanol	124-68-5		
Benzoates		2010, De Cuyper	
Benzophenone	119-61-9	2012, Lehner, thesis	
Benzoic acid	65-85-0	P 2015, Baeumler (Ispra) (0.02%); P 2015, Michel (Ispra); P 2015, Mildau-Blume (Ispra) (0.02-54, av. 18.6); 2014, Hauri (0.010-0.12%); 2010, De Cuyper; 2008, Nederlandse Voedsel en waren autoriteit (>0.05%)	2014, Hauri (0.010-0.12%); 2008, Nederlandse Voedsel en waren autoriteit (>0.05%)
Benzoisothiazolinone (BIT)	2634-33-5	P 2015, Baeumler (Ispra); P 2015, Mildau-Blume (Ispra) (0.01-170, av.26.9); Blume; 2014, Hauri (30-424)	2014, Hauri (30-424)

Preservatives	CAS number	tattoo inks	PMU inks
2-Bromo-2-nitropropane-1,3-diol	52-51-7	P 2015, Mildau-Blume (Ispra)	
Buthylparaben	94-26-8	P 2015, Mildau-Blume (Ispra)	
Chlorhexidine	55-56-1	P 2015, Baeumler (Ispra) (0.018%)	
4-Chloro-3,5-dimethylphenol (Chloroxylenol)	88-04-0	P 2015, Baeumler (Ispra) (0.25%)	
Dehydroacetic acid	520-45-6 771-03-9	P 2015, Mildau-Blume (Ispra); 2014, Hauri (0.038-0.089%)	2014, Hauri (0.038-0.089%)
Dibenzofuran	132-64-9	2012, Lehner, thesis	
1,2-Dibromo-2,4-dicyanobutane	35691-65-7	P 2015, Mildau-Blume (Ispra)	
2-4 Dichlorobenzylalcohol	1777-82-8	P 2015, Mildau-Blume (Ispra)	
DMDM Hydantoin	6440-58-0	2014, Hauri	2014, Hauri
Ethylparaben	120-47-8	P 2015, Mildau-Blume (Ispra); 2008, Nederlandse Voedsel en waren autoriteit (>0.01%)	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
9-Fluoenone	486-25-9	2012, Lehner, thesis	
Formaldehyde	50-00-0	P 2015, Baeumler (Ispra) (0.02%); 2014, Hauri (0.005-0.035%)	2014, Hauri (0.005-0.035%)
Glyoxal	107-22-2	P 2015, Baeumler (Ispra) (0.013%)	
Hexachlorobutadiene	87-68-3	2012, Lehner, thesis	
Hexamethylenetetramine	100-97-0	2012, Lehner, thesis	
p-Hydroxy benzoate	456-23-5	P 2015, Mildau-Blume (Ispra); 2008, Nederlandse Voedsel en waren autoriteit (>0.01%)	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
Hydroxymethylamino ethanol			
Iodopropynyl butylcarbamate	55406-53-6	P 2015, Mildau-Blume (Ispra)	
Isobuthylparaben	4247-02-3	P 2015, Mildau-Blume (Ispra); 2008, Nederlandse Voedsel en waren autoriteit (>0.01%)	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
Isopropylparaben	4191-73-5	P 2015, Mildau-Blume (Ispra)	
Isothiazolon (Kathon CG)	96118-96-6	P 2015, Mildau-Blume (Ispra) (0.001%)	
Listerine (mouth wash) for thinning of traditional inks - this contains thymol, eucalyptol, menthol, methyl-salicylate, benzoic acid, sodium benzoate, water, alcahol, poloxamer		2010, De Cuyper	
Melamine	108-78-1		
Methylchloroisothiazolinone	26172-55-4	2014, Hauri (1.1-1.5)	2014, Hauri (1.1-1.5)
Methyldibromo glutaronitrile	35691-65-7	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Methylisothiazolinone (2-methyl-4-isothiazolinone)	2682-20-4	P 2015, Mildau-Blume (Ispra) (39-74, av. 43); 2014, Hauri (0.42-70)	2014, Hauri (0.42-70)
Methylparaben	99-76-3	P 2015, Mildau-Blume (Ispra); 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
MI/MCI	26172-55-4 2682-20-4	P 2015, Baeumler (Ispra) (9.9); 2014, Hauri (2.3-2.7)	2014, Hauri (2.3-2.7)
Octylisothiazolinon	26530-20-1	P 2015, Baeumler (Ispra) (0.06%); 2015, Blume	
o-Phenylphenol	90-43-7	P 2015, Baeumler (Ispra) (0.06%); 2014, Hauri (0.084-0.11%)	2014, Hauri (0.084-0.11%)
Phenol	108-95-2	P 2015, Baeumler (Ispra) (0.29%); 2015, Blume; 2014, Hauri (0.008-0.47%)	2014, Hauri (0.008-0.47%)
Phenoxyethanol	122-99-6	P 2015, Baeumler (Ispra) (0.98%); P 2015, Mildau-Blume (Ispra) (0.013-0.019%, av. 0.016); 2014, Hauri (0.015-0.80%); 2008, Nederlandse Voedsel en waren autoriteit	2014, Hauri (0.015-0.80%); 2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
Polyaminopropyl biguanide	32289-58-0 133029-32-0		
Preservative		2012-a, Danish EPA; 2008, Nederlandse Voedsel en waren autoriteit (>0.01%)	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
Propylparaben	94-13-3	P 2015, Mildau-Blume (Ispra); 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
Salicylic acid	69-72-7	P 2015, Mildau-Blume (Ispra); 2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit (>0.01%)
Sodium Borat	1330-43-4		
Sodium Chloride	7647-14-5		
Sorbic acid	110-44-1	P 2015, Mildau-Blume (Ispra) (0.01%); 2014, Hauri (CH) (0.063-0.076%); 2008, Nederlandse Voedsel en waren autoriteit (>0.05%)	2014, Hauri (0.63-0.076%); 2008, Nederlandse Voedsel en waren autoriteit (>0.05%)
Thymol	89-83-8	2008, Nederlandse Voedsel en waren autoriteit	2008, Nederlandse Voedsel en waren autoriteit
Triclosan Irgasan	9012-63-9	P 2015, Mildau-Blume (Ispra)	
Toluenesulfonamide resin			

Annex VIII

RAPEX notifications

Table A: RAPEX notifications related to microbiological risks.

Notification	Year/Week	MS	Brand Name/ Product	Microbiological agent	Legal basis	Origin	Action
0049/06	2006	FR	Intenze/Lemon yellow (1), Hard orange (2)	(1) Moraxella spp, (2) Staphylococcus warneri		US	Voluntary stop of distribution
0890/07	2007-34	NL	Euro Sumi Outlining ink	Pseudomonas spp:1500 cfu /ml		UK	Sales ban ordered by the authorities
1050/07	2007-41	DE	Eternal Tattoo/Colour Plum No 29	Aerobic mesophile bacteria count: 7.7 x 10^5 CFU/g		US	Voluntary withdrawal from the market by the importer
1071/09	2009-31	NL	Eternal Ink	Pseudomonas spp		US	Sales ban and withdrawal from the market ordered by the authorities.
1609/10	2010-44	IT	Starbrite 2 /Golden Yellow, Baby Blue	Multiple-use containers (15 ml and 30 ml), absence of a non-return valve= no guarantee of preserving the sterility of the pigment		US	Imports rejected by the customs authorities
0133/15	2015-5	DE	Vibes/Energy Ink/Brigth Green	Aerobic mesophilic bacteria: 1.6 x 10^6 cfu/ml		DE	Withdrawal of the product from the market

Table B: RAPEX notifications related to chemical risks.

Notification	Year/Week	MS	Brand Name/ Product	Chemical	Legal basis	Origin	Action
0915/07	2007-36	NL	Atom Colour/Sonic Green (1), Hot Yellow (2) and Blaze Orange (3)	o-anisidine: (1) 1130 mg/kg, (2) 374 mg/kg, (3) 277 mg/kg; 2,4-toluenediamine: (3) 344 mg/kg		UK	Sales ban and withdrawal from the market ordered by the authorities
1176/07	2007-45	NL	Intenze	the azo-dyes contained in the products may cleave into carcinogenic aromatic amines		UK	Sales ban, withdrawal from the market ordered by the authority.
1177/07	2007-45	NL	Millenium-Mom's/Agent Orange	the azo-dyes contained in the products may cleave into carcinogenic aromatic amines		IT	Sales ban, withdrawal from the market ordered by the authority.
0490/10	2010-11	IT	Skin Candy	o-toluidina		US	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.
0506/10	2010-11	IT	Starbrite 2	anisidine		US	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.
0507/10	2010-11	IT	Starbrite 2	o-toluidine; anisidine; 3,3'-dichlorobenzidine		US	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.
0786/10	2010-19	IT	Intenze/Cherry Bomb	o-toluidine; anisidine		Unknown	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.
0788/10	2010-19	IT	Intenze/Sienna	anisidine		Unknown	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.
0789/10	2010-19	IT	Yakuza ink	toluidine; 2-methyl-5-nitroaniline		Unknown	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.
0362/11	2011-16	IT	Eternal Ink/Sunflower (1), Bright Yellow (2)	o-anisidine: (1) 16.2 mg/kg, (2) 7.1 mg/kg	Nat leg	US	Withdrawal from the market and recall from consumers.
0903/11	2011-36	DE	Tribal Black/Lot 0310	PAHs: 27 mg/kg	Nat leg	US	Voluntary withdrawal from the market by the importer.
1275/11	2011-46	DE	Intenze/True Black	PAHs: 31.4 mg/kg	Res	US	Voluntary recall from consumers by the importer
1276/11	2011-46	DE	Intenze/Zuper Black	PAHs: 55.6 mg/kg; BaP: 0.3 mg/kg	Res	US	Voluntary withdrawal from the market
1277/11	2011-46	DE	Intenze/Lining Black	PAHs: 56.6 mg/kg; BaP: 0.2 mg/kg	Res	US	Voluntary recall from consumers by the importer

Notification	Year/Week	MS	Brand Name/ Product	Chemical	Legal basis	Origin	Action
1283/11	2011-46	DE	Intenze/Black	PAHs: 55.7 mg/kg	Res	US	Voluntary withdrawal from the market by the importer and seizure of the product ordered by the authorities
1348/11	2011-48	DE	Makkuro Sumi/Dark Gray Tone	PAHs: 17.9 mg/kg; BaP: 0.2 mg/kg	Res	Unknown	Voluntary recall from consumers by the importer
1513/11	2011-52	DK	Intenze/Cherry Bomb, Light Green, Lemon Yellow, Bright Red	aniline; 3,3'-dichlorbenzidine		US	Withdrawal of the product from the market
1515/11	2011-52	DK	Tattoo ink/Red, Brown	aniline; 3,3'-dichlorbenzidine		Unknown	Withdrawal of the product from the market
1516/11	2011-52	DK	Millenium-Mom's/Agent Orange	aniline; 3,3'-dichlorbenzidine		Unknown	Withdrawal of the product from the market
1536/11	2011-52	DK	Starbrite Colors/Tribal Black, Rusty Orange, Crimson Red, Grape Ape	BaP; aniline; o-anisidine		US	Withdrawal of the product from the market
1537/11	2011-52	DK	Eternal Ink/Crimson Red, Eternal Dark Red	BaP; aniline; o-anisidine		US	Withdrawal of the product from the market
1243/11	2011-45	IT	Intenze	o-anisidine: 22 mg/kg	Res	US	Withdrawal of the product from the market
0063/12	2012-3	IT	Millenium, Mom's/Viper Red (1), Snot green (2)	o-toluidine: (1) 8.7 mg/kg, (2) 12 mg/kg; aromatic hydrocarbons	Res	US	Withdrawal from the market and recall from consumers ordered by the authorities
0101/12	2012-4	DE	Intense Black	7 carcinogenic PAHs: 1.808 mg/kg (Total EPA-PAH content: 22.07 mg/kg)	Res	US	Voluntary withdrawal from the market
0178/12	2012-5	DE	Intenze/True Black	PAHs: 53.3 mg/kg	Res	US	Seizure of the product ordered by the authorities
0463/12	2012-11	DE	Intenze/Brown	Ni: 30.1 mg/kg; As: 7.5 mg/kg	Res	US	Withdrawal from the market ordered by the authorities
1193/12	2012-32	DE	Lilo M: Cocoa 5310 for Eyebrow Pigmentation (PMU)	Ni: 10.6 mg/kg	Res	DE	Withdrawal from the market and warning consumers
1230/12	2012-33	IT	Intenze/ Bright Red	o-anisidine: 48 mg/kg; styrenes; alpha-methyl styrenes	Res	US	Ban on the marketing of the product
1231/12	2012-33	IT	Intenze/Bright Orange	o- anisidine: 156 mg/kg	Res	US	Ban on the marketing of the product
1232/12	2012-33	IT	Intenze/Bright Red	o-anisidine: 160 mg/kg; 2-ethoxyaniline	Res	US	Ban on the marketing of the product
1263/12	2012-34	DE	Fantasia/Tribal Black	PAHs: 8.7 mg/kg	Res	US	Withdrawal from the market
1298/12	2012-35	DE	Intenze/Lining black	PAHs: 6.6 mg/kg	Res	US	Recall of the product from end users.
1357/12	2012-37	IT	Intenze/Coral	o-anisidine: 62 mg/kg	Res	US	Ban on the marketing of the product
1366/12	2012-37	IT	Intenze/Rubber Doll	o-anisidine: 39 mg/kg	Res	US	Ban on the marketing of the product
1367/12	2012-37	IT	Intenze/Salmon	o-anisidine: 33 mg/kg	Res	US	Ban on the marketing of the product
1368/12	2012-37	IT	Intenze/Sangria	o-anisidine: 86 mg/kg	Res	US	Ban on the marketing of the product
1369/12	2012-37	IT	Intenze/Sunburn	o-anisidine: 26 mg/kg	Res	US	Ban on the marketing of the product
1370/12	2012-37	IT	Intenze/Yellow Orchid	o-anisidine: 333 mg/kg	Res	US	Ban on the marketing of the product
1358/12	2012-37	IT	Intenze/Dijon	o-anisidine: 536 mg/kg	Res	US	Ban on the marketing of the product
1359/12	2012-37	IT	Intenze/Dragon Yellow	o-anisidine: 270 mg/kg	Res	US	Ban on the marketing of the product
1360/12	2012-37	IT	Intenze/Egg Shell	o-anisidine: 167 mg/kg	Res	US	Ban on the marketing of the product
1361/12	2012-37	IT	Intenze/Lemon Yellow	o-anisidine: 96 mg/kg	Res	US	Ban on the marketing of the product
1362/12	2012-37	IT	Intenze/Maroon	o-anisidine: 149 mg/kg	Res	US	Ban on the marketing of the product
1363/12	2012-37	IT	Intenze/Maroon Honey	o-anisidine: 304 mg/kg	Res	US	Ban on the marketing of the product
1364/12	2012-37	IT	Intenze/Mustard	o-anisidine: 430 mg/kg	Res	US	Ban on the marketing of the product
1365/12	2012-37	IT	Intenze/Persian Red	o-anisidine: 137 mg/kg	Res	US	Ban on the marketing of the product

Notification	Year/Week	MS	Brand Name/ Product	Chemical	Legal basis	Origin	Action
1403/12	2012-38	IT	Intenze/Golden Rod	o-anisidine: 190 mg/kg	Res	US	Ban on the marketing of the product
1508/12	2012-40	IT	Yakuza Ink/Smoke of London	Cd: 0.67 mg/kg	Res	IT	Ban on the marketing of the product
1571/12	2012-40	IT	Sunskin Ink/Mint Green	Cd: 0.86 mg/kg	Res	Unknown	Ban on the marketing of the product
1595/12	2012-43	IT	Eternal Ink	Cd: 1.74 mg/kg	Res	Unknown	Ban on the marketing of the product
1773/12	2012-48	IT	Goldeneye (PMU)	Ni: 78 mg/kg	Res	ES	Ban on the marketing of the product
1774/12	2012-48	IT	Eternal Ink/Lighting Yellow	o-anisidine: 185 mg/kg; o-toluidine: 89 mg/kg	Res	US	Ban on the marketing of the product
1775/12	2012-49	IT	Eternal Ink/Lipstick Red	o-anisidine: 193 mg/kg; 2-ethoxyaniline	Res	US	Ban on the marketing of the product
1380/12	2012-37	DE	Intenze/Light Brown	Ni: 12.2 mg/kg		US	Recall of the product from end users
1777/12	2012-48	IT	Beautify Skin Art (PMU)	Ni: 2 mg/kg and 26 mg/kg	Res	DE	Ban on the marketing of the product
1903/12	2012-52	DE	Killer Ink-Intenze/Super Black	PAHs: 82.9 mg/kg	Res	US	Ban on the marketing of the product
1944/12	2012-52	DE	Intenze/Super Black	PAHs: 83.2 mg/kg	Res	US	Destruction of the product
0007/13	2013-1	DE	Intenze/Super Black	PAHs: 96.5 mg/kg	Res	US	Withdrawal of the product from the market
0045/13	2013-2	DE	Ragonhawk Tattoo	PAHs: 0.71 mg/kg; BaP: 0.01 mg/kg	Res	CN	Import reject at border
0064/13	2013-3	DE	Kuro Sumi Tattoo Outlining Ink	PAHs: 20.13 mg/kg; BaP: 0.84 mg/kg	Res	JP	Withdrawal of the product from the market
0084/13	2013-4	DE	Tattoooo/baby blue	PAHs: 5.04 mg/kg; BaP: 0.10 mg/kg	Res	CN	Import reject at border
0096/13	2013-4	NL	Intenze/Sienna, Dragon Red, Tangerine, Banana Cream and Lime Green	o-anisidine: 1753 mg/kg	Res	US	Withdrawal of the product from the market
0139/13	2013-5	SI	Eternal Ink/Jungle Green Tattoo	BaP: 21 ppb	Res	Unknown	Withdrawal of the product from the market
0140/13	2013-5	SI	Jet France/Violet Rouge D 51 F (PMU)	Ni: 4900 mg/kg	Res	FR	Withdrawal of the product from the market
0170/13	2013-6	DE	Eternal Ink/Nuclear Green	o-toluidine: 120mg/kg		US	Withdrawal of the product from the market, Destruction of the product
0169/13	2013-6	DE	Intenze/Japaneze Black Sumi	PAHs: 60.1 mg/kg	Res	Unknown	Destruction of the product
0177/13	2013-6	DE	Profi Colors/Brown Black Eyebrow-Eyeliner (PMU)	Ni: 72 +/- 10 mg/kg	Res	DE	Withdrawal product from the market
0399/13	2013-12	FR	Fantasia/Flesh Tone	Ba: 196 ppm; Cr: 61; Zr: 1170 ppm	Res	US	Recall product from end users
0475/13	2013-16	DE	Fantasia/Lining Black	BaP: 186 ppb	Res	US	Withdrawal product from the market
0684/13	2013-23	DE	Electrick Ink/Light Brown	3.3'-dichlorobenzidine: 710 mg/kg	Res	US	Withdrawal product from the market
0724/13	2013-24	DE	Dragonhawk Tattoo/True Magenta	4-methyl-m-phenylendiamine: 1577 mg/kg	Res	CN	Import reject at border
0725/13	2013-24	DE	Classical tattoo/Red Peach	4-methyl-m-phenylendiamine: 1331 mg/kg	Res	CN	Import reject at border
0790/13	2013-25	DE	Universal Black/Sumi Black	PAHs; BaP: 1151 µg/kg	Res	Unknown	Recall product from end users
0826/13	2013-27	NL	Eternal Ink/Tangerine, Lime Green, Old Orchid	o-toluidine; 5-nitro-o-toluidine	Res	US	Withdrawal product from the market
0903/13	2013-28	NL	Eternal Ink /Bright Orange,Caramel	o-toluidine: 156 mg/kg ; 2.4-toluenediamine: 135 mg/kg; o-anisidine: 972 mg/kg	Res	US	Withdrawal product from the market
0908/13	2013-28	DE	Alla Prima/Prima Black	PAHs: 2.2 ppm	Res	US	Withdrawal product from the market
0874/13	2013-28	DE	Eternal Ink/Lighting Yellow	PAHs: 25.03 mg/kg; BaP: 0.20 mg/kg,	Res	US	Withdrawal product from the market
1198/13	2013-36	DE	Eternal Ink/brown	Ni: 12.3 mg/kg; Cd: 0.31 mg/kg ; As: 14.0 mg/kg	Res	US	Withdrawal of the product from the market
1236/13	2013-36	AT	Eternal Ink /Lighting Yellow	o-toluidine: 34.1 mg/kg; Ba: 6 860 mg/kg	Res	US	Withdrawal product from the market
1290/13	2013-38	DE	Intenze/Zuper Black	PAHs: 10 946 µg/kg; BaP: 350 µg/kg	Res	US	Withdrawal product from the market
1326/13	2013-39	IT	Eternal Ink/Nuclear Green	Ba: 562 mg/kg	Res	US	Ban on the marketing of the product
1328/13	2013-39	DE	Electric Ink/Light Shadow Black Tattoo Ink	PAHs: 1420 µg/kg	Res	US	Withdrawal product from the market
1333/13	2013-39	IT	Incredibile Tattoo Supply-Sacred Color/Red Rubens Incredibile	Ba: 502 mg/kg	Res	US	Ban on the marketing of the product

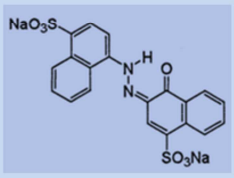
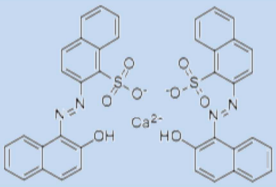
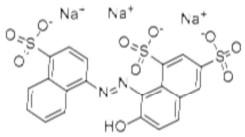
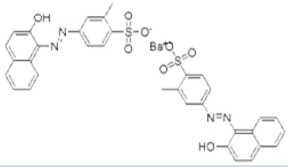
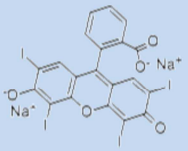
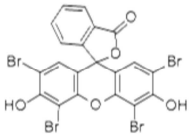
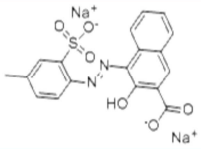
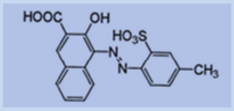
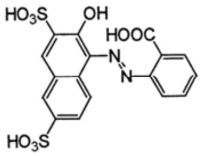
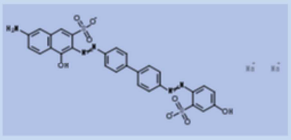
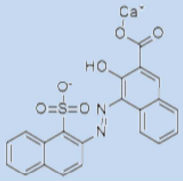
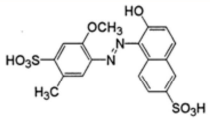
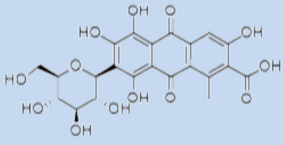
Notification	Year/Week	MS	Brand Name/ Product	Chemical	Legal basis	Origin	Action
1334/13	2013-39	IT	Incredibile Tattoo Supply-Sacred Color/Pink Warhol Incredibile	Ba: 72 mg/kg	Res	US	Ban on the marketing of the product
1452/13	2013-42	DE	Eternal Ink/Lining Black	PAHs: 3.4 mg/kg	Res	US	Withdrawal from the market
1499/13	2013-43	DE	Eternal Ink/Triple Black	Naphtalene: 4.8 mg/kg	Res	US	Withdrawal from the market
1508/13	2013-43	DE	Eternal Ink/Lining Black	PAHs; Naphtalene: 4.4 mg/kg	Res	US	Withdrawal from the market
1703/13	2013-48	DE	Risoft (PMU)	Ni: 19.9 mg/kg	Nat leg	DE	Withdrawal from the market
1787/13	2013-48	DE	Kuro Sumi/Tattoo Outlining Ink	PAHs: 16617 µg/kg; BaP: 71 µg/kg	Res +Nat leg	JP	Destruction of the product
1851/13	2013-50	DE	Silverblack Ink	PAHs: 28.1 mg/kg; BaP: 0.29 mg/kg	Res +Nat leg	US	Withdrawal from the market
0026/14	2014-2	DE	Dragon Tattoo Ink	4-methyl-m-phenylendiamine: 308 mg/kg; As: 3.1 mg/kg; Pb: 2.4 mg/kg; Ni: 19.7 mg/kg	Res	CN	Import reject at border
0030/14	2014-2	DE	Silverback Ink	PAHs: 0.43 mg/kg; BaP: 0.06 mg/kg; naphthalene: 0.37 mg/kg	Res +Nat leg	US	Withdrawal from the market
0101/14	2014-3	DE	Colourking/Tribal Black, Crimson Red, Lavender	PAHs: 1.32 mg/kg; 4-methyl-m-phenylendiamine: 325 mg/kg	Res	CN	Import reject at border
0161/14	2014-4	DE	Intenze/Dark Purple	Ni: 6.8 mg/kg	Res	US	Withdrawal from the market
0739/14	2014-21	DE	Bio Touch (PMU)	Pb:16.5 mg/kg	Res	CN	Import reject at border
0994/14	2014-26	DE	Eternal Ink/Decomposed Skin	Ba: 152 mg/kg; Cr: 83 mg/kg; As: 123 mg/kg; Ni: 15.4 mg/kg	Res	US	Withdrawal from the market
1000/14	2104-26	DE	WEFA Colours/Brown (PMU)	As: 8.8 mg/kg; Pb: 6.7 mg/kg; Ni: 67.8 mg/kg	Res	DE	Withdrawal from the market
1113/14	2014-29	DE	Intenze/Bulls Blood (1), Moss (2), Black Cherry (3)	Ni: (1) 9690 mg/kg ; Prohibited colourants (1) Cl 77260, Cl 21110, Cl 12477;(2): Cl 11740; (3): Cl 77260, Cl 21110, Cl 12477	Res	US	Import reject at border
0601/14	2014-16	DE	Intenze/Cherry Bomb	4-methyl-m-phenylendiamine: 1133 mg/kg	Res	CN	Import reject at border
0584/14	2014-16	DE	Eternal Ink/Lipstick Red	4-methyl-m-phenylendiamine: 302 mg/kg	Res	US	Import reject at border
0609/14	2014-16	DE	Intenze/Advanced Black and Grey	4-methyl-m-phenylendiamine: 260 mg/kg; Pb: 14.85 mg/kg; Cu: 4310 mg/kg	Res	US	Import reject at border
0644/14	2014-18	IT	Start Brite/Scarlet Red	o-anisidine: 8.3 mg/kg	Res	US	Ban on the marketing of the product and any accompanying measures
0800/14	2014-22	IT	Eternal Ink	o-anisidine: 4mg/kg; o-toluidine: 14.2 mg/kg	Res	US	Ban on the marketing of the product
1708/14	2014-43	IT	Eternal Ink/Tangerine	methyl-5-nitroaniline: 41 mg/kg; 2,4 diaminotoluene: 377 mg/kg	Res	US	Ban on the marketing of the product
1718/14	2014-43	IT	Eternal Ink/Bumble Bee	o-toluidine: 119 mg/kg	Res	US	Ban on the marketing of the product
1723/14	2014-43	DE	Hao Tattoo/Bright Black, True Magenta, Dark Chocolate	As: 8.78 mg/kg; Pb: 14.2 mg/kg; aromatic amines: 600 mg/kg; Cu: 163 mg/kg; Ni: 36.1 mg/kg	Res	CN	Import reject at border
1782/14	2014-45	DE	Hao Tattoo/True Black	PAHs: 0.529mg/kg; BaP: 0.058mg/kg; Pb: 15.7 mg/kg	Res	CN	Import reject at border
1941/14	2014-49	DE	Unknown	PAHs:7 mg/kg	Res	CN	Import reject at border
1944/14	2014-49	DE	Intenze/True Black	PAHs: 4.9 mg/kg ; BaP: 0.016 mg/kg	Res	US	Withdrawal from the market
1958/14	2014-49	DE	LCN (PMU)	Ni: 24.1 mg/kg	Res	DE	Withdrawal from the market
1959/14	2014-49	DE	Bio Touch (PMU)	As: 17.6 mg/kg; Zn: 518mg/kg; Ni: 35.9 mg/kg	Res	US	Import rejected at border

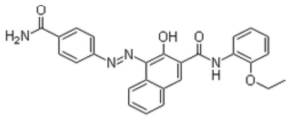
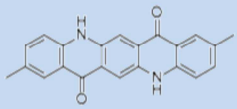
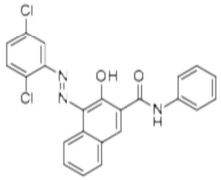
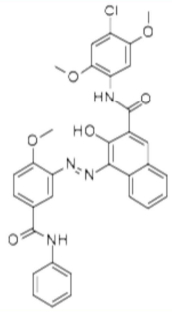
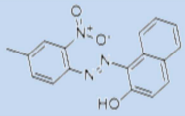
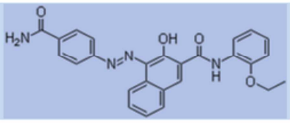
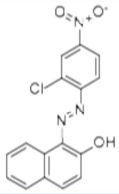
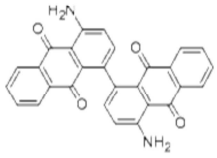
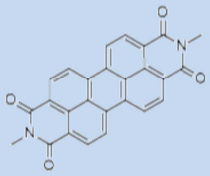
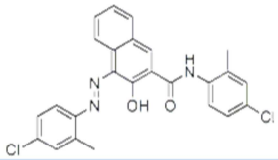
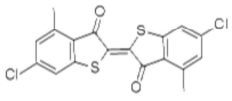
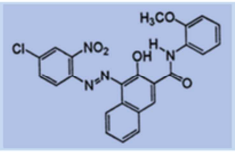
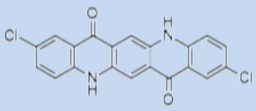
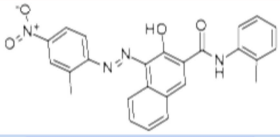
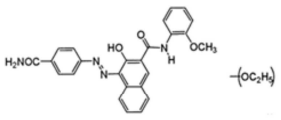
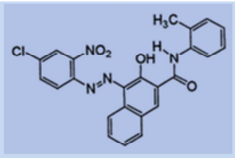
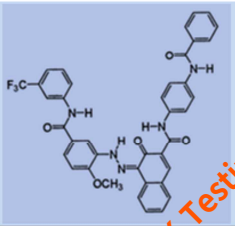
Notification	Year/Week	MS	Brand Name/ Product	Chemical	Legal basis	Origin	Action
0505/14	2014-13	DE	Kuro Sumi Colors/Dragons Breath Red	4-methyl-m-phenylenediamine: 260-1133 mg/kg; Pb: 14.85 mg/kg	Res	JP	Import rejected at border
1439/14	2014-38	IT	Incredibile Tattoo/Sacred Color Red Rubens	Ba: 181 mg/kg	Res	IT	Ban on the marketing of the product and any accompanying measures
1441/14	2014-38	IT	Eternal Ink/Spearmint Green	Ba: 6950 mg/kg	Res	US	Ban on the marketing of the product and any accompanying measures
1442/14	2014-38	IT	Eternal Ink/Lightning Yellow	Ba: 7800 mg/kg	Res	US	Ban on the marketing of the product and any accompanying measures
1999/14	2014-50	DE	Waverly Color Company/Black	PAHs: 1.13 mg/kg	Res	US	Import rejected at border
0012/15	2015-2	DE	Eternal Ink/Light Red	Ni: 9.56 mg/kg ; 4-methyl-m-phenylendiamine: 5521 mg/kg	Res	US	Withdrawal from the market
0454/15	2015-14	IT	Sacred Color/Blue Giotto	As: 3.79 mg/kg	Res	IT	Ban on the marketing of the product and any accompanying measures
0477/15	2015-14	SE	Bloodline Red	PAHs: 1.1-1.2 ppm	Res	US	Withdrawal of the product from the market
0492/15	2015-15	FR	Styliderm (PMU)	Ni: 20 ppm	Res +Nat leg	FR	Withdrawal of the product from the market

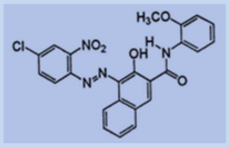
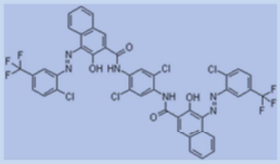
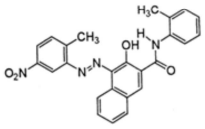
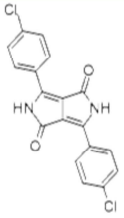
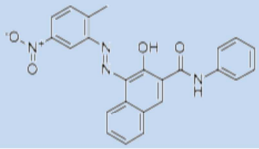
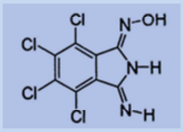
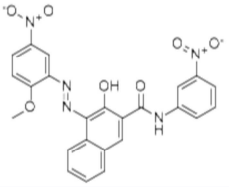
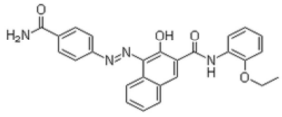
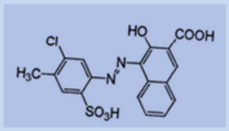
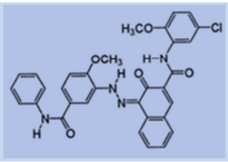
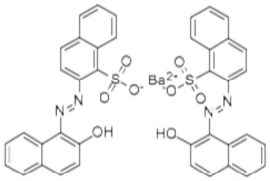
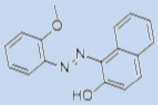
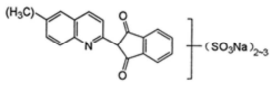
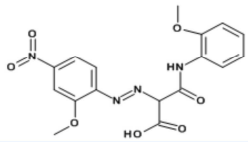
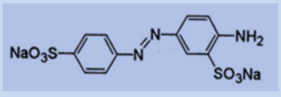
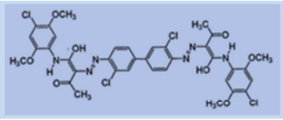
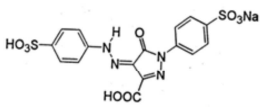
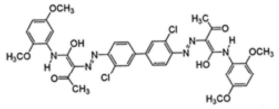
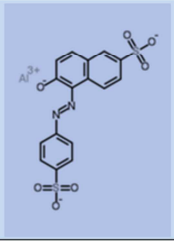
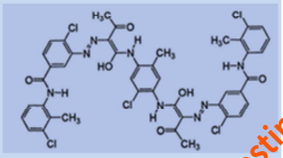
Annex IX

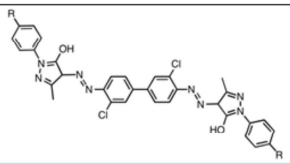
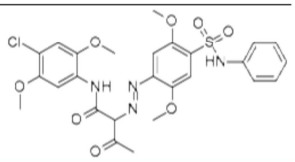
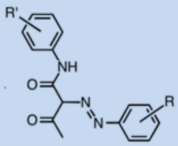
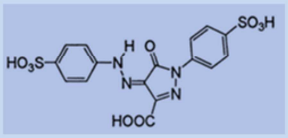
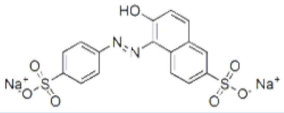
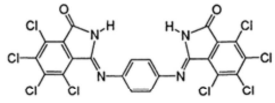
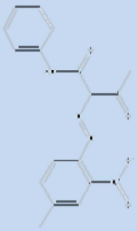
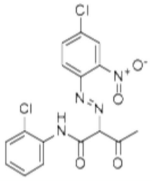
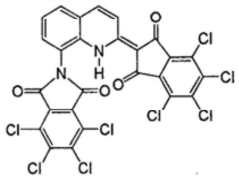
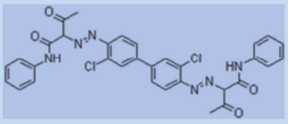
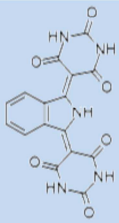
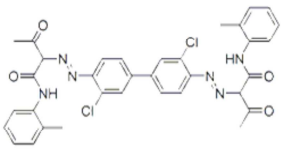
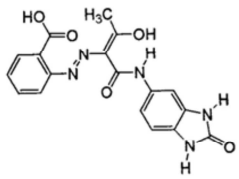
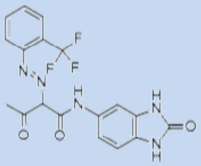
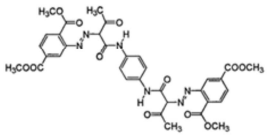
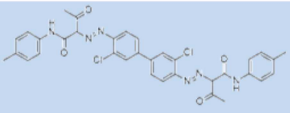
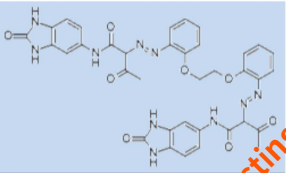
Pigment structures and fate

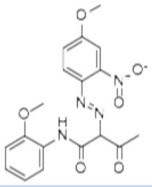
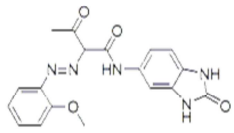
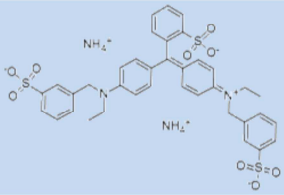
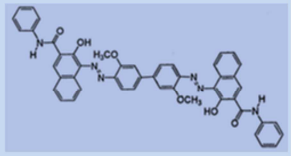
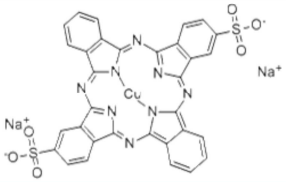
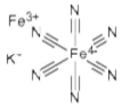
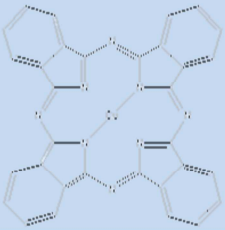
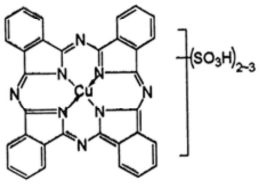
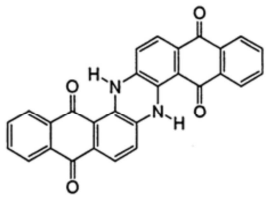
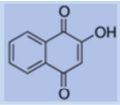
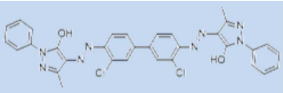
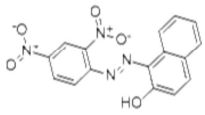
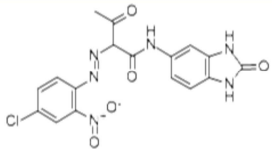
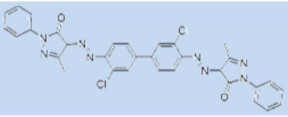
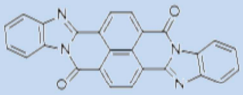
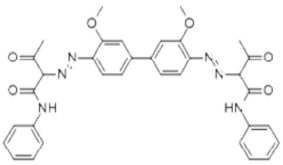
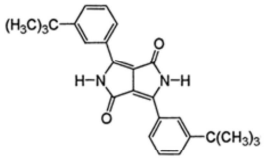
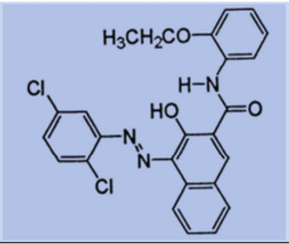
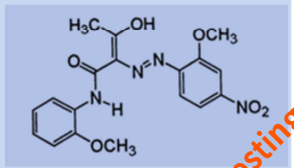
Table A: List of all colorants identified through all sources with their chemical structure.

Colour Index Generic Name	Chemical class	Structure	Colour Index Generic Name	Chemical class	Structure
AR 14	monoazo		PR 49:2	monoazo	
AR 18	monoazo		PR 51	monoazo	
AR 51	xanthene		PR 53:1	monoazo	
AR 87	xanthene		PR 57:1	monoazo	
BR 1	xanthene		PR 57:2	monoazo	
Cinnabar	Inorganic pigments	HgS	PR 60	monoazo	
DR 53	diazo		PR 63:1	monoazo	
FR 17:1	monoazo		PR 101 and102	Inorganic pigments	
NR 4	natural dyes		PR 112	monoazo	

Colour Index Generic Name	Chemical class	Structure	Colour Index Generic Name	Chemical class	Structure
NR 22	natural dyes		PR 120	monoazo	
NR 23	natural dyes		PR 122	indigoid (quinacridone)	
PR 2	monoazo		PR 146	monoazo	
PR 3	monoazo		PR 170	monoazo	
PR 4	monoazo		PR 177	anthraquinone	
PR 5	monoazo		PR 179	anthraquinone	
PR 7	monoazo		PR 181	indigoid	
PR 9	monoazo		PR 202	indigoid (quinacridone)	
PR 12	monoazo		PR 210	monoazo	
PR 14	monoazo		PR 222	monoazo	

Colour Index Generic Name	Chemical class	Structure	Colour Index Generic Name	Chemical class	Structure
PR 15	monoazo		PR 242	diazo	
PR 17	monoazo		PR 254	aminoketone	
PR 22	monoazo		PR 257	heterocycle	
PR 23	monoazo		PR 266	monoazo	
PR 48:1	monoazo		PR 269	monoazo	
PR 49	monoazo		PR 340		
			SR 1	monoazo	
AY 3	quinoline		PY 74	monoazo	
AY 9	monoazo		PY 83	diazo	
AY 23	monoazo		PY 87	diazo	
AY 104	monoazo		PY 93	diazo	

Colour Index Generic Name	Chemical class	Structure	Colour Index Generic Name	Chemical class	Structure
Diarylide Y	diazo		PY 97	monoazo	
Arylide Y	monoazo		PY 100	monoazo	
FY 3	monoazo		PY 110	aminoketone	
PY 1	monoazo		PY 119	inorganic pigments	(Zn,Fe)Fe2O4
PY 3	monoazo		PY 138	aminoketone	
PY 12	diazo		PY 139	aminoketone	
PY 14	diazo		PY 151	monoazo	
PY 36	inorganic pigments	(Zn2(CrO4)O)•H2O	PY 154	monoazo	
PY 42 and 43	inorganic pigments		PY 155	diazo	
PY 55	diazo		PY 180	diazo	

Colour Index Generic Name	Chemical class	Structure	Colour Index Generic Name	Chemical class	Structure
PY 65	monoazo		PY 194	monoazo	
AB 9	triarylmethane		PB 25	diazo	
DB 86	phthalocyanine		PB 27	Inorganic pigments	
PB 15	phthalocyanine		PB 29	Inorganic pigments	$Na_2OSAl_2O_3SiO_2$
PB 17	phthalocyanine		PB 60	anthraquinone	
Lawsone	natural dyes		PO 34	diazo	
PO 5	monoazo		PO 36	monoazo	
PO 13	diazo		PO 43	anthraquinone	
PO 16	diazo		PO 73	pyrrole ketone	
PO 22	monoazo		PO 74	monoazo	

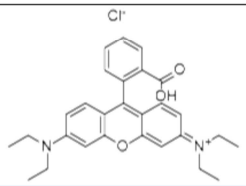
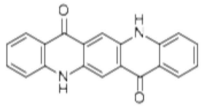
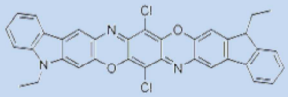
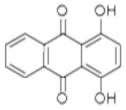
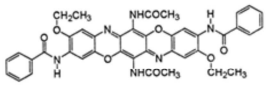
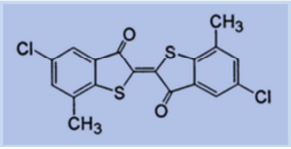
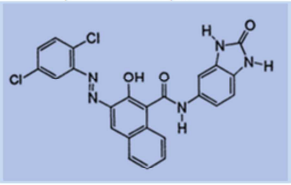
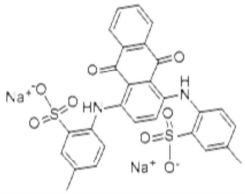
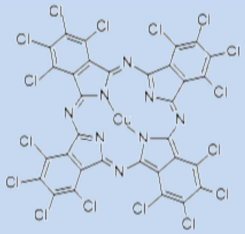
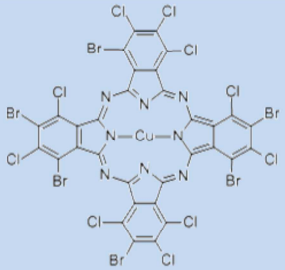
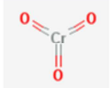
Colour Index Generic Name	Chemical class	Structure	Colour Index Generic Name	Chemical class	Structure
BV 10	xanthene		PV 19	indigoid	
PV 1	xanthene		PV 23	oxazine	
PV 12	anthraquinone		PV 37	oxazine	
PV 15	inorganic pigments	$Na_2OSAl_2O_3SiO_2$	VV 2	indigoid	
PV 16	inorganic pigments	ammonium manganese (3+) diphosphate			
Ferous oxide , black	inorganic pigments	FeO	PBlack 9	inorganic pigments	bone charcoal CH4
PBlack 2			PBlack 11	inorganic pigments	Fe3O4
PBlack 6 and 7	inorganic pigments	carbon black C	PBlack 15	inorganic pigments	CuO
PBr 6 and 7	inorganic pigments	(Fe2O3+FeO)•nH2O	PBr 175		
PBr 25	monoazo				
AG 25	anthraquinone		PG 18	inorganic pigments	
PG 7	phthalocyanine		PG 36	phthalocyanine	
PG 17	inorganic pigments				
Aluminium Silicate (bentonite, White)	inorganic pigments	Al2O3•2SiO2•2H2O	PW 4	inorganic pigments	ZnO
Barium	inorganic pigments	BaSO4	PW 6	inorganic pigments	TiO2

Table B: Fate of pigments.

Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	Irradiation with different light sources	Laser irradiation products	Reference
PY 14	21095	2-methylformanilide (2013, Wezel, thesis) 2-methyl-acetanilide (2013, Wezel, thesis) 3,3'-dichlorodiphenyl (2013, Wezel, thesis) 3,3'-dichlorobenzidine (2011, Gaugler, thesis)	3,3'-dichlorobenzidine (2013, Wezel, thesis)	2015, Hauri
PY74*	11741	2-methoxyacetanilide (2013, Wezel, thesis) In vitro decomposition product after simulated solar light: o-acetoacetanisidide (P2015, Baumler-Ispra; 2004, Cui) 2-(hydroxylmine)-N-(2-methoxyphenyl)-3-oxobutanamide (P2015, Baumler-Ispra; 2004, Cui) N,N-bi(2-methoxyphenyl)urea (P2015, Baumler-Ispra; 2004, Cui)	none identified (2013, Wezel, thesis)	2015, Hauri
PY 83	21108	not investigated	3,3'-dichlorobenzidine (2013, Wezel, thesis)	2015, Hauri
PY 97	11767	none identified (2013, Wezel, thesis)	aniline (2013, Wezel, thesis)	2015, Hauri
PO 13	21110	3,3'-dichlorobenzidine (2011, Gaugler, thesis; 2013, Wezel, thesis) 3,3'-dichlorodiphnyl (2013, Wezel, thesis)	3,3'-dichlorobenzidine (2013, Wezel, thesis) aniline (2013, Wezel, thesis)	2015, Hauri
PO 16	21160	formanilide (2013, Wezel, thesis) acetanilide (2013, Wezel, thesis) 3,3'-dimethoxydiphenyl (2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PO 34	21115	3,3'-dichlorobenzidine (2011, Gaugler, thesis)	not investigated	2015, Hauri
PR		2-amino-4-nitroanisole (2010-a, Swedish Chemical Agency)		2010-a, Swedish Chemical
PR 9	12460	not investigated	In vitro decomposition products: 2,5-dichloroaniline (2004, Vasold;2010-a, Swedish Chemical Agency) 1,4-dichlorobenzene (2004, Vasold;2010-a, Swedish Chemical Agency) methoxy-naphthol AS (2004, Vasold)	2015, Hauri 2010-a, Swedish Chemical Agency
PR 9	12460		Extraction from skin after laser treatment: 2,5-dichloroaniline (2006, Engel; 2008, Vasold) 1,4-dichlorobenzene (2006, Engel; 2008, Vasold)	2006, Engel 2008, Vasold
PR 22	12315		2-methyl-5-nitroaniline (2010-a, Swedish Chemical Agency) 4-nitrotoluene (2010-a, Swedish Chemical Agency)	2010-a, Swedish Chemical Agency
PR 22	12315	In vitro decomposition products (UVB, natural sunlight): 2-amino-4-nitrotoluene (P2015, Baumler-Ispra; 2007, Engel) 4-nitrotoluene (P2015, Baumler-Ispra; 2007, Engel)	In vitro decomposition products: 2-amino-4-nitrotoluene (2004, Vasold) 4-nitrotoluene (2004, Vasold) naphthol AS (2004, Vasold)	2015, Hauri
PR 22	12315		Extraction from skin after laser treatment: 2-methyl-5-nitroaniline (2006, Engel) 4-nitrotoluene (2006, Engel; 2008, Vasold; 2009, Engel)	2006, Engel 2009, Engel 2008, Vasold
PR 112	12370	2-toluidine (2013, Wezel, thesis) 2,4,5-trichloroaniline (2013, Wezel, thesis) 2-methylformanilide (2013, Wezel, thesis) 2-methylacetanilide (2013, Wezel, thesis)		2015, Hauri
PR 122	73915	none identified (2011, Gaugler, thesis; 2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PR 170	12475	benzamide (2011, Gaugler, thesis; 2013, Wezel, thesis) 4-hydroxybenzamide (2011, Gaugler, thesis) 4-aminobenzamide (2011, Gaugler, thesis)	not investigated	2015, Hauri

Colour Index Generic Name (CIGN)	Colour index Constitution Number (CICN)	Irradiation with different light sources	Laser irradiation products	Reference
PR 202	73907	4-chloroaniline (2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PR 254	56110	none identified (2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PG 7	74260	none identified (2011, Gaugler, thesis; 2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PB 15	74160	none identified (2011, Gaugler, thesis; 2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PV 23	51319	none identified (2011, Gaugler, thesis; 2013, Wezel, thesis)	none identified (2013, Wezel, thesis)	2015, Hauri
PW 6 (titanium dioxide)	77891	UVA radiation combined with visible light: in vitro test for cytotoxicity and photocytotoxicity; 0% cytotoxic but 80% are photocytotxic (10 inks analysed) (2011, Wamer)		2011, Wamer

*In vitro using microsomal proteins metabolised into 2 metabolites:
2-((2-methoxy-4-nitrophenyl)azo)-N-(2-methoxy-4-hydroxyphenyl)-3-oxobutanamide (2005, Cui)
2-((2-hydroxy-4-nitrophenyl)azo)-N-(2-methoxy-4-hydroxyphenyl)-3-oxobutanamide (2005, Cui)

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