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Inks for tattoos and permanent make-up – pigments, preservatives, aromatic amines, polyaromatic hydrocarbons and nitrosamines

Number of samples tested:		*Total samples objected to*	*Banned from use*
Total:	229	129 (56%)	103 (45%)
Tattooing inks:	206	126 (61%)	103 (50%)
PMU dyes:	23	3 (13%)	0 (0%)

Reasons for objection:*	*Tattoo*	*PMU*
Banned due to declaration of prohibited substances	*24*	-
Banned due to prohibited pigments	*49*	-
Banned due to prohibited preservatives	*54*	-
Banned due to increased nitrosamine content	*4*	-
Banned due to increased aromatic amine content	*12*	-
Banned due to increased PAH content	*13*	-
Objection due to undeclared ingredients	*124*	*2*
Objection due to declaration	*40*	*2*

* *More than one reason for objection is possible per sample.*

Summary

- The national investigation campaign, "Inks for tattoos and permanent make-up", initiated by the Swiss Association of Cantonal Chemists (Verband der Kantonschemikerinnen und Kantonschemiker der Schweiz – VKCS), resulted in a high objection rate of 56% of 229 inspected products. However, it is important to note that PMU dyes largely comply with legal requirements (no dyes banned from use). After objections were raised for four out of every five tattooing inks in 2009 and every second tattooing ink in 2011, no further improvement was achieved this year, with an objection rate of 61%. In the interests of consumer protection, the frequent use of prohibited products is unacceptable. The investigation also confirmed the fact that many non-compliant products were discovered in the studios whose dyes were being inspected for the first time. It was noted, for example, that a large number of products from two manufacturers were used, which appear on the black list of the Federal Food Safety and Veterinary Office (FSVO) and in the European rapid alert system RAPEX. It is evident that many tattoo studios do not perform sufficient checks of their own and use products that are clearly and unambiguously non-compliant with legal regulations or products which they ought to suspect are in breach of Swiss legislation due to their frequent appearance on black lists. A further problem is that every fifth dye contained prohibited pigments, but the prohibited pigments were only correctly declared on every twentieth dye. It was noted that two particular manufacturers consistently provided misinformation. The situation concerning prohibited preservatives is comparable.
- Many European countries have recently introduced laws for tattooing inks, with matching regulations for pigments for the most part. Nevertheless, the ink manufacturers on the market still do not find pigments that have been toxicologically tested for their suitability for tattooing or that were produced to a particularly pure standard for use under the skin. The manufacturers of the pigments generally developed and tested these products for other application purposes (such as for use in car paints). The manufacturers of tattooing inks primarily take technical properties such as resistance to fading and brightness into account. As the intended use of these pigments is very different to the use associated with the

production of tattooing inks, toxicological data for the introduction of the product into living layers of skin is either insufficient or non-existent.
Often the pigments used by the manufacturers are mixed with other unknown additives. This not only prevents toxicological assessment or the correct declaration of ingredients, but, most importantly, leads to the risk of contaminants such as nitrosamines being produced. In some cases, however, manufacturers make a conscious decision not to declare the ingredients in order to protect their commercial secrets. At best, the ingredients are then listed as "Preservatives" or "Detergents", or even as "Proprietary" ingredients. In the interests of consumer protection, this should be an obvious indication to the studios to steer well clear of these products.

- It appears that many consumers are too little aware that the ingredients of tattooing and PMU dyes are not subject to any kind of testing or licensing by national health authorities. For example, there are no lists with toxicologically evaluated pigments that are approved for use in tattooing. Furthermore, pigments can be broken down into toxic substances by exposure to UV light or if tattoos are removed by laser. These aspects are also not taken into account in legislation.
- In view of these poor results, tattooing inks and permanent make-up dyes must continue to be tested regularly over the coming years.

Initial situation

According to a study [1] by the University of Leipzig, every fourth person between the ages of 15 and 35 in Germany in 2009 had a tattoo. There is no comparable data about the situation in Switzerland. Permanent make-up is a special form of tattooing which is mainly used to highlight the eyebrows or lips, or to conceal scarring after surgery. In view of how widespread tattooing is, it is surprising that the dyes used were not legally controlled until recently and that to this day they are still not regulated in many countries in Europe.

In Switzerland, tattooing and the inks used for it and PMU became subject to the Swiss Foodstuffs Act (Lebensmittelgesetz – LMG) in 2006 and specifications were defined for the microbiological and chemical quality of the products that are used, and for how these should be declared. The Swiss requirements are based on the non-binding European Council Resolution [2] of 2003. The ban on preservatives was not incorporated in Swiss legislation. In Switzerland, preservatives permitted in leave-on products are allowed. In the new European Council Resolution of 2008 [3] the ban on preservatives was lifted and no requirements de facto for the preservatives used were put in place. This point represents the biggest difference today between Swiss legislation and the various laws of other European countries. However, the newly introduced thresholds in the European Council Resolution of 2008 for heavy metals and polyaromatic hydrocarbons (PAH) were incorporated. The European Union still does not have a uniform regulation in place, but efforts to change this are underway.
Non-existent or inconsistent regulations have a negative influence on quality assurance for the dyes used, a fact that was established in an initial investigation in Switzerland in 2009. Bans had to be imposed on the use of 54% of the dyes, most of which were collected from tattooing studios, and on 11% of PMU dyes. Only one in five products (21%) was legally compliant. On the basis of the results of this study, which were reported on in detail in the Bulletin [4, 5] produced by the Federal Office of Public Health (FOPH), the general public were informed and the banned products were listed on the FOPH website. In this way, the tattooing studios were able to find out which products they would no longer be allowed to use in future. Guidelines for assessing tattooing inks were also published by both the FSVO and the State Laboratory of the Canton Basel City (FSVO, KLBS).
An improvement was seen in a repeat investigation in 2011. However, 37% of tattooing inks and 9% of PMU dyes still had to be withdrawn from circulation.

Purposes of the investigation

The purpose of repeating the national campaign led by the VKCS (Swiss Association of Cantonal Chemists) was to find out whether the studios' self-regulation with regard to the use of tattooing and PMU dyes had further improved and whether the proportion of non-compliant products had fallen noticeably.

Legal foundations

The specifications for tattooing and PMU dyes are defined in the Swiss Human Contact Ordinance (Verordnung über Gegenstände für den Humankontakt – HKV). Most of the chemical specifications are based on the regulations for cosmetics (CMR substances, colourants, preservatives) or for consumer goods (aromatic amines).

Parameter	Assessment
Aromatic amines and prohibited azo dyes	Human Contact Ordinance, Art. 5, Para. 3a
Colourants	Human Contact Ordinance, Art. 5, Para. 3b and 3c
Fragrances	Human Contact Ordinance, Art. 5, Para. 3d
CMR substances* (nitrosamines, phthalates, etc.)	Human Contact Ordinance, Art. 5, Para. 3e
Preservatives	Human Contact Ordinance, Art. 5, Para. 4
Polyaromatic hydrocarbons	Human Contact Ordinance, Art. 5, Para. 3 bis
Requirements for the declaration	Human Contact Ordinance, Art. 8, 1a-f

**CMR substances: substances which are categorised as carcinogenic (C), mutagenic (M) or toxic to reproduction (R)*

There is zero tolerance for substances with CMR properties and for banned colourants and preservatives. However, since very low concentrations of colourants and preservatives can be introduced into the products by the raw materials and some CMR substances are technically virtually impossible to avoid, traces of these substances at a safe level were not objected to, in the interests of proportionality.

Description of the samples

A total of 229 samples were collected from 78 tattooing and seven PMU studios and from five importers, an online shop and one manufacturer from Switzerland and the Principality of Liechtenstein. The samples came from 32 tattooing ink and 8 PMU dye brands. Despite the wide range of brands, 53% of the tattooing dyes inspected came from three manufacturers.

Country	No. of samples	Tattoo	PMU
USA	102	102	
Germany	64	56	8
Italy	14	12	2
Unknown	13	13	
Switzerland	9		9
Japan	9	9	
Brazil	8	8	
United Kingdom	6	6	
Austria	4		4
Total	**229**	**206**	**23**

Test procedures

Preservatives and other UV-active substances

In analysing the tattooing and PMU inks, three methods from the field of cosmetics were used to identify the preservatives.

Well over 50 UV-active preservatives were identified, following extraction using methanoic phosphoric acid, by using the UHPLC/DAD multi-wavelength method. This method was also used to screen for dibutyl, benzylbutyl and diethylhexyl phthalates, UV-active fragrances and other ingredients (tensides, impurities, etc.)

The polar preservatives methylisothiazolinone and methylchloroisothiazolinone were identified and quantified using HPLC/DAD, after being extracted using aqueous phosphoric acid. DMDM hydantoin was only analysed qualitatively.

Formaldehyde was also detected by HPLC/DAD following derivatisation with 2,4-dinitrophenylhydrazine. The same method was used to screen for glutardialdehyde and glyoxal.

Organic pigments

The main method used for qualitative analysis of organic pigments was MALDI-TOF mass spectrometry. This allowed most of the pigments that were used to be analysed directly from the dyes themselves, without adding a matrix. The plausibility of the results was tested using UV/VIS spectroscopy with samples dissolved in sulphuric acid, chlornaphthalene or methylnaphthalene. HPLC was also used following extraction of the samples using N,N-dimethylmethanamide.

Carcinogenic aromatic amines as evidence of banned azo pigments

Evidence of banned azo dyes was obtained by using a standard method used on textiles. [6]. The reduced extracts were analysed directly with no purification using LC/MS/MS (as described in [7]).

Carcinogenic N-nitrosamines

An LC/MS/MS method was used to analyse ten carcinogenic N-nitrosamines. Samples were extracted using water.

Polyaromatic hydrocarbons (PAH)

An HPLC/FLD method was used to analyse 24 PAH (EPA and EFSA). The samples were extracted using toluene at 120°C in a microwave oven.

Results

Overview

In 2014, objections were raised about 129 (56%) of the 229 tattooing and PMU dyes that were investigated. PMU dyes demonstrated a clear improvement from the first two national campaigns (Table 1).

Table 1 – Comparison between the numbers of objections in 2014, 2011 and 2009

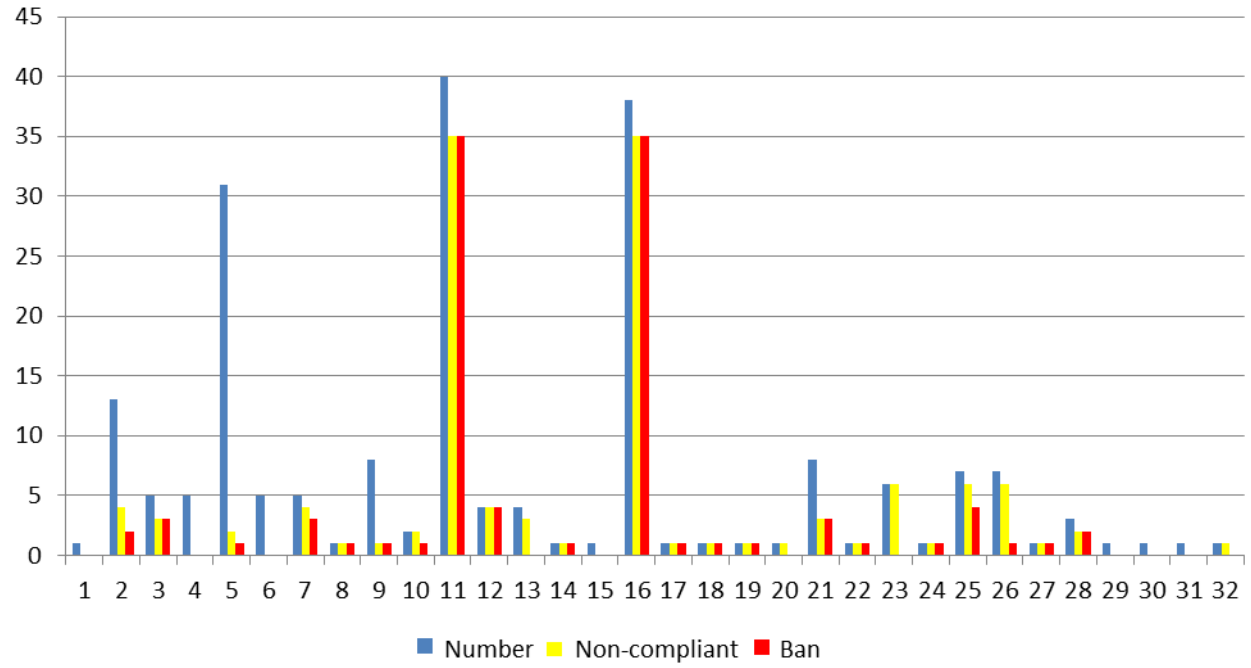
	Number of samples tested			***Total samples objected to***			***Banned from use***		
	2014	*2011*	*2009*	*2014*	*2011*	2009	2014	2011	2009
Total:	229	190	152	56%	51%	76%	46%	33%	41%
Tattooing inks:	206	167	105	61%	53%	87%	50%	37%	54%
PMU dyes:	23	23	47	13%	35%	60%	0%	9%	11%

Despite the high number of tattooing dyes tested (206), the objection statistics are not representative of the situation pertaining to studios in Switzerland, due to two conditions of the campaign in particular:

- Only one sample of each product was collected wherever possible. A dye that is used very frequently has the same value in the statistics as a product used in just one studio.
- Not all studios could be inspected. Emphasis during this campaign was placed on inspecting studios that had opened recently or had not previously been inspected. Experience has shown that dye compliance will be less satisfactory in these types of studios.

Furthermore, the campaign's poor result is significantly influenced by products from two manufacturers (78 samples, of which 70 were banned from use; Figure 1). Other brands also have high non-compliance rates, but their share of the Swiss market is markedly smaller.

Figure 1 – Objections and bans from use by brand (anonymised)



One of the two main reasons for being banned from use continues to be the presence of prohibited pigments (Table 2). More than one in every five dyes contains prohibited pigments. Most of these are not declared on the packaging. It is clear that two large manufacturers

knowingly make false declarations regarding the pigments in order to give the appearance of legally compliant products.

Table 2 – Comparison between the bans from use in 2014, 2011 and 2009

Reason for the ban from use	2014	2011	2009
Banned colourants	22%	29%	23%
Banned preservatives***	24%	8%	14%
Preservative thresholds exceeded	0%	3%	0.7%
Aromatic amines/azo dyes	5%	0.5%	6%
N-nitrosamines**	4%	0%	7%
Polyaromatic hydrocarbons	6%	*	*
Microbiology	*	*	3%

** Analysis not performed; ** content > 150 µg/kg; *** content > 50 mg/kg*

A decisive factor in the observed increase of products with prohibited preservatives (24%) is the use of benzisothiazolinone (BIT; 21%) by the two most frequently inspected manufacturers. This year, no approved preservatives were found to exceed thresholds; however, the majority of preservatives were not declared.
Unfortunately a higher number of products had to be banned due to raised levels of carcinogenic aromatic amines (5%). Findings mainly came up positive for pigments C.I. 12315 (Red 22) and C.I. 21095 (Yellow 14).
Worse results compared to the previous campaign were also identified for nitrosamines. The rate of excessive levels rose to 4%, attributable to a single manufacturer.
Polyaromatic hydrocarbons (PAH) were investigated throughout Switzerland for the first time in 2014. Given the number of RAPEX (European rapid alert system for non-food products) notifications about increased PAH content, it is not surprising that, in Switzerland too, 6% of the products (or 25% of black dyes) were withdrawn from circulation because of high PAH content.
The products with the fewest bans from use were black (27%), brown (26%), white (25%) and grey (17%) colours (Table 3).

Table 3 – Numbers of objections by dye

Colour	Number	Objections	Banned from use	
Violet	16	12	12	75%
Green	31	22	19	61%
Blue	15	10	9	60%
Magenta	15	9	9	60%
Red	37	21	18	49%
Yellow	20	11	9	45%
Orange	15	8	6	40%
Black	51	27	14	27%
Brown	19	5	5	26%
White	4	2	1	25%
Grey	6	2	1	17%
Total	229	129	103	

Organic pigments

Even though Swiss legislation on colourants is in line with the European Council resolution, a fifth of the samples (49 samples, 57 reasons for objection; Table 4) had to be banned from use because they contained prohibited organic pigments.

Table 4 – Organic pigments – Reasons for objection

Reason for objection	No. of pigments	No. of samples	Frequency
Banned colourants	57	49	22%
Declared *banned* colourants	14	11	5%
Failure to declare *banned* colourants	43	38	
Failure to declare approved colourants	16	15	

An above-average number of prohibited pigments contained the colours violet (63% of samples), green (52%), magenta (40%) and red (30%; Table 5). At least one colourant was not declared for 53 dyes. It is noted that prohibited pigments in particular were often not declared (38 dyes) – a clear sign that the manufacturers knowingly neglected to list the prohibited pigments.
In three samples we found the explicitly banned colourants C.I. 12075 (2) and C.I. 15585 (2), while the other 46 samples contained colourants which are not permitted for all purposes in cosmetics, and therefore are not permitted in tattooing and PMU dyes (C.I. 11680 (2), C.I. 21108 (3), C.I. 51319 (11), C.I. 73900 (7), C.I. 73915 (13) and C.I. 74260 (15)).
While the white, grey and black colours presented no problem with regard to the pigments that were used, 29% of the coloured products contained banned pigments.

Table 5 – Organic pigments – Reasons for objection by colour

Colour	No. of samples	Samples with prohibited pigments		Prohibited pigments
Black	51	0	0%	
Red	37	11	30%	C.I. 12075, 15585, C.I. 51319, C.I. 73900, C.I. 73915
Green	31	16	52%	C.I. 74260
Yellow	20	2	10%	C.I. 11680, C.I. 21108, C.I. 71105
Brown	19	0	0%	
Violet	16	10	63%	C.I. 51319, C.I. 73900, C.I. 73915
Blue	15	0	0%	
Magenta	15	6	40%	C.I. 51319, C.I. 73900, C.I. 73915
Orange	15	2	13%	C.I. 12075, C.I. 73915
Grey	6	0	0%	
White	4	0	0%	
Total	229	47	21%	

In four out of ten cases, tattoo studios through their own assessment of the declared ingredients would have had to have discovered that the products either contained prohibited pigments (11 of 47 samples) or were missing necessary information on the pigments (7 of 47 samples). This indicates that many of the studios were not carrying out their own controls properly.
Whilst some manufacturers do declare the prohibited pigments as they should, two manufacturers consistently fail to declare prohibited pigments. The fact that banned pigments are either not declared, or incorrectly declared, in so many cases suggests that most of these products were being deliberately labelled incorrectly in order to be able to offer consumers a seemingly legal product.
For example, in seven cases of green inks, the pigment C.I. 74265 was declared, but the samples contained the banned pigment C.I. 74260. Similarly, for three inks a yellow and a blue pigment were declared, but again C.I. 74260 was responsible for the colour.
For 18 magenta or violet-coloured samples with prohibited pigments, generally a red and a blue pigment were declared or an incorrect violet (e.g. C.I. 73385) or magenta (C.I. 45170:2) pigment was declared. The declaration on a violet ink was obviously incorrect: according to the

declaration, the ink contained the white pigment titanium dioxide and the blue pigment C.I. 74160 – together these would make light blue. Two magenta-coloured products, which according to the declaration should only have contained red (C.I. 12466, C.I. 12475) and white pigments, also came to light.
We regard the regulation of colourants using negative lists to be unsatisfactory, because the indirect consequence of this is that all colourants whose use is not regulated by the Cosmetics Ordinance, and which do not release carcinogenic aromatic amines following reductive splitting in accordance with EN 14362, are permitted for use in tattooing and PMU dyes. This means that colourants are indirectly permitted that have not been subjected to toxicological testing for either cosmetics or tattooing use, with the result that organic pigments in this category are being used in half of the dyes (Table 6). The substitute pigments are also sometimes closely related chemically to the banned pigments, for example C.I. 74265 instead of C.I. 74260, or C.I. 73907 instead of C.I 73900 or C.I. 73915.

Table 6 – Organic pigments in tattooing and PMU dyes: legal status

Proportion of samples containing colourants*:		Legal basis
Permitted	18%	Cosmetics Ordinance, Appendix 2, Column 1
Banned	22%	Cosmetics Ordinance, Appendix 2, Columns 2–4 (31%); Human Contact Ordinance, Appendix 2 (1%)
Not regulated	50%	Not listed in either the Cosmetics Ordinance or the Human Contact Ordinance

***** *Does not total 100%, as some products may contain colourants from multiple categories and products with purely inorganic pigments were also counted.*

The frequency and legal status of the organic pigments found in tattooing and PMU dyes are given in Table 7.

Table 7 – Organic pigments in tattooing and PMU dyes: frequency of use and legal status

Pigment	Colour	Frequency in samples	Legal status	Comments
C.I. 74160	Blue	18%	Permitted	
C.I. 12475*	Red	11%	Not regulated	* Sometimes in combination with C.I. 12474 as C.I. 12477
C.I. 56110	Red	10%	Not regulated	
C.I. 56300	Yellow	8%	Not regulated	
C.I. 561170	Orange	7%	Not regulated	
C.I. 74260	Green	7%	Banned	
C.I. 11740	Yellow	6%	Not regulated	May release o-anisidine*
C.I. 12474*	Red	6%	Not regulated	* Always in combination with C.I. 12475 as C.I. 12477
C.I. 21110	Orange	6%	Not regulated	May release 3,3'-dichlorobenzidine
C.I. 73915	Magenta	6%	Banned	
C.I. 11741	Yellow	5%	Not regulated	May release o-anisidine*
C.I. 51319	Violet	5%	Banned	
C.I. 51345	Violet	5%	Not regulated	
C.I. 11767	Yellow	3.5%	Not regulated	
C.I. 12315	Red	3.5%	Not regulated	May release 2-nitro-4-aminotoluene or 2,4-diaminotoluene
C.I. 74265	Green	3.5%	Not regulated	
C.I. 21095	Yellow	3.1%	Not regulated	May release 3,3'-dichlorobenzidine and o-toluidine*
C.I. 73900	Magenta	3.1 %	Banned	
C.I. 73907	Magenta	3.1%	Not regulated	
C.I. 13980	Yellow	2.2%	Not regulated	
C.I. 21160	Orange	2.2%	Not regulated	May release o-dianisidine*
C.I. 15630	Red	1.7%	Not regulated	
C.I. 21108	Yellow	1.3%	Banned	May release 3,3'-dichlorobenzidine
C.I. 11680	Yellow	0.9%	Banned	
C.I. 12075	Orange	0.9%	Banned	
C.I. 12085	Red	0.9%	Permitted	
C.I. 12490	Red	0.9%	Permitted	
C.I. 15585	Red	0.9%	Banned	
C.I. 19140	Yellow	0.9%	Permitted	
C.I. 11781	Yellow	0.4%	Not regulated	
C.I. 12120	Red	0.4%	Not regulated	
C.I. 12310	Red	0.4%	Not regulated	
C.I. 12370	Red	0.4%	Banned	May release o-toluidine
C.I. 15850	Red	0.4%	Permitted	
C.I. 15880	Red	0.4%	Permitted	
C.I. 47005	Yellow	0.4%	Permitted	
C.I. 71105	Orange	0.4%	Banned	
C.I. 73360	Red	0.4%	Permitted	

Aromatic amines – banned azo pigments

In addition to the explicitly banned pigments, those azo dyes which can be broken down into carcinogenic aromatic amines by reductive splitting are also banned. In view of the lack of reference material and the very large number of possible colourants, these substances are detected indirectly by identifying the listed amines which are formed by reductive splitting. Also banned are free carcinogenic aromatic amines, which may be present as impurities in the inks. Since this has been a known problem in tattooing for years, many manufacturers have their products tested for these substances and then provide certificates of analysis with the products. Despite this, however, objections still had to be raised for significantly more samples this year due to aromatic amines. The number of objections increased compared with the previous survey from 0.5 to 5%.

The many red and orange colours that separated 2,4-diaminotoluene or its reduced product 5-nitro-o-toluidine stood out (Table 8). The findings were based on pigment C.I. 12315 (red 22), which was often only found as a contaminant in tattooing inks. It is not known why this pigment is increasingly used. o-toluidine was mainly found in yellow and green colours. We suspect the source to be pigment C.I. 21095 (yellow 14) in most cases. o-toluidine is usually present as a free amine here.

Table 8 – Detection of banned azo dyes – aromatic amines after reductive splitting

Aromatic amine from azo dye reduction	Lowest value [mg/kg]	Highest value [mg/kg]	Median [mg/kg]	Samples with content > 1 mg/kg	Samples with content > 30 mg/kg
3,3'-dichlorobenzidine	1.0	11	1.7	13 (7%)	
o-toluidine	1.2	129	5.3	21 (13%)	6 (3.6%)
o-anisidine	1.4	24	13	23 (14%)	
2,4-diaminotoluene	5.9	6900	20	22 (13%)	10 (6.0%)
Total coloured samples > 30 mg/kg					14 (8.3%)

Preservatives

The inspections in 2009 and 2011 showed that few tattooing inks contain preservatives compared to cosmetics. In Switzerland, preservatives permitted in leave-on cosmetics are allowed.
In some products, the high ethanol or isopropanol content, sometimes combined with other ingredients (especially glycols), will act as an adequate preservative. Other products are preserved using glass powder or γ-ray radiation. Experience suggests that tattooing inks are not a good culture medium for bacteria [5] and in 2009 only 3% of the samples had to be banned from use because the number of bacteria was too high. 55% of the tested inks contained no preservatives. The preservatives found are listed in Table 9.

Banned preservatives

The banned technical preservatives phenol (6) and benzisothiazolinone (BIT; 55) were found in 61 samples (27%). BIT was only declared correctly for a few products. Octylisothiazolinone (OIT), in contrast, was not found in any samples this time, which can be explained by the fact that Swiss tattooing studios have since stopped purchasing this manufacturer's products. In 2009 the brand was still one of the most frequently used products (14% of samples), but in 2011, only two samples from this manufacturer (1%) were found.
Phenol is a substance that is suspected to be a carcinogenic (Carc. Cat. 2B). Its use in cosmetics has been banned for a long time.
The use of BIT is tolerated in Germany, for example, where the Tattooing Inks Ordinance is oriented toward the European Council Resolution of 2008. However, just like in Switzerland, this substance must be declared. BIT is therefore declared on the packaging of the samples of an American manufacturer's products sold in Germany. If the products are imported from England or the USA, there is no such declaration.
BIT has not been authorised for use in cosmetics despite attempts by the cosmetics industry to change this. The SCCS (Scientific Committee on Consumer Safety) of the European Union last assessed the use of BIT as a preservative in cosmetic products on 26/27 June 2012 [8]. Due to:

- a potential for skin sensitisation similar to that of methylisothiazolinone (MI);
- the fact that MI in a concentration of 0.01% in cosmetics causes contact allergy and allergic contact dermatitis and
- the fact that BIT in a concentration of 20 mg/kg in gloves has caused sensitisation

the use of BIT in cosmetics has been classified as unsafe. We have no evidence that the tattooing ink manufacturers can present more convincing toxicological data than the cosmetics manufacturers and therefore consider the stricter Swiss ordinance to be justified.

Table 9 – Preservatives in tattooing inks and PMU dyes

Preservative	No. of samples		Lowest value	Highest value	Median	Objection due to missing declaration**		Banned due to thresholds being exceeded***	
Benzisothiazolinone (BIT)*	55	24%	30 mg/kg	424 mg/kg	105 mg/kg	34	15%	43	19%
Benzoic acid	25	11%	0.010%	0.12%	0.019%	2			
Methylisothiazolinone (MI)	18	8%	0.42 mg/kg	70 mg/kg	1.2 mg/kg	1			
Formaldehyde	15	7%	0.005%	0.035%	0.007%				
Phenoxyethanol	8	3%	0.015%	0.80%	0.20%	6	3%		
DMDM hydantoin	7	3%		Not quantified		6	3%		
Phenol*	6	3%	0.008%	0.47%	0.017%	6	3%	6	3%
Methylchloroisothiazolinone (MCI)	5	2%	1.1 mg/kg	1.5 mg/kg	1.3 mg/kg				
Total MI/MCI	5	2%	2.3 mg/kg	2.7 mg/kg	2.6 mg/kg	5	2%		
Dehydroacetic acid	5	3%	0.038%	0.089%	0.050%	5	2%		
Sorbic acid	3	1%	0.063%	0.076%	0.067%				
o-phenylphenol	2	1%	0.084%	0.11%	0.098%	2	1%		
Objections due to missing declaration, total						**67**	**29%**		
Banned from use, total								**54****	**24%**

* Banned preservatives

** Traces of preservatives are tolerated. They had to be declared where the content was more than 10% of the threshold. For formaldehyde the limit is 0.01% (this is 20% of the threshold, upwards of which a warning notice is required).

*** Objections were raised about banned preservatives upwards of 50 mg/kg.

**** 5 products contained BIT according to the declaration. The measured concentration was below 50 mg/kg, however. For this reason, the number of products with objections due to banned preservatives totalled 54.

Failure to declare preservatives

Preservatives are still rarely declared. 61 samples contained a total of 67 undeclared preservatives. In addition to undeclared prohibited preservatives, the declaration was also omitted in the case of all products containing MI or MI/MCI preservatives. This is especially unsatisfactory because these preservatives have high allergy rates. However, phenoxyethanol, dehydroacetic acid, o-phenylphenol and DMDM hydantoin were also missing from declarations for the tested tattooing inks.

N-nitrosamines

N-nitrosamines are impurities made up of secondary amines and nitrite. Many N-nitrosamines are carcinogenic substances which have been found in animal testing to cause cancer even in low concentrations.

In 15 (7%) of the samples tested, either N-nitrosodiethanolamine (NDELA; 14) or N-nitrosodimethylamine (1) were found at levels of more than 10 µg/kg (Table 10).

Table 10 – N-nitrosamines in tattooing inks and PMU dyes

N-nitrosamine	No. of samples		Lowest value [µg/KG]	Highest value [µg/KG]	Median [µg/kg]
Nitrosodiethanolamine	14	6%	12	66700	79
Nitrosodimethylamine	1	0.4%	26		
Objection (> 15 µg/kg)	11	5%			
Banned from use (> 150 µg/kg)	4	2%			

The number of samples containing nitrosamines has continued to drop since 2011. In contrast to the last campaign, however, four products had to be banned from use this year. As in 2009, several inks contained more than 1000 µg/kg and one product even had 67,000 µg/kg NDELA. Three of the four products were from the same manufacturer. Only one of six products from this manufacturer did not contain NDELA. The formation of nitrosamines can be prevented by using suitable stabilisers or by not using triethanolamine.

Polyaromatic hydrocarbons

Polyaromatic hydrocarbons (PAH) are formed when there is incomplete combustion of organic matter. Eight PAHs are officially classified as class 1 carcinogens and therefore banned in tattooing inks. A threshold of 0.005 mg/kg was defined for the carcinogenic lead substance benzo(a)pyrene, and a threshold of 0.5 mg/kg PAH was defined for the total of all PAHs.

The pigment carbon black (C.I. 77266 or C.I. 77288) is responsible for the black colour in most black inks. It is used in different degrees of quality in various products (rubber, inks and dyes, cosmetics).

Fourteen samples (6%) contained clearly excessive levels of PAH. With levels between 4.1 and 64 mg/kg, they exceeded the total threshold of 0.5 mg/kg by a factor ranging from ten to one hundred (Figure 2). One sample contained only naphthalene (9.4 mg/kg). An objection was not raised for this sample.

The polyaromatic hydrocarbons found are listed in Table 11.

Figure 2 – Benzo(a)pyrene and total PAH content of grey and black tattooing inks

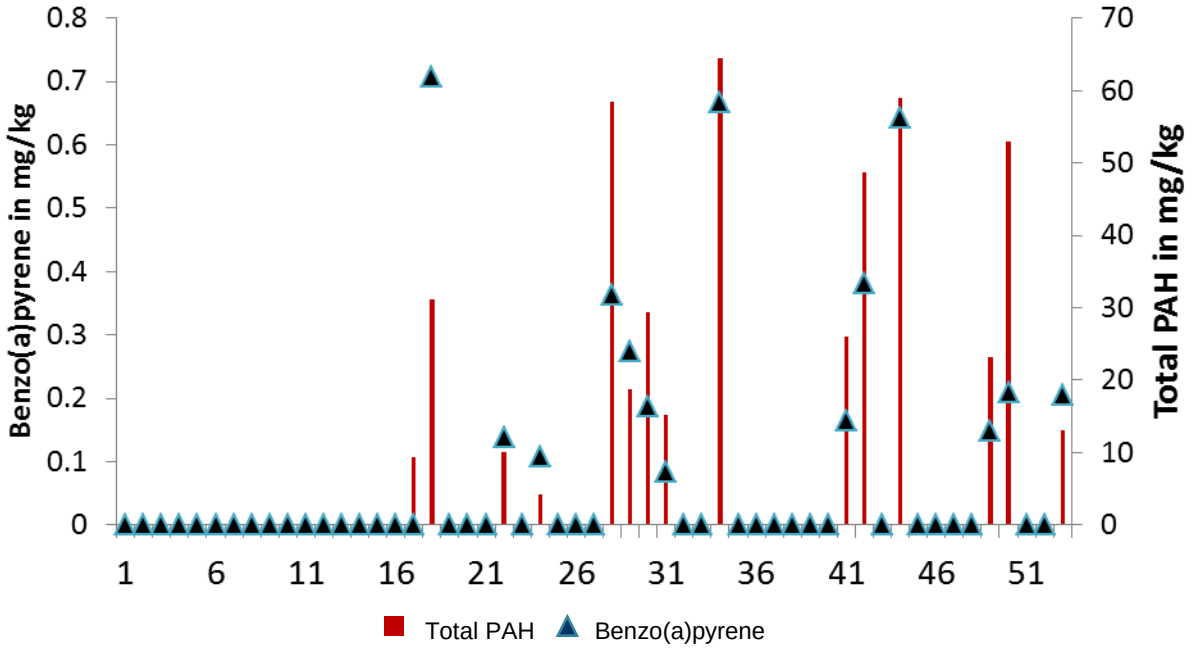


Table 11 – Polyaromatic hydrocarbons in black and grey tattooing inks and PMU dyes

	Number of samples with PAH		Number > 0.005 mg/kg	Number > 0.5 mg/kg	Lowest value	Highest value	Median value
Naphthalene	11	19%	11	11	2.08	9.4	3.6
Acenaphthene	2	4%	2	0	0.064	0.15	0.11
Fluorene	12	21%	12	0	0.011	0.079	0.018
Phenanthrene	24	42%	24	12	0.019	35.1	0.53
Anthracene	17	30%	17	3	0.006	2.0	0.074
Fluoranthene	18	32%	18	14	0.040	11.9	2.0
Pyrene	19	33%	19	14	0.011	40.5	7.3
Benz(a)anthracene*	14	25%	14	2	0.037	0.56	0.11
Chrysene*	12	21%	12	1	0.007	0.53	0.048
Benzo(b)fluoranthene*	14	25%	14	2	0.025	1.1	0.052
Benzo(k)fluoranthene*	13	23%	13	2	0.006	0.74	0.017
*Benzo(a)pyrene**	*14*	*25%*	*14*	*3*	*0.085*	*0.71*	*0.21*
Dibenz(a,h)anthracene*	5	9%	5	0	0.032	0.096	0.032
Benzo(g,h,i)perylene	14	25%	14	12	0.17	5.1	2.0
Indeno(1,2,3-cd)pyrene	13	19%	11	3	0.12	0.90	0.32
Total PAH	*26*	*46%*	*26*	*15 (26%)*	*0.019*	*65.1*	*9.7*

* Officially classified as carcinogenic category 1B.

Defective declarations

42 samples (18%) were found to have defective declarations, for example:

- Missing contents list: 9 (4%)
- Catch-all terms used such as "Organic pigments", "Preservatives", "Emulsifiers", "Dispersing agents" or "Proprietary": 38 (17%)
- Missing use-by date or date after opening: 2 (1%)
- Batch number: 2 (1%)

The studios themselves should have been able to recognise that these defective declarations were not legally compliant when carrying out their own checks.

A clear improvement in comparison with the first two campaigns can be seen in terms of declarations (with the exception of false declaration of contents). In 2009, 68% of the declarations were still not legally compliant. This statistic improved to 44% in 2011 and to 18% in the current campaign.

[1] Press release, University of Leipzig, 13 July 2009: Verbreitung von Tätowierungen, Piercing und Körperhaarentfernung in Deutschland; Ergebnisse einer Repräsentativerhebung in Deutschland im Mai und Juni 2009 [The spread of tattooing, piercings and body hair removal in Germany; results of a representative survey carried out in Germany in May and June 2009].

[2] “Resolution ResAP(2003)2 on tattoos and permanent make-up”, adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers Deputies; Council of Europe, Strasbourg, 2003

[3] “Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up)”, adopted by the Committee of Ministers on 20 February 2008 at the 1018th meeting of the Ministers Deputies; Council of Europe, Strasbourg

[4] Bundesamt für Gesundheit (BAG) (2009) Konformität von Tätowier- und Permanent-Make-up-Farben nicht zufriedenstellend. [Federal Office for Public Health (FOPH) (2009) Inadequate compliance of tattooing and permanent make-up dyes] FOPH Bulletin 29:535–541

[5] Andreas Baumgartner and Sylvia Gautsch; Hygienic-microbiological quality of tattoo- and permanent make-up colours, J. Verbr. Lebensm. (2011) 6:319–325

[6] European Standard EN 14362:2003, Textiles – Methods for the determination of certain aromatic amines derived from azo colourants

[7] Urs Hauri, Beat Lütolf, Urs Schlegel and Christopher Hohl: Determination of carcinogenic aromatic amines in dyes, cosmetics, finger paints and inks for pens and tattoos with LC/MS; Mitt. Lebensm. Hyg. 96, 321–335 (2005)

[8] Scientific Committee on Consumer Safety (SCCS) – Opinion on Benzisothiazolinone, Colipa n° P96; The SCCS adopted this opinion at its 15th plenary meeting of 26-27 June 2012.