

# **Adverse health effects linked to tattoo and permanent make-up practices**

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**Replies to questionnaires  
National Authorities**

**Table A:** Frequency of health issues amongst people having undertaken tattoo/PMU.

		HEALTH EFFECTS/TATTOO APPLICATION Q 1.1																													
		Local												Systemic																	
		Acute side-effects						Persistent side-effects						Acute side-effects						Persistent side-effects											
	infections	allergic reactions	edema	itching	numbness	wound healing problems	other	frequency	eczema	psoriasis	scars	scleroderma	photosensitivity	granulomas	tumours	other	frequency	fever	infections	dizziness	headache	nausea	behavioural changes	other	frequency	infections	hepatitis	AIDS	psychic problems	other	frequency
BE	R	R	F	C	E	R		na	E	E	R	N	C	E	N		na	E	E	R	R	R	E		na	E	na	na	na		No data if viral infections are tattoo related
BG																														Only studios are controlled, not able to answer.	
CZ																														na	
DK																														No systematic official registration of negative effects from tattoos.	
ES								N									N								N				N		
FI								R									R								N/E				N/E		
FR	X	X						F	X								C								X				F		
IT																														No register of complaints/side effects thus no data available on frequency.	
NL	F	C	E	F	R	E		R	R	C	N	R	C	R			E	E	N	N	N	N			E	N	N	E			
RO																														na	
SE																										R				No requirements in legislation to report side-effects coupled to tattooing.	
SK																														No information in this area. Only market surveillance for Tattoos notified through RAPEX - according national law.	

Frequency: **N**= never, **E**= exceptional, **R**= rare, **C**= common, **F**= frequent **na**: not available

**Table B:** Frequency of health issues amongst people having undertaken tattoo/PMU removal.

HEALTH EFFECTS/TATTOO REMOVAL Q 1.2														
MS	Immediate skin reactions						Delayed symptoms							
	pain	blistering	pinpoint bleeding	crusting	urticarial	other	frequency	local (photo) allergic reactions	systemic (photo) allergic reactions	scars	hyper- and hypopigmentation	ink retention and darkening	other	frequency
BE	C	R	C	R	E	All symptoms are considered as acceptable after laser tattoo removal		R	E	C	C	C/R		
CZ	na											na		
DK												No systematic official registration of negative effects from tattoos or removal from tattoo.		
ES	X					N			X			Keloid	R	
FI	na											In two cases reported scars and skin burns after applying do-it-yourself-removalcream (Verruxin)	na	
FR												No information. More and more questions regarding the status of tattoo removal products (and laser). Real problem because not under the scope of French legislation on tattoos. Real need for a harmonization and a common European status for these products.		
NL	F	N	E	C	N		E	E	E	C	C	E		
SE	na											na		
SK	na											na		

Frequency: **N**= never, **E**= exceptional, **R**= rare, **C**= common, **F**= frequent **na**: not available

**Table C:** Correlation between health issues and tattoo characteristics.

<b>HEALTH EFFECTS/CORRELATION Q 1.3</b>									
<b>Are the following factors correlated to higher frequency of medical complications?</b>									
<b>MS</b>	<b>Number of tattoos</b>	<b>Size of the tattoo</b>	<b>Gender differences</b>	<b>Customer's age</b>	<b>Colour of the tattoo</b>	<b>Localisation of the tattoo</b>	<b>Type of tattooist</b>	<b>Other</b>	<b>Frequency</b>
<b>BE</b>	Yes	Yes	na	na	Yes RED	Yes Exposed areas	Yes Poor quality tattoos and scarring	Little tattooing under the age of 18!	
<b>CZ</b>									na
<b>FI</b>	na	X	na	na	na	na	na		
<b>FR</b>					Yes			Strong suspicions concerning bad practices of tattooist	
<b>NL</b>			Women; propably because women are currently more frequently tattood		Red (following black, blue, yellow)	Possibly sunlight-exposed areas.	na	Sunlight exposure	
<b>SE</b>									na
<b>SK</b>									na

na: not available

**Table D:** Experience with the Council of Europe Resolution (2008)1 – Chemicals.

EXPERIENCE WITH THE COUNCIL OF EUROPE RESOLUTION (2008/1) Q 2.1a

Chemicals						
MS	CoE ResAP(2008)1, Table 1		CoE ResAP(2008)1, Table 2		CoE ResAP(2008)1, Table 3	
	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale
DE			Add Solvent Yellow 14			
DK	yes + aniline and limit value of 10 ppm					The limit values are unnecessarily restrictive (low). For lead we suggest 10 ppm and for Bap 0,2 ppm.
ES	Revision	Update: Add aniline	Revision	Evaluate the following dyes, already mentioned for their possible toxicity: 45170.2 CI, CI 11741, CI 12390. CI 73360, CI 12490, CI 11680.	Revision	Update: Nickel content limit.
FI	Should be taken into account		Should be taken into account		Should be taken into account	
IT	Determination of further dangerous aromatic amines: qualitative screening revealed that other aromatic amines were not carcinogenic but toxic (aniline CAS n° [62-53-3], 2-etoaniline CAS n° [94-70-2] and IPPD CAS n° [101-72-4]) were found in certain samples. Extension of aromatic amines list in Resolution ResAP Introduction of concentration limits for AA in table 1 as provided for Benzo(a)Pyrene in table 3	Table 1 is not complete for different aspects	The use of the following colorants, in addition to the 35 listed in the CoE ResAP (2008)1, should be avoided: Pigment Violet 1; Pigment Yellow 74; Pigment Red 17; Pigment Red 181; Pigment Blue 15; Pigment Green 7; Pigment Red 5; Pigment Yellow 1.	Nowadays there aren't enough evidences for the effective hazard of these colorants listed in the suggestion box. The introduction of these colorants should be done after a verification study	<ul style="list-style-type: none"> <li>• "Copper (Cu) soluble" to be defined.</li> <li>• Fix a maximum allowed concentration for Ni</li> <li>• Base actual limit on toxicological study</li> </ul>	Some unclear aspects in ResAP lead to controversy and are a problem for producers, importers, retailers and control authorities. General PAHs index does not clarify mixtures composition that need to be classified in terms of hazards and cancer risk.
NL					Nickel PAH Barium	<ul style="list-style-type: none"> <li>• Nickel's allowed concentration to be clarified as different countries and labs give their own interpretation of this item. When Fe oxides used as pigments, Ni concentration higher.</li> <li>• Specify which PAH have to be chosen.</li> <li>• Barium – in art. 2 BaSO4 specified; not in accordance with Ba requirement of 50 mg/kg.</li> </ul>
SI					Nickel (Ni)	Setting maximum allowed concentration based on risk assessment and technical ability

EXPERIENCE WITH THE COUNCIL OF EUROPE RESOLUTION (2008/1) Q 2.1b

Chemicals								
MS	Requirements for further organic impurities for colorants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC		Ingredients mentioned in Annex II to EC Regulation 1223/2009 on Cosmetics		Colorants specified in Annex IV, column g of EC Regulation 1223/2009 on Cosmetics		CMR substances classified under categories 1A, 1B and 2 in Table 3.1 of Annex VI to EC Regulation 1272/2008 on Classification, Labelling and Packaging	
	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale
DE							Yes	
DK							Yes	
ES							Include updated website CMR substances in list	To facilitate knowledge and consultation of manufacturers and authorities.
FI			Should be banned in tattoo colours	Is continuously changing. Same level of safety should be required when chemicals are injected into the skin as with chemicals on the skin.		Not relevant as risk is assessed only for skin contact and not inside skin.	Should be banned	The CLP-classification as a CMR substance triggers a lot of consequences in other legislations and should be taken into account in restrictions on tattoo inks
FR	Yes							
IT	Yes					Yes		
NL	(Yes)							

**EXPERIENCE WITH THE COUNCIL OF EUROPE RESOLUTION (2008)1 Q 2.1c**

Chemicals			
MS	Establish positive lists of colorants		Single lists of chemicals (e.g. colorants, aromatic amines, impurities) instead of cross references lists
	Suggestion	Rationale	Suggestion Rationale
BE	Yes	Safety guarantee	Yes Easier
DE	Yes	Best way to ensure consumer protection; negative lists cannot be exhaustive.	No Cross references lists mirror the actual state of regulation; otherwise changes in other areas would have to be regularly incorporated into tattoo regulation.
FI	Not easy to establish. Would be good to establish but needs time and resources	Wide number of ingredients can be carcinogenic according to the WHO	
FR			Yes Positive lists ideal and more understandable for operators. But needs updating according to other regulations evolution. Given lack of human resources, this option is impossible to follow.
IT	Italy would favourably consider positive lists of colorants, but there are positive elements and negative elements to be taken into account (see Rationale column).	A positive list of colorants means that each substance is associated with a very accurate risk assessment dossier that would be stable over time. But random tests would be needed to check the composition of inks. It is easier that substances not properly investigated, could result to further study toxic or carcinogenic. So the negative list should be periodically updated. Negative lists speed up controls: check label to assess ink composition and absence of banned components. Negative lists allows producer to avoid components that should not be present in the ink formulation.	Yes
NL	The Netherlands is in favour of an exhaustive list of substances proved safe for this use under specified conditions	List should be supported by safety assessments from competent bodies and harmonised at the European level.	
SE	A EU-COM scientific committee performs the examination of colorants and safe colorants are listed on a positive list	<ul style="list-style-type: none"> <li>Easier for companies to check the ingredient list/documentation to make sure their tattoo colors only contain permitted colorants.</li> <li>The companies would have to invest less time choosing colorants and evaluating their safety, however they must ensure that their tattoo color do not exceed limitations for contaminants found in table 3 Resap2008.</li> </ul>	No. Instead we suggest a single positive list of colorants in tattoo legislation instead of reference to appendix IV colorants in regulation (EU) nr 1223/2009 on cosmetics  Companies can easily check forbidden colorants in table 2 Resap2008. But with the current cross reference to appendix IV regulation (EU) nr 1223/2009, such company could be tempted to choose those colorants and think that they are automatically safe to use in tattoo colours. But these colorants are evaluated for cosmetic use and not for injection through the skin. Furthermore, there are no requirements that substances listed in this appendix IV should be re-evaluated once they have been put in such annexes.
SI	Yes	Positive list of colorants based on risk assessment provides more safety	Yes Would be easier
SK	positive list of colorants	Positive list of colorants better to increase consumer safety	



**EXPERIENCE WITH THE COUNCIL OF EUROPE RESOLUTION (2008/1) Q 2.1 d**

MS	Chemicals			
	Harmonise analytical methods for testing hazardous chemicals		Other	
	Suggestion	Rationale	Suggestion	Rationale
BE	Absolutely		All products forbidden in cosmetics should be banned from tattoo inks and all products (ea preservatives) in tattoo inks should have the same limits of concentration as drugs used for injection in the body	It is logical that products injected in the body should be as safe as food or products in contact with the skin
DE	Yes	Better comparability of results.	Guidance values for technically unavoidable amounts.	Guidance for manufacturers and market surveillance authorities.
DK	Yes		We recommend a safety assessment	
ES	Agree	Need to have harmonized analytical methods to compare results.		
FR			Establishing a European consensus on the status of tattoo removal products.	
IT	<p>More information strongly needed for Table 3 elements:</p> <ul style="list-style-type: none"> <li>• sample preparation (maximum allowed concentrations for product as such or dry substance; or analysis of part or entire amount of an element present in sample)</li> <li>• can the microwave-assisted acid digestion be applied</li> <li>• How to make extraction for "Copper (Cu) soluble" <ul style="list-style-type: none"> <li>• PAH and BaP</li> </ul> </li> <li>• AA (because the concentration of sodium dithionite (the reductive agent) could influence the AA cleavage from the pigment).</li> </ul>	The described unclear aspects in the ResAP are a great problem for producers, importers, retailers and control authorities		
NL	The method of NVWA		According the resolution 2008(1) preservatives should only be used after a safety assessment. Therefore a positive list of conservatives is	
SE	There would be optimal for the analysis of the hazardous chemicals in tattoo inks (powders and solutions) if there are harmonized methods, aimed for this group of product. Further, methods for the determination of the impurities (eg primary aromatic amines, residual organic solvents, softeners like phthalate, heavy metals) of the tattoo inks that are relevant for the safe use of tattoo inks should, if possible, also be harmonized.	The analytical methods that are commonly used for the qualitative and quantitative determination of the hazardous chemicals, mainly aromatic amines, in tattoo inks (eg EN 14362, part 1 , 2 and 3) are aimed for azo colorant in textiles, while the determination of PAHs are often carried out by the ZEK 01.2-08 method GC-MS, which is harmonized by GS - "Geprüfte Sicherheit" mark bodies.		
SI	Yes	Comparability		
SK	Harmonise analytical methods for testing tattoos and PMU	Harmonisation of methods will be helpful for market control activities		

**Table E:** Experience with the Council of Europe Resolution (2008)1 – Labelling.

LABELLING Q 2.2a

MS	PAO (period of durability after opening)		Quantitative composition of inks (decreasing order of concentration for each ingredient)		Date of production		Storage conditions	
	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale
BE	As for cosmetics		Yes		Yes		Yes	
DE	Yes	Sterility is difficult to maintain after opening; PAO indicates period of safe use after opening.	No	Qualitative composition should be given to inform consumers (as suggested by ResAP 2008).	No		Yes	If specific storage conditions are necessary.
DK	Yes		Yes List to begin with "Ingredients"; listed in descending order according to weight when added to ink; concentration < 1% not listed (unless classified as skin sensitiser); use international nomenclature (INCI, EINECS or ELINCS) - if substance not found then ISO or IUPAC names; for dyes use Colour Index (CI) Constitution Numbers and the container's nominal amount (nominal mass or nominal volume)		Yes Wording "May not be used after ..." should be placed before the expiry date clearly stating either 'month and year' or 'day, month and year'.			If necessary, the conditions under which the shelf life can be maintained may be stated.
ES	In addition to the PAO, include the following sentence: "the sterility of the contents is guaranteed for X applications"	For more safety.	Yes	For added safety and information for users and authorities.	yes		Yes	
FI	Yes		Yes		Yes		Yes	
FR	Present in national legislation		Present in national legislation				Present in national legislation	
IT	Yes		Yes		Yes		Yes	
NL	Yes		Datasheet with concentration of all relevant parameters				Yes	
SI	Yes	Should be supplemented by an indication of conditions which must be satisfied to guarantee the stated PAO					Yes	To provide safe storage after opening
SK	PAO for non-single-use packaging	Irrelevant for single-use packaging			Not required	It depends of form of labelling date of durability, please see Other	Required	It is required for safety of products

LABELLING Q 2.2b											
MS	Type of product: tattoo colour/PMU ink		Address of distributor		Health warnings		Sterilization method		Other		
	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	
BE	Yes		Yes		Yes		Yes				
DE	Yes	Consumer information. However, technical differences are small.	No	Name and address of manufacturer, importer or person responsible for placing on the market should be given (as suggested by ResAP (2008)1)	Yes	Useful in case of allergy, if known	No	Guaranteed sterility (as suggested by ResAP 2008).			
DK				The manufacturer's and the importer's (if for resale) company name and address.						The batch number of manufacture or reference to identify the tattoo ink.	
ES	Yes		Yes	Address of distributor in the EU and manufacturer if a third country.	Yes			It is not necessary to indicate the manufacturing method			
FI			Yes		Yes					Identification of the manufacturer and a batch number	
FR				Present in national legislation							
IT	The products could be labelled differently	Considering the different use and injected quantities, the products could be separated in two different categories		Address of the person responsible for placing the product on the market		They may be included in a separate document		The declaration of sterility should specify the sterilization method and be accompanied by technical/ analytical documents	It is a useful tool for surveillance authorities	The label should be written in the language of the country in which it is marketed	The label must be easily understood by the final client.
NL				Preferably phone number							
SE	Such labeling requirements could help avoid the usage of inks that is not supposed to be injected like drawing inks	Sweden has noticed that drawing inks are sometimes used by tattooist's for injection even though such colors should not be injected because it endangers consumers health		The Swedish legislation on tattoo colors requires name and address of the manufacturer if outside Sweden		Name and address of the manufacturer is useful during market surveillance (if help is needed from authorities abroad) and when performing Rapex-notification		The Swedish legislation says that a tattoo color is considered sterile if it fulfils European Pharmacopeia about sterility		The Swedish legislation requires that the tattooist gives the following information (printed form or electronically using e-mail) to the consumer immediately after being tattooed: <ul style="list-style-type: none"> <li>Name of the tattoo colour</li> <li>Ingredient list</li> <li>Batch-number</li> <li>Name and address of distributor or manufacturer in Sweden + name and address of foreign manufacturer</li> </ul>	If doctors / patient / consumers know which colours had been used for injection, they could inform authorities or doctors in the case of side-effects that would then help researchers studying health effects.
SI					Yes	About possible allergic reactions, phototoxicity, other health effects (infection, keloid,..)					
SK				Not required				Information only relevant for specialists. No list of sterilisation methods for tattoos and PMU.		Date of minimum durability- can be used symbol (sand-glass) which is used for cosmetics and medicines.	For simplification

**Table F:** Experience with the Council of Europe Resolution (2008)1 – Safety assessment.

SAFETY ASSESSMENT Q 2.3			
MS	A register of complaints/side effects would improve the safety of tattoo/PMU inks?	How should the safety assessment be performed?	Would a pre-marketing authorisation for tattoo/PMU inks be necessary to improve the safety?
BE	1. It would give a better view on the number of side effects and offer more info for researcher to focus on specific problems. 2. It would give the authorities a better view on the weak points in tattoo parlors, border control, distribution etc		If the requirements are clear and sufficient to guarantee safety and if they are respected by the producers premarketing authorisation is not necessary
CZ	Yes It should be based on the resolution resap(2008)1		
DE	Yes A "tattoovigilance" system would be helpful to track undesirable effects and take appropriate measures.	For each ingredient (helpful, if effect can be traced back to a specific ingredient) and for the final product	A pre-marketing authorisation would guarantee a high level of consumer protection. However, there are still data gaps that need to be filled. A compulsory safety assessment to be commissioned by manufacturers, importers or persons responsible for the placing on the market and performed by qualified persons is a step towards safer products.
ES	Through a form that that could be filled by dermatologists, users, professionals or those responsible for the placing on the market.	Final product	Yes In Spain a process of authorization is required prior to marketing, which includes an evaluation of the safety of products and of labels.
FI	Similar kind of notifications as in Article 23 of the Cosmetics Regulation (SUE notifications)	Final product	NA
FR	Yes Vigilance of tattoo products not specifically addressed by the CoE ResAp 2008. France has established a national vigilance system of tattoo products in 2008 to monitor the risk of side effects from the use of tattoo products that are available on the market.	In the French notification form, it is requested to indicate the composition of the colorants in the product.	No The spirit of the resolution of the Council of Europe and the French legislation, is that the responsibility to place tattoo products on the market is supported by the responsible person.
IT	Yes A register of complaints/side effects is a useful tool to acquire information about the extent and the frequency of complications and side effects. It could be correlated with the inks used, to provide traceability.	Each and final ingredients. The simultaneous presence of more ingredients may give an amplified or a different effect compared to the single ingredient one.	Yes It would improve the safety: the long contact time of the ink in the body could be considered similar to that of implantable devices.
NL	• Stimulation from the consumer side for 'good work practices' • Side effects/complaints should be included in an 'informed consent' form people should sign before taking a tattoo.	Final product	Yes It will probably improve the transparency
SE	• Requirements for reporting side-effects should be discussed before a discussion about a register. • Side-effects could be caused by for example hygiene issues or a harmful tattoo colour. • Even if the tattoo colour fulfils the legislation the consumer might react to the tattoo colour getting a side-effect. • Even if the side-effect is reported it is not easy for the authority to decide what have caused the side effect. • In Sweden also different authorities control the tattoo colours and the hygiene at the tattooist.	Final product	No Authorities should guide companies on how to fulfil the legislation. An pre-marketing approval of tattoo colours would demand a lot of resources, but such authorisation could be financed through fees from the companies.
SI	No But a register of complaints/side effects would improve public and tattoo artist awareness about health risks.	Both (if a register would be set)	Yes If a tattoo/PMU ink is not safe, it is not placed on the market
SK	Reports about serious undesirable effect of inks (e.g. the same way like SUE of cosmetics, can be used IC SMS system (The internet-supported information and communication system for the pan-European market surveillance)	Final product	Yes

**Table G:** Experience with the Council of Europe Resolution (2008)1 – Hygiene/sterility.

HYGIENE Q 2.4						
MS	Do you have any suggestion on how to improve safety of tattoo/PMU inks?					
	NO	YES				
		Inks	Tools	Studio	Dose	Other
BE						1.Materials should be sterile. The sterilisation method should be adapted to the material. (ea ink and tools will be sterilised in a different way) 2. single dose units (although the best guarantee for sterility) are utopy and not practical for tattooist; Sterile products and limited duration of use (PAO) is more realistic.
DE					Or multi use containers with a design that ensures that the contents will not be contaminated during the period of use.	
DK		Yes			Yes	
ES		Yes	Yes		In Spain the use of single-dose containers is recommended to ensure the sterility of each application. Multidose containers are accepted for a maximum content of 30ml , guaranteeing the sterility of each application.	In Spain tattoo/PMU parlors are regulated by the regional authority. In particular, methods of disinfection and sterilization of instruments are listed .
FI	No					
FR		Yes	Yes	Yes	Yes	
IT		It is necessary to identify the most effective sterilizing method for inks.	It could be referred to the harmonized standards concerning the validation of sterilization methods applicable to medical devices.	Regarding "parlor premises" it should be more appropriate referring to sanitization and disinfection.	preferentially single use, if technically possible.	
SE		The Swedish legislation says that a tattoo color is seen sterile if it fulfils European Pharmacopeia about sterility				
SI		hygiene and sterility recommendations are good, but use of single dose containers should be enhanced because of difficulties in keeping ink sterility after opening				
SK		Yes	Yes	Yes		e.g. Good Application Practices for tattoo artists

**Table H:** Experience with the Council of Europe Resolution (2008)1 – Other suggestions.

OTHER SUGGESTIONS Q 2.5a														
MS	Control web sales		Collaboration		Ban backyard		List of recognised		Compulsory training for tattooists		Set GMP for inks		Other	
	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale
BE	Absolutely	Fakes and unsafe origin	Yes		Yes		Yes		Yes		Yes		Border control	Import in one EU country means free transport allover EU
CZ														More comprehensive and binding
DE	Yes	Market surveillance should include web sales.								In Germany the need for dual vocational training must be presented to the Federal Ministry for Economic Affairs	Yes		Production conditions are essential for safe products.	
ES	Yes	To improve safety	Yes	In Spain there is a close collaboration with manufacturers to register tattoo inks and permanent	Yes	They should be banned as they do not guarantee the proper sanitary conditions			Yes	A certificate issued by regional authorities is required in Spain	Yes		To improve manufacturing conditions	
FI	Difficult due to the limits of jurisdictions and powers of the authorities. Can be done on national level only.		Yes		Qualified yes - Finland already has legislation on safety of the consumer services. Though surveillance of homemade tattoos is nearly impossible.			na			na		Yes	

OTHER SUGGESTIONS Q 2.5b

MS	Control web sales		Collaboration		Ban backyard		List of recognised tattooists		Compulsory training for tattooists		Set GMP for inks		Other	
	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale	Suggestion	Rationale
FR										In France, the regulation indicates that tattoo artists should attend training in hygiene and sanitary. An order of the Minister of Health determines the categories of institutions and organizations authorized by the State representative in the region to deliver this training, and the contents thereof and diplomas accepted by the equity method.	Yes	In France, there is an order regarding the GMP for tattoo products (Arrêté du 15 septembre 2010)		
IT	Harmonisation of surveillance procedures within the EU in order to prevent the sale of fake inks	Problems related with the presence of fake inks of unknown origin on the market.	Yes		See next item		Definition of a uniform professional profile for tattooists. Institution of a national register of licensed tattooists on the basis of an European standard	Protect clients, preventing illegal tattooist and backyard tattooing	Harmonize tattooist training, with the aim to guarantee the same performance and reliability all over EU.	Ensure a minimum level of skill. Ensure uniform criteria for the definition of the professional requirements for tattooists.	Yes		Sterilisation: As the scientific literature on the subject is insufficient, Italy proposes a working group to validate ink sterilization methods and procedures. It is necessary to identify an effective sterilization method. There is no common regulation about age limits. An age limit should be seriously considered at European level. It should be forbidden to perform tattoos under the age of 14. Performing tattoos under the age of eighteen would be possible only with the informed consent of the parents or guardian.	Microbiological analysis show that some sealed inks, marketed as sterile on the label, are contaminated. These results elicit doubts about the effectiveness of the sterilization procedures. Minors do not have a full awareness of the risks.
SE							In Sweden tattooists/PMU-artists have to notify their business to the local authorities. Lists of such companies may be extracted from our 290 local authorities		Sweden think obligatory training regarding hygiene is a good suggestion					
SI	Yes	A the moment there are no control measures for web sales. Most problematic tattoo inks and permanent make-up colorants are probably sold via web sites	Yes	Pre - autorisation	Yes	Most health problems are probably associated with backyard tattooing. Better control of hygiene and sterility	Better control	Yes	Better knowledge of tattooists about safe practices	Yes	Good manufacture practices would improve the safety of tattoo and PMU inks			
SK												prepare EN standard		

**Replies to questionnaires**  
**Dermatologists**



**Table A:** Complication following tattoo/PMU application.

**COMPLICATIONS Q 1.1-1.3**

MS	Interest in tattoos/PMU complications	Removals performed	Number of tattoo complications	Number patients/year	Interval between application and onset of symptoms									
					Infectious complications					Non-infectious complications				
					<1w	1w-1m	1m-1y	>1y	Uncertain	<1w	1w-1m	1m-1y	>1y	Uncertain
BE-1	yes	yes	50	6000	<1%	<1%	<1%				10%	10%	20-30%	>30%
BE-2	yes	no	1	5000										
BE-3	yes	yes	10	2700		50%			50%		30%	30%	30%	
BE-4	yes	yes	2	200										
DE-1	yes	no	10	1200		80%						80%		
DE-2	yes	no	2-6	6000	50%	50%					50%	50%		
DE-3	yes	yes	0	30-50										
DE-4	yes	no	3	6000	70%	30%						50%	50%	
DE-5	yes	yes	15/300	6000		35%	20%		45%	10%	15%	25%	20%	30%
DK-1	yes	no	1-2	10000					X					X
DK-2	yes		0-1	1200					X					X
DK-3	yes	yes	5	50								X		
DK-4	yes	yes	2-5	50	50%	50%						100%		
DK-5	yes	yes	150+	5000	90%	10%				5%	25%	40%	25%	5%
FI-1	yes	no	na	na	80-90%	10-20%				10%		90%		
NL-1	yes	no	4-5	?		50%	50%				10%	70%	20%	
NL-2	no	no	2	3500									100%	
NL-3	yes	no	75	7500							30%	60%	10%	
SE-1	yes	no	4	2000								50%	50%	



COMPLICATIONS 1.6

MS	Previous known allergies/skin diseases														
	Allergy							Other diseases							
	Atopic or contact dermatitis	Allergy to metals	Allergy to para-phenylen diamine	Allergy to latex	Allergy to preservatives	Allergy to medical drugs	Other		Other skin diseases	Urticaria	Wart	Vitiligo	Other		NA
							Pollen						Sarcoidosis	Eczema	
BE-1	R	C	N	N	N	E	R		N	N	N				
BE-2	N	N	N	N	N	N	N		N	N	N	N			
BE-3	R								E						
BE-4	E		N	N	N	N	N	E	E	N	N	N			
DE-1	F	F	F	R	R	R		C	N	R	E				
DE-2	C	C	E	N	N	E	E		N	R	N				
DE-3															
DE-4															
DE-5	C	R	E	E	E	E		E	E	E	E				
DK-1	X	C	N	N	N	N	N	N	N	N	N	N			
DK-2															
DK-3															
DK-4	R	E	R	N	N	N	N		E	R	N				
DK-5	C	C	E	E	R	E	R		R	R	N		R		
FI-1											E				X
NL-1	R	R	E	R	E	E	R		R	E	E				
NL-2	N	N	N	N	N	N	N		N	N	N	N	N		
NL-3		R	N	N	R	N		C	N	NA	R			R	
SE-1		R	R	E					R	R					50% of cases

Frequency: **N**= never, **E**= exceptional, **R**= rare, **C**= common, **F**= frequent

COMPLICATIONS Q 1.7-1.8

Frequency of diagnosis and main histopathologic diagnosis

MS	Allergic skin reactions					Non-allergic inflammatory reactions					Cutaneous infections			Regional infections		Systemic infections			Benign tumours			Malignancies				Others				Histopathological diagnosis																
	Contact dermatitis	Plaque elevation	Hyperkeratosis	Ulceration/necrosis	General rash	React on products after treatment	Other	Papulo-nodular inflammatory reactions	Nodules and granulomas including cutaneous sarcoidosis	general sarcoidosis	non-allergic immune activation	pain syndrome	lymphopathies	blow-out	bacterial	virus	fungal	other	erysipelas	abscess	local infection in tattoo	hepatitis B/C	AIDS	septicaemia	other	Hyperplastic scar or keloid	Keratoacanthoma	Other	Basal cell carcinoma	Squamous cell carcinoma	Melanoma	Lymphoma	Other	Hypo/hyper pigmentation	Photosensitivity	Urticaria	Lymphoedema and lymph node reaction	Other	Inflammation only	Lichenoid reaction	Granulomatous reaction	Sarcoid reaction or sarcoidosis	Pseudolymphoma	Pseudoepitheliomatous hyperplasia	interfase dermatitis	Other
BE-1	E	R	N	N	E		R																																							
BE-2	N	N	N	N	N		N	N	E					N	N	N		N	N	N	N	N	N		E									E	N	N	N			N			N	N	N	
BE-3	C	N	N	N	N		N	E	N			N		C	E	E	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N		E	N	N	N	N		N	N	N	N	N	N		
BE-4	E	N	N	N	E	E	N	N	N					N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N		R	E	E	N	N		E	N	N	N	N	N	N	N
DE-1	C	C	N	N	N		N	N	N					R	N	N	N	E		N	N	N		E	E	N	N	N	N	N	N		N	E	N	N		R	N	R	N	N	N			
DE-2	F	C	E	N	N		E							E	E					N	N	N		E	N	E	N	N	N		E	N	N	E												
DE-3																																														
DE-4	R	F	F	N	R		R	N	N					R	N	N																														
DE-5	C	E	N	R	N		C	C	N					C	N	N	C	C		N	N	N		C	N	N	N	N	N	N		F	R	N	E		C	N	C	N	N	N				
DK-1	C	N	N	N	N		C	R	N		N			R	N	N	N	N	N	N	N	N	N	X	C	N	N	N	N	N	N	R	R	N	N	N		N	C	C	N	N	N			
DK-2	N									F				N	N	N	N	N		N	N	N		N	N	N	N	N	N	N		N	N	N	N											
DK-3	N	C	C	E			E	N	N					N	N	N	N	N		N	N	N	N	N	E	N		N	N	N		E	R	R	N		R	R	E	N	N	N				
DK-4	C	C	C	C	N		R	N						R	R	R	R	R		R	N	N		C	E		N	N	N		C	R	R	C		R	C	C	N	R	C					
DK-5	R	F	C	R	R	R	F	R	R	R	R			C	R	N	R	R	C	E	N	R		R	R		N	N	N	N		R	C	R	R		C	E	R	R	E	E	C			
FI-1	-	C	C	E	N		R	R	R					R	E	E	N	N	N		N	N	N		E	N	E		N	N	E	N		N	C	N	E		C	C	C	R	C	C		
NL-1	E	R	E	E			C	C	C					R	E	E					N	N	N		C	R		N	N	N		R	C	E	N		C		C		R	R				
NL-2	R						R							N	N	N	N	N		N	N	N		N	N	N	N	N	N		N	N	N	N	N											
NL-3	C	F	E	E	N		E	E	N		X			C	N	N	N	N		N	N	N		C	N	N		E	N	N		N	E	N	N		R	F	F	E	C	E				
SE-3	R	R												R																																

Frequency: **N**= never, **E**= exceptional, **R**= rare, **C**= common, **F**= frequent

**Table B:** Complication following tattoo/PMU removal.

2. COMPLICATIONS FOLLOWING A TATTOO/PMU REMOVAL Q 2.1-2.3

MS	Number of complications linked to tattoo removals	Number patients/y ear	Acute symptoms						Delayed symptoms					Technique/instrument used
			Pain	Blistering	Pin-point bleeding	Crusting	Urtical	Other	(photo) allergic reactions	Scars	hyper- and hypopigmentation	ink retention and darkening	Other	
BE-1	20	6000	C	E	R	E		E	R	C	E		QS Lasers (ND-Yag 1064,532, Alexandrite 755)	
BE-2	0	5000												
BE-3	20	2700	E	E	E	E	N	N	N	N	N		Q Switched 1064/532 nm	
BE-4	2	200	R	E	E	E	E	N	R	E	R	E	Trivantage Alexandriet 1064/755 2mm/3mm	
DE-1	na	na	na	na	na	na	na	na	na	na	na	na		
DE-2	na	na	na	na	na	na	na	na	na	na	na	na		
DE-3	0	30-50	C	E	R	CR	E		0	0	0	0	Revlite si cynosure (ND:YAG laser)	
DE-4	na	na	na	na	na	na	na	na	na	na	na	na	Rubin Laser	
DE-5	5/300	6000	F	R	C	C	N		N	R	R	E	ERB YAG - LASER	
DK-1	0	10000												
DK-2	0	0												
DK-3	5	5	na	N	N	N		N	F	F				
DK-4	2-3	600	F	C	R	R	E		E	C	C	E	ND:YAG laser	
DK-5	3	20	F	F	C	C	R	R	N	F	F	C	Some Q-switched Yag but most complications come from low cost lasers. In the hospital only apply Q-switched Yag.	
FI-1	0	0												
NL-1	?	?	C	R	C	C	R		E	R	R	E	na	
NL-2														
NL-3	5	7500	C	N	N	N	N		N	C	N	N		
SE-1	0	2000												

Frequency: **N**= never, **E**= exceptional, **R**= rare, **C**= common, **F**= frequent. **na**: not available

**Table C:** Correlation between health complications and tattoo characteristics.

3. CORRELATIONS BETWEEN HEALTH COMPLICATIONS AND CERTAIN TATTOO CHARACTERISTICS/PARAMETERS Q 3.1-3.6

MS	Number of tattoos								Tattoo size				Gender/age				Colours								Localisation						Procedure													
	1	2	3	4	5	>5	na		small=<150 cm2	medium=151-300 cm2	large=301-900 cm2	extra large=>900 cm2	na	women	young	adult	men	young	adult	na	black	red	orange	violet/purple	henna colors	blue/green/turquoise	brown	white	yellow	multi-coloured	na	legs	arms	trunk	head/neck	genitals	multiple locations	na	Professional tattooist	Amateur tattooist	Professional cosmetic	Henna application	Traumatic tattoo	Medical
BE-1	E	R	C						C	E			E	F	E	F				F	C	C		F		R	R	C			C	F	C	E	F			F	F	C				
BE-2								F	R	E	N		E	C	E	C				F	F	E	C	E	R	R	R	C			C	C	R	N	C									
BE-3	F	C	E	N	N	N		F	F	R	E		E	F	E	F				F	R	N	E	E	E	N	N	N	R		R	C	F	E	N	E		F	F	F	R	R	E	E
BE-4						X					X							X	F	R	E	R	R	R	E	N	R	R		R	F	R	E	N	R									
DE-1	C							C					C	C	C				C	C	E	N	E	E	E	N	E	R				C					C	C	E	E	E	N		
DE-2																																												
DE-3						X		F	F	F	R		E	F	R	F			F	C	E	C	E	F	E	E	R	F		F	F	F	R	E	R									
DE-4														F			F																											
DE-5	F	F	F	C	R	R		F	F	C	R		F	R	F	F	R	F	F	F	R	F	F	C	R	E	C	C		F	F	F	R	E	F		R	F	F	F	C	R		
DK-1	C							C					N	C	N	C			C	C	C	C	N	C	N	N	C	C		R	C	C	R	E	C		C	R	R	E	R	R		
DK-2						X					X							X										X		C	C	C												
DK-3	R	C	R					C	C				N	C	N	C			C	R	R		R							R	C				X									
DK-4	R	R	C	C	F			R	C	C	C		F	R	C	C	R	C	R	F	C	F	E	R	R		C			F	F	R	N	F			F	C	N	F	E	N		
DK-5	R	C	C	C	C	R		C	C	R	R		F	C	F	F	C	F	F	F	R	R	R	F	R	F	F	F		F	F	F	F	E	F		F	R	R	C	R	C		
FI-1						X		F	N	N	N		C	C	C	C			F	F	R	C	N	R	N	N	F								X		F	R						
NL-1																			C	C	E	E	E	E	E	E				C	E	C	C	E	E									
NL-2	1					1		1		1				1		1			F	C	N	C	R	C	N	R	C			C	C	C	R	N	C									
NL-3	C	C	C	R	E	E		F	C	E	N		F	E	F	C	E	F	F	F	E	E	E	C	E	E	R	F		E	F	R	E	N	F		F	C	R	N	N	N		
SE-1	C							C	R				C				C		R	C	C		R			C	C			R	R	C					R		R					

Frequency: **N**= never, **E**= exceptional, **R**= rare, **C**= common, **F**= frequent

**Adverse health effects  
Supplementary information**

**Table A:** Adverse health effects: allergy/inflammation.

Reference	Country of study	Sample size	Study covered years	Age range (Years)	Time of onset after tattooing	Colour/Location/ Gender	Incidence rate	Minor symptoms <3 months
2015, Hutton-Carlsen	DK	40 (34 Females, 6 Males)	Sept-Nov 2012	Mean age: 33				
2015, Høgsberg	DK	19	2009-2011	18-52	Average 3 months	Red nuances (red, pink, purple, bordeaux)		
2012, Fors	SE		2000-2004	15-23				
2010, Klügl	DE	3411 (Internet survey)	July 2007-March 2008		Immediately to 4 weeks after tattooing		67.5% transitory skin problems; "moderate" in 10% of cases and "intense" to "very intense" in 1.8%. 4 weeks after tattooing, 9% still had health problems, 6% persistent skin effects: oedema, itching, papules and scarring; 6.6% systemic reactions:dizziness,headache, nausea or fever; 1.3% reported burning and itching of tattooed skin when exposed to sun. 3% stated psychic problems and light sensitivity of tattoo	Bleeding, crusts, itching edema and pain, followed by burning sensation, blister formation
2010, Wenzel	DE				6 weeks to several months	Pigment Red 181 (C173360). Female, PMU		
2009, Mataix	Multi				Delayed allergic reactions:weeks-years after tattooing (difficult to classify); they may last years despite treatment 10 years after tattooing			Acute inflammation lasting for 1 to 2 weeks.
2008, Ali Saba	US	1		31	10 years after tattooing (incubation period=3-20 years)			
2008, De Cuyper	Multi						Rare	Swelling and crusting may persist for a few days; swelling or burning when undergoing MRI
2007, Kazandjeva	BG	234					Overall prevalence of skin complications = 2.1% (5 of 234 cases), including infections and allergic/granulomatous complications	Immediate (after few hours) inflammatory reaction always appears; transient symptoms at the site of tattoo (swelling, heating,skin irritation) in small n° of patients (< 10) after magnetic resonance imaging
2006, Teixeira		1		30	1 day	PMU: black eyelash and eyebrow dye		
2003, Bhardwaj	US	1		38		Red (Patchy red 904A)		

[55], [107], [108], [18], [109], [43], [65], [110], [69], [111], [112]



Reference	LIC+ECZ (linked to SRC & Granuloma)	SRC+FBD (linked to Granuloma)	Systemic sarcoidosis	Pseudolymphomatous reactions	Contact Dermatitis	Plaque Elevation	Ulceration/ Necrosis	Papulo-nodular inflammatory Reactions (non specific)	Anaphylactic reaction	Fibro-Scleroderma (scars)	Reactivation of Underlying Dermatoses	Dermatofibroma	Other
2015, Hutton-Carlisen													Quality of life evaluation according to the Itch Severity Scale (ISS) and the Dermatology Life Quality Index (DLQI). The ISS has been used to evaluate patients with pruritus, genital pruritus and nephrogenic pruritus as well as atopic dermatitis, psoriasis and urticaria, which revealed ISS scores from 7.4-13.4. Patients with tattoo reactions revealed an average ISS score of 7.2. The DLQI has also been utilized on patients with hand eczema, pruritus and neurodermatitis with scores from 8-13.3. Tattooed patients DLQI score was 7.4
2015, Høgsberg	6 cases; The granulomatous pattern has been found on a background of interface dermatitis				14/19 cases of interface dermatitis.		1/19 cases					13/19 cases	14/19 Patients were patch tested with European standard because suspected to be allergic. 5/14 resuted allergic towards potassium dichromate, fragrance mix, hydroxyisohexyl-3-cyclohexene-carbonaldehyde, sorbic acid, cobalt chloride and nickel sulphate. 11/19 were patch tested with a textile series consisting of 42 dispersed dyes. Two reacted with reactions to red and orange dyes. 13/19 patients were patch tested with a selection of eight problematic stock tattoo ink products. One patient reacted against the red and yellow inks.
2014, Huynh	Granulomatous, lichenoid and pseudolymphomatous reactions represent the most common dysimmune reaction and may be the direct result of the tattooing practice.												
2013, Juhas	Reported	Reported	Reported	Reported				Reported	Reported	Less common	Koebner phenomenon in preexisting psoriasis, systemic lupusand sarcoidosis	Following trauma or coincidence	Vasculitis
2012, Fors					The study is <u>not directly related</u> to adverse effect of tattooing practice. It tries to correlate the effect of lifestyle (for instance the presence of a tattoo) with nickel allergy by patch testing some volunteers. Conclusion is that in comparison with not tattooed people, tattooed boys showed a 3-fold and girls almost 2-fold increase in Nikel allergy by patch test.								
2010, Klügl							0.7% (n=3411) complained of "elevated skin"	0.4% (n=3411) complained of "skin papules"					
2010, Wenzel					3/4 resulted positive to prick test of both PMU colorant and C173360 (red). 1 patient declined prick test. Patch test negative in all cases.								

LIC+ECZ: Lichenoid and eczematous reaction. SRC+FBD: Cutaneous Sarcoidosis and Foreign body reaction

[55], [107], [113], [44], [108], [18], [109]

Reference	LIC+ECZ (linked to SRC & Granuloma)	SRC+FBD (linked to Granuloma)	Systemic sarcoidosis	Granuloma	Pseudolymphomatous reactions	Contact Dermatitis	Photoallergy	Plaque Elevation	Papulo-nodular inflammatory Reactions (non specific)	Fibro-Scleroderma (scars)	Reactivation of Underlying Dermatoses	Other
2009, Bocca				Granulomatous reaction can be induced by pigments containing Al and Ti		Reported a case of skin hypersensitivity caused by the presence of Co in the blue ink used for tattoo; Hg contained in some tattoo red dyes is reported to produce a delayed hypersensitivity reaction						
2009, Forte				Granulomatous reaction can be induced by pigments containing Al and Ti. Sarcoid granulomas developed in a black area of a tattoo; patch test positive to Ni, Co, Cd. Analysis of pigment revealed the presence of Ni and Co. Acute dermatitis overlying a granuloma has been reported at the site of a violet tattoo.					Erythematous papules scattered within a black area			
2009, Mataix	Lichenoid reactions are the most common type of tattoo reaction, with lesions that are clinically and histologically similar to lichen planus.	Granulomatous reactions reported in association with chromium, mercury, cobalt, and magnesium; Less common, sarcoid granulomas may be non specific but can also be an early manifestation of systemic sarcoidosis.			Indurated, erythematous, violaceous nodules confined to the tattoo, mainly described for red pigment tattoo but also for green and blue pigments.	Eczematous lesions confined to the tattooed area, with occasional secondary spread; patch test inconclusive;		UV-induced erythematous oedema most often caused by yellow and red Cd-containing pigments.				Koebner phenomenon in association with sarcoidosis, pyoderma gangrenosum, and cutaneous lupus erythematous.
2008, Ali Saba		Intermittent swelling, blistering, burning, confined to brown areas of tattoo; edematous papules with surrounding erythema	Known hilar lymphadenopathy									
2008, De Cuyper	Foreign body epithelioid granuloma after cosmetic eyebrow tattooing.	Frequent								Eyelid necrosis, loss of eyelashes, and secondary cicatricial ectropion, hypertrophic scars, and keloids		
2007, Kazandjieva	Lichenoid reactions more often to the red pigment.	Single cases (Days to months)		Single cases (Days to months)	Always in the red areas of the tattoo	Single cases (Days to weeks)		Single cases: After sun exposure and cadmium in sufficient amount in tattoo dye (yellow)			Single cases: Psoriasis (10 d-30 y)	Lichen planus, Lupus erythematous chronicus discoides (always in the red areas of the tattoo)
2006, Teixeira						Positive patch results to: p-phenylenediamine both at 0,1 and 1%. Disperse red 17, disperse red 1, disperse orange 3, disperse orange 1 and dye as it has been used. Allergy manifested as intense itching, erythema, swelling and exudation.						Important: the permanent eyelash used contained p-phenylenediamine.
2003, Bhardwaj						Patch test positive for "Patchy Red 904A" both on normal skin and on scar tissue after tattoo removal		Swelling and itching confined to the red areas				

[114], [115], [43], [65], [110], [69], [111], [112]

**Table B:** Correlations among tattoo characteristics and adverse health effects.

Reference	COLOUR						LOCATION			GENDER		
	BLK	COLOR	RED	OR	VL	BG	WH	Extremities	Trunk	Head	F	M
2015, Hutton-Carlson								35	5	1	34	6
2015, Høgsberg								18 (arms=6, legs=11, foot=1)	1		12	7
2013, Juhas		Anaphylactic reaction	Pseudolymphomatous lichenoid and granulomatous reactions		Pseudolymphomatous reactions							
2010, Klügl		Slightly more short-term skin or systemic reactions									Crusts, itching, edema and systemic health problems directly after tattooing slightly more frequent in females. After 4 weeks, health problems were graded as more severe by females; 7.3% (n=3411) reported persistent skin problems. Solar sensitization and psychic problems more frequent in young people (not gender related)	4.2 % (n=3411) reported persistent skin problems. Solar sensitization and psychic problems more frequent in young people (not gender related)
2009, Bocca			Cinnabar and Vermilion contain Hg which is known to produce delayed hypersensitivity		Al and Ti were detected by microscopic examination of excised tumor in the violet areas of a tattoo.	Co containing tattoo ink caused skin hypersensitivity						
2009, Forte	Sarcoid granulomas developed in a black area of a tattoo; patch test positive to Ni, Co, Cd. Analysis of pigment revealed the presence of Ni and Co; erythematous papules originating from "India Ink"		Cinnabar and Vermilion contain Hg which is known to produce delayed hypersensitivity. In the present work Cr is the predominant metal in ink composition while other metals reported giving strong allergic reaction (Hg, Ni and Cd) did not reach µg/g level.		Al and Ti were detected by microscopic examination of excised tumor in the violet areas of a tattoo. Large amount of Mn was found in the biopsy specimen of a granuloma at the site of a violet tattoo. In the present work Mn was not analysed, but analysis of violet ink revealed high contents of Cr and Ni	Co contained as component or impurity is reported to cause urticaria; Ti (linked to granulomatous reactions) found in a commercial available blue ink; Co, when present in blue dyes, is reported being cause of deep granulomas and urticarial symptoms. Green may contain Cr which is deemed to cause eczematous reactions. Hg and Cr have been found at high concentration in the present work.	From Ti or ZnO. In the present work, Ni was the prevailing metal followed by Cd. Traces of Cr and Co were observed. It could potentially contain other metallic derivatives. µg/g concentration was never reached.					
2009, Mataix			Red inks, particularly if containing Hg, are the most common causes of delayed allergic reactions.									
2008, De Cuyper			Red inks, containing Hg, cause lichenoid reactions.									
2007, Kazandjeva	case of sarcoid granulomas developing in blue-black tattoo reported					Case of sarcoid granulomas developing in blue-black tattoo reported						

[55], [107], [44], [18], [114], [115], [43], [110], [69]

**Table C:** Adverse health effects: infections.

Reference	Country of study	Sample size	Study covered years	Age range (Years)	Time of onset after tattooing	Colour/Location/Gender	Tattoo Application
2015, Mudedla	Multi	114	2003 -2013		Within 4 to 6 weeks (majority of cases), up to 6 months after tattoo		
2014, Gulati	US	1		48		Female, tattoo on the back	Home made tattoo
2013, Falsey		3	Jan-Mar 2012		First papules appeared 7-21 day after tattoo placement. New papules developed in the subsequent 1-4 months		
2012, Kennedy	Rochester, NY, US	19	Oct-Dec 2011	18-48	Within 3 weeks	Premixed grey ink	
2012, Morbidity and Mortality weekly report (CDC)	US: New York (refers to 2012, Kennedy), Washington, Iowa and Colorado	Washington, cluster 1: 27 Washington, cluster 2: 4 Iowa: 2 Colorado: 1	2011-2012			Washington, cluster 1: Black Washington, cluster 2: Grey Iowa: Back Colorado: Black	
2012, Tohme	Multi		1994-2011				
2011, Giulieri	CH	12	2009-2010	56	Range 2-7 weeks	Female, with PMU	
2011, Rodriguez-Blanco	ES	5 (plus 2 suspected but not analysed)	Sept 2008-April 2009	18-23	3 to 30 days	Grey	
2011, Urbanus	NL	375 tattooed persons among total 434 interviewed.		23-37			
2010, Bechara	FR (Brazilian man) +internet review	1 + review (36 patients)		51	10 days after tattoo (review: 1 w.- 3 months)		
2010, Drage	US	6	Oct 2007-May 2008	20-49	1-2 weeks	Grey (by water dilution of black ink)	
2010, Klügl	DE	3411 (survey)					
2010, Pérez-Cotapos							Depends on the hygienic conditions under which the procedure was carried out, and the expertise of the tattooist
2008, De Cuyper					LASER/PMU		
2007, Kazandjeva	BG	234					Overall prevalence of skin complic. = 2.1% (5 / 234 cases), including infections and allergic/granulom.reactions
2006, Morbidity and Mortality weekly report (CDC)	US	34 primary cases, 10 secondary cases. The persons with secondary cases were exposed to persons with primary cases by direct contact because they were living in the same house or had close personal contact.	Jun 2004- Aug 2005	15-42	4-22 days among all 34 primary cases	73% male, 27% female. Outbreaks was reported in three different states: Kentucky, Ohio and Vermont	During interviews, 13 unlicensed tattooist were identified. 7 tattooist were located and interviewed. Adherence to some infection control measures were not practiced.
2005, Porter	NZ	2		45 and 29 years old	within 2 days		Both cases of Samoan tattooing, performed in unlicensed premises by temporary tattooist

[98], [116], [117], [118], [119], [42], [120], [121], [46], [122], [123], [18], [72], [110], [69], [124], [125]

Reference	% contaminated inks	Bacterial				Viral	
		Incidence rates	Pyogenic	NTM	Other	Hepatitis B and C	Other
2015, Muedda		unknown		Unspecific erythematous papules, pustules, and nodules, predominantly within the borders of tattoos, generally the gray part; <i>Chelonae</i> most common cause; contamination occurs through unsterile instrumentation or tap water used for diluting tattoo ink.			
2014, Fowler				This paper cites a number of reports of cutaneous <i>Mycobacterium Chelonae</i> infections in immunocompetent hosts due to subcutaneous inoculation with contaminated tattoo ink			
2014, Gulati	Same ink and equipment were used by her husband who also developed IPA due to <i>Staphylococcus aureus</i> .		lipsoas abscess due to <i>Staphylococcus aureus</i>				
2014, Huynh						A predominance of warts among a variety of opportunistic infections may result from a local immune disregulation (rather than from direct inoculation or coincidence) caused by tattooing practice.	
2013, Falsey	2 different inks (A and B), from 2 different companies (A and B) arose concerns. Company A reported receiving 35 complaints of unusual skin reactions to brand A ink. Company A had identified a single batch of ink that was associated with these complaints and voluntarily issued a recall. Company B declined to provide ingredients or sources of inks, and denied receiving any complaints. Nevertheless, no NTM was recovered from brand A ink samples; brand B ink samples obtained from the tattoo artist grew <i>M. chelonae</i> indistinguishable from patient 1's	An health alert was sent out and an investigation was initiated. 2 tattoo artists involved were contacted and interviewed. This investigation revealed 2 unlinked clusters of NTM infections. Cluster A comprised 27 infections, all tattooed by the same artist by using the same bottle of brand A black ink. Three of these infections were confirmed by biopsy and culture; the remaining infection swere suspected. Cluster B comprised 4 infections (2 confirmed through biopsy and culture), all of whom were tattooed by using the same bottle of brand B gray wash ink. No infections were identified among either artist's clients tattooed with previous or subsequent bottles of ink.		Tissue culture grew nontuberculous mycobacteria (NTM) in all cases. Speciation from patient 1 revealed <i>Mycobacterium chelonae</i> ; speciation in patients 2 and 3 revealed <i>Mycobacterium abscessus</i>			
2012, Kennedy	Premixed grey ink from 1 company	4 probable	14 confirmed suspected	1	chelonae, giving the pathologic evidence as papules, pustules		
2012, Morbidity and Mortality weekly report (CDC)	Total of 3 companies. Washington cl 2 and Iowa cases used ink from the same company.	Washington, cl 1: 3 confirmed and 24 possible Washington, cl 2: 2 confirmed and 2 possible Iowa: 2 confirmed Colorado: 1 confirmed			Washington, cl 1: Abscessus Washington, cl 2: <i>Chelonae</i> Iowa: <i>Chelonae</i> Colorado: <i>Chelonae</i> Always giving the pathologic evidence as papules, pustules		
2012, Tohme (included in 2013,Carney)						No evidence for an increased risk of HCV infection in professional parlors.	
2011, Giulleri	All procedures were performed by the same artist. Microbiological investigation of oil and cold sterilising agents were negative. Direct examination of 18 inks resulted negative. Nevetheless 6/18 samples, broad-spectrum PCR resulted positive for <i>Mycobacterium haemophilum</i>				Index patient presented with skin lesion of the eyebrow and ipsilateral lymphadenitis. <i>Mycobacterium haemophilum</i> was identified by sequencing. 11 additional patients with lesion of the eyebrow and ipsilateral lymphadenitis were identified. 10/12 had microbiological diagnosis of <i>M. Haemphilum</i> . For the remaining 2 diagnosis was based on clinical presentation.		
2011, Rodriguez-Blanco					<i>Chelonae</i> giving the pathologic evidence as skin lesions		
2011, Urbanus						375 people bearing at least one tattoo (median number 5, median body surface 18%) have been tested for anti-HBc and HCV. The study population included both tattoo related variables (number of tattoos, % of body tattooed, being a tattoo artist, have had a tattoo in a HBV endemic country) and tattoo-unrelated variables (HBV vaccination, being born in HBV endemic country, residence, snorting drugs). NONE OF THE TATTOO-RELATED VARIABLES WERE SIGNIFICANTLY ASSOCIATED WITH HBV. As for HCV, only 1 participant resulted infected. The participant was a tattoo artist who received a tattoo more than 100 times and reported several other risk factors, including needle-stick accidents.	375 people bearing at least one tattoo (median number 5, median body surface 18%)

[98], [126], [116], [113], [117], [118], [37], [42], [120], [121], [46]

Reference	% contaminated inks	Bacterial			Viral		AIDS	Other	Fungal	Septicaemia
		Incidence rates	Pyogenic	NTM	Other	Hepatitis B and C				
2010, Bechara		RGM rarely documented after tattoo, but in progression; <i>M. abscessus</i> : 1st case published		<i>M. abscessus</i> : erythematous papulo-pustula, limited to the colored parts of tattoo; symptoms: pruritus, tenderness						
2010, Drage	Grey ink used by the same artist at a single establishment	5 confirmed 1 suspected		chelonae, giving the pathologic evidence as papules, pustules						
2010, Klügl		0,50%	Bacterial skin infections (pus-filled skin areas)							
2010, Pérez-Cotapos		Bacterial infections are more common following piercing than tattooing procedures. The most frequent are local bacterial infections at the site of the procedure.		1) Often <i>Streptococcus pyogenes</i> and <i>Staphylococcus aureus</i> 2) Severe secondary infections have been reported such as erysipelas, cellulitis, sepsis, and spinal abscesses, either due to <i>Streptococcus pyogenes</i> , <i>Staphylococcus aureus</i> , or <i>Pseudomonas</i> species 3) outbreak of <i>Mycobacterium chelonae</i> infection in 6 patients tattooed by same tattooist				Different types of viral infections can be transmitted. Papiloma virus-induced warts, Mollusca contagiosa, herpes simplex, blood-transmitted diseases such as hepatitis and HIV		
2009, Mataix		Incidence difficult to determine	Relatively common			Epidemiologically, the risk factor of HIV/ hepatitis C virus e transmission through tattoo is not statistically relevant.		Isolated cases of skin infection caused by the human papilloma virus and molluscum contagiosum		Increase in systemic infections due to bacteria that gain access to the body via tattoos.
2008, De Cuyper		Bacterial superinfection is rare				Through nonsterile equipment and needles				
2007, Kazandjeva			Impetigo, Acne varioliformis, Ecthyma: Usually located in tattooed area (First few days)		Historical: Tetanus, Chancroid, Tuberculosis cutis, Lepra, Syphilis (onset from weeks to years)	Reported	Reported	Only few cases: Verruca, Molluscum contagiosum (Incubation: weeks to months)	Single cases: Zygomycoses (After years), Tinea cutis glabrae (After weeks)	Toxic shock syndrome
2006, Morbidity and Mortality weekly report (CDC)			A primary case of tattoo-associated Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) skin infection was defined as a skin infection consistent with staphylococcal infection (e.g., boil, folliculitis, erythema, or abscess) that occurred near or at the site of a recent tattoo in a person from whom a culture from that site yielded MRSA. A secondary case was defined as a skin infection consistent with staphylococcal disease that occurred in a person who had not received a recent tattoo but had been in close contact with an MRSA patient who had received a tattoo. A total of 34 primary cases and 10 secondary cases were identified in the three states.							
2005, Porter	Samoan tattoo equipment was analysed in one case and grew various quantities of mixed Gram + organisms. Most extensive growth came from ink and yellow pigment.		<i>Streptococcus pyogenes</i> and <i>Staphylococcus aureus</i> were grown in both cases. In one case <i>Pseudomonas aeruginosa</i> was grown as well. Tissue cultures also grew <i>Corynebacterium</i> species and <i>Klebsiella oxtoca</i> in the second case.		Bacterial infection caused skin necrosis septic shock that led to death in one case.					Septic shock registered in both cases

[122], [123], [18], [72], [43], [110], [69], [124], [125]

**Table D:** Adverse health effects: tumours.

Reference	Country of study	Sample size	Study covered years	Age range (Years)	Time of onset after tattooing	Colour/Location/Gender
2015, Høgsberg	DK	19	2009-2011	18-52	Average 3 months	Red nuances (red, pink, purple, bordeaux)
2014, Soran	US	1		73		
2010, Klugl	DE	3411 (survey)				
2009, Dos Santos Gon	BR	1		60	4 months	woman
2009, Kürle	DE	1		22		Female. Tattoos on the right ankle, right groin and coccyx.
2009, Lee	KR	1 (plus 7 already reported in the past)		60 (other cases from 28 to 74)	3 years (other cases from 1 to 46 years)	Black PMU on left eyebrow. Woman
2008, Goldenberg	US	1		38	1 month	
2007, Kazandjeva	BG	234				
2006, Birnie				28	6 years	Black,/central back/Female
2005, Baker	UK	1		35	7 years	

[107], [127], [18], [128], [129], [130], [131], [69], [132], [70]

Reference	Benign tumours			Malignancies					Lymph nodes
	Frequency	Keratocanthoma (KA)	Pseudolymphoma (PSL)	Frequency	Basal cell carcinoma (BCC)	Squamous cell carcinoma (SCC)	Melanoma (MEL)	Other	
2015, Høgsberg			6 cases: pseudolymphomatous infiltration pattern has been found on a background of interface dermatitis						
2014, Huynh					BCC, SCC and MEL may result from the local dysimmune reactions triggered by tattooing				
2014, Soran								Tattooing causes difficulties in assessing a sentinel lymph node biopsy specimen because the pigment can mimic metastatic disease and thus provide a challenge for surgeons and pathologists. Sentinel lymph node biopsy was performed to stage a ductal carcinoma in situ (NOT NECESSARILY RELATED TO THE PRESENCE OF THE TATTOO). Intra-operatively four colored nodes were harvested, labeled and sent separately for histopathology. The first and third nodes were hot with technetium 99 and contained blue dye staining, the second node was blue in color and the fourth axillary SLN was palpable only. The pathology report of the lymph nodes revealed that all axillary SLN were free of tumor. In addition, the second axillary SLN which was grossly blue/black in color haextracellular anthracotic pigmentation and pigment-laden macrophages.	
2010, Klugl				0.1% (all male, n=3411)					

[107], [113], [127], [18]



Reference	Benign tumours			Malignancies			Lymph nodes	
	Frequency	Keratocanthoma (KA)	Pseudolymphoma (PSL)	Other tissue reactions	Frequency	Basal cell carcinoma (BCC)		Squamous cell carcinoma (SCC)
2009, Dos Santos Gon		Keratocanthoma confirmed by histological analysis						
2009, Kürle							Noticed at first as brownish-black skin lesion noticed in the region of the right thigh, then confirmed by histological analysis.	Black pigmented lymph node found negative at histological analysis.
2009, Lee	8 cases reported in the literature over 33 years					Confirmed by histopathologic findings		
2009, Mateix	Purely coincidental	5 cases cited			7 cases cited	3 cases cited	12 cases cited	
2008, Goldenberg						The case reports a superficially invasive squamous cell carcinoma, keratocanthoma type (in the form of erythematous hyperkerathotic papules)		
2007, Kazandžieva					5 cases reported	Single cases (no proof for a link with tattoo)	6 cases reported	
2006, Birnie					Basal cell carcinoma of no special type confirmed by histology, manifesting as asymptomatic nodule			
2005, Baker	This is reported as the first case of dermatofibrosarcoma protuberans occurring in a decorative tattoo			Dermatofibrosarcoma protuberans has an intermediate grade of malignancy. It is reported being locally aggressive and rarely methastatic. In this case it manifested as cutaneous nodule.				

[128], [129], [130], [43], [131], [69], [132], [70]