EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection (IHCP)
Physical and Chemical Exposure Unit (PCE)

Workshop

on

"Technical/scientific and regulatory issues on the safety of tattoos, body piercing and of related practices"

**organised by the JRC/PCE/IHCP
on behalf of Directorate General for Health and Consumer Protection
(DG SANCO)**

**Ispra (VA), Italy
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Opening Address by the European Commission, DG SANCO

Panagiotis Daskaleros

European Commission
Directorate-General for Health & Consumer Protection (DG SANCO)
Directorate B – Consumer Affairs

Regarding the safety of tattoos and body piercing there are recent concerns expressed by Member States and the European Parliament, in particular because of the health risks involved and the absence of a clear legislative background in the EU and at world scale. In this light, the JRC has been requested by DG SANCO to undertake action with the overall aim to collect and assess all necessary information for establishing a common knowledge basis for the conception of a future legislation at EU level. The main axes are:

- Take stock of the actual situation in the EU on tattooing and body piercing activities in terms of prevalence
- Review the regulatory situation on tattooing/body piercing in the EU and elsewhere
- Review the safety data, epidemiology, of tattooing dyes and pigments, piercing, tattooing/body piercing practices
- Review the professional aspects (training, requirements, hygiene standards, etc)

In this undertaking, the JRC and DG SANCO are working together with the Council of Europe, which is preparing a resolution on “tattoos and permanent make-up”.

As a first step, a technical working group from experts active in Member States in the above areas was established. The working group is assisting the JRC in the planning of the work, the information exchange/assessment and the review of the deliverables. Three meetings have been held at the JRC, Ispra on December 16th 2002, in Brussels on January 28th 2003 and in Amsterdam on March 18th –19th.

In these meetings the members of the TWG reviewed the currently available information and agreed that the currently available policy options are the following:

- provisions on authorisation/registration of the activity
- provisions on skills/education of the practitioners
- provisions on the equipment/space
- provisions on hygienic practices
- provisions on sterility of products/equipment/practices
- request for risk assessment
- introduction of a negative list of substances
- introduction of a positive list of substances

The end of the day goal is to assess the need of, and, if appropriate, come up with regulatory proposals to harmonise these activities across the EU. In this light. we are confident, the present workshop will open the avenues to pragmatic and efficient solutions.

Opening Address by the Council of Europe

Sabine Walser
Council of Europe, Department of Health and of the Partial Agreement in the Social and Public Health Field

Mr Kotzias,
Mr Daskaleros,
Mr Papameletiou,
Dear Experts

Let it be a promising omen for the coming two days devoted to the discussion of technical scientific and regulatory issues of tattoos, body piercing and related practices that the philosophy of "Health and Consumer protection" figures prominently in the working agenda of these departments in the European Commission and the Council of Europe concerned with above issue. Subsequently reflection is given to this mandate in the denomination of the European Commission, Consumer Affairs, Health and Consumer Protection, Directorate General and the Council of Europe, Partial Agreement Division in the Social and Public Health Field.

- Introduction
In order to tighten the bonds of co-operation and mutual understanding by enhanced information I would like to introduce you briefly to the basic principles and elements of the Council of Europe health policies particularly with regard to its working priorities in Public Health sector: the Council of Europe legal initiative taken to promote safety in tattoos and related practices which will be referred to later as a result of the working programme.

Before continuing with my presentation allow me to express on behalf of the Council of Europe my gratitude to the leaders of the project and the technical working group at the European Commission and the Joint Research Centre, Institute for Health and Consumer Protection, particularly Mr Daskaleros and Mr Papameletiou, for the kind invitation and the creation of an open, participative discussion and working climate from the very beginning of this project.

May I use this opportunity to say a hearty thank you to all delegates and experts being represented in the Council of Europe, Committee of Experts of cosmetic products and the Technical Working Group for their dedication and contribution to this project focused at increasing the safety of tattoos and related practices for the European consumer.

Mandate, organisation, instruments of the Council of Europe Public Health agenda
The Council of Europe stands for a health policy, which is based on the principles enshrined in the European Human Rights Convention, in force since 1953, and European Social Charter and its revisions, the Convention of Human rights and Bioethics and supplementary protocols.

These international treaties are giving rise and inspiration to subsequent health initiatives, which are targeted at raising the level of health protection for more than 800 Mio European citizens in 45 member states. To close the loop between the spirit guiding treaties and reality: - only a healthy population is a pledge for economic welfare and the political stability of a community.

"Health is a fundamental human right indispensable for the exercise of other human rights".

Within the Council of Europe, Social Cohesion Directorate General, the Department of Health and of the Partial Agreement in the Social and Public Health Field is concerned with covering wide- set aspects of Health and Ethics and Public Health in the above-mentioned spirit.

The Partial Agreement in the Social and Public Health Field was concluded in 1959 and comprises to date 18 Member States of the Council of Europe, among them 14 European Union Member States with the view of raising the level of health protection of the Consumer in its widest sense and adding to the rehabilitation and integration of people with disabilities. Partial Agreements allow the active engagement and co-operation of a certain number of all Council of Europe Member States in a specific field of interest and concern. I would like to point out that Partial Agreements can only be concluded with the consent and acknowledgement of all other Council of Europe Member States. May I refer you to a renowned example of a Partial Agreement –which is the European Pharmacopoeia Convention.

Dedicated Committees of experts are working currently within the Council of Europe Public Health sector on the following topics of Public protection and promotion:
- Cosmetic products: (plants/plant preparations used in cosmetics),
- Materials coming into contact with food,
- Nutrition, food safety and consumer health,
- Flavouring substances,
- Issues concerning pharmaceutical practice in its wide sense,
- The legal classification of medicines with regard to their supply.

The Committees decide on the appropriate instruments for the outcomes of the working programme which may take the form of resolutions, guidelines and reports, codes of good practice, safety evaluations of substances, pinions for the superior bodies.

- What is the legal power of a Resolution elaborated by a Committee of experts under the Partial Agreement in the Social and Public Health?

The Committee of Ministers may address recommendations for a common policy to the governments of member states by adopting resolutions. It is important to note that these resolutions require a unanimous vote of the representatives and after adoption constitutes a joint expression of European governmental opinion (in the case of Partial Agreement resolutions - restricted to the 18 member states) on the given subject. Even though they have not the direct binding force of conventions they constitute a distinct political call to member states to consider them in their national policies.

The statute foresees the possibility of monitoring the implementation of the resolution in national legislation either by the Committee of Ministers or the concerned and supervising steering Committee.

The Partial Agreement Resolutions are not reserved for the Member States alone but are strongly recommended for adoption and consideration in all Member States of the Council of Europe: This conveys additional importance of the standard setting carried out by the Partial Agreement Public Health sector for accession and candidate countries to the EU and other European countries: model legislation is provided for reference to in their resp. national legislation. It goes without saying that the resolutions are revised periodically in order to react in a dynamic way to the varying and rapidly changing Public Health challenges and to be adapted to recent scientific knowledge.

- Conclusion

Within its long-standing mandate for Public Health the Council of Europe has contributed to the improvement of the health protection of the consumer and harmonisation of legislation by guidelines and technical reports (substance lists) on ingredients used in cosmetics, borderline

products, pesticides, materials coming into contact with food, medicinal products. It is well founded to say that this work triggered respective legislation or revision of current legislation on the level of the European Union.

May I invite the interested audience to consult the Council of Europe web site for detailed information on the Social Cohesion and Public Health working agenda under www.coe.int

The draft resolution on tattoos and permanent makeup, to be dealt with in more detail during the working sessions of tomorrow, was elaborated with regard to its scientific and policy contents by the Member States' delegates of the Partial Agreement Committee of Experts of cosmetic products.

Several Health Authorities of the Partial Agreement Member States have performed during 2000 and 2001 studies on the chemical and microbiological purity of products used for tattoos and permanent makeup. Based on findings of microbiological contamination of opened and even sealed containers, the presence of harmful chemical substances the Committee of Experts agreed to develop outlines for a specific and harmonised regulation in the 18 Partial Agreement Member States.

The present draft resolution illustrates some aspects of the Partial Agreement approach towards standard – setting in the Public Health sector by using the methods of safety evaluation, setting specifications and preparation of inventory lists of ingredients used, elaboration of maximum or -guideline levels for contamination. The working programme is dictated by great sensitivity to early safety signals for Public Health sequels from technical evolution and scientific progress or from social trends.

The Council of Europe Partial Agreement Division is committed to follow in this field of tattoos and related practice the precedence of good co-operation opened up earlier by existing co-operation agreements and the Joint declaration of partnership (2001) between the Council of Europe and the European Commission.

I would like to conclude wishing to all participants of this workshop interesting debates and a fruitful outcome and thank you very much for your attention.

Status report
on the current situation, nature and size of the problem regarding the safety of tattoos, body piercing and of related practices in the EU

by
Demosthenes Papameletiou, Alexandre Zenié and Dieter Schwela

JRC/IHCP/PCE

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1. 1 General Prevalence Studies

- **Data situation in the EU: poor**. Some examples:
  - 4000 tattooists are practising in the UK placing ca. 1 million tattoos per year
  - ca. 2 million are owners of piercings in Germany
  - 20 % of the adolescents in Italy have a piercing
  - 6.6 % of the adolescents in Italy have a tattoo

In the EU it is believed that 5-10% of the general population is having a tattoo/piercing.
Prevalence studies are generally missing in the EU.

1.2 Adolescents

Highschool-Studies / Armstrong ML and Murphy KP (Appl. Nurs. Res. 1997; 10:181)

- A 1993 study of 642 adolescents from six suburban high schools in Texas revealed 8.6% had a tattoo with the youngest being 11 years old when the tattoo was obtained.
- Gender distribution of the 105 adolescents with tattoos were 65% male and 35% female.
- In 1995 among 1762 students (nationwide) the proportion of adolescents with a tattoo was higher at 9% with the youngest being only 8 years old at the time the tattoo was obtained.
- The average age of first tattoo dropped from 16 years in the 1993 study to 14.5 years.
- In 1995, 55 % of the adolescents expressed an interest in tattooing compared to 33% in the 1993 study.
- Very few markings were identified as gang markings and 60-65% of the students with tattoos reported academic grades of As and Bs.

Number of adolescents engaging in tattooing at a younger age:
increasing!

1.3 Teens in general

Special Report on Youth, Piercing, Tattoing and Hepatitis C/ TrendScan Findings, Health Canada, March 2001

Total number 1208, ages between 12-19 years / Male 565/Female 643/ Sept-Nov. 2000

- 23% of teens aged between 12 and 19 had a piercing and
- 8% had a tattoo
- 20% want a piercing
- 21% want a tattoo
- Half of the teens have no plans for either
- 69% of pierced teens are girls and 61% of tattooed teens are girls
- desire for a piercing is also greater in girls (29%) than boys (13%)
- desire for a tattoo is split evenly: boys (20%) and girls (22%)
- piercing is initiated at the age of 13
- Piercings increase as teen ages (18% in 12-13yr olds vs 26% in 18-19 yr olds)
- tattoos show a surge at age 15 (5%) and then an increase at age 18 (15%), which probably corresponds to teens being of an age where parental control is removed

Tattooing/piercing is a strongly growing trend

1.4 Students

In a recent study at a small Midwest private college 116 men and 186 women were surveyed. 25% and 33%, respectively, had at least one tattoo or body piercing.

(Forbes, GB. Psychol Rep 2001 Dec;89(3):774-86)

A 2001 study among 491 university students in New York State found prevalences of:

- 51% for body piercing
- 23% for tattooing respectively
- there is a significant (17%) incidence of medical complications among students with piercing.
- Male athletes are significantly more likely to be tattooed than male nonathletes
- Eighteen percent of piercings (58/315) and 4% of tattoos (6/149) had been removed

(Mayers LB et al. Mayo Clin Proc 2002 Jan;77(1):29-34)

1.5 Military Recruits

Another US study found tattooing prevalence in military recruits to be 36% (Armstrong ML et al. Mil. Med. 2000: 165:135-141).

1.6 "16-55 years old" population group studies

In the USA a study (Rooks JK et al. Minn Med 2000; 83:24-27) surveying patients presenting to a hospital emergency department found the following tattooing prevalence data for different age groups:

- 16-35 years old: 35%
- 36-50 years old: 28%
- 51-55 years old: 6%

1.7 Tattoos as a possible marker of risk

- The tattooed and pierced teen emerges as significantly different from the mainstream teen. The tattooed teen (and to a lesser extent the piercing teen) is an early style adopter, generally prone to risky behaviour and likely to be a user of drugs and alcohol. This is a "cool" teen who is a peer influencer in terms of style and behaviour. Having or wanting a piercing/tattoo correlates strongly with:
  - use of alcohol, cigarettes and marijuana

- a desire to take risks sometimes
- an image of being a trendsetter
- a preference for particular music genres (Goth, Punk, Metal, and mElectronica)
- a higher tendency to "hang out" with friends

(TrendScan Findings, Health Canada, March 2001)

- In a chart review of a three-year sample of 134 consecutive suicides in Mobile County, Alabama, was conducted. Tattoos were found in 21% of suicides. Dhossche D. et al. J Affect Disord 2000 Aug;59(2):165-8

2. Understanding and Monitoring Health Effects

- JRC working paper on "Health Effects and Risks Review"

- Presentations and expert panel discussions of the first day (06/05/2003) of present workshop.

- **Germany:** Eine Studie zu Piercing-Komplikationen führte Heico Krause, Oberarzt am Zentralkrankenhaus Bremen, durch. Das Ergebnis zeigte, dass von 270 gepiercten Leuten

  - etwa 50 unter Entzündungen bis hin zu Nekrosen (Absterben von Gewebe) litten.

  - 9 Personen mussten ins Krankenhaus und

  - 14 trugen bleibende Schäden davon.

- **The 1999 UK survey** in Bury and Rochdale : GPs found half of all local piercing centres left people with problems which needed medical attention. Ninety-five per cent said they had seen patients with a complication resulting from a piercing

- **In France** between 10% and 20% of all piercings are reported to lead to a local infection

2.1 Examples of recent press reports about adverse effects and deaths

- **Milano, muore dopo il piercing giovane ucciso dall'epatite. Ventiquattro anni, si era fatto bucare sulla lingua -Sirchia ordina ispezioni dei Nas in tutta Italia, Republica, 13 Marzo 2003**

- **Promising musician Daniel Hindle 17, died in December 2001 of septicaemia - two months after he visited a Sheffield studio to have a ring fitted to his lip. The A-level student, who had battled against a potentially fatal heart condition since birth, fell ill just days after the piercing……..**
  http://news.bbc.co.uk/2/hi/uk_news/politics/2798441.stm

- **An 18-year-old woman who came to the emergency room at LDS Hospital in the USA died from overwhelming infection caused by bacteria in a tongue piercing in her own mouth (1999)**

http://abcnews.go.com/sections/living/DailyNews/bodypiercing000927.html

- **In September 2000 a woman with 118 piercings, including six lip rings and 11 belly bars, died from bacterial septicaemia. The woman refused to seek medical attention, believing she could offset any infection with saline swabs** http://www.studentbmj.com/back_issues/0202/news/7.html

3. Regulation: Development and implementation

- Opinion of the Scientific Committee on Cosmetics and Non Food Products (SCCNFP). In its opinion of the 17 February 2000

- DRAFT RESOLUTION RESAP (2003). ON TATTOOS AND PERMANENT MAKE-UP; COUNCIL OF EUROPE/ COMMITTEE OF MINISTERS (PARTIAL AGREEMENT IN THE SOCIAL AND PUBLIC HEALTH)

- DG SANCO/JRC /Technical Working Group:

  - JRC TattooNet

    General working Papers:
  - **Review of health effects and risks** (JRC & University Regensburg)
  - **Chemicals used in tattoos/piercings** (Norwegian Food Control Authority & CHEMTOX A/S & University Regensburg)
  - **Regulatory Review** (JRC)

    Working papers on policy options:
  - **Positive & negative list** (Norwegian Food Control Authority)
  - **Risk Assessment** (Dutch Inspectorate for Health Protection)
  - **Authorisation & Registration** (Danish EPA & CHEMTOX A/S)
  - **Education & Skills (**National Consumer Agency, Finland)
  - **Hygiene Practices (**Dutch Inspectorate for Health Protection & GC&GD Amsterdam)

Outlook: Implementation needs to be supported by

- **Prevalence & epidemiology studies**
- **R&D on photo-toxicology, blood and lymphatic transport mechanisms, development of alternative pigments/chemicals etc**
- **Risk monitoring and communication tools**

Results of a model survey on a large population sample in Italy

Elisabetta Santori
Eurispes,
Rome, Italy

PIERCING E TATUAGGI: LA MANIPOLAZIONE VIOLENTA DEL CORPO E IL RIFIUTO DEL CORPO ADOLESCENTE

Introduzione
È sempre più frequente incontrare ragazzi di ogni età, estrazione sociale o provenienza culturale che sfoggiano con orgoglio i propri piercing e tatuaggi. Questo elemento della moda giovanile è diventato così diffuso negli ultimi anni che non desta più stupore. Tuttavia, sarebbe opportuno porsi alcune domande per comprendere meglio il linguaggio e i messaggi che gli adolescenti veicolano attraverso il corpo. Perché i tatuaggi sono così diffusi? Perché molti giovani desiderano conficcarsi nella pelle delle orecchie, del sopracciglio, dell'ombelico e persino della lingua o degli organi genitali dei pezzi di metallo coronati da sferette ornamentali? Come mai si diffondono sempre di più tecniche affini che interessano il corpo quali il *body painting*, i tatuaggi di luce o l'applicazione di vere e proprie *parure* di brillanti tra i denti?

Tali pratiche non sono certo una invenzione degli ultimi anni, ma risalgono ad epoche ben più lontane e a differenti culture. Un rapido sguardo agli aspetti antropologico-culturali di questo fenomeno potrebbe aiutarci a comprenderne le origini ed i significati.

Aspetti antropologico-culturali
L'"arte corporale", cioè l'arte di decorare, personalizzare, abbellire il proprio corpo in modo estremo e permanente, è una pratica antica. Fin dai tempi più remoti l'uomo ha agito sul corpo artificialmente, trasformandolo, marchiandolo o dipingendolo, fondamentalmente per un bisogno istintivo di differenziarsi dagli animali; in questo processo troviamo i primi segni di civilizzazione, di una ricerca spirituale, oltre che fisica, della nostra identità di uomini. L'organizzazione delle società tribali è molto precisa e si fonda sulla suddivisione degli individui per ruoli sociali. In questo contesto lo scopo principale del piercing, come dei tatuaggi e delle scarificazioni, delle pitture corporali e delle decorazioni temporanee, è quello di distinguere i ruoli che ogni membro assume all'interno della tribù; regola i rapporti tra i vari individui sia nel quotidiano sia durante le cerimonie, rendendo immediatamente palese, al solo sguardo, una serie di informazioni sull'individuo, in rapporto al gruppo. Tramite la posizione di un piercing (o di un tatuaggio, o di una scarificazione), il materiale usato e la forma, i giovani saranno immediatamente in grado di distinguersi e di riconoscersi.

Mentre le decorazioni hanno uno scopo principalmente cerimoniale, le modificazioni permanenti segnano generalmente momenti importanti della vita di un individuo. L'iniziazione all'età adulta, ad esempio, è un passaggio fondamentale comune a tutte le società tribali. Essa segna la transizione da un periodo di relativa incoscienza legata agli "istinti originari" (l'infanzia), all'acquisizione di un controllo delle emozioni con il riconoscimento della condizione civile. Tramite un passaggio violento e doloroso si simboleggia una morte ed una contemporanea rinascita, momento che resterà impresso sul corpo per tutta la vita. Fra le pratiche più antiche di cui siamo a conoscenza annoveriamo forme di adornamento permanente come tatuaggi, scarificazioni, marchi a fuoco e piercing e forme di modifiche corporali estreme come l'allungamento del collo, dei lobi delle orecchie o il restringimento del giro vita, dei piedi, del cranio, la circoncisione maschile e femminile o la

limatura dei denti. Diversi sono i popoli interessati, come ad esempio i popoli dell'Amazzonia, dell'Africa, i berberi del Marocco, gli indigeni del Borneo, gli esquimesi, le donne dell'India, i popoli arabi fino ad arrivare ai recenti gruppi punk.

Come si legge in *Segni indelebili*, il bel saggio della semiologa Betti Marengo sull'argomento, negli ultimi trenta anni, invece la "Body art" si è diffusa uniformemente fra i giovani e non sta più a simboleggiare l'appartenenza a gruppi particolari o emarginati. All'inizio degli anni Settanta tatuaggi e piercing cominciarono a diffondersi negli Stati Uniti, ma ad averli addosso erano ancora in pochi. Dagli anni Ottanta in poi il tatuaggio divenne il contrario di ciò che era stato per secoli, fu il tentativo di esorcizzare la propria insicurezza corporea e di *status*. Oggi i giovani tatuati, marchiati, perforati sono milioni in tutto il mondo e migliaia in Italia.

Alcuni dati
Da una recente indagine dell'Eurispes – nell'ambito del *3° Rapporto Nazionale sulla Condizione dell'Infanzia e dell'Adolescenza* – condotta su un campione di 3.800 studenti italiani tra i 12 e i 18 anni, emerge che il fenomeno del piercing interessa circa il 20% dei ragazzi mentre la pratica del tatuaggio il 6,6%. Il piercing è più diffuso rispetto al tatuaggio, ed interessa in prevalenza le ragazze. Quest'ultimo dato è chiaramente spiegabile come un fatto culturale. È infatti molto più frequente e naturale l'idea che una donna operi delle perforazioni sul corpo (pensiamo semplicemente agli orecchini), rispetto all'uomo. La minore diffusione del tatuaggio rispetto al piercing potrebbe essere attribuita al fatto che questa pratica, a differenza dell'altra, è reversibile, più facile e veloce da realizzare, e probabilmente anche meno costosa.

Se osserviamo le tabelle di seguito riportate abbiamo un'idea della diffusione dei piercing e dei tatuaggi in base al sesso ed alla appartenenza geografica dei giovani intervistati.

Tabella 1

Giovani che hanno applicato un piercing sul proprio corpo in Italia, per sesso
Anno 2002
Valori percentuali

Hai un piercing?	Sesso		Totale
	Maschio	Femmina	
Si	14,4	25,6	20,3
No	85,6	74,4	79,7
Totale	100,0	100,0	100,0

Fonte: Eurispes.

Tabella 2

Giovani che hanno applicato un piercing sul proprio corpo in Italia, per area geografica
Anno 2002. Valori percentuali

Hai un piercing?	Nord-Ovest	Nord-Est	Centro	Sud	Isole	Totale
Si	26,3	14,3	22,0	18,2	19,9	20,3
No	73,7	85,7	78,0	81,8	80,1	79,7
Totale	100,0	100,0	100,0	100,0	100,0	100,0

Fonte: Eurispes.

Colpisce la ridotta diffusione del piercing al Nord-Est, soprattutto se la mettiamo in relazione ai dati del Nord-Ovest. Questo dato può essere attribuito ad un fatto culturale e geografico. L'Italia del Nord-Ovest, a differenza di quella del Nord-Est, risente di più dell'influenza dei paesi della mitteleuropa, dove tale pratica è più diffusa tra i giovani; inoltre presenta grandi città, luoghi dove il piercing è certamente più praticato rispetto ai piccoli centri. La diffusione del fenomeno nel resto d'Italia appare, invece, più uniforme.

Tabella 3

Giovani che hanno tatuaggi sul proprio corpo in Italia, per sesso. Anno 2002. Valori percentuali

Hai un tatuaggio?	Sesso		Totale
	Maschio	Femmina	
Si	7,2	5,7	6,6
No	92,8	94,3	93,4
Totale	100,0	100,0	100,0

Fonte: Eurispes.

Tabella 4

Giovani che hanno tatuaggi sul proprio corpo, per area geografica
Anno 2002. Valori percentuali

Hai un tatuaggio?	2 Nord-Ovest	Nord-Est	Centro	Sud	Isole	Totale
Si	7,4	4,6	6,3	7,5	7,1	6,6
No	92,6	95,4	93,7	92,5	92,9	93,4
Totale	100,0	100,0	100,0	100,0	100,0	100,0

Fonte: Eurispes.

Anche rispetto ai tatuaggi si ripete l'andamento relativo al fenomeno del piercing, ovvero la minore diffusione nell'Italia del Nord-Est rispetto alle altre aree del Paese. Rispetto al sesso, invece, possiamo notare che è più utilizzato dai maschi che dalle femmine. Probabilmente questo dato è spiegabile con il significato rituale e simbolico che il tatuaggio riveste e con il fatto che probabilmente le donne hanno a disposizione, e preferiscono, altre pratiche di abbellimento del corpo.

Significati e motivazioni
Secondo il prof. Piero De Giacomo, direttore del Dipartimento delle Scienze neurologiche e psichiatriche dell'Università di Bari, alla base della scelta di praticarsi un piercing, di farsi un

tatuaggio o di marchiarsi a fuoco c'è sicuramente il desiderio di *rendersi più belli*. «Non necessariamente agli occhi degli altri», spiega il professore. «Questi ragazzi non cercano l'approvazione della società nel senso convenzionale del termine».

Secondo un'altra corrente di pensiero, modificare il proprio corpo diventa una estrema forma di libertà, una maniera per ristabilire un *contatto più profondo con se stessi* e con le proprie emozioni e sensazioni. Questi giovani identificherebbero nel dolore l'unica maniera per giungere alla completa conoscenza della mente, passando attraverso il corpo. La pelle è un'interfaccia tra esterno e interno, un punto di confine e di passaggio. Funziona come una barriera, ma anche come un involucro e un contenitore. Attraverso la pelle il nostro corpo comunica con il mondo e, al tempo stesso, difende il corpo interno dalle intrusioni. La pelle ci rivela agli altri, oltre che a noi stessi; così da rendere "superficiale" ciò che normalmente riteniamo "profondo": pensieri, emozioni sentimenti».
Accanto ai giovani che decidono di modificare il proprio corpo per apparire più belli o un contatto più profondo con le proprie emozioni e con se stessi, c'è tutta un'altra schiera di giovani che è mossa da diverse motivazioni: per moda, per sancire una appartenenza, per distinguere le generazioni, per colmare un vuoto, per cercare di differenziarsi dal genitore, per scelte ideologiche e culturali, per trattenere un ricordo, per scopi erotici o sessuali, o addirittura per una disturbata percezione del proprio corpo.

Due ricercatori in accordo con il Comune di Milano hanno intervistato 60 adolescenti fra i 16 e i 19 anni che frequentano licei, istituti tecnici e scuole d'arte del territorio milanese. Gli adolescenti affermano che prima viene il piercing e poi il tatuaggio, poiché «quest'ultimo è una cosa che resta». Il piercing sembra avere un valore prevalentemente di esibizione, mentre il tatuaggio è vissuto come il segno di una tappa raggiunta nello sviluppo di una persona, un modo per dare il carattere di durevolezza ad un momento o ad un episodio che si vorrebbe durassero per sempre o che si desidera ricordare.

Un problema rilevante che emerge da questa indagine è che gli adolescenti soffrono di una grande difficoltà, quella di "esserci". Automutilarsi è quindi un modo per provare che dentro il corpo c'è qualcosa invece che il nulla, è un sistema per manifestare che si è padroni di se stessi, fino al limite dell'autopunizione o della mutilazione. Piercing e tatuaggio sono pratiche trasversali, che riguardano tutti i gruppi e le classi sociali, e non più i reietti e gli esclusi. Paradossalmente il piercing ed il tatuaggio sono diventati un fatto di omologazione, un "identity marker". Più i legami familiari e sociali sbiadiscono, più ci si fa incidere nel corpo segni di *appartenenze immaginarie*. L'ultimo segno, il più disperato, è la "marchiatura": quella che si faceva sul bestiame, o sugli schiavi, con le iniziali del padrone o il simbolo dell'allevamento. L'essere umano ha bisogno di appartenere a qualcosa: una famiglia, una tribù, una patria. E se non ci sono più né l'una né l'altra, e neppure la terza, vengono inventate appartenenze immaginarie.

I rischi e le norme

Di fronte al diffondersi spontaneo dei fenomeni sociali ci sono sempre dei rischi e delle questioni connesse al loro controllo e alla loro regolamentazione. L'espandersi delle pratiche di modificazione corporea di cui abbiamo fin ora parlato ha comportato problemi legati alla professionalità di chi le effettua, all'igiene dei luoghi dove si svolgono, alla disinformazione e all'ignoranza.

I rischi — Vi sono, dal punto di vista medico, tre rischi principali che si corrono se non si rispettano alcune precauzioni. Tatuaggi e piercing, secondo il famoso immunologo Fernando Aiuti, sono tra le possibili fonti di trasmissione di epatite B, epatite C, Aids. Ci sono diversi casi accertati di Aids trasmesso dai tatuaggi e tre sospetti da piercing. Per eliminare il rischio non basta sterilizzare gli strumenti, ma usare attrezzi a perdere, monouso. In caso di ago infetto la probabilità di contagio è del 16% per l'epatite B, del 12% per la C, dello 0,5% per l'Hiv.

Anche il prof. Giovanni Francesco Contento, chirurgo plastico ed estetico raccomanda di rivolgersi a persone esperte che forniscano garanzie igieniche: strumenti sterili, aghi o lame monouso, prodotti (coloranti o gioielli) di qualità per scongiurare il rischio di infezioni. È opportuno sapere inoltre che il piercing sulla cartilagine dell'orecchio può causare gravissime "condriti", ovvero mandare in necrosi tutta la parte interessata. Le scarificazioni invece possono provocare "cheloidi", ovvero le cicatrici possono superare le dimensioni della ferita vera e propria con effetti deturpanti facilmente immaginabili. Un altro problema è legato al "pentimento". Sono molti coloro che vogliono eliminare un tatuaggio magari fatto con troppa leggerezza. Molti non sanno però che non è facile cancellare un disegno sulla pelle. Sia che si usi il laser sia che si usi la chirurgia, la cicatrice rimane. Molto spesso sono gli stessi esecutori di tatuaggi e piercing a parlare ai giovani attraverso giornali e altri mezzi di informazione, per distinguersi dagli improvvisatori e fornire indicazioni da seguire. Il titolare del negozio "Body and Soul", uno dei primi specializzati in Italia, afferma che gli esperti nel campo sono davvero pochi. Il suo studio pratica soprattutto piercing sui genitali. Afferma che questo tipo di piercing – una volta – era raro, ma ora è sempre più frequente, anche fra le donne. Per farsi bucare bastano cinque minuti e 40 euro. Viene inserito solo acciaio chirurgico, garantito contro il rigetto; lo stesso materiale del bisturi. Il *piercer* afferma inoltre che i piercing non vengono fatti a tutti poiché, una volta fatti, bisogna essere in grado di curarli. Ad ogni cliente viene consegnato un opuscolo con quattro pagine fitte di raccomandazioni d'uso. Un'altra avvertenza è quella di non farsi praticare un piercing con una "pistola spara orecchini" perché non è sterilizzabile. L'ago è ritenuto più sicuro e indolore. Un'altra regola è: mai farlo da soli. Può capitare che i ragazzi «entrino nel panico» se non sentono di avere una persona esperta accanto che li rassicuri. Il piercer intervistato ricorda a questo proposito un ragazzo che si era recato impaurito nel suo negozio poiché gli si era incarnato un piercing che si era autoprocurato sulla lingua. In questi casi non si può far altro che correre subito al pronto soccorso, ma sarebbe bene seguire le indicazioni e le raccomandazioni spesso diffuse per prevenire tali episodi.
È importante ricordare però che esiste sempre una variabilità nelle reazioni individuali e sarebbe sbagliato sottovalutare i rischi possibili, come pure – del resto – demonizzare il fenomeno.

Le norme — Una delle strade per limitare tali rischi potrebbe essere quella di regolamentare il fenomeno, fissando standard e norme igieniche di riferimento. In realtà una normativa ci sarebbe, sotto forma di "linee guida", ma le linee non hanno guidato quasi nessuno e sono rimaste praticamente lettera morta. Nel 1998 Rosy Bindi decise di occuparsi di tatuaggi e piercing. Dal Ministero della Sanità furono predisposte due circolari che istituirono una sorta di patentino per *piercer* e tatuatori. Per poter esercitare questi mestieri, prevede il Ministero, occorre aver frequentato corsi di 30 ore. Nell'attesa dei corsi, gli interessati devono chiedere alle Asl di zona un permesso temporaneo, che certifichi il rispetto delle norme igieniche e di sicurezza. Purtroppo, a quasi quattro anni dall'emanazione delle linee guida, gli enti che hanno istituito i corsi si contano sulle dita di una mano; i controlli sono inesistenti. Come denunciano gli stessi interessati, «le norme non vengono applicate» spiega Giuseppe Serra, presidente dell'Associazione Tatuatori Italiani Riuniti (ATIR) «e non sono previste sanzioni, con il risultato che imperversano dilettanti che mettono a rischio la salute di tutti». Tra le regioni all'avanguardia, se così si possono definire, ci sono Lazio, Puglia, Trentino e Campania, che sta per varare una legge. In campo europeo è stata di recente emanata una normativa, definita come una sorta di "bollino blu europeo". Con una norma apposita, infatti (la UNI EN 1810), il Comitato europeo di normazione (Cen) ha stabilito che per evitare irritazioni cutanee o, peggio, lesioni all'epidermide, gli oggetti metallici inseriti in parti perforate del corpo devono avere una percentuale massima di nichel compresa fra lo 0,03% e lo 0,07%. Questo a prescindere dal metallo base utilizzato per realizzare il piercing, che può essere acciaio, alluminio, titanio, rame, argento o oro. La norma stabilisce anche il metodo con cui la misurazione della percentuale di nichel nel piercing deve essere effettuata in laboratorio. Una regola, al momento, lasciata alla libera adesione di ogni singolo paese, ma anche dei produttori di gioielli che vorranno offrire maggiore sicurezza ai loro clienti. Il Prof. Sergio Chimenti, direttore della clinica dermatologica dell'Università Tor Vergata di Roma, commenta con soddisfazione l'arrivo del marchio europeo, considerato che sono circa tre milioni gli italiani a rischio allergia da piercing.

Alcune brevi conclusioni

La pratica di modificare il proprio corpo con metodi più o meno tradizionali o invasivi si sta sempre più diffondendo tra i giovani ed in particolare fra gli adolescenti compresi tra i 13 e i 19 anni. Piercing, tatuaggi e chirurgia estetica sono praticati non più da particolari gruppi o frange giovanili, ma sono divenuti pratiche abituali a prescindere dalla appartenenza sociale e culturale. Tale stato di cose costringe ad interrogarsi sulle motivazioni che spingono le nuove generazioni a scegliere di incidersi, dipingersi, modificare permanentemente il corpo. Quale è il messaggio che lanciano attraverso un tale comportamento? Che nesso hanno tali pratiche applicate ai giorni nostri con i significati simbolici e rituali che veicolavano nelle tribù o nell'antichità? Quali sono i rischi connessi all'ignoranza sull'argomento? Nel corso della nostra trattazione abbiamo cercato di dare parziali risposte a queste domande, ma, poiché un fenomeno così antico si è diffuso su larga scala solo di recente, la sua osservazione e la sua comprensione costituiscono una sfida stimolante che coinvolge antropologi, psicologi, sociologi al pari di genitori, insegnanti o dei giovani stessi

Session I

Technical/scientific issues:

"health effects & risks"

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Chemicals used in tattooing and permanent make up products

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Introduction[3] / main features of the products

n the following a survey is given as concerns the chemical composition of products applied for tattooing and permanent makeup purposes.

On the basis of product information collected by different means in the marketplace the authors recognise that these products, like most other products meant to confer a colour to a substrate, consists mainly of chemicals that absorb visible light – i.e. the actual colorants - and some auxiliary ingredients that are of different kinds.

The colorants fall in two subgroups; pigments and dyes[4]. Normally, it seems, they are making up the bulk of the product; concentrations being well above 50% (w/w).

When dyes are being used they are in combination with – or blended with - small amounts of a "stabiliser" that most often is the very stable and water insoluble salt *Barium sulphate (a white pigment)*.

Chemically the pigments can be either metallic salts (oxides, sulphides, selenides) or organic molecules of different kinds[5]. The dyes are organic molecules.

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[3] working paper on behalf of the JRC/TWG

[4] According to the American Dry Color Manufacturers' Association pigments are any coloured, black, white or fluorescent particulate solid, which is insoluble in, and essentially unaffected by, the vehicle or substrate in which it is incorporated. It will alter the appearance of an object by the selective absorption and/or scattering of light. A pigment will retain a crystal or particulate structure throughout the colouring process." *Dyes* on the other hands are soluble colorants either in water or in some organic non-polar solvent. In other words: Whereas a pigment refers to a colorant that is insoluble in the medium in which it is applied, a dye is a colorant that is soluble in its applicable medium. If the solubility in water is less than 1 mg /mL at 22 ^{o}C a chemical compound is generally characterised as *insoluble*. It's observed that pigments are generally considered to be *insoluble* in water according to this standard. However, it has been shown that at least some pigments are in fact soluble or slightly soluble in water – and most can be solved in some other solute.

[5] These are organic molecules that share many physico-chemical properties with the *disperse*, *solvent* and *mordant* dyes with respect to molecular size, structure and hydrophobic property

As concerns the products applied for the traditional tattooing purposes pigments seems to be the preferred colorant type. The pigments have high light stability and are chemically resistant – especially the metallic salts. This is favourable having in mind that a tattoo is meant to last a lifetime. The "stabilised" dyes seems to occur mostly in the PMU products – but are used to some extent also in the traditional products.

The pigment particle size is critical giving only the desired colour and transparency if the size is well defined and controlled[6].

The ready-to-use tattooing/PMU product is a blend of different kinds of chemicals (as are also other colour-products like paint, ink etc). It's desirable to avoid physical separation of the products. Therefore, efforts are made to make the colorant particles "float" in a stable suspension – the particles should be dispersed. In a hydrophilic matrix like that normally present in these products such dispersion is a challenge to formulators since the chemical nature of the pure pigments makes them strongly hydrophobic. This pertains to the organic pigments mostly.

In order to make a stable suspension it's often necessary to use only pigments having been so-called "wetted" - that is, certain other molecules have been adhered to the surface of the microcrystalline particulates so as to modify their polar properties (to make the particle more hydrophilic). The bonding involved in such "wetting" processes is of an electrostatic/ van der Waals nature. These are comparatively weak bonds – and one would hold it probable that an adhered chemical may to a certain extent leach out to the surroundings under physiological conditions in the skin tissues.

Chemicals used to "wet" the colorant particles are called additives.

In order obtain a homogenous solution with appropriate properties as concerns fluidity etc even other chemicals are needed – also these are termed additives. This concerns chemicals having a "thickening" effect and also certain surface-active chemicals or resins/binders. These latter substances are important for having a well functioning tattooing product because they help to make the product stick to the tattooing needle.

As is the case with other colouring products that comprise organic material and water – and therefore often are excellent growth media for bacteria and fungi – preservatives are not seldom added to the tattooing/PMU products also.

Since tattooing involves breaking of the skin and a certain level of pain one is not surprised to observe that in certain instances also a local a local anaesthetics, have been mixed in.

A product contains also certain solvents that function as carriers for the above -mentioned colorants and additives. It seems to be normal for tattoo/PMU products to use ethanol or isopropanol. A content of not less than 15 % alcohol by some producers is regarded sufficient to assure sterility – i.e. the solute in some cases function as anti microbial agent.

Sources of information

The colorants listings shown below have been prepared on the basis of information provided by the Finnish, Danish, Dutch, Finnish, German and Norwegian authorities being represented in the Council of Europe (CoE) Committee of Experts on Cosmetics Products. These authorities collected information by direct contact to market players. To some extent also scientific articles in the medicinal literature have been used as a source of information. As concern the overview

[6] Pigments are present in a microcrystalline particulate state with a very fine mesh (1 μm and often even smaller than 0.5 μm) when being used in certain industrial colouring products like for example paint, ink, or products that set colour to plastic materials like PVC. It's presumed that this is the case also as concerns the material going into tattooing and PMU

for the auxiliary ingredients this has been based on direct contact by the authors to market players.

Colorants having been identified

Within the framework of the Council of Europe (CoE) activity on tattooing 1999- 2003, a survey was undertaken by several of the participating countries in order to unravel the chemical nature of the colorants that are being used for these purposes these days. The lists shown below show the finds.

In addition the CoE expert group also included a literature search in order to find out about the nature of colorants detected by others over the years. It was deemed important to unravel whether changes in the use pattern has occurred through time.

The actual chemical identity of the molecules in question is to be found in Appendix I.

Colorants mentioned in the literature (traditional tattooing)

The authors de Groot *et al* (1994) mention only the following 9 coloring materials - of which 7 are metallic oxides / hydroxides/ sulphides / aluminates.

Colour	**Coloring material**
Blue	Cobalt blue (*) and indigo
Green	Trivalent chromic oxide, hydrated chromium sesquioxide
Red	Mercury sulphide (cinnabar)
Yellow	Cadmium sulphide, ochre (**), curcuma yellow (curcumine)
Purple	Manganese (***)

(*): Cobaltous aluminate (**): Ferric oxide (***): Some non-identifiable manganese salt

The literature referred to by de Groot *et al* are more than 15 years old - and in addition the problematic tattoos dealt with were several years old at the time of reporting (since, normally, there is a delay of many years from the tattoo is made to the outbreak of a reaction).

Researchers at the Saarland University in Germany undertook an investigation in 1988 in order to find out what colors were in use at that time. They detected nine different dyes - but couldn't see any trace of the metals *mercury*, *cadmium* or *chromium* in their analysis. They were of the impression that classic dyes had been superseded by newer, mainly synthetic dyes (Lehmann 1988).

In 1991 the researchers Sowden *et al* detected the presence in tattoos of both *mercury* and *cadmium* when performing X-ray microanalysis of biopsies from red tattoos in eighteen patients who had developed cutaneous inflammatory responses (Sowden 1991).

In 1997 the authors Waldmann *et al* conveyed the view that:

«In most cases the reactions are caused by different red pigments. While in the past these reactions have been ascribed to mercury salts (cinnabar) and cadmium sulphide, now synthetic azo dyes have also been found to be responsible for such reactions» (Waldmann 1997).

A search on the Internet the indicated that the following coloring material are mentioned by tattooing artists (Steve Gilbert 1997): Cadmium red (*cadmium selenide*), Sienna (Fe_2O_3), Sandalwood (*Natural red 22/23*) and Brazilwood (*Natural red 24*).

Colorants reported by market player to be in use

In this survey it's also shown whether the colorant in question are permitted in the related field of cosmetics products or not. This information was deemed interesting because it shows which tattooing colorant are allowed on the surface of the skin in the form of a cosmetics ingredient.

In this connection the reader should keep in mind that the colorant use within cosmetics is strictly regulated. This regulation has emerged over the years; 1976-to date. At least in parts it has been based on safety assessment carried out by the EU Scientific Committee on Cosmetics (SCC) – and the EU Scientific Committee on Cosmetics and Non-food Consumer Products (SCCNFP) since 1997. The reader should also observe that with the exception of lipsticks and mascara the concentration of colorants being used in cosmetics products are very low: 1 – 100 ppm normally. Recalling also that this concerns medium sized or large molecules that pass through the skin to a small degree only, it's clear that the systemic doses received because of cosmetics is small indeed. A chemical absorbed through the skin will have a different impact on the live tissues that a chemical placed intra dermally by injection as is done in tattooing and PMU. However, the largeness of the dosing need not be many orders of magnitude different from that involved in tattooing/PMU. On this background it was judged of some importance to show the status of the chemical within the frame of the cosmetics regulation.

Colors reported to be currently used by firms performing permanent makeup (PMU) (list established on inputs from Norway, Denmark and Finland)

Colour index (CI) (1)	**Conventional name**	**Chemical class**	**Allowed in all kinds of cosmetics (2)**
11741	Pigment yellow 74	-"-	No (not in any kind)
12150	**Solvent red 1**	-"-	**Yes**
12315	Pigment red 22	-"-	No (not in any kind)
12355	Pigment red 23	-"-	No (not in any kind)
12420	Pigment red 7	-"-	No (only in rinse-offs)
12475	Pigment red 170	-"-	No (not in any kind)
12477	Pigment red 210	-"-	No (not in any kind)
12510	Pigment brown 25	-"-	No (not in any kind)
13015	**Acid yellow 9**	-"-	**Yes**
15850:1	Pigment red 57:1	-"-, Ca salt	**Yes**
15850:2	Pigment red 57:2	-"-, Ba salt	Yes if insoluble (3)
16035	**Food red 17**	Azo	**Yes**
16255	**Acid red 18**	Azo	**Yes**
19140	**Acid yellow 23**	-"-	**Yes**
21107:1	Pigment yellow 87	-"-	No (not in any kind)
21160	Pigment orange 16	-"-	No (not in any kind)
42090	**Acid blue 9**		**Yes**
45170	**Basic violet 10**	Xanthene	No (not in any kind)
45380	**Acid red 87**		Yes, on condition
45430	**Acid red 51**	-"-	Yes, on condition
47005	**Acid yellow 3**		**Yes**
73360	Pigment red 181(Vat red 1)	Indigoid	**Yes**
73900	Pigment violet 23	Quinoacridine	No (only in rinse-offs)
73915	Pigment red 122	-"-	No (only in rinse-offs)
74160	Pigment blue 15	Phthalocyanin	**Yes**

		e	
74260	Pigment green 7	-"-	**Yes**
74265	Pigment green 36	-"-	No (not in any kind)
75510	**Natural red 22/23**	Natural	No (not in any kind)
77007	Pigment blue 29 (Ultramarine blue)	Alumino-sulfosilicate	**Yes**
77266	Pigment black 6 and 7 (graphite)	Pure carbon	**Yes**
77288	Pigment green 17	Trivalent chromium oxide	Yes, on condition
77489		Iron (II) oxide	**Yes**
77491	Pigment brown 6 and 7 Pigment red 101 and 102	Iron (III) oxide	**Yes**
77492	Pigment brown 6 and 7 Pigment yellow 42 and 43	Hydrated ferric oxide	**Yes**
77499	Pigment brown 6 and 7 Pigment black 11	Iron oxide	**Yes**
77510	Pigment blue 27 (Prussian blue)	Ferric ferrocyanide	Yes, on condition
77742	Pigment violet 16 (Manganese Violet)	Ammonium manganese(3+) diphosphate	**Yes**
77891	Pigment white 6	Titanium dioxide	**Yes**

(1): According to the Rowe Colour Index having been produced the Society of Dyers and Colourists , Bradford, UK
(2): This is according to the Annex V of the Cosmetics Directive of the EU

Colors reported by the German delegation that were used in tattoo and permanent make-up studios in the year 2001

Colour index (CI)	**Conventional name**	**Chemical class**	**Allowed in all kinds of cosmetics**
11680	Pigment yellow 1	Azo	No (not in those used close to mucous membranes)
11741	Pigment yellow 74	-"-	No (not in any kind)
12315	Pigment red 22	-"-	No (not in any kind)
12355	Pigment red 23	-"-	No (not in any kind)
12475	Pigment red 170	-"-	No (not in any kind)
12485	Pigment red 146	-"-	No (not in any kind)
12510	Pigment brown 25	-"-	No (not in any kind)
15630	Pigment red 49	-"-	Yes on condition (8)
21108	Pigment yellow 83	-"-	No (only in rinse-offs)
21110	Pigment orange 13	-"-	No (not in any kind)
21115	Pigment orange 34	-"-	No (not in any kind)
21160	Pigment orange 16	-"-	No (not in any kind)
51319	Pigment violet 19	Oxazin	No (only in rinse-offs)

71105	Pigment orange 43	Antraquinone	No (not in those used close to mucous membranes)
73360	Pigment red 181 (Vat red 1)	Indigoid	**Yes**
73900	Pigment violet 23	Quinoacridine	No (only in rinse-offs)
73915	Pigment red 122	-"-	No (only in rinse-offs)
74160	Pigment blue 15	Phthalocyanine	**Yes**
74260	Pigment green 7	-"-	**Yes**
77015	Pigment red 15	Aluminium silicium oxide	**Yes**
77266	Pigment black 6 and 7 (graphite)	Pure carbon	**Yes**
77288	Pigment green 17	Trivalent chromium oxide	Yes, on condition
77489		Iron (II) oxide	**Yes**
77491	Pigment brown 6 and 7 Pigment red 101 and 102	Iron (III) oxide	**Yes**
77492	Pigment brown 6 and 7 Pigment yellow 42 and 43	Hydrated ferric oxide	**Yes**
77499	Pigment brown 6 and 7 Pigment black 11	Iron oxide	**Yes**
77891	Pigment white 6	Titanium dioxide	**Yes**
77941	Pigment white 4	Zinc oxide	**Yes**

Colors reported by the Danish authorities that are used for traditional tattooing

CI	**Conventional name**	**Chemical class**	**Allowed in all kinds of cosmetics**
11680	Pigment yellow 1	Azo	No (not in those used close to mucous membranes)
11741	Pigment yellow 74	-"-	No (not in any kind)
11767	Pigment yellow 97	-"-	No (not in any kind)
11780	Pigment yellow 36	-"-	No (not in any kind)
12474	Pigment red 266	-"-	No (not in any kind)
12475	Pigment red 170	-"-	No (not in any kind)
12485	Pigment red 146	-"-	No (not in any kind)
12510	Pigment brown 25	-"-	No (not in any kind)
51319	Pigment violet 19	Oxazin	No (only in rinse-offs)
71105	Pigment orange 43	Antraquinone	No (not in those used close to mucous membranes)
74160	Pigment blue 15	Phthalocyanine	**Yes**
74260	Pigment green 7	-"-	**Yes**
77266	Pigment black 6 and 7 (graphite)	Pure carbon	**Yes**
77491	Pigment brown 6 and 7 Pigment red 101 and 102	Iron (III) oxide	**Yes**

77891	Pigment white 6	Titanium dioxide	**Yes**

Comments concerning the PMU colorants

Its noteworthy that so many different synthetic *organic colorants* have come in use in addition to the traditional inorganic pigments. Another remarkable feature is that as many as 39 % the 28 *organic pigments/dyes* finding use within the new business of *permanent makeup* actually aren't allowed *on* the skin in the form of cosmetics products ingredients.

The studies undertaken in Denmark, Finland, and Norway show that the 28 organic colorants are mostly *pigments*. As many as11 are *dyes*, however (in bold letters in the table). The latter is surprising since *dyes* are generally much less fast to the light than pigments and expectedly will fade much faster due to the detrimental effect of the light to the molecules. *Dyes* are also generally much more soluble than *pigments* and may potentially be metabolized and distributed around the body faster and to a much lager degree than the *pigment* molecules.

Possibly, *dyes* have found extended use in the permanent makeup practices because all colorants inserted will after all be removed from the body in 4 –7 years time due to the constant renewing of the epidermis (constant shedding off of skin).

As many as 16 of the 28 organic colorants encountered are of the *azo* type and may possibly split metabolically into aromatic amines.[7] 4 of the 16 *azo* colorants "contain" amines that are classified carcinogens: *Solvent red 1* that "contains" *o-anisidine*, *Pigment red 7* that "contains" *4-chloro-o-toluidine* and the two pigments *Pigment yellow 87* and *Pigment orange 16* that "contain" *3,3'-dichlorobenzidine*. The amines and the other metabolites of the colorant molecules may, of course, possess also other inherent toxic properties to take into accounts. The *non-azo* dye *Basic violet 10*, that are banned in cosmetics products, seems to possess carcinogenic properties indicating that also the *xanthene* molecules deserve to be paid special attention to.

With two exceptions, *Natural red 22/23* and *Basic violet 10*, the 11 *dyes* identified are permitted in all kinds of cosmetics products according to the EU Cosmetics Directive. In Denmark *all* the identified colorants are allowed in *all* kinds of cosmetics. This may possibly indicate that at least to some degree the professionals operating within the business of permanent makeup feel that also their products should better be subjected to some kind of specific regulation. According to the Danish contribution many of the professionals offering permanent makeup services are also beauticians, makeup artists, hairdressers etc – i.e. persons that are more familiar with the cosmetics regulations than with any other products regulation (chemicals, medicinal device).

Comments concerning the colorants being used within traditional tattooing

The Danish contribution to the CoE study indicates that only *pigments* are used for traditional tattooing – which isn't surprising since these colorants are much more fast to the light than the *dyes* and are meant to last a lifetime. Seemingly, also within the practice of traditional tattooing

[7] Aromatic amines may be metabolically activated with the result that cancer precipitates. The first step involves N-hydroxylation and N-acetylation, and the second step involves O-acylation yielding acyloxy amines. These compounds can degrade to form highly reactive nitrenium and carbonium ions. These electrophilic reactants may readily bind covalently to genetic material, namely cellular DNA and RNA (Brown & DeVito, 1993). Comparatively few aromatic amines are, however, classified carcinogenic within the framework of the EU Chemicals regulations. The food-related ones (among others the 3 encountered in this study that is; CI 16035, 16255, 19140) have been very thoroughly investigated and presently they seem freed for suspicion of being carcinogens.

very many organic colorants are now being used: 14 of the 17 identified all in all. None of the 8 *azo pigments* identified "contain" carcinogenic amines.

Other observations taking into account all the studies carried out

Four studies within the work of the CoE have been performed with the aim to identify *the exact chemical nature* of the colorants that find use within the practices of permanent makeup and traditional tattooing. This has been done by direct contact to the market operators. 40 organic and 12 traditional inorganic colorants have been identified.

Only limited resources have been put at the disposal of these studies. The market is a dynamic thing and colorants can be phased in and out of use depending upon the changes in taste among people thinking of having a tattoo. The impression is that the colorants being used are ordinary industrial pigments and dyes – of which there are many hundreds that can be easily obtained. One thinks it probable, therefore, that even more *organic* colorants than have been identified are being used – and can be used. One has, however, managed to get a certain impression of the conditions in the current marketplace.

Seemingly, inorganic salts of *mercury* (Hg), *cadmium* (Cd) and *cobalt* (Co) do not find use any more. Such salts were not encountered in the four studies. The Dutch authorities analyzed 63 samples collected from the market (mostly from the traditional tattooing segment), looking for Cd and Co (and also other heavy metals – but not for Hg). Only traces levels were measured: Cd in the range 0.001 – 0,5 ppm, Co in the range 0,02 – 3 ppm. One holds it highly probable that in event one or more of the 63 individual products did contain either a Cd or a Co salt *as an ingredient* much higher amounts indeed would have been measured. Hence, conceivably the traces amounts observed (in many of the samples) most probably were impurities[8].

The Dutch authorities analyzed also for other metals the salts of which have been identified as tattooing ingredients - notably *manganese* (Mn), *chromium* (Cr), *zinc* (Zn) and *barium* (Ba).

Mn: Four of the samples contained relatively much: 220, 710, 1500 and 3000 ppm, whereas the rest were in the range 0,01 - 41 ppm. Possibly at least some of the four high-level samples contained a genuine Mn-salt ingredient.

Cr: Measurements were in the range 0,01 – 12 ppm. None of the somewhat higher levels measured correspond with a green colour of the sample analysed so conceivably none of the samples contained the *chromic oxide* ingredient (obviously it's used only seldom).

Zn: Only trace levels. *Ba:* possibly present as an auxiliary ingredient in several of the samples (80 – 2000 ppm).

Out of the 40 organic colorants identified 24 (60%) are azo compounds – and out of these, 9 "contain" an amine that has been classified carcinogenic within the framework of the chemicals regulations. The amines in question are[9]

Amine	*Containing azo colorant*

[8] This is not to say though that also trace levels may possibly be troublesome when present in live tissues. All Cd-salts have been classified as carcinogenic compounds. IARC: Cadmium and cadmium compounds are carcinogenic to humans (Group 1). CdCl (which is also genotoxic) has a TD_{50} as low as 0,00611 mg/kg body weight per day (Cheeseman E *et al* 1999) – meaning that an exposure level as exceedingly low as 10^{-7} mg/Kg body weigh per day involves a lifetime risk of cancer of 10^{-5} (regarded as an acceptance level in some of the Partial Agreement States)

[9] Their human dose descriptor is in the range 5 –19 mg/Kg bodyweight /day meaning that they are all rather potent (genotoxic) carcinogens

o-Anisidine	CI 12150 / Solvent red 1
5-Nitro-o-toluidine	CI 12315/Pigment red 22 and CI 12355/ Pigment red 23
4-Chloro-o-toluidine	CI 21107/ pigment yellow 87
3,3'-dichlorobenzidine	CI 21107/ pigment yellow 87, CI 21108/Pigment yellow 83, CI 21110/Pigment orange 13, CI 21115/pigment orange 34, CI 21160/Pigment orange 16

Hence, 17 % of the 52 colorants identified in the marketplace contain a carcinogenic aromatic amine – and so do also the 63 samples studied by the Dutch authorities. Also the Dutch study revealed the presence of *o-anisidine* and *3,3-dichlorobenzidine* but failed to detect *5-nitro-o-toluidine* and *4-chloro-o-toluidine*. On the other hand the Dutch study detected *o-toluidine* in 1 sample and *2,4-diaminotoluene* in 3 samples. These were not present in the 24 azo compounds identified by DK, FIN, G and N. Also the latter observation indicates that there are many more organic colorants being used than the 40 encountered in the market studies. Both the Dutch analytical study and the other 4 studies show that mostly it's the *3,3'-dichlorobenzine* molecule that can possibly be released from the *azo* pigments finding use in these products.

Auxiliary ingredients

PMU products

Only spars information is available as concerns the auxiliary ingredients being used in these products. Up till now the following ones have been identified:

- Distilled water
- Ethanol
- Isopropanol
- Glycerol
- Hydrochloric acid (HCl)
- Sodium hydroxide (NaOH)
- Benzoic acid (preservative)
- Poloxamer 407 (see formula below)
- Rosa canina (an extract of some kind from this plant)
- Aroma (could be many different chemicals mixed together)
- Barium sulfate
- Aluminium hydroxide
- Rosin
- Neodecanoic acid
- Butanamid
- Amorphous silica
- Kaolin

Poloxamer confines to the following formula:

$HO(CH_2CH_2O)_x(C(CH_3)HCH_2O)_y(CH_2CH_2O)_zH$

X = 98, y= 67, Z= 98

One important distributor in the European market this the American based firm Starlight Inc. This firm announces its palette of products on the Internet.[10]. According to this source the different auxiliary ingredients are used with different frequency:

[10] Advertisement at : http://www.starlightuk.com/colours.htm and http://www.starlightcalifornia.com/catai4.html

Solutes

Distilled water: 11 out of 12 products announced
Isopropanol: 12 out of 12 products announced

Additives (possibly the "wetting" agents have not been declared in the list of ingredients)

Barium sulfate 3 out of 12 products (stabilizer of contained dye)
Aluminium hydroxide 1 out of 12 products
Rosin 1 out of 12 products
Neodecanoic acid 1 out of 12 products
Butanamid 1 out of 12 products
Amorphous silica 1 out of 12 products
Kaolin 1 out of 12 products

Traditional tattooing products

The study performed by the Danish authorities concentrated on the traditional tattooing product. According to this contribution these products seems to contain the following auxiliary ingredients

Glycerol
Ethanol
Isopropanol
Thickening powder (not specified) (Cellulose based thickener is used in at least one case)
Emulsifier (not specified)
Resin (in the drawing ink it was linseed oil)
Benzoic acid
Sodium hyalonate

Methylparabene (preservative)
Aqua Rosae
Dexpanthenol

A special ***drawing-ink*** has been observed as a ready to use. Aside from incorporating the above- mentioned auxiliary ingredients and also linseed oil as a binder it also contains:

CAS 1303-96-4 di sodiumtetraboratedecahydrate
CAS 57-13-6 Urea
CAS 108-95-2 Phenol (< 0.3%) (a polluting chemical)
26172-55-4 5-chlor-2,3-dihydroisothiazol-3-on (< 0.003%) (a polluting chemical)

Thinning of traditional tattooing products

If the tattoo colour needs to be thinned before use, the recommendations are a little different, often Listerine is used.

Listerine is also normally used for cleaning the wounds made by piercing.
It is a product intended for mouth hygiene, containing:

Active Ingredients:
Thymol 0.064%,
Eucalyptol 0.092%,

Methyl Salicylate 0.060%,
Menthol 0.042%.

Also Contains:
Water,
Alcohol (21.6%),
Sorbitol Solution,
Flavoring,
Poloxamer 407,
Benzoic Acid,
Sodium Saccharin,
Sodium Benzoate,
D&C Yellow #10
FD&C Green #3.

Other advice's for thinning tattoo colours are to use vodka.

Chemical analysis of ready to use products

The results from a survey carried out in the Netherlands (*Reus HR and van Buuren RD, 2001*) on the chemical composition of products used for tattoos and PMU give a glimpse of the health risks involved with these practices: 63 samples of products used for tattoos and PMU from the Dutch market and taken from opened and sealed containers were analysed for the presence of carcinogenic aromatic amines and for the presence of several heavy metals.

Azo-colorants, based on carcinogenic aromatic amines, were identified in ten samples (17%) applying a chemical examination procedure that in details only deviates from that recently adopted within the context of control of textiles etc[11] . Considerable amounts of the potent carcinogen *3,3'-dichlorobenzidine* were measured; in one instance as high as 3400 mg/ per Kg tattooing product (0,34%).

These tests may indicate that many different *azo* pigments of the *3,3'-dichlorobenzidine* congener type can be reductively cleaved to a slight extent *in vitro* applying an all-chemical reduction procedure. The *in vivo* reductive cleavage reactions at ambient body temperatures involving *cytochrome P450* and *NAD (P)H-quinone* are, of course, radically different mechanistically. It's presumed, however, that the tests established enables one to identify *hazardous azo* colorants – and that one is erring on the safe side in that respect.

The results obtained in the Dutch analytical study could also be interpreted to mean that the azo compounds haven't been reductively cleaved to a noticeable extent - but that the material analysed contained heavily contaminated colorants.

Dr Baeumler and co-workers have found that ordinary tattooing colorants appear to be heavily contaminated by reactants and by-products occurring in the chemical method applied for production of the colorants.

(To be finalized by including the contributions by Dr Vasold/Baeumler)

[11]Confer the newly adopted EU directive as concerns the ban on azo compounds in textiles that could be reductively cleaved into carcinogenic aromatic amines. Main traits: *sodium dithionate* as reductant, 70 ^{o}C reaction temperature, *ethanol* reaction medium

Availability of high purity materials

Background

At the expert team meeting in Amsterdam on 18 & 19 March 2003, the purity of the pigments being used in the production of tattoo colours were discussed. In the light of these discussions, it was decided to try to form a general overview of the present purity criteria of colorants available at the European market.

Extent

The following pigment producers have been involved in this investigation:

Sun Chemicals
Francolor
Clariant
Ciba
Bayer
BASF

Due to the limitation of the possible time consumption for this investigation, the information collected is principally based on official available information from the internet as well as from contact to the sales departments of some of the companies.

In general

There are many pigment producers. The main part of these producers produce industrial pigments for which the only available purity information consists of information about colour intensity, hiding power and light fastness for the individual type of pigment. Generally, there are no available information about impurity profiles for these industrial pigments. Normally, the producers of these industrial pigments know that their pigments are not sufficiently pure to be used in food or cosmetics, and, in most cases, you must presume that the producer himself will dissuade the use for cosmetics, foodstuff, medicine and also for tattoo colours.

As the person manufacturing tattoo colours generally use very little pigment compared to e.g. the paint industry, the pigments will normally very rarely be bought directly from the pigment producer but most frequently in second or third link.

Therefore, the pigment producer does often not know that his pigments are used for the manufacturing of tattoo colours and, on the other hand, the person manufacturing the tattoo colour does often not know the producer's attitude to this kind of use.

However, there are a range of pigment producers and products meeting the approved demands to purity within cosmetics, foodstuff and medicine.

The specifications for colorants for these purposes are fixed in the regulations mentioned below.

Regulations

The pigments being used for cosmetics and/or food in Europe have to meet a range of demands.

The basis for cosmetics colorants can be found in the EU directive 76/768/EOF (”the cosmetics directive”), here you'll find descriptions of the colorants approved for use in different kinds of cosmetics.

It appears from the cosmetics directive that the colorants mentioned in the positive list and at the same time having an E number ("E ###") have to meet the purity demands in the food directive from 1962, later revised in the EU directive 95/45/EC.

The colorants that do not have an E number have to meet the general demands in the directive from 1962.

There is an EU directive no. 78/25/EC laying down the demands to the colorants being used in medicine, however, in this one you will only find a reference to the fact that colorants being used in medicine are affected by the demands in the food directive.

This means, that In Europe, there is basically only one set of criteria for the purity of all the colorants being used in cosmetics, food and medicine, namely the food directive from 1962 with its succeeding revision in the directive 94/45/EC.

The content of the food directive from 1962 (annex 1) and directive 95/45/EC (annex 2)

Colorants approved for cosmetics **but not for Food** have to meet the following purity demands:

General criteria of purity

Unless otherwise provided in the specific criteria, the colouring matters are required to satisfy the following criteria of purity, quantities and percentages being calculated on the pure colour.

1. Inorganic impurities

- They should contain not more than 5 mg/kg of arsenic and
- not more than 20 mg/kg of lead;
- They should contain not more than 100 mg/kg of the following substances, taken separately : antimony, copper, chromium, zinc, barium sulphate ; and not more than 200 mg/kg of these products taken together;
- They should not contain cadmium, mercury, selenium, tellurium, thallium, uranium or chromates, or soluble combinations of barium in detectable quantities.

2. Organic impurities

- They should not contain 2-naphthylamine, benzidine, amino-4-diphenyl (or xenylamine) or their derivatives;
- They should not contain polycyclic aromatic hydrocarbons;
- Synthetic organic colouring matters should contain not more than 0,01 % of free aromatic amines;
- Synthetic organic colouring matters should contain not more than 0,5 % of intermediate synthetic products other than free aromatic amines;

- Synthetic organic colouring matter should contain not more than 4 % of accessory colouring matters (isomers, homologues etc.);

- Sulphonated organic colouring matters should contain not more than 0,2 % of substances extractable by diethyl ether.

Colorants **approved for food** (and also approved for use in cosmetics):

These colorants have to meet the individual purity demands mentioned in annex 2.

Availability of pigments for use in food and cosmetics

Five out of six pigment producers involved in this investigation produce pigments meeting the demands in the food and cosmetics directives.

This means that you as a pigment purchaser**,** if specified, can buy pigments meeting the demands for cosmetics and/or food colours from these suppliers. It has to be mentioned that you also from the same supplier can buy the same pigments in a not purified quality and that they have the same C.I. number. But they are due to the lower purity not allowed for use in cosmetics or food.

The fact that a content of a pigment which is on the list of approved pigments in cosmetic products is found in a tattoo colour (through analysis or recipe information) does not imply that the purity used does meet the demands. It is only the producer of the tattoo colour who knows if he uses the technical quality or the more expensive cosmetic quality.

Furthermore, it is stated (Hans Joergen Talberg: Chemicals used in tattoos and piercing 14/3-03 working paper) that at least half of the pigments identified in tattoo colours at the European market is not even approved for use in cosmetics.

When the producers of tattoo colours use pigments not even being approved for use in cosmetics for their colours, it is probably due to the following two facts:

- The producer of the tattoo colour is not aware of the problem - this is the fact for some producers (based on personal communication with the producers)

- The producer wishes to manufacture colours which in intensity, tint and light fastness are different (better) that the ones you can achieve by using pigments approved for cosmetics.

Tattoo colours with a content of pigments approved for use in all kinds of cosmetics

For the sake of illustration the following table has been prepared. It shows the 27 colorants that have been found in tattoo / PMU products and which are allowed in all kinds of cosmetics.

C.I. number	**Conventional name**	**Specific purity criteria in accordance with 95/45/EC**	Notes	Purity criteria
12150	Solvent red 1	no		general

13015	Acid yellow 9	E 105	This colour was in the original (1962 directive) but is not allowed any longer	Water insoluble parts < 0.2 % Accessory colourings < 3 % Unsulphonated aromatic amines and aniline <10 mg/kg. Specific test method for 2- and 4-aminoazobenzene. See annex 1.
15630	Pigment red 49	no	less than 3% allowed in finalised product	General
15850:1	Pigment red 57:1	no		General
15850:2	Pigment red 57:2	no		General
16035	Food red 17	no		General
16255	Acid red 18	E 124		The pigment should be more than 80 % pure. Other specific demands see annex 2.
19140	Acid yellow 23	E 102		The pigment should be more than 85 % pure. Other specific demands see annex 2.
42090	Acid blue 9	no		general
45380	Acid red 87	no	Max 1% Fluorescein and max 2 % monoflourescein	general
45430	Acid red 51	E 127		The pigment should be more than 87 % pure. Other specific demands see annex 2.
47005	Acid yellow 3	E 104		The pigment should be more than 70 % pure. Other specific demands see annex 2.
73360	Pigment red 181	no		general
74160	Pigment blue 15	no		general
74260	Pigment green 7	no		general
77007	Pigment blue 29	no		general
77015	Pigment red 15	no		general
77266	Pigment black 6 and 7	no		general
77288	Pigment green 17	no	Should be without chromate ion	general
77489	Ironoxide	E 172		Yellow pigment should contain more than 60 % of total iron. Red and black more than 68 % of total iron. Other specific demands see annex 2.

77491	Pigment brown 6 and 7, pigment red 101 and 102	E 172		Yellow pigment should contain more than 60 % of total iron. Red and black more than 68 % of total iron. Other specific demands see annex 2.
77492	Pigment brown 6 and 7, pigment yellow 42 and 43	E 172		Yellow pigment should contain more than 60 % of total iron. Red and black more than 68 % of total iron. Other specific demands see annex 2.
77499	Pigment brown 6 and 7, pigment black 11	E 172		Yellow pigment should contain more than 60 % of total iron. Red and black more than 68 % of total iron. Other specific demands see annex 2.
77510	Pigment blue 27	no	Should be without cyanide ion	general
77742	Pigment violet 16	no		general
77891	Pigment white 6	E 171		Content not less than 99% TiO_2 on silicate and alumina free basis. Other specific demands see annex 2.
77941	Pigment white 4	no		general

Conclusion

- Today there's an unambiguous regulation for the colorants being approved for use in cosmetics and food. Apart from the demands to the colorant's chemical identity, this regulation also contains demands to the purity of the pigments used.

- The colorants approved for use in cosmetics and food are available in a cosmetic/food quality, with documentation for the purity.

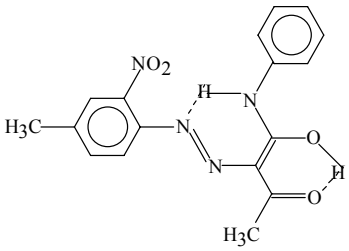
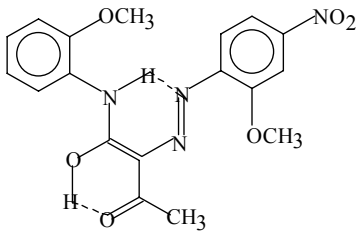
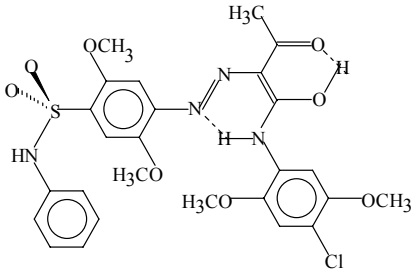
- The fact that a tattoo colour contains a colorant on the list of approved cosmetic pigments does not imply that the colorant used meets the demands.

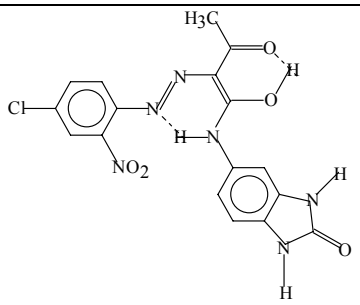
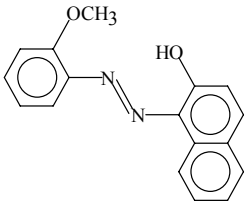
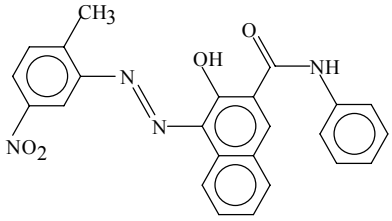
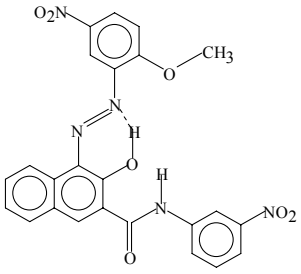
- The same colorants are produced in several qualities and only the particularly purified qualities meet the demands. It is only possible to see if it's the right quality being used by looking at the producer's batch certificate.

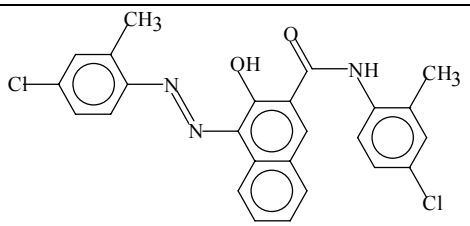
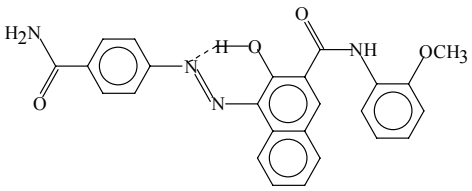
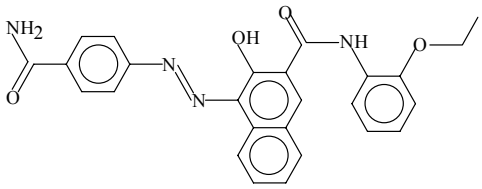
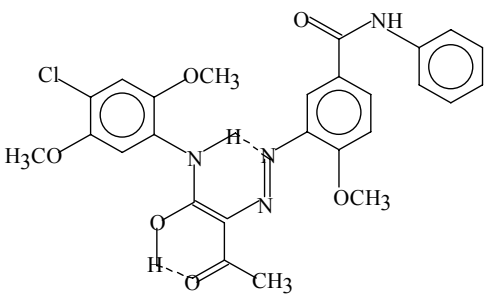
- It is possible that there are particularly pure pharmaceutical qualities of colorants but, in that case, they are not generally available.

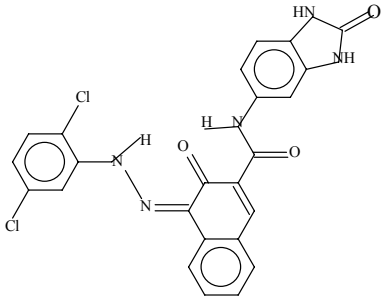
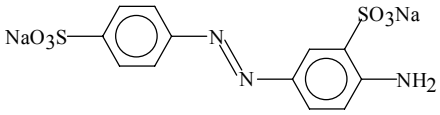
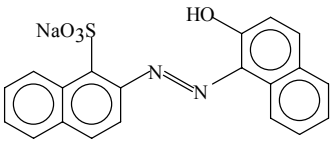
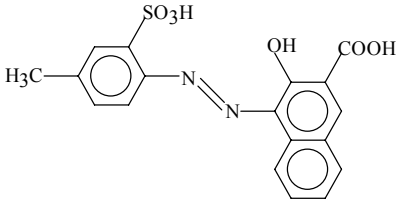
The only "pharmaceutical" qualities of colorants which it has been possible to find in connection with this investigation are colorants meetin

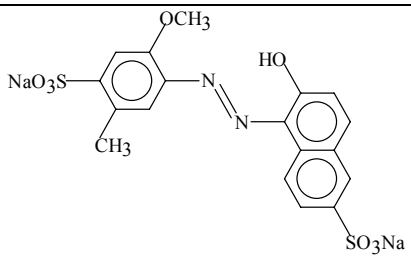
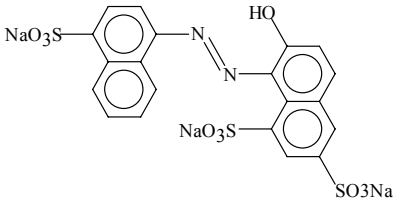
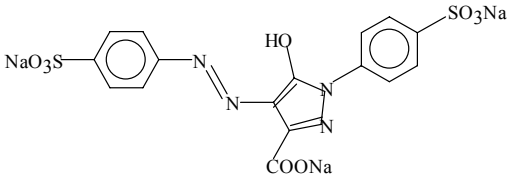
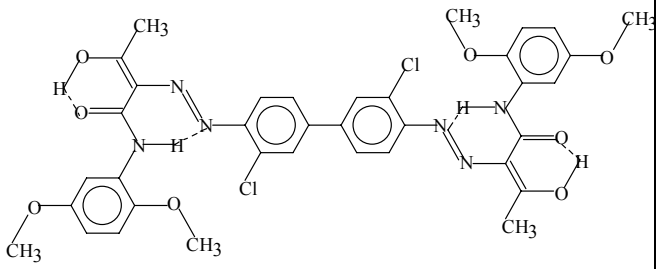
Appendix I / Chemical identity of colouring material

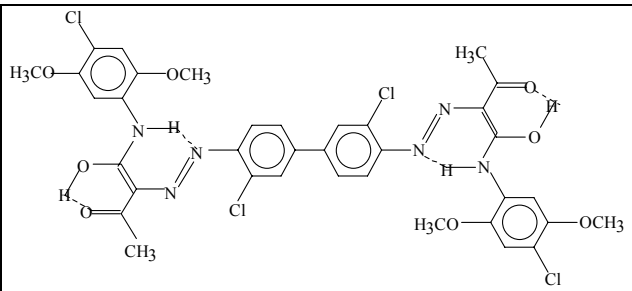
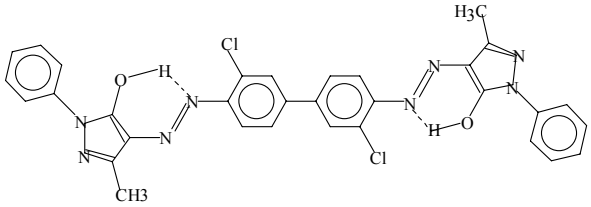
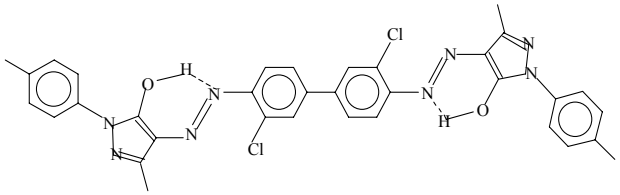
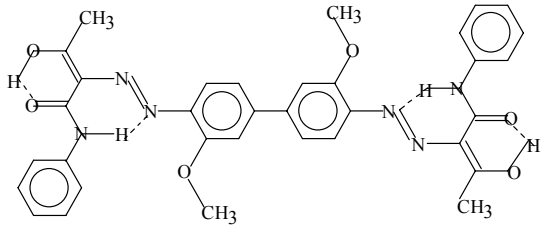
Colour index (CI)	Trivial name(s)	Structural formula and chemical name	CAS-No (*Einecs*) European E-number
11680	**Pigment yellow 1** (Hansa yellow)	 **2-((4-Methyl-2-nitrophenyl)azo)-3-oxo-N-phenylbutanamide**	2512-29-0 (*219-730-8*)
11741	**Pigment yellow 74** (Luna Yellow)	 **2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxo-butanamide**	6358-31-2 (*228-768-4)*
11767	**Pigment yellow 97**	 **N-(4-chloro-2,5-dimethoxyphenyl)-2-((2,5-dimethoxy-4-((phenylamino)-sulfonyl)-phenyl)azo)-3-oxo-butanamide**	12225-18-2
11780	Pigment orange 36		12236-62-3

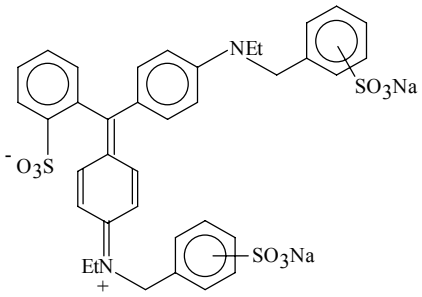
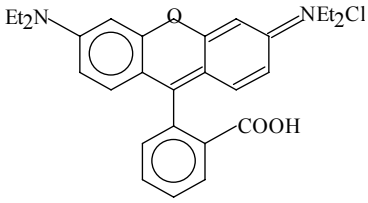
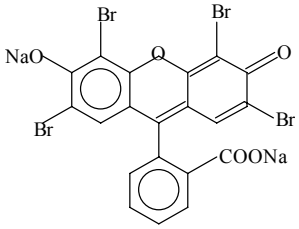
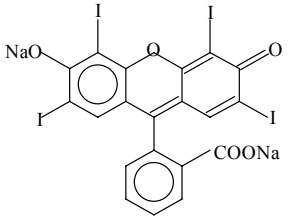
		 **2-((4-chloro-2-nitrophenyl)azo)-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutanamid**	
12150	**Solvent red 1** (Sudan red)	 *1-[(2-methoxyphenyl)azo]-2-naphthol*	1229-55-6 (*214-968-9*)
12315	**Pigment red 22** (Art red)	 *2-naphtalenecarboxamide, 3-hydroxy-4-((2-methyl-5-nitrophenyl)azo-N-phenyl*	6448-95-9 *(229-245-3*)
12355	**Pigment red 23**	 *2-naphtalenecarboxamide, 3-hydroxy-4-((2-methoxy-5-nitrophenyl)azo)-N-(3-nitrophenyl*	6471-49-4 (*229-313-2)*
12420	**Pigment red 7**		647-51-8 (*229-315-3)*

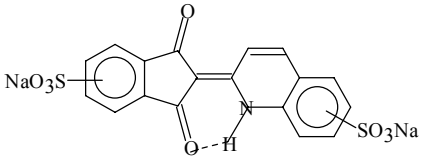
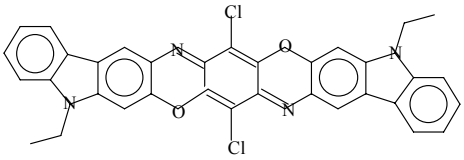
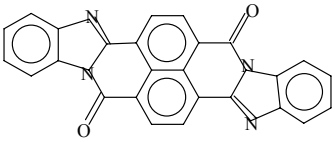
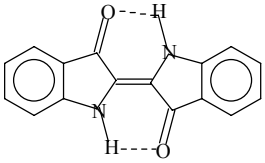
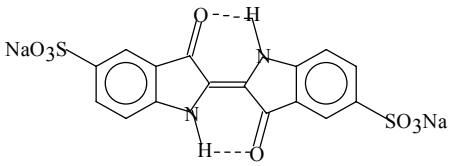
		 *N-(4-chloro-2-methylphenyl)-4-((4-chloro-2-methylphenyl)azo)-3-hydroxy-2-naphtalenecarboxamide*	
12474	**Pigment red 266** • Medium Shade Naphthol Red	 *2-Naphthalenecarboxamide, 4-[[4-(aminocarbonyl) pehenyl]azo]-3-hydroxy-N-(2-methoxyphenyl)-*	36968-27-1
12475	**Pigment red 170**	 *2-naphtalenecarboxamide, 4-((4-aminocarbonyl)phenyl)azo)-N-(2-ethoxyphenyl)-3-hydroxy-*	2786-76-7
12477	**Pigment red 210**	See figure below this table This dye is mixture of Pigment red 170 and a derivative which instead of the ethoxyphenyl moiety contains a methoxypheny moiety	61932-63-6 (*non-existent*)
12485	**Pigment red 146**		5280-68-2 (*226-103-2*)

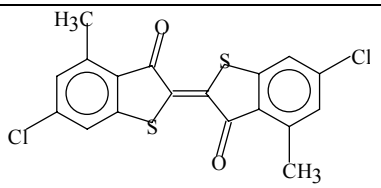
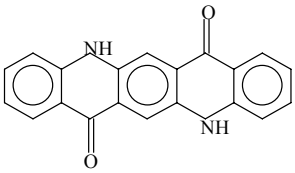
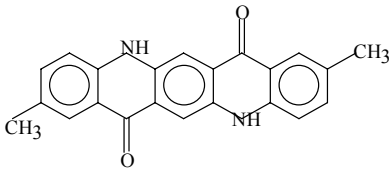
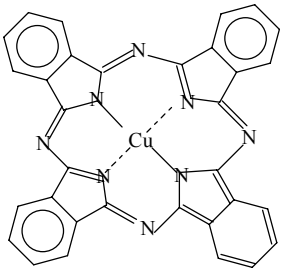
		N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl] phenyl] azo]-2-naphthalenecarboxam	
12510	**Pigment brown 25**	 4-[(2,5-dichlorophenyl)-azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-2-naphthalenecarboxamide	1860-12-7 (*230-258-1*)
13015	**Acid yellow 9** Acid yellow Fast Yellow AB C.I. Food Yellow 2	 *Disodium 2-amino-5-[(4-sulphonatophenyl)azo] benzenesulphonate*	2706-28-7 (220-293-0) E105 (not Allowed in Foodstuffs)
15630	• **Pigment red 49** • Lithol red • FDA: **DC red 10**	 **Sodium 2-((2-hydroxy-1-naphtalenyl)azo)-1-naphtalenesulphonate**	1248-18-6 214-998-2
15850:1	• **Pigment red 57:1** • Lithol Rubine B Ca (used in connection with foodstufs) • *FDA:* ***D&C Red No 7, calcium lake***	Calsium salt of the following acid  *3-hydroxy-4-((4-methyl-2-sulphonatophenyl)azo)-2-naphtalene-caboxylic acid.*	5281-04-9, *226-109-5* ***E180***
15850:2	• Pigment red 57:2	Barium salt of the above acid	17852-98-1 *241-806-4*
16035	• **Food red 17**		25956-17-6

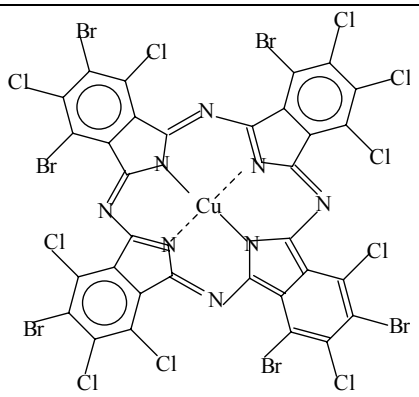
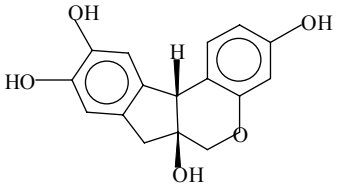
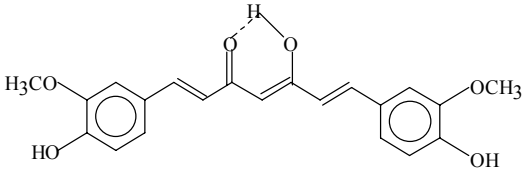
	• **Curry red** (used in connection with foodstuffs) • **Allura red** • *FDA:* ***FD&C Red No 40***	 *Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo] naphthalene-2-sulphonate.*	**247-368-0** ***E129***
16255	• **Acid red 18** (to be applied when substance is used as hair dye) • **Cochenille Red A** (used in connection with foodstuffs) • **Food red 7**	 *Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate*	2611-82-7 **220-036-2** E124
19140	• **Acid yellow 23** (to be applied when substance is used as hair dye) • **Tartrazin** (used in connection with foodstufs) • **Food yellow 4** • *FDA:* ***FD&C Red No 5***	 *Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-*	*12225-21-7* 217-6995-5 E102
21107:1	Pigment yellow 87	 (*o-dichlorobenzidine coupled with acetoacet-o-m-dimethoxyanilide*) *Butanamid, 2,2'-(3,3'-chloro-1,1'-biphenylene)bis(azo)bis(2',5'-dimethoxyacetoacetanilide*	15110-84-6 *239-160-3*
21108	Pigment yellow 83		5567-15-7 **226-939-8**

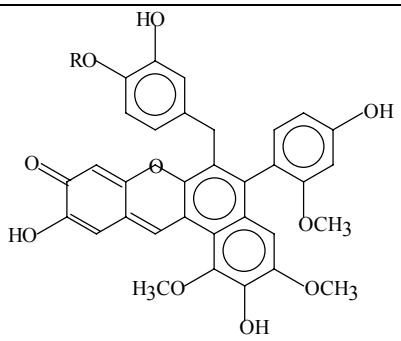
		 **2,2'-((3,3'-dichloro-1,1'-biphenyl)-4,4'-diyl)bi8azo)bis(N-(4-chloro-2,5-dimethoxy-phenyl)-3-oxobutanamide**	
21110	Pigment orange 13	 **3H-Pyrazol-3-one, 4,4'-((3,3'-dichloro (1,1'-biphenyl)-4,4'-diyl)bis(azo))bis (2,4-dihydro-5-methyl-2-phenyl**	3520-72-7
21115	Pigment orange 34	 **3h-pyrazol-3-one, 4,4'-((3,3'-dichloro(1,1'-biphenyl)-4,4'-diyl)bis(azo))(2,4-dihydro-5-methyl-2-(4-methylphenyl)-**	15793-73-4
21160	Pigment orange 16	 (*o-dianisine coupled with acetoacetanilide*) *Butanamid, 2,2'- (3,3'-dimethoxy-1,1'-biphenyl-4,4'-diyl)bis(azo) bis 3-oxo-N-phenyl*	6505-28-8 *229-388-1*
42090	• **Acid blue 9** (to be applied when substance is used as hair dye)		*3844-45-9* 223-339-8 E 133

	• **Briliant blue FCF** • **Food blue 2** • *FDA:* ***FD&C Blue No1***	 *Dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)] amino]-2'-Sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene] (3-sulphonatobenzyl)ammonium, disodium salt*	
45170	• **Basic violet 10** • Rhodamine B • FDA: ***D&C Red No 19***	 Tetraethylrhodamine **N-(9-(2carboxyphenyl)-6-(diethylamino)-3H-xanthen-3-yøiden)-N-ethylethanamminium chloride**	81-88-9 **201-383-9**
45380	• Acid red 87	 **2,4,5,7-tetrabromofluororecin**	17372-87-1 **241-409-6**
45430	• **Acid red 51** • **Erythrosine** (used in connection with foodstuff) • Food red 14 • *FDA* ***FD&C Red No. 3***	 **3',6'-Dihydroxy-2',4',5',7'-tetraiodospiro(iso-benzofuran-1(3H),9'-(9H)xanthene)-3-one Disodium salt**	16423-68-0 **240-474-8** E127
47005	• **Acid yellow 3** • **Quinoline yellow** (in connection with		8004-92-0 (*305-897-5*) E 104

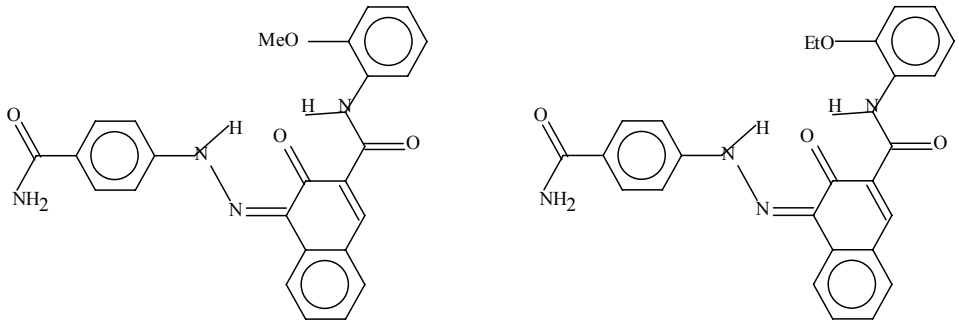
	(in connection with foodstuff) • *FDA:* ***D&C Yellow No 10***	 *1H-Indene-1,3(2H)-dione, 2-(2-quinolinyl)-, sulfonated, sodium salts* Which is a mixture of mono and disulfonic acids of *2-(2-quinolyl)-2H-indene-1,3(2H)dione*	
51319	Pigment violet 23	 *8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo(3,2-b:3'2'-m)triphenodioxazine*	6358-30-1 **228-767-9**
71105	Pigment orange 43 Vat orange 7	 Bisbenzimidazo(2,1-b:2',1'-l)benzo(1mn)(3,8)phenanthroline-8,17-dione	
73000	Indigo Vat blue 1	 *2-(1,3-dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one.*	482-89-3 **207-586-9**
73015	• **Acid blue 74** (to be applied when substance is used as hair dye) • **Indigotindisulfonate sodium (INN)** (pharmaceutical) • **Indigotine** (in connection with foodstuff) • **Indigo carmine** (in connection with foodstuff) • **Food blue 1**	 *Disodium 5,5'-(2-(1,3-dihydro-3-oxo-2H-indazol-2-ylidene)-1,2 -dihydro-3H-indol-3-one)disulphonate*	860-22-0 *212-728-8* E132
73360	Helidone pink		2379-74-0 219-163-6

	Vat red 1	 *6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene) -4-methylbenzo[b]thiophene-3(2H)-one.*	
73900	Pigment violet 19	 *5,12-dihydroquino(2,3-b)acridine-7,14-dione*	1047-16-1 *213-879-2*
73915	Pigment red 122	 *5,12-dihydro-2,9-dimethylquino(2,3-b)acridine-7,14-dione*	980-26-7 *213-561-3*
74160	Pigment blue 15	 *Copper (29H, 31H-phthalocyaninato (2-)-N29N30N31N32)- (SP-4-1)-*	147-14-8 *205-685-1*
74260	Pigment green 7	This colour is a chlorinated derivative of Pigment blue 15	1328-53-6 *215-524-7*
74265	Pigment green 36		14302-13-7 -

		 *copper, 1,3,8,16,18,24 –hexabromo - 2,4,9,10,11,15,17,22,23,25 - decachloro - 29H, 31 H - phthalocyaninato (2-) - N29, N30, N31, N32 -, (SP-4-2) -, Brutto formula:* C_{32} Br_6 Cl_{10} Cu N_8	
75280	Natural red 24 *Brazilin* (Traditionall use: textiles, lipsticks red ink)	Ancient natural red dye (first mentioned in the year 1321) extracted from heartwood of various species of *Caesalpinia* (*echinata, sappan and others*) and related trees. It complies with the following chemical formula (Hagers 1972):  *7,11b-dihydrobenz(b)indeno-(1,2-d)pyran-3,6a,9,10(6H)- tetrol*	474-07-7
75300	• Curcumin • Natural yellow 3	 *1,7-bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione*	458-37-7, *207-280-5* E100
75510	Natural red 22/23	This is a colouring material extracted from the plant specie *Pterocarpus santalinus* or *Santalum rubrum* which is also called *«Red Sandalwood»* - or «*Sanders-wood*». According to the «Society of Dyers and Colourists» the extracted red colour is also called *«Dioxy santaline»* . The expression *«Dioxy santaline»* indicates that it goes about a derivative of one or the other of the following two red pigments which are also isolated from Red Sandalwood:	6771-96-6 (*non-existent*)

		 Santalin A: R = H , CAS-no: *38185-48-7* Santalin B: R = CH3, CAS-no: *51033-46-6*	
77007	Pigment blue 29 Ultramarine blue	*Lazurite* or *Ultramarine blue* $Na_8Al_6Si_6O_{24}S_x$ x = 1-2 Lazurite is the sodalite group mineral dominant in lapiz-lazuli, ultramarine being a synonyme generally applied specificially to synthetic materials. The mineral has a structure related to zeolites. It contains «trapped» S_2^- or S^{2-} sulphur species	**Lazurite**: 1302-83-6 *215-111-1* **Ultramarin** **blue** 1317-97-1 *235-811-0*
77015	Pigment red 1	$Al_4(SiO_4)_3$ stained with Fe_2O_3 *Aluminum silicate* coloured with *ferric oxide*	1309-37-1
77266	Graphite Pigment black 6 and 7 Carbon black	$C_{graphite}$ Almost pure *carbon* in the form of *graphite*	1333-86-4 *215-609-9*
77 288	Pigment green 17	Cr_2O_3 *Dichromium trioxide*	1308-38-9 *215-160-9*
77 289	Pigment green 18	$Cr_2O(OH)_4$ *Chromic oxide hydrated* or *hydrated chromium sesquioxide* or *chromium hydroxide*	12001-99-9
77 346	Pigment blue 28 Cobalt blue	$CoOAl_2O_3$ Cobaltous aluminate	1345-16-0
77 489		FeO *Ferous oxide*	1345-25-1 *215-721-8* E 172
77 491	Pigment brown 6 and Pigment red 101 and 102 Ochre (Mars brown)	Fe_2O_3 Ferric oxide	1309-37-1 *215-168-*
77492	Pigment brown 6 and 7 Pigment yellow 42	$FeO(OH).H_2O$ Hydrated ferric oxide	20344-49-4 **215-570-8** E172

	and 43		
77499	Pigment brown 6 and 7 Pigment black 11	$FeO \cdot Fe_2O_3$ (Fe_3O_4) *Triiron tetraoxide* or *ferrous-ferric oxide*	1317-61-9 **215-277-5** E172
77510	Pigment blue 27 Prussian blue	$Fe_4(Fe(CN)_6)_3$ Ferric ferrocyanide	14038-43-8 **237-875-5**
77743	Pigment violet 16 (Manganese Violet)	Mn $(NH_4)(P_2O_7)$ *Ammonium manganese(3+) diphosphate*	10101-66-3 **233-257-4**
77891	Pigment white 6	TiO_2 *Titanium dioxide*	13463-67-7 **236-675-5** E171
77941	Pigment white 4	ZnO *Zinc oxide*	1314-13-2 *215-222-5*



Pigment red 210

Clinical complications from piercing practices- experiences in Germany

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Klinik für Hals-Nasen-Ohren Heilkunde,
Germany

Introduction

Piercing body art has existed for thousands of years in some cultures, but has become a relatively recent fashion in western society.
Piercing has become very popular amongst adolescents. The paucity of information available in medical literature regarding soft tissue piercing of the head and neck region is contrary to this increasing trend. Only singular case reports can be found, not clearly reflecting the percentage of complications. As these can be severe in different patients it appears to be demanding to start controlled studies. The aim of those studies should clearly be the definition of piercing standards including the different metals are used as piercing materials (Titan, Gold, Silver, Stainless Steal) to reduce complication rates.

General complications

Body piercers are of variable experience and competence but all should follow infection control standards to prevent transmission of infections, such as human immunodeficiency virus HIV or hepatitis. In the head and neck area frequent species leading to infections are bacterial infections with Staphylococcus aureus, Neisseria mucosa and Pseudomonas aeruginosa. Each piercing may lead to its site specific problems.

Site specific complications

Ear: Ear piercing is common and multiple piercing of the ear has become fashionable. Over the last few years there has been a noticeable increase in the number of young people wearing earrings high up through the cartilage of the pinna rather than through the earlobe. High ear piercing seems to have a higher risk for infection, most likely attributably to to the avascular nature of the auricular cartilage. Infection at this site results in auricular perichondritis which often leads to the loss of cartilage and to an unsightly deformity known as cauliflower ear, which has a poor chance of a good reconstruction. The typical postpiercing chondritis deformity presents as a structural collapse of the superior helical rim, scaphal cartilage and the adjacent anthelix. The skin envelope is usually preserved, but severely scarred from the infectious process and from previous drainage incisions. Proximity of hair or pressure on the ear during sleep promotes infections. Additionally the formation of keloids appears to be a frequent problem.

Piercing of the earlobe can split or tear, especially if it is gradually stretched to accommodate a so called flesh tunnel ring.

Oral cavity: The tongue is the most commonly pierced intra-oral site followed by piercing of the lower lip and lip frenula. The procedures of piercing usually occurs without anesthesia after ring clamping the tongue or lip with a forceps. A 14 or 16g sheeted needle is normally used to perform the channel.
There are many complications of piercing in the oral cavity and some of these may be life threatening. Beside the risk of prolonged bleeding, the acute inflammation may lead to severe swelling with obstruction of the upper airway as well as impairment of swallowing and speaking. Chronic irritation or chipping may cause gingivo-dental injury, e.g.broken teeth. There may also be difficulties with speech, chewing, taste and swallowing. With time there may be scar tissue formation and the development of hypersensitivity to the metallic bar.

The recipients of oral piercings must be warned that they may inadvertently swallow or aspirate the jewellery leading to choking. The moist environment of the mouth as well as the frequent introduction of fingers into the mouth leads to frequent piercing-based infections. A single case of cephalic tetanus after tongue piercing has been described.

Facial Skin / Nose/ Neck: The most frequent place for piercing of the face appears to be the lateral eye brow, lateral nasal ala or base of the nose or different location of the frontal neck. Puncture of the lateral eye brow or neck is fairly well tolerated apart from rare cases of prolonged bleeding, scar formation that will be difficult to treat cosmetically and infection involving subsequent lymphatic draining pathways through the cheek.

Puncture of the lateral lower wall of the nose can be followed by severe complications, as again like the ear, cartilage is involved that is prone to infection and pressure caused necrosis. Since the nose can be colonised by by staphylococcal organisms this site is particularly susceptible to infections leading to granulomatous perichondritis of the nasal ala. Defects in this region of the face are difficult to reconstruct by locoregional flaps.
One case of staphylococcal endocarditis following nasal piercing has been described.

Suggestions from our point of view :

1. Who does the piercing ?
No statutory regulations exist on body piercing to date. The practise of body piercing remains uncontrolled with no specialist qualification required. The vast majority of piercings are performed by non-medical pactitioners such as jewellers,hairdressers or tattooists. These practitioners and their customers may not fully appreciate the implications of specific damage that is done to different organs in the head and neck region. Standards of sterility should be increased.

2. Informed consent ?
Patients should fully informed about consequences and complications that might occur subsequent to piercings. A written informed consent, including pictures should be developped

3. Studies ?!
The need for studies to statistically document the incidence of piercing complications and habits or age group distributions is obvious.

Tattoing/Body Piercing and Infectious Diseases

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The frequency of tattooing and body piercing is rising in many countries, both in the general population and in population subgroups, such as adolescents and young adults. Not surprisingly, a higher proportion of risk-taking behaviours is observed among those with tattoos and piercings than among those without (Carroll et al 2002; Roberts and Ryan 2002). The infectious disease risks associated with tattooing and piercing have been extensively reviewed (eg. Beerman and Lane 1954; Long and Rickman 1994) and case reports and epidemiological studies (eg. Delage et al 1999; Nishioka et al 2002; 2003) continue to advance scientific knowledge on risk behaviours and transmission (eg. Kao and Chen 2000). Because of the concern regarding the risk of transfusion-transmissible infections (eg. Schreiber et al 1996), a review of the importance of tattooing and body piercing with respect to the occurrence of infectious diseases is timely and will inform health policy, especially with respect to blood donor eligibility.

There is rigorous scientific evidence documenting the association of several transfusion-transmitted infectious diseases and tattooing. These include hepatitis B infection, hepatitis C infection and syphilis (Nishiola and Gyorkos 2001). In addition, evidence is accumulating for other diseases as well (most notably, HIV infection). Epidemiological research provides a rigorous methodological framework in which to assess the nature and magnitude of the association between tattooing and infectious diseases. The dynamic nature of both disease outcomes and exposures necessitates a periodic re-evaluation of the association between risk behaviours such as tattoos and the occurrence of infectious diseases. We therefore sought to update information on tattoos and infectious diseases of local public health concern in Brazil (ie. hepatitis B infection, hepatitis C infection, HIV infection, syphilis and Chagas' disease) and to provide additional evidence for current discussions taking place on a more global scale, especially those focussing on the screening and eligibility of blood donors. We summarize below the cross-sectional study we conducted in Brazil between 1998 and 2000 (Nishioka et al 2002a; 2003).

Briefly, following ethics approval from both Canada and Brazil, one hospital (the Hospital de Clinicas da Universidade Federal de Uberlandia) in Uberlandia, Brazil was chosen as the study site. Inclusion criteria among the exposed (tattooed) group were: older than 18 years of age, admitted to the hospital for at least 12 hours or visiting the outpatient department or the blood bank, having at least one ornamental tattoo, and consented to participate. Inclusion criteria for the non-exposed (non-tattooed) group were the same except for the presence of an ornamental tattoo. In addition, the non-exposed group was matched to the exposed group on the basis of age (+/- 10 years), sex and presenting complaint. The single exclusion criterion was the presence of any intellectual or physical condition that made it impossible to provide information. Recruitment proceeded from April 1998 to January 2000. In general, the matching between the exposed and the non-exposed was completed within two weeks.

The outcomes of interest were serological markers for five infections obtained by venipuncture: HBV (HBsAg and anti-HBc by ELISA), HCV (anti-HCV by ELISA), HIV (anti-HIV by third generation ELISA), syphilis (VDRL) and Chagas' disease (IFA or ELISA). The exposures of interest were ascertained via an interviewer-administered questionnaire. The primary exposure

of interest was the presence of at least one ornamental tattoo. Additional details on tattooing included their number, location on the body, design, whether done professionally or not, and whether the needles used were disposable or not. Other covariates included: drug use, sexual orientation, alcohol intake, smoking, schooling, color, use of earrings or other types of piercings, history of blood transfusion, history of blood donation, history of a sexually transmitted infection, and history of arrest or incarceration.

Sample size calculations determined that a sample size of 310 (155 exposed and 155 non-exposed) would be sufficient to detect risk ratios of 4 and 2.5 for a prevalence in outcome of 3% and 10%, respectively. Statistical analyses were performed for each outcome separately and then for at least one of the outcomes. Results of univariate analyses informed the development of multivariate models (unconditional logistic regression). Where correlation between variables was high, one of the variables was selected to be included in the model. All analyses were carried out using SAS programs (SAS Institute, Cary, NC, USA).

A total of 345 (182 tattooed and 163 non-tattooed) subjects were recruited. The following prevalences were obtained: HBV 15.4%, HCV 9.9%, HIV 8.4%, syphilis 5.0% and Chagas' disease 2.9%. The prevalences in the tattooed group and the non-tattooed group as well as crude and adjusted odds ratios are shown in Table 1. All prevalences except for Chagas' disease were higher in the tattooed group compared to the non-tattooed group. Statistically significant associations were found between tattoos and HCV (OR= 6.41; 95%CI: 1.29, 31.84), and between tattoos and having at least one test positive for any one disease (OR= 2.05; 95%CI: 1.11, 3.81). No other statistically significant associations were found although odds ratios for HBV, HIV and syphilis infections were above one. Despite some large (adjusted) odds ratios (eg. 6.46 for HIV infection), the large confidence intervals indicate that the sample size of the study may not have provided the opportunity for sufficient power to more precisely estimate the odds ratios. Thus, these results are suggestive of additional associations which require corroboration in larger studies.

Among the tattooed, further analyses were undertaken to explore selected details of tattoos and their association with the disease outcomes (Tables 2 and 3).

These results suggest that certain types of tattoos are associated with one or more of the study infections while some are not. These observations need to be replicated in other countries. They may provide useful evidence when tattooing criteria are considered in blood donors (Nishioka *et al* 2002b). In particular, using tattoo features within the screening process may provide a suitable substitute for obtaining self-reported information on other risky behaviours - which may be more prone to reporting bias. Further research focusing on blood donation should include a review of the infectious risk in different population subgroups in different countries, a review of screening and deferral options and the cost-effectiveness of these options. This cumulative evidence can then inform appropriate health policies and services.

Table 1. Crude and adjusted odds ratios for the association between tattoos and transfusion-transmitted diseases (n = 345), in a hospital-based population (outpatients, in-patients and blood donors) in Uberlandia, Brazil (2000)

Outcome	Tattoo(n=182) % sero +	No tattoo (n=163) % sero+	Crude Odds Ratio	(95% CI)	Adjusted Odds Ratio	(95% CI)
Hepatitis B	21.4	8.6	2.90	(1.51, 5.57)	1.90	(0.94, 3.83)
Hepatitis C	17.8	1.2	17.41	(4.10, 73.90)	6.41	(1.29, 31.84)
HIV infection	15.5	0.6	29.65	(3.99, 220.57)	6.46	(0.72, 58.22)
Syphilis	6.8	3.1	2.30	(0.79, 6.67)	1.25	(0.37, 4.18)
Chagas' disease	1.1	4.9	0.21	(0.05, 1.02)	0.12	(0.01, 1.05)
At least one marker for HBV, HCV, or HIV	32.4	10.4	4.12	(1.77, 5.05)	2.04	(0.99, 4.21)
At least one marker for any disease	35.6	15.3	2.99	(1.71, 5.26)	2.05	(1.11, 3.81)

Table 2. Positive associations between tattoo location and design and HBV, HCV, HIV and syphilis infections.

Exposure	Outcome	Odds ratio	95% CI
Tattoo location			
Chest	HBV	5.00	2.19, 11.41
Forearm	HCV	4.14	1.84, 9.26
Forearm	HIV	4.24	1.62, 11.13
Leg	HIV	3.42	1.35, 8.69
Head	syphilis	32.80	6.31, 170.55
Tattoo design			
Dragon	HBV	5.02	1.59, 15.82
Sun	HCV	2.71	1.05, 6.91
Snake	HIV	4.70	1.51, 14.52
Heart	syphilis	5.00	1.09, 21.85
Unicorn	syphilis	18.00	4.78, 67.79

Table 3. Positive associations between other tattoo features and HBV, HCV, HIV and syphilis infections.

Outcome	Crude Odds Ratio	95% CI	Adjusted Odds Ratio	95% CI
Nonprofesssional (vs professional) tattoos				
At least one disease	3.30	1.70, 6.41	3.25	1.39, 7.59
Two tattoos (vs 1 tattoo)				
HBV	2.83	1.12, 7.14	2.04	1.80, 9.97
Three or more tattoos (vs 1 tattoo)				
HBV	4.24	0.76, 5.50	3.48	1.41, 8.58
At least one disease	5.69	2.58, 12.39	2.98	1.03, 8.64
Did not know needle status				
HCV	3.29	0.98, 11.04	6.01	1.05, 34.59

References:

Beerman H, Lane RAG. Tattoo: a survey of the literature concerning the medical complications of tattooing. Am J Med Sci 1954;227:444-465.

Carroll ST, Riffenburgh RH, Roberts T, Myhre EB. Tattoos and body piercings as indicators of adolescent risk-taking behaviors. Pediatrics 2002;109:1021-1027.

Delage G, Infante-Rivard C, Chiavetta J-A, Willems B, Pi D, Fast M. Risk factors for acquisition of hepatitis C virus infection in blood donors: Results of a case-control study. Gastroenterol 1999;116:893-899.

Kao J-H, Chen D-S. Transmission of hepatitis C virus in Asia: past and present perspectives. J Gastroenterol Hepatol 2000;15 (Suppl):E91-E96.

Long GE, Rickman LS. Infectious complications of tattoos. Clin Infect Dis 1994;18:610-619.

Nishioka S de A, Gyorkos TW, Joseph L, Collet J-P, MacLean JD. Tattooing and transfusion-transmitted diseases in Brazil: A hospital-based cross-sectional matched study. European J Epidemiol 2003 (in press)

Nishioka S de A, Gyorkos TW, Joseph L, Collet J-P, MacLean JD. Tatooing and risk for transfusion-transmitted diseases: the role of the type, number and design of the tattoos, and the conditions in which they were performed. Epidemiol Infect 2002a;128:63-71.

Nishioka S de A, Gyorkos TW, MacLean JD. Tattoos and transfusion-transmitted disease risk: Implications for the screening of blood donors in Brazil. Brazilian J Infect Dis 2002b;6:172-180.

Nishioka S de A, Gyorkos TW. Tattoos as risk factors for transfusion-transmitted diseases. Int J Infect Dis 2001;5:27-34.

Roberts TA, Ryan SA. Tattooing and high-risk behavior in adolescents. Pediatrics 2002;110:1058-1063.

Schreiber GB, Busch MP, Kleinman SH, Korelitz JJ. The risk of transfusion-transmitted viral infections. New Engl J Med 1996;334:1685-1690.

Overview of allergic reactions resulting from tattoos

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Definition

According to the Encyclopaedia Britannica, a tattoo is a permanent mark or design made on the body by the introduction of pigment through ruptures in the skin – certainly a description that is true for so-called permanent tattoos. But this definition seems invalid for temporary tattoos, where the pigment/dye is applied onto the skin, with the help of a plaster or a brush. The latter procedure should probably be excluded from the tattoo legislation, since it seems to be covered by the Cosmetics Regulation and causes different problems. But the terms are frequently used synonymously; thus if one searches the literature (Pubmed/National Library of Medicine/www.pubmed.org) for the terms "tattoo and allergy", out of the 30 articles dating from 2000 to 2003, at least 19 relate to temporary tattoos (and most of the rest to the problem of tattoo removal).

According to the Austrian legislation regarding tattooing, §1 (2) states: " Tattooing according to this decree is the insertion of pigments into the human skin or mucosa for decorative purposes. This also includes the application of permanent-make-up" [1]; thus again, application of dyes onto the skin is excluded.

Introduction

Dye mixtures containing many different substances are applied (in)to the skin deliberately for religious purposes, social recognition or fun (decorative skin paintings); for medical purposes (prior to radiotherapy); occupationally (mining industry) and traumatically (gunpowder, quartz powder, etc.). Different classes of tattoo-asscociated dermopathies can be distinguished[2]:

- allergic, granulomatous, lichenoid reactions
- inoculation, infection (hepatitis, HIV, lepra, etc.)
- coincidental lesions, Koebner response
- reactions resulting from tattoo removal (allergic or non-allergic inflammation, scars and keloids, hypopigmentation)

This article will deal with non-infectious skin problems in association with decorative skin paintings only; the main focus is placed on tattoos applied by needles, but temporary tattoos are not excluded because of their current importance in the discussion.

Skin problems after application of tattoos

The cutaneous incorporation of ornamental tattoo dyes (and accidental dirt particles) is not an inert process. Even years later, non-specific macrophage activation as well as discrete (histological) inflammatory changes in an attempt to degrade the foreign material can still be documented[3]. This may result in clinically relevant allergic or non-allergic inflammatory processes. Various types of skin reactions have been reported in tattooed areas. The time interval before the reaction appeares varies between a few days and several years. Allergic contact dermatitis was in most cases related to metal salts (in permanent tattoos) and to (henna)-p-phenylenediamine (in temporary tattoos). Lymphoid and granulomatous reactions, even sarcoidosis, pseudolymphoma and lymphadenosis benigna cutis have also been reported, mainly in response to red colours. Reactions to black colours seemed to be rare previously; this has changed with the introduction of "black henna".

Allergic reactions

According to text books on Contact dermatitis, "allergic reactions to metal salts used for tattooing are not infrequent"[4]. This is however not the general opinion, although absolute numbers (allergic reactions in treated persons) do not exist. Concurrent, very few allergic problems haven been reported from customers in Denmark[5]. Such reactions have been reported to produce various types of reactions in tattooed areas in sensitized individuals[6].

Mercury (mercury sulfide / cinnabar and vermillion): In the form of red cinnabar in a tattoo, mercury may produce itching, swelling, and eczematous and granulomatous reactions in sensitized individuals. Often the red tattoo areas are quiescent for many years, and then suddenly an acute allergic reaction occurs. In one instance, the red portions of a tattoo began to itch and swell following intradermal injections of a vaccine containing thimerosal, an orga-nic mercurial compound used as a preservative[7]. In another instance, an itchy swelling of the red areas occurred in an individual who ingested calomel (mercurous chloride) and showed a positive patch-test reaction to ammoniated mercury and mercurochrome. A generalized eczematous eruption resulted from laceration of a tattoo in a mercury-sensitive patient[8].

Chromium oxide powder is one of the principal green dyes used in tattooing[4]. This powder is known as chrome green or Casalic green, and it is very stable, resistant to acids, and insoluble in water, alcohol, and acetone. Guignet´s green is a closely related green pigment that contains a mixture of hydrous chromium oxides. These chrome salts are probably not the sensitizers, but it is suspected that the cause is hexavalent chrome, which is an impurity.

Apparently these chrome particles may lie latent in tattoos for 20 years or more and then suddenly produce an allergic eczematous dermatitis[4]. Chromium sesquioxide (viridian), emerald green, may also be used in tattoos.

Cobalt, in the form of cobalt blue (azure blue and cobaltous aluminate), has been reported as causing a sarcoidal type of allergic reaction in areas in which it was used as a light blue tattoo pigment[9]. Patch testing with cobalt evoked a positive reaction, and cobalt was also detected in the pathologically altered parts of the tattoo. A tattoo test with cobalt blue elicited an inflammatory tissue reaction.

Cadmium, in the form of cadmium sulfide, is sometimes used as a yellow pigment in tattoos, and these areas may itch and swell on exposure to sunlight. Experimental areas tattooed with cadmium sulfide showed an erythematous reaction only when exposed to light of 3800, 4000, and 4500 A wavelengths[10]. The swelling reaction to cadmium sulfide in yellow tattoos seems to be phototoxic. Occasionally commercial red tattoo pigment shows traces of cadmium sulfide, which may induce a photosensitive reaction after exposure to sun[4].

Other colors used for tattooing, that may or may not contain metals[4]:

- Black: logwood (containing chrome), black waterproof ink (containing charcoal suspended in ammoniacal solution containing phenol), carbon ioxide;
- Brown: Venetian red (hydrate of ferric oxide) and cadmium salts, ferric sulfate;
- White: Titanium or zinc oxide and lead carbonate;
- Violet: manganese violet;
- Purple: manganese oxide;
- Flesh: iron oxide;
- Red: aside from mercury sulfide, non-metallic red colors in tattoos may include an organic pigment (organic lake), carmine (dried insect bodies / cochinilla), cadmium red (selenide) and sienna;
- Green: Chlorinated copper (phthalo-cyanine) may be employed in green tattoos; copper salts mixed with azo dyes;
- Blue: In some blue tattoos copper phthalocyanine may be used. Indigo is occasionally added.

An excellent survey of pigments used for tattooing is summarized in a paper by the *Danish Environmental Protection Agency*[5].

"Temporary" henna tattoo and para-phenylenediamine (PPD)

Skin painting using henna is part of religious, social and ritualistic traditions in many parts of the world. Henna is one of the most frequently used dyes[11]. Common red henna (Lawsonia inermis family *Lythraceae*) is prepared by powdering the dried leaves and stems of *Lawsonia*, a shrub cultivated in India, North America, North Africa and Sri Lanka. The grey powder is mixed with water to prepare a thick paste that is left on the skin for 5 min to 24 h. The active staining ingredient is a naphtoquinone (lawsone, 2-hydroxy-1,4-naphtoquinone), being responsible for a red-brown stain. Henna staining is known to be temporary and may last a few weeks. Despite their ubiquitous use, contact sensitization to skin paintings has been reported rarely. This is probably due to the fact that the sensitizing potential of henna (lawsone) is low; some single case reports indicate sensitization by lawsone[rev. in 11], but most of the reactions are supposed to be caused by contaminating ingredients. PPD (dark brown dye) or indigo blue (blue-black dye) are nowadays frequently added to darken the lawsone stain[11].

In the past 5 years, numerous reports from all parts of the world, but mostly originating in tattooes applied during a vacation around the mediterannean sea, demonstrate a worrying trend towards the use of PPD in "henna" dye and tattoos (black Henna t., temporary t., streetside t., non-permanent t., paint-on t., labile t.), with subsequent PPD sensitization. The patients present their reaction frequently only 5 days after painting, a relatively rapid onset for contact sensitization. This might be an indication for active sensitization by the Henna-PPD tattoo, a phenomenon that is well known for PPD when skin testing[12]. The extremely high concentration of PPD in these paintings may be responsible for this strong effect; concentrations of more than 15% (as detected by HPLC) have been reported[13]. In most instances, children are affected; this poses a health hazard with potential long-term consequences: Some people with this allergy also have trouble with sulfa drugs[14] and sunscreens based on PABA[4], others may have trouble with anesthetics like benzocaine[14]. These individuals will be severely disadvantaged when they are older and want to use hair dyes[11]. And sensitization of children to PPD has even important consequences for their future choice of occupations, e.g. hairdressing[15]. PPD/Henna-induced tattoo dermatitis may also be observed in persons with primary sensitization to clothing dyes[16].

These delayed-type allergic reactions to PPD, in some cases associated with skin necrosis and scarring, may frequently be followed by long-lasting hypopigmentation[15]. Mechanisms like photoleukomelanoderma due to pigment blockade, reduction of melanin synthesis, selective destruction of melanocytes, as well as Koebner-induced vitiligo have been postulated.

Immediate type-reactions, manifesting with extensive urticarial lesions and erythema multiforme-like generalized reactions can be attributed to the PPD-content[15].

Concomitant fragrance sensitization induced by "henna"-tattoos was also published[17].
The problems associated with these temporary tattoos should be covered by the cosmetics regulation. PPD is considered so hazardous that its use in hair dyes was banned in Germany, France, Denmark, and Sweden. The ban had to be dropped according to the Cosmetics Directive of the EU. Currently its incorporation in cosmetic products is allowed in the EU to a maximum concentration of 6%. But this concentration is exceeded by far in many of the streetside temporary tattoos, and thus "officially not allowed". But controls are scarce.

Non-eczematous skin reactions

Granulomatous reactions have been described being caused by metallic salts in tattoo pigments. Mercury, chromium, cobalt and cadmium[4], but also aluminium[18] are known causative agents. An unknown substance in purple tattoo pigment has also been reported to cause such a reaction[19]. Granulamatous reactions may be preceeded by or associated with eczematous reactions. The lesion is usually non-itchy. Biopsy shows typical granulomas. These patients usually have positive patch test reactions to the respective metallic salts[19].

Lichenoid reactions have been described in association with a permanent red tattoo, where nickel was suspected to play an etiologic role[20]. Such reaction types have also been evoked by temporary tattoos[21]. Some tattoo reactions may mimick morphea histologically[22].

Pseudolymphomas and lymphadenosis benigna cutis as a result of tattoos have occasionally been reported in the literature. They occur mainly in reddish areas (mainly cinnabar), but have also been observed in blue (cobalt salts) and green (chrome salts) areas[rev. in 23]. Granulomatous tattoo reactions can also be a manifestation of systemic sarcoidosis[24].

Urticaria in a tattooed patient was attributed to hypersensitivity to cobalt chloride contained in the blue ink used for the tattoo. The patch test was positive to cobalt chloride only; cobalt was thus believed to be responsible for contact urticaria through a non-immunological mechanism. This argumentation however seems quite arbitrary[25].

Needles

There is one single case report in the literature (Pubmed) in the past 17 years and a few in the older literature indicating that nickel release from acupuncture needles caused contact eczema[26]. In contrast to piercing procedures, where nickel release from the piercing products may bear considerable importance regarding elicitation and even induction of nickel allergy. This point seems to be of minor importance regarding tattooing. But for general precaution, only needles that do not release any nickel should be used.

Treatment of intolerance reactions

Many times, acute erythematous reactions subside after treatment with topical corticosteroids, although the allergen remains in the tissue[27]. Thus skin reactions after tattooing do not necessarily require surgical removal of the responsible agent in all instances. Induction of local clinical tolerance is hypothesized to be attributable to modification of the pigments allergenicity. And in fact, some authors report that tattoos occasionally become inflamed and pruritic only to clear without any therapy[28]. But persistent eczema may necessitate total excision of the tattoos[29].

An allergic reaction in a red tattoo was successfully treated with the Nd:YAG laser[30].
Intralesional steroids and excision have been reported in the literature as treatment options for pseudolymphomas associated with tattoos. Treatment with laser may not remove the pigment completely and is therefore not recommended[31]. Since evolution of a pseudolymphoma into a malignant lymphoma can never be excluded, surgical excision or – if other treatment modalities are chosen – regular follow-up visits are advised[23].

Problems associated with removal of tattoos

Methods of tattoo removal include dermabrasion, skin grafts or surgery, and laser surgery. All such methods may leave scars or keloids.

Laser treatment of a tattoo may cause local and systemic delayed as well as immediate-type hypersensitivity reactions[32]. A 26-year-old female with two multicoloured 6-year-old tattoos (placed at different times), that had remained entirely asymptomatic since placement, experienced no untoward effects when the Tasmanian devil was removed by the help of a Nd:YAG laser. However, with treatment of the Mardi Gras mask tattoo, she repeatedly developed extensive urticarial reactions. Prophylactic treatment suppressed all subsequent reactions during laser treatment[32]. Two patients without previous histories of skin disease experienced localized as well as widespread allergic reactions after treatment with two Q-switched lasers (ruby and Nd-YAG)[33]. This laser type targets intracellular tattoo pigment causing rapid thermal expansion that fragments pigment-containing cells and causes the pigment to become extracellular. This extracellular pigment is then recognized by the immune system as foreign.

CO2 laser treatment was reported to cause a local tattoo allergic reaction becoming generalized[34]. And some experienced laser experts warn, that laser removal of iron and

titanium-containing pigments might induce granulomatous reactions – and is thus contraindicated.

Current legislation (in Austria)

§4 (2) of the Austrian decree states that "one must use exclusively sterile devices, dyes, and substances with defined lot numbers, and there must not be any defined health risks associated with their use. Dyes and substances, that come into contact with the body, must not exert … any dangerous features and must not release any dangerous substances upon correct usage. The devices, pigments/dyes and substances must exclusively be bought from companies that are authorized to market them in Austria"[1].

This is an excellent piece of work; but it is totally ignored by the tattoo "artists". If it were executed, no allergic reactions would occur any more.

Summary

Allergic reactions to pigments used for permanent tattoos do occur occasionally; no reliable data exist regarding the frequency, but according to considerable experience, the numbers seem to be low. The literature mostly consists of single case reports. Testing for the causative agent is frequently unproductive, since the ingredients are usually unknown. Regarding the literature data, some reports conclude from test results on the possible causative agent, but the relevance is not proven in many cases.

It is essential for the allergist to know the contents of the substances applied in order to be able to plan adequate testing procedures. Ignorance not to test but just to remove the tattoo in case of problems is however acceptable, due to the lack of therapeutic consequences.

Tattoos are increasingly popular in today´s society, especially with the advent of laser tattoo removal. As a result, observed adverse reactions within tattoos are likely to become more frequent, if there is no regulation on the procedure of application, the employed inks, and the techniques used for their removal. It is worrying, that tattoo salons are more and more advertising and offering tattoo removal.

Concluding remarks

Size of the problem

Allergic reactions resulting from permanent tattoos are infrequent. Absolute numbers are not known, but clinical experience does not indicate a major problem.

This is in contrast to the high numbers of problems associated with temporary Henna tattoos.

Options for improved monitoring of health effects

Since most (almost all) tattoos are being performed under questionable circumstances, legislative measures – "allergic health effects must be reported to a certain institution" – won´t hardly be successful. In order to get better data, cooperation with certain tattooists on a friendly/cooperative basis would probably be more helpful. For this purpose, no legislation is necessary. The voluntary approach seems more promising.

For this purpose it would be extremely helpful if one could offer the potentially affected persons some incentives such as

- guaranteed anonymity
- free medical advice, testing and removal of the tattoo
- a small financial help.

Need for regulation

There is a need for regulation, regarding

- the persons performing the tattoos

- the working place
- the performance (information before, realization, …)
- materials (needles, inks, devices, …)
- waste removal,
- tattoo removal

But: as mentioned above, there exists an excellent regulation in Austria, “but nobody cares”.

R&D needs

We need better data (see above)
Safe procedures have to be defined.
Safe products must be defined.
For all these purposes, a trusting cooperation with tattooists is essential.

References

1. Bundesgesetzblatt für die Republik Österreich. 141. Verordnung über Ausübungsregeln für das Piercen und Tätowieren durch Kosmetik(Schönheitspflege)-Gewerbetreibende. 14.2.2003 (www.bgbl.at)
2. Jacob CI: Tattoo-associated dermatoses: a case report and review of the literature, Dermatologic Surgery 2002; 28:962-5
3. Muller KM; Schmitz I; Hupe-Norenberg L: Reaction patterns to cutaneous particulate and ornamental tattoos, Pathologe 2002; 23:46-53
4. Fisher´s Contact Dermatitis, 4th ed. Rietschel RL; Fowler JF Jr. Williams & Wilkins, 1995
5. Survey of chemical compounds in consumer products (2-2002). Investigation of pigments in tattoo colours. Lundsgaard J, Chemtox A/S. Danish Environmental Protection Agency
6. Levy J; Sewell M; Goldstein N: A short history of tattooing, J Derm Surg Oncol 1979; 5: 851-4
7. Sulzberger MB; Tolmach JA: Allergic flare-up reactions in red tattooing: Observations on development and subsidence of mercurial sensitivity and on allergic granulomatous and sarcoid reactions, Hautarzt 1959; 10:110-5
8. Biro L; Klein WP: Unusual complications of mercurial (cinnabar) tattoo, Arch Dermatol 1967; 96:2-4
9. Bjoernber A: Allergic reaction to cobalt in light blue tattoo markings, Acta Derm Venereol 1961; 41:259-61
10. Bjoernber A: Reactions to light in yellow tattoos from cadmium sulfide, Arch Dermatol 1963; 88:267-70
11. Nikkels AF; Henry F; Pierard GE: Allergic reactions to decorative skin paintings, JEADV 2001; 15:140-2
12. Skog E; Sensitization to p-phenylenediamine, Arch Dermatol 1965; 92:276-80
13. Brancaccio RR; Brown LH; Chang YT; Fogelman JP; Mafong EA; Cohen DE: Identification and quantification of para-phenylenediamine in a temporary black henna tattoo, Am J Contact Dermat 2002; 13:15-8
14. Arroyo MP: Black henna tattoo reaction in a person with sulfonamide and benzocaine drug allergies, J Am Acad Dermatol 2003; 48:301-2
15. Jappe U; Hausen BJ; Petzoldt D: Erythema-multiforme-like eruption and depigmentation following allergic contact dermatitis from a paint-on henna tattoo, due to para-phenylenediamine contact hypersensitivity, Contact Dermatitis 2001; 45:249-50
16. Simpson-Dent SL; Hunt SH; Davison SC; Wakelin SH: Tattoo dermatitis from primary sensitization to clothing dyes, Contact Dermatitis 2001; 45:248
17. Temesvari E; Podanyi B; Ponyai G; Nemeth I: Fragrance sensitization caused by temporary henna tattoo, Contact Dermatitis 2002; 47:240
18. McFadden N; Lyberg T; Hensten-Pettersen A: Aluminium-induced granulomas in a tattoo, J Am Acad Dermatol 1989; 20:903-8
19. Schwartz RA; Mathias CGT; Miller CH; Rojas-Corona R; Lamber WC: Granulomatous reaction to purple tattoo pigment, Contact Dermatitis 1959; 16:198-202
20. Corazza M; Zampino MR; Montanari A; Pagnoni A; Virgili A: Lichenoid reaction from a permanent red tattoo: has nickel a possible aetiologic role? Contact Dermatitis 2002; 46:114-5
21. Rubegni P; Fimiani M; de Aloe G; Andreassi L: Lichenoid reaction to temporary tattoo, Contact Dermatitis 2000; 42:117-8
22. Mahalingam M; Kim E; Bhawan J: Morphea-like tattoo reaction, Am J Dermatolopathol 2002; 24:392-5
23. Kahofer P; El Shabrawi-Caelen L; Horn M; Kern Th; Smolle J: Pseudolymphoma occurring in a tattoo, Eur J Dermatol 2003; 23:209-12
24. Sowden JM; Cartwright PH, Smith AG; Hiley C; Slater DN: Sarcoidosis presenting with a granulomatous reaction confined to red tattoos, Clin Exp Dermatol 1992; 17:446-8
25. Bagnato GF; De Pasquale R; Giacobbe O; Chirico G; Riccardi L; Gangemi S; Purello d'Ambrosio F: Urticaria in a tattooed patient, Allergol Immunopathol 1999; 27:32-3
26. Morimoto M; Kawata K; Tsuchiya N; Murakami H; Kura M; Koga Y: A case of acupuncture needle dermatitis, Masui 2000; 49:887-9
27. Treudler R; Tebbe B; Krengel S; Orfanos CE: Allergic contact dermatitis from black tattoo, Contact Dermatitis 1997; 37:295
28. Scutt R; Gotch C: The mystery of tattooing, skin deep, London: Peter Davies, 1974
29. Lowenthal LJA: Reactions in green tattoos, Arch Dermatol 1960; 82:237

30. Dave R; Mahaffey PJ: Successful treatment of an allergic reaction in a red tattoo with the Nd-Y laser, Br J Plast Surg 2002; 55:456
31. Zelickson BD; Mehregan DA; Zarrin AA; Coles C; Hartwig P; Olson S; Leaf-Davis J: Clinical, histologic and ultrastructural evaluation of tattoos treated with three laser systems, Laser Surg Med 15; 364-72
32. England RW; Vogel P; Hagan L: Immediate cutaneous hypersensitivity after treatment of tattoo with Nd:YAG laser: a case report and review of the literature, Ann Allergy Asthma Immunol 2002; 89:215-7
33. Ashinoff R; Levine VJ; Soter NA: Allergic reactions to tattoo pigment after laser treatment, Dermatol Surg 1995; 21:291-4
34. Zemtsov A; Wilson L: CO2 laser treatment causes local tattoo allergic reaction to become generalized, Acta Derm Venereol. 1997; 77:497-9

Hazards and Long term risks of pseudo-tattoos (skin paints) with “black henna”

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Skin painting (pseudo-tattooing) is traditionally performed in Muslim or Hindu populations. For a few years, the vogue of transient tattoos has dramatically increased, especially in tourist areas. Instead of henna of vegetal compounds used by “classical” painters, the artists frequently use hair dye preparations, exposing the customers to several adverse reactions. Several publications have reported allergic contact dermatitis, induced or revealed by the sensitizing components of such inadequately used preparations. Skin paints are frequently achieved in young people, and even in children. In the following recently published case reports, we present 9 patients, of 7 presented different side-effects due to skin paints performed with “black henna”.

Case Reports

CASE N°1

A 24-year-old man was referred in July 2000, for refractory atopic dermatitis. Patch tests were realized with with the revised ICDRG series, our additional series and other possibly relevant allergens. Patch tests removed after 48 hours were quoted at D2 and D3 as recommended by the ICDRG. They showed a +/++ reaction only to para-phenylenediamine (PPD) 1% pet. Looking for patch test relevance revealed no usual contact with sources of PPD or related allergens, excepted an acute dermatitis after skin paint with “black henna” realized 3 years ago on the Riviera.

Case n°2

A 40-year-old man consulted in September 2000, for itching lesion of his shoulders. During a touristy travel in Thailand, a skin paint was stained on his right shoulder with “black ink”. This pseudo-tattoo representing a dolphin was paid around 1.5 € and progressively disappeared within 10 days. Then, the same artist applied a second dolphin on patient’s left shoulder. Fours days later, the second tattoo became strongly eczematous with itching, inflammatory oedema and vesicles. In the same time, flare-up occurred on the first tattoo, which became increasingly itching, erythematous and oedematous. Patch tests were realized later with the same series as in the first report, the dying components of the hairdressers' series, and the dyes of the textile and finish series. Positive reactions were observed to PPD, Toluene-2,5-diamine (hair dye) and Disperse Orange 3 (textile dye).

Case n°3

A 26 year-old woman consulted in October 2000 for an acute allergic contact dermatitis of her face, head and neck with cervical adenopathy. Lesions occurred within 24 hours after first hair coloration. Medical interrogatory revealed that the patient had had skin-paint 2 years ago. As she was in Egypt, she had pseudo-tattoo with “henna” representing a bangle on her right arm. Four weeks after its realization, a flare-up arose, and the dermatitis that progressively disappeared with scaling. Patch tests were done after total recovery with the same allergens as patient n°2. Positive reactions were seen to PPD, *p*-Aminophenol *m*-Aminophenol Toluene-2,5-diamine, 2-Nitro-*p*-phenylenediamine (hair dyes), Disperse Orange 1 and 3, Disperse Yellow 3 and Disperse Red 1 (textile dyes).

CASE N°4
A 12-year-old girl had holidays in Mexico in April 2000. She had skin tattoo on 14th April, and developed a sharply demarcated flare-up over the painted dolphin, at least 10 days after she paint. Lesions were observed 19 days later. Patch testing revealed positive reactions to PPD and Disperse Orange 3.

CASE N°5
A 10 year-old girl did a journey in Tunisia in April 2000. A hairdresser stained a pseudo-tattoo on her right arm with liquid black henna. Within a few minutes, she had a burning sensation that rapidly decreased. Lesions then became swelling and scaling, persisting for 2 months as said the patient's mother. She was referred in October 2000 with a hyperchromic scar on her right arm. Patch tests were performed on both upper back and the tattoo area with PPD 1% pet. As previously reported, they were applied during a short period, here 30 minutes. Readings after 24 and 72 hours were negative.

CASE N°6
This young woman was seen in August 1999. She had skin painting representing a turtle in South of France with black henna in July. Mixture was applied and dried on her skin within 3 hours, and was then removed with a tissue. Within 72 hours, she developed itching dermatitis, with vesicles that persisted for at least 15 days. Patch tests were not performed.

CASES N°7 AND N°8
A 40-year-old hairdresser consulted in July 2000, for facial melasma. During her holidays in Brittany, she had skin paint on her right shoulder, performed with black henna 7 days ago. Despite a transient dysidrotic palmo-plantar eczema in March 2001, she remained free of symptoms during a one-year follow-up. A 41-year-old woman was referred in June 2001, with onychomycosis. She had had skin paint with "black henna" in Tunisia 2 weeks ago. Four months later, the patient is free of symptoms.

CASE N°9
During her holidays in Tunisia in August 2000, a 21-year-old atopic woman had had one "black henna" skin paint on the dorsum of her foot. A second painting was performed 4 days later to improve the colouring effect and the black paint was removed after 24 h. After 6 additional days, she consulted with dermatitis strictly located under the painted areas that had started 3 days ago. There were no objective signs of allergic contact dermatitis, the painted areas being no pruritic and slightly erythematous, surrounded by thick black scales eliminating the coloured epidermis. Diagnosis was that of a chemical burn, but lack of patch tests could not strictly exclude an associated delayed sensitization.

Discussion

These reports illustrate the consequences and discuss possible hazards due to skin contact with an offending irritant and potentially sensitizing agent. Skin painting (pseudo-tattooing) was mainly performed in Muslims and in Hindus. As for hairs and nails, this process was traditionally realized with henna (*Lawsonia inermis*) powder or other labile vegetal substances. Henna gives a transient auburn to red colour, and admixture of other vegetal extracts like dried powder of indigo plant leaves gives a darker shade. Addition of *para*-phenylenediamine (PPD) or "black powder" to henna is used to speed up the process of hair dyeing and to give a darker brown to black colour, giving a so named "black henna" mixture. Decorating the skin with transient paints has recently become popular in occidental countries, mainly by transient artists or even by consumers themselves.

As hair dying preparations are often basic with pH >10, they can induce caustic chemical burns. Such situation happened in 2 of our patients. Dyschromic scar following burning may then be observed, like in patient n°4.

Many patients likely do not develop symptoms, and without patch testing, nobody knows if patient has become sensitive or not. Further patch test session can however indicate occult sensitization, like in patient n°1.

In some people, allergic contact dermatitis may occur. This phenomenon has been reported worldwide, like in Italia, France, the United-States, Middle East, Asian countries and mainly Egypt. Patients who experience flare-up develop an inflammatory itchy oedema, sharply demarcated and reproducing the paint. Delay for onset of dermatitis is around 1 to 2 weeks, which corresponds to time necessary to induce active sensitization. As they are not worried by dermatitis, some patients are not patch tested. So, the allergic nature of dermatitis and the sensitizing agent remain frequently unknown. In patients formerly sensitized by skin paints, further contacts with identical or cross-allergens will permit elicitation of sensitization. A second skin paint will result in acute allergic dermatitis, sometimes contemporary of the flare-up in a previous painted area. The so elicited dermatitis spreads out of the painted area, is sometimes extensive or even generalized despite use of topical potent corticosteroids, and may require systemic steroids. Erythema-multiforme-like dermatitis has been described. Dyschromic scar can be observed and persistent depigmentation is a possible consequence of acute dermatitis. Hyperpigmentation is possible, mainly in patients with high phototype.
Henna and vegetal extracts commonly used for natural hair dyeing are exceptionally responsible of allergic contact dermatitis. When they have been tested in patients with temporary tattoos, henna powder or henna leaves were exceptionally positive and it is not obvious that henna is the real sensitizer since a positive reaction is sometimes observed to PPD. Although containing a potentially sensitizing agent 2-hydroxy-1,4-naphtoquinone, namely lawsone, natural henna would likely not account for such successive observations. Lawsone was sometimes tested with negative results, although concomitant sensitization remains possible. In most observations, PPD was regarded as the sensitizer and identified as such in black henna preparations. This compound of the diaminobenzenes class, largely utilized in industrial or chemical applications is known as a strong delayed-type skin sensitizer, mainly by the way of hair dying in which it has been used for more than hundred years in hair dying, and fast recognized as a potent cosmetic allergen since 1895 by Cathelineau. Ambulant artists, who claim using henna preparations or even black ink, often use “black henna” (containing PPD) or commercial hair dye preparations, which necessarily contain diaminobenzenes (PPD or derivatives) to produce dark and persistent shade. It is however sometimes possible that the exact sensitizer is not PPD itself but other component(s) of the mixture, PPD acting as a marker of allergy for other diaminobenzenes. In a patient with dermatitis to skin paint and positive to PPD, the authors could not detect PPD in the henna paste that provoked sensitization.

Although PPD and derived diaminobenzenes seem to be the major allergens, concomitant sensitization is possible to other substances contained in hair dyes used as skin painting preparations, like diaminotoluenes and aminophenols. Sensitivities were reported to toluene-2,5-diamine (*p*-toluene-diamine), to *p*-aminophenols, and/or *m*-aminophenol, as a result of co-sensitization. The use of PPD and other diaminobenzenes (*ortho*-, *meta*- and *para*-diaminobenzenes), is allowed in the European Union for hair dyes to a maximum concentration of 6% free-base in the final reconstituted product, and at 10% for diaminotoluenes (28). Their employ is forbidden for dying lashes or eyebrows, and moreover for a direct skin application. In skin painting, concentrations are much higher than allowed, and were up to 15.7 % for PPD in a recent study. Moreover, the lack of oxidizing agent like H_2O_2 into the mixture leads to a prolonged contact with *para*-phenylenediamine monomer or oligomers, which dramatically enhances the risk of active skin sensitization.

Other contacts with aromatic amines may occur with hair dying, triggering acute allergic contact dermatitis after a first dye application. A further contact with PPD can happen during patch testing session performed for another reason. The research of relevance of a positive patch test to PPD has to include previous skin temporary tattoo, which will be very likely if this skin paint has been followed by dermatitis.

Patients can be sensitive to disperse azoic dyes more or less related to PPD. Positive reactions to Disperse Orange 3 and PPD are frequently associated, due to metabolism of this dye degraded into PPD in the skin. Disperse Orange 1, Disperse Red 1, Disperse Red 17 and Disperse Yellow 3 have some structural likeness with PPD, likely after hydrolysis of the azo bond, that could explain positive concomitant reactions. Clinical relevance of such reactions remains questionable, but could be predictive of risk of further allergic contact dermatitis due to some synthetic textiles. Moreover, Disperse Red 17 and Disperse Orange 3 may be also used in hair dyes. On the contrary, sensitization to Disperse Blue 106 and/or 124, the most currently positive textile dyes, is unlikely since their chemical structure is very different to that of PPD.

Finally, skin paints could induce sensitization in patients occupationally exposed to PPD and derivatives. This could lead to occupational dermatitis with dramatic socio-economical consequences. Contact sensitization can be hazardous in hairdressers, printers, shoemakers, fur workers and leather traders, in chemical industry, rubber and textile production…

Conclusion

Patients and practitioners have to be advertised about this new way of sensitization to PPD, other aromatic amines and aminophenols, due to a misappropriated use of hair dye preparations, mainly by ambulant skin painters. Long term risks include acute allergic dermatitis after a hair dying, allergic contact dermatitis to some azo dyes contained in synthetic fibres, or even occupational dermatitis.

References

Down AMR, Kirkup M. Minerva-photofinish. BMJ 1997;315:1722.

Wakelin SH, Creamer D, Rycroft RJG, White IR, McFaden JP. Contact dermatitis from paraphenylenediamine used in a skin paint. Contact Dermatitis 1998;39:92-93.

Gallo R, Ghigliotti G, Cozzani E, Balestrero S. Contact dermatitis from para-phenylenediamine used as a skin paint: a further case. Contact Dermatitis 1999;40:57.

Lestringant GG, Bener A, Frossard PM. Cutaneous reactions to henna and associated additives. Br J Dermatol 1999;141:598-600.

Castelain M. Allergie à la PPD: une cause inhabituelle de sensibilisation. La Lettre du GERDA 1999;16:57-58.

Le Coz CJ, Lefebvre C, Keller F, Grosshans E. Allergic contact dermatitis caused by skin painting (pseudotattooing) with black henna, a mixture of henna and p-phenylenediamine and its derivatives. Arch Dermatol 2000;136:1515-1517.

Raison-Peyron N, Meunier L, Vian L, Meynadier J. Eczéma de contact à un tatouage labile contenant du henné. Ann Dermatol Venereol 2000;127:1083-1086.

Le Coz CJ, Tromp G. Skin paints (pseudo-tattoos) with « black henna » : hazards and long term risks. Exogenous Dermatology. 2002; 1: 246-252.

Chung W-H, Chang Y-C, yang LJ, Hung SI, Wong WR, Lin JY, Chan HL. Clinicopathologic features of skin reactions to temporary tattoos and analysis of possible causes. Arch Dermatol 2002;138:88-92.

Andersen KE, White IR, Goossens A. Allergens from the standard series. Para-Phenylenediamine. In: Rycroft RJG, Menné T, Frosch PJ, Lepoittevin JP. Textbook of contact dermatitis. 3rd edition, Springer-Verlag, Berlin-Heidelberg, 2001, 640-641.

WenningerJA, Canterbery RC, McEwen Jr GN, Eds. International Cosmetic Ingredient Dictionary and Handbook, 8th edition 2000. Washington DC: The cosmetic, toiletry and fragrance association, 2000.

Gupta BN, Mathur AK, Agarwal C, Singh A. Contact sensitivity to henna. Contact Dermatitis 1986;15:303-304.

Cathelineau M. Accidents provoqués par une teinture pour cheveux, à base de chlorhydrate de paraphénylène-diamine. Bull Soc Fr Dermatol Syphil 1895;6:16-18.

Official Journal of the European Communities. N° L 188/15. Third directive of the Commission, 29th June 1983 (83/341/CEE).

Le Coz CJ. Clothing. In : Textbook of contact dermatitis, 3rd Edition. Rycroft, Menné, Frosch, Lepoittevin (Eds). Springer-Verlag, Berlin-Heidelberg, 2001, pp 725-749.

Lepoittevin JP, Le Coz C. Dictionary of occupational allergens: chemical structures, sources and references In : Handbook of occupational dermatology. Kanerva, Elsner, Wahlberg, Maibach (Eds). Springer Verlag, Berlin-Heidelberg 2000, pp 1125-1191.

Possible Risks of Tattoo Removal Using Laser Therapy

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Abstract

In the EU and the USA there are up to 100 millions of people with tattoos and since a few years the number is clearly increasing. Decorative tattooing is not considered to be a medical treatment and thus, there was no need for a clinical approval for the application of tattoo pigments and consequently no pharmacologic or toxicologic studies. Most of the coloured pigments used are organic compounds (e.g. azo compounds) originally manufactured by the chemical industry to stain consumer goods.

A significant number of people request for removing their tattoos due to an improved self-image or social stigmatization. In contrast to the production of a tattoo its removal from the skin is usually performed by physicians of different fields. Since several years laser light at very high intensities is applied to the skin in order to destroy these tattoo pigments. Due to the high laser intensities the tattoo pigments were heated up to a few hundred Centigrade leading to a cleavage of the pigment molecules. However, the laser induced cleavage of tattoo pigments and consequently its decomposition products has been not investigated in the past.

Recently, experiments of laser induced cleavage of tattoo pigments were performed for the first time by the department of dermatology and the institute of organic chemistry (University of Regensburg). The results showed clearly, that the high laser intensities cleaved azo compounds and an increase of decomposition products such as 2-methyl-5-nitroaniline, 2-5-dichloranilin and 4-nitro-toluol were measured. These products are proven to be toxic or even carcinogenic.

In both, after tattooing or laser treatment, the pigments, unknown admixtures and decomposition products are not only present in the skin but are additionally transported through the blood vessels and the lymphatic system into the human body. It is known that these chemical compounds are present in the lymph nodes at least. However, there are no investigation on that issue so far. Additionally, there is no review on adverse reaction to tattoos and laser treatment in the literature, in particular regarding long-term effects.

Thus, there is a significant need for further research in the field of chemical analysis of tattoo pigments and its laser induced decomposition products. Moreover, research has to be performed regarding the transport and the location of these compounds in the human body.

Introduction

In the western world tattooing is considered to be a sign of self-destructive and rebellious behaviour (1). 100 of millions of people have at least one decorative tattoo. Cosmetic tattoos, in which black, red or flesh-toned pigments are used to mimic eye, lip or eyebrowliner, have also become increasingly popular (2).

In the past, colouring agents were inorganic pigments, whereas for dark-blue amateur tattoos, commercially available ink is still in use. Since tattoo compounds in comparison to cosmetics are not officially controlled, the origin and chemical structure of these colouring agents are

hardly known. Consequently, neither the tattoo artist nor the tattooed patient have any information about the compounds punctured into skin.

Recently, an extensive analysis of a large number of tattoo compounds was performed for the first time (3). Most of the commercially available tattoo compounds are organic pigments, which are classified by their chemical constitution (4). A rough distinction is made between azo and non-azo (polycyclic) pigments.

Generally, the pigments used for tattooing are well tolerated by the skin. Nevertheless, adverse reactions have been published in the literature (5-8). Moreover, several malignant lesions have occurred in tattoos (maybe coincidential) (9-11). Due to an improved self-image or social stigmatization a significant number of people undergo a therapy of tattoo removal, which is predominantly performed using laser therapy. The laser light penetrates the skin and is absorbed selectively by the pigment molecules which are agglomerated inside the dermis to small particles of a few µm in size. According to the principles of selective photothermolysis (12) the laser impulses show a high intensity and an ultrashort pulse duration of a few nano seconds (Q-switched lasers). Due to interaction with laser pulses the shape and the size of the tattoo particles are changed abruptly proven by histology (13).

However, the exact mechanisms of action regarding the destruction of tattoo pigments are still unclear. After being absorbed in the pigment molecule the energy of the laser light is either converted to heat or breaks chemical bonds inside the molecule. The ultrashort heating (~ns) of the pigment may lead to disruption of the pigment. At the same time, the extremely hot surface of the pigment raise a rapid expansion of the surrounding water inducing a negative pressure and a shock wave near to the surface of the pigment. As demonstrated for a suspension of small particles in water these shock waves may help to destroy the tattooed compounds (14).

As a response, a multitude of mechanisms may occur at the same time. Particles pulverize and form a solution of pigment molecules. Molecules can break up, resulting in decomposition products or molecular structure change. Due to fragmentation of the tattoo particles small pigment particles, unknown decomposition products and newly generated chemical compounds may then be removed from the skin via lymphatic system. This mechanism induces a decrease of the colour strength of the pigments responsible for a noticeable clearance of a tattoo.

Since there is no clinical approval of the tattoo pigments punctured into the skin, so far there are no investigations regarding the decomposition products induced by laser therapy of tattoos. In view of the numerous patients treated with these laser systems it is time to start investigations regarding chemical analysis of decomposition products of tattoo pigments induced by high laser intensities.

Moreover, there are no investigations regarding the transport of the tattoo pigments and the decomposition products in the human body. It was detected only by chance that tattoo pigments are present not only in the skin but also in the sentinel lymph nodes.

Tattoo removal

At least 10 % of the millions of tattooed people decide to remove their tattoos. Besides adverse reactions (15-20) of the tattoo pigments itself, the main reasons for removing tattoos are improved self-image or social stigmatization. Traditional modalities are the removal of the pigment-containing skin using salabrasion (21,22), cryosurgery (22,24), surgical excision (25,26) or CO_2 - laser application (27,28). However, these methods induce permanent scarring. Selective photothermolysis has been published (12) for the treatment of vascular lesions. The tattoo pigments have smaller diameters as compared to the vessels. Thus, the application of laser pulses with a high intensity (~ 10^7 W/cm²) and an ultrashort pulse duration of a few nano seconds is necessary to destroy the pigments inside the skin. Using such laser pulses a selective therapy is achieved showing a very low rate of scarring.

Therefore, the removal of tattoos by laser irradiation is a widespread therapy used by physicians of different fields. It is estimated that about 10 % of tattoos are removed by laser therapy leading to millions of patients. Tattoos were treated using different laser systems such as ruby lasers (694 nm), alexandrite lasers (755 nm) or Nd:YAG lasers (532, 1064 nm) at the respective wavelength (29-31). In case the laser light is absorbed in the pigment molecule the corresponding energy is converted predominantly to heat leading to a substantial increase of the temperature of the molecule and consequently inside the pigment particle.

It is well known that azo pigments cleave thermally when a temperature of 280 °C is achieved (32). Since shock waves were produced by pigments after an ultra-short heating (10^{-9} s) using laser pulses it is obvious that high temperatures inside the pigments were achieved (14). Moreover, the laser irradiation of tattoo pigments inside the skin leads to small explosions. Histology of the skin shows small vacuoles in places the pigments particles were located prior to irradiation (13).

In spite of the numerous patients treated with lasers by physicians there are no investigations of the decomposition products of compounds. Recently however, experiments of laser induced cleavage of tattoo pigments – in pigment suspensions - were performed for the first time by the department of dermatology and the institute of organic chemistry (University of Regensburg).

Already with the first two tattoo pigments (Cardinal Red, I8) hazardous decomposition products were found. The heat energy of the absorbed laser light leads to the cleavage of the azo group of the pigment molecules. As a result 2-methyl-5-nitroanilin (2-MNA), 4-nitrotoluol (4-NT), 2-5-dichloroanilin (2,5-DCA), 1-4-dichlorobenzene (1,4-DCB), naphthol-AS or 1-amino-naphthol-AS appeared in the suspension. Due to laser irradiation of the tattoo pigments the concentration of these decomposition products increased significantly. When using Cardinal Red, the concentration of 2-MNA or 4-NT increased 33-fold or 45 fold, respectively. After laser irradiation of I8 the concentration of 2,5-DCA or 1,4-DCB increased 7-fold or 33-fold, respectively.

Conclusion

Since up to hundred million people in the EU and USA have a tattoo and millions of people undergo laser treatment of their tattoos, there is a significant and urgent need of research. The problems are as following:

- The pigments used for tattoos are mostly unknown
- There is no disclosure of admixtures
- There is no clinical approval for tattoo colours
- The amount of pigment inside the skin is unknown
- Therefore, the amount of decomposition products due to laser treatment is unknown
- The transport mechanisms of pigments and its admixtures in the human body is unknown
- The amount of pigments and its admixtures outside the skin is unknown (e.g. lymph nodes, liver)
- There is nothing known about systemic health effects of tattoos, in particular about long-term effects (e.g. cancer)
- There is no review on adverse reactions regarding tattoos and laser treatment, only case reports

In order to quantify and to judge the problems and the health risks of tattoos and laser treatment, the following research is necessary:

- chemical analysis of tattoo colours
- chemical analysis and quantification of laser induced decomposition products
    - in vitro
    - in human skin
- tattoo pigments, admixtures and decomposition products

    - transport mechanisms
    - concentrations outside the skin (e.g. lymph node, liver)
- reports of adverse reactions
- risk assessment of systemic health effects

References

1. Fried RI. The psychodynamics of tattooing A review. Clev Clin Quart 1983; 50:239-242.
2. Kilmer SL, Anderson RR. Clinical use of the Q-switched ruby and the Q-switched Nd:YAG (1064 nm and 532 nm) lasers for treatment of tattoos. J Dermatol Surg Oncol 1993; 19:330-338.
3. Bäumler W, Eibler E, et al., Q-switch laser and tattoo pigments -first results of the chemical and photophysical analysis of 41 compounds, Lasers Surg. Med. 2001
4. Herbst W, Hunger K. Industrial organic pigments. 1995; VCH publishers, New York
5. Goldberg HM. Tattoo allergy (letter) Plast Reconstr Surg 1998; 98:1315-1316.
6. Blumental G, Okun MR, Ponitch JA. Pseudolymphomatous reaction to tattoos. Report of three cases. J Am Acad Dermatol 1982; 6:485-488.
7. Hindson C, Foulds I, Cotterill J. Laser therapy of lichenoid red tattoo reaction (letter) Br J Dermatol 1992; 133:665-666.
8. Clarke J, Black MM. Lichenoid tattoo reactions. Br J Dermatol 1979; 100:451-454.
9. Wiener DA, Scher RK. Basal cell carcinoma arising in a tattoo. Cutis 1987; 39:125-126.
10. Kircik L, Armus S, van-den-Broek H. Malignant melanoma in a tattoo. Int. J. Dermatol. 1993; 32:297-298.
11. Sangueza OP, Yadav S, White CR Jr, Braziel RM. Evolution of B-cell lymphoma from pseudolymphoma. A multidisciplinary approach using histology, immunohistochemistry, and Southern blot analysis. Am J Dermatopathol 1992; 14:408-413.
12. Anderson RR, Parrish JA. Selective photothermolysis: precise microsurgery by selective absorption of pulsed radiation. Science 1983; 220:524-527.
13. Zelickson BD, Mehregan DA, Zarrin AA, Coles C, Hartwig P, Olson S Leaf-Davis J Clinical, histologic, and ultrastructural evaluation of tattoos treated with three laser systems. Lasers Surg Med 1994; 15:364-372.
14. Chen H, Diebold G. Chemical generation of acoustic waves: a giant photoacoustic effect. Science 1995; 270: 963-966.
15. Hindson C, Foulds I, Cotterill J. Laser therapy of lichenoid red tattoo reaction. Br J Dermatol 1992; 133:665-666.
16. Sowden JM, Byrne JP, Smith AG, Hiley C, Suarez V, Wagner B, Slater DN. Red tattoo reactions: X-ray microanalysis and patch-test studies. Br J Dermatol. 1991 Jun;124(6):576-80.
17. Goldberg HM. Tattoo allergy (letter) Plast Reconstr Surg 1998; 98:1315-1316.
18. Nilles M, Eckert F. Pseudolymphoma following tattooing. Hautarzt 1990; 41:236-238.
19. Zinberg M, Heilman E, and Glickman F. Cutaneous pseudolymphoma resulting from a tattoo. Dermatol Surg Oncol 1982; 8:955-958.
20. Blumental G, Okun MR, Ponitch JA. Pseudolymphomatous reaction to tattoos. Report of three cases. J Am Acad Dermatol 1982; 6:485-488.
21. van-der-Velden EM, van-der-Walle HB, Groote AD. Tattoo removal: tannic acid method of Variot. Int J Dermatol 1993; 32:376-380.
22. Strong AM, Jackson IT. The removal of amateur tattoos by salabrasion. Br. J. Dermatol. 1979; 101:693-696.
23. Colver GB, Dawber RP. Tattoo removal using a liquid nitrogen cryospray. Clin Exp Dermatol 1984; 9:364-366.
24. Dvir E, Hirshowitz B. Tattoo removal by cryosurgery. Plast Reconstr Surg 1980; 66:373-379.
25. O'Donnell BP, Mulvaney MJ, James WD, McMarlin SL. Thin tangential excision of tattoos. Dermatol. Surg. 1995; 21:601-603.
26. Kumagai N, Matsuzaki K, Fukushi S, Masayoshi T, Hideo O, Ishida H. Grafting of autologous-cultured epithelium after excision of tattoos. Ann Plast Surg 1994; 33:385-391.
27. Arellano CR, Leopold DA, Shafiroff BB. Tattoo removal: comparative study of six methods in the pig. Plast Reconstr Surg 1982; 70:699-703.
28. Reid R, Muller S. Tattoo removal by CO_2 laser dermabrasion. Plast Reconstr Surg 1980; 65:717-728.
29. Levine VJ, Geronemus RG. Tattoo removal with the Q-switched ruby laser and the Q-switched Nd:YAGlaser: a comparative study. Cutis 1995; 55:291-296.
30. Fitzpatrick RE, Goldman MP. Tattoo removal using the alexandrite laser. Arch Dermatol 1994; 130:1508-1514.
31. Kilmer SL, Lee MS, Grevelink JM, Flotte TJ, Anderson RR. The Q-switched Nd:YAG laser effectively treats tattoos. A controlled, dose-response study. Arch Dermatol 1993; 129:971-978.
32. Az R, Dewald B, Schnaittmann D. Pigment decompositionin polymers in applications at elevated temperatures. Dyes and pigments 1991; 15:1-14.
33. Sayama M et al. Mutagenicities of 2,4-and 2,6-dinitrotoluenes and their reduced products in Salmonella typhimurium nitroreductase- and O-acetyltransferase-overproducing Ames test strains. Mutation Research 1998;420:27-32
34. Huang QG et al. Relationship Between Molecular Structure and Chromosomal Aberrations in In Vitro Human Lymphocytes Induced by Substituted Nitrobenzenes. Bulletin of Environmental Contamination and Toxicology 1996;57:349-353.

From health effects to regulation – The Dutch approach

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In the Netherlands the Ministry of Welfare has made a report[12] about the chemical and microbiological contamination in 2002. The conclusions of the study indicated that there were severe risks to be expected after injection with PMU or tattoo colorants. These risks were sue to microbiological contamination with high levels of micro-organisms and carcinogenic amines. It was also clear that the hygiene working conditions at the shops were bad. Also there was a total lack of knowledge about the colorants at the importers and producers.

The Ministry made an inventory of the importers of tattoo and PMU colorants as well as their branch organisations. Also an inventory was made of the "user" branch organisations (the beauticians and tattooists).

Legal Basis: The Ministry of Welfare decided legislation should be made by the Dutch Government. Waiting for "Brussels" seemed not to be realistic, since several documents (Council of Europe, Germany) were sent to the commission years before without result. The first draft was made within two month. This draft was intensive discussed with all involved national and local governmental bodies, the PMU and tattoo branch organisations, the user organisations (beauticians and tattooists) and consumer organisations. The Ministry ordered the RIVM (the reference institute for the ministry) to do a risk assessment for the (heavy) metals which were found in the colorants. Also a study was discussed about the influence of the removal of tattoo's by lasering.

The first draft included chemical regulations (absence of amines and several azo dyes, absence of Annex IV cosmetic colorants column 2, 3, 4 and CMR substances as listed in the DS). Microbiological all the colorants should be germ-free before injection. Very strict hygienic regulations were made for the tattoo, PMU and Piercing shops, including the sterilisation parameters for the instruments.

The first draft was accepted by all participants. The importers and the branch organisations were very much in favour of strict legislation, since they realise there are a lot of bad shops and importers.

The second draft excluded unfortunately the hygienic regulations. It was foreseen that the implementation of these hygienic regulations would cause an enormous impact on the enforcement system, and that this aspect has to be discussed extensively with the enforcement organisations before. Since the Ministry did not wanted to wait with the legislation, it was decided that the legislation should be in force on a short term, a second draft was made. This second draft was sent to all members of the first meeting. Since it is not to be expected to get a lot of comments, legislation will be in force in 2003. The structure of this legislation is more or less equivalent to the proposed legislation made by the Council of Europe.

[12] H.R. Reus; R. D. van Buuren, Inspectorate for Health Protection North, Ministry of Health: Tattoo and Permanent Make-up Colorants. An exploratory examination of: -Chemical and microbiological composition; - Legislation, Report no ND COS 012, November 2001

Discussions will be organised with all the involved organisations how to deal with the "missing" parameters; risk assessment, hygienic regulations, stability, lasering, long term human effects etc.

Definitions: The draft Dutch legislation includes definitions practices and materials/chemicals for tattooing, PMU and piercing. Sterility is also defined as the absence of viable organisms, including viruses.

Licencing, education and skills: These aspects are not dealt with. Hygiene practices/inspections are handled through local guidelines /jurisdictions[13].

Sterility requirements: The draft Dutch legislation clearly states that the materials and chemicals used in tattooing and piercing practices must be sterile.

Special safety requirements on chemicals/materials used (summary):

- do contain or release aromatic amines and other substances listed in an annexes I and II of the draft text.
- do not contain substances listed in appendix IV of the directive 76/768/EEC of the Council of 27 July 1976 (columns 2-4).

[13] Joan Worp & Albert Boonstra: Hygiënerichtlijnen voor piercen, Afdeling Hygiëne & Preventie, GG&GD, AMSTERDAM, 2003 and
Joan Worp & Albert Boonstra: HYGIËNERICHTLIJNEN VOOR TATOEËREN EN PERMANENT MAKE UP, Afdeling Hygiëne & Preventie, GG&GD, AMSTERDAM, 2003

Experimental Studies to Determine the Safety of Tattoo Pigments

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The full text will be included following the approval of the US FDA.

Session II

Regulatory issues

7th May 2003

Regulatory Review in the EU

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JRC, Ispra

Country	Inventory of existing legislation and ongoing regulatory actions
EU Member States of the Partial Agreement in the Social and Public Health Field[14]	1. Opinion of the Scientific Committee on Cosmetics and Non Food Products (SCCNFP). In its opinion of the 17 February 2000 2. DG SANCO/JRC (see chapter 1: project description) 3. DRAFT RESOLUTION RES AP (2003) 39 ON TATTOOS AND PERMANENT MAKE-UP; COUNCIL OF EUROPE COMMITTEE OF MINISTERS
AUSTRIA[15]	- 111. Bundesgesetzt: Aenderung der Gewerbeordung 1994, des Berufsbildungsgesetzes, des Konsumentenschutzgesetzes, des Neugruendungs-Foerderungs und Arbeitskraefteueberlassungsgesetzes, Wien, 23 Juli 2002 - 139. Verordnung: Zugangsvoraussetzungen für das reglementierte Gewerbe der Kosmetik(Schönheitspflege) - 141. Verordnung über Ausübungsregeln für das Piercen und Tätowieren durch Kosmetik(Schönheitspflege) Gewerbetreibende;BUNDES-GESETZBLATT FÜR DIE REPUBLIK ÖSTERREICH, Jahrgang 2003 Ausgegeben am 14. Februar 2003 Teil II, Bundesministerium für Wirtschaft und Arbeit - 100. Verordnung der Bundesministerin für Arbeit, Gesundheit und Soziales betreffend den Gesundheitsschutz von Spendern und die Qualitätssicherung von Blut und Blut-bestandteilen (Blutspenderverordnung - BSV)
BELGIUM	1. Loi relative à la sécurité des produits et des services , Royaume de Belgique, 9 février 1994(modifiée par les lois du 4 avril 2001 et du 18 décembre 2002 2. Conseil supérieur d'Hygiène Avis du CSH-HGR N° 7674. Recommandations à faire aux tatoueurs et pierceurs en matière d'hygiène de leur instrumentation pour éviter la transmission des maladies infectieuses et surtout virales, Bruxelles, 26 février 2002. 3. Arrêté royal chargeant de missions supplémentaires la Commission de la Sécurité des Consommateurs, Bruxelles, le 28 mars 2003, 4. "Belgian Hygiene Quality Label" Code de bonne pratique pour les professionnels effectuant des piercings et/ou des tatouages, 14 Avril 2003

[14] Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom

[15] See http://www.bgbl.at

DENMARK	1. The only regulation in Denmark regarding tattooing is an old legislation from 1966 stating that it is illegal to tattoo persons under 18 years of age, to tattoo persons on the head, on the hands and on the neck. 2. There's no regulation regarding the chemicals used in piercing in Denmark other than the EU Directive 94/27/EC on prohibition of import and sale of certain nickel-containing products.
FINLAND	
FRANCE	1. Projet de réglementation du tatouage et du perçage en France, Ministère de la santé, de la famille et des personnes handicapées, Paris, le 20 mars 2003, DIRECTION GENERALE DE LA SANTE, Sous-direction des pathologies et de la santé, Bureau SD5C 2. AVIS DU CONSEIL SUPERIEUR D'HYGIENE PUBLIQUE DE FRANCE CONCERNANT LES REGLES DE PROPHYLAXIE DES INFECTIONS POUR LA PRATIQUE « D'ACTES CORPORELS » SANS CARACTERE MEDICAL AVEC EFFRACTION CUTANEE (TATOUAGE, PIERCING, DERMOGRAPHIE, EPILATION PAR ELECTROLYSE, RASAGE), *Séance du 15 septembre 2000*
GERMANY	
GREECE	1. Draft Public Health Regulation: Hygiene rules and opening and operating requirements for tattoo studios, Athens, 5.9.2002, MINISTRY OF HEALTH & WELFAREDIRECTORATE-GENERAL OF HEALTH , DIRECTORATE OF PUBLIC HEALTH, SECTION C 2. Decision no. DY1d/C.P/9780/8.11.2001 by the Minister for Health & Welfare setting up a committee to lay down the rules and opening and operating requirements for tattoo studios and the proposal tabled by the committee 3. Decision no. 18 of 11.3.99 by the 147th plenary session of the Central Health Council, stating that experience is required in order to apply tattoos, whereas their removal is a purely medical procedure.
IRELAND	1. There is no legislation specifically regulating the activities of persons providing tattooing or body piercing services. 2. Health boards are empowered under the Infectious Diseases Regulations, 1981, to carry out an investigation and take necessary measures
ITALY	1. Linee-guida per l'esecuzione di procedure di tatuaggio e piercing in condizioni di sicurezza " n. 2.8/156 of 5.February 1998 and n. 2.8/633 of 16.July 1998 ", Ministero della Salute, on the basis of the mandate of Consiglio Superiore di Sanità (National Health Council)
LUXEMBOURG	There is no specific legislation. Tattoing dyes are considered as general consumer products under the General Product Safety Directive (92/59/EEC)
PORTUGAL	1. There is no specific legislation on piercing or tattoing. Services not covered by any specific legislation are decided by the "Safety Commission". 2. There is a study concerning hairdressers and beauty centres instalment and functioning, including permanent make-up, tattoos and body piercing.

SPAIN	1. In Spain there is no specific regulation on tattoos/piercing practices. These practices are covered to some extend by the "Real Decreto 414/1996" on sanitary products and accessories, which transponds the Council Directive 93/42/CEE. 2. Tattoo/piercing practices handled through local laws/jurisdictions such as the 2001/50519 Decreto 28/2001, de 23 de enero, por el que se establecen las normas sanitarias aplicables a los establecimientos de tatuaje y/o piercing. DEPARTAMENTO DE SANIDAD Y SEGURIDAD SOCIAL (C.A. CATALUÑA)
SWEDEN	1. Sweden has no specific legislation on piercing or tattooing. These activities are covered by the Environmental Code.
THE NETHERLANDS	1. Draft Law 2003 2. Hygiene practices/inspections are handled through local guidelines /jurisdictions such as: Joan Worp & Albert Boonstra : Hygiënerichtlijnen voor piercen, Afdeling Hygiëne & Preventie, GG&GD, AMSTERDAM, 2003 Joan Worp & Albert Boonstra : HYGIËNERICHTLIJNEN VOOR TATOEËREN EN PERMANENT MAKE UP, Afdeling Hygiëne & Preventie, GG&GD, AMSTERDAM, 2003
UK	- The Local Government (Miscellaneous Provisions) Act 1982, London Local Authorities Act 1991, the Greater London Council (General Powers) Act 1981 and the City of Edinburgh District Council Order Confirmation Act 1991 - The Health and Safety at Work etc Act 1974 and associated regulations e.g. the Control of Substances Hazardous to Health Regulations. - Tattooing of Minors Act 1969, - Medicines Act 1968
NORWAY	1.Regulation of the hygiene in connection with hairdressing, skin care, tattooing, piercing and related activities", Ministry of Health 1998. 2. Since 20 October 1999 Norway regulates Tattoo and PMU products as cosmetics products. They are subject to the Norwegian regulation of import, production and sales etc of cosmetic products as of 26 Oct 1995 No 871
SWITZERLAND	In Switzerland there is no legislation related to tattoos / PMU and body piercings currently in force.
USA[16]	1. Tattoo/piercing practices handled through states/local laws/jurisdictions[17] and by the U.S. Office of Safety & Health Administration[18] (OSHA) 2. Sec. 320.100 Ear Piercing Devices (CPG 7124.13)/ Issued: 3/8/77/Reissued: 10/1/80, 9/24/87

[16] See presentation by S. Bell, US FDA in these proceedings

[17] 2002 Health Policy Tracking Service, National Conference of State Legislatures: State Activity: Tattooing and Body Piercing
http://www.stateserv.hpts.org/HPTS2003/Issueb03.nsf/cd5fe07d402115ac852564f0007cb093/126a56b6666ea22885256cfd006950af?OpenDocument

[18] OSHA Bloodborne Pathogen Standard, http://www.osha-slc.gov/OshStd_data/1910_1030.html

CANADA	Pratiques de prévention des infections dans les services personnels : tatouage, perçage des oreilles, perçage corporel et électrolyse, Volume: 25S3 – juillet 1999[19] Alberta Health: Health Standards and Guidelines for Piercing Alberta Health: Health Standards and Guidelines for Tattooing
AUSTRALIA	1. Standards of Practice for Tattooing and Body Piercing Health (Infectious Diseases) Regulations, 1990[20] 2. Infectious Disease Regulations. The Health (Infectious Diseases) Regulations 2001 (incorporating brothels provisions) and the Health (Prescribed Accommodation) Regulations 2001, 15 May 2001[21]

[19] http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/99vol25/25s3/index_f.html
[20] http://www.dhs.vic.gov.au/phd/standardsofpractice/tattooing.htm
[21] http://www.dhs.vic.gov.au/phd/infectious_disease/regulations/index.htm

Progress Report on the preparatory work for the Resolution of the Member States of the Council of Europe Partial Agreement in the Social and Public Health Field

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Norwegian Food Control Authority

The overall aim of the Council of Europe Partial Agreement public health activities is to raise the level of health protection for consumers and food safety in its widest sense. The work priorities of the Committee of Experts on cosmetic products (Partial Agreement) contribute to this overall aim and related to specific issues in the field of cosmetics and related applications.

Background of the Draft Resolution Res AP (2003) 39 on tattoos and permanent make-up

As an extension of their work on the issue of borderline products the Committee of Experts on cosmetic products in 1999 started up an activity on the unresolved safety issue of the products used for tattooing and permanent makeup (PMU).

The basis for the intiation of the work was a survey presented to the Committee showing that in Norway there seemed to be widespread tattooing use of organic colorants many of which are not allowed *on* the skin in the form of cosmetics ingredients. It was assumed that this was the case also in the other Council of Europe Partial Agreement Member States.

On 17 February 2000 the Scientific Committee of the EU Commission dealing with cosmetics and non-food products (SCCNFP) submitted an opinion that concerned the safety of tattoos. According to this opinion an enormous "grey" area existes as regards to the colorants being applied. The SCCNFP recommended that data on the chemical identity and toxicology be obtained so that a formal assessment could be carried out. The SCCNFP was opf the opinion that the products used for tattoos should be regulated ("…regulation is indispensable.."). As the EU Commission didn't follow-up this scientific view before December 2002 the Council of Europe Committee of Experts on cosmetic products continued its work to achieve a harmonised regulation of these products throughout the Partial Agreement Member States.

In the year 2000 the Dutch authorities analysed 63 products used for tattoos for their chemical composition and microbiological contamination. They found that eleven samples (18%) were microbiologically contaminated – seven of them to a serious degree. *Azo* colorants "containing" carcinogenic amines were identified in ten samples (17%).

On the basis of their worrying findings the Dutch authorities started 2001 drawing up legislation with the aim to regulate these products.

In 2000 also the Danish, Finnish and German authorities performed studies with the aim to identify the colorants that are being used for tattooing /PMU. These authorities visited traditional tattooing artists, beauty salons practicing permanent make-up and also manufacturers supplying colorants (tattoo products) to the tattooists, beauticians . The study results were forwarded to the Committee of Experts on cosmetic products

Essential elements of the draft Resolution Res AP (2003) 39 on tattoos and permanent make-up (PMU):

At the December 2002 meeting of the Committee of Experts on cosmetic products it was unanimously agreed between delegations to have a specific regulation. The basic principle of the current draft resolution is that under the conditions of the expected application and use, tattoo- and PMU products should not endanger the health or safety of man and environment. The draft resoolution shares many essential concepts with the Directive (76/768/EC).

The draft resolution applies to pre-marketing risk evaluation, composition and labelling of the products used for tattoos and PMU, conditions of application of tattoos and PMU and obligatoy information on specific health risks to the general public and the consumers. The draft of the current resolution is based on the "negative list approach", however foresees explicitly a revision once it is possible to establish a reasonably large positive list.

Definitions: The draft resolution defininies tattooing and PMU practices and sterility .

Licensing, education and skills: These aspects have not been dealt with specifically.

Sterility requirements: The draft resolution requires that the tattoo and PMU products used be sterile, be supplied in a container maintaining sterility until application, be free from preservatives, be supplied in a packaging size appropriate for single use on an individual consumer.

Special safety requirements:

- **Practice**

The tattooist, PMU cosmetician is requested to apply the hygiene regulations laid down by national public health services in the practice of tattoos and PMU, maintenance of the instruments.

- Information obligations to the consumer and public on specific health risks (reliable, evidence-based)
-

- Products

The resolution foresees a regulation based on a "negative list" of different substances which must not form part of the products in question, which is appended to the draft resolution, in addition to those banned in the Annexes II and IV of the Directive (76/768/EC) and the carcinogenic, mutagenic, reprotoxic substances of the categories 1,2,3 of the Directive 67/548/EEC.

The product labelling is requested to contain

- Name and address of the manufacturer or person placing the product on the market,
- the date (month/year) until which the product fulfils its function and remains safe for the intended use,
- appropriate storage conditions- if applicable,
- conditions of use and warnings-if applicable,
- the list of ingredients,
- reference to sterility of the contents.

- Pre-marketing safety assessment:

- The person responsible for placing the products on the market should perform a risk evaluation based on recent toxicological data and knowledge to be laid down in a dossier readily available to the competent authorities.

Adoption progress and timelines

Resolutions elaborated by the Committees of experts (Partial Agreement) are approved by the Public Health Committee (Partial Agreement) and adopted by the Committee of Ministers as a joint expression of governmental opinion (restricted to the Representatives of the

Member States of the Partial Agreement).They have to be considered statements of policy, statements for policy makers of the Partial Agreement Member States to be taken into account in the national laws and regulations, with the view to of harmonising regulations at European level, each government remaining free to impose stricter regulations. After the Council of Europe internal legal approval (3 March 2003), the draft resolution was sent out for written approval to the Liaison sections and the delegations of the Public Health Committee (Partial Agreement) with a deadline to comment (10 May 2003). The submission to the Committee of Ministers with a view to its adoption is envisaged for 19 June 2003 at its 844 th session.

Follow –up

The Netherlands and the French authorities are currently developing national legislation based on the draft resolution.

On the basis of recent and long-dating co-operation agreements between the Council of Europe and the European Commission there has been an exchange of information between the organisations and the participation in the activities of their respective committees.

An agreement on the co-operation in the field of “technical/scientific and regulatory issues on the safety of tattoos, body piercing and of related practices” is being sought by the competent departments of the Council of Europe and the European Commission (…further revisions of the resolution ..)

The current regulatory situation in Italy : tattoo and piercing practices

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Ministero delle Attività Produttive – Rome, Italy

Legal Basis: In Italy a specific legislation concerning tattoos and piercing practices does not exist. Health and safety of the consumers is guaranteed by the Ministero delle Attività Produttive and by the Ministero della Salute also on the basis of the precaution principle, by means of the application of Legislative Decree n. 115 of 17 March 1995 (enforcement of 92/59/EEC Counsel Directive of 29 June 1992 concerning general safety of the products). This Directive is a complement to sectorial comunitary legislations in the case of products, risks and safety aspects not covered, in addition to administrative and enforcement control rules in the same manner not covered. The wide diffusion of tattoos and piercing practices, has lead the Ministero della Salute, on the basis of the mandate of Consiglio Superiore di Sanità (National Health Council), to lay down in 1998 the specific guidelines n. 2.8/156 of 5.February.98 and n. 2.8/633 of 16.July.98 *" Linee-guida per l'esecuzionedi procedure di tatuaggio e piercing in condizioni di sicurezza* " (Guidelines to the practice of tattoos and piercing in safe conditions) with the purpose to implement good practices in order to prevent risks connected to tattos and piercings. On the basis of the legislative frame discussed in the previous paragraphs, the planning of the legislative activity at the national level is still at the initial phase and requires decisions on implementation actions. The final target will be a uniform action to ensure the safety of all the products in the trade, proposed and destined both to the consumers and, in the meantime, not to hinder the free trade of the goods. Art.5 of the mentioned 115/95 Decree "Procedure di consultazione e coordinamento" indicates several Ministers (Attività Produttive, Salute, Lavoro e Politiche Sociali, Interno,Economia e Finanze, Infrastrutture and Trasporti) as Authorities Responsible, each one for its field of action, in the control of the products circulating in the market. According to what above, these Ministers joint in a conference two times in a year, under the coordination of the Ministero delle Attività Produttive, that is the Responsible Authority for the Notification to European Commission of the measures taken in compliance with art.6 of the above mentioned legislative decree. In particular, the aim of this joint conference is to define common criteria to coordinate the controls foreseen by law. The Ministers involved in these controls act by means of pheriferical structures that operate directly in the market with targeted plans. As regards the topic of tattoos and piercing, the NAS (Nucleo Anti Sofisticazione) of the Carabinieers Army, on the basis of an agreement with Ministero della Salute, act in real time with targeted actions. Several Regions in Italy settled provisions to implement the Guidelines of the Ministero della Salute of 1998. For an example, the Regione Veneto laid down the Circolare 1 giugno 2001, n. 9. (BOLLETTINO UFFICIALE DELLA REGIONE DEL VENETO - 15-6-2001 - N. 55). Its main points are: hygienic requirements of the spaces, authorisation and license of the structure and the personnel, hygienic measures and provisions, information, training and control.

Moreover, the Guidelines of Ministero della Salute of 1998 define a number of tasks to be implemented at the Regional level, connected with preventive measures for consumer protection. These measures deals with several topics and actions:

- description of health and hygienic measures"
- professional training of practitioners
- information about risk connected to tattoo and piercing practices

- monitoring by local authorities of hygienic, structural and functional rules related to tattoo and piercing practice

In this context, a key point is the definition of a procedure to ascertain the standards of both the structures where the practice occurs and the skills of the practitioners

Monitoring and control actions are regularly carried out by NAS and peripheral control boards (Regional, Municipal). Diseases, or adverse reactions connected to tattoos and percings are reported in the Medical Structures (Hospitals, Physicians, First Emergency etc) where the patient is under medical care. A recent survey published by EURISPES (January 2003, www.Eurispes.com) reports statistic data about tattoo and piercings in Italy. According to this publication, 1/5 kids (age 12-18) has a piercing, while only 6,6% of them has a tattoo. The percentage of the girls with a piercing is 25,6% and is higher than the percentage of the boys (14,4%). Also data about geographic distribution have been presented.

Definitions: Tattoos and piercing practices are covered by the 1998 Guidelines of the Ministero della Salute.

Licencing, education and skills: Authorisation and license of the structure and the personnel is required Professional training of practitioners is described in the 1998 Guidelines of the Ministero della Salute.

Sterility requirements: - Hygiene conditions are covered by the 1998 Guidelines of the Ministero della Salute .

Special safety requirements on chemicals/materials used: Hygiene and safety requirements are covered by the 1998 Guidelines of the Ministero della Salute.

Policy Options

JRC/TWG Working Papers

The question of positive or negative lists

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Norwegian Food Control Authority

Types of chemicals that ought to be subjected to regulation

Tattooing / PMU products currently encountered in the market place consist of different types of ingredients. In addition to the main one, namely the colorant molecule (s), a ready to use product normally contain also certain amounts of auxiliary ingredients like solvents, vehicles and additives. Vehicles provide stability like anti-agglomerating properties, fastness to light, etc. Additives may for example be chemicals providing the right viscosity/fluidity. Also preservatives are sometimes added. Regardless of the function it has in the product an ingredient may be a chemical that could possibly make harm to the health of the tattooed person. Therefore, not only the colorants but also the auxiliary components should in principle be considered as potential regulatory subjects.

The problem of impurities is not dealt with here. It should be observed, though, that colorants relatively often contain non-negligible trace amounts of the reagents having been used to form them (aromatic amines in *azo* colorants for example). The impurity issue is tackled when considering the safety in use of the different ingredients.

Problem

Contemplating different regulative models one is faced with the question of whether to apply either a positive or a negative list solution.

The negative list solution means that some chemicals – be they colorants, solutes, vehicles or something else - are explicitly prohibited, whereas all other chemicals are in principle permitted on condition that the use made of them could be considered safe. The positive list model means that only those colorants (vehicles etc) that figure on the list are allowed as ingredients whereas all other chemicals are banned for tattooing/PMU uses.

The present annex provides *pro* and *contra* arguments for the two models.

Overall premises

With certain exceptions - notably medicinal products and certain foodstuffs - the responsibility for a product's safety in use rests, legalistically speaking, primarily if not entirely with the marketers. Since many years this principle has been at the base of most EU product regulations. It has been introduced in recognition of the fact that public bodies will on their own be able to secure products using but prohibitively large parts of societies economic resources. Also, it is sound in that industry is forced to know exactly what they are supplying within a safety context and that the main responsibility for safety securing is placed on their shoulders. Like the decorative cosmetic products also the tattooing/PMU products are used to adorn. Although medicinal practice makes good use of them for example in connection with breast cancer surgery, they cannot be considered necessities. They are, therefore, not any different from most other consumer products as concerns the question of whom is primarily responsible for the safety in use. In principle this responsibility should rest primarily if not entirely with the marketers of the ready-to-use tattoo/PMU products - and as well as with professionals that place tattoos/PMUs

on customers. The situation could be compared to that pertaining to for example ready-to-use hairdressing products and hairdressers. The role of the authorities is to provide adequate science based regulations and to control that these are respected.

Ideally, the placing of a chemical on either positive or negative lists ought to be done on the basis of *risk evaluations* that take account of the dose of material being placed within the skin layers (injected). However, reliable information on the exposure is lacking for the time being. Therefore, currently the prohibition/ authorisation has to be based on *hazard evaluations* only. These are evaluations whereby one takes into account solely the inherent toxicological properties in question. By application of feasible safety factors a tolerable daily subcutaneous exposure may in theory be obtainable.

Positive List Option

Premises

1. It is foreseen that a positive list is prepared on the basis of safety assessments undertaken by highly qualified industry independent scientists

2. Right from the start a feasible positive list should contain enough ingredients to secure that market players having signalled interest in official regulations will also respect these regulations. What would be a sufficient number of authorised chemicals in this respect is not known. In light of the many colorants now being used[22] it is foreseen, though, that not only a couple of colorants is enough.

3. Reflecting on the situation in the related field of cosmetic products it could be argued that one could have two sorts of positive lists: a Part 1 and a Part 2 list. The Part 1 list displays chemicals that have been authorised for (restricted) use on a more or less permanent basis. The Part 2 list shows some chemicals that are permitted on a temporary basis until enough knowledge of their safety in use have been harvested to decide whether to delete them or to move them to the Part 1 list. The experience with the Part 2 list is that the chemicals on it reside there for very many years because of lack of progress in finding out about their safety in use. Although the use of the Part 2 temporary list has recently come in use again in connection with the establishing of a positive list on hair dyes, the incentives have for a long time been to try to abolish the use of them because of the disadvantages mentioned (lack of progress). It's presupposed; therefore, that one doesn't establish a Part 1/ Part 2 model as concerns the tattooing/PMU products.

Advantages

- To the best of abilities and within the limits of toxicological knowledge and technology one could trust that only safe colorants (auxiliary ingredients) will be applied in legally sold products.
- Companies/professionals responsible for the ready-to-use products are not burdened with having to carry out safety assessments on their own.

[22] *They are probably in their hundreds although only 41 have been identified this far by the Council of Europe Committee of Experts on Cosmetic Products*

Disadvantages

- The main disadvantage is that the responsibility for having only safe products will rest with the authorities in an unfortunate disproportionate manner having regard to the general principles mentioned under the overall premises.[23]

- On the basis of present day toxicological/ clinical knowledge it's uncertain whether any chemical at all that are now being used in the marketplace can be placed on a positive list. .

- Probably, comparatively large efforts will have to be mobilised on the hand of publicly financed bodies.

- It will most probably take many years to get a sufficient list.

Negative List Option

Premise

It is presupposed that a negative list is supplemented with a hazard evaluation requirement on the hand of market players in order to make sure that efforts are made to secure safe use of chemicals that are not placed on the list.

Advantages

- Except for the establishing of the list the responsibility for having only safe products is with those placing ready-to-use products on the market – and with them using these products professionally (confer overall premises).

- Such a list can be implemented on the basis of current knowledge of the inherent toxicological properties of the different kinds of chemicals that are of interest in connection with these products.

- It can be implemented rapidly. In this connection it's observed that some EU countries are already in the process of preparing a regulation based on the negative list concept (confer what is mentioned beneath as concerns the work having been done by the Council of Europe).

- The list can be lengthened progressively as new knowledge becomes available.

- Costs on the hand of the authorities will not be prohibitively large.

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[23] ***Under an intermediate negative list regime one could envisage that in the long run the branch would progressively be better able to sort out on their own which chemical to use and not to use for safety reasons.*** This is because of the of the safety assessment/dossier requirement under this regime. The knowledge harvested over time under this regime could possibly be utilised to establish a feasible positive list in the end of the day without violating the responsibility principle too much.

Disadvantage

- Experience of surveillance authorities this far is that many SME take lightly on their responsibility to make safety assessments. Also many such enterprises simply lack the necessary resources to have these assessments made in a sufficient manner. This pertains to the situation in the related product field of cosmetics products where responsible market players are obliged to prepare and hold readily available to the inspecting authorities, dossiers containing these safety assessments.

- The market players within the product field of tattooing/PMU ready-to –use products will, to a large degree, not be the same as those operating in the field of cosmetics. There are reasons to fear, though, that many of them will behave even less responsible than some of those within the field of cosmetics. Also, many will simply not have the resources to look after their products in a proper manner. Efficient enough enforcement would therefore, probably, lead to the removal from the market of a very large proportion of the ready-to –use products being applied today. However, it's an open question whether an efficient enough enforcement can be installed throughout Europe given the nature of many of the businesses operating in this market. There is the risk, therefore, that the unresolved safety issue of the tattooing/PMU products/practices will be only "half-solved" establishing a negative list regime on a permanent basis. If one establishes the negative list regime as an intermediate solution only, prospects may look brighter

Solution reached by the Council of Europe

It's observed that the Council of Europe (CoE) has dealt with the unresolved safety issue of tattooing and permanent makeup (PMU) since 1999. The Health Committee of the CoE authorised the CoE Committee of Experts on Cosmetic Products (CECP) to look into this issue. CECP is soon to finalise a technical report that will form the basis of a CoE Resolution on the regulation of tattooing/PMU products. CoE will adopt this resolution officially later in the year 2003.

Also, the subject of having either a positive or a negative list model solution has been contemplated by the CECP of the CoE. CECP concluded that a negative list model is the best solution in the short run all the above-mentioned arguments taken into consideration. It's a prerequisite that those responsible for the products prepare and make readily available to the inspecting authorities dossiers containing assessments of their products that show that they are safe as used. The Resolution foresees that a positive list is likely to be drawn up in the future.

Implementation mechanisms

As concerns this issue it's thought only natural to draw on the experiences with the mechanisms having been in place since many years in the field of the related cosmetics products. Within the important market segment of the PMU products the market players are well acquainted with the cosmetics regulations.

One would assume that to a large extent the more general traits of the cosmetics regulations could be adopted when drawing up a tattooing/PMU regulation. This is regardless of whether one chooses the negative or the positive list solution (with the exception that one do not need the dossier requirement under the latter regime). In the following we mention the relevant provisions to take into account.

The EU Cosmetics Directive (76/768/EC) comprise both negative and positive lists – and also a requirement to prepare and hold readily available to the surveillance authorities a dossier containing among other things also a safety assessment. The dossier must also contain a listing

of all the specific chemicals that form part of the product as well as the extent to which they are present (the receipt)[24]. By way of the safety assessment the responsible market player is supposed to ascertain that the product in question will not cause harm to the consumer when used normally or in a way that can be reasonably foreseen. The assessment has to be based on toxicological evaluations.

There has to be a dossier for each and every ready-to-use product that is placed on the common market. The dossier is to be held at the address that is mentioned in the products label. Products for which a dossier doesn't exist cannot be marketed lawfully. It's the competent authority in the country where the dossier is placed that is empowered by law to gain access to it if so wished for. Other countries experiencing problems with a product can ask the authorities of the "dossier-owning-country" to look up what is says in the dossier about certain things of relevance to the case faced with.

All products must carry an ingredient-list so that the consumer (client in a beauty saloon, or a tattooing shop) can observe which ingredients it consists of [25]. This is not the receipt being disclosed. The ingredients are, however, displayed in descending order of weight at the time they are added.

Authorities make it obligatory by law to place on the market only ready-to-use products that comply with requirements laid down in a regulation that is officially published and enforced by a competent surveillance authority. Products that do not comply with the regulations cannot be sold lawfully and must be removed from the market without undue delay. Competent surveillance authorities are empowered by law to require removal of products judged to pose a threat to the health of the consumer.

Obligations following from the regulation are on the EU based manufacturer of a ready-to-use product and also on the EU based juridical subject that for the first time imports a ready-to-use product into the EU. This pertains to products going to be sold/used on the common market. Also professionals applying a ready-to-use product are obliged by law to see to it that only products complying with the laid down regulation are used on their customers.[26]

[24] Specific chemicals are identified by CAS No, ENIECS No, UPAC name. NB! "Pelican ink" cannot be considered an ingredient within this context

[25] The CoE Resolution mentioned introduces such a requirement also as concerns the ready-to-use tattooing/PMU products.

[26] Within the field of cosmetics this concerns for example hairdressers, manicurists, beauticians, nail designers, aroma "therapists", dentists and similar professions. All enterprises are obliged seeing to it at all time and on their own initiative that their businesses are run in compliance with all laws and regulations having been made publicly available in a special law publication. Not knowing about laws and regulations is no excuse for violating them.

Testing of tattoo ingredients for their safety evaluation

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Introduction

Questions about the safety of Tattoo and Permanent Make Up (PMU) colorants exist for considerable time. The past years publications about viral and bacteriological infection, (high and/or heavy) metal concentrations and carcinogenic aromatic amines initiated discussions about the safety issue. Besides the results of the examined colorants there were considerable doubts at the suitability of the colorants for injection into the dermis of human. Most of the tattooists do not know the composition of the colorants. Some of the colorants used are developed as printer's or normal pen ink. Indian ink, Pelikan ink and Inkjet-printer ink are regularly used in the tattoo branch.

The safety of the ink for human purpose is very often not considered. Guidelines for testing the tattoo ingredients for their safety evaluation are not made, however the Council of Europe Resolution and the proposed Dutch legislation both lay down that the tattoo and PMU ink should be safe for human application.

Possibilities for safety evaluations

The inks put on the market are as such chemicals mentioned in the "Dangerous Substance" Directive. For all these chemicals dossiers or files should have been made. In these files the HAZARD of the chemicals is calculated. The outcome of these calculations are the foundation of the MSDS, on which all the warning sentences and symbols are placed on. Since the calculations are resulting in a HAZARD and not a RISK outcome, this system is not applicable for tattoo and PMU chemicals.

Basically there are two options left open to regulate the safety assessment of the tattoo colorants.

1. Since the tattoo colorants are intradermal injected it seems reasonable to draw a parallel between medicine and tattoo colorants. The same parallel has also been drawn before in the proposed Dutch legislation. At he establishment of the proposed Dutch legislation, it was laid down that the tattoo colorants should be, like medicine, sterile and should not contain preservatives. Requiring a safety assessment of the tattoo colorant before releasing the product on the market (pre market authorisation) will pursue this comparison.

   This procedure however is not very realistic for the tattoo branch. The procedure is much more extensive than needed for tattoo colorants. Besides the pre registration issue, doss effect relations, target-effect studies etc. are neither necessary nor realistic.

2. The other parallel, which can be drawn, is between tattoo & PMU colorants and cosmetics. The 6th Amendment of the Cosmetic Directive 76/768/EEC is requiring a safety assessment of cosmetics. The safety assessment itself is part of the product file, and should be made before the product is release on the EU market. The competent authority can enforce the product file, after the product is released on the market. The manufacturer or the person/company, which is responsible for releasing the product on the EU market, is responsible for the safety evaluation. The European Commission has made "notes of guidance for testing of cosmetic ingredients for their safety evaluation" which has been regarded as general guidelines for cosmetic safety evaluation by member states of the EU.

Since the above described system seems to be a realistic one (it is al ready in force for cosmetics) it is the question know whether this system is applicable or not for tattoo colorants.

Safety evaluation of tattoo colorants; the "cosmetic approach"

The content of the 6th amendment is expressed in article 7a of the cosmetic directive 76/768/EEC;

Article 7a
The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the
Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):

(a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;

(b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;

(c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;

(d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

(e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

All the above mentioned aspects can be considered as applicable for tattoo colorants. If a tattoo colorant manufacturer effectuates all these aspects, it is reasonable to assume the product is save. The article 7a covers the control of production (GMP, under a, b and c), the safety assessment (under d) and the judgement of the safety assessment (under e).

Applicability of the "Notes of guidance for testing of cosmetic ingredients for their safety evaluation" for tattoo colorants.

Volume 3 of "The Rules Governing Cosmetic Products in the European Union" incorporates the "Notes of guidance for testing of cosmetic ingredients for their safety evaluation". These guidelines have been prepared at the initiative of and by the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) of the European Commission. They take into account both the experiences gained by the SCCNFP in its past work in evaluating the toxicological profiles of many cosmetic ingredients, as well as the development of scientific knowledge in the field of specific areas of toxicology.

These Notes of guidance, which are not legally binding, should not be used as a check list but could be of assistance for those responsible for consumer health protection. Their purpose is to provide guidance for testing cosmetic ingredients and for the safety assessment of the finished product, both to the competent monitoring authorities of the Member States, and to persons responsible for putting cosmetics on the market (manufacturer or importers within the European Union). They will apply to all cosmetic ingredients for which the producer must perform a safety evaluation to be included in the Product Information, as requested by Directive 76/768/EEC and especially by its Article 7a, as well as to new cosmetic ingredients, for inclusion in Annexes IV, VI and VII of Directive 76/768/EEC, and to those cosmetic ingredients about which safety concerns have been expressed.

Article 2 of Council Directive 76/768/EEC requires that cosmetic products put on the Community market must not cause damage to human health when they are applied under normal and reasonably foreseeable conditions of use. Adequate information should therefore be provided in order to evaluate the safety of the final product. In general this can be derived from knowledge of the toxicity of the ingredients, with no need to test the final product. However, in a few cases, testing of the final product may be necessary. Examples are when the vehicle used results in considerably greater skin penetration than that observed in the toxicity studies on the ingredients or if interaction between ingredients is likely to result in the formation of a new, potentially toxic substance, or when there is a claim of reduced skin penetration or toxicity resulting from the formulation. It is up to the suppliers of new products placed on the Community market to ensure that adequate information can be provided for a safety assessment of the finished product.

Content of the "assessment of the safety for human health"

In case of (cosmetic) ingredients, the manufacturer should provide information about:

1) ***Acute toxicity***
2) ***Skin (Percutaneous) absorption;***
3) ***Skin irritation;***
4) ***Mucous membrane (Eye) irritation;***
5) ***Skin sensitisation;***
6) ***Sub-chronic toxicity;***
7) ***Mutagenicity;***
8) ***Phototoxicity and Photomutagenicity (in case of UV-light absorbing substances);***
9) ***Human data (if available)***
   When considerable oral intake can be expected or when the data on skin absorption indicate a considerable penetration of the ingredients through the skin, taking into account the toxicological profile of the substance and its chemical structure, the following further information may be necessary:
10) ***Toxicokinetics;***

11) Teratogenicity, Reproduction toxicity, Carcinogenicity, and additional Genotoxicity.
12) Metabolism studies

Since tattoo & PMU colorants are injected into the dermis, the toxicological parameters under 10, 11 an12 are mandatory.

The basis for the determination of the toxicity of the ingredients is the calculation of the Margin of Safety. The margin of safety is calculated from a comparison of the relationship between the critical NOAEL observed in the most sensitive species from appropriate repeated-dose animal studies and systemic human exposure to the tested component. This general approach is not appropriate in those cases where it is prudent to assume that the effect does not have a threshold (e.g. mutagenicity, genotoxic carcinogenicity). Furthermore, other data relevant to health risk assessment, such as irritancy or sensitisation are considered separately.

The percentage or rate of skin absorption is normally determined by an *in vitro* method. In case of tattoo colorants this percentage can be assessed as 100.

CALCULATION OF THE MARGIN OF SAFETY	
Maximum amount of ingredient applied (mg)	**I**
Typical body weight of human (kg)	**60**
Maximum absorption through the skin (%)	**A**
Systemic Exposure Dose (mg/Kg/Bw) SED	**(I x A) / 60**
Margin of Safety	**NOAEL / SED**

Conclusion

A tattoo or PMU colorant put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. This is a clear principle and should be part of the legislation about the subject.

It is now the question how to perform the assessment of the safety for human health of the ingredients and finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.

The “cosmetic approach” seems to be very suitable for tattoo & PMU colorants too. This approach covers the control of production, the safety assessment and the judgement of the safety assessment.

Also the “Notes of guidance for testing of cosmetic ingredients for their safety evaluation” made by the SCCNFP, can be used in order to determine the safety of the tattoo & PMU colorants. For the calculation of the different Margins of Safety (MOS), it will be sufficient to set the “maximum absorption through the skin” (A) on 1 (100%).

Outline for a possible regulation of the tattooing and piercing area through a certification and approval arrangement

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Denmark

Background

Tattooing and piercing are body ornaments that are carried out by full-time professional performers with a solid knowledge and a great insight in the area as well as persons who completely lack the basic knowledge of this area. In Denmark at least 50-60 full-time professional performers (of which 25 is member of DTL (Danish Tattooist Association)) and up to 200 part time performers are active, to this adds an unknown number of persons performing PMU (Permanent Makeup).

As there will always be buyers within this area there will also always be some who offer to make the ornaments.

Therefore, the purpose of a regulation within this area must be to ensure that buyers when choosing the performer have a basis for making this choice and through recognition of this option ensure a regulation of behaviour.

The basis of the regulation should therefore be that a serious/responsible performer can get a recognised education, have their equipment and methods certified, use approved materials and thus achieve a certificate/approval. This certificate they can show their customers and thus allow their customers to choose a safe performer (and opt out the risky - frivolous performer).

The proposed regulation cannot prevent that frivolous performers still work in secrecy. However, there will be a pressure from customers who will gradually ask for the certificate/approval and authorities will have a possibility to take action against non-certified performers.

Proposal for the Content of a certification arrangement

An approval of a supplier must imply that the person in question has completed a specific course and passed a final examination.

The course shall include subjects like:

- Personal hygiene,
- Customer hygiene before starting the tattooing and afterward
- Equipment hygiene
- Arrangement of rooms
- Requirements to equipment
- Requirements to materials (jewellery, colours, etc.)
- Responsibility
- Regulations
- First aid

In addition to having completed the compulsory course the premises and the equipment also have to be approved (e.g. the efficiency of autoclaves, etc. has to be documented).

When the education, premises and equipment of the performer are in order an approval to make tattoos and /or piercing at the premises in question and under the responsibility of the performer in question will be issued by local authorities.

The demand for approval also includes that only approved/legal (see next paragraph) materials should be used. This means that approved/legal colours have to be used in connection with tattooing and approved/legal jewels have to be used in connection with piercing, implantation, etc.

Approval of materials

The purpose of certifying performers is to allow the customers to choose between the serious (safe) performer and the frivolous performer.

Likewise an approval arrangement of the materials used is to ensure a regulation of behaviour by the performer, through recognition of the materials which are safe (and legal to use) and which are not safe.

The requirements to an approved product may be:

- A content of approved substances and materials (from a positive list)
- No content of banned substances and materials (from a negative list)
- Documentation of other substances and materials which are not mentioned on the positive list (health evaluation)
- Documentation of production hygiene and purity of raw ingredients
- Documentation of the sterility of the finished product

This package of documentation will be presented to an impartial instance, which will evaluate it according to the criterions drawn up and approve it if all conditions are met. The producer will pay the expenses.

Maintenance of certificate and approval status

Certified performers will be subject to a control at which the authorities will pay them a visit at intervals to check that everything still complies with the requirements drawn up.

Approved products could also be subject to periodic control in connection with their content of banned substances and observance of the microbiological limits as well as the manufacturer shall accept audit visits. With time intervals the documentation shall be reviewed and the manufacturer confirm that the content is still within the approved.

How it works in practice

There are rules similar to these within many other areas.

Normally private companies can offer the necessary education of performers after a preliminary approval of the content of the courses by a national/EU? authority.

The authorities, which already approve companies within the food industry or health clinics, will be able to approve the arrangement of rooms, the hygienic level, etc.

Impartial companies can make approval of materials after preceding accreditation that is the case within many other areas today (an example is the “European flower” that certifies that a product is environmentally acceptable).

Advantages seen in this set-up.

- The customers will easily be able to choose a safe (certified) performer by looking for the certificate which should be exposed openly in the studio
- The communication to the public will be simple: “If you want a tattoo/PMU/piercing you should go to a certified studio”
- The pressure from customers preferring certified studios will diminish the number of customers going to the uncertified studios, and thereby make the “unsafe” market smaller.
- As the number of certified studios increases the demand for approved colours will increase, an unapproved colours will be hard to sell.
- This set-up will be very cost efficient for the authorities.
  1. The producer of colour pays for the approval of the colour
  2. The performer pays for his own education
  3. The performer pays for the regular visits from the health authorities
- The performers do not need to know anything about the content of the colours/jewellery he only has to look for the approval sign on the product.
- The producer of colour/jewellery only has to reveal his full recipe information to the approving party.

Disadvantages seen in this set up

- The responsibility for the safety of the products will end up with the authorities, as they decide on the positive/negative list, and has to decide on the criteria that will be used in the evaluation of acceptable/non acceptable products.

Education & Skills

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Background

The techniques used in performing traditional tattooing and applying permanent make-up (cosmetic tattooing) are essentially the same. However, there are marked differences in emphasis in different respects between the two procedures.

Traditional tattooing involves injection of pigments into a deeper layer of the skin (the dermis) than during permanent make-up (which involves injection just below the epidermis). The technique used in traditional tattooing is more "aggressive" than that used in applying permanent make-up. The machine used for traditional tattooing, which resembles a sewing machine, is furnished with "big" needles because the skin at sites on the body where tattooing is undertaken is often thick (e.g. on the back, arms or buttocks). Responsible traditional tattoo artists do not generally tattoo the face because of the difficulty of removing the ornamentation, and risk of development of scars, if the skin becomes inflamed. It is clear that a face that is damaged or bears (later) unwanted ornamentation is extremely undesirable.

The education of traditional tattoo artists varies. It is most often provided by established practitioners, since by its nature the techniques can only be learned through practice.

Permanent pigmentation (make-up) is undertaken mainly for cosmetic purposes, around the eyes and lips. Medicinal activity in this field can cover the eyebrows, lips and nipples. If the eyes are close to the area being tattooed the procedure must clearly be carried out precisely, with greater accuracy and technical skill than are needed in more traditional tattooing. The situation is similar in relation to the lips. Adoption of a responsible approach in such cases may correlate with standard of education. Although the ornamentation disappears in time (after from one to three years), any inflammation that develops can be followed by permanent scarring.

Training of practitioners of permanent pigmentation takes place in Finland in schools for the education of beauticians. It forms an extension to the basic education of a beautician. A Finnish regulation applies to this area (5/011/2000, Requirements relating to Specialist Examination for Beauticians). Under the heading "Special techniques: permanent pigmentation of the skin" are listed e.g. (a) Professional skills:

- A beautician must be able to plan and perform permanent pigmentation (cosmetic tattooing) following assessment of individual needs. Requirements to be met include appropriate hygiene, correct technique, ability to provide clients with necessary information.
- A beautician must have adequate knowledge of the compositions of the colouring agents used, of the equipment and techniques employed, and of the effects of all of these on the skin.

Education of practitioners

Because of the differences in procedures and backgrounds in relation to training, different educational approaches to traditional tattooing and permanent pigmentation are needed.

Education of practioners of permanent pigmentation

In carrying out permanent pigmentation, various factors must be taken into consideration if safety is to be assured. Primarily, a thorough knowledge of the structure and behaviour of the skin is needed, together with adequate general knowledge of the anatomy of the face (including the eyes). A slight error in technical procedure can have serious consequences (e.g. eye damage). For this reason, permanent pigmentation is primarily carried out (in Finland) by beauticians who have received advanced training.

Educational skills of traditional tattoo artists

Most traditional tattoo artists have learned their techniques from experienced practitioners. Although the basic education of traditional tattoo artists is reasonable, most know very little about the structure, physiology and anatomy of the skin. They have learned empirically during their career how to avoid risks.

Injection of substances into the dermis is, however, fairly demanding. A tattoo artist ought to know about skin behaviour, use of pigments, which areas may and which areas should not be tattooed, hygiene, contraindications (skin diseases, general diseases), size of area that can in general be tattooed without risks etc.

If it is assumed in general that knowledge of tattoo artists in this area is inadequate various kinds of basic courses are needed to make tattooing safer.

Responsibility on the part of tattoo artists is of primary importance. Appropriate education should therefore reflect this priority. Such education would increase the regard in which tattoo artists are held.

Minimum requirements for education of traditional tattoo artists

The suggestions made here are intended to be realistic in relation to the present situation with regard to education. In future, requirements could be extended in various directions.

As a starting point, knowledge of the contents of the courses listed below might be regarded as a minimum requirement:

Anatomy and physiology of the body

- the various tissues (fatty, connective, bony, cartilaginous, nervous, vascular)
- repair of tissue damage (paying attention to various points)

Physiology of the skin

The commonest skin diseases

The contraindicated general diseases/ physiological status (e.g pregnancy)

Toxicology of pigments

Hygienic conditions

Regulations

A course would last for six weeks, including a final examination, which would need to be passed in order to qualify.On the basis of this passed examination a traditional tattoo artist would also be capable to make body piercings.

Practical considerations

The education of practioners of permanent pigmentation would seem to be already under control, and to need only detailed refinement. It would seem reasonable to preserve the current educational system.

The situation relating to the training of traditional tattoo artists is more complex. Should it, for example, be private or official? Policy in relation to education should in general favour an official approach. If training were to be provided via private schools or courses there could be problems in relation to authorization and supervision.

The schools in which beauticians are trained would all be competent to undertake training of traditional tattoo artists as well. The problem would be how such schools could be motivated to undertake this kind of education, since tattooing is not held in high regard.

Training could also be offered by other training centres associated with provision of various kinds of health education.

Hygiene Legislation of tattooing and piercing in Amsterdam - a proposed model for the EU -

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In May 1982 the Public Health Service in Amsterdam received a letter from an American army doctor because the Hepatitis B virus during their stay in Amsterdam infected eight American soldiers. After some investigation the Public Health Service found out that they all visited the same tattoo studio in Amsterdam. A male nurse from the Public Health Service went to the studio and he saw that the tattooist was working very unhygienic. The tattooist had a bucket with a sponge in black bloody water. With the sponge he 'cleaned' the spot where the client was tattooed. He also used the same needles for every client. The tattooist used the needles on his own hands to determine the sharpness of the needles. It was the normal way of working in 1982. HIV wasn't known and Hepatitis B not a big problem. Afterwards, everybody realised that it was a very risk full way of working. This was the immediate cause to set up local regulation for the tattoo studios and later for the piercing industry. One of the measures, we took, was to change the tattoo machine. From now on, needles could be changed easily after every client. Later on, we introduce a lot of other changes.

Tattooing, Permanent make up and body piercing is normally done in regulated and unregulated shops, jewellery shops, beauty salons and homes in the Netherlands. Generally no antibiotic is used, and various sterilisation methods are used. In general, tattooing and piercing is in the hands of unlicensed personnel, who have learned techniques from magazines, videos, and from other people who do tattoos and piercings. Although some piercers and tattooists claim to have a quality mark, there are no official agencies in the Netherlands that give quality marks and it is up to the tattooist or piercer to understand and use aseptic working techniques and sterilise equipment correctly.

Infection risks

Infection risks are caused by using dirty needles, needlebars and tubes, dirty pliers, jewels and by using contaminated pigments. A Dutch study[1] on the microbiological conditions of tattoo- and permanent make up pigments proved that 18 % of the samples were microbiologically contaminated. If the way of working is not very hygienic, there is a big risk of infection during tattooing or piercing. But there is also a risk of infection after the tattooing or piercing. The healing of a tattoo takes one or two weeks, but the healing of a piercing can take more than 9 months. During that time it's important that the client is very careful with dirty hands, cloths and other possible infection sources. The Public Health Service would like to see that the tattooist or piercer informs the client about these risks.

Listed below are the viruses and bacteria that can infect the client during and or after tattooing and piercing.

Viral infections

Blood borne viral infections like Hepatitis B and C and HIV can infect the client. These infections are mainly transmitted by blood. In the piercing and tattooing practice it's possible that blood from one client infects the next client because, for example, by a dirty needle, needlebar, pliers or a re-use jewel. Also the piercer and the tattooist him or herself is at risk. Any sharp instrument can transmit the viruses.

How big is the risk of infection after exposure to contaminated blood? There is a bigger chance to get Hepatitis B than Hepatitis C or HIV. Just because more people are contaminated with Hepatitis B, but also the Hepatitis B virus is easier to transmit than for example HIV. In short we can say that after exposure to Hepatitis B positive blood, you have 30 % risk of infection. After exposure to Hepatitis C positive blood there is 3 % risk of infection and for exposure to HIV positive blood there is a 0.3 % risk of infection.

As you can see the risk of contracting a blood borne viral infection isn't very big, but the complications are serious. It's of vital importance that piercers and tattooist follow the prevention measures.

The most important prevention measures for piercers and tattooist are:
- Using disposable needles. Nothing is as dangerous as to re-use needles.
- Non disposable instruments must be clean and sterile. Disposable materials must be thrown away immediately after using.
- Wear gloves every time there is a possible contact with blood or other human fluids.
- Vaccinate all tattooists and piercers against Hepatitis B.
- Follow the guidelines for needle stick accidents if, in spite of all prevention measures, the tattooist or piercer has an accident involving blood. There will be a serious risk for infection, because a vaccination <u>can</u> only protect against Hepatitis B but <u>not</u> against Hepatitis C and HIV.

Bacterial infections

The most common causal agents are *Staphylococcus aureus*, group A streptococcus, and *Pseudomonas* spp, which can cause chronic complications even in the earlobe. In other words, also a harmless superficial infection can lead to forming of cysts and scar tissue. Typical symptoms of a local bacterial infection are redness, swelling, warmth, pain and wound fluid.

One out of three piercings results in a bleeding or an acute local infection. As well as an acute infection there is a risk of an abscess or forming of scar tissue. Nickel allergy can result in an allergic reaction. If a piercing is put in the wrong place or put in the wrong way the jewel can be rejected.

Most important problems with piercing are:
- Extreme swelling and intensive bleeding after a tongue piercing.
- Dental problems; Common dental problems include chips, cracks, and broken off teeth as well as selective dental abrasion after a tongue piercing.
- Navel piercing complications; 40% of reported piercing complications result from navel piercing.
- Urinary tract infections have been report after genital piercings. Other problems with genital piercings are ruptures and bleedings after intercourse for male piercings as well as female piercings.
- More STD's (Sexually Transmitted Diseases) reported after genital piercings because condoms can become damaged by piercings during intercourse

With tattooing the penetration is not so deep as with piercing. Infections are usually more superficial than with piercing. A new tattoo is like a graze. Typical symptoms directly after tattooing are redness and some swelling and pain. Those are not signs of an infection. If there is still redness, swelling, pain and wound fluid after a week, than there probably is an infection.

Most of the local infections disappear after a few weeks or months. Nevertheless some bacterial infections give complications. Complications like sepsis, tissue trauma, forming of cysts or forming of keloid scar.
In conclusion we can say that the knowledge about hygiene must be improved to reduce infections and complications. With legislation of the tattoo, permanent make up and piercing industry we hope we can achieve our aim. Up till today it's a highly unregulated industry with uninformed clients who have difficulty knowing whether the tattooist or piercer is using proper procedures and equipment. However, professional piercers and tattooists in several countries promote good practice. They profit from guidelines for hygiene and techniques.

The current situation in Amsterdam
In 1987 we published the first version of our guidelines for tattoo, followed in 1990 by the guidelines for piercing. The knowledge and development of materials and way of working change very fast, so we have to update the guidelines regularly. The cleaner the tattooists and piercers work the better the result and the better the name of the studio. Now, in 2003 we have over 40 studios in Amsterdam, permanent make up studios included. We inspect the studios twice a year with a checklist, but we only inspect the hygiene not the artistically part. At this moment the Dutch government has a law in preparation for skin penetrated actions performed by non-medical persons.

The guidelines concern the next seven main topics:

1. General conditions of a well equipped studio
Necessary in a well equipped studio are:
- Easy to clean floors and walls
- An easy to clean consulting chair or table
- A basin for hand washing with a no-touch tap and disposable paper towels
- A waste bin with a pedal for the litter.
- A quiet consultation room and a separate waiting room.
-

2. The use of the right instruments and materials
To bring quality on a high level the tattooist or piercer need the right instruments. To work with these instruments they also need experience. The most important hygiene rule to prevent transmission is to use sterile and packed needles for every client.
An innovation is the using of disposable tubes and needlebars with tattooing. When they use these disposables, they don't need a sterilizer.
Furthermore they need a needle box to prevent needle stick accidents. Never throw a used needle in a rubbish bag because a bin man can easily prick himself when he collects the garbage. It's forbidden to throw away a full needle box in the rubbish bin. They must bring the full needle box to a pharmacist or specialised firm. Instruments and jewellery that are used for the procedure, must be of high quality and off course sterile.
The same applies to ink and pigments. An ultrasonic is necessary to remove ink and blood from parts that are difficult to clean or unreachable by normal cleaning. After cleaning in the ultrasonic the instruments must be rinsed with demineralised water.
It's necessary to use a vacuum steam sterilizer if one works with hollow and packed instruments. It has to be vacuum because only when all the air is out of the sterilizer, the steam can reach every part of the instrument. Furthermore one need a sterilizer with a dry zone because the tattooist and piercer work only with packed instruments. The instruments must be packed in a sterilisation bag.

3. A good preparation
Firstly personal hygiene is very important. That means clean hands, proper cloths and the wearing of gloves when it's prescribed. So before starting to put in a piercing or tattoo all materials must be within reach. When the spot that has to be tattooed or pierced is very hairy, the skin must be shaved before cleaning and disinfecting. In the Netherlands the age limit for tattooing and piercing is 16 years. The Public Health Service has more reasons for not allowing

children under 16 to get a tattoo or piercing: Children younger than 16 years still grow. That's why tattoos can be transformed and a piercings can be rejected or translocated over the body.
It's forbidden to use injectable or topical anaesthetics. Injectable anaesthetic is restricted only to medical or other health personnel. Tattooists and piercers don't belong to this group. The tattooist or piercer may use topical ointment only after prescription by a physician.
Last but not least it's very important to keep sterilised instruments sterile.

4. conditions while tattooing and piercing

First of all calmness while tattooing or piercing is very important. Second, it's important that the tattooist wears clean gloves while tattooing and the piercer wears disinfected gloves while piercing. It's not necessary for them to wear sterile gloves because it's almost impossible to put on sterile gloves when you are alone and piercers mostly work alone. Furthermore it's not necessary because they don't work in a sterile area like an operation room. In the case of tattooing one have to use for every client single used ink caps. That's important because, while tattooing, the ink can be contaminated with blood. Never use ink caps for the second time.

5. The aftercare

After tattooing the skin is often rubbed in with a sterile ointment. We recommend single used packages of sterile ointment and they must use a spatula to rub it on the skin.
Non disposable instruments should be put in a bin with a protein dissolving fluid. All other materials must be thrown away.
And maybe the most important thing to prevent infections is to inform the clients orally and written. The tattooist and piercer must give a clear instruction for aftercare.

6. Cleaning, disinfecting and sterilising

During tattooing or piercing the materials, surfaces and other areas become dirty. To prevent a cross contamination with bacteria and viruses it is important to work clean and safe. Cleaning is necessary for workplaces and instruments that have not been in contact with the naked skin. Workplaces with spoiled blood must first be cleaned and afterwards disinfect with alcohol 70 %. Sterilising is recommended for all instruments that have been in contact with the damage skin or instruments that have penetrated the skin.
The methods of cleaning, disinfecting and sterilising are as follows:

- After tattooing or piercing the instruments are put in a protein dissolving fluid.
- At the end of the day, pick them up out of the bin and rinse them.
- Put the instruments in the ultrasonic and clean according a specified program.
- Rinse the instruments again with demineralised water, dry and pack them in the sterilisation bags.
- Put the sterilisation bags in the vacuum steam sterilizer.

7. Supervision and maintenance

The inspector of the Public Health Service visits the studios at least twice a year. He or she comes whenever he or she wants. The owner of the studio has to let the inspector in and give all the information he asks. With a checklist (according to the guidelines) the inspector checks all the items of the guidelines. The municipal government of Amsterdam has also rules for maintenance. The type of measures that has to be taken (a warning, a fine or closing of the studio) depends on what kind of mistake a studio makes. If there is a direct health risk than it is possible to close the studio immediately. When there is not a direct health risk than we give them a written warning and the possibility (within some weeks) to adjust the situation. The studio has to inform the Public Health Service when everything is adjusted, within the time we gave them. If not, they will get a fine.

In spite of the guidelines and our inspections, we still see some bottlenecks:

- It's difficult for non-medical persons to understand what it means to work aseptic. They open a drawer with disinfected gloves, but lay down a sterile jewel on an unsterile table. Tattooists smoke while tattooing and this, off course, isn't hygienic.
- In some aftercare instructions we read the most strange advises, for example; to take a shower 5 times a day during the healing period of a nipple piercing or rub the wound with ointment of dubious level.
- Tattooists and piercers use detergents and disinfectants not in the right way. For example; a disinfectant for the skin is used for cleaning the floor.
- Risks are not always mentioned before tattooing or piercing. For instance: a nipple piercing will heal within 6 to 9 months. Is the client willing to take care of the piercing all this time? If not, don't do it, because the risk of an infection is high.
- The packing, opening and dating of sterilisation bags is not always done properly.
- Some piercers use the informed consent to safeguard the piercer. It's NOT a safeguard. A piercer is always responsible for his work. Furthermore the piercer must keep the informed consents for ten years.

Perhaps we can conclude that we hope to reduce the bacterial and viral infections due to better hygiene and improving knowledge in the tattoo, permanent make up and piercing industry. But it's important to note that infections can not always be prevented and last but not least, unknown infections may be recognised in the future.

Reference

(1) Reus H.R., Buuren van R.D., Keuringsdienst van Waren Noord, Kleurstoffen voor Tatoeage en Permanent Make-Up, november 2001

The Belgian Hygiene Quality Label
- a proposed model for the EU-

Els Keytsman, Cel Economie, Begroting, Fiscaliteit
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Fullltext available on request.
Summary Version to be included in the proceedings

United States Perspectives on the Regulation of Body Tattooing, Permanent Make-up and Medical Tattooing

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The full text will be included following the approval of the US FDA.

Roundtable discussion

To be inserted

Conclusions

To be inserted

Annex: List of Participants

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