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

Recommendations for regulatory action in the EU on the safety of tattoos, body piercing and of related practices in the EU

on behalf of the
Directorate General
Health and Consumer Protection
(DG SANCO)

Final D r a f t

Ispra, 19 December 2003

Foreword

The report summarises the final conclusions and recommendations obtained in a series of actions of the Institute for Health and Consumer Protection (IHCP)/Physical and Chemical Exposure Unit (PCE) carried out in 2003 to support the work of DG SANCO, European Commission in the field of "Technical/scientific and regulatory issues on the safety of tattoos, body piercing and of related practices".

At first a Technical Working Group (TWG) of experts from Member States was established to carry out the action plan of the project. The members of the TWG developed in collaboration with other experts and organisations, the following working papers:

- **Regulatory Review** (JRC)
- **Chemicals used in tattoos/piercings** (Norwegian Food Control Authority & CHEMTOX A/S & University Regensburg)
- **Review of health effects and risks** (JRC & University Regensburg & WHO)
- **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)
- **Status Report on the current situation, nature and size of the problem in the EU** (JRC)

The draft versions of these working papers were presented and discussed in a workshop in 6-7 May 2003 at the premises of the JRC in Ispra, Italy.

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Contents

1 Executive Summary

The fashion usage of tattoos and body piercing is growing, along with concerns about the health risks associated with them, in the absence of a clear legislative background. The European Commission has been asked by European Parliament and Member States to take action. The Scientific Committee on Cosmetics and Non Food Products (SCCNFP) noted on 17 February 2000 that the chemical structure, identity, and toxicological profiles of the large number of dyes used in tattooing are incomplete or unknown, thereby precluding proper risk assessment. The Health and Consumer Protection Directorate General requested to the Joint Research Centre to collect and assess all necessary information and establish a common knowledge basis. The results of this work were presented and debated among scientists and stakeholders in a workshop organised at the JRC Ispra. On this basis, the JRC is proposing to the Commission potential policy options outlined in the present report.

During recent years, there has been an explosion in tattooing and piercing, particularly among the young population. Although systematic prevalence studies are widely missing in Europe, preliminary data show that roughly 30 percent of the young populations have either tattoos and/or piercings. Trendsetters from the show business are among the facilitators, in conjunction with a lack of awareness of health risks and the absence of effective regulations.

Health effects of tattooing and piercing

Materials used in tattooing are administered directly into the skin. Because of the anticipated high exposure of humans to the chemicals used in tattoos or in piercing posts one would expect that the chemical substances used in tattoos and piercing posts would be subject to strict requirements concerning safety (including purity and sterility specifications). In reality the situation is different and safety requirements isn't embedded into existing regulations. Thus, except for some dyes and pigments that have been approved for use in cosmetics, most chemicals used in tattoos are industrial pigments originally produced for other purposes, such as automobile paints, writing inks and have little or no safety data to support their use in tattoos. Apparently, organic colorants have come more and more in use in later years partially replacing the inorganic pigments having been used traditionally for tattooing purposes. The long-term health effect because of this development remains to be seen. Some of the organic colorants now finding use are azo compounds that potentially may be cleaved metabolically into aromatic amines classified as carcinogens.

A number of adverse health effects and infectious diseases associated with tattoos have been reported in the scientific and medical literature, such as:

- Viral infections such as hepatitis, HIV, and cutaneous infections;
- Bacterial and fungal infections;
- Allergic reactions such as cutaneous irritation and urticaria;
- Malignant lesions such as melanoma and skin cancer;

In addition, a number of reports in the medical literature link body piercing with a number of diseases such as viral hepatitis, leprosy lesions, devastating chondritis, endocarditis. Studies show that up to half of the piercings can lead to acute infections requiring medical or even clinical treatment. At least two cases of death after piercing have been reported in Europe during the last year.

Existing Regulations

Surprisingly, existing regulations are mostly limited to prescribing hygiene practices such as the use of gloves and the sterilisation of needles. They do not tackle the issue of sterility of materials, dyes and pigments, their purity, or the need for proper risk assessments based on toxicological evaluations. This is a legal paradox that clearly needs to be addressed urgently. To this end, the Joint Research Centre and

the Health and Consumer Protection Directorate General have been working together with the Council of Europe, which recently presented a resolution on "tattoos and permanent make-up" whereby a concrete regulatory model is recommended to governments.

The Technical Working Group (TWG) [1] and the Policy Options

As a first step, a technical working group was established, composed of experts active in the above areas in Member States. There was consensus among the members that action is needed to ensure safety of tattooing/piercing practices across the EU.

The working group reviewed currently available information and elaborated proposals for policy action comprising several options. According to the options a "negative list" of substances and materials associated with adverse health effects would need to be established. These substances and materials would be prohibited for use in tattooing and piercing. Other chemicals being used as ingredients may be secured by those responsible for the safety of these products – namely the marketers. This pertains to a regulatory model now implemented in the EU cosmetics regulations (the dossier provision). In the future, a sufficient "positive list" of substances and materials may possibly be established containing substances that fulfil certain purity, sterility and other safety requirements and have been assessed and shown to be safe by applying risk assessment procedures to be specifically developed for piercing/tattooing materials and practices. This possible future positive list regime may replace a negative list regime that can be established rapidly. At present, very few if any tattooing ingredients at all can be safely placed on a positive list.

Furthermore, the TWG explored the "Authorisation/Registration" options available to regulate the marketing of tattooing/piercing materials on the basis of safety considerations. Finally, the TWG identified and analysed options for developing harmonised requirements for education, training and application of hygienic practices across the EU.

An initial presentation and discussion of these policy options among scientists, public administrations, practitioners and stakeholders from the piercing/tattooing industry was made in the first workshop of its kind held at the JRC Ispra in May 2003. There was consensus among participants that action is needed. The discussions also showed that the proposed policy goals are ambitious and need to be achieved in a realistic time frame. They also need to be supported by specific actions, outlined in the present report, to deliver currently unavailable scientific knowledge about the actions and fate tattooing/piercing substances in the human body for the risk assessment process.

[1] See Annex 1

2 Introduction

The present report summarises the recommendations of the JRC – Technical Working Group (TWG) "Technical/scientific and regulatory issues on the safety of tattoos, body piercing and of related practices" on behalf of DG SANCO.
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 considering possible legislation proposals on the safety of tattooing dyes, the Commission/DG SANCO initially requested the opinion of the Scientific Committee on Cosmetics and Non Food Products (SCCNFP). In its opinion of the 17 February 2000, the SCCNFP noted the large number of dyes used in tattooing for which the chemical structure, identity, and toxicological profile are incomplete or unknown thereby precluding a proper risk assessment. In its opinion, the SCCNFP recommended that a systematic effort is undertaken to amass the needed chemical and toxicological information so that a proper risk assessment can be conducted.

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)

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 undertaking, the JRC and DG SANCO are working together with the Council of Europe, which recently[2] presented 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. Four meetings have been held at the JRC, Ispra on December 16th 2002, in Brussels on January 28th 2003, in Amsterdam on March 18th –19th, and finally at the JRC, Ispra on June 27th 2003.

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 hygienic practices
- request for risk assessment
- introduction of a negative list of substances
- introduction of a positive list of substances

[2] 19 June 2003, see http://press.coe.int/cp/2003/331a(2003).htm

3 Current trends in the prevalence of tattooing & piercing practices in the EU

In the EU it is believed that 5-10% of the general population is having a tattoo/piercing. However, prevalence studies are generally missing in the EU. Systematic studies in the USA show a recent strongly growing trend in tattooing/piercing practices applied to young population groups, which may be relevant to the EU. Since these prevalence data show that about 20-35% of the young people may be tattooed and/or pierced, the absence of regulation at EU level constitutes an urgent problem, in particular because of the health effects than can be associated with these practices [3], [4], [5], [6], [7].

4 Chemicals involved in tattooing & PMU

An extensive survey and information exchange with stakeholders was carried out as concerns the chemical composition of products applied for tattooing and permanent makeup purposes[8].

Generally there is no disclosure of the ingredients of the tattoo and PMU colours. To gain such information, a variety of tattoo colorants (pigments and dyes in the form of lakes**)** have been analysed recently[9], [10], [11], [12] In addition to the colorants also certain auxiliary ingredients are being used in the ready to use products. For example, certain preservatives find use (which seems unfortunate because of risk for adverse immunological reactions).

All together the studies conducted show that 46 organic and 12 traditional inorganic colorants are being used in today's marketplace. Due to limitations of the studies the JRC thinks it probable that even more organic colorants are being used – and can be used. About half of the colorants identified are not allowed on the surface of the skin in the form of cosmetic ingredients.

The results showed that colorants also have high microbiological load.

The most striking feature as concerns the inorganic colorants is the apparent disappearance from the marketplace of the earlier "prominent" ingredients HgS, CdS and the Cobalt blue.

Out of the 46 organic colorants identified, as many as 32 (70 %) are azo compounds that may potentially be reductively cleaved metabolically into an aromatic amine when situated in the viable skin layers – or in the liver upon release into the bloodstream. Out of the 32 azo colorants identified 10 "contain" an

[3] Special Report on Youth, Piercing, Tattoing and Hepatitis C, TrendScan Findings, Health Canada, March 2001
[4] Forbes, GB. Psychol Rep 2001 Dec;89(3):774-86
[5] Mayers LB et al. Mayo Clin Proc 2002 Jan;77(1):29-34)
[6] Armstrong ML et al. Mil. Med. 2000: 165:135-141
[7] Rooks JK et al. Minn Med 2000; 83:24-27
[8] WORKING PAPER OF THE TWG/JRC "Chemical Composition of Tattooing and Permanent Make Up Products", Final version: November 2003. Authors: Hans Jørgen Talberg / Norwegian Food Control Authority, Norway (editor); Wolfgang Bäumler / Department of Dermatology, University of Regensburg, Germany, John Lundsgaard / Chemtox A/S, Denmark; Rudolf Vasold / Institute of Organic Chemistry, University of Regensburg, Germany
[9] 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
[10] Lundsgaard J: Chemtox A/S: Investigation of pigments in tattoo colours, Survey no 2 – 2002, on behalf of the Danish EPA
[11] Baeumler W; Eibler ET; Hohenleutner U; Sens B; Saeur J; Landthaler M: Q-switch laser and tattoo pigments: first results of the chemical and photophysical analysis of 41 compounds, Lasers Surg Med. 2000;26(1):13-21
[12] Investigation conducted by the Council of Europe and that are referred to in the working paper mentioned in footnote 8

aromatic amine classified carcinogenic within the frames of EU chemical legislation. Azo dyes that release detectable amounts of these amines (except for aniline) are not allowed in clothing bedding, leather articles or other textile articles that come in contact with the human skin (New EU directive entering into force mid 2003).[13] At least four of the identified azo pigments were banned for cosmetics uses in the 80s and early 90s. Some of the azo colorants are found to be allergenic.

Also among the other types of encountered organic colorant ingredients one can easily pick out some for which well documented inherent toxic properties strongly indicate that the use made of them for tattooing/PMU purposes may entail health damage.

Very few green, violet, blue and brown organic molecules are on the palette. To the extent that these will not be banned under a new regime it will be of considerable importance to the branch to sort out their safety in use.

Seemingly the purity of the colorants in question is more or less similar to that for colorants being used for industrial purposes like paints, printing inks, coatings, plastics coloration, car lacquers etc. The overall impression is that plain industrial colorants are being used. The pigment producer never secured them for tattooing purposes. More expensive colorants that are additives permitted for foodstuffs, cosmetics and drug use hold a higher degree of purity. Competent bodies following up on the work done so far should treat the question arising as to whether there should be a separate purity regime pertaining to the tattooing products. The branch and other stakeholders must, of course, be connected to this work in the usual manner when settling the question.

5 Review of health effects & risks[14]

This review carried out on health impacts and risks associated with tattooing and piercing as reported casually in the medical literature shows that a systematic observation and registration of health impacts is widely missing.

The origin and chemical structure of colouring agents used for tattooing are hardly known. Pigments are mainly industrial organic pigments with high microbiological and impurities and a load of metals such as cobalt and mercury.

The observed health effects, which are potentially associated with tattooing and piercing, include

- Viral infections such as hepatitis, AIDS, and cutaneaous infections;
- Bacterial infections such as impetigo, toxic shock syndrome, tetanus, cancroids, tuberculosis and leprosy;
- Fungal infections such as sporotrichosis and zygomycosis;
- Allergic reactions such as cutaneous irritation and urticaria;
- Granulomateus/lichenoid reactions;
- Pseudo-lymphomas;
- Lymphadenopathy;
- Sarcoidosis;

[13] European Parliament and Council Directive amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants).
Commission approved a Common position 11 June (no 31/2002). The European Parliament approved it 11 May. The directive is now awaiting publication in the Official Journal. (Internet, new directive).

[14] WORKING PAPER OF THE TWG/JRC "Risks and Health Effects from Tattoos, Body Piercing and Related Practices" by Demosthenes Papameletiou, Alexandre Zenié (Joint Research Centre), Wolfgang Bäumler (Department of Dermatology, University of Regensburg, Germany), Dieter Schwela (World Health Organization), May 2003

- Malignant lesions such as melanoma and skin cancer;
- Behavioural changes;
- Other skin diseases such as psoriasis, photosensitisation, photo toxicity and photogenotoxicity.

Little is known with respect to the transport and metabolism of the colouring agents in the body both with respect to tattooing and removal of tattoos by laser treatment. Risk assessment studies for these substances are only emerging. At present, existing knowledge is insufficient to quantify the administered dose of harmful substances.

The review of the scientific literature leads to the following recommendations

- The ingredients of substances used for tattoos should be analysed and a systematic risk assessment with respect to potential health impacts performed; the same applies to materials used in piercing. An appropriate methodology needs to be developed.
- The awareness of studios for tattooing and piercing and their customers on the health impacts should be raised.
- Ingredients of colours and materials should be properly labelled.
- It should be obligatory to have licensed colours and materials to be used in tattoo and piercer studios.
- The hygienic conditions of tattoo and piercing studios should be standardized and regularly controlled. Minimal hygiene rules should be made obligatory.
- Regular training courses on the potential health impacts should be performed for tattooists and piercers.
- An accreditation bureau/laboratory should be established for education of tattoers and piercers and supervision of their studios.
- Surveillance of occupational diseases of tattooers and piercer mandatory. Harmonised schemes should be developed at the European level.
- There is a need for epidemiological studies on the prevalence and causal association of tattoo- and piecing-related adverse effects.
- The debate on epidemiological studies of tattoo- and piercing-related viral hepatitis needs to be clarified.
- A warning should be given to clients informing them on the potential adverse health effects in vulnerable individuals due to even admissible colours and materials. Vulnerable individuals include
    - Pregnant women
    - Children and infants
    - Atopic individuals
    - Individuals with heart diseases
    - Individuals with dermatoid diseases
    - Individuals exposed occupationally to heavy metals, VOCs, PAHs, UV.

The implementation of these recommendations would provide systematic data for upgrading the first version of the health effects report. The JRC and DGSANCO would consider the possibility of updating this report once a year by review of the surveillance process, the additional information gathered in this process and scientific publications. An Editorial Committee would ensure the scientific standard of the annual review.

6 Regulatory review

The objective of this chapter is to present an overview of the different specific provisions covered in national regulations/projects and to offers a starting point for future EU activities on this subject. Currently, tattooing dyes and piercing materials represent a legal paradox, at least in the EU. These are used for cosmetic purposes yet the route for their administration (injection/skin penetration) puts them outside the scope of the Cosmetics Directive (76/768/EEC) which considers that "substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics". To seek clarity on this the Commission/DG SANCO has consulted informally with the Member States and the emerging consensus was that tattooing dyes should be considered as general consumer products and hence should be under the General Product Safety Directive (92/59/EEC) and the Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations. This trend is also reflected by the overview presented below.

Country	**Inventory of existing legislation and ongoing regulatory actions**
EU Member States of the Partial Agreement in the Social and Public Health Field[15]	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 Introduction) 3. RESOLUTION RES AP (2003) 39 ON TATTOOS AND PERMANENT MAKE-UP; COUNCIL OF EUROPE COMMITTEE OF MINISTERS 19 June 2003
AUSTRIA[16]	- 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)

[15] Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom
[16] See http://www.bgbl.at

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
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	1. There is no legislation specifically regulating the activities of persons providing tattooing or body piercing services. 2. The Finnish Product Safety Act (914/86), amended through 539/1993, corresponds to the General Product Safety Directive 92/59/EEC except that the Act also covers consumer services (or practices). This is why tattooing and body piercing activities, too, could be brought within the scope of the Product Safety Act (914/86). In this case the Act should also regulate the suitability of needles and other instruments used in tattooing. 3. The Health Protection Act (763/94) is a national regulation which is also applicable to the regulation of hygiene at the place where tattooing is being performed. This regulation covers instruments and their use, e.g. the working of autoclaves.
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. Tattooing 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 tattooing. 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	1. Information on state regulations is available on most state websites. For example, the State of New Jersey has issued regulations on body art procedures, including tattooing, that are available on the following website: http://www.state.nj.us/health/eoh/phss/bodyart.pdf. 2. FDA discusses tattoos and permanent make-up, including safety concerns and removal techniques, in an article available on the following website: http://vm.cfsan.fda.gov/~dms/cos-204.html. FDA discusses temporary tattoos on the following website: http://vm.cfsan.fda.gov/~dms/cos-tatt.html.
CANADA	Pratiques de prévention des infections dans les services personnels : tatouage, perçage des oreilles, perçage corporel et électrolyse, Volume: 25S3 – juillet 1999[17] 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[18] 2. Infectious Disease Regulations. The Health (Infectious Diseases) Regulations 2001 (incorporating brothels provisions) and the Health (Prescribed Accommodation) Regulations 2001, 15 May 2001[19]

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

7 Policy options

7.1 Positive & negative lists[20]

Objectives
As already mentioned, the safety of tattoos and body piercing has recently been questioned. Therefore, and as wished for by the DC SANCO, the JRC carried out a safety assessment as presented in the subsequent chapter 2.2. It provides a survey as to the many different kinds of adverse health effects observed over time. Also, it indicates potential long-term health risks that may follow from an observed marked swing in the marketplace over the past 20 years or so away from traditional inorganic tattooing colors towards much use of organic colorants of different kinds. Up till now health authorities haven't paid much attention to the latter risks because so little has been known about the chemistry involved.

JRC would advice that the subsequent safety management to be undertaken within the EU Commission involves also deliberations as to whether there is a need for a particular EU regulation of the ready-to-use products and practices involved. It's reminded in this connection that already 17 February 2000 the Scientific Committee of the EU Commission dealing with cosmetics and non-food products (SCCNFP) drew the conclusion that regulation is indispensable as concerns the tattooing and PMU ready-to-use products. Also, it's observed that as of 19 June 2003 the Council of Europe recommends a specific regulation of these products - and the Netherlands has already such a regulation in place and working. Other European Countries are to follow suit.

Should safety managers eventually conclude there is a need for EU regulations the next question would be how these should preferably look like. JRC foresaw this quest and evaluated what would be an optimal solution as concerns regulation of the use of the different kinds of ingredients being used in these products. An ingredient is a chemical that is deliberately added to a ready-to-use product[21].

Reaching for an optimal solution JRC analysed the advantages and disadvantages of two principally different regulation models, e.g. *a negative list solution* and *a positive list solution.*

The negative list solution means that some obviously harmful ingredients are explicitly prohibited, whereas all other ingredients 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.

In the following the analysis of the two models and the recommended regulation is presented

[20] by H. J. Talberg**,** Norwegian Food Control Authority
[21] The problem of impurities is not dealt with here. There seems, however, to be a need for a specific purity regime. As a first step one would think it appropriate to require that as a minimum requirement the colorants being used are subjected to the same purity regime as that pertaining to colorants being used in cosmetics, foodstuffs and drugs (there is one common regime for these colorants). The JRC is of the opinion this issue should be treated at a later stage.

Analysis of the two regulatory options: Benefits and difficulties

Premises

- The responsibility for the safety in use of the products, rest primarily if not entirely with the marketers.[22]
- A positive list should be finally decided upon on the basis of safety assessments undertaken by highly qualified industry independent scientists.
- Right from the start an approved positive list should contain enough ingredients to secure that market players having signalled interest in official regulations will also respect these regulations. It is foreseen that not only a couple of colorants is enough.
- Within the framework of an eventual positive list solution – also as a possible long-term solution - there will be no room for a secondary positive list showing ingredients that are allowed on a temporary basis until enough knowledge is harvested to eventually authorise them on a more permanent basis.[23]
- A negative list must be supplemented with a pre marketing risk evaluation requirement on the part of market players in order to make sure that the ready-to-use products as a whole are safe as used. Preparations of such risk evaluations should be based on a scheme as shown elsewhere in this document.[24]

7.1.1 Positive list option

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 entirely on their own.

Disadvantages

- The main disadvantage is that the responsibility for having only safe products will rest with the authorities in an unfortunate disproportionate manner.[25]

- 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.

[22] Since many years this principle has been at the base of most EU product regulations. Public bodies will on their own not be able to secure products using but prohibitively large parts of societies economic resources. Also, the principle 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.

[23] This standpoint has it's rational in the unfortunate experience with the Part 2 positive lists within the domain of the EU Cosmetics Directive.

[24] This is a regulatory element collected from the EU regulation of cosmetics products

[25] *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.*

7.1.2 Negative list option

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.
- The 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.[26]
- The list can be lengthened progressively as new knowledge becomes available.
- Costs on the hand of the authorities will not be prohibitively large.

Disadvantages

Many SME could be expected to take lightly on their responsibility to make safety assessments. 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.

Recommendations

On the basis of the above analysis JRC is of the view that the negative list solution is the best solution – and the only one in the short run. Among other advantages it can be rapidly established[27]. It also places the responsibility for the safety of the products appropriately. The market players are obliged to secure their products by making pre marketing safety assessments following the scheme described elsewhere in this paper. There is the risk that the quality of many a safety assessment will not be up to the desirable standard. Therefore, the safety assessments should be made available to (registered with) the authorities in the country where the corresponding product is made. These authorities and their local producers should preferably engage in a close co-operation with the aim to try to establish a positive list in the long run. It should be the responsibility of the branch of ready-to-use tattooing/PMU products to launch proposals for a possible positive list. On the basis of national efforts the EU Commission should engage in a work with the aim to try to establish a harmonised positive list in due time.

[26] *It's observed that some EU countries are already in the process of preparing a regulation based on the negative list concept (this following the recommendation of the CoE).*

[27] The negative list of the recently adopted CoE resolution regulation could serve as a first step model

7.2 Risk Assessment[28]

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.

[28] by Richard van Buuren, Inspectorate for Health Protection, The Netherlands

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 and 12 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%).

7.3 Authorisation & Registration[29]

Objective

The objective is to make a possible regulation of the tattooing and piercing area through a certification and approval arrangement

The purpose of a regulation within this area must be:
- to ensure that buyers when choosing the performer have a basis for making a "safer" choice.
- to give the authorities the possibility to regulate the market
- to ensure there will come more secure products to be used in piercing and tattooing

The basis of the regulation should be that a serious/responsible performer can get a kind of certificate through a recognised education laid down by the authorities, a control of their equipment and working areas by the local authorities and a commitment to used approved materials. When fulfilling these demands they get a certificate they can show their customers and thus allow their customers to choose a safe performer (and opt out the risky - frivolous performer).

The education which must be completes with a passed examination shall include subjects like hygiene, requirements to equipment, materials and rooms, responsibility, regulation and first aid.

In addition to having completed the course, the premises and the equipment also have to be approved by local authorities and the performer must commit to only using legal/approved materials.

Legal/approved materials

The materials used for tattooing or piercing must obey the demands of the regulation described in chapter 2.1 and 2.2. To ensure this it might be recommended to make some kind of system to ensure that the products are legal. This might be taken out through an impartial instance, which will evaluate the documentation according to the criterions drawn up and approve it if all conditions are met. The producer must 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.

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.
- The producer of colour pays for the approval of the colour
- The performer pays for his own education
- The performer pays for the regular visits from the health authorities

[29] by Anette Ejersted (Danish EPA) and John Lundsgaard (Chemtox) Denmark

- The producer of colour/jewellery only has to reveal his full recipe information to the approving company.

Disadvantages seen in this set up
It might give the consumers a false feeling of security to think that there will be absolutely no risk in getting a tattoo of a piercing if they choose a certificated performer.

Recommendations
To make a certification system of the performers so the consumers can make a safe choice.
To make some kind of system to authorise the products by an impartial company which looks through and approve the documentation.

7.4 Education & Skills[30]

The objective in preparing this chapter is to ensure the safety of tattooing and the application of permanent make-up by imposing a requirement that tattoo artists and those engaging in the application of permanent make-up be adequately educated. It is of primary importance, that tattoo artists and those applying permanent make-up adopt a responsible approach to their work. For education to be appropriate it needs to reflect this. Education of this kind is likely to increase the regard in which tattoo artists are held.

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 between the two procedures in a number of respects that need to be taken into consideration as appropriate.

Minimum requirements for the design of education and training courses

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

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

Human anatomy and physiology

- The various tissues (fatty, connective, bony, cartilaginous, nervous, vascular)
- Repair of tissue damage (paying attention to various particular aspects)
- Physiology of the skin
- The commonest skin diseases
- Diseases in general and physiological conditions (e. g. pregnancy) that constitute contra-indications to tattooing
- Toxicology of pigments
- Hygienic conditions
- Regulations/advising clients about risks

Possible benefits/difficulties

Possible benefits

- The likelihood of tattooing procedures being safe is increased.
- Members of an appropriately educated profession are likely to earn greater respect

Possible difficulties

- Motivating practioners to educate themselves
- Determination of the extent of knowledge needed: the basic education of practitioners varies greatly.

[30] by Eeva-Liisa Sainio, The Finnish National Consumer Agency

Recommendations

The need for differentiation in the education, training and examination contents/requirements among the different types of activities, such as body piercing, ear piercing, tattooing, and PMU needs to be investigated.

The duration of the mandatory courses listed above needs to be estimated, including a final examination, which would need to be passed for a qualification to be awarded.

Participation in courses covering topics of the kinds outlined above should be mandatory for everyone intending to engage in the activities in question. However applicants who could demonstrate that they already possessed the knowledge required (beauticians, nurses etc.) could ask for the requirement for participation in the courses to be waived.

7.5 Hygiene Practices[31]

Objective
Guidelines produced and implementation experiences obtained during the last 20 years in the Netherlands[32], are being proposed as a starting point for EU wide application following peer review and updating . These guidelines cover seven key topics:

- General conditions of a well equipped studio
- The use of the right instruments and materials
- A good preparation
- Conditions while tattooing and piercing
- The aftercare
- Cleaning, disinfecting and sterilising
- Supervision and maintenance

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.

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 needle bars 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.

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:

[31] by Joan Worp and Albert Boonstra, Public Health Service Amsterdam

[32] 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

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.

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.

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.

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.

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.

Difficulties:

- 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.

7.6 Policy support actions

The following policy support actions need to be promoted, in parallel to the policy development, to improve policy implementation and risk communication.

- **Prevalence studies**: There is a strong need to develop robust prevalence data in the EU.
- **Health effects & regulatory reviews** – Continuation and yearly update of the health effects & regulatory reviews by the EC-JRC "TattooNet", a web-based method for the interested government officials and scientists to communicate and exchange information on tattoo issues.
- **Organisation of a yearly conference** like the one in May 2003 organised by the JRC, with separate devoted sessions for the basic science, inventory of chemicals used, research on health effects and for risk assessment/management/policy.
- **Microbiology** – Regulatory requirements on tattoo inks regarding sterility are going to present a serious chemical/microbiological challenge, that needs to be investigated in terms of the availability of best practices and the related cost/benefit.
- **Testing of existing materials**: To assess the risk of existing tattoos in humans the pigments and its impurities injected into skin so far must be evaluated.
- **Development and testing of novel materials**: There is a need to promote the development and testing of novel materials that are appropriate for injection into the human skin (in terms of purity and toxicity) and provide the performance characteristics that are needed from the artistic point of view
- **Epidemiology:** Epidemiological studies could provide considerable information on the safety of laser-based tattoo removal, long-term safety of tattoos, or the impact of solar light or tanning light exposure of tattooed-citizens. There are also other possibilities to enlist freshly tattooed and body-pierced individuals into a program to quantify health impact (checkup, dermatological assessment, urinalysis).
- **Man/mouse extrapolation** – There is a need to develop qualitative and quantitative information about the presence and fate of the tattoo pigments and the associated impurities in human skin and to try to generate similar data with mice such as pigment particle size in the skin, relationship of particle size to depth in skin. Moreover the transportation of pigments and impurities to other organs in the human body could be investigated using animal and/or human models.

8 Conclusions and recommendations

- There is currently an explosion in the prevalence of tattooing/piercing practices across the EU, however, in conjunction with a lack of awareness of health risks and the absence of effective regulations.
- The emerging consensus is that action is needed to ensure safety of tattooing/piercing practices across the EU.
- The marketing of tattooing/piercing materials needs to be regulated on the basis of safety considerations.
- A general sterility requirement needs to be introduced for all chemicals, products/articles/preparations that are intended to be injected into the human skin
- A list of substances and materials leading to adverse health effects ("negative list") could be developed. These substances and materials should not be applied.
- Adverse health effects associated to tattooing and piercing could be avoided by applying only substances and materials ("positive list"), which are not harmful, do not dissolve in the blood stream, do not contain impurities and toxic elements and are compatible with the skin and blood vessels.
- Risk assessment procedures need to be developed to take into account the particularities of tattooing/piercing practices.
- Requirements for education, training and application of hygienic practices need to be developed and harmonised across the EU.
- Laser removal and the impact of solar light need to be investigated with respect of potential adverse health effects
- Policy support actions need to be promoted, in parallel to the policy development, to improve our understanding about the potential health effects, risk communication and policy implementation.

Technical Working Group (TWG)

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

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