

THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS
INTENDED FOR CONSUMERS

CONSULTATION

CONCERNING

RISKS AND HEALTH EFFECTS FROM
TATTOOS, BODY PIERCING AND RELATED PRACTICES

adopted by the SCCNFP during the 25th Plenary meeting
of 20 October 2003

1. Background

The safety of tattoos and body piercing has been the subject of 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.

Furthermore, the Scientific Committee on Cosmetics and Non Food Products (SCCNFP) in its opinion of the 17 February 2000 noted the large number of colorants used in tattooing for which the chemical structure, identity, and toxicological profile are incomplete or unknown, thereby precluding a proper risk assessment. The SCCNFP recommended that a systematic effort be undertaken to amass the needed chemical and toxicological information so that a proper risk assessment can be conducted.

Tattooing colorants and piercing materials represent a legal paradox, at least in the EU. Although they are used for cosmetic purposes, the route for their administration (injection/skin penetration) puts them outside the scope of the Cosmetics Directive (76/768/EEC). To seek clarity on this, the Commission/DG SANCO has consulted informally with the Member States. The emerging consensus is that tattooing dyes should be considered as general consumer products and hence should be under the General Product Safety Directive (92/59/EEC) and possibly under the Limitations Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC).

In this light, DG SANCO (unit B.3) asked the Joint Research Centre (JRC) to undertake action to establish a common knowledge basis on the safety of tattoos and body piercing. This activity is part of the EIS-CHEMRISKS project that the JRC is conducting at the request of DG SANCO to collect, process and assess information on the consumer exposure and associated health risks from chemicals in consumer products/articles.

The main axes of work 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).

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. A technical/scientific workshop took place in Ispra on 5-6 May 2003.

An essential requirement for this activity and the entire EIS-CHEMRISKS project that both DG SANCO and the JRC have agreed on, is the need for independent review of the scientific/technical outputs. The attached report on the Risks and Health Effects from Tattoos, Body Piercing and Related Practices is in the first document that we consider appropriate to seek the advice of a Scientific Committee.

The document is a compilation of publicly available information on adverse health effects associated with tattoos and body piercing activities. Because of the nature of the report we have purposely avoided to name a single Scientific Committee that we would want to review this document. In our view, members with medical/clinical, microbiological, and dermatological experience from all three non-food Scientific Committees would be best placed to comment on the report. We do however leave the decision on the organisation of the work to your services.

2. Terms of Reference

The SCCNFP was asked :

1. To assess the overall scientific quality of the report titled “Risks and Health Effects from Tattoos, Body Piercing and Related Practices”. In considering this, The Committee is asked to comment as to whether the report has identified and reviewed to a satisfactory degree the types of risks and health effects that are associated with tattoos and body piercing.
2. To identify additional risks and adverse health effects that the report should include in order for it to be complete and comprehensive.
3. To advise the Commission on the types of activities (studies, research, epidemiology, prevalence, etc) that need to be undertaken in order to establish a solid data base on the size and severity of the risks and health effect associated with tattoos and body piercing.

3. Response of the SCCNFP

3.1. Introduction

An Opinion of The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning the Safety of Tattoos was adopted by the SCCNFP during the 11th Plenary meeting of 17 February 2000.

It was pointed out that as tattoos are administered by injection of appropriate inks intradermally, they do not fall under the Cosmetics Directive. The recitals of the original Directive 76/768/EEC demonstrate that this is the case. The 5th Whereas of the preamble of the Directive states :

"Whereas this Directive relates only to cosmetic products, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics;"

Tattoos are widely used to adorn the human body. Pigments are applied permanently into the skin. This procedure is also used for cosmetic purposes, the so-called ‘permanent makeup tattooing’ e.g., lip lining, eyebrow lining.

There is a large number of colorants used. In part the chemical identity of these agents as well as their toxicological characterisation is incomplete or unknown. Thus their safety evaluation is not possible.

Well recognised adverse effects of tattoos are known. Examples of these include amongst others granuloma formation, phototoxicity, contact dermatitis, and koebnerisation of skin diseases such as psoriasis and lichen planus.

Important additional health concerns include the transmission of infective agents such as human papilloma viruses, hepatitis and HIV.

For the adequate assessment of the toxicological aspects of tattoos it is necessary for the chemical identity of the colorants (dyes and pigments) to be provided. Therefore, it was recommended that the identity of these substances and materials (e.g., tools and appliances) used in the procedure be obtained so that a formal assessment could take place.

JRC was requested by DG SANCO to collect and assess all necessary information for establishing a common knowledge basis for the conception of future EU legislation. These organizations are also working with the Council of Europe which is preparing a resolution on 'permanent make-up and tattooing colours'.

3.2. JRC Working Paper

In line with the objectives of the above, JRC has prepared a working paper "Risks and Health Effects from Tattoos, Body Piercing and Related Practices". The paper is a literature review and consists of the following relevant sections:

- Infectious diseases
Viral infections, Hepatitis B, Hepatitis C, Hepatitis D, Human immunodeficiency virus, Papilloma virus, Vaccinia
- Bacterial infections
Fungal infections
- Non-infectious risks
Allergic reactions ; primarily type 4, Allergic contact dermatitis, Granulomatous/lichenoid reactions, Pseudo-lymphomas, Sarcoidosis, Cutaneous malignancies
- Other skin diseases
Psoriasis / Koebnerisation, Phototoxicity
- Transport of tattoo pigments in the body
Risks of laser treatment of tattoos. Tattoos and body piercing, as markers of risk-taking behaviour.

Following from the available information of reported adverse effects, recommendations were given:

- Ingredients of substances used for tattoos and materials used for piercing should be properly identified, labelled and systemic risk assessments with respect to potential health impacts performed.
- Positive ('licensed') list of colorants and materials and negative list ('prohibited') of colours and materials established.

- Schemes to increase awareness in studios for tattooing and piercing of health impacts, control of their hygiene standards, training courses for practitioners and surveillance of the occupational health of tattooists and pierces established.
- Establishing epidemiological studies on the prevalence and causal association of tattoo and piercing-related adverse effects – infectious and non-infectious.
- Appropriate warnings to be given to clients on potential adverse health effects.

Conclusion

The document “Risks and Health Effects from Tattoos, Body Piercing and Related Practices” provides a competent review of the recognised adverse effects of tattoos and body piercing and possible associations with others; it demonstrates the need to establish the characterisation of the substances and materials used in the procedures. The report has identified and reviewed to a satisfactory degree the types of risks and health effects that are associated with tattoos and body piercing and indicated where there is insufficient knowledge.

There is a brief discussion only of the role of ear piercing and the development of allergic contact sensitivity to nickel. However, the Nickel Directive (94/27/EEC), if properly enforced, should minimise this important association. Piercing may cause hypertrophic scarring, particularly in Afro-Caribbeans.

It is acknowledged that the document does not deal with so-called ‘temporary tattoos’ as they are skin stains. However, use of these products may pose a risk to health as discussed in document n° SCCNFP/0442/01 of 17 February 2000.

The following are required to be undertaken in order to establish a solid database on the size and severity of the risks and health effect associated with tattoos and body piercing:

Establishing chemical identity of the substances used as tattoo pigments and products for piercing; quantities used and batch variations, data on impurities of the products used, the long-term stability of the pigments applied and on the degradation products related to the removal of them.

Risk assessment of chemicals/products used following Notes of Guidance for Safety Evaluation, i.e. the bioavailability (systemic exposure) of the constituents including their major impurities (possibly aromatic amines) following intradermal application should be analysed.

Formulation of a ‘positive list’.

Licensing of premises/individuals undertaking procedures to ensure appropriate standards to reduce microbiological risks, suitability of individuals to receive procedures. ‘Clinical standards’.

Comprehensive record keeping to allow prospective studies.