Some Tattoo Colours Contain Carcinogenic PAH

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As part of official market surveillance, a government agency investigated three black tattoo pigments and found polycyclic aromatic hydrocarbons (PAH) contents totalling between 27 and 55 mg/kg.

The group of PAH consists of more than 100 substances, eight of which are classified as carcinogenic. Insufficient data is currently available on the health effects of tattoo colours. Thus little is known on how the components of the tattoo colours are distributed in the body and how they are metabolized. However, it is to be assumed that immediately after tattooing, part of the PAH is released into the areas surrounding the tattoo, into the lymph stream and possibly even into the blood stream. In addition, it is likely that PAH are constantly released from the tattoo and are thus distributed in the body.

The PAH contents measured by the authority pose a serious health and safety risk to the consumer. The BfR recommends that PAH in tattoo products are reduced to technically unavoidable amounts.

1 Subject of the Investigation

As part of official market surveillance, a government agency investigated three black tattoo pigments and found polycyclic aromatic hydrocarbons (PAH) contents totalling between 27 and 55 mg/kg. In addition, levels between 2.1 and 5.2 mg/kg were found for seven PAH which are classified as carcinogenic. The Federal Institute for Risk Assessment (BfR) was asked to provide a toxicological assessment.

2 Result

In the opinion of the BfR, PAH should not be contained in tattoo products. Technically unavoidable levels should use as a guidance the values recommended by the Council of Europe in its Resolution “ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up”: 0.5 mg/kg (total amount of all PAH) and 5 µg/kg for benzo[*a*]pyrenes (BaP). In the view of the BfR, tattoo pigments which exceed these levels constitute a serious risk in terms of Article 12 of the Guideline 2001/95/EG (RAPEX).

3 Explanatory Statement

3.1 Risk Potential

The group of PAH comprises more than 100 substances which are chemical compounds of several condensed benzene rings. It can be demonstrated that PAH are ubiquitous in the environment. They are formed through incomplete combustion of organic materials as well as during frying, smoking and grilling of foodstuffs. PAH are also contained in tobacco smoke.

PAH posses properties which are harmful to human health. According to Appendix VI of Regulation (EC) 1272/2008 (CLP-VO), eight representatives of this substance class are currently classified as carcinogenic. Substances and preparations must in turn be marked as carcinogenic and in accordance with Appendix XVII of Regulation (EC) 1907/2006 (REACH)

must not be sold to the general public, if they contain these eight PAH in concentrations above certain concentration limits.

The United States Environment Protection Agency (US-EPA) has named the following 16 PAH which in environmental testing constitute relevant proportions of the total contents of PAH: naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthen, pyrene, benzo[*a*]anthracene, chrysene, benzo[*b*]fluoranthene, benzo[*k*]fluoranthene, BaP, dibenz[*a,h*]anthracene, benzo[*g,h,i*]perylene and Indeno[1,2,3-*cd*]pyrene. This list predominantly takes into account environmental aspects and emissions and consists of a selection of very volatile to hardly volatile compounds. BaP is the carcinogenic lead compound used for the assessment of PAH contamination.

Germany aims at a Europe-wide regulation of PAH in consumer products through REACH and has submitted a restriction dossier to that effect to the European Commission. In this connection, the BfR has conducted a quantitative risk analysis with particular emphasis on the lead compound BaP. However, the suggested restriction would not apply to tattoo colours.

The restriction dossier for consumption products submitted by Germany made use of various approaches to derive dermal DMELs (Derived Minimum Effect Levels). Depending on the approach, various ranges were established:

Large Assessment Factor approach:	0.1 – 30 ng/kg bw/d
Linearised Approach, 10^{-5} risk level:	0.03 – 10 ng/kg bw/d
Linearised Approach, 10^{-6} risk level:	0.004 – 1 ng/kg bw/d

In cosmetic products, various PAHs classified as carcinogenic are banned in accordance with Appendix 1 of the Cosmetics Regulation. In addition, there are purity requirements for the colorants permitted in cosmetic products as laid out in Appendix 3. Such products must not contain traces of PAH.

In Germany, the standards for tattoo products are laid down in the Regulation on Tattooing Products (Tätowiermittelverordnung). The supervisory body tested three tattoo products that only use carbon (CI 77266) as a colorant. Carbon is permitted in cosmetic products and is not subject to any restrictions in tattoo products either. The 16 EPA PAH were determined for the tested samples. Between 27 and 55 mg PAH/kg and a total of between 2.1 and 5.2 mg/kg of all seven PAH classified as carcinogenic were detected in the probes. In one of the three samples, a BaP content of 0.6 mg/kg was found.

The Regulation on Tattooing products (Tätowiermittelverordnung) does not specify any purity standards for the used colorants. However, as is the case with cosmetic products, the use of PAH is banned in tattoo products. Recommendations regarding maximum values for various contaminants in tattoo products can be found in Resolution “ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up” of the Council of Europe. These values take into account both health aspects and the current state of technology. For PAH, a total value of 0.5 mg/kg and for BaP a value of 5 µg/kg was recommended.

3.2 Exposure Estimation

The BfR does not have dependable data for a quantitative exposure calculation. According to a non-representative online survey, tattoos vary both in terms of the number of tattoos (1 to > 8) and size (up to > 900 cm^2) in those tattooed (Klügl et al. 2010). PAH are to be expected in black tattoo pigments, although the proportion of black colour in tattoos is likely to vary to a great extent. Nor does the BfR have data on the concentration of the pigments in tattoo products. However, it is to be assumed that the proportion of pigments is between 10 and 50 percent. The quantity applied during the tattooing process to a very large degree depends on the experience of the tattooist. In experiments with an *ex vivo* model with pig skin and human skin from biopsies, pigment quantities between 0.63 and 2.49 mg/cm² were applied for 10-percent test solutions with pigment Red 22 and between 1.42 and 9.42 mg/cm^2 for 25-percent pigment solution in pig skin as well as between 0.95 and 1.69 mg/cm² for 25-percent pigment solution in human skin (Engel et al. 2008). For the 25-percent pigment solution, the median for experiments with pig skin was 3.5 mg/cm². This value is used for a realistic worst-case exposure estimation for the measured total PAH content of 55 mg/kg of a tattoo product. Furthermore, a 25-percent solution is used as a basis, and it is assumed that the equivalent of 14 mg/cm^2 of tattoo product is injected into the skin in order to achieve a pigment concentration of 3.5 mg/cm^2. For a tattooed person (with a body weight of 60 kg) with five tattoos of 900 cm^2 each, an intradermal exposure of 58 µg PAH / kg bodyweight can under these circumstances be estimated. Compared to the carcinogenic PAH, the exposure is lower by approximately factor 10, the exposure compared to BaP by about factor 100.

If a tattooed area of 600 cm^2 is taken as a basis of calculation for less tattooed individuals and if it is assumed that an experienced tattooist applies 0.6 mg of pigment per cm^2 of skin (corresponding to an equivalent of 2.4 mg/cm^2 of tattoo product), this results, under the further assumptions made above, in an interdermal exposure of 1.32 µg PAH/kg bodyweight for a person who weighs 60 kg.

However, additional aspects must be taken into account for the quantitative exposure estimation. Firstly, no validated method currently exists for determining the PAH in tattoo products. It is therefore unclear whether the measurement method used detected all PAH in the sample. Secondly, very little is known about kinetic parameters such as distribution and metabolisation of the substances from tattoo products. For this reason, it is not possible to estimate what quantities of the PAH injected under the skin become locally or even systemically available. More research is urgently needed in this area. It is to be assumed, however, that immediately after tattooing, part of the PAH are released into the surrounding tissue, into the lymph streamand possibly even into the bloodstream. In addition, it is very likely that PAH are continuously released from the pigments deposited in the skin, so that tattooed individuals are additionally subject to long-term exposure.

Scientific studies confirm that pigments are transported from the skin. Tests were conducted using a nude mouse model to establish the transport behaviour of pigments in the skin. For this purpose, mice were tattooed on their back. On average, 584 µg of pigment was injected per animal. The decrease in pigment concentration after 42 days amounted to 32 percent. This means that pigments and / or pigment components are transported from tattooed skin areas and possibly become systemically available (records of the ad-hoc committee “Tattoo Products” of the BfR Commission for Cosmetic Products, Engel et al. 2007, 2009).

4 Assessment

Given the complexity of the exposure and the limited data available, it is not possible at the present time to characterise the risk in this case. Due to the exposure explained above and the DMELs inferred by the BfR, however, a serious health risk resulting from the use of tattoo pigments containing PAH is very probable.

Various types of PAH are genotoxic carcinogens for which the levels for users should, in accordance with the ALARA principle (as low as reasonably achievable), be reduced to the lowest level that is technically achievable. Thus in the dossier submitted by Germany for carcinogenic PAH in consumer products, a limitation to 0.2 mg/kg is recommended for consumer products and / or their components. This corresponds to the current detection limit of the analysis method of the German GS seal of approval.

In cosmetic products, which as a rule are used *on* the skin, PAH are prohibited, and for permitted colorants, clear purity criteria exist. From the viewpoint of consumer health protection, the protection level for substances which are used *in or under* the skin should under no circumstances be lower than those for cosmetic products which are used on the skin. As is the case in cosmetic products, PAH are also banned in tattoo products and should therefore be minimised to technically unavoidable levels. This is also confirmed by the Council of Europe: its Resolution “ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up” for this purpose lays down content limits of 0.5 mg/kg for the total amount of all PAH and 5 µg/kg for BaP.

In the samples investigated, these PAH limits were clearly exceeded.

5 Possible Measures to be Taken

In the opinion of the BfR, PAH should not be contained in tattoo products. Technically unavoidable amounts should observe the values recommended in the Resolution “ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up” of the Council of Europe. Tattoo products which exceed these levels in the view of the BfR constitute a serious health risk in terms of Article 12, Guideline 2001/95/EC (RAPEX).

In addition, threshold values for technically avoidable PAH contents and for other contamination types such as aromatic amines, heavy metals and nitrosamines should be included in the revision of the Regulation on Tattooing Products (Tätowiermittelverordnung).

Literature

Engel E, Spannberger A, Vasold R, König B, Landthaler M, Bäumler W, 2007, Photochemical cleavage of a tattoo pigment by UVB radiation or natural sunlight. JDDG 7,583-589

Engel E, Vasold R, Santarelli F, Maisch T, Gopee NV, Howard PC, Landthaler M, Bäumler W, 2009, Tattooing of skin results in transportation and light-induced decomposition of tattoo pigments – a first quantification in vivo using a mouse model. Exp. Dermatol. 19, 54-60

Klügl I, Hiller KA, Landthaler M, Bäumler W, 2010, Incidence of health problems associated with tattooed skin: a nation-wide survey in German-speaking countries. Dermatology 221, 43-50

Records of the first meeting of the ad-hoc committee “Tattoo Products” of the BfR Commission for Cosmetic Products, 4 November 2009

http://www.bfr.bund.de/cm/343/1_sitzung_des_adhoc_ausschusses_taetowiermittel_der_bfr_kommission_fuer_kosmetische_mittel.pdf

ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up)
http://www.coe.int/t/e/social_cohesion/soc-sp/ResAP_2008_1%20E.pdf

Annex XV Restriction Report. Proposal for a Restriction. Benzo[a]pyrene, Benzo[e]pyrene, Benzo[a]anthracene, Dibenzo[a,h,]anthracene, Benzo[b]fluoranthene, Benzo[j]fluoranthene, Benzo[k]fluoranthene, Chrysene.
http://www.bfr.bund.de/cm/343/pak_annex_XV_restriction_report_proposal_for_a_restriction.pdf

BfR Opinion No. 032/2010 from 26 July 2010, Carcinogenic polycyclic aromatic hydrocarbons (PAHs) in consumer products to be regulated by the EU - risk assessment by BfR in the context of a restriction proposal under REACH
http://www.bfr.bund.de/cm/349/carcinogenic_polycyclic_aromatic_hydrocarbons_pahs_in_consumer_products_to_be_regulated_by_the_eu.pdf