

Introduction to Session V: Risk Assessment and Regulation

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Problems associated with tattoo inks

Potentially harmful substances in tattoo inks:

- azo dyes
- heavy metals
- polycyclic aromatic hydrocarbons
- preservatives
- CMR substances

Adverse reactions to tattoo inks:

- allergies
- non-allergic skin reactions
- infections
- inflammation
- cancer (?)

Problems for Risk Assessment

Exposure

- High variability in size and number of tattoos
- High variability in amount of ink per cm²
- Biokinetics
- Cleavage products/metabolites
- Acute vs. long term effects

- „Special effects“ (glow in the dark, UV-tattoos, encapsulated pigments, ...)

German Regulation on Tattoo Inks (Tätowiermittelverordnung):

Effective from May 1, 2009

Elements from CoE ResAP(2008)1 and German Cosmetics Regulation

General Principles:

- Products must not be detrimental to health
- Good Manufacturing Practice
- Labelling requirements
 - Address of manufacturer or importer
 - List of ingredients
 - Expiration date
- Notification (Federal Office of Consumer Protection and Food Safety)

German Regulation on Tattoo Inks (cont`d):

Regulation of Ingredients:

- Substances not allowed in cosmetics (listed in Annex 1 of the German Cosmetics Regulation)
- Substances which should not come into contact with eyes or mucuous membranes or should not stay on the skin for a prolonged time (Annex 3 of German Cosmetics Regulation)
- Appendix 1: List of aromatic amines which should not be present or be released from azo-dyes
- Appendix 2: List of colorants which should not be present



Risiken erkennen – Gesundheit schützen

Thank you for your attention

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