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 cm$^2$
- 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
Thank you for your attention

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