BfR-Symposium
„First International Conference on Tattoo Safety“
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Stakeholder Position

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- Official Lab of the Federal State Baden-Wurttemberg (southwestern part of Germany, 10 million inhabitants)
- Central Lab in terms of Cosmetics & Tattoo/PMU-Inks, 1500 risk-orientated samples per year
- Physico-chemical analysis of Tattoo/PMU since 1999
- Consulting competent authorities at inspections of Tattoo/PMU-parlors or Tattoo-Conventions
- Cooperation with small tattoo-ink-manufacturers, lectures at tattoo-artist-trainings
- Engagement in different national/international WG (BfR, European Commission, Council of Europe, CEN/ISO)
- Regular Risk Campaign in schools, radio & tv-interviews
Headlines as reactions to our results

BILD 2001, PMU „The ugly of the beauty“

Stuttgarter Nachrichten 2011, Tattoo: „Where Ferrari-Red attacks the skin“
Newest inquiries in Germany

• 2013: market research institute GfK Nürnberg made a representative inquiry for the health magazin „Apotheken-Umschau“ (1925 women, men, 14 - ? years old)

• 60 percent of 14-19 years old young persons see tattoos as attractive – „tattoo is in“

• 78,6 percent require strict legislation and surveillance to minimize health risks

• 57,1 % believe that tattooing is related to absolutely avoidable healthy risks
BUT...

NOT ENOUGH HAPPENS UP TO NOW

to really protect consumer (and serious tattoo/PMU-manufacturer and serious tattoo/PMU-artist)
in comparison to e.g. Cosmetics legislation (EU)

WHY?
Where is the political responsibility in the EU?
Some risks are well-known, there are many data gaps. There is no EU-mandate for research and no Regulation-draft up to now!!!
Our newest Results – chilling!

- Tattoo- Campaign 2012:
  30 % non-compliant
  5 serious risk cases (RAPEX)
  - Nickel 12 mg/kg & 45 mg/kg
  - PAH in black tattoos
    - Benzo-a-pyrene (BaP) 1150 µg/kg (Resolution EC: 5 µg/kg)
    - BaP 186 µg/kg
    - BaP 79 µg/kg

http://www.ua-bw.de/pub/beitrag.asp?subid=0&Thema_ID=
- http://www.ua-bw.de/pub/beitrag.asp?subid=2&Thema=
2012 Federal Council of Germany, Berlin: important statement:
  – German government should improve the existing German Tattoo Regulation 2008
  – or better: European Tattoo Regulation should be created

Basis of the future legislation:
  – Resolution 2008 of the Council of Europe on requirements and criteria for the safety of tattoos and PMU
  – German Tattoo Regulation 2008

Plus important amendments
My proposed Pillars of a future European Tattoo-Regulation

- **Positive list** approach for **pigments**
  - „Gold standards“ based on a risk-assessment strategy (data gap -> worst case scenario), i.e. well-defined criteria for purity (e.g. >98%), stability, toxicological endpoint-assessment by weight of evidence approach

- **Positive list** approach for **auxiliary ingredients** (solvents, stabilisers, pH-regulators, emollients etc)

- **No preservatives, but sterile products** (absence of viable organisms including viruses)
  
  **Only solution:** single use packages (e.g. 5ml), irradiation process like food irradiation (electron, gamma)
  - **low cost batch production is surely possible!!!!**
Proposed Pillars of a future European Tattoo-Regulation 2

- **Negative list** approach for **hazardous substances including impurities (raw material) or traces (finished product)**
  - Should be based on opinions of the SCCS
  - Shall constitute **limit values for traces** ("weight of evidence"-approach in case of data gap)
    - Nickel, other relevant metals (chromium VI, Cadmium etc.)
    - PAH, which are relevant (EFSA, EPA...)
    - PAA, definition of cleavage conditions
    - Nitrosamines, relevant (NDELA...)
    - Phthalates (CMR)
    - Other CMR
    - Fragrances (should be banned generally, Traces: relevant)
Proposed Pillars of a future European Tattoo-Regulation

- Application of harmonised methods for reliable and reproducible analysis of traces -> development of CEN/ISO-Standards if necessary (PAH, Nickel, Chromium VI, Arylamines etc.)
- Safety assessment before marketing of products analog Cosmetics Product Regulation including nanomaterials (e.g. Carbon Black – Fullerenes?)
- EU-Notification analog CPNP (Cosmetic Product Notification Portal) at European Commission-database, including Nanomaterials
- Labelling criteria see Resolution 2008 EC
Proposed Pillars of a future European Tattoo-Regulation

- Good Manufacturing Practice for tattoo/PMU production
- Youth protection analog oxidative hair dye-regulation in Europe: not allowed below 16 years
- Information of Consumer
  - Published list of withdrawn or recalled products, see BAG Switzerland (RAPEX isn’t consumer-friendly)
  - Certificate from parlor in terms of applied tattoo/PMU (pigments)
  - Campaigns: Not tv/newspaper but youtube, blocks, apps
- Qualification standards for tattoo/PMU artist
Important step: Sufficient Surveillance

• more risk-orientated
  – Close Cooperation with customs (e.g. airports)
  – Internet-products!
    • E.g. Glow in the dark & black light tattoo inks (stilbenes?)

• Cheap products
  (see e.g. ebay 2013-06-03 german website
  – 2076 results for tattoo guns and supplies
  – 537 results for tattoo inks (e.g. from Hong Kong)

• Regular exchange of information of competent authorities in the EU and worldwide („tattoo-vigilance“)
My impatience grows more and more!