

BfR-Symposium  
„First International Conference on Tattoo Safety“  
June 6-7, 2013 Berlin

## Stakeholder Position

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# CVUA Karlsruhe, Germany

- Official Lab of the Federal State Baden-Wuerttemberg (south-western 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“

Stuttgarter Nachrichten - Stadtausgabe / 19.02.2011 /

## Wo das Ferrari-Rot die Haut angreift

Land will strengere Regeln für Tätowierfarben erreichen

Die einen sehen es als Körper-

ne, Nitrosamine und Phenol. „Diese Ergebnisse zeigen, dass gesetzlich dringend nachgebessert werden muss,

re entwickeln. Als besonders heikel gelten schwarze Farben, die meist aus Ruß bestehen - so wie man ihn von



CVUA Karlsruhe



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# 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=0&Thema_ID)

- <http://www.ua-bw.de/pub/beitrag.asp?subid=2&Thema>



# Legislative Initiative of Baden Württemberg, federal state of German

- 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 1

- **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 3

- 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 4

- 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

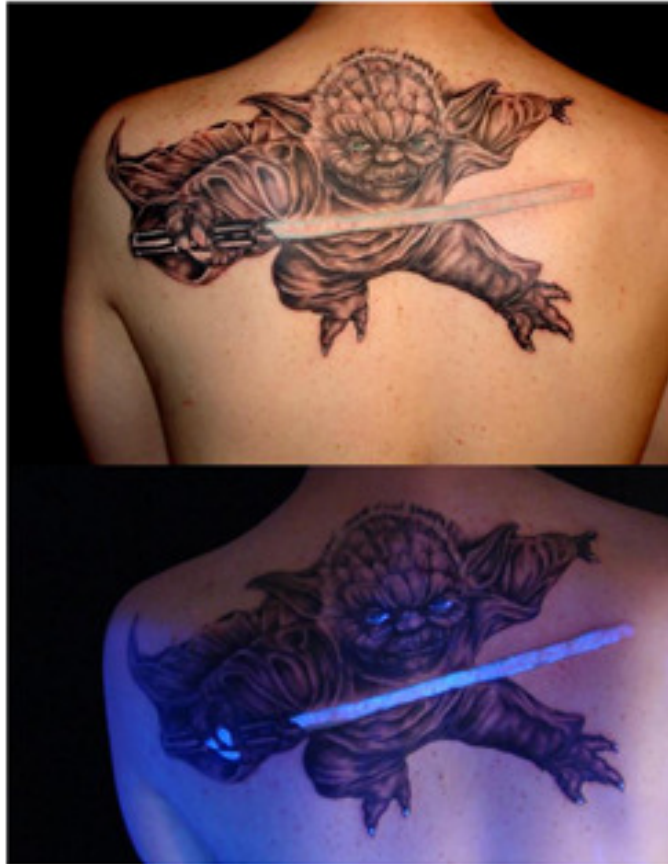


# Important step: Sufficient Surveillance

- 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!



Black light tattoos offer a unique opportunity to make your design more interactive. In this case, [Kenneth Bryan of Intimate Body Art Studios](#) made Yoda poised for battle in regular light, but with a little UV, his lightsaber is ready to strike down the Dark Side.

<http://mentalfloss.com/article/50096/18-stunning-black-light-responsive-tattoos>

