



Danish Ministry of
Environmental Protection

tattoo inks – example of non EU- regulated consumer products

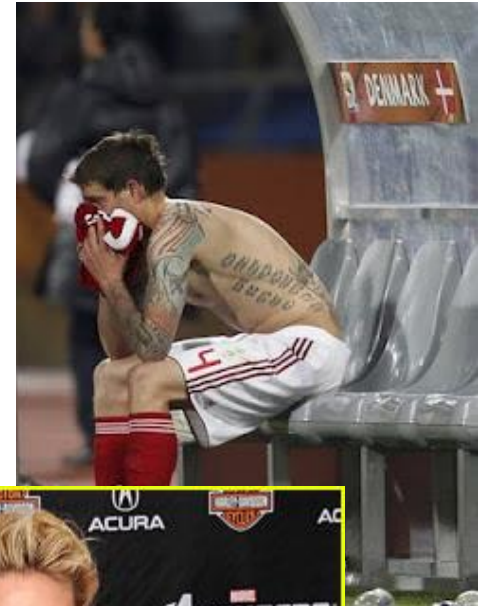
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1. Why is it necessary to regulate tattoo inks?
2. Which EU-regulation exists?
3. Why is it not sufficient?
4. How could it be solved?

Tattoo's are an integrated part of our culture

- 15 % of the Danish population has a tattoo
- 20 % in the age group 18-35
- 17 % is considering to have one
- 58 % of the already tattooed are considering to have more
- 12 % seems to have some kind of skin problems - 25% of those with colours
- The popularity is growing



Tattoo inks are imported consumer mixtures



- Mostly imported from: S, UK, US, (China)
- Mostly produced in: US, UK, D, It, Japan, (China)

Results from danish surveys - comparable to other countries

- Black pigments:
 - The cheap ones: PAH (118ppm), BaP (5,3ppm)
 - The expensive ones: no PAH
- Coloured:
 - All yellow, red, green contains carcinogens
PAA: azodyes, O-anisidine (1775ppm), aniline (300 ppm)...
 - Around 50 % in amounts that may potentially pose a risk
- Sterility in inks: around 10-15 % are contaminated

Risk - challenges

- **Chemicals** - carcinogens, allergens
- **Bacterial** - sterility
- **Exposure** - by injection, on purpose, into the skin
- **No labelling** - no user knowledge of ingredients or impurities and degradation products
- **No safety evaluation** of chemical ingredients, impurities, degradation products

What a challenge!



Existing EU-regulation for chemicals and other risks

- Tattoo inks are chemical mixtures: REACH and Classification and Labelling
- Tattoo inks are consumer products: Product Safety Directive

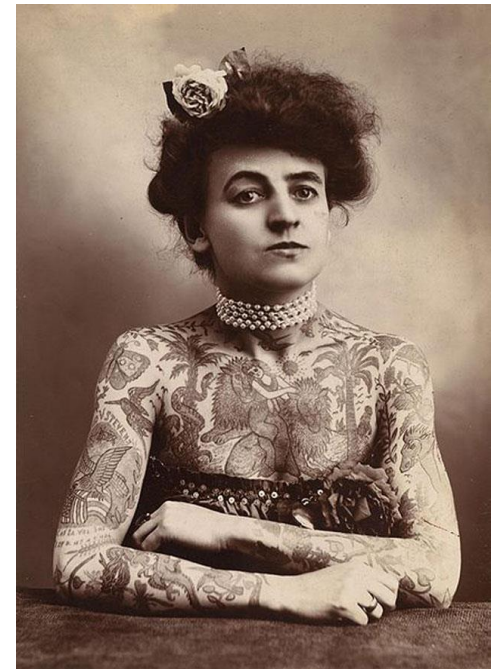


REACH – chemicals

- **Information:** Registration dossiers
 - In practice no information about specific use – only about generic use f.inst. “*pigments*” (probably not produced inside EU with the purpose of use in tattoos)
- **Restriction:** No specific restriction for use of chemicals in tattoo inks – however possible, but only by regulating substance-by-substance or group restriction based on identified risk

Classification & Labelling - chemicals

- C&L is based on warnings - if the chemicals accidentally comes into human contact (hazard identification)
- Are not considering exposure into the skin
- Quite high concentrations needed for CMRs for classification and labelling (0,1%)



Product Safety Directive (GPSD)

- all risks for consumers

- Covers only specific products where the authorities can document a risk for instance based on chemical or bacterial analysis and risk assessment



Challenges for existing EU-regulation – tattoo's

1. A soup of many different chemicals, impurities and degradation products
2. Not only chemical risk- also bacterial risk
3. The exposure – not covered by criteria in REACH
4. Ingredient list needed: some people allergic to small amounts of specific chemicals and also we are not familiar with all ingredients and their potential risks
5. Safety evaluation needed – how to evaluate the risk
6. Serious impact if risk – can not be removed by rinsing water f. instance

Danish initiatives

- An information campaign for the consumers: "Think before you ink"
- A national regulation has been notified to the Commission covering all the risks (chemicals, bacteria, labelling with ingredient list, safety evaluation)
- The Commission finds that REACH and the Classification and labelling regulation should be sufficient to deal with the chemicals – therefore the national regulation must wait/be stopped



Conclusion - tattoo inks

- Need for a specific EU-product regulation because:
 - tattoo inks are a specific product area with specific challenges which can not be sufficiently covered by existing EU-regulation
 - National regulation is not sufficient to get safe tattoo inks for the consumers





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Thanks
for
Your
Attention!

