Chemicals in articles and the General Product Safety Directive

ANEC-CONCO-BEUC Conference on
How to eliminate hazardous chemicals from consumer articles?

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SANCO.B.3 – Product and Service Safety
The core of the GPSD

- Producers shall be obliged to place only safe products on the market.
The core of the GPSD (cont'd)

"Safe product"
- any consumer product
- normal or reasonable foreseeable use
- does not present any risk or ...
- ... presents only the minimum risk considered to be acceptable
- consistent with a high level of protection
A product shall be deemed as safe when it conforms to
- a EU standard referenced in the Official Journal
- a national standard transposing a EU standard
- a national standard
The core of the GPSD (cont'd)

- Commission recommendations setting guidelines
- Product safety codes of practice
- The state of art and technology
- Reasonable consumer expectations concerning safety

Yardsticks for safety
Chemical standards referenced in the OJ

- Provide the presumption of safety
- Under the GPSD: None
- Under the Toys Directive: EN 71-3 (heavy metals), etc.
- Perhaps others
Article 13

- Product presents a serious risk
- Member States deal differently with the serious risk
- Urgent measures are necessary (and there exist none in EU legislation)
- Only Community measures can eliminate the serious risk
Dimethylfumarurate (DMF): RAPEX notifications 2007/2008
- Serious risk of dermatitis
- DMF a fungicide for transport
Dermatitis from DMF

GPSD rapid action (cont'd)

Recalls 2007/2008
- 32,000 pcs of furniture in the UK
- 38,000 pcs of seats in France
- >1,000 pairs of footwear in France
Different measures in some Member States

- France 4.12.08: Ban in seats and footwear
- Spain 22.12.08: Ban in all products with skin contact
- Belgium 12.1.09: Ban in all consumer products
GPSD rapid action (cont'd)

Commission Decision of 17.3.2009
(OJ L 74, 20.3.2009, p. 32)

As of 1.5.2009 consumer products with more than 0.1 mg/kg DMF
- must not be placed on the market
- must not be made available to consumers
- have to be withdrawn from the market
- have to be recalled from consumers

Valid for 12 months
Extensions of validity of the DMF ban

1st extension: Decision 2010/153/EU -> 15.3.2011


3rd extension in preparation -> 15.3.2013 or until REACH Annex XVII restriction in force = permanent
Possible improvement of rapid action: 2 options (GPSD revision)
- Initial validity longer than 1 year
- Validity until a certain event in the future
Strengthening chemicals risk assessment under the GPSD

Authorities
- take action when product is not safe
  - "Action limits" from REACH, referenced standards, etc.
- notify to RAPEX when product poses a serious risk
  - "Serious risk limit" may be higher than the "action limit"
  - to be developed and agreed
Example: Benzene, toluene, chloroform in glue of bicycle repair kit

"Action limit" in REACH: 0.1% for each of the 3 chemicals
"Serious risk limit": Proposal from NL authorities

- Exposure scenario of a consumer repairing a bicycle tyre in a small room
- Benzene
  - Additional lifetime cancer risk (LCR) of $10^{-6}$
  - $\Rightarrow$ "Serious-risk limit" at 3.5%
- Toluene
  - Margin of Safety = 100
  - $\Rightarrow$ "Serious-risk limit" at $>99.9\%$
Strengthening chemicals risk assessment (cont'd)

- Chloroform
  - Margin of Safety = 100
  - => "Serious-risk limit" at 8%

- Discussions with market surveillance authorities starting (RAPEX Contact Points)
Example: Lead and cadmium in a lipstick

- Prohibited under the Cosmetics Directive => Action by authority
- But traces acceptable if the cosmetic product remains safe:
  - non-intended presence
  - small quantity of a prohibited substance
  - from impurities (natural or synthetic), manufacture, storage, packaging
  - technically unavoidable in good manufacturing practice
Comparison of lead and cadmium concentrations in the lipstick with toxicological limit values => No serious risk

More & more cases expected.
A special role for chemicals under the GPSD?

Chemical risk is 2nd important risk in RAPEX
- 19% = about 1900 notifications since 2005)
  - Phthalates 674 notifications
  - DMF 196, azo dyes 152, chromium 121
  - Hydroquinone 90
  - Formaldehyde, toluene, nickel, nitrosamines, benzene: around 50
A special role for chemicals under the GPSD? (cont'd)

- GPSD covers all risks
  - Injury, strangulation, choking, electric shock, burns, etc.
  
  => No special role for chemical risk
Thank you for your attention!