



Chemicals in articles and the General Product Safety Directive

A faint, light-green illustration of various fruits and vegetables, including an apple, a banana, and a bunch of grapes, arranged in a stylized, overlapping manner.

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



The core of the GPSD (cont'd)

- 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



GPSD rapid action

■ 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

GPSD rapid action (cont'd)

■ Dimethylfumarate (DMF): RAPEX notifications 2007/2008

- Serious risk of dermatitis
- DMF a fungicide for transport





GPSD rapid action (cont'd)

■ Dermatitis from DMF

Rantanen T (2008) The cause of the Chinese sofa/chair dermatitis epidemic is likely to be contact allergy to dimethylfumarate, a novel potent contact sensitizer. Concise communication. British Journal of Dermatology 159: 218-221.



GPSD rapid action (cont'd)

Williams JDL, et al (2008) An outbreak of furniture dermatitis in the U.K. . British Journal of Dermatology 159: 233-234.





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



GPSD rapid action (cont'd)

■ 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**



GPSD rapid action (cont'd)

■ Extensions of validity of the DMF ban

- 1st extension: Decision 2010/153/EU
-> 15.3.2011
- 2nd extension: Decision 2011/135/EU
-> 15.3.2012
- 3rd extension in preparation
-> 15.3.2013 or until REACH Annex XVII restriction in force = permanent



GPSD rapid action (cont'd)

- 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



Strengthening chemicals risk assessment (cont'd)

- Example: Benzene, toluene, chloroform in glue of bicycle repair kit
 - "Action limit" in REACH: 0.1% for each of the 3 chemicals



Strengthening chemicals risk assessment (cont'd)

■ "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}
- => "Serious-risk limit" at 3.5%

■ Toluene

- Margin of Safety = 100
- => "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)



Strengthening chemicals risk assessment (cont'd)

■ 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



Strengthening chemicals risk assessment (cont'd)

■ 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!

