Toys and child care articles

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ANEC ASI CC Conference
"Hazardous chemicals in products - The need for enhanced EU regulations"
29th October 2013, Brussels
Outline

- what does AGES stand for?

- what are toys - definition?

- legal situation regarding chemicals in toys

- what are child care articles - definition?

- legal situation regarding chemicals in child care articles
Our vision

„Health for people, animals and plants“
AGES Structure

1) Austrian Federal Office for Food Safety
2) Austrian Federal Office for Safety in Health Care

Radiation Protection
Data, Statistics & Integrative Risk Assessment
Knowledge Transfer & Applied Research

1) Austrian Federal Office for Food Safety
2) Austrian Federal Office for Safety in Health Care

29.10.2013
Toys - definition

DIRECTIVE 2009/48/EC on the safety of toys - TSD

Article 2 - Scope

This Directive shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys).

Wikipedia: In psychology and ethology, play is a range of voluntary, intrinsically motivated activities normally associated with recreational pleasure and enjoyment.
Toys - examples
Article 10 - Essential safety requirements

General safety requirement ->

Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

Particular safety requirements ->
Annex II
ANNEX II - PARTICULAR SAFETY REQUIREMENTS

III. Chemical Properties

- Nitrosamines / nitrosable substances: 0.05 / 1 mg/kg

- Allergenic fragrances: 100 mg/kg
- Allergenic fragrances - labelling: 100 mg/kg

- Elements - different migration limits
<table>
<thead>
<tr>
<th>Element</th>
<th>mg/kg in dry, brittle, powder-like or pliable toy material</th>
<th>mg/kg in liquid or sticky toy material</th>
<th>mg/kg in scraped-off toy material</th>
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</thead>
<tbody>
<tr>
<td>Aluminium</td>
<td>5 625</td>
<td>1 406</td>
<td>70 000</td>
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<tr>
<td>Antimony</td>
<td>45</td>
<td>11.3</td>
<td>560</td>
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<tr>
<td>Arsenic</td>
<td>3.8</td>
<td>0.9</td>
<td>47</td>
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<tr>
<td>Barium</td>
<td>4 500</td>
<td>1 125</td>
<td>56 000</td>
</tr>
<tr>
<td>Boron</td>
<td>1 200</td>
<td>300</td>
<td>15 000</td>
</tr>
<tr>
<td>Cadmium</td>
<td>1.9</td>
<td>0.5</td>
<td>23</td>
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<tr>
<td>Chromium (II)</td>
<td>37.5</td>
<td>9.4</td>
<td>460</td>
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<tr>
<td>Chromium (VI)</td>
<td>0.02</td>
<td>0.005</td>
<td>0.2</td>
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<tr>
<td>Cobalt</td>
<td>10.5</td>
<td>2.6</td>
<td>130</td>
</tr>
<tr>
<td>Copper</td>
<td>622.5</td>
<td>156</td>
<td>7 700</td>
</tr>
<tr>
<td>Lead</td>
<td>13.5</td>
<td>3.4</td>
<td>160</td>
</tr>
<tr>
<td>Manganese</td>
<td>1 200</td>
<td>300</td>
<td>15 000</td>
</tr>
<tr>
<td>Mercury</td>
<td>7.5</td>
<td>1.9</td>
<td>94</td>
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<tr>
<td>Nickel</td>
<td>75</td>
<td>18.8</td>
<td>930</td>
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<tr>
<td>Selenium</td>
<td>37.5</td>
<td>9.4</td>
<td>460</td>
</tr>
<tr>
<td>Strontium</td>
<td>4 500</td>
<td>1 125</td>
<td>56 000</td>
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<tr>
<td>Tin</td>
<td>15 000</td>
<td>3 750</td>
<td>180 000</td>
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<tr>
<td>Organic tin</td>
<td>0.9</td>
<td>0.2</td>
<td>12</td>
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<tr>
<td>Zinc</td>
<td>3 750</td>
<td>9.38</td>
<td>48 000</td>
</tr>
</tbody>
</table>

Ba 1500 / 375 / 18750 mg/kg
Cd 1,3 / 0,3 / 17 mg/kg
ANNEX II - PARTICULAR SAFETY REQUIREMENTS

III. Chemical Properties
Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures (REACH / CLP)

food contact materials / Regulation (EC) No 1935/2004
Cosmetic toys / Directive 76/768/EEC

Ban of CMR-substances
substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys

Exceptions:
- Concentration lower as classification limit
- inaccessible to children in any form, including inhalation
- a decision has been taken to permit the substance or mixture and its use -> Appendix A
## Classification limits

<table>
<thead>
<tr>
<th>Component classified as</th>
<th>Limit of concentration, which leads to the classification of the mixture within the following category:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C/M/R der category 1A/1</td>
</tr>
<tr>
<td></td>
<td>C/M/R der category 1B/2</td>
</tr>
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<td></td>
<td>C/M/R der category 2/3</td>
</tr>
<tr>
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<td>$\geq 0,1/0,1/0,3 \ %$</td>
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<tr>
<td></td>
<td>$\geq 0,1/0,1/0,5 \ %$</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>$\cdots$</td>
</tr>
<tr>
<td>C/M/R der category 1B/2</td>
<td>$\cdots$</td>
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<tr>
<td></td>
<td>$\geq 0,1/0,1/0,3 \ %$</td>
</tr>
<tr>
<td></td>
<td>$\geq 0,1/0,1/0,5 \ %$</td>
</tr>
<tr>
<td></td>
<td>$\cdots$</td>
</tr>
<tr>
<td>C/M/R der category 2/3</td>
<td>$\cdots$</td>
</tr>
<tr>
<td></td>
<td>$\cdots$</td>
</tr>
<tr>
<td></td>
<td>$\geq 1,0/1,0/3,0 \ %$</td>
</tr>
<tr>
<td></td>
<td>$\geq 1,0/1,0/5,0 \ %$</td>
</tr>
</tbody>
</table>

REACH

REGULATION (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

ANNEX XVII - RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

- Benzene - 5 mg/kg (in its free state)
- Azocolourants - aromatic amines 30 ppm
- Phthalates - 0.1 % by mass
- Flame retardants - TRIS, TEPA, PBB - textile / skin contact
- Nickel - articles / direct and prolonged skin contact
EN 71 Safety of toys

EN 71-3 Migration of certain elements
EN 71-4 Experimental sets for chemistry and related activities
EN 71-5 Chemical toys (sets) other than experimental sets
EN 71-7 Finger paints - Requirements and test methods

EN 71-9 Organic chemical compounds - Requirements
EN 71-10 Organic chemical compounds - Sample preparation and extraction
EN 71-11 Organic chemical compounds - Methods of analysis

EN 71-12 N-Nitrosamines and N-nitrosatable substances

*EN 71-13 Olfactory board games, gustative board games, cosmetic kits and gustative kits*
Toys

Particular safety requirements regarding chemical substances in toys – TSD, REACH, standards

But:
- elements - some limits higher than in the old TSD
- allergenic fragrances - relatively high limits,
  55+11 fragrances are regulates, IFRA 184 substances
- phthalates - limits for only 6 substances - other phthalates are SVHC
- Generic requirement for CMR - limits are high (e.g. PAH)
  and ...
Toys

- No generic requirement for sensitiser (Kathon)

- No generic requirement for flame retardants (except TRIS...)

- No generic requirement for monomers

- No generic requirement for solvents

- No generic requirement for preservatives and biocides

- No generic requirement for nano materials

-> positive lists
Toys

Actual changes - committee procedures:

- limits Cd have been lowered
- limits Ba have been lowered
- limits Pb are under discussion

- written procedure regarding TCEP, TCPP, TDCP / annex C
- written procedure regarding BpA / annex C
- other substances / annex C are under discussion

Annex C:
- limits for toys for children under 3 years and for toys which are intended to be but in the mouth
- limits for single substances
Child care articles - definition

**REACH** / phthalats - footnote „childcare articles“:
For the purposes of this point "childcare article" shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.

**Wikipedia**: Child care (or "childcare", "child minding", "daycare" or "preschool") is the caring for and supervision of a child or children, usually from newborn to age thirteen.

**Scope CEN TC 252** “Child use and care articles”
Standardization of requirements of any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, transportation and protection for young children.
Child care articles
DIRECTIVE 2001/95/EC on general product safety

-> general safety requirement

Article 3 - Producers shall be obliged to place only safe products on the market

'safe product' shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular ...

-> no particular safety requirement
Child care articles

**REACH:** phthalates 0,1 % by mass

**Directive 93/11/EEC:** rubber teats and soother – nitrosamines ans nitrosable substances 0,01 ppm /0,1 ppm

**National regulations**
For example AT
- Verordnung über das Verbot der Verwendung von Bisphenol A in Beruhigungssaugern und Beißringen - BpA in soothers and teethers

**Standards**
Child care articles

EN 1400 - Soother

- elements EN 71-3 - lower limits
- nitrosamines - 0,01 bzw. 0,1 mg/kg (EN 12868)
- MBT (Benzothiazol-2-thiol) - 8 mg/kg
- antioxidants - 0,0625-0,3125 mg/l
- formaldehyde - 0,375 mg/l
- BpA (Bisphenol A) - 0,125 mg/l
- colour fastness (test with saliva DIN 53160-1)
- volatile compounds content - 0,5 %
Child care articles

Other standards - for examples

EN 12586 Soother holder
EN 1273 baby walking frames
EN 13209 baby carriers
EN 14344 Child seats for cycles
EN 1930 Safety barriers

......

-> cross reference to EN 71-3

**EN 14372** Cutlery and feeding utensils: elements, phthalats, volatile compounds content, formaldehyde, nickel, BpA

**FCM**

**EN 14350-2** Drinking equipment: requirements as in EN 1400
Child care articles

What is missing regarding chemical requirements?

**almost all** (see toys/list of deficiencies)

Soother

Child care articles which are food contact materials

Other child care articles
Toys and Child care articles

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Thank you for your attention