

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

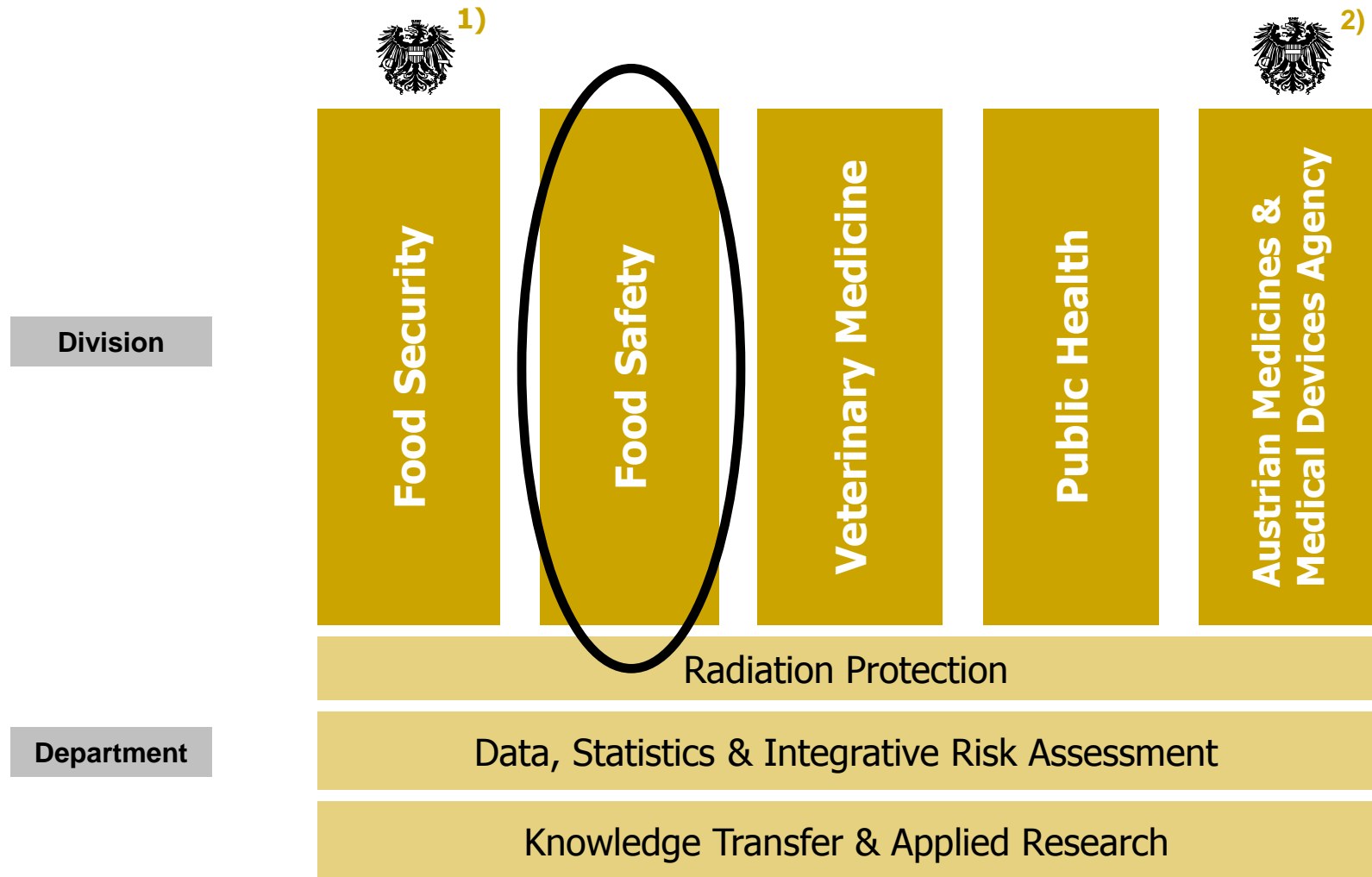
Our vision



„Health for people, animals and plants“



AGES Structure



1) Austrian Federal Office for Food Safety

2) Austrian Federal Office for Health Care

Toys - definition



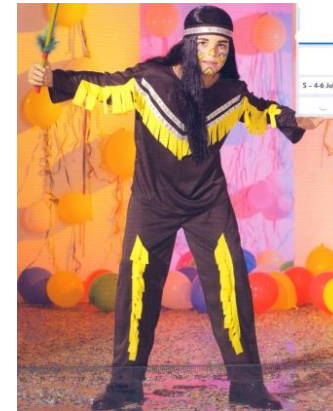
DIRECTIVE 2009/48/EC on the safety of toys - TSD

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

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	4 500	1 125	56 000
Boron	1 200	300	15 000
Cadmium	1,9	0,5	23
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

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

Component classified as	Limit of concentration, which leads to the classification of the mixture within the following category:		
	C/M/R der category 1A/1	C/M/R der category 1B/2	C/M/R der category 2/3
C/M/R der category 1A/1	$\geq 0,1/0,1/0,3 \%$ $\geq 0,1/0,1/0,5 \%$	---	---
C/M/R der category 1B/2	---	$\geq 0,1/0,1/0,3 \%$ $\geq 0,1/0,1/0,5 \%$	---
C/M/R der category 2/3	---	---	$\geq 1,0/1,0/3,0 \%$ $\geq 1,0/1,0/5,0 \%$

Regulation (EC) No. 1272/2008 - Directive 1999/45/EG

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 it's 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 regulated, 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

~~Biocidal Products Regulation~~



-> **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 put 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

AGES 



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 and 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

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