Hazardous chemicals in products

EU regulations for chemicals in products:
Key areas to be addressed

Dr. Franz Fiala
Consumer Council/Austrian Standards Institute
ANEC

2013-10-29
Studies: Chemical requirements for consumer products – parts I-IV

Commissioned by:
Consumer Council
Austrian Standards Institute

Carried out by:
FORCE Technology
Denmark
October 2010 - October 2013
Conclusions parts I and II
(review of broad range of articles legislation)

EU regulation for articles inadequate

- clear-cut rules often insufficient or missing altogether (many gaps, ‘make it safe’)  
- Comitology to include/change limits largely missing  
- ad-hoc regulation – reactive  
- no systematic approach/evaluation  
- covers only certain aspects of chemicals e.g. safety (not environment)  
- nanomaterials mostly not addressed  
- no obligation to provide information on chemicals in products

Consistent approach is missing!
Producer / importer of **articles** needs to:

- Register substances in articles if substance
  - is intended to be released and
  - is present in amounts > 1 tonne / year

- Notify SVHC substances in articles if substance
  - is present in amounts > 1 tonne/ year and
  - is above a concentration of 0.1% (w/w)
  - is included in the candidate list
  - but: no obligation to notify if P/I can exclude exposure
Article related problems:

- Relies heavily on industry self assessments
- Registration/Authorisation address use of chemicals - no product limits - particular problem for imported articles!
- Restriction path laborious and time consuming – not pragmatic
- Lack of flexibility - no quick adaptation (e.g. for exceptions as in ROHS)
- Substance-by-substance evaluation:
  - excludes bans of groups of substances (e.g. CMR, brominated FRs)
  - excludes a positive list approach (as in FCM regulation)
  - excludes non-toxic effects of chemicals (e.g. smell, TVOC, etc.)
  - excludes non-intentionally added substances (e.g. nitrosamines)
- Inadequate consumer information provisions

REACH is no substitute for product regulation!!!
Purpose of the study part III

Outline of chemical requirements for:

- Materials in contact with drinking water
- Materials in contact with food
- Packaging
- Emissions to indoor air from materials
- Personal protection equipment
- Clothing
- Products for children
- Electric and electronic products
- Flame retardants in various products
Current situation

- still many gaps after ~40 years of regulating
- even existing specific implementing measures are incomplete – e.g. colorants in plastic materials
- „Positive lists“ for plastics – only authorised substances may be used (exceptions)
- Not only toxicological considerations – overall migration, organoleptic properties
- Comitology to adopt specific measures

Gaps in FCM regulation must be filled, e.g. printing inks, paper, coatings...
Food Contact Materials Legislation

Proposal – regulations based on:

- **National regulations** on non-plastic FCMs
- **EFSA** – Report of WG on non-plastic food contact materials 2012 - ESCO list with ~ 3000 substances (somehow) evaluated in MS was established – only ~10% evaluated from 1991 following SCF guidelines
- Resolutions and guidelines from the **Council of Europe** on: colourants in plastic materials, surface coatings, silicones, paper and board materials, rubber products, packaging inks, metals/alloys...

**COM Roadmap for non-plastics FCMs**

- IA, public consultation 2013
Materials in contact with drinking water (water supply)

Current situation

- No specific EU legislation
- CPR does not allow to set limits
- 4 Member States Group (GE, NL, UK and FR) – discussion of possible harmonisation
- No EU solution in sight

Adoption of new EU regulation required!
Materials in contact with drinking water (water supply)

Proposal – Regulation based on EAS

- Initial type testing
- Information on material composition
- Compliance with positive lists (plastics), composition lists (metals) and approved constituents lists (cementitious materials)
- Organoleptic test: odour, flavour, colour, turbidity
- General hygiene (TOC and chlorine demand)
- Drinking Water Directive parameters (e.g. Pb, Cd, Hg, PAH, pesticides)
- Check for unsuspected organic substances
- Microbial growth
- Addition: ban of CMRs, PBTs, vPvBs
Emissions to indoor air

Construction Products Regulation (CPR)

- No performance requirements for products!!!
- Just harmonised declaration rules
- National performance requirements
- No national rules – no declaration necessary ("no performance determined - NPD")

General Product Safety Directive (GPSD)

- No Comitology to establish requirements
- "Emergency measures“ and standardisation mandates

CPR/GPSD do not allow to establish indoor related product requirements!!!
Emissions to indoor air

Proposal – New regulation based on

  - TVOC limits (SVOC/VVOCs later)
  - exclusion of volatile CMR substances
  - LCI (Lowest Concentration of Interest) values to be set/harmonised (other limits later)
  - sensory evaluation later
  - emission measurement test chamber 3 and 28 days (ISO 16000, CEN TC 351 standards after finalization)
Clothing

Current situation

- no European legislation including specific requirements for chemicals in clothing
- falls in the scope of the GPSD - no adequate framework for setting chemical requirements in products
- EU (and national) Ecolabel criteria for textiles
- ÖKOTEX 100
- available studies

Adoption of EU regulation based on above specifications required!
Clothing

Proposal – New regulation

- General exclusion of CMR, PBT and vPvB substances
- Substance specific requirements covering:
  - formaldehyde
  - pesticide residues
  - metals
  - phthalates
  - chlorinated benzenes and toluenes
  - flame retardants
  - colourants......
- Elimination of other dangerous substances based on Comitology
Products for children

Current situation – inadequate protection

- Requirements in **Toy Safety Directive** insufficient
  - CMR-thresholds (CLP) too high – cat. 2 carc. and mut.: ≥ 1.0%, cat. 2 reprotoxic substances: ≥ 3.0%
  - CMR exceptions - only in direction less restrictive
  - some limits questionable (elements, fragrances)
  - restrictions for other categories of substances only possible for toys for children below 36 month or toys intended to be mouthed

- **Child care articles** inadequately covered by GPSD, a few requirements in standards, CEN TR 13387 “Safety guidelines” currently revised
Products for children

Proposal Toys

- general CMR and EDC (cat.1A/1B) exclusion based on migration (solid) or content (liquid, powder) or evaporation (VOCs) and low level of detection, for PBTs and vPvBs content limit of 0,1%
- specific restrictions for: phthalates, formaldehyde, phenol, elements - lower limits (e.g. lead), fragrances (SCCS opinion!), isothiazolinones (kathone!), other sensitizers, TCEP, TCPP, TDCP and other flame retardants (positive list!), colourants, solvents, preservatives (positive list!), n-nitrosamines (lower limit), nanomaterials (positive list!)
- make use of (adapted) FCM regulation for toys for children < 36 months or placed in the mouth
- elimination of dangerous substances based on Comitology (all toys)

Proposal Child care articles

- adapt revised TSD requirements to child care articles – broaden TSD?
Packaging

Current situation – Packaging Directive

- Total concentration of lead, cadmium, mercury, and chromium VI shall not exceed 100 ppm
- Minimize other dangerous substances
- EN 13428 (Prevention) – only “N”-substances (others ignored) – “use minimum amount”

Proposal – Revise Packaging Directive

- Packaging (including inks) shall not contain CMR, PBT and vPvB substances exceeding 0.1 % – lower levels if necessary
- Systematic review of substances used/found
- Elimination of (other) dangerous substances (health and environment) based on Comitology
Electric and electronic equipment

Current situation – a few ROHS bans

- Ban of Pb, Hg, Cd, Cr VI, PBBs, PBDE
- Comitology to change annexes
- Preamble (10) – priority substances for review: hexabromocyclododecane (HBCDD), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP) and dibutyl phthalate (DBP)

Proposal – more restrictions

- Many substances not covered, e.g. organochlorine or organobromine FRs, TBBP-A, beryllium, indium phosphide, gallium arsenide, americium, germanium, antimony trioxide, ….
Nano materials

REACH

- no specific nano requirements
- tonnage triggers questionable for nano
- tests have to be done with bulk AND nano form?
- tests for bulk materials not always appropriate

Articles legislation

- specific nano provisions only for plastic materials in contact with food!

Incorporate specific nano requirements in REACH and in product regulation!
Article 33

- On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

- The relevant information shall be provided, free of charge, within 45 days of receipt of the request.
Incorporation of chemical requirements:

- REACH extension - include full product dimension
- Expand existing directives to cover chemicals
- Specific chemical sector legislation - follow ROHS model
- Horizontal directive for chemicals in products
- Expansion of ERP directive - all products and aspects - mirroring the Ecolabel Regulation - using synergies - all chemical rule making for products and enforcement in “one hand”
- Mix of above
Options for articles legislation

Horizontal and product specific aspects

- Flexible coverage of one or more product groups, e.g. indoor air: construction products, furniture, textiles,....
- Restrictions for groups of chemicals, e.g. CMRs, general low thresholds + deviations (more or less strict), + other substance limits via Comitology
- Positive lists, e.g. flame retardants, preservatives
- Special issues, e.g. nano product register
- Consistent approaches, but keeping the product dimension e.g. systematic screening
- (Comprehensive) product declaration schemes
For a non-toxic environment!
Contact details Franz Fiala

Address
Austrian Standards Institute - Consumer Council
Heinestrasse 38
1020 Vienna

Email
f.fiala@austrian-standards.at

Telephone
0043 1 21300 709