

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!

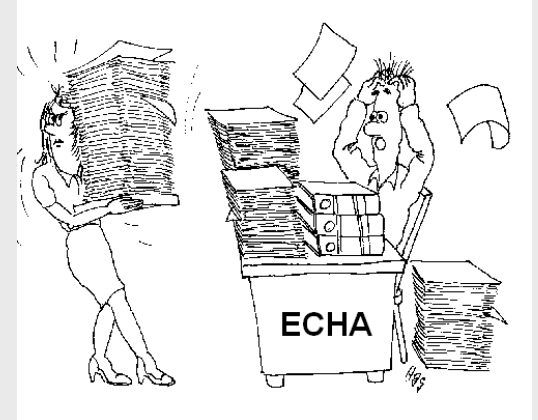
REACH - articles

(“shape, surface and design determine function”)

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



REACH - articles

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!!!

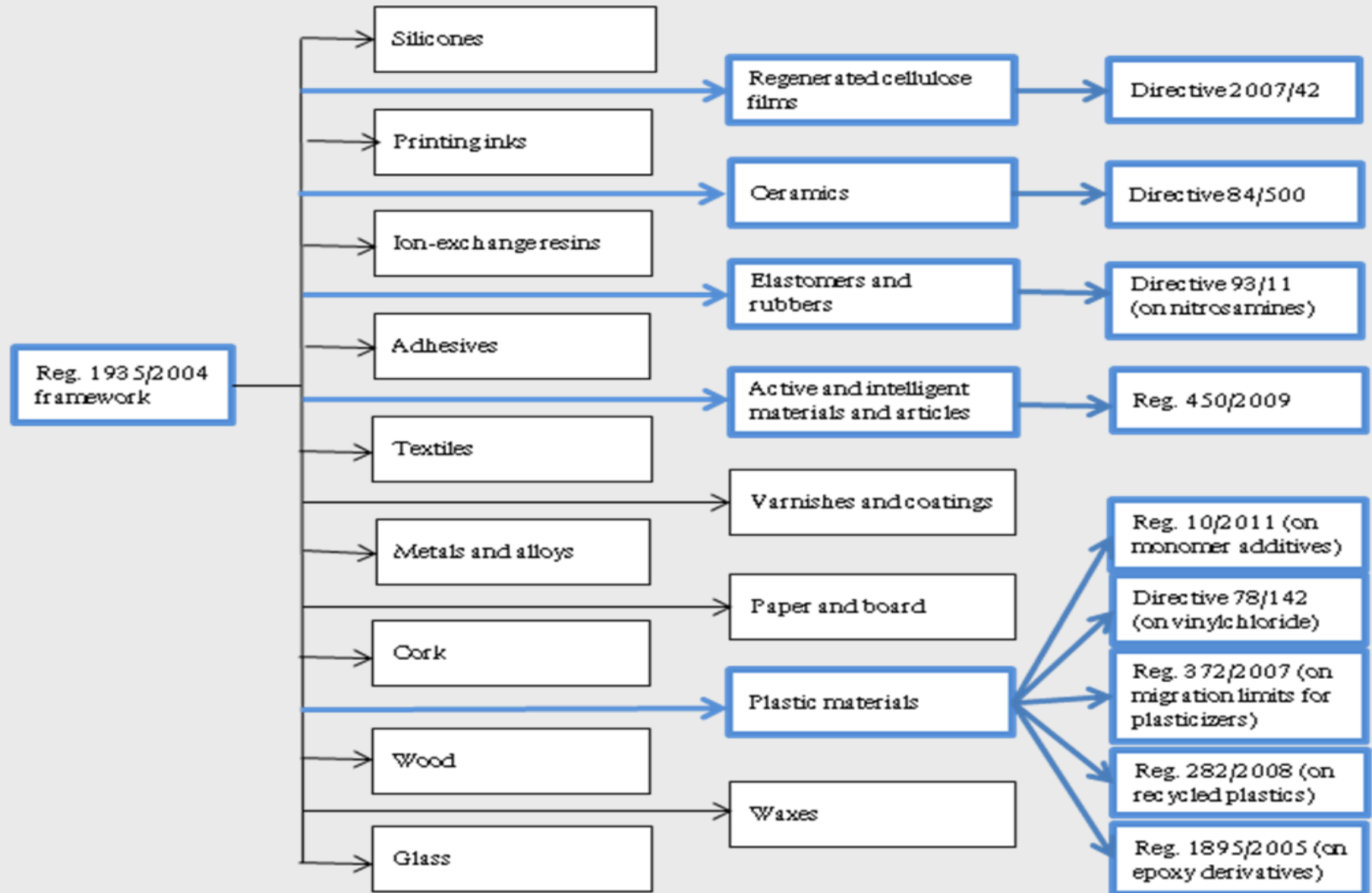
Purpose of the study part III

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**



Food Contact Materials Legislation



Food Contact Materials Legislation

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
- EAS – “The European Acceptance Scheme for construction products in contact with drinking water” proposal – many years of discussion (1999-2005) – but finally stopped – no legal basis!
- 4 Member States Group (GE, NL, UK and FR) – discussion of possible harmonisation
- No EU solution in sight

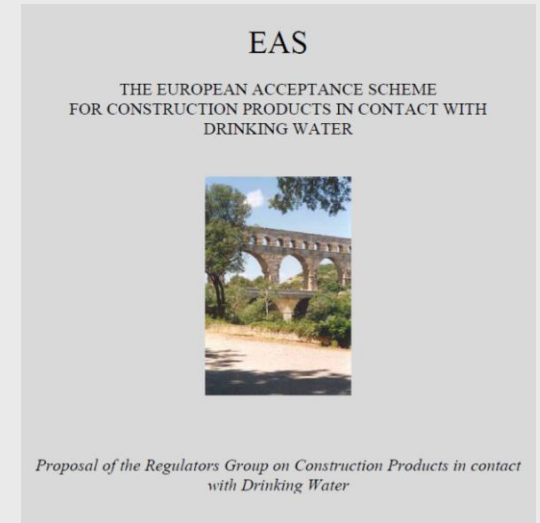


Adoption of new EU regulation required!

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

- **European Collaborative Action (ECA) Report No 27
Harmonisation framework for indoor products labelling schemes in the EU, 2012**
 - **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.: $\geq 1.0\%$, cat. 2 reprotoxic substances: $\geq 3.0\%$
- 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!

REACH - consumer information

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.



Options regulatory framework

Incorporation of chemical requirements:

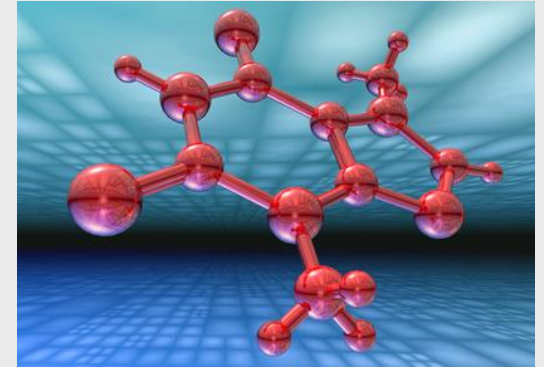
- REACH extension - include full product dimension
- Expand existing directives to cover chemicals
- Specific chemical sector legislation - follow ROHS model
- Horizontal directive for chemicals in products
- Expansion of ERP directive - all products and aspects - mirroring the Ecolabel Regulation - 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