How to eliminate hazardous chemicals from consumers articles?

The need for a new framework for chemical requirements for products

Dr. Franz Fiala

Consumer Council/Austrian Standards Institute

ANEC - European Association for Consumer Representation in Standardisation

2011-10-05

Study: Chemical requirements for consumer products – Parts I and II

Commissioned by:

Consumer Council

Austrian Standards Institute

Carried out by:

FORCE Technology

Denmark

Final Reports October 2010/April 2011

Purpose of the study

Analysis of chemical requirements for products in:

- REACH Regulation
- General Product Safety Directive (GPSD)
- Personal Protective Equipment Directive (PPE)
- Toy Safety Directive (TSD)
- Construction Products Directive/Regulation (CPD/CPR)
- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS)
- Ecodesign Requirements for Energy-related Products Directive (ErP)
- Appliances Burning Gaseous Fuels Directive
- Placing of Pyrotechnic Articles on the Market Directive

Purpose of the study *(cont.)*

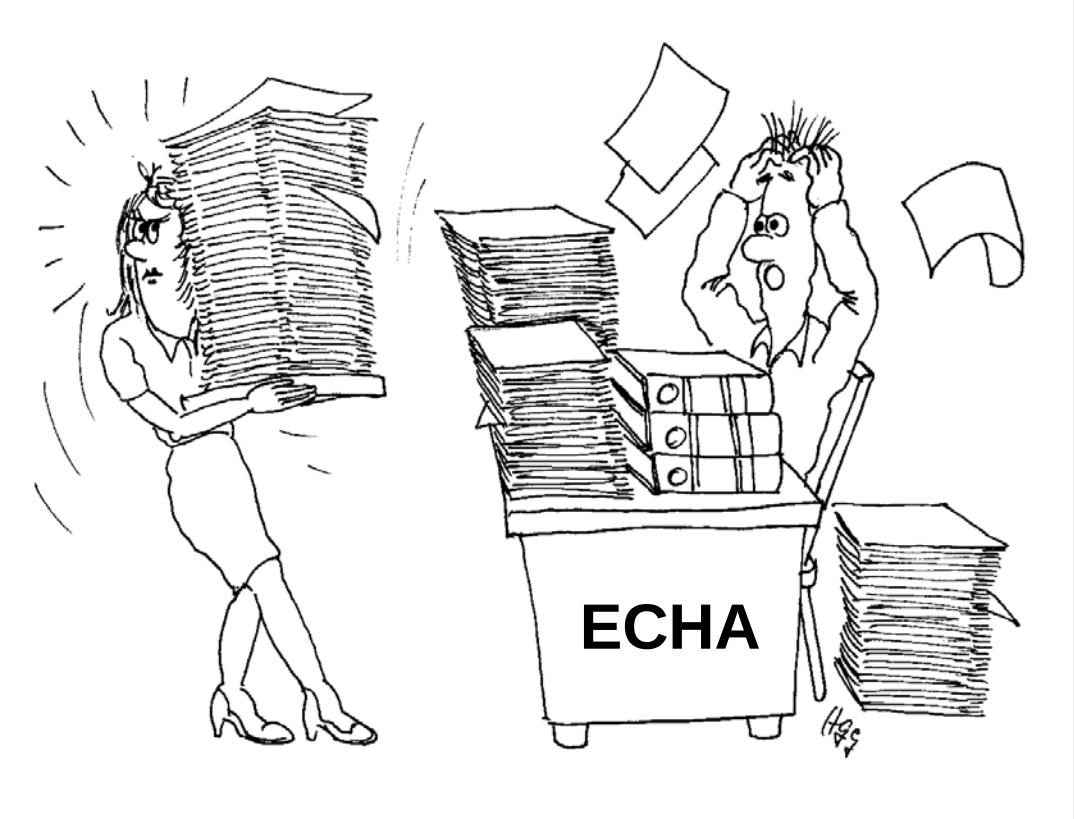
Analysis of chemical requirements for products in:

- **Low Voltage Electrical Equipment Directive (LVD)**
- **Radio and Telecommunications Terminal Equipment Directive (R&TTE)**
- **Medical Devices Directive**
- **Packaging and Packaging Waste Directive**
- **Food Contact Materials Legislation (several)**
- **Simple Pressure Vessels Directive**
- **Recreational Craft Directive**
- **EC-type Approval System for Motor Vehicles**

Proposals for addressing chemicals in products properly

REACH Regulation

Registration, Evaluation, Authorisation and Restriction of Chemicals



REACH General problems

- limited capacity of MSCAs and ECHA for dossier (min. 5%) and substance evaluation
- relies heavily on industry assessments – not reliable!
- authorisation procedures very slow – assumption 25 substances/year – 1500-2000 chemicals – 60-80 years!
- long implementation period – last registration deadline 2018....
- tonnage philosophy – data needs are quantity dependent
- poor coverage of articles – see later

REACH provisions for articles

("shape, surface and design determine function")

Producers / importers of articles need to:

- Register substances contained in articles if the substance in articles
  - is intended to be released and
  - is present in amounts totalling > 1 tonne / year
- Notify SVHC substances, meeting the criteria of article 57 if the substance is present in those articles
  - in amounts totalling > 1 tonne / year and
  - above a concentration of 0.1% (w/w)
  - if included in candidate list
  - but no obligation to notify if P/I can exclude exposure during normal and reasonably foreseeable conditions of use and disposal

REACH articles related problems

- Registration/Authorisation address use of chemicals - no product limits!
- Restriction path laborious and time consuming - no quick adaptation
- Substance-by-substance evaluation:
  - excludes bans of groups of substances (e.g. CMR)
  - excludes a positive list approach (as in FCM regulation)
  - excludes non-toxic effects of chemicals (e.g. smell) or proxy indicators (e.g. TVOC)
- Inadequate consumer information provisions
- No systematic checks of chemicals in articles

REACH is no substitute for product regulation!

Nanomaterials in products

REACH

- many question marks regarding the nano coverage
- tonnage triggers may be inadequate for nanomaterials
- not clear whether tests have to be done with bulk AND nano form
- risk assessment methods for bulk materials not necessarily appropriate

Product legislation

- No specific nano provisions in any of the directives investigated with the exception of plastic materials in contact with food!

Specific nano requirements must be incorporated in REACH and in product regulation!

General Product Safety Directive

Relevant provisions

- Article 1: "*The purpose of this Directive is to ensure that products placed on the market are safe*"
- Article 4, 1.(a): specific safety requirements, form basis for mandates
- Article 13: temporary measures for serious risks e.g. substance bans

Problems

- no chemical requirements, no comitology to establish limits
- no systematic evaluation, chemical competence MSCA ?
- hardly any chemical requirements in mandates or standards

(Current) GPSD is not adequate for regulating chemicals

Personal Protective Equipment Directive

Annex II – Basic health and safety requirements

- **GENERAL REQUIREMENTS FOR ALL PPE**

  1.2. Innocuousness of PPE - 1.2.1.1. Suitable constituent materials:

  "*PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health*"

Problems

- **Similar to GPSD**

PPE Directive is not adequate for regulating chemicals

Toy Safety Directive

CMR-thresholds (CLP) may be much too high

- Category 1A and 1B carcinogens and mutagens: e 0.1% (=1000ppm)
- Category 1A and 1B reproductive toxants: e 0.3%
- Category 2 carcinogens and mutagens: e 1.0%
- Category 2 substances toxic for reproduction: e 3.0%
- For reproductive effects on or via lactation the limit is: e 0.3%

Example PAH

- Benzo(a)pyrene: specific limit 0.01% (100ppm), Germany (based on BfR): general limit for toys - 1ppm! For toys intended to be mouthed or for children below 36 months - 0.2ppm!

Toy Safety Directive (2)

Further problems:

- exceptions to CMR rules possible only in one direction (less restrictive) but not in the other direction (more stringent) via Comitology
- restrictions for other categories of substances (e.g. endocrine disrupters, very toxic, toxic, sensitizing, etc) not possible
- however, restrictions via Comitology are possible for toys for childern below 36 month or toys intended to be mouthed
- requirements for elements partly a step backwards (e.g. lead)
- certain fragrances allowed if labelled, 100 ppm limit?
- systematic evaluation required – but what is the consequence?

TSD needs revision!

Construction Products Directive

Different from other NA Directives/Regulations

- Does not establish requirements for products!!!
- Just declaration of parameters in accordance with standards
- National building rules establish performance requirements and have to make use of harmonised methodology
- No national rules – no declaration necessary ("no performance determined - NPD")
- Only few countries have regulatory indoor requirements ("dead law")
- CEN TC 351 test methods will NOT become product requirements!!!

CPD is an inadequate framework for establishing chemical or indoor related harmonised product requirements

RoHS Directive

Restrictions

- Ban of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), in annex IV
- Many exemptions
- RECAST: Comitology to change annexes (e.g. banned substances)
- RECAST: for additional bans, follow REACH procedure for restrictions
- RECAST: candidate substances for restrictions

Problem

- Many substances not covered, e.g. flame retardants (Öko-Institut study)

Ecodesign Requirements for Energy-related Products Directive

Principles

- Commission shall consider the life cycle of the product and all its significant environmental aspects, inter alia, energy efficiency (art. 15)
- Research projects for product groups
- Comitology for “implementing measures” + Consultation forum
- Financial support for NGOs
- Dark side: priority to voluntary agreements

Future development

- Expand to all products and other environmental aspects of products

ANEC: Model for all product and services regulation

Medical Devices Directive

Requirements

- Essential requirements (Annex I) – "*minimize the risk posed by contaminants and residues*"
- EN ISO 10993 series "*Biological evaluation of medical devices*" – essentially risk assessment approach + test methods
- Limits only EN ISO 10993-07 on ethylene oxide sterilization residuals
- Labelling for certain devices containing phthalates CMR cat. 1 or 2
- No Comitology in place to establish specific chemical limits
- REACH authorisation – "*the Commission shall not consider the risks to human health arising from the use of a substance in a medical device…*"

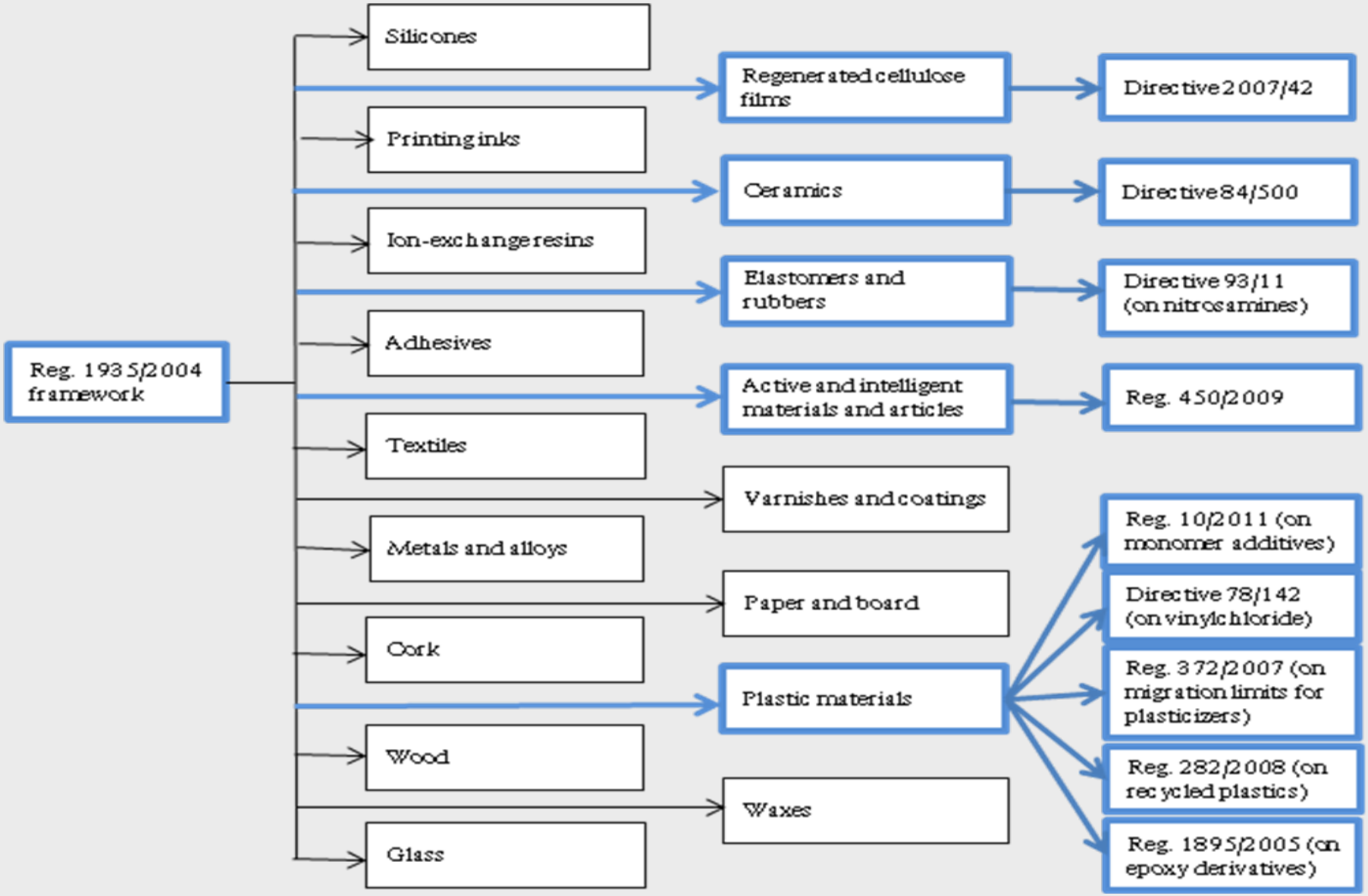
Packaging Directive

Requirements

- The sum of concentration levels of lead, cadmium, mercury, and hexavalent chromium present shall not exceed 100 ppm by weight.
- No Comitology to establish limits for chemicals
- Essential requirements - presence of noxious and other hazardous substances and materials (...) is minimized with regard to their presence in emissions, ash or leachage when ....incinerated or landfilled.
- EN 13428 “Packaging - Prevention by source reduction” - only N” substances (others ignored) – “use minimum amount” – ANEC/ECOS fundamentally disagreed!

Do not use standardisation for chemical requirements !!!

Food Contact Materials Legislation



Food Contact Materials Legislation

Issues

- still many gaps after 30 years of regulatory activities – many materials not covered
- even where specific legislation measures exist they are incomplete – e.g. colorants in plastic materials
- limited to human health aspects
- does not apply to water supply equipment
- comitology to adopt specific measures
- „Positive lists“ – only authorised substances may be used (exceptions)
- Not only toxicological considerations – overall migration, organoleptic properties

And the rest?

Conclusions product regulation

Existing product regulation inadequate because

- clear-cut rules missing or inadequate (‘make it safe’)
- without clear limits no market surveillance
- ad-hoc regulation - reactive approach - no systematic approach
- substance by substance evaluation very time consuming
- horizontal approaches missing (e.g. CMR-ban)
- covers only certain aspects of chemicals e.g. safety (not environment)
- multiple exposure and combination effects often not considered
- no obligation to provide information on chemicals in products

Consistent approach for chemicals is missing!

Options regulatory framework

Incorporation of chemical requirements:

- Expand existing directives to cover chemicals
- Specific chemical sector legislation - follow RoHS model
- Horizontal directive for chemicals in products
- REACH extension - include full product dimension
- Use ErP Directive as model – Future extension of ErP?

  all products and aspects - mirroring the Ecolabel Regulation –

  using synergies - all chemical rule making for products and enforcement

  in “one hand”

Options horizontal approaches

Cover one or more product groups

- example indoor air – construction products, furniture, textiles…

Restrictions for one or more groups of chemicals

- ban of SVHC substances (and others)
- general thresholds e.g. 0,1 % + deviations (more or less strict)

Positive lists

- e.g. for flame retardants

Special arrangements

- e.g. for indoor air, nano product register…

Consistent approaches – keeping the product dimension

- e.g. for risk assessment, screening, market surveillance,...

(Comprehensive) product declaration schemes


Dangerous
chemicals


Change
Next Exit


TOXIC-FREE
ZONE

Contact details Franz Fiala

Address

Austrian Standards Institute - Consumer Council
Heinestrasse 38
1020 Vienna

Email

franz.fiala@as-institute.at

Telephone

0043 1 21300 709

ANEC (Environment WG)

Laura Degallaix, laura.degallaix@anec.eu