



POSITION PAPER

Hazardous chemicals in products

The need for enhanced EU regulations

June 2014

Contact Person: Michela Vuerich

ANEC-PT-2014-CEG-002

List of Contents

Executive Summary	2
1. European policy vision – "A non-toxic environment"	4
2. Current EU regulatory provisions for chemicals in products	4
2.1 EU regulations for articles.....	5
2.2 REACH and articles.....	7
3. Options for a regulatory framework for chemicals in products	10
4. Specific regulation needs	12
4.1 Materials in contact with food	12
4.2 Drinking water contact materials.....	15
4.3 Emissions to indoor air.....	18
4.4 Clothing and other consumer textiles.....	21
4.5 Toys	24
4.6 Child use and care articles.....	28
4.7 Packaging.....	29
4.8 Tattoo inks	31
4.9 Nanomaterials (in various products)	32
4.10 Other product areas.....	35
Acknowledgements	37
About ANEC	38

Executive Summary

The present specific European regulatory provisions for chemicals in (consumer) products, particularly in articles, are insufficient. They are either:

- inadequate because of serious restrictions - as in case of food contact materials where only plastics materials are comprehensively regulated; or missing clear limits (medical devices) or lack of a high level of protection (toys), or
- (almost) non-existent for many products consumers come into contact with, such as materials in contact with drinking water, products releasing emissions to the indoor air, clothing and other consumer textiles, child care articles, packaging, tattoo inks, personal protective equipment, furniture, sports and playground surfaces and equipment, car interiors, ...

REACH does not, and will not, compensate for these deficits because articles - particularly imported ones - are barely covered. Moreover, the process of restriction is laborious and related to (comprehensive) single substance risk assessments: for example, generic bans of all CMR (carcinogenic, mutagenic or toxic for reproduction) substances in articles cannot be established. An approval system for chemicals in articles - similar to the positive lists in cosmetics and food contact legislation - is not possible. Non-toxic effects or parameters cannot be addressed (e.g. organoleptic parameters, such as smell or taste).

A systematic approach to address chemicals in products relevant for consumers needs to be developed. It should cover overarching principles and basic strategies for all kinds of products, identify priorities, elaborate on product specific requirements including information provision as well as monitoring and market surveillance. Consideration also needs to be given to a horizontal framework to be complemented by product specific implementing measures.

As a matter of highest priority (enhanced) requirements for the following product groups must be adopted:

- *materials in contact with food* - especially for materials not yet covered in specific implementing measures according to the framework regulation, including - at a minimum - printing inks, paper & board, metals & coatings, and strengthened requirements for ceramics;
- *materials in contact with drinking water* - based on the "The European acceptance scheme for construction products in contact with drinking water (EAS)", proposed in 2005, and the subsequent harmonisation work done by a group of 4 Member States (FR, GE, NL and UK) initiated in 2007;
- *products releasing emissions to the indoor air* - based on existing national legislation (particularly the German AgBB scheme) and the reports published under the "European Collaborative Action - Urban Air, Indoor Environment and Human Exposure";

- *clothing and other consumer textiles* – including generic exclusions of substances of high concern (such as CMR) as well as substance-specific provisions using existing specifications (such as the OEKOTEX® Standard 100 and the EU ecolabel criteria) and related research (e.g. by the Swedish Chemicals Agency, KEMI) as a departure point;
- *toys* – aimed at a considerable strengthening of the inadequate chemical provisions of the Toy Safety Directive including e.g. a significant reduction of the CMR thresholds and addition of limits for substance categories not yet covered (such as colorants, monomers, nanomaterials, endocrine disrupting chemicals);
- *child care articles* – based on (improved) requirements for toys adapted to the specific use and exposure situation of child use and care articles;
- *packaging* – complementing current requirements for lead, cadmium, mercury and hexavalent chromium by e.g. excluding CMR chemicals (all categories) or endocrine disrupters and including specific limits based on risk assessment;
- *tattoo inks* - using recommendations of the Council of Europe as a departure point to establish a stand-alone regulation or to broaden the Cosmetics Regulation.

Specific provisions for nanomaterials to be implemented (nano specific product requirements, nano registry).

The need to set (additional) chemical requirements for other product groups - such as medical devices, electrical and electronic products, personal protective equipment, furniture, sports/playground surfaces and equipment or products made from leather or paper - needs to be investigated.



The current regulatory framework for chemicals in consumer articles

1. European policy vision – "A non-toxic environment"

In November 2013, the Council of the EU and the European Parliament agreed on the text of the 7th Environmental Action Programme - the General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'¹. It identifies chemicals in products as an action point: "*The Union will also set out a comprehensive approach to minimising adverse effects of hazardous substances, including chemicals in products*"(point 50).

It also states that it shall be ensured that by 2020"*...risks for the environment and health, in particular in relation to children, associated with the use of hazardous substances, including chemicals in products, are assessed and minimised. Long-term actions with a view to reaching the objective of a non-toxic environment will be identified*" (point 54 d).

As we emphasised at the ANEC - ASI Consumer Council conference – '[Hazardous chemicals in products, the need for an enhanced EU regulation](#)'², ANEC warmly welcomes the commitment of the EU to strengthen its regulatory framework to address chemicals, particularly as regards chemicals in products. ANEC believes that the current provisions at the European level are insufficient and that there is no community approach to address chemicals in products in a systematic manner. A horizontal regulatory approach to address chemicals in products in a systematic way is dramatically needed.

2. Current EU regulatory provisions for chemicals in products

Two studies commissioned by the Consumer Council at the Austrian Standards Institute (ASI)³ looked into the shortcomings of the current European regulatory framework with respect to chemicals in products which are referred to as "articles" in REACH⁴. This includes an analysis of the most relevant EU product regulations as

¹ <http://tinyurl.com/on4x7ss>

² ANEC and the Austrian Standards Institute (ASI) Consumer Council organised a conference on hazardous chemicals in products on 29 October 2013 in Brussels. The conference saw speakers from the European Commission, and authorities from Europe, addressing food contact materials, water supply materials, indoor emissions, textiles, toys, child care articles, tattoo colours and nano-materials.

³ "Chemical requirements for consumer products - Part I", October 2010: <http://tinyurl.com/oq99qus> and

"Chemical requirements for consumer products - Part II", April 2011: <http://tinyurl.com/p2z7fab>

⁴ Regulation concerning the Registration, Evaluation, Authorisation and restriction of Chemical substances (EC) No 1907/2006

well as an analysis of the requirements related to articles in REACH. The following analysis is based on the studies mentioned above.

2.1 EU regulations for articles

A review of the chemical requirements in selected product legislation including:

- General Product Safety Directive 2001/95/EC (GPSD)
- Personal Protective Equipment Directive 89/686/EEC (PPE)
- Toy Safety Directive 2009/48/EC (TSD)
- Construction Products Directive 89/106/EEC (CPD)⁵
- Restriction of the use of certain Hazardous Substances in electrical and electronic equipment Directive 2002/95/CE (RoHS)⁶
- Ecodesign requirements for Energy-related Products Directive 2009/125/EC (ErP)
- Gas Appliances Directive 2009/142/EC (GAD)
- Pyrotechnic Articles Directive 2007/23/EC
- Low Voltage Directive 2006/95/EC (LVD)
- Radio and Telecommunications Terminal Equipment Directive 1999/5/EC (R&TTE)
- Medical Devices Directive 93/42/EEC
- Packaging and Packaging Waste Directive 94/62/EC
- Food Contact Materials legislation (various)
- Simple Pressure Vessels Directive 2009/105/EC (SPV)
- Recreational Craft Directive 94/25/EC
- EC-type Approval System for Motor Vehicles (various)

revealed that specific chemical requirements for (consumer) articles are:

- missing entirely in several legal texts. For instance, the GPSD contains only a generic requirement that products shall be safe and offers the possibility to adopt only temporary emergency measures, valid for a maximum of 1 year (unfortunately rarely taken in case of chemical risks). Other directives without any chemical provisions include the Gas Directive (apart from combustion

⁵ Replaced by Regulation No 305/2011 laying down harmonised conditions for the marketing of construction products (CPR), which is based on similar principles as the CPD. The conclusions regarding chemical requirements are equally valid for the new legislation.

⁶ Replaced by Directive 2011/65/EU. The conclusions regarding chemical requirements are equally valid for the new legislation.

products and gas leakage), the LVD, R&TTE Directive, the SPV Directive, the Recreational Craft Directive (except for combustion products and leakage of oil and fuel), the ErP Directive and related implementing measures (which merely focus on energy efficiency) and the EC-type Approval System for Motor Vehicles (except for combustion products);

- hardly addressed in the PPE Directive (only a vague provision requiring that materials shall not adversely affect health⁷) and the Pyrotechnic Articles Directive (saying that fireworks may be constructed only of materials that minimize risk to health, property, and the environment from debris);
- questionable in the Medical Devices Directive, as chemical requirements are dealt with in the form of so-called “essential requirements” and are complemented by European Standards which contain only risk assessment procedures and no requirements for limit values of chemicals (with the exception of ethylene oxide residues);
- not sufficiently ambitious in the TSD (e.g. high content of CMR substances allowed and several other categories of dangerous substances not even mentioned), the RoHS Directive (too few substances restricted: lead, mercury, cadmium, chromium VI, PBB and PBDE) and the Packaging & Packaging Waste Directive (only a limit for the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium);
- incomplete in the Food Contact Materials Legislation (only plastics comprehensively regulated, and even this with significant gaps related to colorants, solvents or printing inks);
- just referred to as ‘declaration requirements’ linked to regulations in Member States in the CPD/CPR (with the option of not declaring chemicals in case there are no national requirements) and no possibility to establish product requirements (limit values).

From this follows that for many consumer articles (such as clothing, furniture, floor coverings, indoor textiles, personal protective equipment, child use and care articles, sports equipment, construction products, interior of cars, ...) specific chemical requirements are missing. In addition, also chemicals in nano size (nanomaterials) are mostly not covered, except for the directive on plastics materials in contact with food which provides that substances in nanof orm may be used only if explicitly authorised and the cosmetics directive.

In most cases, the scope of the product regulation is restricted to either human health or environment, but not covering both. Moreover, few of these regulations allow for establishing restriction measures for hazardous chemicals or adapting existing ones quickly where the need arises by using a Committee procedure

⁷ Article 1.2.1.1. “PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.”

(Comitology) or Delegated Acts. Only the revised RoHS Directive and the Food Contact Materials Legislation allow for adapting the existing chemical requirements. The Toy Safety Directive includes a restricted committee procedure for only certain purposes⁸.

Finally, generic phrases in product related legislation - such as "producers shall be obliged to place only safe products on the market"⁹ or "products must not adversely affect human health" - are not sufficient to compensate for the shortcomings identified above. Such legal provisions are indeed often difficult to interpret and comply with for producers/importers, as far as chemicals are concerned at least. In addition, such provisions place a big burden on enforcement authorities, which have to prove that a substance contained or released from a product is posing a risk to consumer health. Hence, often no action is taken¹⁰. Enforcement cannot be expected to work in absence of clear-cut chemical provisions for products.

With the above, it is obvious that the current European legal framework regarding chemicals in products is insufficient to ensure a high level of safety to consumers and the environment. ANEC thus concludes that the adoption of a strengthened regulatory framework for chemicals in consumer products is necessary. Generic safety provisions, when already present in product specific legislation, need to be complemented by clear-cut restrictions for substances of concern - such as bans or specific limit values - in order to ensure a high level of safety for consumers and benefit manufacturers and enforcement authorities.

2.2 REACH and articles

Despite claims to the contrary, REACH does not and cannot compensate for these deficits for a number of reasons. REACH primarily addresses the manufacturing and use of chemical substances and mixtures (in Europe) and hardly covers chemicals in (consumer) articles, particularly in imported articles. The main article-related deficits of REACH are:

- Registration of substances in articles is required only if a substance is present in articles in quantities above 1 tonne per year and if the substance is intended to be released (e.g. a scented product which is rather exceptional).
- Just a notification of the use of a Substance of Very High Concern (SVHC)¹¹ is required if the substance is present in articles in quantities exceeding 1 tonne

⁸ e.g. to establish limits for toys intended to be used by children up to 3 years of age or intended to be placed in the mouth, elements or fragrances

⁹ Article 3 of the GPSD (Directive 2001/95/EC)

¹⁰ This is for instance confirmed by the RAPEX notifications related to chemicals which are mainly the result of non-compliance with existing limit values rather than the result of a proper risk assessment by authorities. This is notably due to the vagueness of the generic safety requirements of the GPSD.

¹¹ Substances that are CMR category 1A and 1B, PBTs, vPvBs and "substances of equivalent concern" (such as endocrine disruptors or sensitizers) which have been identified according to the given procedure

per year and if the substance is present in those products above a concentration of 0,1 % weight by weight (w/w), unless the manufacturer or importer can exclude exposure to humans or the environment (Article 7(2)). It should be noted that a substance complying with the SVHC criteria (e.g. CMR category 1A and 1B) is not *per se* a SVHC. It becomes a SVHC only if the substance has been identified as such and has been included in the candidate list. Hence, this provision covers just a limited number of substances, is difficult to enforce and, in particular, does not exclude the presence of SVHCs in articles.

- Neither registration nor authorisation leads to chemical limits in products. Only the restriction path of REACH can establish such requirements. However, the restriction path, which requires a so-called Annex XV dossier, is laborious and time consuming. It does not come as a surprise that very few restrictions have been adopted since REACH was adopted in December 2006. At that time, the Annex XVII included 50 entries. By end of 2013, the number had increased to 63 entries. Even though some additional restrictions were incorporated by modifying existing entries, the progress was rather modest to say the least. This is in stark contrast to the pragmatic approach to regulate chemicals employed in other areas (e.g. chemical requirements in other EU legislation or at the MS level).
- REACH restrictions are generally based on single substance risk assessments. From this follows that generic bans of substances falling in a certain hazard class (e.g. all CMR substances) in articles are not possible. This is a severe limitation bearing in mind that such generic bans allowing to exclude a huge number of substances have been used in certain EU product regulations for good reasons (e.g. Cosmetics Regulation, Toy Safety Directive). A possible exception is given by Article 68(2) for CMR substances category 1A and 1B (including in articles) which could be used by consumers where the Commission may use a streamlined procedure without Annex XV dossier. Whether this means that a generic CMR ban in certain articles may be imposed is an open question (the paragraph refers to "a substance") which needs to be further explored. But in any case it is obvious that this option is restricted to 1A and 1B CMRs whilst the CMR ban in the legislation for cosmetics and toys includes also category 2 substances. Hence, its usefulness for consumer protection is rather limited where it is desirable to ban also the latter category. However, it may still be useful to explore opportunities for making use of Article 68(2) where this is not the case, particularly in areas where more comprehensive legislation is not feasible or not necessary.
- REACH does not allow using an approval system for chemicals in articles. However, positive lists as used in cosmetics and food contact legislation are preferable from a consumer protection perspective even if it may take a long time to establish them. It is inherent to such systems that non-approved substances are not allowed. Hence, the positive list system reverses the

burden of proof – only substances which have been shown to be safe can be used. In addition, the positive list system typically relies on approval by a scientific industry independent assessment. It is the preferred choice whenever a very high level of safety is needed (as in case of material in contact with food or drinking water).

- Non-toxic effects or parameters cannot be addressed in REACH. However, these parameters have been used to establish chemical requirements in various articles. This includes, for example, organoleptic parameters (smell, taste) or sum parameters used to assess indoor air quality (TVOC, SVOC) or sweat/saliva resistance or overall migration limits used to limit the release of substances from materials.
- REACH addresses intentionally added substances and their impurities but does not address reaction products formed in the processing of materials. This includes, for instance, N-nitrosamines formed during the vulcanisation process of rubber for which limits have been established (e.g. for soothers).
- REACH information requirements are insufficient, particularly as regards information on chemicals in consumer articles. REACH Article 33 just provides an obligation for a supplier of an article to provide a consumer "on request" with "sufficient information" including the name of the substance in case an article contains a SVHS above 0,1 %. This is far from a desirable requirement calling for a comprehensive chemicals declaration to be provided to the public (without request). Note: from this follows that there is big room for improvement with respect to these information provision requirements in REACH which is out of the scope of the present document. For example, there are still several Member States which believe that the 0,1% limit should apply to each part of an article rather than to the article as a whole.

There are further significant limitations of REACH which are not specific for articles. For instance, the data requirements in REACH depend primarily on the production or import volume of a substance and only to a limited extent on the hazardousness of the substance. Registration of substances also mainly relies on industry self-assessment. Only a small fraction of registration dossiers will be (independently) evaluated by ECHA and the Member States.

Moreover, the implementation period of the REACH Regulation is extremely long. It will, for instance, take a long time before every substance meeting the criteria of SVHC will be subject to proper independent assessment via the authorisation route. It is acknowledged that the adopted SVHC roadmap aims to include in the candidate list all "relevant" SVHCs by the end of 2020. However, it remains to be seen whether this can be accomplished given the current procedural and resource constraints. But even if so, this is still a very, very long way to go and would still not exclude identified substances meeting the SVHC criteria from imported articles.

There are no specific requirements on nanomaterials in REACH (for further details see below under 4.9).

The REACH provisions can thus not ensure elimination of dangerous chemicals from consumer products and cannot compensate for deficits in product regulation. Hence, it is necessary to develop a new approach to address chemicals in products.

3. Options for a regulatory framework for chemicals in products

There are various possibilities for strengthening the regulatory framework for chemicals in consumer products including the following options:

1. Expand/revise existing product directives to (adequately) cover chemicals in all relevant consumer products
2. Introduce new sector specific chemical legislation following the RoHS model
3. Extend REACH to address chemicals in (consumer) products in a comprehensive way
4. Adopt a horizontal framework directive for chemicals in products to be complemented by sector specific rules
5. Extend the scope of the ErP Directive to cover also non-energy related products and to include generic and specific chemical restrictions in principle for all kinds of products

The first two options would necessitate the adoption of quite a few pieces of legislation for different product categories, or amendments to existing legislation. This would not only be time-consuming and burdensome but would also not facilitate the application of a horizontal approach.

The third option, which is to revise the REACH Regulation in order to integrate more stringent provisions for chemicals in consumer products, seems unrealistic. REACH is indeed already a very complex legislation, and the European Chemicals Agency is overburdened with administering the system. It may be even a better option to eliminate all product related elements from REACH and to use it for the manufacturing and use of chemicals only. The restriction path of REACH could be shifted to a new framework for addressing chemicals in products/articles.

The fourth option, i.e. the adoption of a horizontal directive for chemicals in products, may be useful but its adoption would possibly face some opposition and take many years before being achieved. On the other hand, it is appealing to think of a horizontal regulatory framework for products focusing on chemicals only.

Thus the fifth and last option envisaged, which consists of an extension of the scope of the ErP Directive to cover all relevant consumer products (whether or not energy related) and address all environmental aspects, including chemicals, seems the most promising one in terms of (technical) feasibility.

First, the broadening of the scope of the ErP Directive is already foreseen in the Directive itself. Article 21 of the Directive indeed reads that, in 2012: "*the Commission shall assess, notably, the appropriateness of extending the scope of the Directive to non-energy-related products, in order to significantly reduce environmental impacts throughout such products' whole life cycle*".

Moreover, the ErP Directive requires considering the full life cycle of a product and all significant environmental aspects. The work has so far merely focused on energy efficiency and efforts would be needed to ensure that all relevant environmental aspects of products are addressed in product-specific implementing measures. Considering the potential risks for human health and the environment, the use of hazardous chemicals deserves particular attention in this implementation process.

This development of the ErP Directive would be in line with the Commission's political will to increase coherence between existing schemes as it would somehow mirror the implementation process of the EU Ecolabel Regulation. This would offer opportunities for synergies and efficient resource use as both baseline and excellence criteria for various product groups would be developed simultaneously.

Both option four and option five would allow establishing chemical requirements going beyond the current limitations of specific product legislation. For instance, it could allow establishing indoor air emission requirements for products such as furniture, carpets, floor coverings, paints, laser printers or air fresheners which are currently covered by various other pieces of legislation. It could also allow addressing human health and/or environmental aspects of products.

In addition, both option four and five could allow to establish generic exclusions for a broad range of products. For example, one could eliminate CMR substances, as well as some other categories of chemicals classified as dangerous, in all consumer products.

Moreover, a product declaration of content scheme could be established for all (consumer) products requiring that all chemicals classified as hazardous above a certain threshold must be declared.

Going for a horizontal legislative framework – be it a generic chemicals in products regulation or an extended eco-design directive – does not necessarily mean that all products need to be incorporated. Where an adequate framework already exists (e.g. in the field of food contact materials), it could continue to be used.

Anyway, it is important that the existing gaps regarding chemicals in products are closed. If a horizontal solution cannot be agreed, specific legislation is the next best option.

Whatever legal framework is chosen, it should also include the possibility of adopting or changing the chemical requirements by using delegated acts rather than by co-decision of Council and Parliament, and foresee a systematic monitoring and assessment of the occurrence of chemicals in (certain) products.

4. Specific regulation needs

Inspired by several further studies of the Consumer Council at the Austrian Standards Institute (ASI)¹², and on the basis of an analysis of ongoing political initiatives at European and national levels, ANEC developed a priority programme of regulatory chemical requirements for products that need to be implemented or revised as soon as possible. Top priority areas include:

- Materials in contact with food
- Materials in contact with drinking water
- Emissions to indoor air
- Clothing and other textiles
- Toys
- Child use and care articles
- Packaging
- Tattoo inks
- Nanomaterials (in various products)

Some of the key features of the envisaged regulatory requirements are outlined below. In addition, there are some other product areas of second priority which are briefly mentioned at the end of the document.

ANEC considers that chemical rules for products in key areas should not be delegated to industry-dominated standards bodies but need to be adopted at the regulatory level to ensure a high level of protection based on the application of the precautionary principle. However, standards may play a valuable role in the development of the related test methods. Incorporating chemical limits in legislation is also necessary because of the need to involve independent scientific committees (which are not available in standardisation bodies) and because legal certainty must be ensured. As standards are voluntary, industry is not bound to follow any limits for chemicals. This places authorities in the difficult and burdensome position to "prove" that exceeding a limit results in a health hazard.

4.1 *Materials in contact with food*

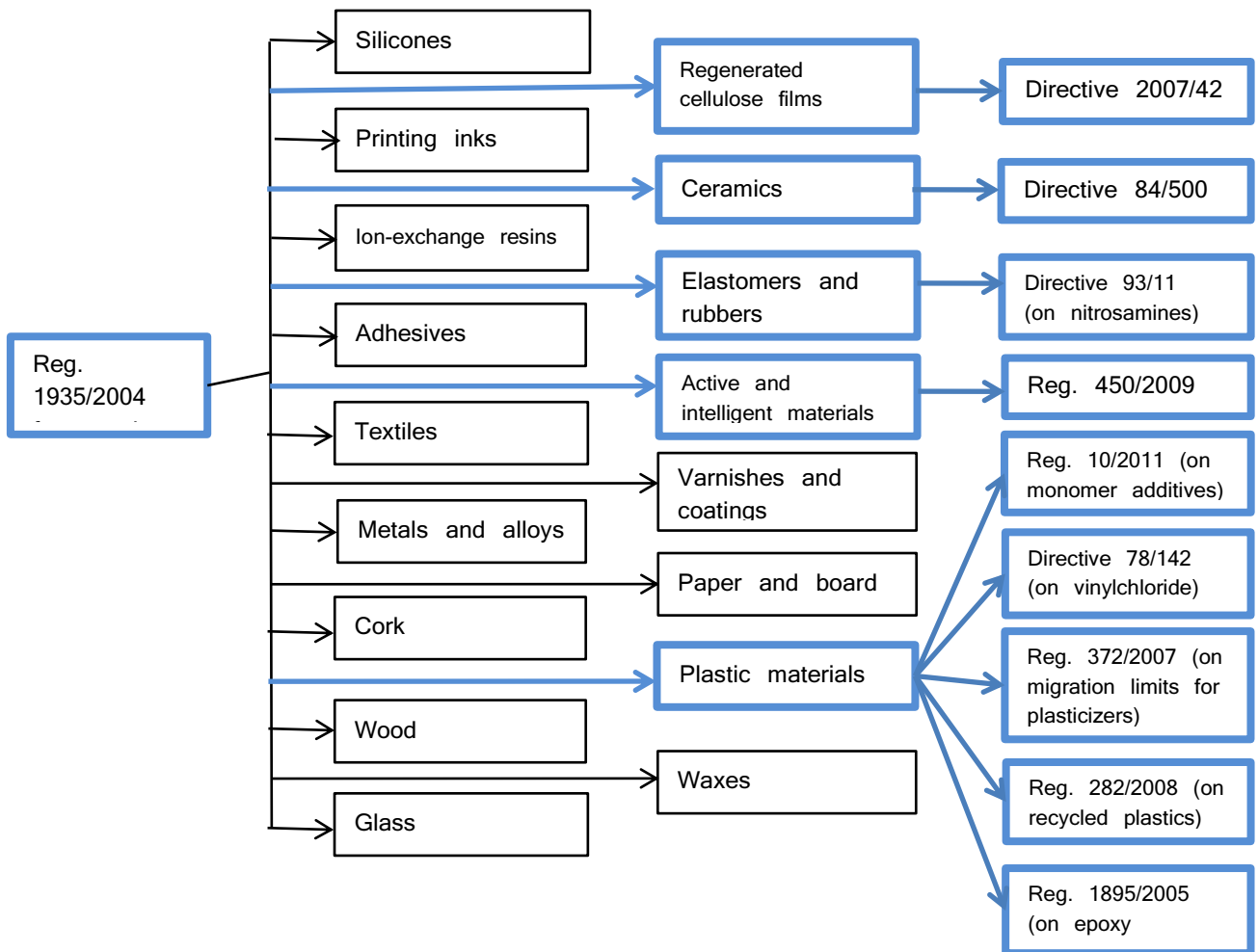
Regulation (EC) No 1935/2004, on materials and articles intended to come into contact with food, is the framework regulation that sets out general requirements

¹² "Chemical requirements for consumer products - Part III", December 2012:
<http://tinyurl.com/pbletnn>

Chemical requirements for toys, October 2013:
<http://tinyurl.com/o6ejr8g>

for all food contact materials. It contains general safety requirements and provides that food contact materials must not transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its organoleptic properties (taste, colour and odour).

For the group of materials and articles listed in Annex I of the Regulation, specific measures may be adopted or amended by the Commission using a Comitology procedure. In fact, implementing measures have been adopted for only a few materials, as shown in the picture below (blue framed boxes).



Only plastics materials are comprehensively regulated (Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food), but there are still gaps that need to be closed (i.e. colorants, solvents and aids to polymerisation are not yet regulated). From a consumer perspective, it is welcome that plastics materials are regulated by means of a positive list

(authorisation list), i.e. only approved substances are allowed to be used. A comitology procedure allows limits to be established in a rather flexible way. A further welcome aspect is that nanomaterials need an explicit authorisation.

The implementing measure on ceramics (Council Directive 84/500, amended by Regulation No. 1935/2004) needs updating as regards the limits for the release of lead and cadmium. Provisions for further relevant elements should be introduced. The Commission started a discussion process in 2012 but there does not seem to be any progress.

The deficits of the regulation are well known and have been debated for some time. In July 2012 the Commission published a "Roadmap"¹³ entitled "Food Contact Materials - Specific provisions for materials other than plastics - implementing measure". It states: "Recent food scarce originating from food packaging led to criticism by Member States, Industry and the European Parliament on the lack of EU specific legislation for materials other than plastics". The Roadmap is intended to "focus on the safety of these other materials and in particular those for which there is a high risk from transfer of its constituents into food (printing inks, coatings, silicones, adhesives, rubber, metals, paper and board and combinations of materials). However, the foreseen Impact Assessment which was envisaged to be initiated in September 2012 has been postponed.

European rulemaking in this field could be based on existing national rules¹⁴ (some Member States such as The Netherlands have comprehensive legislation in place). In addition, a report of the EFSA Scientific Cooperation (ESCO) Working Group¹⁵ gathered and analysed information about substances identified in FCM other than plastics partly evaluated by Member States. It includes an inventory list of about 2800 substances. However, a more comprehensive assessment is available only for a fraction of them. Several recommendations of the Council of Europe¹⁶ may also be a useful source of information for developing EU rules for non-plastics FCMs.

ANEC proposals for non-plastics food contact materials:

- The implementing measure on ceramics (Council Directive 84/500) needs to be updated as quickly as possible with a view to reducing the limits for cadmium and lead release and incorporating further elements.
- A list of priority materials for regulation needs to be established and shall

¹³ <http://tinyurl.com/p99a97d>

¹⁴ <http://tinyurl.com/ps6z29q>

¹⁵ <http://tinyurl.com/o38q8up>

¹⁶ <http://tinyurl.com/n9wwlr2>

in include at a minimum printing inks, paper and board, metals and coatings.

- For the priority materials new implementing measures shall be adopted in accordance with Regulation (EC) No 1935/2004 based among other on existing national regulations, the ESCO report and the statements by the Council of Europe.
- Where feasible the same approach as for plastics FCMs shall be used for the selected priority materials, i.e. an approval system for substances allowed to be used complemented by specific content and/or migration limits.
- Substances in nanoform shall be separately assessed from their bulk forms.
- The environmental dimension shall be incorporated (e.g. ban of PBTs and vPvBs) though human health aspects must remain priority.
- The approval of substances as well as their prioritization shall be based on an assessment of an independent scientific committee.
- Transitional arrangements will have to be made as the establishment of the positive lists will take many years. This shall include the elimination or restriction of priority substances such as a general ban of CMR substances (category 1A, 1B and 2) or other substances of concern which have been identified based on risk assessments (e.g. limitation of mineral oil in paper and board). For some materials the negative list approach may be more appropriate in the short term.

The regulation shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in non-food contact materials in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).

4.2 Drinking water contact materials

In 1999, a "Regulators Group" for Construction Products in contact with Drinking Water (RG-CPDW) was established by the European Commission with the task of developing a common European approach to the assessment and certification of CPDW. Their work resulted in the publication of the "EAS - The European acceptance scheme for construction products in contact with drinking water"¹⁷ in 2005. An approval system for such products has been already in place in several Member States (i.e. in France, Germany, Netherlands and United Kingdom). It was envisaged that this EAS would replace existing national regulatory schemes.

¹⁷ <http://tinyurl.com/ph4r2dq>

The principles underlying the EAS are:

- High level of consumer protection
- A sound scientific basis for the protection of public health, and an equal opportunity for putting products on the European Market
- Transparency of the EAS process.

The main elements of the EAS proposal are:

- Provision of full information on the composition of materials making up the product
- Compliance of these materials with agreed Positive Lists, Composition Lists and Approved Constituents Lists
- Initial type testing of the product by way of a suite of tests applied as appropriate to cover:
 - (a) Organoleptic aspects (odour, flavour and turbidity)
 - (b) General hygiene (including TOC (total organic carbon) and chlorine demand)
 - (c) Materials and substances (including DWD parameters, substances in the lists mentioned above and screening of unsuspected substances)
 - (d) Enhancement of microbial growth.

The EAS covers water supply products that come into contact with drinking water. Thus, products from 'the consumer's tap and onward' – for instance, kettles and cooking equipment – are not covered.

It is important to note that the Construction Products Directive (CPD) did not allow any performance requirements for construction products to be established. This is equally true for the successor Construction Products Regulation (CPR, No 305/2011). Apart from that, not all products used in the water supply are construction products. One of the conclusions in the EAS Proposal was that the Drinking Water Directive (DWD, 98/83/EC) should be amended to create a legal basis for the operation of the EAS in addition to the existing legal basis for CE marking of construction products provided for by the CPD. In fact, article 10 of the DWD provides that the Member States shall take appropriate measures to ensure that human health is not adversely affected by water supply materials. However, specific rules and appropriate operational basis for the EAS (e.g. scientific support, adaptation to technical progress, provisions for conformity assessment, enforcement) are missing.

Although the EAS proposal received broad support from various stakeholders (authorities, industry, drinking water service operators) the Commission did not pursue the case further. After around 10 years(!) of discussion, the Commission discovered that the regulatory basis for the EAS was missing and claimed that the necessary resources for making the system operational were not available. In 2006,

the Commission withdrew its support for the EAS. It seems the Commission did not have sufficient ambition to ensure a high level of safety in this area.

The one thing that is certain is that a regulatory basis must be created which allows harmonised European rules for water supply materials to be stipulated. It could be a revised DWD but it could also be a separate piece of legislation. Or one could envisage a broadening of the Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food which currently excludes "fixed public or private water supply equipment" from its scope.

In the absence of such rules, 4 Member States (FR, GE, NL and UK) united to harmonise their existing approval schemes. The co-operation started in 2007 and was formalised in 2011. The group is open to new members from other Member States (Portugal has expressed its intention to become a full member once national legislation has been implemented). Several documents have been published already¹⁸.

ANEC considers that the EAS proposal, and the work of the 4 Member States, is a good basis for a European approval system for drinking water supply materials. However, some additional requirements are proposed to be incorporated as outlined in the list below.

ANEC proposals for materials in contact with drinking water:

- A regulatory framework needs to be established to set requirements for all materials in contact with drinking water, covering the full water supply chain from the source to the water tap and all parameters which may affect the drinking water quality.
- This can be accomplished by modifying the existing Drinking Water Directive (DWD, 98/83/EC), by extending the scope of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food or by establishing a new legal framework.
- The new regulatory measure shall be based on the "EAS – The European acceptance scheme for construction products in contact with drinking water" proposal published in 2005, and the subsequent harmonisation work by the group of 4 Member States (FR, GE, NL and UK) initiated in 2007 and formalised in 2011.
- The new regulation shall cover:
 - Provision of full information on the composition of materials making up the product

¹⁸ <http://tinyurl.com/px2jjyg>

- Compliance of these materials with agreed Positive Lists (organic materials), Composition Lists (metallic materials) and Approved Constituents Lists (cementitious materials)
- Initial type testing of the product by way of a suite of tests applied as appropriate to cover:
 - (a) Organoleptic aspects (odour, flavour and turbidity)
 - (b) General hygiene (including TOC and chlorine demand)
 - (c) Materials and substances (including DWD parameters such as Pb, Cd, Hg, PAH, pesticides, etc., substances included the lists mentioned above and screening of unsuspected substances)
 - (d) Enhancement of microbial growth
- The environmental dimension (ban of PBTs and vPvBs)
- Separate assessment and approval of nanomaterials
- Rules for conformity assessment.
- The regulatory framework shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in materials in contact with drinking water in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).

4.3 Emissions to indoor air

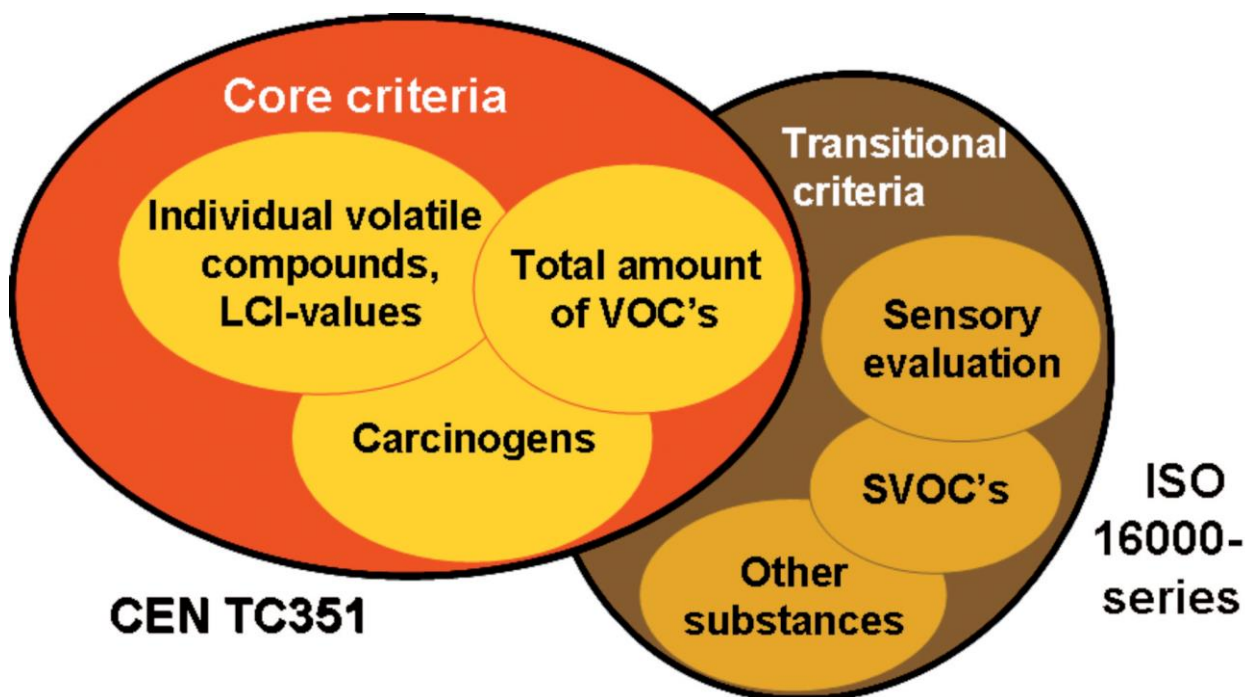
The situation regarding materials which release substances to the indoor air is comparable with the one on materials in contact with drinking water. EU regulation is missing and a suitable regulatory framework does not exist. The CPR is not an adequate instrument to establish harmonised performance requirements for construction products. Apart from that, not only construction products are causing indoor emissions – there are, for example, indoor textiles such as carpets or curtains, furniture, paints, plastics materials, products emitting fragrances (air fresheners), printers and so forth. Unfortunately, appropriate legal instruments are also missing for such products. The General Product Safety Directive (GPSD, 2001/95/EC) does not allow limits for chemicals in products to be stipulated either.

But there are several Member States that have regulation in place regarding emissions from construction products. This holds true in particular for Germany (AgBB scheme), France and Belgium (based on German rules). In addition, voluntary labelling schemes exist in several countries.

Another similarity is that the need for European harmonisation was recognized a long time ago. In the framework of the "European Collaborative Action - Urban Air, Indoor Environment and Human Exposure", several reports co-ordinated by the EC

Joint Research Centre in Ispra (Italy) were published. Report No 24¹⁹, entitled "Harmonisation of indoor material emissions labelling systems in the EU - Inventory of existing schemes", was published in 2005 and reviewed the compulsory and voluntary indoor schemes existing at the time.

This was followed by Report No 27²⁰, "Harmonisation framework for indoor products labelling schemes in the EU", in 2012 which includes a consensus of the parties involved on "common core and transitional criteria" (as regards the latter further work is required) on testing and evaluation methodologies related to chemical emissions of indoor products. The basic concept is shown on the graph below.



The concept of the harmonisation framework for indoor labelling schemes in EU (from ECA report No 27, page 41).

As regards core criteria, the system relies on a limit for the "Total amount of Volatile Organic Compounds (TVOC), the elimination of volatile CMR substances (category 1A and 1B only) and limits for individual compounds making use of the so-called LCI-values (Lowest Concentration of Interest) which are available for about 170 substances.

It was envisaged to set requirements in a subsequent step also for formaldehyde, for substances not having LCI values (i.e. "not-yet-assessed" substances), for semi-

¹⁹ <http://tinyurl.com/ngkcm3z>

²⁰ <http://tinyurl.com/q4hmlss>

volatile organic compounds (SVOCs) and for sensory evaluation. The emission testing should be based on harmonised European Standards, when available (CEN/TC 351 'Construction Products - Assessment of release of dangerous substances').

Report No 29²¹, "Harmonisation framework for health based evaluation of indoor emissions from construction products in the European Union using the EU-LCI concept" established a master list containing a total of 177 compounds subdivided into two groups, the first containing 82 compounds with agreed interim EU-LCI values and the second containing 95 compounds for which EU-LCI values are still to be derived. It is based on existing approaches established mainly by AgBB in Germany and ANSES in France, and also experiences in Finland, Denmark and Belgium.

Although the principal goal of the ECA reports is to harmonise existing national schemes, it is obvious that the results can also be used for establishing EU performance (and labelling) requirements.

In addition, research work has been conducted to address emissions from products other than construction products, such as cleaning agents, air fresheners and personal care products (e.g. the EU funded EPHECT programme).

ANEC proposals for emissions to indoor air:

- A new regulatory framework needs to be established to set harmonised performance requirements with clear pass/fail criteria for all products and materials which can release substances to the indoor air (construction products such as floor coverings, paints, coatings, wall coverings, adhesives, home textiles such as carpets, printers, cleaning agents, air fresheners, etc.). It is acknowledged that it may not be possible to set rules for all parameters and all relevant products immediately. However, a legal framework can be adopted which allows to establish rules in form of implementing measures.
- The new regulatory measure shall be based on existing national legislation (particularly the German AgBB scheme) and the reports published under the "European Collaborative Action - Urban Air, Indoor Environment and Human Exposure". As regards the latter the Commission shall make available the funds needed to finalise the work under the lead of JRC in Ispra.
- The new regulation shall be based on the following principles:

²¹ <http://tinyurl.com/ocbd4ms>

- Elimination of volatile CMR substances categories 1A, 1B and 2
 - TVOC limits
 - TSVOC limits
 - Limits for substances for which EU-LCI values are available
 - Limits for substances for which EU-LCI-values are not available
 - Limits for formaldehyde
 - Sensory evaluation (ISO 16000-28)
 - Measurement method using ISO 16000 series and CEN TC351 standards, testing after 3 and 28 days
 - A separate test methods will have to be developed for certain products such as air fresheners (combustible air fresheners, sprays, passive air fresheners and electric units)
- The same approach shall be used for the EU ecolabel system but lower limits shall be applied (as in the German Blue Angel ecolabel).
 - The regulatory framework shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in products that release substances into indoor air in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).

Final remark: it should be noted that additional requirements need to be established for non-volatile chemicals in the various product groups mentioned above (such as construction products). However, this aspect is not dealt with in the current ANEC position paper. For clothing and other textiles, see the recommendations below.

4.4 Clothing and other consumer textiles

Clothing and many other textiles used by consumers (e.g. curtains, carpets, upholstered furniture) are covered by the General Product Safety Directive (GPSD, 2001/95/EC). However, this directive (as well as the Consumer Product Safety Regulation which is intended to replace the GPSD) does not allow limits to be stipulated for chemicals in products. There are only two options to address chemicals: either using temporary bans based on article 1 (in case of a "serious risk", so-called "emergency measures") for a maximum of one year, or stipulating safety requirements in accordance with article 4 1.(a) as a basis for mandates to standardisation.

Both options are unsatisfactory. The former route – it was used e.g. to impose a temporary ban on phthalates in toys and child use & care articles – must be transformed into a permanent rule, i.e. essentially into restrictions under REACH (annex XVII). However, the room for manoeuvre under REACH is rather limited as

explained above (note: there are, of course, a few REACH restrictions which are applicable to textiles, e.g. on azocolourants). The latter option shifts decision-making to the European Standardisation Organisations which are dominated by industry and e.g. whose processes do not ensure that limits are based on the precautionary principle or the recommendations of independent scientific committees. In addition, chemical limits in standards do not provide for legal certainty (standards are voluntary). From this follows that a legal framework for clothing and other consumer textiles must be established.

The need for regulating chemicals in textiles has been endorsed by the Swedish government. In a letter of October 2012²² to Commissioners Potocnik (Environment) and Dalli (Health and Consumer Policy), the Swedish Minister for the Environment (Lena Ek) and Minister for EU Affairs and Minister responsible for Consumer Issues (Brigitta Ohlsson) called for the "development of coherent legislation on requirements concerning chemicals in textiles". In particular, the need to protect people from exposure to hazardous chemicals such as substances that are carcinogenic, mutagenic or toxic to reproduction, or may cause allergic reactions by skin contact or inhalation and endocrine disruptors, was stressed. The prevention of the accumulation of persistent and bio-accumulative substances used in the production of textile products was also emphasised.

Subsequently, the Swedish Chemicals Agency (KEMI) investigated the chemicals of concern used in the textile industry. A list of the substances that may remain in the finished textile products has been compiled and a more detailed proposal for EU regulation was made. The report²³ was published in 2013. In this report, the Textile Fibre Regulation (No 1007/2011) was presented as the main regulatory option to be considered, but other alternative ways to regulate chemicals in textiles are also discussed. It was proposed to restrict chemicals primarily based on their intrinsic properties using the hazard classification and thresholds according to the CLP regulation. However, also a procedure for setting specific limits on a case-by-case basis was foreseen.

Apart from the KEMI report, there are several other specifications which should be taken into account when European legislation is developed. First of all the OEKO-TEX® 100 standard²⁴, developed by the Austrian Textile Research Institute (ÖTI) and the German Hohenstein Research Institute, needs to be mentioned. This label was created more than 20 years ago. Today, more than 9,500 textile and clothing manufacturers in over 90 countries are involved in the certification system OEKO-TEX® Standard 100. Over 125,000 certificates have been issued and millions of items bearing the label in all retail product segments.

²² <http://tinyurl.com/pb4yfxq>

²³ <http://www.kemi.se/en/Content/News/Proposal>

²⁴ <https://www.oeko-tex.com>

Requirements have been set for the following product categories:

Product class I: Textiles and textile toys for babies and small children up to the age of three, e.g. underwear, romper suits, bed linen, bedding, soft toys etc.

Product class II: Textiles which, when used as intended, have a large part of their surface in direct contact with the skin, e.g. underwear, bed linen, terry cloth items, shirts, blouses etc.

Product class III: Textiles which, when used as intended, have no or only a little part of their surface in direct contact with the skin, e.g. jackets, coats, facing materials etc.

Product class IV: Furnishing materials for decorative purposes such as table linen and curtains, but also textile wall and floor coverings etc.

The standard covers a broad range of substances such as metals, formaldehyde, pesticides, chlorinated phenols, phthalates, colorants, chlorinated benzenes and toluenes, polycyclic aromatic hydrocarbons (PAH) and several others. In addition, it contains limits for colour fastness and odours.

There are also EU ecolabel criteria for textile products (2009/567/EC) and for textile floor coverings (2009/967/EC) which should also be considered.

The use of flame retardants has been a subject of great concern. Moreover, these concerns have effectively blocked the establishment of flammability requirements. This despite the fact that, according to fire statistics²⁵, several million fires are reported per year, resulting in at least 5.000 fire deaths and fire injuries. The full figure for Europe is probably a multiple of this figure every year. About 80% of the fatalities occur in private homes.

Fire safety is often played-off against chemical safety: lobbyists trying to prevent fire safety measures for commercial reasons (e.g. textile trade chains) on the one hand, and flame retardant manufacturers understating risks associated with this kind of chemical on the other, resulting in an unproductive blockade. This can probably be overcome only if flammability requirements are linked to an approval system for flame retardants to ensure that only safe chemicals are used.

DG Health & Consumers commissioned a study²⁶ on flame retardant substances in consumer products in domestic environments which was published in 2011 ("Arcadis study"). It identified those flame retardants and their applications which were relevant for the European market. 42 substances were addressed in more detail. Risk assessment was possible to a limited extent only, because data publicly available were insufficient or missing in the majority of cases. A categorisation was made depending on the level of risk identified based on the methodology used: "no

²⁵ <http://tinyurl.com/nc8e38e>

²⁶ <http://tinyurl.com/pdt3qku>

need for immediate risk management" (6 substances), "no need for immediate risk management, but with concerns" (3 substances), "inconclusive" (10 substances), "risk" (1 substance) and "data gaps" (22 substances). The authors considered their study as a starting point for more in-depth assessments. However, no further action has been taken by the Commission.

ANEC proposals for clothing and other consumer textiles:

- A regulatory framework needs to be established to set requirements for clothing and other consumer textiles excluding emissions to the indoor air which should be addressed separately and which are part of the ANEC proposals for emissions to indoor air.
- The new regulatory measure shall be based on generic substance exclusions based on hazard classes defined in the CLP regulation (e.g. a ban of CMR substances of categories 1A, 1B and 2 or sensitising substances) or based on PBT or vPvB criteria as well as substance specific and other provisions.
- The substance specific provisions shall take into consideration criteria included e.g. in the OEKOTEX® Standard 100 and the EU ecolabel criteria and relevant research (e.g. by the Swedish Chemicals Agency, KEMI).
- Specific limits shall be set at least for metals, formaldehyde, pesticides, chlorinated phenols, phthalates, organic tin compounds, colorants, chlorinated benzenes and toluenes, polycyclic aromatic hydrocarbons (PAH), flame retardants, solvent residues, wetting agent residues and perfluorinated compounds.
- It may be useful to categorise products depending on the intensity of skin contact or exposure.
- The criteria shall also address issues like saliva resistance or odour.
- Flame retardants shall be subject of an approval system (positive list) in line with the principles of the OEKOTEX® Standard 100.
- Specific requirements for nanomaterials shall be included.

The regulation shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in consumer textiles in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).

4.5 Toys

During the revision of Directive 88/378/EEC on the Safety of Toys, ANEC and BEUC repeatedly expressed strong concerns about the inadequate chemical requirements proposed by the Commission. The revised Toy Safety Directive (2009/48/EC) was

adopted in 2009 after 8 years of discussion. The insufficient chemical requirements entered into force only in July 2013.

As a result of the growing criticism from various stakeholders, including several Member States, the Commission established a working group on chemicals in toys (formally a subgroup of the Commission's Expert Group on Toy Safety) with the aim to make proposals within the legal framework for improving the chemical requirements of the Directive. In fact, the Directive includes a limited Comitology procedure which allows to change the limits for allergenic fragrances and elements (points 11 and 13 of Part III of Annex II), and to "adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth" according to its article 46. This chemicals WG - with ANEC participation - first met in November 2010.

On the occasion of its second anniversary, ANEC and BEUC published a position paper entitled "EU Subgroup on chemicals in toys fails its mission"²⁷ which presented a critical review of the results of two years of discussions. ANEC and BEUC concluded that very little progress had been made (apart from an insignificant reduction of the cadmium limits; a similarly insignificant reduction of the barium limits was in the pipeline at the time) and that as a result, the subgroup had failed its mission to protect children from dangerous chemical substances in toys, as most problems remained unsolved. This was not meant to blame the members of the group who did their best to make progress; rather it is a critique of its structural and organisational constraints. The process is too slow and must be significantly accelerated.

It has become clear that the significant shortcomings of the Directive, like the lack of a generic ban of CMR substances in toys intended for use by children under 36 months, or in mouth-actuated toys based on a low limit of detection, can be solved only by a fundamental revision of the chemical requirements of Directive 2009/48/EC.

It is also clear that sufficient resources must be made available to accomplish the work, i.e. to have preparatory work done by consultancies. This cannot be done solely on the basis of voluntary contributions by the working group members.

Meanwhile another 2½ years have passed and the situation has not changed much. The envisaged reduction of the limits for lead by a factor of about 7, based on an EFSA opinion, is still pending. The chemicals group had suggested the lowering of the limits already in January 2011. However, as a result of industry objections, the Commission decided to go for an impact assessment which strongly delayed the process. It is still an open question whether the proposed limits will be strict enough. Apart from that, there are only a few other items for which measures have been proposed by the Commission: limits for certain flame retardants (TCEP, TCPP

²⁷ <http://tinyurl.com/o3s3lr8>

and TDCP) and for bisphenol A used in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth, based on article 46(2). Some further restrictions are in discussion e.g. for the preservative kathon (a strong sensitizer), for phenol and for emissions of formamide from puzzle mats. By contrast, much more needs to be done to protect children adequately.

There are, of course, several REACH restrictions applicable to toys (e.g. on phthalates or PAHs).

ANEC proposals for toys:

- Requirements for CMR substances shall be significantly strengthened to protect children's health. Current limits are based on high thresholds which are based on the rules for classification of mixtures according to Regulation 1272/2008/EC on classification, labelling and packaging of substances and mixtures (CLP) allowing e.g. up to 1% of a category 2 carcinogen or up to 3% of a category 2 substance toxic for reproduction. At a minimum the generic content based CMR limits should be reduced to 0,01% with stricter limits for certain CMR substances where required.
- An even stricter approach shall be followed for CMR substances in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth, eliminating such substances entirely using a low level of detection of 0,01 mg/kg (10 ppb) based on a dynamic migration test (head-over-heels), such as the one contained in EN 71-10 (to be modified). Equivalent approaches shall be used for volatile CMR substances and the dermal contact route.
- The recently adopted limits for PAHs in REACH (entry 50 of Annex XVII) shall be reduced as regards toys and child use and care articles from 0,5 mg/kg to 0,1 mg/kg.
- In the long run an approval system (positive list system) shall be established for toys' materials intended for use by children under 36 months, or in other toys intended to be placed in the mouth based on current legislation in the field of food contact materials.
- Only non-allergenic fragrances shall be used in toys. Requirements for allergenic fragrances need to be considerably strengthened taking into account among other the opinion by SCCS concerning "Fragrance allergens in cosmetic products", adopted in June 2012²⁸, which stated that many more fragrance substances than those identified in the SCCNFP opinion of

²⁸ Scientific Committee on Consumer Safety: Opinion on fragrance allergens in cosmetic products, June 2012, SCCS/1459/11.

1999 (on which the respective provisions of the Cosmetics Regulation are based, and which formed the basis of the TSD requirements) have been shown to be sensitizers in humans.

- Sensitizers other than allergenic fragrances shall be addressed.
- Some of the limits for elements have to be reviewed and adapted. In particular, the lead limits shall be reduced to 2.0 mg/kg for dry material, to 0.5 mg/kg for liquid material and 23 mg/kg for scraped-off material without exemptions. It should be recalled that point 22 of the preamble to the TSD requests limits for arsenic, cadmium, chromium VI, lead, mercury and organic tin at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee.
- Migration limits in the TSD for nitrosamines and nitrosatable substances in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth (0,05 mg/kg for nitrosamines and 1 mg/kg for nitro sable substances), are inadequate as the Commission itself has admitted in its response to the German request to maintain the more stringent national values of 0,01 mg/kg and, respectively, 0,1 mg/kg). Hence, the limits shall be reduced.
- Endocrine disrupting chemicals (EDCs) shall be addressed in toys. For the time being a product specific approach to tackle EDCs in toys is urgently needed. Once a harmonised classification for EDCs is available, the classes of EDCs which are of particular concern shall be eliminated.
- Biocides used in toys were exempted from the authorization requirement for biocides when the Regulation "concerning the making available on the market and use of biocidal products" (No 528/2012) was approved. This means that biocides used in toys do not need to be authorized. This is a serious omission. Either an approval system for biocides shall be introduced in the TSD, or the exemption for toys in the biocidal products regulation shall be removed.
- Chemicals falling in other classes of dangerous substances such as "very toxic", "toxic", "harmful", "corrosive", "irritant" or non-classified (or not yet classified) substances which pose health hazards shall be covered.
- Specific requirements shall be established for additional substances such as formaldehyde, plasticizers, flame retardants, colourants, monomers, solvents, etc. using EN 71-9 'Safety of Toys – Part 9: Organic Chemical Compounds Requirements' as a starting point.
- Nanomaterials shall not be used in toys unless endorsed by a scientific committee.
- Persistent, bio-accumulative and toxic chemicals (PBT), as well as very toxic and very bio-accumulative (vPvB) chemicals, are substances of very high concern and shall be prohibited.

- Deviations from the above suggested rules shall be possible based on an assessment by a scientific committee.
- The Directive shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in all kinds of toys for all kinds of substances including generic limits for groups of substances in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).
- Sufficient resources shall be made available by the Commission and the Member States to systematically identify, assess and regulate chemicals in toys. The Commission shall provide an annual working plan for the systematic evaluation.

4.6 Child use and care articles

Child use and care articles are defined by the correlated CEN Technical Committee (TC) 252 as "any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, transportation and protection of young children" (from the scope of the TC included in its Business Plan). It is further stated that these articles are intended for children up to four years of age.

Child use and care articles are mainly covered by the General Product Safety Directive (GPSD, 2001/95/EC). As explained in the chapter on clothes and other textiles, the GPSD is not an adequate instrument to set chemical requirements for any kind of product. For certain products additionally other regulations apply (e.g. for cutlery and feeding utensils legislation on food contact materials). There are, of course, several REACH restrictions applicable to child use and care articles (e.g. on phthalates or PAHs).

For about 17 products (such as changing units, baby walking frames, baby carriers, wheeled child conveyances) CEN/TC 252 has prepared European standards. In addition, there are some other committees which have produced standards which satisfy the definition (e.g. children's high chairs). Typically only compliance with EN 71-3 'Safety of toys - Part 3: Migration of certain elements' is required for accessible parts of the article. More comprehensive requirements are included in standards for products with food contact (e.g. drinking equipment) or pacifiers.

In addition, CEN/TC 252 published the document CEN/TR 13387 "Child use and care articles - Safety guidelines" in 2004, including a clause on chemicals. These guidelines are currently being revised. The chemicals part will be completely re-written. It will be based on the concept to make use of existing regulatory and normative requirements in the field of toys and adapt them for child use and care articles.

ANEC proposals for child use and care articles:

- A regulatory framework needs to be established to set requirements for child use and care articles excluding clothing and other textiles which should be addressed separately and which are part of the ANEC proposals for clothing and other textiles.
- This can be accomplished by broadening the scope of the Toy Safety Directive (2009/48/EC) or by establishing a new framework (for child use and care articles in general or just for chemical requirements).
- A regulatory definition for child use and care articles needs to be adopted based on the (broad) definition included in the scope of CEN TC 252. An illustrative list of articles covered would be helpful.
- The chemical requirements shall be based on the related (improved) requirements for toys adapted to the specific use and exposure situation of child use and care articles.
- The regulatory framework shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in child use and care articles in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).

4.7 Packaging

The Packaging Directive (94/62/EC) includes limits for heavy metals. According to Article 11, the sum of concentration levels of lead, cadmium, mercury, and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight (i.e. 0.01%). In addition there is a so-called "essential requirement" in Annex II which provides: "Packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimized with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled". The requirement is rather vague and does not seem to take into account adverse health effects arising from the direct exposure of users of packaging.

Some additional requirements have been incorporated in the related harmonised European standards. EN 13428:2004 "Packaging — Requirements specific to manufacturing and composition — Prevention by source reduction" essentially requires suppliers to determine whether substances or preparations classified as dangerous to the environment - indicated by the symbol 'N' are likely to be present in emissions, ash or leachate when packaging or residues from management

operations or packaging waste are incinerated or landfilled. If so, the supplier needs to be able to demonstrate that such substances have been minimised. This is a highly questionable approach. ANEC and ECOS (the European Environmental Citizens' Organisation for Standardisation) have very heavily criticised this (and other standards) prepared by the CEN packaging committee for many reasons. As regards chemicals it was stated:

"The Packaging Directive calls for a general minimisation of hazardous material to the environment in packaging material. The European standard 13428 however limits itself to a restricted number of substances or preparations, namely those classified as dangerous to the environment in accordance with legislation and which need to be labelled with the symbol "N". Many potentially dangerous chemicals falling in other danger classes (such as CMR substances) are not even considered. Furthermore, once a dangerous substance for the environment has been identified, according to the standard it must only be demonstrated that the minimum amount of this substance has been used to satisfy the functional requirements. Hence, it is allowed to use dangerous substance for the environment despite the general environmental concerns about the substance. The standard does not encourage the search for an alternative less hazardous substitute. In many cases the manufacturer will use the minimum amount for economic reasons anyway and therefore it could be argued that this standard justifies the continued use of substances dangerous for the environment".

One might say that the standard is of little use, if any. Consequently, ANEC and ECOS called upon the Commission to solve the issues by including specific requirements in the Packaging Directive.

EN 13432:2000 "Packaging — Requirements for packaging recoverable through composting and biodegradation — Test scheme and evaluation criteria for the final acceptance of packaging" includes limits for 11 elements which are based on limits included in the EU eco-label to soil improvers.

In April 2014, the European Parliament voted in plenary to phase out substances that are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to the CLP Regulation (Regulation (EC) No 1272/2008). In addition, substances having endocrine disrupting properties fulfilling certain criteria should also be prohibited. A threshold of 0,01% was established for both kinds of substances. It remains to be seen whether the Council can accept the proposed amendments which can be welcomed as a step in the right direction. However, much more needs to be done (e.g. ban of all CMRs including category 2 and not only CMRs with harmonised classification but also self-classified ones).

ANEC proposals for packaging:

- The chemical requirements included in the Packaging Directive (94/62/EC) shall be considerably strengthened. Generally, protection of human health

shall be raised to the same level as the protection of the environment.

- The limits shall be defined in legislation rather than in standardisation.
- CMR substances of categories 1A, 1B and 2 shall be banned from packaging.
- Substances which meet the criteria of PBTs or vPvB included in Annex XIII of REACH shall be banned from packaging.
- Specific limits shall be established based on a comprehensive assessment of chemical substances used in packaging including printing inks.
- Nanomaterials shall not be used in packaging unless endorsed by a scientific committee.
- The Packaging Directive shall include a procedure (such as Delegated Acts) which allows the adoption or modification of limits for chemicals in packaging in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council).

4.8 Tattoo inks

Tattoo inks are covered by the General Product Safety Directive (GPSD, 2001/95/EC). As explained in the chapter on clothes and other textiles the GPSD is not an adequate instrument to set chemical requirements for any kind of product.

Several Member States have implemented legislation on tattoo inks (France, Germany, Netherlands, Sweden). Austria and Denmark have notified draft legislation.

The Council of Europe (CoE) adopted a resolution "on requirements and criteria for the safety of tattoos and permanent make-up" (Resolution ResAP(2008)1)²⁹. This resolution formed the basis of some of the national regulations mentioned above. It does not allow using:

- aromatic amines as such or from azocolourants
- listed colourants
- substances which are not allowed to be used in accordance with European cosmetics legislation (at the time Directive 76/768/EEC, now Regulation (EC) No 1223/2009) or colourants with restricted application
- carcinogenic, mutagenic and reprotoxic substances (CMR) of all categories

In addition, there are some other requirements e.g. concerning impurity (e.g. metals, PAHs) and sterility or recommendations concerning product information and preservatives.

²⁹ <http://tinyurl.com/mz7rze8>

This resolution constituted a step forward at the time but it is also clear that it is not really satisfactory as the level of safety is considerably lower compared with rules on cosmetics. For instance, the Cosmetics Regulation requires an approval of colorants and preservatives (positive list) and includes specific requirements for nanomaterials. The resolution recommends that the governments:

"Regulate the use of substances in tattoos and PMU by taking steps towards establishing – on the basis of safety assessments carried out by the competent bodies and harmonised at European level – an exhaustive list of substances proved safe for this use under certain conditions ("positive list")".

Hence, the implementation of the CoE resolution can be only an interim step in the development of a more robust regulation representing a similarly high level of protection as the Cosmetics Regulation (e.g. by expanding its scope).

ANEC proposals for tattoo inks:

- Tattoo inks represent a product group for which EU legislation must be implemented as soon as possible as a matter of highest priority.
- The regulation shall follow the principles of the Cosmetics Regulation (Regulation (EC) No 1223/2009) and include the positive approval of ingredients – colorants and preservatives in particular - based on an assessment of an independent scientific committee.
- Preference should be given to a stand-alone regulation for tattoos. Alternatively, requirements for tattoos could be incorporated into the Cosmetics Regulation.
- As an interim step, ANEC could accept to adopt rules based on the Council of Europe Resolution cited above (for instance, in the form of temporary emergency measures under Article 13 of the General Product Safety Directive (GPSD)).
- Complementary requirements regarding tattooing services could be established in form of a European Standard which should include requirements to permit only the use of tattoo inks in compliance with the regulatory provisions to be adopted.

4.9 Nanomaterials (in various products)

The adequacy of European legislation to address the specific concerns related to nanomaterials has been questioned and debated for many years. The European

Commission has published two regulatory reviews on the subject. The first one³⁰ was published in June 2008 and concluded that "current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials". Hence, no regulatory action was deemed to be necessary and the Commission envisaged just "improving implementation of current legislation". This was welcomed by industry but met with strong opposition from other parties including the European Parliament which in a resolution³¹ deplored "the absence of a proper evaluation" and did not agree with the Commission's conclusions. It called on the Commission to review all relevant legislation within two years.

A second regulatory review³² on nanomaterials by the Commission was published in October 2012. It is along the same lines as the first one but acknowledges the need to adapt some of the REACH annexes and REACH guidance documents. In addition, it was indicated that an impact assessment "to identify and develop the most adequate means to increase transparency" would be launched.

Also the second regulatory review conclusions were subject to fierce opposition. A coalition of NGOs, including ANEC and BEUC, expressed "extreme disappointment and deep concerns", questioned and challenged "the unbalanced approach chosen" and called on the Commission "to consider efficient ways to close the loopholes in the legal framework for the regulation and safe management of nanomaterials" in its response³³.

In fact, REACH does not include any specific measures for nanomaterials – not even a definition. There are no nano-specific information or test requirements. The adequacy of the tonnage thresholds for nanomaterials has been questioned. The Commission's assessment of registration dossiers revealed that hardly any useful nano specific information is provided. Many stakeholders have pointed to the need of changes in REACH which go beyond adaptations of annexes.

Several Member States have expressed their dissatisfaction with the nano policy of the Commission. In July 2012, the Dutch Minister of Infrastructure and the Environment, Joop Atsma, sent a letter to the Commission requesting "to take action to guarantee the health of European citizens and the protection of the environment by ensuring that EU legislation takes possible risks associated with the production and use of nanomaterials into account". He insisted that "additional steps are required". The letter was written on behalf of the Member States Austria, Belgium, Czech Republic, Denmark, France, Italy, Luxembourg, the Netherlands, Spain, Sweden and (the then) candidate country, Croatia. By referring to a

³⁰ <http://tinyurl.com/mflbnt>

³¹ <http://tinyurl.com/qa6edjq>

³² <http://tinyurl.com/penpa6b>

³³ <http://tinyurl.com/nfuqq22>

conference hosted by the Netherlands in 2012 the letter says: "None of the participants considered the current situation adequate to limit and manage the risks of nanomaterials and all the participants were of the opinion that additional guidance or legislation at European level is necessary". Among others it was suggested "to propose legislation on registration or market surveillance of nanomaterials or products containing nanomaterials".

The MS critique was reinforced after the publication of the second regulatory review. At the meeting of the Competent Authorities for REACH and CLP (CARACAL) in November 2012³⁴ "a number of MS expressed doubts as to whether changes to REACH Annexes would suffice" and "several MS regretted that the European Commission had not responded more substantially to the letter sent to the European Commission by the Netherlands in July with the support of 9 other MS". Several Member States have already submitted proposals for nano patches of REACH.

In absence of a reasonable EU nano policy, several Member States have started their own initiatives and have implemented legislation. France was the first country to adopt a decree concerning mandatory registration of products containing nanomaterials. The decree entered into force in January 2013. It requires companies that manufacture, import and distribute nanomaterials in quantities of more than 100g to submit an annual declaration containing information on quantities and use to the authorities. In Belgium, a political agreement was reached in February 2014 within the Belgian Council of Ministers on a draft Royal Decree which would apply from January 2016 to nanomaterials, and from January 2017 to mixtures containing nanomaterials. Denmark notified a draft order on a register of mixtures and articles that contain nanomaterials in November 2013.

Some limited progress has been made regarding the incorporation of nano specific requirements in regulation concerning products relevant for consumers, i.e. cosmetics, plastic materials in contact with food and information on nano ingredients in food. However, the European Parliament has recently rejected a proposal from the Commission to amend the Regulation on the provision of food information to consumers (No 1169/2011) to modify the definition of "engineered nanomaterial" included in this regulation and to adapt it to the definition adopted by Commission Recommendation 2011/696/EU. The Commission had tried to weaken the nano information provisions in the regulation by excluding all food additives included in the Union lists from the new definition (which *de facto* annuls the labelling provisions). Meanwhile this piece of legislation has been withdrawn.

A new Commission proposal on "Novel food" presented in December 2013 requires that food containing or consisting of "engineered nanomaterials" shall be assessed and authorised under this Regulation before being placed on the EU market.

³⁴ <http://tinyurl.com/ppg6urh>

However, nano-specific requirements in other legislation regarding products of relevance for consumers are widely missing.

ANEC proposals for nanomaterials:

- REACH shall be revised in line with proposals from NGOs and some Member States such as Sweden to adequately cover nanomaterials. This shall include *inter alia* a definition of nanomaterials, lowered tonnage thresholds, a provision to ensure that nanomaterials generally are considered as new substances to be registered independently of any corresponding bulk substances, and so forth. An adaptation of the annexes of REACH alone is neither sufficient nor acceptable.
- All existing relevant product legislation (such as for toys) shall be reviewed with a view to incorporating nano specific requirements. In any new product legislation such requirements shall be included from the onset.
- A compulsory nano register shall be implemented at the EU level following (in principle) the schemes which were adopted at the national level (France, Belgium, Denmark).

4.10 Other product areas

There are several other product areas that lack substantive legal chemical requirements. They are just briefly mentioned here and will be addressed in more detail in future versions of this paper.

Medical devices are covered by Directive 93/42/EEC. Some of its "essential requirements", included in Annex I, touch upon chemicals. Section 2 addresses chemical, physical and biological properties. It is stated that particular attention must be paid to "the choice of materials used, particularly as regards toxicity..." and biocompatibility. Furthermore, the "devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues...". And finally, "the devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention must be given to substances which are carcinogenic, mutagenic or toxic to reproduction...". In 2007 a labelling requirement for certain phthalates in some medical devices was added. However, specific limits for chemicals are missing.

The Directive is in the process of being revised. The proposal by the Commission, presented in September 2012, hardly went beyond the existing chemical rules. However, the European Parliament called for a significant strengthening at its plenary vote in October 2013. In particular, a ban of CMR substances with harmonised classifications (listed in Part 3 of Annex VI to the CLP Regulation) and

(certain) endocrine disrupters in concentrations above 0,1% by weight in homogeneous materials was requested in "medical devices - or parts thereof - that are invasive or come into contact with the body of patients, or (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body". These provisions are subject to derogations.

It remains to be seen whether the Council will accept the proposed changes by the European Parliament which definitely constitute a significant (first) step forward. But it should not be forgotten that much more needs to be done. Many CMR substances do not have a harmonised classification and there are other substances of concern. The 0,1% threshold will not be appropriate in all cases. This calls for a comprehensive assessment of chemicals used in medical devices and a regulatory framework which allows establishing limits for all kinds of chemicals.

Personal protective equipment (PPE) is regulated by Directive 89/866/EEC. Annex II of the directive lists so-called essential requirements regarding health and safety that PPE must satisfy. As regards chemicals, there is a requirement called "Innocuousness of PPE – suitable constituent materials" that states: "PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health". However, specific chemical requirements are missing. Just a few standards include chemical requirements (e.g. a limit for chromium VI). This is not satisfactory.

Electric and electronic equipment are covered by the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS). It includes limits (Annex II) for lead (0,1 %), mercury (0,1 %), cadmium (0,01 %), hexavalent chromium (0,1 %), polybrominated biphenyls (PBB, 0,1 %) and polybrominated diphenyl ethers (PBDE, 0,1 %) subject to derogations. This list can be amended by the Commission using Delegated Acts. However, this can be done only with a view to protecting the environment or workers. The health of users of the equipment - such as consumers - regrettably does not play any role.

In addition, the preamble provides: "In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority". Meanwhile a "Study for the review of the list of restricted substances under RoHS2"³⁵, including a methodology for the assessment of chemicals, has been carried out. It established a list of 56 substances assigned to priority categories. The following substances are e.g. considered as highest priority: 4 phthalates di-(2-ethylhexyl)phthalate (DEHP), di-n-butyl phthalate (DBP), butyl benzyl phthalate (BBP) and diisobutyl phthalate (DiBP), the chlorinated flame retardant tris(2-chloroethyl)phosphate and the 2 brominated

³⁵ <http://www.umweltbundesamt.at/rohs2>

flame retardants hexabromocyclododecane (HBCDD) and 2,3-dibromo-1-propanol and dibromoneopentyl-glycol. It remains to be seen how the Commission will react.

There are some additional product groups which will be investigated by ANEC in the near future: leather products such as shoes; hygiene products such as tampons; paper products with a special focus on printed matter (newspapers, magazines); furniture, sports surfaces and equipment, playground surfaces and equipment and various plastics products. Specific recommendations may be incorporated in the next edition of this paper.

Acknowledgements

Special thanks go to Dr Franz Fiala, Chair of the ANEC Sustainability WG, as the main author of this paper.

The studies commissioned by the ASI Consumer Council referred to in ANEC position paper on chemicals in consumer products can be accessed at the link: <http://www.verbraucherrat.at/en/news>

About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 33 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.



Raising standards for consumers

**European association for the coordination
of consumer representation in standardisation aisbl**

Avenue de Tervuren 32, box 27, B-1040 Brussels, Belgium

Tel.: +32 2 743 24 70 / Fax: +32 2 706 54 30

E-mail: anec@anec.eu

EC Register of Interest Representatives:

Identification number 507800799-30

www.anec.eu

<http://companies.to/anec/>



ANEC is supported financially by the European Union & EFTA

This document may be quoted and reproduced, provided the source is given.

This document is available in English upon request from the ANEC Secretariat or from the ANEC website at www.anec.eu

© Copyright ANEC 2014