

# Chemical requirements for consumer products – Part II



**bmask**

FEDERAL MINISTRY OF  
LABOUR, SOCIAL AFFAIRS AND  
CONSUMER PROTECTION

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# Summary

## Introduction

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been criticized for being insufficient.

The project entitled “Chemical requirements for consumer products – Proposals for regulatory measures to improve chemical safety for consumers” (Chemical requirements Part I) prepared by FORCE Technology in 2010 reviewed selected existing legislation with the purpose of identifying chemical requirements in the legislation. The overall conclusion from this review was that the current legal framework was insufficient primarily due the fact that very few chemical requirements were applied in legislation regarding consumer products.

## The purpose of this study

This study was intended to be a supplement to the former project carried out by FORCE Technology, 2010 (Chemical requirements Part I).

This study has reviewed additional product legislation within the EU and the (lack of) chemical requirements in the selected product legislation have been discussed. The main purpose was to extend the ‘statistical’ data/material from which the problematic lack of chemical requirements in consumer products could be concluded.

## Review of European legislation

An overview of the review of the above Directives and Regulations is given in the table below.

Table 0-1: Overview of chemical requirements in the reviewed Directives/Regulations

Name of Directive/Regulation	Chemical req. in legislation	Chemical req. in standards	Comitology to establish chem. req.
Gaseous fuels appliances (NA)	No	Yes, but only for Cd, Pb and no use of asbestos-based materials	No
Pyrotechnic articles (NA)	Yes, but only for silver fumerate	Yes, for certain metal-compounds	No
Low voltage electrical equipment (NA)	No	No	No
Radio and telecommunications (NA)	No	No	No
Medical devices (NA)	Yes, but mainly	Yes, for sterilization	No

Name of Directive/Regulation	Chemical req. in legislation	Chemical req. in standards	Comitology to establish chem. req. (but comitology to alter standards)
	through risk assessment	residuals. Others through risk assessment.	
Packaging and packaging waste (NA)	Yes, but only for heavy metals	Yes, to some degree. (min. amount of substances classified as 'N' if released to the environment)	Only exemptions from existing metal requirements
Food contact materials	Yes, but mainly for plastics	No	Yes
Simple pressure vessels (NA)	No	No	No
Recreational crafts (NA)	No	No	No
EC-type approval system motor vehicles	Only limits for CO and NOx emissions	No	(No)*
General safety of motor vehicles	No	No	No

NA = New Approach Directive

\* In principle chemical requirements (e.g. for indoor air) could be established. It is in reality unlikely to be done as it is specified in the directive that this should be carried out on areas like tests and technical requirements, performance requirements of tyres, rolling resistance and rolling noise, noise levels etc.

## Identified gaps

The gaps identified in this report support the findings of gaps from the previous report (Chemical requirements Part II). The major gaps are:

1. Limited consumer product regulation
  - a. In general very few chemical requirements
  - b. Use of weak phrases instead of specific limit values
  - c. Only a small number of products/chemicals covered by regulations
  - d. Multiple exposures not considered in all cases
  - e. Cocktail effects not considered
  - f. Nanosubstances currently not regulated properly
2. Limitations in the regulatory frame
  - a. Lack of comitology procedure for setting or changing chemical requirements
  - b. Business controlled standard bodies do not set (strict) chemical requirements
  - c. Insufficient market surveillance of consumer products
  - d. Ad hoc based regulation
3. Lack of information on chemicals in consumer products

Therefore, the chemical requirements must be set directly in the legislation or at least a comitology procedure should be in place making it possible to change or set new chemical requirements subsequently.

## Suggested horizontal approach in short

The results of this project do not change the horizontal approach suggested in the previous report (Chemical requirements Part I). The horizontal approach suggested in the previous study includes in short the following elements:

- Expansion of the ERP (Energy-Related Products) Directive to include generic and specific chemical restrictions for all products. Thus, the ERP Directive should be expanded to cover all products rather than just energy related ones and to cover a multitude of environmental aspects mirroring the EU Eco-label Regulation at a somewhat lower level of ambition. This offers opportunities for synergies and efficient resource use.
- The approach for chemical restrictions may rely on positive lists, negative lists, or a combination of both.
- The generic approach for restrictions of chemicals in consumer products should be based on the definition of SVHCs in REACH (i.e. to ban substances falling in this category such as carcinogenic, mutagenic, toxic for reproduction, etc.). However, it should be further considered (in expert groups) whether further categories of chemicals should be included (as for instance sensitising substances or substances that are toxic).
- The general concentration limit of the chemicals restricted by the generic approach should be set at 0.1% (as in REACH) for any homogenous component of the product.
- It should be further discussed whether in some cases (or in which cases) the relevant type of limit-requirements should be based on migration or emission levels instead of content or concentration.
- It should be possible to allow for exemptions for certain substance in certain consumer products.
- It should be possible to establish more specific chemical requirements in special cases (like products emitting dangerous substances to our indoor environment) or for specific groups of products (like e.g. toys addressing a certain consumer group) or specific chemical substances not covered by generic restrictions. In these cases, a risk assessment must be performed. Perhaps an extra uncertainty/safety factor could be used in order to account for the combination effects or for multiple exposures. Risk assessments including possible exemptions should be assessed by an independent scientific committee (e.g. SCHER).
- A product declaration scheme should be introduced for all consumer products. It is suggested that all chemicals classified as hazardous with a content of 100 ppm or higher should be declared. Concentration intervals should be stated.
- The legal framework should include the possibility of adding new or changing the existing chemical requirements by using a committee procedure.

- A systematic assessment of the occurrence of chemicals in (certain) products should be carried out.
- Establishment of an adequately funded and more efficient market surveillance system including random tests and control measurements.
- The random tests carried out by the authorities should give feedback to the process of establishing limit values for special chemical substances for special consumer products. If necessary, the special limit values could be changed or new could be adopted – again by use of a committee procedure.

# 1 Introduction

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been criticized for being insufficient.

The project entitled “Chemical requirements for consumer products – Proposals for regulatory measures to improve chemical safety for consumers” (Chemical requirements Part I) prepared by FORCE Technology in 2010 reviewed selected existing legislation with the purpose of identifying chemical requirements in the legislation. The overall conclusion from this review was that the current legal framework was insufficient primarily due to the fact that very few chemical requirements are applied in legislation regarding consumer products. The project also included a long list of examples of dangerous chemicals that have been found in consumer products, illustrating the fact that dangerous chemicals in consumer products are common and an everyday occurrence, which supports the criticism that the current European regulatory framework on chemicals in consumer products is insufficient.

## 1.1 Purpose

This study was intended to be a supplement to the former project carried out by FORCE Technology, 2010 (Chemical requirements Part I).

This study reviewed additional product legislation within the EU and the (lack of) chemical requirements in the selected product legislation had been discussed. The main purpose was to extend the ‘statistical’ data/material from which the problematic lack of chemical requirements in consumer products could be concluded.

A further purpose of this study was to identify potential further problems (not identified in the previous project) associated with the limited chemical restrictions, and if such further problems were identified to propose adjustments to the suggested horizontal approach.

This was carried out by:

Reviewing

- Chemical requirements in selected product legislation.

Identifying and discussing:

- The major gaps in the selected product legislation (in the legal framework).

Discussing and concluding:

- Whether this review of selected product legislation influences the horizontal approach and the recommendations concerning changes of the European regulatory framework suggested in the former project.



## 2 Selection of relevant product legislation to be reviewed

Before going into a more detailed review of product legislation not reviewed in the former project by FORCE Technology, an initial selection of relevant product legislation was carried out, as it is not possible to review all remaining product legislation within the scope of this project.

### 2.1 Method for selecting relevant product legislation

In order to select relevant product legislation, the website of the EU that summarizes all EU legislation<sup>1</sup> was used. The entries named “Internal market” and “Consumers” were examined, as the entry “Internal market” covers product related legislation and the entry “Consumers” covers legislation relevant for consumers.

The initial selection of relevant product legislation contained the stages listed below:

1. A fairly quick “scan” of relevant legislation with the purpose of identifying product legislation which fulfilled the following selection criteria:
  - The legislation must be product legislation. Products that were used by consumers (but not necessarily purchased by consumers) were in focus. Legislations only related to workers (professional users) were thus excluded.
  - Legislation that included equipment which was not related to consumers such as equipment and protective systems in potentially explosive atmospheres, in vitro diagnostic medical devices or non-automatic weighing instruments was not included.
  - Legislation concerning chemical products (like cosmetics, biocides, medicine, detergents, fertilizers etc.) was excluded.
  - Legislation that involved products/articles where chemical impacts were relevant was selected. I.e. regulations regarding noise emissions, CO<sub>2</sub> emissions, biofuels, electromagnetic compatibility etc. were not included.
  - Legislation that involved products/articles, which are often used by consumers, was selected.
  - Legislation that involved products/articles that have the closest contact with consumers was selected.
2. From this generated list, the final product legislation was chosen. The final selection was determined in cooperation with the Consumer Council, Austrian Standards Institute.

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<sup>1</sup> [http://europa.eu/legislation\\_summaries/index\\_en.htm](http://europa.eu/legislation_summaries/index_en.htm)

## 2.2 List of relevant product legislation

By use of the selection procedure presented above, the following list of product legislation was identified (see the tables below). Legislation marked with 'bold text' was chosen for further review.

Table 2-1 presents New Approach Directives, a series of Directives which are based on the principle of establishing so-called essential requirements in regulation and leave the elaboration of detailed technical requirements to standardization.

Table 2-2 presents Non-New Approach Directives, meaning Directives not defined as a New Approach Directive.

Table 2-1 List of relevant New Approach Directives

	New Approach Directives	Products covered (examples)	Why include this legislation?
2009/142/EC (90/396/EEC)	Appliances burning gaseous fuels	Appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting, etc. <b>Not including appliances specifically designed for use in industrial processes.</b>	Cooking appliances are often used products by consumers. Even on a daily basis.
2000/9/EC	Cableway installations designed to carry persons	Cableway installations designed to carry persons. For use in carriage of persons in vehicles or by towing devices (skiing lifts, etc.)	Lifts are used regularly by consumers. However, less direct contact.
2007/23/EC	Placing of pyrotechnic articles on the market	Fireworks, theatrical pyrotechnic articles, and other pyrotechnic articles	Relevant for consumers, but not used regularly. <b>However, intense use during new years.</b>
93/15/EEC	Explosives for civil uses	Explosives, however not explosives intended for use by the armed forces.	Direct contact, however probably not on a daily basis.
95/16/EC	Lifts	Normal lifts.	Used often, however limited direct contact.
2006/95/EC	Low voltage electrical equipment	Any electrical equipment designed for used with a voltage rating between 50 and 1000 V.	Often used products by consumers. Contact on daily basis.
2006/42/EC	Machinery safety	Machinery in general. An assembly of linked parts or components, at least one of which moves. For instance machines used for packaging. Machinery, safety components, lifting accessories, chains, ropes, partly completed machinery. Mostly industrial machinery, but also machinery used by consumers.	They state that it must be assured that the machinery does not compromise health. However, probably limited direct contact with consumers.
2004/22/EC	Measuring instruments	Water meters, gas meters, heat meters, automatic weighting instruments, taximeters, dimensional measuring instruments etc.	May be relevant for consumers, but not all are used on a daily basis
93/42/EEC	Medical devices: General	Any instrument intended for use in diagnosis, prevention, monitoring, and treatment etc. of diseases. Or replacement or modification of the anatomy (implants) or control of conception.	Not necessarily contact that often, but direct contact. <b>Relevant for all consumers.</b>

	New Approach Directives	Products covered (examples)	Why include this legislation?
90/385/EEC	Active implantable medical devices	Devices inserted into the human body	Very close contact (into) the human body, but not relevant for most consumers.
94/62/EC	Packaging and packaging waste	All products of any material meant for protection, handling, delivery and presentation of goods.	Highly important, due to often and direct contact with consumers.
97/23/EC	Pressure equipment	Vessels to contain fluids under pressure, piping, safety accessories, and pressure accessories. Safety valves, relief systems, etc. Max. allowed pressure: 0.5 bar.	Some workers might have direct contact on a regular basis, however in general consumers are not in regular contact.
1999/5/EC	Radio and telecommunications terminal equipment	Telecommunication appliances. I.e. phones, radios, network termination points.	High importance due to regular/daily direct contact with consumers.
94/25/EC	Recreational craft	Any boat of any type, regardless of means of propulsion. Up to 24 m hull length.	Used regularly by many. However, perhaps only for a limited number of consumers.
2009/105/EC	Simple pressure vessels	Any welded vessel subject to an internal gauge pressure greater than 0.5 bars which is intended to contain air or nitrogen and which is not intended to be fired. The parts and assemblies contributing to the strength of the vessel under pressure shall be made either of non-alloy quality steel or of non-alloy aluminum or non-age hardening aluminum alloys.	Allowed materials limited, thus not of high importance. However products could probably include spray deodorants etc. which are commonly used by consumers.

Table 2-2 List of relevant non-New Approach Directives

	Non-New Approach Directives	Products covered (examples)	Why include this legislation?
Reg. 3922/91	Harmonization of civil aviation requirements and procedures	Design, manufacture, operation and maintenance of aircraft	Relevant for consumers, but not on a daily basis. No close contact
96/98/EC	Marine equipment	Equipment used/installed on board ships	Relevant for some consumers, but not on a daily basis. Not necessarily close contact
Reg. 2009/661/EF	Concerning type-approval requirements for the general safety of motor vehicles, trailers,	Type-approval of motor vehicles, trailers, systems, components, etc. regarding their safety. Tires (fuel efficiency, CO2 emission, etc). Focus is on safety (i.e. preventing accidents)	Replaces the “Interior fittings” Directive (74/60/EEC) and the “Heating systems for motor vehicles” (2001/56/EC) and the “Fire behavior of materials used in interior fittings” (95/28/EC). However, the word “health” is not mentioned in the Directive.
2006/40/EC	Emissions from air conditioning systems in motor vehicles	Systems must not emit GHG with a Global Warming potential above 150	The word ‘health’ is not mentioned in the Directive
2007/46/EC	EC-type approval system	Concerns administrative and technical	The word ‘health’ is not

	Non-New Approach Directives	Products covered (examples)	Why include this legislation?
	for motor vehicles	requirements for all new vehicles. Technical requirements concerning construction – exhaustive list in Annex IV. Refers to a number of other Directives.	mentioned in the Directive. However, the Directive links to several other Directives focusing on requirements regarding ‘devices’ and interior products in motor vehicles.
Reg. 2004/1935/EC	On materials and articles intended to come into contact with food	All materials/articles intended to come into contact with food. All types of packaging, bottles (plastic and glass), cutlery, and even adhesives and inks for printing labels. Includes also ‘active/intelligent’ packaging (i.e. changes color when the food is too old, etc.)	Interesting due to the new type product “active/intelligent” packaging. High degree of contact with humans. Must not transfer substances to food, which may endanger human health”.

## 2.3 Selected product legislation

As presented in Table 2-1 and Table 2-2, the review of legislation in this project focused on the following areas/products:

### *New-Approach Directives*

- Appliances burning gaseous fuels
- Placing of pyrotechnic articles on the market
- Low voltage electrical equipment
- Medical devices: General
- Packaging and packaging waste
- Radio and telecommunications terminal equipment
- Recreational crafts (boats)
- Simple pressure vessels (sprays)

### *Non-New Approach Directives*

- Type-approval requirements for the general safety of motor vehicles, trailers, etc.
- EC-type approval system for motor vehicles
- Materials and articles intended to come into contact with food

# 3 Review of chemical requirements in selected product legislation

This section reviews selected product legislation with the purpose of clarifying whether the legislation ensures that consumers are not exposed to health risks (caused by a content/release of chemicals) by using the products.

Each review is divided into three sub-sections:

- **Description of the Directive.** The Directive is described from an objective perspective, focusing on:
  - 1) products covered;
  - 2) requirements related to health aspects (chemical restrictions are of course described, if found);
  - 3) potentially associated harmonized standards (which may include more specific chemical requirements than those mentioned in the Directive) and finally
  - 4) comitology procedure.
- **Discussion of the Directive.** It is discussed whether the Directive in reality ensures that consumers are not exposed to health risks related to a content/release of chemicals in the products. Thus, in this section, potential chemical requirements are also discussed in terms of usefulness.
- **Conclusions,** which in short summarize the findings identified during the discussion.

## 3.1 Appliances burning gaseous fuels

### 3.1.1 Description of the Directive

*Directive 2009/142/EC of 30 November 2009 relating to appliances burning gaseous fuels* is a New Approach Directive.

#### 3.1.1.1 Products covered

The Directive covers 'appliances' burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing (a normal water temperature must not exceed 105 °C). The Directive also applies to 'fittings' meaning safety devices, controlling devices or regulating devices and sub-assemblies etc. Gaseous fuels mean any fuel which is in a gaseous state at a temperature of 15 °C under a pressure of 1 bar.

Product examples are stoves, water heaters, etc.

### 3.1.1.2 Requirements related to health aspects

The 'overall' regulation is stated as "Member States shall take all necessary steps to ensure that appliances may be placed on the market and put into service only if, when normally used, they do not compromise the safety of persons, domestic animals and property."

Additionally, the appliances and fittings must satisfy – among other things - the following essential requirements (described in Annex I in the Directive):

- **When placed on the market**, all appliances must be accompanied by
  - *Technical instructions* which include for instance the type of gas used, gas supply pressure used, required flow of fresh air for the combustion, and for avoiding formation of dangerous unburned gas mixtures for appliances (not fitted with a specific device), and the conditions for dispersal of combustion products.
  - *Instructions for use* which must include all information required for safe use.
  - *A warning notice* on the appliance and its packaging which states the type of gas used, gas supply pressure, restrictions on use – especially where the appliance must be installed only in areas with sufficient ventilation.
- **Materials:**
  - Materials must be appropriate for their intended purpose and must withstand the technical, chemical, and thermal conditions to which they will be foreseeable subjected.
  - The properties of materials that are important for safety must be guaranteed by the manufacturer/supplier of the appliance.
- **Design and construction:**
  - There are 24 sub-requirements, all mainly related to 'physical' safety, such as for instance the requirement of "Appliances must be so designed and constructed as to minimize the risk of explosion in the event of a fire of external origin". Below is described all the requirements which to some (vague) degree involve safety related to chemicals:
    - Appliances must be designed/constructed to avoid hazards of electrical origin – where relevant, they must fulfill Directive 2006/95/EC regarding low voltage equipment (see section 3.3).
    - Appliances must be so constructed that the gas leakage rate is not dangerous.
    - Several restrictions regarding avoidance of dangerous accumulation of unburned gas.
    - Large-scale kitchen appliances and appliances powered by gas containing toxic components must be equipped with a specific device.
    - When used normally, appliances must be so constructed that flame stability is assured and combustion products do not contain unacceptable concentrations of substances harmful to health.
    - In the room or space concerned, independent flueless domestic heating appliances and flueless instantaneous water heaters must not cause a carbon monoxide concentration likely to present a danger to the health of

persons exposed, bearing in mind the foreseeable duration of their exposure.

### 3.1.1.3 Associated harmonized standards

As of December 2010, a total of approximately 90 harmonized standards were associated with this Directive. The titles of these were scanned, and a few of the most relevant (in terms of health risks associated with a content/release of chemicals) are reviewed below:

- EN 30-1-1:2008 Domestic cooking appliances burning gas - Part 1-1: Safety – General (including the proposed amendment from January 2010 (EN 30-1-1:2008. FprA1)).
- EN 30-1-2:1999 Domestic cooking appliances burning gas – Part 1-2: Safety – Appliances having forced-convection ovens and/or grills.
- EN 89:1999 Gas-fired storage water heaters for the production of domestic hot water (including amendments).
- EN 549:1994 Rubber materials for seals and diaphragms for gas appliances and gas equipment.

#### *EN 30-1-1: Domestic cooking appliances burning gas - Part 1-1: Safety – General*

A general *material-requirement* is “The nature and state of the surface of materials intended to come into contact with food shall be such that they cannot contaminate or degrade this food” ... as well as “Materials containing asbestos shall not be used in the construction of the appliance”.

- Regarding combustion outlets there are requirements of “the volume content of CO in the air- and water-free products of combustion shall not exceed 0.10%, 0.15%, and 0.20% respectively according to certain tests. Several sub-requirements further specify when and where these limits are valid.

#### *EN 30-1-2: Domestic cooking appliances burning gas – Part 1-2: Safety – Appliances having forced-convection ovens and/or grills*

As for the above EN 30-1-1 standard, this standard only sets a requirement for CO in the air:

- For certain ovens and/or grills “it shall be verified... that the volume concentration of CO in the dry, air-free products of combustion does not exceed 0.20 % after 15 min previous operation at the full-on rate”.

#### *EN 89: Gas-fired storage water heaters for the production of domestic hot water* **Material** related requirements comprise:

- “The use of asbestos-based materials is forbidden”.
- “The use of cadmium containing solder is forbidden”.
- “Materials that come into contact with water intended for human consumption ... shall not contaminate the water”
- “The release of lead and cadmium ions or compounds into the water shall not exceed the following limits: Lead: cold water test: 0.3 g/(m<sup>2</sup>·d); hot water test: 0.3 mg/(m<sup>2</sup>·h). Cadmium: cold water test: 0.03 mg/(m<sup>2</sup>·d); hot water test: 0.03 g/(m<sup>2</sup>·h).
- “Plastic materials ... must not pose any health threat”. “Special attention must be paid to microbiological properties of the plastic materials used and to the prevention of substances leaching out”.

#### **Combustion** related requirements comprise:

- “The content of CO content of the dry, air-free combustion products shall not exceed: 0.10% under the normal conditions ... when the appliance is

supplied with the reference gas ... and 0.20% under the limit condition ... when the appliance is supplied with the incomplete combustion limit gas ...”.

- There is no requirement of restricting NO<sub>x</sub> emission. However “If the manufacturer declares the NO<sub>x</sub> emission, he shall select the NO<sub>x</sub> class given” (class 1-6 ranging from NO<sub>x</sub> limit content of 70 – 260 mg/kWh).

*EN 549: Rubber materials for seals and diaphragms for gas appliances and gas equipment*

- Physical and chemical properties of rubber materials used for the manufacture of seals shall have certain hardness, tensile strength, resistance to ageing/gas/lubricants/ozone, etc. No requirements regarding content of chemicals.

#### 3.1.1.4 Comitology procedures

There is no comitology in place to establish limits for CO or other substances.

However, Member States may formally object to provisions in harmonized European standards which may result in a withdrawal of its reference published in the Official Journal and the request to change the standard following consultations with a standing committee established under Article 5 of Directive 98/34/EC (if Member States or the Commissions consider that the standards do not entirely meet the essential requirements).

### 3.1.2 Discussion of the Directive

Even though the main regulatory statement in the Directive includes the sentence “the appliances ... must not compromise the health of persons...” very few (if any) requirements towards a content of (hazardous) chemicals are included in the Directive. The main focus of the requirements is towards securing ‘physical’ safety, exemplified by the requirement “Appliances must be so designed and constructed as to minimize the risk of explosion in the event of a fire of external origin”.

However, Directives are meant to cover large number/variations of products. Thus it is difficult in the Directive to make very specific demands related to all these products. Therefore a number of associated standards are developed – standards that further elaborate the requirements in the Directive. If looking at two of the most interesting - the standard for domestic cooking appliances and the standard on water heaters - it seems that the two main areas regulated (related to health) are materials and combustion. Below, these are discussed further.

#### *Materials*

Two main requirements related to materials are included in the Directive:

- 1) “Materials must be appropriate for their intended purpose and must withstand the technical, chemical, and thermal conditions to which they will be foreseeable subjected” and
- 2) “The properties of materials that are important for safety must be guaranteed by the manufacturer/supplier of the appliance”.

The second requirement is especially interesting since this in theory means that a material which is composed of (or include) dangerous chemicals cannot be assumed to fulfil this requirement (assuming that the word “safety” comprises ‘physical’ safety as well as ‘safety related to not being exposed to dangerous substances’). But how does the manufacturer know which substances to ban (or restrict)? The associated standard on ‘general safety for domestic cooking appliances burning gases’ does specify this to some degree, since it includes a specific requirement of not using

asbestos-based material. And the standard on water heaters specifies even further and includes restrictions on (besides asbestos) release of lead and cadmium ions/compounds to the water (0.3 mg/(m2d) and 0.03 mg/(m2d) respectively) and a ban on use of cadmium containing solder. In principle, these requirements seem reasonable (a discussion of the limit values is outside the scope of this study) due to the fact that it is desirable to avoid that materials used to produce water heaters release toxic substances to the drinking water. However, even though the choice of regulating cadmium and lead seems reasonable due to the material type used in producing water heaters (metal), it cannot be excluded that other substances should be regulated as well (for instance nickel, chromium, copper, and selenium – substances attempted regulated in drinking water). Likewise, why is it only the standard regarding water heaters that restricts release of heavy metals? No chemical requirements are set for ‘domestic cooking appliances’ even though they may pose a health risk by releasing heavy metals to water and food.

Thus – to sum up - can it be said that the restrictions in the standard (ban on asbestos, cadmium solder, and restrictions on release of cadmium and lead compounds) in reality fulfil the requirement in the Directive of “The properties of materials that are important for safety must be guaranteed by the manufacturer/supplier of the appliance”? Probably not!

The requirements seem to focus only on metals and asbestos. It cannot be ruled out that other problematic substances could pose a problem. Yet, the standard regarding water heaters does include restrictions regarding one other ‘substance’ – plastic materials, which “... must not pose any health threat. Special attention must be paid to microbiological properties of the plastic materials used and to the prevention of substances leaching out”. However, no further elaboration of the requirements is included in the standard which makes it difficult to comply in reality.

In 2005 DG Enterprise was involved in the development of a proposal for a comprehensive European Acceptance Scheme (EAS) for construction products used with water intended for human consumption (DWI, 2010). However, the system seems to have been pushed aside<sup>2</sup>. In 2008 four member states (UK, France, the Netherlands, and Germany) issued a report to the Commission and CEN in order to answer questions on this area. The report focused on these four member states own established schemes in the area and discussed the possibilities of a harmonization of a common EU approval of products in contact with drinking water (4MSR, 2008). In contrast to the EAS that focused only on construction products in contact with drinking water, the schemes of the four member states deal with all kinds of products in contact with drinking water. This shows that the aspect of chemicals migrating into drinking water is an area that is not regulated at all on the European level. The directive of ‘appliances burning gaseous fuels’ does not allow to set any chemical requirements and therefore it is not the place for introducing chemical requirements for products in contact with drinking water. In other words, a new regulatory framework, which allows for establishing chemical requirements of all kinds of materials in contact with drinking water is needed.

#### *Combustion products*

In the Directive it is stated that appliances must be so constructed that “when used normally, flame stability is assured and combustion products do not contain unacceptable concentrations of substances harmful to health”. It is a promising

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<sup>2</sup> Statement from Franz Fiala, The Consumer Council at the Austrian Standards Institute.

requirement regarding control of exposure of chemicals to the consumers. However, no further specification in terms of the identification of the harmful substances, neither a specification of the concentration-level when they are 'unacceptable' is provided which makes this requirement somewhat useless. However, the associated standards regarding general safety for domestic cooking appliances burning gas as well as the specific standard regarding water heaters do include identification of the harmful substances (CO) as well as limits (content of CO in the dry air-free combustion products is limited to 0.10% and 0.20% respectively (under specific conditions)). Furthermore, NO<sub>x</sub> emissions are not restricted, only an obligation to use a classification of the NO<sub>x</sub> emissions if the NO<sub>x</sub> emissions are reported.

Regarding the CO emission limits, a previous study has looked at emission limits in gas appliances standards, in particular heating boilers, and judged that the limits were too high (Hübner and Boos, 1998). Furthermore, ANEC have called for regulatory CO levels in connection with a revision of the directive (Appliances burning gaseous fuels) because the standard values are judged inappropriate. ANEC suggested the possibility to establish regulatory limits for CO via comitology in the directive (ANEC paper, 2008).

The issue of emission limits was also discussed in the context of the implementation of the EUP/ERP Directive and the discussion is still active. (This could be an alternative route to set legal limits for CO). However, it seems that the Commission will only propose NO<sub>x</sub> limits for boilers. The argument being that a meaningful CO limit needs a test method which reflects an intermittent operation (start/stop) which the current standards do not deliver<sup>3</sup>. The counter-argument was that it is necessary to have a CO limit (even if it is based on a steady state basis) because NO<sub>x</sub> levels can be reduced at the expense of CO (ANEC paper, 2008).

A position paper from ANEC (2010) stated further that "The exhaust gas parameters (e.g. temperature, CO and CO<sub>2</sub> concentration) affect not only the performance of the appliance, but also the quality of the air, and thus pose a risk to health when released indoors. Several European Standards (ENs) permit high concentrations of CO to be emitted in the room where the appliance is installed, even up to 2000 ppm (or 0.2% CO) in an abnormal operation of the appliance (low voltage or high gas pressure). We consider that this value is very high indeed and poses extreme risk to health".

Thus, it seems that more work is needed in securing no health risks related to release of chemical compounds in the area of 'Appliances burning gaseous fuels'.

### **3.1.3 Conclusions**

The main conclusions from the review of *Directive 2009/142/EC of 30 November 2009 relating to appliances burning gaseous fuels* are:

Conclusions:

- In the standard regarding water heaters, there are specific chemical restrictions regarding release of cadmium and lead ions/compounds – but no restrictions regarding release of for instance nickel, chromium, copper, and selenium. Substances which in proposed standards for securing the quality of drinking water have been suggested to be regulated.

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<sup>3</sup> Statement from Franz Fiala, The Consumer Council at the Austrian Standards Institute.

- It seems that the standard regarding water heaters is the only one restricting release of heavy metals. Yet it is reasonable to assume that some of the other ‘domestic cooking appliances’ also may pose a health risk by releasing heavy metals.
- All in all some doubt exists of whether the standards (with their restrictions) ensure that the main Directive requirement of “The properties of materials that are important for safety must be guaranteed by the manufacturer/supplier of the appliance” is fulfilled.
- The specific requirements in the standards focus only on metals and asbestos (and plastics to a minor degree). It could not be ruled out that other problematic substances should be regulated in ‘appliances burning gaseous fuels’.
- Limits regarding CO are introduced in the general safety standard on domestic cooking appliances (thus covering a wide range of products); however, the limits are too high.
- There are unresolved issues regarding the regulation of NO<sub>x</sub> compounds.
- Requirements in the Directive seem to mainly focus on securing ‘physical’ safety (i.e. prevent accidents).
- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.
- I.e. more work is needed in securing no health risks related to the release of chemical compounds for these products.

## 3.2 Placing of pyrotechnic articles on the market

### 3.2.1 Description of the Directive

*Directive 2007/23/EC of 23 May 2007 on the placing on the market of pyrotechnic articles* is a New Approach Directive.

#### 3.2.1.1 Products covered

The Directive covers ‘pyrotechnic articles’ meaning “any article containing explosive substances or an explosive mixture of substances designed to produce heat, light, sound, gas, or smoke, or a combination of such effects through self-sustained exothermic chemical reactions”.

Examples of products covered are fireworks (pyrotechnic articles intended for entertainment purposes) and theatrical pyrotechnic articles (for stage use, film, etc.).

Products not covered by the Directive comprise pyrotechnic articles intended for non-commercial use or for use in the aerospace industry. Equipment falling under the scope of Directive 96/98/EC (marine equipment), percussion caps specifically for toys falling under Directive 88/378/EEC (safety of toys) or explosives falling under Directive 93/15/EEC (explosives for civil uses) is likewise not covered by this Directive. Pyrotechnic articles presented at trade fairs, exhibitions, and demonstrations need not to comply with this Directive. Though appropriate safety measures must be taken during the presentations.

Article 3 in the Directive states that pyrotechnic articles shall be categorized by the manufacturer according to their type of use or their purpose and level of hazard, including their noise level. The articles must be categorized as fireworks (four sub-

categories), theatrical pyrotechnic articles (two sub-categories), or other pyrotechnic articles (two sub-categories).

### 3.2.1.2 *Requirements related to health aspects*

The Directive establishes rules for achieving the free movement of pyrotechnic articles in the internal market while ensuring a high level of protection of human health and public security and the protection and safety of consumers while at the same time taking into account environmental protection. More specifically, the Directive establishes the essential safety requirements which pyrotechnic articles must fulfill with a view to their being placed on the market.

Generally manufacturers (or importers) shall ensure that pyrotechnic articles placed on the market comply with the essential safety requirements set out in Annex I.

One of the essential safety requirements involves a test 'under realistic conditions'. If this is not possible in a laboratory, the tests must be carried out under the conditions in which the pyrotechnic article is to be used. The following information and properties – where applicable – must be considered or tested:

- Design, construction, and characteristic properties, including detailed chemical composition (mass and percentage of substances used) and dimensions;
- The physical and chemical stability of the pyrotechnic article in all normal, foreseeable environmental conditions;
- Sensitivity to normal, foreseeable handling and transportation;
- Compatibility of all components as regards their chemical stability;
- Resistance of the pyrotechnic article to moisture where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by moisture;
- Resistance to low and high temperatures, where the pyrotechnic article is intended to be kept or used at such temperatures and its safety or reliability may be adversely affected by cooling or heating of a component or of the pyrotechnic article as a whole;
- Safety features intended to prevent untimely or inadvertent initiation or ignition;
- Suitable instructions and, where necessary, markings in respect of safe handling, storage, use (including safety distances), and disposal in the official language or languages of the recipient Member State;
- The ability of the pyrotechnic article, its wrapping or other components to withstand deterioration under normal, foreseeable storage conditions;
- Specification of all devices and accessories needed and operating instructions for safe functioning of the pyrotechnic article.

Another of the essential safety requirements involves restrictions on a specific chemical (silver fulminate). "Throwdowns in category 1 fireworks must not contain more than 2.5 mg silver fulminate. Another essential safety requirement states that "fireworks may only be constructed of materials which minimize risk to health, property, and the environment from debris.

The remaining essential safety requirements do not involve requirements related to chemicals. Examples of the remaining essential safety requirements are for instance "Each pyrotechnic article must be designed and manufactured in such a way that it can be disposed of safely by a suitable process with minimum effect on the environment" and "Pyrotechnic articles must not contain military explosives".

Finally there are requirements concerning the categorization of the pyrotechnic articles, the safety distance, noise level, ignition devices, burning time of fuses, etc.

#### 3.2.1.3 *Comitology procedures*

There is no comitology in place to allow for the establishment of specific requirements including chemical limits. Comitology procedures do exist, but only for changing conformity assessment procedures (annex II and III), labeling and adaptations necessary to take account of any future amendments to United Nations recommendations.

#### 3.2.1.4 *Associated harmonized standards*

As of December 2010 a total of one standard (divided in five different parts) is associated with this Directive. Part 1 to 4 of the standard concern elements like terminology, categorization, labeling requirements, and test method and are thus not expected to include chemical restrictions. However, part five concerns requirements for construction and performance and is reviewed below. Elements which resemble chemical restrictions are presented. It seems that only Part 1 and 2 of the standards have been published in the Official Journal and thereby are harmonized standards.

#### *EN 15947-5:2010 Pyrotechnic articles – Fireworks, Categories 1, 2, and 3 – Part 5: Requirement for construction and performance*

- Requirements regarding construction materials comprise:
  - The body of the firework must be made of paper, cardboard, or plastics. There are other requirements of which material that is allowed for certain products (sticks shall be made of wood, for instance).
- Requirements regarding pyrotechnic composition comprise:
  - Different requirements regarding net explosive content (black powder, nitrate/metal-based, perchlorate/metal-based) according to firework type. For instance:
    - Christmas crackers: “Not more than 16 mg report composition based on potassium chlorate and red phosphorous, or not more than 1.6 mg silver fulminate as report composition”.
    - Fountains: “Not more than 7.5 g (for indoor use) pyrotechnic composition that is based on nitrocellulose with a mass fraction of not more than 12.6% of nitrogen, with no additional oxidizing substances.

The use of plastics is mentioned, but no requirements of which substances that should not be allowed in the plastics are mentioned.

It should be mentioned that only part 1 and part 2 seem to be active at present time. The status of part 3, 4, and 5 are not known.

### **3.2.2 Discussion of the Directive**

As in many other Directives, this Directive also makes use of the sentence “...ensuring a high level of protection of human health and public security and the protection and safety of consumers...”. The Directive elaborates this requirement in the essential safety requirements, of which the most specific requirements are “Throwdowns in category 1 fireworks must not contain more than 2.5 mg silver fulminate” and “fireworks may only be constructed of materials which minimize risk to health”. Below these two elements are – among others - discussed further.

*Fireworks may only be constructed of materials which minimize risk to health*

One of the essential safety requirements states that “fireworks may only be constructed of materials which minimize risk to health, property, and the environment from debris”. In theory an excellent requirement, but the wordings are so elusive that the requirement in reality is very difficult to fulfill.

Furthermore, there is no comitology in place to establish limits in the Directive. However, the associated harmonized standard – part 5 “Construction and performance” - does specify the requirement further. There are requirements of which materials that are allowed to be used for the container/body of the firework (paper, cardboard, or plastics). Interesting requirement since it resembles the use of ‘positive lists’ – namely stating what is *allowed* to be used and not just lists elements/substances which are *not allowed* to be used. However, the types of plastics which are allowed to be used are not elaborated and the ‘material-demands’ only concern the body of the firework.

*Content requirement of a specific chemical*

The other essential requirement states that “Throwdowns in category 1 fireworks<sup>4</sup> must not contain more than 2.5 mg silver fulminate”. As opposed to the former reviewed Directive (concerning appliances for burning gaseous fuels), this requirement not only identifies a specific chemical to be restricted, but also states an allowed content limit, which makes it more usable than the requirement stated in the former Directive. However, it seems like the amount of silver fulminate restricted is not related to volume or weight, meaning that the restricted amount applies to very small products as well as very large products, which still may cause problems. However, the standard part 5 applies this principle (max. content of X mg substance according to product type) to many different product types – thus due to the nature of these products this may be a functional requirement (perhaps a throwdown is always in a certain size?).

*Use of perchlorate/metal based*

The standard also specifies different requirements regarding net explosive content (black powder, nitrate/metal-based, perchlorate/metal-based) according to firework type. Whether it is established with certainty that the use of perchlorate-metals in fireworks does not compromise the health of consumers is uncertain.

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<sup>4</sup> Category 1 fireworks comprises “fireworks which present a very low hazard and negligible noise level and which are intended for use in confined areas, including fireworks which are intended for use inside domestic buildings”.

#### *Identification of chemical composition focus on explosives*

An interesting aspect in this Directive is its requirement of a 'test under realistic conditions'. One of the elements to be tested (or considered) is "design, construction, and characteristic properties, including detailed chemical composition (mass and percentage of substances used) and dimensions". This requirement could be interpreted as an obligation for the manufacturer to describe the chemical composition of the pyrotechnic product, thus identifying (all?) the chemical compounds used. This makes it an interesting requirement, first of all because it establishes the basic needs (the identification (and mass content) of the chemicals used) for evaluating whether the product contains hazardous chemicals which can constitute a health risk for the consumer. And secondly, it is interesting because a requirement regarding the identification of the chemicals used (and their mass content) is rarely seen in product legislation. However, when looking at the associated standard concerning 'test methods' it seems like the determination of the chemical composition more resembles a determination of the 'pyrotechnic composition' – meaning a characterization of the explosives. Thus, the method is probably designed to analyze for the content of the known explosives, and thus it will not reveal a potential content for dangerous substances as for instance heavy metals.

#### *Securing chemical stability*

The test-requirement concerning "The physical and chemical stability of the pyrotechnic article in all normal, foreseeable environmental conditions" introduces a higher level of 'chemical knowhow' and could involve some sort of 'chemical risk assessment', an element which is appreciated in terms of securing no health risks related to the chemicals used. However, the 'chemical risk assessment' performed here focuses on maintaining the stability of the product (which ensures controlled explosions), and probably not on whether dangerous chemicals are included or formed in the product (not necessarily making the product unstable).

No requirements of no or restricted use of specific/named hazardous substances are included in the Directive or associated standards.

### **3.2.3 Conclusions**

The main conclusions from the review of *Directive 2007/23/EC of 23 May 2007 on the placing on the market of pyrotechnic articles* are:

- The standard specifies use of certain net explosives (black powder, nitrate/metal-based, perchlorate/metal-based, etc) but specifies the max. content (for instance 2.5 mg) only related to product type – and not product volume. This may give rise to problems.
- A requirement (resembling the use of positive lists) specifies what materials that are allowed to be used in the body of the firework (paper, cardboard, and plastics). However, the type of plastic material is not specified and the requirement is only valid for the body of the firework.
- According to the standard, the applied net explosives comprise the use of perchlorate/metal based compounds. Whether it is established with certainty that the use of perchlorate-metals in fireworks does not compromise the health of consumers is uncertain.
- Identification of chemical composition focuses on identification of known explosives and not potentially dangerous substances – like heavy metals.

- A requirement regarding securing the chemical stability could be interpreted as a form of chemical risk assessment. However, the focus of the ‘risk assessment’ seems to be on securing ‘controlled explosions’ and not on whether dangerous substances are included or formed in the product.
- No requirements of no or restricted use of specific/named hazardous substances are included in the Directive or associated standards. An exemption is silver fulminate, though the requirement does not comprise a mg/kg limit, but only states that the substance must not be present in an amount above 2.5 mg.
- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.
- I.e. there are no chemical requirements that will ensure that consumers are protected from the chemical hazards related to the product group.

## 3.3 Low voltage electrical equipment

### 3.3.1 Description of the Directive

*Directive 2006/95/EC of 12 December 2006 relating to electrical equipment designed for use within certain voltage limits* is a New Approach Directive. No amendments have been made so far to this Directive (LVD – Low Voltage Directive).

#### 3.3.1.1 Products covered

The Directive covers ‘electrical equipment’ designed to be used within a certain voltage limit. The limits are defined in the Directive as follows:

- Alternating current: between 50 and 1000 V
- Direct current: between 75 and 1500 V

Product examples are alarm systems, multimedia systems and equipment, gas detectors, lamps, household electrical appliances, rotating machinery, measuring equipment etc. Annex II of the Directive mentions electrical equipment that is outside the scope of the Directive, such as electrical equipment for use in an explosive atmosphere, for radiology and medical purposes, for goods and passenger lifts, plugs and socket outlets for domestic use, specialized electrical equipment for use on ships, aircrafts, or railways.

#### 3.3.1.2 Requirements related to health aspects

According to the Directive “Member States shall take all appropriate measures to ensure that electrical equipment may be placed on the market only if ... it does not endanger the safety of persons, domestic animals, or property, when properly installed and maintained and used in applications for which it was made.

The principal elements of the safety objectives are listed in Annex I of the Directive. The most important issues regarding safety are listed below:

- **General conditions**
  - User instructions that will ensure safe use shall be marked on the equipment.
  - The electrical equipment should be made in such a way as to ensure that it can be safely and properly assembled and connected.
  - The electrical equipment should be so designed and manufactured as to ensure that protection against the hazards listed below is assured.
- **Protection against hazards arising from the electrical equipment**

- Measures of technical nature should be prescribed in order to ensure that persons and domestic animals are adequately protected against the danger of physical injury or other harm, which might be caused by direct or indirect contact.
- **Protection against hazards which may be caused by external influences on the electrical equipment**
  - Technical measures are to be laid down in order to ensure that
    - The electrical equipment meets the expected mechanical requirements in such a way that persons, domestic animals, and property are not endangered.
    - The electrical equipment shall not endanger persons, domestic animals, and property in foreseeable conditions of overload.

Compliance with the principal elements of the safety objectives can be met by use of national standards related to harmonized standards or national standards when no harmonized standards exist. The products must be CE marked.

### 3.3.1.3 *Associated harmonized standards*

As of December 2010, a total of several hundred harmonized standards is associated with this Directive. The titles of these have been scanned, and a few of the most relevant (in terms of health risks associated with a content/release of chemicals) are presented below. Several standards concern restrictions related to human exposure to electromagnetic fields, but this aspect is not discussed as the purpose is chemical risks.

- EN 50497: 2009 Recommended test method for assessment of the risk of plasticizer exudation from PVC insulated and sheathed cables.
- EN 60335-1:2002 Household and similar electrical appliances - Safety - Part 1: General requirements IEC 60335-1:2001 (Modified).
- EN 60335-2 Household and similar electrical appliances - Safety Part 2: There are in all 108 standards entitled 'Part 2'. A few of these have been selected for a review of chemical requirements. The most interesting product from a consumer viewpoint has been chosen. These standards are:
  - EN 60335-2-8:2003 Household and similar electrical appliances - Safety - Part 2-8: Particular requirements for shavers, hair clippers, and similar appliances IEC 60335-2-8:2002 (Modified).
  - EN 60335-2-15:2002 Household and similar electrical appliances - Safety - Part 2-15: Particular requirements for appliances for heating liquids IEC 60335-2-15:2002.
  - EN 60335-2-21:2003 Household and similar electrical appliances - Safety - Part 2-21: Particular requirements for storage water heaters IEC 60335-2-21:2002 (Modified).
  - EN 60335-2-23:2003 Household and similar electrical appliances - Safety - Part 2-23: Particular requirements for appliances for skin or hair care IEC 60335-2-23:2003.

Standard 50497 "Recommended test method for assessment of the risk of plasticizer exudation from PVC insulated and sheathed cables" has nothing to do with a human risk assessment of the migration of plasticizers out of the products. No evaluation of risk to human health is included or mentioned. The standard describes a qualitative assessment of the loss of plasticizer to ensure that no cable damage happens because of the altered characteristics of the PVC.

Standard EN 60335-1 Household and similar electrical appliances – Safety – Part 1: General requirements, a part (clause no. 32) specifically mentions the toxicity of the products: “Appliances shall not ... present a toxic or similar hazard due to their operation in normal use”. It is furthermore stated that compliance is checked by the limits or test specified in Part 2 of the standard series (EN 60335-2). However, if no limits or tests are specified in Part 2, then the appliance is deemed to comply with the requirements without testing. When looking closer at some of the Part 2 standards for specific products (listed above), no requirements are specified under this clause no. 32, meaning that no specific chemical requirements are set in the Part 2 standards – the appliances must simply not present a toxic hazard in operation under normal use (and no testing is required).

The standards covering “Particular requirements for appliances for heating liquids” and “Particular requirements for storage water heaters” (i.e. EN 60335-2-15 and EN 60335-2-21) do neither contain any chemical requirements. The appliances must not present a toxic hazard in operation under normal use, but no testing is required. This again illustrates the gap of missing chemical requirements for materials/products in contact with drinking water as discussed in section 3.1.2 “Discussion of the Directive” in the chapter of “Appliances burning gaseous fuels”. The aspect of chemicals migrating into drinking water is an area that is not regulated at all on the European level. A new regulatory framework, which allows for establishing chemical requirements of all kinds of materials in contact with drinking water, is needed.

#### 3.3.1.4 *Committee procedure*

No committee procedure (comitology) is in place to establish specific chemical requirements.

### **3.3.2 Discussion of the Directive**

#### *No specific chemical requirements in either Directive or standards*

As described this Low Voltage Directive does not contain any chemical requirements. Only the safety of persons is mentioned in the Directive. When looking at the harmonized standards it seems that the picture is the same for the harmonized standards, as the few standards reviewed (out of the many hundred existing standards) do not contain any specific chemical requirements. It is merely mentioned (at most) that the appliances may not present a toxic hazard in operation under normal use. No specific guidance or test methods are prescribed in order to meet this general requirement.

#### *No comitology in place to establish chemical requirements*

Furthermore, no committee procedure (comitology) is in place to establish specific chemical requirements. This means that new chemical requirements cannot be adopted quickly. This can only be done by amending the Directive, which is a comprehensive and time-consuming process. However, chemical requirements could be set by changing e.g. clause 32 in all the Part 2 standards.

#### *RoHS Directive covers low voltage products*

This means that this Low Voltage Directive and its associated standards do not protect the consumers from the chemical hazards that may be present in low voltage electrical equipment. However, the RoHS Directive (2002/95/EC) as described in the former project by FORCE Technology (2010) also applies for these low voltage electrical products. This means that the following heavy metals and flame retardants

are restricted: Pb, Hg, Cd, Cr VI, PBB, and PBDE. With the new RoHS proposal, a comitology to change the annexes which include bans of chemicals (Annex IV) and candidate for bans (“priority list” – Annex III) is introduced. As discussed in the former project by FORCE Technology (2010), it can be questioned whether the concentration limits for the above substances are strict enough and why not more hazardous substances are covered. Hopefully the link with REACH will lead to problematic substances being restricted in the new ROHS as soon as they are identified as problematic in REACH.

### **3.3.3 Conclusions**

The main conclusions from the review of *Directive 2006/95/EC of 12 December 2006 relating to electrical equipment designed for use within certain voltage limits (the Low Voltage Directive)* are:

- Requirements only focus on securing ‘physical’ safety (i.e. prevent accidents).
- There are no specific chemical restrictions (in terms of identification of the restricted chemicals or concentration-levels). Only vague phrases like “may not present a toxic hazard” are applied.
- No comitology procedure is in place to establish specific chemical requirements. This can only be done by amending the Directive or by adding chemical requirements to the many hundred standards.
- I.e. the Directive and the standards do not protect the consumers from the chemical hazards that may be present in low voltage electrical equipment. But the RoHS Directive that applies for the same products does that to some extent.

## **3.4 Radio and telecommunications terminal equipment**

### **3.4.1 Description of the Directive**

*Directive 1999/5/EC of 9 March 1999 on radio equipment and telecommunication terminal equipment and the mutual recognition of their conformity* is a New Approach Directive. The latest amendments to the Directive have been made in 2009.

The Directive establishes a regulatory framework for the placing on the market, free movement and putting into service in the Community of radio equipment and telecommunications terminal equipment.

#### *3.4.1.1 Products covered*

The Directive applies to radio equipment (equipment that communicates by means of emission/reception of radio waves) and telecommunication terminal equipment (i.e. products which are intended to be connected directly/indirectly to interfaces of public telecommunication networks).

Products covered by the Directive are all products using the radio frequency spectrum, e.g. car door openers, mobile communications equipment like cellular telephones, CB radio, broadcast transmitters, etc. and all equipment attached to public telecommunications networks, e.g. ADSL modems, telephones, telephone switches.

#### 3.4.1.2 *Requirements related to health aspects*

According to the Directive, some essential requirements covering “protection and health and the safety of the users” as well as the safety requirements as mentioned in the above Low Voltage Directive are applicable to all apparatus. Only this rather vague statement of “protection and health and safety of the users” is mentioned in the Directive. No other requirements/statements related to health aspects or chemicals are mentioned.

Apparatus complying with all relevant essential requirements shall bear the EC conformity marking.

#### 3.4.1.3 *Associated harmonized standards*

As of January 2011, several hundred harmonized standards are associated with this Directive. The titles of these have been scanned in order to search for standards that could contain requirements concerning health risks associated with a content/release of chemicals.

- Most of the standards deal with electromagnetic compatibility and radio spectrum matters, i.e. no requirements concerning content or release of chemicals.
- Some of the associated harmonized standards concern human exposure to electromagnetic fields from e.g. mobile phones. However, as this is not a chemical exposure, this aspect is not described further in this report.
- Other standards only deal with “safety requirements”, i.e. not chemical hazards and are therefore not described further in this report.

#### 3.4.1.4 *Comitology procedure*

Chapter IV of the Directive uses a regulatory committee procedure for adopting design requirements e.g. to ensure that the equipment interworks via networks with other apparatus, that it functions properly, that personal data and privacy of the user are protected, that fraud is prevented, that emergency services are accessible, and that they can be used by persons with disabilities. An advisory committee procedure is foreseen among others for standards related matters (e.g. withdrawal of references to harmonised standards in the Official Journal). However, the comitology does not allow for the establishment of regulatory health and safety related requirements including chemical requirements.

### **3.4.2 Discussion of the Directive**

#### *No specific chemical requirements in either Directive or standards*

As described this Directive on radio equipment and telecommunication terminal equipment does not contain any chemical requirements. Only the protection of health and safety of the user is mentioned in the Directive. When looking at the harmonized standards it seems that the picture is the same for the harmonized standards – they cover aspects like electromagnetic compatibility, human exposure to electromagnetic fields, and general safety requirements, but no specific chemical requirements.

#### *No comitology to change essential requirements*

A committee procedure (comitology) is in place to change the Directive, but there is no comitology in place to allow for the establishment of specific requirements including chemical limits. This means that new chemical requirements cannot be adopted quickly. This can only be done by amending the Directive, which is a

comprehensive and time-consuming process. However, chemical requirements could be set by changing the standards (by adding chemical requirements to the standards).

*Radio and telecommunication products are covered by the RoHS Directive*

This means that this Directive on radio equipment and telecommunication terminal equipment and its associated standards do not protect the consumers from the chemical hazards that may be present in this type of products. However, the RoHS Directive (2002/95/EC) as described in the former project by FORCE Technology (2010) also applies for these radio and telecommunication products. This means that some heavy metals and flame retardants are restricted. See the above discussion under ‘Low Voltage Electrical Equipment Directive’.

### **3.4.3 Conclusions**

The main conclusions from the review of *Directive 1999/5/EC of 9 March 1999 on radio equipment and telecommunication terminal equipment and the mutual recognition of their conformity* are:

- Some health aspects of the users (consumers) are addressed, such as human exposure to electromagnetic fields, but there are no specific chemical restrictions (in terms of identification of the restricted chemicals or concentration-levels). Only vague phrases like “protection of health” are applied.
- A comitology procedure is in place to establish requirements related to e.g. interoperability, functioning of networks or data protection, but does not allow for establishing specific chemical requirements. This can only be done by amending the Directive. Chemical requirements could in theory be set in the harmonised standards, but this seems a more theoretical option as the regulation obviously focuses on other protection goals.
- I.e. the Directive and the standards do not protect the consumers from the risks related to dangerous substances that may be present in radio and telecommunication equipment. But the RoHS Directive that also applies for these types of products does that to some extent.

## **3.5 Medical devices: General**

### **3.5.1 Description of the Directive**

*Directive 93/42/EEC of 14 June 1993 concerning medical devices* is a New Approach Directive. The version reviewed is the consolidated version, latest amended in September 2007.

#### *3.5.1.1 Products covered*

The Directive applies to medical devices and their accessories. A medical device means any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, ... with the purpose of diagnosis, prevention, monitoring, treatment, or alleviation of disease in humans. Medical devices used for investigation, control of conception, replacement or modification of the anatomy or of a physiological process are (among other things) also covered. For further details, see the Directive.

Examples of products not covered by this Directive comprise cosmetic products covered by Directive 76/768/EEC, active implantable devices covered by Directive 90/385/EEC and in vitro diagnostic devices.

### 3.5.1.2 *Requirements related to health aspects*

The overall regulation states that the devices shall meet the essential requirements set out in Annex I of the Directive. Below, the essential requirements (of Annex I) concerning or resembling chemical requirements are presented.

The main general essential requirement (section 1 in Annex I) is that “The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety”.

More specific essential requirements regarding/resembling chemical restrictions or consumer health comprise:

1. Clinical test: Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X, thus meaning that the evaluation of for instance the side-effects and of the acceptability of the benefit/risk ratio must be based on a clinical test. The clinical evaluation can be based on existing scientific literature or on results of clinical investigations.
2. Chemical, physical and biological properties: The devices must be manufactured so as to guarantee the characteristics mentioned in section 1 – particular attention must be paid to the “choice of materials used, particularly as regards toxicity and where appropriate, flammability” as well as “compatibility between the materials used and biological tissue..” and where appropriate, the “results of biophysical or modeling research..”. Furthermore, the “devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (...), particular attention must be paid to the tissues exposed and to the duration and frequency of exposure”. Further, the “devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during normal use..”. 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, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC (Classification and labeling, related to REACH – the Directive is replaced by Regulation 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP regulation))”.
3. Requirements (added in September 2007) regarding phthalates  
“If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on

the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates”.

4. The remaining essential requirements concern elements like radiation, protection against mechanical, thermal and electrical risks, flow rates, instructions for use (extensive), etc.

The remaining requirements/articles concern elements like:

- Free movements, CE marking
- Reference to standards (how the Member States shall presume compliance)
- Committee on Standards and Technical Regulations
- Safeguards clause
- Classification of the devices
- Notified bodies

It should be noted that some specific devices (machinery covered by article 2(a) of 2006/42/EC) must meet essential health and safety requirements in Annex I of Directive 2006/42/EC if those requirements are more specific than those in this Directive. There are other deviations like this.

#### 3.5.1.3 *Associated harmonized standards*

Compliance with the essential requirements is assumed if the products are in conformity with relevant national standards adopted pursuant to the harmonized standards. Additionally, this Directive also refers to monographs of the European Pharmacopoeia (on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products) if they have been published in the Official Journal of the European Communities.

As of December 2010 there are approximately 400 harmonized standards associated with this Directive. The titles of these have been scanned and a few of the most relevant (in terms of health risks associated with a content/release of chemicals) are reviewed below:

- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances.
- EN ISO 10993-07:2008 Biological evaluation of medical devices - Ethylene oxide sterilization residuals.
- EN ISO 10993-10:2010 Biological evaluation of medical devices - Tests for irritation and skin sensitization.
- EN ISO 10993-3:2009 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- EN ISO 14607:2009 Non-active surgical implants - Mammary implants.
- EN ISO 4074:2002 Natural latex rubber condoms - Requirements and test methods.

#### EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: *Evaluation and testing within a risk management process*

This is the basic standard of the EN ISO 10993 series. The main elements are:

- *General principles* for biological evaluation. The evaluation shall include:
  - Physical and chemical characteristics of the materials
  - Any history of clinical use or human exposure data

- Any existing toxicology and other biological safety data on product and component materials, breakdown products, and metabolites
- Test procedures
- *Material characterization*: “the extent of chemical characterization depends on what pre-clinical and clinical safety and toxicological data exists and on the nature and duration of body contact. Must as a minimum address the constituent chemicals of the device and possible residual process aids/additives used in manufacture”. And further “the identity and quantity of novel materials and chemicals present should be established or measured”. Refer to ISO 10993-18.
- *Test methods*: the standard guides on which test methods should be used - and what elements that should be taken into account.

*EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)*

Establishment of tolerable intake (TI) doses by:

- Collecting toxicity data from the literature.
- Add modifying factor approach for noncancer endpoints. The modifying factor takes into account the type, amount and quality of data evaluated, the severity of the hazard identified, the uncertainty inherent in the risk assessment, and the level of safety assurance deemed appropriate, etc.
- Data from multiple routes of exposure (oral, dermal, parenteral, inhalation) shall be evaluated.
- TI value is calculated differently according to whether it is related to a specific device or to all devices (permanent-contact TI).
- If a device belongs to several categories, the TI shall be calculated according to the more rigorous category.
- Data necessary for evaluating a leachable substance comprise: Chemical/physical properties, occurrence and use, pharmacology, toxicokinetics (absorption, distribution, metabolism and elimination), toxicology, effects in humans.
- Etc.

All in all it seems like the procedure of calculating the allowable limits for leachable substances is rather thorough. The typical approach and the elements applied are similar to the more conventional risk assessment procedures (however, an in-depth investigation and discussion of the method is outside the scope of this study). Though, it seems like no consideration towards cocktail-effects is included in the calculation of allowable limits for leachable substances. Also, no requirements of ban of certain leachable substances are included.

However, by using a risk assessment approach the user is given many choices and the approach requires that industry/companies are capable of performing risk assessment correctly. Furthermore, this approach gives industry a big room for manoeuvres and makes enforcement very difficult or virtually impossible. An authority can ask a manufacturer to present a risk assessment file but it would be very difficult to challenge any conclusion unless the authority conducts a risk assessment itself. Enforcement would be much easier, if limits for specific chemicals were set. Then it would simply be a question about comparing legal limit values/migration limit values with the analysed values.

EN ISO 10993-07 Biological evaluation of medical devices - Ethylene oxide sterilization residuals.

The standard includes:

- *Permanent contact devices*: The standard sets limits for daily dose of ethylene oxide<sup>5</sup> (EO) to patients. The limit must not exceed 0.1 mg/day – further the maximum EO dose shall not exceed 4 mg in the first 24 h, 60 mg in the first 30 d, and 2.5 g in a lifetime. Likewise ethylene chlorohydrin (ECH) must not exceed 0.4 mg/day – and maximum ECH dose must not exceed 9 mg in the first 24 h, 60 mg in the first 30 d and 10 g in a lifetime.
- For *prolonged exposure devices* and *limited exposure devices* the limits are adjusted.
- Other limits apply for *tolerable surface contacting devices* and implants. An example being the tolerable contact limit for ethylene oxide, which must not exceed 10 ug/cm<sup>2</sup>.
- And for *multi-device systems* the limits shall apply to each individual patient-contact device.
- Also requirements such as for instance “residue of ethylene oxide in intraocular lenses shall not exceed 0.5 µg/EO per lens per day are included (as well as many other related to ‘special situations’).

The interesting element here is the fact that limits *are* set (in various ways) for the problematic carcinogenic substance ethylene oxide. It is not within the scope of this study to evaluate whether the limits of EO and ECH are set at a reasonable level. However, it must be noted that it does not seem that potential cocktail and/or additive effects have been considered in establishing the limits for ethylene oxide which could mean that the daily dose could be exceeded if other ways of exposure exist. Furthermore, there is of course the discussion of the need for using a carcinogenic substance for sterilisation, if safer sterilisation alternatives exist (this has, however, not been investigated further). Finally, it is questionable how the maximum EO dose of 2.5 g in a lifetime can be verified.

EN ISO 10993-10 Biological evaluation of medical devices - Tests for irritation and skin sensitization

The standard includes:

- *General principles* and pre-test considerations:
  - “It shall be taken into consideration that, during manufacture and assembly of medical devices, additional chemical components may be used as processing aids, e.g. lubricants or mould-release agents”. In addition to the chemical components of the starting material and manufacturing process aids, adhesive/solvent residues from assembly and also sterilant residues or reaction products resulting from the sterilization process may be present in a finished product ... These components shall be taken into account for their potential irritation/sensitization activity”.
  - Guidance on typical problems related to different materials (for instance, polymers are chemically more complex, and a number of reaction products/impurities/additives may be present)
  - Test for biologically derived materials does not account for cross-species sensitization.

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<sup>5</sup> Ethylene oxide is a flammable gas that is irritating to body surfaces and highly reactive. It is mutagenic under many conditions, has fetotoxic and teratogenic properties, can adversely effect testicular function and can produce injury to many organ systems in the body.

- Full qualitative data on the chemical constituents of the material shall be established. Quantitative only where relevant to biological safety.
- *Irritation tests and skin sensitization test*
  - Mainly guidance in choice of method.

The standard provides a framework for which tests to use and to give further specific guidance on how to perform the tests (and evaluate the results). It seems reasonable that medical devices which comply with this standard are safe from causing skin irritation or sensitization (however, an in-depth investigation of this aspect is outside the scope of this study). For instance, it is stated that it must be taken into consideration (during the evaluation of the irritating and sensitization evaluation of the device), that during manufacture and assembly of medical devices, additional chemical components may be used as processing aids.

EN ISO 10993-3:2009 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

The standard includes:

- Before testing the medical device for causing genotoxicity, carcinogenicity, and reproductive toxicity, the ISO standard 10993-1 (evaluation and testing) and ISO 10993-18 (chemical characterization) must be taken into account. Specifically applies:
  - *Genotoxicity tests:* Testing for genotoxicity is not necessary for medical devices made only from materials known to show no genotoxicity. However, testing for genotoxicity is indicated where a review of the composition of the materials reveals the possible presence in the device of compounds that might interact with genetic material – or when the chemical composition of the medical device is unknown. In the latter case, the genotoxic potential of suspect chemical components should be assessed bearing in mind the potential for synergy, in preference to carrying out genotoxicity tests on the device as a whole.
  - *Carcinogenicity tests:* The decision to perform tests shall be justified on the basis of an assessment of the risk of carcinogenesis arising from the use of the medical device. Carcinogenicity testing shall not be performed when risks can be adequately assessed or managed without generating new carcinogenicity test data.
  - *Reproductive and developmental toxicity tests:* The decision to perform tests shall be justified on the basis of an assessment of the risk of carcinogenesis arising from the use of the medical device. There is no need for the reproductive toxicity testing of resorbable medical devices or medical devices containing leachable substances if there is adequate and reassuring data from absorption, metabolism, and distribution studies.
  - *The standard then describes which test strategy, test methods (OECD tests) etc. to apply.*

It is beyond the scope of this project to evaluate whether the suggested methods for testing for carcinogenicity, mutagenicity, and reproductive toxicity respectively ensure that no consumers can be exposed to such risks by using the medical devices. However, it must be noted that use of the risk assessment approach has not eliminated the use of phthalates in medical products even though they are considered to be toxic to reproduction (endocrine disruptors).

EN ISO 14607:2009 regarding non-active surgical implants – *Mammary implants.*

- *Material requirements* refer to the requirements of ISO 14630 clause 6 which states that “materials shall be selected with regard to the properties required for the intended purpose, also taking into account the effects of manufacture, handling, sterilization, and storage, as well as any treatment (chemical, electro-chemical, thermal, mechanical, etc.) applied to the surface or a part of the surface of the implant material. Possible reactions with human tissues must be taken into account. Effects caused by radiation, magnetic, and electromagnetic fields must also be considered. The acceptable compatibility with biological tissue must be documented in accordance with ISO 10993-1 or by selection from the materials found suitable by clinical use in similar applications.
- *Any residual effects* or undesirable side-effects shall constitute acceptable risks when weighted against the benefits to the patient, taking into account the fact that their benefit is primarily aesthetic and psychological in nature.
- *Pre-clinical evaluation* according to ISO 14630 clause 7.2. Test methods and related limits for specific types of implants shall be defined and justified by the manufacturer.
- *Biological evaluation*: The local and systemic toxicity of *any substance* introduced into the body by mammary implants shall be assessed”. The assessment shall be based on chemical characterization and toxicokinetics of the materials, available scientific data addressing toxicological hazards and risks and, where necessary, specific testing.
- A number of requirements concern *strength, impact resistance, fatigue resistance, etc.* However, no direct chemical restrictions are included.
- An analysis of *extractable or releasable chemicals* (especially the characterization and quantification of materials of low molecular mass) is necessary to assess the safety of the device.
- A detailed chemical characterization of the *filler material* shall be established.
- *Release test* is required. However, no validated test method is currently available. For implants with a silicone shell and silicone filling, it is not clear which proportion of the release comes from the shell or the filler material respectively. The test methods and requirements are under consideration.

There are no specific chemical requirements in the form of a ban of the use of certain hazardous substances which could seem strange since breast implants have a high degree of ‘contact area’ and furthermore are in ‘contact’ with the body for a long time. However, the standard dictates ‘clinical evaluation’ and ‘biological evaluation’ procedures which in essence require that “the local and systemic toxicity of *any substance* introduced into the body by mammary implants shall be assessed”. The assessment shall be based on chemical characterization and toxicokinetics of the materials, available scientific data addressing toxicological hazards and risks and, where necessary, specific testing. If this is performed correctly, the choice of not including a specific ban on use of certain chemicals seems reasonable. However, this is based on the assumption that the ‘acceptable risk of benefits versus risks’ is not judged wrongly.

The history of breast implants for women clearly proves that this ‘acceptable risk versus benefits’ previously can be (and was) set too high (even though probably not regulated at that time), since an alarming number of women experienced severe problems with their implants. Whether these standards now secure that this will not happen again cannot be said with certainty.

EN ISO 4074:2002 Natural *latex rubber condoms* - Requirements and test methods

- Requirements primarily concern elements like width, thickness, length, burst volume, and pressure.
- The condom and any lubricant, additive, dressing, individual packaging material, or powder applied to it should neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating, or otherwise harmful under normal conditions of storage or use.
- Reference should be made to ISO 10993 for test methods to evaluate the safety of condoms particularly in respect of the risk of local irritation and sensitization.

Even though there are no specific chemical requirements, the condoms must refer to ISO 10993 for test methods to evaluate the safety and these test methods etc. are relatively thorough (see previously).

#### 3.5.1.4 *Comitology procedures*

There are comitology procedures in place to alter standards. However, there is no comitology in place to allow for the establishment of specific requirements including chemical limits.

However, an interesting further element included to assist market surveillance is article 14a which introduces the ‘European databank’ that gives the competent authorities access to relevant data. The databank includes, among other things, the following information: Data relating to certificates issued, modified, supplemented, suspended, withdrawn, or refused according to the procedures laid down in Annexes II to VII (quality assurance system, EC type examination, EC verification, production quality assurance, product quality assurance, EC declaration of conformity). The Commission shall no later than 11 October 2012 evaluate the operational functioning and added value of the databank, and if appropriate, present proposals to the Parliament and the Council.

As an extra ‘feature’ in this Directive (related to amendment of the Directive), the Commission shall (no later than 10 September 2010) submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit any additional proposals it may deem appropriate in order to ensure a high level of health protection.

### **3.5.2 Discussion of the Directive**

#### *Use and meaning of the word ‘minimize’*

The word ‘minimize’ is often used throughout the Directive (as for instance in the requirement “... to minimize the risk posed by contaminants...”). However, the precise meaning of the word is never explained thoroughly. As the precise definition (or level) of ‘minimizing’ is not elaborated, thus it must be difficult for the manufacturers to know when they have ‘minimized’ the risk sufficiently. Of course, a solution could be (as mentioned before) to perform classical exposure and risk assessments (according to REACH guidelines), but this requires information (LC<sub>50</sub> values etc.) and skills which may not be present in the companies. Since the Directives only use vague requirements like “must not compromise safety”, this means that it is up to the industry and standard bodies to establish acceptable limits (and other specific chemical requirements). Yet, the industry may have a tendency to weaken the requirements due to competitiveness issues.

*The Medical Directive does include more specific phrases towards toxicity – further elaborated in standards*

The Medical Device Directive makes use of a more specific phrase than the (also used) general phrase of “must not compromise safety” – namely the phrase “particular attention must be paid to the choice of materials used, particularly as regards toxicity”. In this case the associated standards do in fact elaborate on the toxicity aspect, but mainly in terms of defining risk assessment procedures and not so much in terms of setting limit values for chemicals. This could support the idea of specifying the phrases used in the Directive more in the direction of including considerations ‘towards toxicity’.

*Accepted balance between risks and benefits*

An element, which distinguishes this Directive from many other Directives, is the acceptance of a ‘balance’ between risks and benefits for the patient. It is understandable that this aspect is introduced in legislation regarding medical devices since it can be generally assumed that a person would prefer to be exposed to a small amount of toxic substances if it means that his leg will be functional again (implementation of an implant combined with immune-depressing substances, for instance). How to establish this ‘balance’ or ‘acceptable’ risk is, however, unclear and must be difficult since one has to assume that the level of ‘acceptable’ risk differs from person to person. The acceptance of this ‘balance’ can also be seen as an argument for the industry not to reduce or eliminate substances. It is very difficult to balance benefits and risks as both are not easy to quantify, thus in practice it is a *carte blanche* to accept high levels of chemicals. The possibility of using substitute products without dangerous substances where available is not required to be considered. Even though the Directive states that the acceptable risks must still be compatible with a high level of protection of health and safety, this ‘high level’ is not defined further. History does provide examples of cases where this ‘balance’ was not properly set (or not set at all at the time) – as in the case of the massive problems related to breast implants, which caused a large number of women to suffer health effects.

*Use of a risk assessment approach instead of limit values*

A problem with the risk assessment approach is that it gives the user many choices and requires that industry/companies are capable of performing risk assessment correctly. Furthermore, this approach gives industry a big room for manoeuvres and makes enforcement very difficult or virtually impossible. An authority can ask a manufacturer to present a risk assessment file but it would be very difficult to challenge any conclusion unless the authority conducts a risk assessment itself. Enforcement would be much easier, if limits for specific chemicals were set. Then it would simply be a question about comparing legal limit values/migration limit values with the analysed values.

*Content of phthalates must be described on the label*

The adding (in September 2007) of the requirement regarding phthalates seems to be a slight improvement. However, the requirement only calls for the manufacture to state on the label of the device that the device contains phthalates (and only phthalates that are classified as carcinogenic, mutagenic, or toxic to reproduction, of category 1 or 2). A requirement related only to labeling does not ensure that the consumers are not exposed to health risks from phthalates. A requirement in the form of a ban of use of phthalates seems more reasonable.

The fact that phthalates are still used in medical devices shows that use of the risk assessment approach has not eliminated the use of phthalates in this area even

though they are considered to be toxic to reproduction (endocrine disruptors). Use of a risk assessment method is therefore not enough to ensure that toxic substances are not used in medical devices. In this case, only a ban (or limit value) of use of phthalates would ensure that these problematic substances are not used in the future.

*No consideration of cocktail effects seems to be included in the various standards*

None of the standards (whether they concern allowable limits for leachables, test methods for genotoxicity, breast implants, condoms) seem to include considerations towards cocktail effects – perhaps not strange since the concept of cocktail effects is relatively new and not yet implemented in regulations. However, as stated in the former project by FORCE Technology (2010), cocktail effects may have a critical influence on the toxic effect of some substances.

*No comitology in place to allow for establishment of specific chemical requirements*

There is comitology in place to alter standards. However, there is no comitology in place to allow for the establishment of specific requirements including chemical limits. This is a significant flaw of the Medical Device Directive, as all the requirements in the directive including the chemical risk assessment procedures in the standards have not been able to eliminate phthalates from medical devices (are e.g. still used in blood hoses and bags).

It could be assumed that the upcoming authorisation process for certain phthalates would change this. However, REACH actually specifies (in article 60 Authorisation) that “The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 ... relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC ... of 27 October 1998 on in vitro diagnostic medical devices”. This actually means that it is assumed in REACH that the phthalates are properly regulated under the medical devices directives and therefore specifies that the risks to human health should not be taken into concern under REACH authorisation.

*The Databank*

A further interesting element in this Directive is its introduction of a databank. The databank contains information related to medical devices which are certified or for instance withdrawn from the market. All authorities have access to the databank which makes it easier for the authorities to perform market surveillance. The Commission shall no later than 11 October 2012 evaluate the operational functioning and added value of the databank, and if appropriate, present proposals to the Parliament and the Council. It would be interesting to read this evaluation and see if such a databank in reality improves the market surveillance. If so, the concept of an accessible databank may be relevant to implement in other product Directives.

*In general the review of the standards revealed:*

- There are requirements of identifying and quantifying the materials and chemicals used.
- Relatively thorough guidelines on when to use test methods, which test methods to use, and how to respond to results are included.
- A risk assessment method is generally applied instead of using limit values. This gives industry a big room for manoeuvre and makes enforcement very difficult. The fact that phthalates are still used in medical devices shows that

use of the risk assessment approach is not useful in eliminating problematic substances.

- No considerations towards cocktail effects seem to be included in the standards. However, one standard (regarding test for genotoxicity, carcinogenicity, and reproductive toxicity) does mention that the potential for synergy should be taken into consideration.
- Generally no ban of any dangerous substances (except for the standard regarding ethylene oxide residues).
- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.

### **3.5.3 Conclusions**

The main conclusions from the review of *Directive 93/42/EEC of 14 June 1993 concerning medical devices* are:

- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.
- The Directive makes use of several ‘weak phrases’ like “must not compromise health” which in reality means that it is up to the industry and standard bodies to establish acceptable limits (and other specific chemical requirements). This is troublesome since the industry tends to weaken the demands and as there is no comitology in place to allow for the establishment of specific requirements including chemical limits.
- An interesting element of an acceptable balance between risks and benefits for the patient is introduced in the Directive. Understandable in view of the type of products regulated (medical devices). Yet, it is very difficult to establish this balance (i.e. the troublesome case of health problems related to breast implants), thus in practice this can be seen as a carte blanche to accept high levels of chemicals. The possibility of using substitute products without dangerous substances where available is not required to be considered.
- A new requirement related to phthalates was introduced in the Directive in 2007. However, the requirement only calls for the manufacturer to state on the label of the device that the device contains phthalates. The fact that phthalates are still used in medical devices shows that use of a risk assessment method is not enough to ensure that toxic substances are not used in medical devices. A requirement in the form of a ban of use of phthalates seems more reasonable.
- Neither the Directive nor the associated standards seem to take cocktail effects into consideration when setting limits or describing methods to set limits.
- The standards generally do not ban the use of any dangerous substances (except for the standard regarding ethylene oxide residues).

## 3.6 Packaging and packaging waste

### 3.6.1 Description of the Directive

*Directive 94/62/EC of 20 December 1994 on packaging and packaging waste* is a New Approach Directive. The latest amendments to the Directive have been made in 2009.

The Directive lays down measures aimed at

1. preventing the production of packaging waste, and
2. reusing packaging, recycling, and other forms of recovering packaging waste and, hence, at reducing the final disposal of such waste.

The Directive sets targets for recovery and recycling of packaging waste (e.g. that by 31 December 2008 the recycling target for glass is 60% and 50% for metals). Member States must ensure systems that provide for return/collection of used packaging/packaging waste, reuse, recovery, or recycling in order to be able to meet the set targets.

#### 3.6.1.1 Products covered

The packaging Directive covers all packaging placed on the market in the EU and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household, or any other level, regardless of the material used.

Packaging is defined as “all products made of any materials of any nature to be used for the containment, protection, handling, delivery, and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer”. Packaging waste is defined as “any packaging or packaging material covered by the definition of waste in the waste Directive” (i.e. Directive 2008/98/EC).

Examples of packaging are: film overwrap around a CD case, sweet boxes, and disposable plates and cups (but only if intended to be filled at the point of sale). Tea bags, sausage skins, and wax layers around cheese are example of items considered as non-packaging.

#### 3.6.1.2 Requirements related to health aspects

The following aspects related to health have been identified in the packaging Directive.

##### *Essential requirements*

According to the Directive (article 9) packaging may only be placed on the market if it complies with all the essential requirements as listed in Annex II. Compliance with all the essential requirements is presumed if the packaging complies with relevant harmonized standards.

The Commission shall (as appropriate) present proposals for measures to strengthen and complement the enforcement of the essential requirements (article 4).

The essential requirements (annex II) cover issues as listed below. Only issues related to chemicals and health aspects are listed:

- **Requirements specific to the manufacturing and composition of packaging**, such as:

- Packaging shall be designed, produced, and commercialized in such a way as to permit its reuse or recovery, including recycling, and to minimize its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of.
- 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.
- **Requirements specific to the reusable nature of packaging**, such as:
  - Possibility of processing the used packaging in order to meet health and safety requirements for the workforce.
- **Requirements specific to the recoverable nature of packaging:**
  - No requirements related to chemicals or health aspects.

*Presence of heavy metals and other dangerous substances*

According to article 10 of the Directive it is stated that the Commission shall promote standards relating to methods for measuring and verifying *the presence of heavy metals and other dangerous substances in the packaging* and their release into the environment from packaging and packaging waste.

The Directive sets direct requirements for the concentration levels of heavy metals present in packaging or packaging component (article 11):

- The sum of concentration levels of lead, cadmium, mercury, and hexavalent chromium present shall not exceed 100 ppm by weight (i.e. 0.01%).

The Commission determines under which conditions this concentration level does not apply to recycled materials and to product loops which are in a closed and controlled chain.

*3.6.1.3 Associated harmonized standards*

In total six standards are associated with this Directive (as of January 2011).

According to the packaging Directive (article 4), the standards shall aim at minimizing the environmental impact of packaging in accordance with the essential requirements described in the Directive (article 9 and 10). The six standards are:

- EN 13427:2004. Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste.
- EN 13428:2004. Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction.
- EN 13429:2004. Packaging – Reuse.
- EN 13430:2004. Packaging - Requirements for packaging recoverable by material recycling.
- EN 13431:2004. Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value.
- EN 13432:2000. Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging.

Furthermore, the following (technical) reports apply:

- **CR 13695-1:2000**. Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging.
- **CEN/TR 13695-2:2004**. Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 2: Requirements for measuring and verifying dangerous substances present in packaging and their release into the environment.

The standards marked in bold and underlined mostly concern manufacturing and composition and are therefore the most relevant standards/reports with respect to chemicals and health aspects.

The standards have been scanned in order to search for requirements concerning health risks associated with a content/release of chemicals. The requirements that are related to health and chemicals are described in more details below for each relevant standard/report:

*EN 13427 – Requirements for the use of the packaging standards*

It is stated that the assessment of environmental impact from the four heavy metals in packaging after incineration or landfilling is addressed in CR 13695-1. It is furthermore stated in this standard as a requirement that the supplier shall ensure that due consideration is given to the limiting and if appropriate the further reduction of levels of heavy metals based on the proposal in clause 8.2.3 of CR 13695-1:2000, or for any dangerous substances or preparations as specified in EN 13428 and CR 13695-2:2000.

*EN 13428 – Requirements specific to manufacturing and composition - Prevention by source reduction*

This standard describes the methodology and procedure for determining the presence of the four heavy metals and for determining the presence and minimization of any dangerous substances or preparations if they are present in packaging and are likely to be released into the environment as a result of waste management operations. The procedures are referenced in CR 13695-1 and CEN/TR 13695-2.

The requirements of chemical character in this standard are:

- The supplier shall (clause 4.2.3) determine with the use of relevant safety data sheets if there is a presence of dangerous substances or preparations:
  - Classified with the symbol 'N' and if
  - They are likely to be present in emissions, ash or leachate when packaging residues from management operations or packaging waste are incinerated or landfilled.
- The supplier shall (clause 4.2.1) be able to demonstrate that the substances or preparations classified as dangerous to the environment and assigned with the symbol 'N' present in the packaging components have been minimized (if they are likely to be present in emissions, ash or leachate when packaging residues from management operations or packaging waste are incinerated or landfilled). Using the minimum adequate amount of a substance has to be established in relation to the functional performance or purpose of the substance. The process of how minimization is achieved must be documented (clause 4.3.2).

- The supplier shall (clause 4.2.1) be able to demonstrate that the presence of the four named heavy metals (lead, cadmium, mercury, and hexavalent chromium) in the packaging components does not exceed the specified limits. Must be measured, calculated, or via upstream information (clause 4.2.4).

*EN 13429 – Reuse of packaging*

Only one requirement regarding health is addressed in a rather vague statement and this requirement only covers health aspects related to the workers filling/packing the packaging. According to clause 5.2 (d) “the packer/filler shall for each of the packaging types he places on the market ... establish and record that the packaging can be reconditioned... (cleaned, washed, and repaired)... whilst maintaining its ability to perform its intended function and without risk to the health and safety of those responsible for doing so”.

*EN 13430 – Requirements for packaging recoverable by material recycling*

This standard states (clause B.4.1) that the safety, hygiene, and consumer needs of the packaging must be met. There is no reference to chemicals or health issues in the standard – only indirectly as releases to the environment caused by the used packaging and/or product residues in the recycling process must be taken into account (clause A.4).

*EN 13431 - Requirements for packaging recoverable in the form of energy recovery*

Not relevant as it contains no chemical requirements or requirements related to health.

*EN 13432 - Requirements for packaging recoverable through composting and biodegradation*

This standard specifies requirements and procedures to determine the compostability and anaerobic treatability of packaging and packaging materials. The standard establishes limits for the following heavy metals and other hazardous elements (the limit value in mg/kg on dry substances is listed in brackets: Zn (150), F (100), Cu, Cr and Pb (50), Ni (25), As (5), Mo (1), Se (0.75), Cd and Hg (0.5). No other chemical limit values are set. However, the standard requires that the packaging material is biodegradable to a certain extent (exact defined in the standard).

*CR 13695-1 – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging.*

This is not a standard but a CEN report that is referred to in the standards (e.g. in EN 13428). It describes how compliance with the Directive can be accomplished (sum of heavy metals below 100 ppm) by either testing (measurements) or calculations by use of upstream information, and how the testing should be carried out (description of test methods for different materials). The report furthermore gives an interpretation of how the requirement should be enforced. No additional chemical requirements are listed.

*CEN/TR 13695-2 – Part 2: Requirements for measuring and verifying dangerous substances present in packaging and their release into the environment.*

This is not a standard but a technical report that is referred to in the standards (e.g. in EN 13428). It describes more detailed how dangerous substances (classified with the symbol ‘N’) should be identified and minimized in packaging if they are present in emissions, ash, or leachate when packaging or packaging waste is incinerated or landfilled. No additional chemical requirements are listed.

#### 3.6.1.4 Comitology procedure

Article 21 of the Directive describes the Committee procedure for adapting certain aspects of the Directive (such as exemptions from the heavy metals requirements). However, the comitology procedure is not intended to change existing limits for metals or to introduce new restrictions.

### 3.6.2 Discussion of the Directive

#### *Limits set for four heavy metals*

It is positive that the packaging Directive does contain some chemical requirements. The limit levels set for the sum of the four heavy metals will ensure that heavy metals exposure to consumers is kept as a minimum (e.g. migration to human sweat by skin contact), but also that the total load of heavy metals entering our environment after incineration or landfilling is kept at a minimum – and thereby the indirect exposure of heavy metals from the environment to consumers is minimized.

#### *Limit value for metals may be reasonable*

The limit value set for the heavy metals (100 ppm (0.01%) as a sum of the four heavy metals) is rather low. It can always be discussed whether the limit value should be lowered in order to take into account exposures from other sources etc. However, as some level of impurity always has to be expected for the four heavy metals, it may be difficult to lower the limit value drastically. On the other hand, there are discussions at the moment about limit values of close to 0 ppm for lead as even a small amount of lead is considered too much (when considering the toxicity of lead and the general background lead exposure of consumers today).

#### *Positive that limits apply to all components of the packaging*

It is positive that the limit value set for the four heavy metals applies for all packaging components, meaning that i.e. the label, the paper, the film etc. of the packaging product all individually has to comply with the limit value for the four heavy metals. In this way there is no single component with a higher content of heavy metals.

#### *Lack of definition for 'minimizing'/Procedures for subst. dangerous for the env.*

In the Directive as well as the standards, a phrase such as 'dangerous chemicals must be minimized' is used. The exact meaning of minimizing is not all clear but in a standard it is described as "the minimum adequate amount of a substance has to be established in relation to the functional performance or purpose of the substance". As there is a lack of definition of what 'minimizing' means or how to show it in practice, it must be difficult for the manufactures to know when they have 'minimized' the risk or content sufficiently. Of course, a solution could be to perform a classical exposure and risk assessment but this requires specific information (e.g. LC<sub>50</sub>-values etc.) and skills which may not be present in many companies. Actually, the required data for performing risk assessments may not be present at all as the knowledge of the toxicity of all chemical substances is limited (at present). Furthermore, as discussed earlier (under the Medical Devices Directive), a risk assessment approach gives industry a big room for manoeuvres and makes enforcement very difficult or virtually impossible.

If the wording in the Directive is compared with the wording in the standard (EN 13428, 2004), it can be seen that the standard narrows the provision of the Directive considerably. The Directive talks about minimization of hazardous substances whereas the standard restricts this to just one class of dangerous substances –

substances classified as dangerous for the environment (the symbol 'N'). The associated standard (EN 13428, 2004) of the packaging Directive also addresses other dangerous substances but only if they are classified as dangerous for the environment (classified with the symbol 'N') – and only if the dangerous substances are present in emissions, air, or leachate when packaging waste is incinerated or landfilled. This means for example that toxic substances that would evaporate from the packaging material in a home of a consumer or toxic substances that migrate through human skin at skin contact with the packaging material are not limited. Therefore, the consumer is not protected against risk of dangerous substances (e.g. CMR substances) in the packaging material (except for the specifically mentioned heavy metals). Clear-cut limits are missing even for substances classified dangerous for the environment which can be released, the manufacturer just needs to “document that only the minimum adequate amount has been used of substances thus identified with regard to their functional purpose”. So essentially, minimization just means to use not more of a substance than what is needed to achieve the desired functionality (which is normally done for commercial reasons anyway).

This aspect of minimization has also been criticised by ANEC<sup>6</sup> and ECOS<sup>7</sup> in a position paper on the packaging standards. They state that: “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”. (ANEC-ECOS, 2005).

#### *Comitology not in place to alter metal limits*

A committee procedure (comitology) is in place to adapt certain aspects in the Directive. However, neither a change of the metal limits nor the establishment of additional restrictions is foreseen.

### **3.6.3 Conclusions**

The main conclusions from the review of *Directive 94/62/EC of 20 December 1994 on packaging and packaging waste* are:

- The packaging Directive sets limit values for four heavy metals contained in the packaging material. Other metals and elements are restricted by limit values in EN 13432.
- Other dangerous substances are also regulated but only by the very loose statement that “content must be minimized taking the functional performance or purpose of the substance into consideration”. As manufacturers in many cases will use the minimum amount for economic reasons anyway, it could therefore be argued that this justifies the continued use of dangerous substances. Actually, this means that manufactures just have to argue that they use the minimum amount of a substance needed for a certain purpose.
- In the associated standards, this minimization requirement is, however, only for substances classified as dangerous for the environment with the symbol 'N' and only if the dangerous substances are present in emissions, air, or leachate when packaging waste is incinerated or landfilled.

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<sup>6</sup> The European Consumer Voice in Standardisation ([www.anec.org](http://www.anec.org))

<sup>7</sup> European Environmental Citizens Organisation for Standardisation (<http://www.ecostandard.org/>)

- This means that toxic substances that would evaporate from the packaging material in a home of a consumer or toxic substances that migrate through human skin at skin contact with the packaging material are not limited.
- I.e. the Directive and the standards do not protect the consumers from most of the chemical hazards that may be present in packaging materials (e.g. CMR chemicals, sensitizers, etc.).
- A comitology procedure is in place but does not allow for establishing new chemical requirements or e.g. a lowering of the limit value for the four heavy metals.

## 3.7 Materials and articles intended to come into contact with food

### 3.7.1 Description of the Regulation

*Regulation No. 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food* is a regulation and not a Directive and therefore it does not fall into the New Approach/Non-New Approach Directive categories. The latest amendments to the Directive have been made in 2009.

The regulation is a framework regulation that sets up general requirements for all food contact materials. A long list of Directives on specific materials and individual substances is connected to the framework regulation

The total legislation on food contact materials fulfils two essential goals: the protection of the health of the consumer and the removal of technical barriers to trade.

#### 3.7.1.1 Products covered

The regulation applies to materials and articles, including active and intelligent food contact materials and articles which in their finished state:

- are intended to be brought into contact with food; or
- are already in contact with food and were intended for that purpose; or
- can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

Examples of products covered are packaging materials in contact with food (plastic bags, containers etc.), but also cutlery, dishes, processing machines, containers etc. Materials and articles which are in contact with water intended for human consumption are also included but it does not cover fixed public or private water supply equipment.

#### 3.7.1.2 Requirements related to health aspects

The purpose of the Regulation is to “provide the basis for securing a high level of protection of human health and the interests of the consumers” (article 1).

The Regulation contains different types of requirements:

- General requirements (article 3)

- Specific requirements for active and intelligent materials and articles<sup>8</sup> (article 4)
- Specific measures for groups of materials and articles (article 5)
- National specific measures (article 6)

*The general requirements (article 3)*

Under normal or foreseeable conditions of use, materials and articles must not transfer their constituents to food in quantities which could:

- endanger human health; or
- bring about an unacceptable change in the composition of the food; or
- bring about deterioration in the organoleptic<sup>9</sup> characteristics thereof.

*Special requirements for active and intelligent materials and articles (article 4)*

No chemical requirements are listed. The requirements deal with labelling to ensure that consumers do not accidentally eat non-edible parts.

*Specific measures for groups of materials and articles*

For the group of materials and articles listed in Annex I of the Regulation, specific measures may be adopted or amended by the Commission. The specific measures may include:

- a list of substances authorized for use in the manufacturing of materials and articles;
- list(s) of authorized substances incorporated in active or intelligent food contact materials and articles, or list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for these substances and/or the materials and articles in which they are incorporated;
- purity standards for substances referred to in (a);
- special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used;
- specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;
- an overall limit on the migration of constituents into or on to food;
- provisions aimed at protecting human health against hazards arising from oral contact with materials and articles;
- other rules to ensure compliance with Articles 3 and 4;
- basic rules for checking compliance with points (a) to (h);
- rules concerning the collection of samples and the methods of analysis to check compliance with points (a) to (h);
- specific provisions for ensuring the traceability of materials and articles including provisions regarding the duration for retention of records or provisions to allow, if necessary, for derogations from the requirements of Article 17;
- additional provisions of labelling for active and intelligent materials and articles;

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<sup>8</sup> Active and intelligent (food contact) materials and articles are defined as materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of the packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

<sup>9</sup> Organoleptic refers to any sensory properties of a product, involving taste, colour, odour, and feel (Foodprocessing-Technology.com, 2011).

- (m) provisions requiring the Commission to establish and maintain a publicly available Community Register (Register) of authorized substances, processes, materials, or articles;
- (n) specific procedural rules adapting, as necessary, the procedure referred to in Articles 8 to 12, or making it appropriate for the authorization of certain types of materials and articles and/or processes used in their manufacture, including, where necessary, a procedure for an individual authorization of a substance, process, material, or article through a decision addressed to an applicant.

The specific measures shall be adopted in accordance with the comitology procedure as described in article 23 of the Regulation.

The following specific groups of materials and articles are listed in Annex I of the Regulation. For these groups of materials and articles the above specific measures may be adopted or amended by the Commission:

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

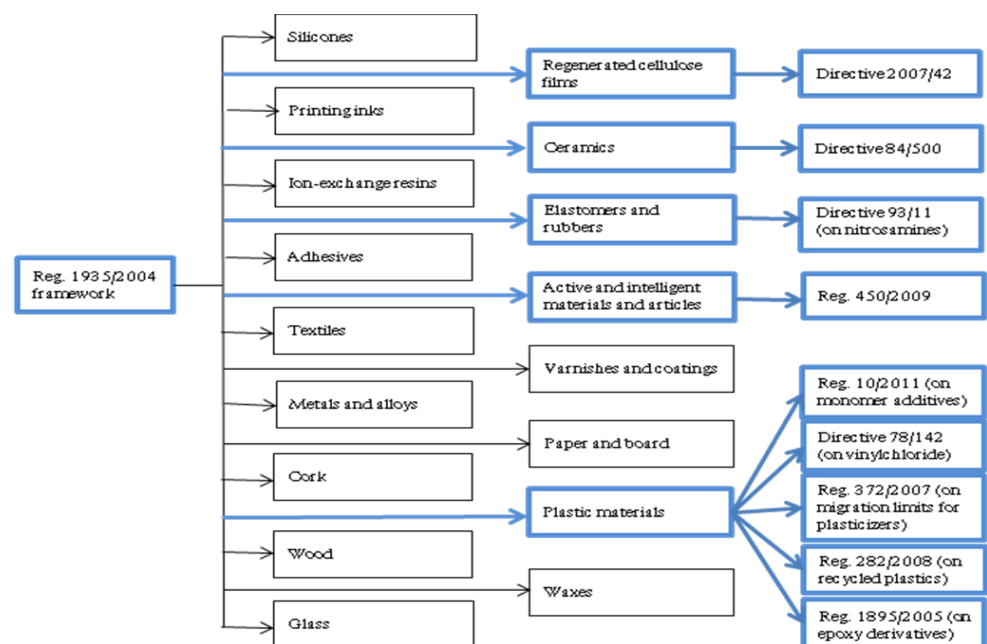


Figure 3-1 Overview of Community legislation on the food contact material area. Simplified version of the overview presented on EU Food Contact Materials webpage (DG Health and Consumers, 2011). Blue boxes represent areas where specific measures (chemical requirements) exist.

Figure 3-1 shows for which specific groups of materials and articles specific measures have been established and the groups are described in more details with respect to the chemical requirements below:

- **Regenerated cellulose film** (Directive 2007/42/EC – contains list of substances that are the only ones to be used in the manufacture of regenerated cellulose films (positive list)).
- **Ceramics** (Directive 84/500/EEC – contains requirement for the transfer of lead and cadmium. The limit depends on the type of food contact material).
- **Plastic materials**
  - monomers additives (Directive 2002/72/EC which is being replaced by Regulation 10/2011 by May 1<sup>st</sup> 2011 – contains a positive list (a so-called ‘Union list’ or list of authorised substances) of monomers, additives (excluding colorants), and other starting substances that may be used for manufacturing of plastics materials in contact with food. The Directive does also contain specific migration limits or maximum permitted quantity of the substance in the finished material for certain substances. Finally, an overall migration limit value of 60 mg/kg food for all constituents in plastics).  
The new Regulation on plastic materials intended to come into contact with food contains an interesting clause on nanomaterials: “Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex 1”.  
This means that the Regulation on plastic materials intended to come into contact with food ensures that *only* authorised substances are allowed to be used
    - *with the exception of* substances used in combination with a functional barrier,
    - *and with the exception of* some additives on a provisional list (not yet harmonised substances).
    - Certain substances (colorants, solvents) are not covered by the Regulation.
  - vinyl chloride/PVC (Directive 78/142/EEC – contains a limit value for the maximum vinyl chloride monomer level in food contact materials of 1 mg/kg).
  - migration limits for plasticizers in gasket in lids (Regulation 372/2007/EC – contains specific migration limits for seven different plasticizers from gasket in lids into food).
  - recycled plastics (Regulation 282/2008/EC – any contamination must not pose a risk to human health).
  - certain epoxy derivatives BADGE<sup>10</sup>/BFDGE<sup>11</sup>/NOGE<sup>12</sup> (Regulation 1895/2005 – contains migration limits for BADGE and non-use or non-presence of BFDGE and NOGE).
- **Elastomers and rubbers** (Directive 93/11/EEC – contains limits (migration limit and a limit for the total content) for N-nitrosamines in teats and soothers made of elastomer or rubber).

<sup>10</sup> BADGE = Bisphenol A diglycidyl ether

<sup>11</sup> BFDGE = Bisphenol F diglycidyl ether

<sup>12</sup> NOGE = other novolac glycidyl ethers.

- **Active and intelligent materials** (Regulation 450/2009/EC – contains a list of authorized substances (positive list) that may be used in active and intelligent components. Substances can also be used even though they are not on the list of authorized substances if they e.g. are not in direct contact with food and are not classified as “mutagenic”, “carcinogenic”, or “toxic to the reproduction” (as defined in Reg. 1272/2008)).

All in all this means that the following types of specific measures are used within the food contact material legislation:

- Positive list of substances for the content of the specific material, i.e. a list of substances that are the only ones to be used in the manufacture of the specific material/article (authorisation list). Is used for regenerated cellulose films, plastic materials, and for active and intelligent materials.
- Maximum permitted quantity of a substance. Restriction of substances to be used for manufacturing of food contact materials, i.e. substances must not be used over a certain limit value (content in w/w). Used in the area of plastic materials.
- Migration limits for specific substances. Used in the area of ceramics (lead and chromium migration limits) and plastics (plasticizers and other substances).
- Overall migration limit, i.e. the total migration of all chemicals allowed from food contact materials. Used in the area of plastic materials and for elastomers and rubbers.

#### *National specific measures (article 6)*

If no specific measures are in place for groups of materials and articles (article 5) Member States can set their own specific measures for these groups of materials and articles.

An overview of the Member States that have set specific measures for other groups of materials can be found at the website of DG Health and Consumers – Food and Feed Safety<sup>13</sup>. According to this overview, several Member States have specific national legislation or standard that applies other than the EU food contact material regulation. Specific national legislation also applies even though specific measures are in place for e.g. ceramics and plastics.

#### *Authorization of substances to be used in the manufacturing of food contact materials and articles*

No substance will be authorized for use in the manufacturing of food contact materials and articles if they do not satisfy the general requirements of article 3 (e.g. “must not endanger human health”). Application for authorization of new substances must be submitted to the competent authorities in the Member States. Authorization of a new substance shall take place in the form of the adoption of a specific measure.

#### *3.7.1.3 Associated harmonized standards*

About 100 European standards are associated with the food contact material area but not all are harmonized standards. The titles of these have been scanned. Most of the standards contain only requirements for/description of test methods for e.g. migration of specific substances into food or for specific materials. These standards are not listed below as they merely describe the test methods and do therefore not contain further chemical requirements compared to the requirements listed in the

<sup>13</sup> [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum\\_nat\\_legis\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf)

Directives connected to the Regulation on food contact materials. Some standards contain material and performance requirements as well as test methods. It is assumed that these material and performance requirements are of a more technical character (than chemical). Hence, no standards are described further.

#### 3.7.1.4 *Comitology procedure*

Article 23 of the Regulation describes the Committee procedure for complementing the Regulation with specific measures (directives) e.g. for specific materials including setting/changing of migration limits etc. I.e. comitology is in place which allows establishing chemical requirements.

### 3.7.2 Discussion of the Regulation

#### *Higher level of chemical regulation in food packaging*

Food contact materials are a much more regulated area with respect to dangerous chemical substances compared to many of the other legislations reviewed in this report. This is also needed as consumers are directly exposed to chemicals from materials in contact with food – via the food, when the chemicals in food contact materials migrate into the food they are in contact with.

#### *Vague phrases included*

The food contact materials regulation includes the overall rather vague statement (general requirement) that “materials and articles should be manufactured so they under normal or foreseeable conditions of use do not transfer their constituents to food in quantities, which could endanger human health”. This vague statement is difficult to act on as it is synonymous with the need for carrying out a comprehensive health and risk assessment of each of the substances that are found to be migrating to food simulants in tests. The risk assessment furthermore depends on reliable and existing data about the toxicity of the chemicals which do not exist in all cases.

#### *The food contact materials regulation only addresses human health aspects*

The above mentioned general requirement shows that the scope of the Food Contact Materials Regulation only addresses human health aspects and not environmental aspects as well.

#### *Specific measures for groups of materials and articles*

It is therefore positive that the general requirement is supplemented by specific measures for groups of materials and articles. Today (January 2011), specific measures have been implemented for 5 of the 17 groups of materials and articles that are listed in the regulation. A strong point of criticism is, however, that for the remaining 12 groups of materials and articles listed in the Regulation, no specific measures (and thereby) no chemical measures have been implemented in order to avoid dangerous chemicals in food contact materials. And even for those 5 groups of materials, where specific measures are set, there are gaps in the chemical requirements. For example no chemical requirements exist for colorants and solvents within the group of plastic materials.

The overview of which Member States that have set specific measures for other groups of materials (found at the website of DG Health and Consumers – Food and Feed Safety<sup>14</sup>) clearly illustrates that the different Member States of the EU are not

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<sup>14</sup> [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum\\_nat\\_legis\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf)

satisfied with the lack of requirements for the other groups of materials and articles – otherwise no additional national requirements would be necessary!

*Use of positive lists seem appropriate – but only used for 3 of 17 materials*

The use of positive lists (authorisation list) seems to be the right way to restrict chemicals, especially when the toxicological profile of all 140,000 chemicals in use today is not known. Then it can be ensured that only safe chemicals are put on the positive list and must be used for food contact materials. The use of a positive list is, however, only used for three of the 17 mentioned materials and articles (plastics, regenerated cellulose films, and for active and intelligent materials). For some natural materials it may not make sense to apply the use of a positive list but for materials and articles such as adhesives, rubbers, paper and board, printing inks, textiles, waxes as well as varnishes and coatings, it would make perfectly sense to make positive lists as well or at least other requirements as no specific requirements exist for these materials on EU level today.

*Safety valve controlling migration of unknown chemicals*

Plastic materials are the most regulated area within food contact materials. Besides the overall authorisation list (positive list) of substances to be used, both migration limits for individual substances are used as well as an overall migration limit for the sum of all substances migrating into food. This is positive as it ensures a maximum load of chemicals in the food and can be used as a safety valve for chemicals where no migration limit has been set, e.g. because the toxicity of the chemical is unknown. It can, however, always be discussed whether the total migration limit is too high (60 mg/kg, i.e. 60 ppm) and should be lowered, but this should be a matter for toxicological experts. It is of course important when setting such a limit to account for other sources of exposures. Consumers are for example exposed to plasticizers through food (food contact materials) and many other consumer products (oilcloths, shower curtains, clothes, waterproofs, clogs, etc.) used in our home.

#### 3.7.2.1 *Examples of shortcomings*

Below some examples of shortcomings of the existing chemical requirements for food packaging materials are given.

*No knowledge about the chemicals used to print food packaging*

BfR, the German Federal Institute for Risk Assessment, has made a press release on printing inks in food contact materials in 2006. BfR states that fact that about 1,000 different chemical substances are used to print food packaging. Whether or not they migrate into food depends on the printing ink, the food, and the packaging material. BfR criticises the fact that for most of these chemicals no toxicological data are available which makes it very difficult to perform a health assessment, especially as data do not seem to be provided by the industry before 2010-2015 and only on some of the relevant effects (BfR, 2006). This is of course problematic as the Food Contact Materials Regulation does not cover printing inks. No specific measures have been taken within this group of materials.

*Difficult to ensure no risks from recycled paper and cardboard*

Furthermore, mineral oils have been known to migrate from recycled cardboard packaging material made of recycled paper in relevant amounts (BfR, 2010). Again paper and board is an area where no specific chemical requirements have been set – neither for recycled paper or board. BfR states that the health assessment of the residues is difficult as mineral oils are complex mixtures. It is therefore complicated (= impossible) to ensure that the overall general requirement of “must not endanger human health” is met on this area.

#### *Food simulants not always representative*

A third example of shortcomings of the existing chemical requirements for food packaging materials is that the food migration simulants mentioned in the standards (typically olive oil and water) not in all cases are the optimal food simulants. Butter (an emulsion of oil and water) may for some chemicals be much more receptive towards migration. This has for example been shown for fluorinated compounds used in grease-proof paper like fast-food paper, popcorn bags etc., where the migration into butter could be up to 10 times higher than into pure oil or even up to 30 times higher in a mixture of oil and soy (Begley, FDA CFSAN).

#### *Nickel release to water heated by electric kettles*

Another example is within the area of household appliances where CENELEC (European Committee for Electrotechnical Standardization) in 2007 suggested amending the standard setting requirements for appliances heating liquids, as a German market surveillance revealed large amount of nickel in potable water which was being heated by electric kettles (CLC/TC 61, 2007). The Food Contact Materials Regulation does not regulate release of nickel, i.e. this problem cannot be solved by this regulation. Electric kettles are household appliances and thereby also fall under the Low Voltage Directive. However, this Directive does not set chemical requirements at all.

### **3.7.3 Conclusions**

The main conclusions from the review of *Regulation No. 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food* are:

- The Food Contact Material Regulation contains a rather vague statement of “should not endanger human health”, which is difficult to act on, if not proceeded by specific requirements as set for plastic materials.
- The Food Contact Material Regulation only addresses human health aspects. Environmental aspects are not considered.
- The Food Contact Material Regulation sets chemical requirements for food contact materials – but only for a few group of materials (especially plastics is regulated), but there are still gaps within the few groups of materials that are regulated (i.e. colorants and solvents are not regulated within plastic materials).
- It is positive that plastics are regulated via an overall migration limit and use of a positive list (authorisation list). But all other materials should be regulated as well on an EU level. Too many national measures illustrate that the missing EU regulation on other materials is not satisfactory.
- The new Regulation on plastic materials (enters into force May 2011) contains an interesting clause on nanomaterials as these are only to be used if they are on the authorisation list.
- A comitology procedure is in place and does allow for establishing new chemical requirements or e.g. a lowering of the limit value for the existing requirements.
- I.e. the Directive and the standards do not protect the consumers from *all* the chemical hazards that may be present in food contact materials. However, the Food Contact Materials Regulation is a positive example to follow despite the many shortcomings.

## 3.8 Simple pressure vessels

### 3.8.1 Description of the Directive

*Directive 2009/105/EC of 16 September 2009 relating to simple pressure vessels* is a New Approach Directive.

#### 3.8.1.1 Products covered

The Directive applies to simple pressure vessels manufactured in series. A simple pressure vessel means any welded vessel subjected to an internal gauge pressure greater than 0.5 bars which is intended to contain air or nitrogen and which is not intended to be fired. The vessel shall be made of either a cylindrical part of circular cross-section etc., or two dished ends revolving around the same axis.

The maximum working pressure of the vessel shall not exceed 30 bar and the product of that pressure and the capacity of the vessel shall not exceed 10,000 bar.l. Minimum working temperature must not be lower than - 50 °C and the maximum working temperature must not be higher than 300 °C for steel and 100 °C for aluminum or aluminum alloy vessels.

Examples of products covered are spray deodorants, whipped cream cans, etc.

Examples of product not covered are vessels for nuclear use or vessels intended for installation in or the propulsion of ships and aircrafts.

#### 3.8.1.2 Requirements related to health aspects

The main requirement states that “the vessels may be placed on the market and put into service only if they do not compromise the safety of persons, domestic animals or property when properly installed and maintained and used for the purposes for which they are intended”.

Vessels of which the product of PS x V is 50 bar.l or less must be “manufactured in accordance with sound engineering practice in one of the Member States”. However, for vessels of which the product of PS x V exceeds 50 bar.l. essential safety requirements apply.

Essential safety requirements (Annex I in the Directive) resembling chemical restrictions or health aspects are presented below:

- Materials used for manufacturing the pressurized parts must be capable of being welded; ductile and tough, not adversely affected by ageing.
- Steel vessels: Non-alloy steels: the content per product of carbon must be less than 0.25% and that of sulphur and phosphorus must each be less than 0.05%. Further requirements are related to tensile strength, elongation after rupture, thickness, etc.
- Aluminum vessels: Non-alloy aluminum must have an aluminum content of at least 99.5%. Specific alloys must display adequate resistance to intercrystalline corrosion, etc.
- Non-pressurized parts: must be made of materials which are compatible with that of the components to which they are mended.
- The vessels must not be subjected to stresses likely to impair their safety in use.
- The remaining requirements include elements like wall thickness, production checks, welding processes, etc.

The remaining requirements/articles concern elements like:

- CE marking
- Certification procedures
- EC type examination (ascertains that a prototype vessel complies with the Directive)
- EC verification (ascertains that the remaining produced vessels are in conformity with the type described in the EC type examination)
- EC declaration of conformity

#### 3.8.1.3 *Associated harmonized standards*

As of December 2010 there are approximately 8 harmonized standards associated with this Directive. The titles of these have been scanned for requirements related to health risks and/or content/release of chemicals. The result was that none of the standards was found relevant for further examination.

#### 3.8.1.4 *Comitology procedure*

There is no comitology in place to allow for the establishment of specific requirements including chemical limits.

### **3.8.2 Discussion of the Directive**

#### *The word 'safety' not defined properly*

As many of the other reviewed Directives, the Directive includes the main requirement of "... must not compromise the safety of persons...". However, it is not specified further what the word 'safety' covers. The Directive includes a number of requirements focusing on the 'physical' safety (i.e. making sure that the can is thick enough to withstand the pressure, etc.)

#### *Content restrictions seem to focus on ensuring stability*

The only requirements resembling chemical restrictions are the content restrictions of carbon (less than 0.25%), sulphur and phosphorus (less than 0.05%) and an aluminum content of at least 99.5% (in non-alloy aluminum) respectively. However, these content restrictions seem to be related to ensuring the stability of the can and not to hinder release of dangerous substances.

#### *Material requirement seems to ensure compatibility and not risks of forming dangerous substances*

The final requirement resembling health aspects related to chemical content is the requirement of non-pressurized parts being made of materials which are compatible with that of the components to which they are melded. However, yet again, this requirement seems to concern the stability of the product and not the risk of forming dangerous substances (in case of 'in-compatibility').

All in all, this Directive contains no chemical restrictions related to ensuring the health risk for consumers. This may be problematic since for instance spray cans, which are consumer products covered by this Directive, can be assumed to be in regular contact with humans, thus making sure that the cans do not release certain hazardous chemicals would seem reasonable.

### **3.8.3 Conclusions**

The main conclusions from the review of *Directive 2009/105/EC of 16 September 2009 relating to simple pressure vessels* are:

- The word 'safety' is used without specifying further what the precise meaning is. It seems that focus lies on securing 'physical' safety and not safety as in not exposing the consumer to dangerous chemicals.
- A few content restrictions are included (carbon, sulphur, phosphorus) but the restrictions seem to focus on securing stability of the cans and not to hinder release of dangerous substances.
- Likewise seems the material restriction (materials used must be compatible with components) to focus on securing compatibility/stability rather than securing no risks related to release of dangerous substances.
- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.
- I.e. the requirements do not protect the consumers from the risks related to dangerous substances in simple pressure vessels.

## 3.9 Recreational crafts

### 3.9.1 Description of the Directive

*Directive 94/25/EC of 16 June 1994 relating to recreational craft* is a New Approach Directive.

#### 3.9.1.1 Products covered

The Directive covers with regard to design and construction: recreational craft and partly completed boats, personal watercrafts, and certain components intended for installation. Regarding exhaust emissions the Directive covers: propulsion engines on recreational crafts or personal watercrafts and propulsion engines (installed on these crafts) which are subject to major engine modification. And finally, regarding noise emissions, the Directive covers recreational crafts with stern drive engines, personal watercrafts, etc. Recreational craft means any boat of any type intended for sports and leisure purposes of hull length from 2.5 m to 24 m. A personal watercraft is a vessel less than 4 m in length which uses an internal combustion engine having a water jet pump as its primary source of propulsion.

Examples of products not covered (with regards to design and construction) are canoes, kayaks, sailing surfboards, historical crafts, experimental crafts, etc.

#### 3.9.1.2 Requirements related to health aspects

The overall regulation (article 2) states that the products must only be placed on the market ... if they do not endanger the safety and health of persons, property or the environment when correctly constructed and maintained.

The products shall meet the essential safety health, environmental protection, and consumer protection requirements set out in Annex I. Below, the essential requirements (of Annex I) concerning or resembling chemical requirements are presented.

- All inboard mounted engines shall be placed within an enclosure separated from living quarters and installed so as to minimize the risk of fires or spread of fires as well as hazards from toxic fumes, heat, noise, or vibrations in the living quarters.
- Regarding the gas system "Materials and components shall be suitable for the specific gas used to withstand the stresses and exposures found in the

marine environment”. “Adequate ventilation must be provided to prevent hazards from leaks and products of combustion”.

- Craft shall be constructed so as to prevent the accidental discharge of pollutants (oil, fuel, etc.) overboard.
- Several requirements regarding exhaust emissions (CO, HC, particulate matter and NOx) and noise emission levels.

The remaining essential requirements concern elements like ‘protection from falling overboard and means of reboarding’, ‘visibility from the main steering position’ and requirements towards stability and buoyancy, etc... Further requirements comprise life raft storage, maximum recommended load, escape opportunities, fuel systems, etc.

The remaining requirements/articles concern elements like:

- Free movements of the products
- Safeguard clause
- Conformity assessment
- Notified bodies
- CE marking

#### 3.9.1.3 *Associated harmonized standards*

As of December 2010 a total of approximately 60 harmonized standards are associated with this Directive. The titles of these have been scanned for requirements related to health risks and/or content/release of chemicals. The result was that none of the harmonized standards seemed to come close to introducing chemical restrictions. An example is listed below.

#### EN ISO 6185-1:2001 Inflatable boats - Part 1: Boats with a maximum motor power rating of 4.5 kW (ISO 6185-1:2001)

The standard includes:

- Materials must be selected according to the stresses to which the craft is subjected (shape, dimensions, maximum load, installed power, etc.). All materials must be rot proof. Certain timber can be used, if treated against fungal decay, etc.
- Remaining requirements concern elements like inflation, deflation, rudder steering system, safety ropes, etc.
- No chemical requirements whatsoever.

#### 3.9.1.4 *Comitology procedure*

There is no comitology in place to allow for the establishment of specific requirements including chemical limits.

### **3.9.2 Discussion of the Directive**

#### *Safety seems to focus on physical safety*

This Directive makes use of the well-known phrase the products “must not endanger the safety and health of persons...”. Yet it seems that the word ‘safety’ primarily concerns physical safety (as in not falling overboard, being trapped in fires, etc.) since no chemical requirements are included in the Directive. Once again a further definition of the word safety would be desirable.

#### *Weak phrases*

The only requirements resembling chemical requirements are the phrases ‘minimize the risk of ... hazards from toxic fumes’ and ‘adequate ventilation must be provided to prevent hazards from leaks and products of combustion’. Both very weak requirements since no identification of the toxic fumes or the hazards from the product of combustion is provided – making it difficult to comply with the requirements.

#### *No chemical requirements in the standard regarding inflatable boats*

Even though inflatable boats may not be a consumer product, which are often used by many consumers, it is still surprising that there are no chemical requirements whatsoever included in the standard. During hot periods it can be assumed that consumers will sit bare-legged on the boat for several hours and sweat/water may enhance the transfer of dangerous substances from the surface of the boat to the skin. It is even stated in the standard that the material of which the boat can be produced shall be treated with fungicides which can cause health effects in humans.

### **3.9.3 Conclusions**

The main conclusions from the review of *Directive 94/25/EC of 16 June 1994 relating to recreational craft* are:

- It seems that the word safety primarily concerns securing ‘physical’ safety as in preventing accidents since no chemical requirements are included in the Directive.
- Two requirements resemble chemical restrictions (“minimize the risk of hazards from toxic fumes” and “adequate ventilation must be provided to prevent hazards from leaks and products of combustion”) but no identification/elaboration of the specific ‘toxic fumes’ or ‘hazards’ are provided.
- The standard regarding inflatable boats does not include chemical restrictions even though some skin contact can be assumed. The standard even calls for fungicides to be used in the construction material.
- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.
- I.e. the requirements do not protect the consumers from the risks related to dangerous substances in recreational crafts.

## **3.10 EC-type approval system for motor vehicles**

### **3.10.1 Description of the Directive**

*Directive 2007/46/EC of September 2007 on establishing a framework for the approval of motor vehicles and their intended trailers, and of systems, components, and separate technical units intended for such vehicles* is a Non-new approach Directive.

The Directive establishes a framework containing the administrative provisions and general technical requirements for approval of all new vehicles.

Chapters comprise:

- EC type approval procedures
- Conduct of EC type approval procedures
- Amendments to EC type approvals
- Validity of an EC type-approval of vehicles
- Certificate of conformity and markings
- New technologies or concepts incompatible with separate Directives
- Vehicles produced in small series
- Individual approvals
- Registration, sale and entry into service
- Safeguard clause
- International regulations
- Provisions of technical information
- Implementation measures and amendments
- Designation and notification of technical services
- Final provisions

If a Member State finds that a type of vehicle, system, component etc., albeit in conformity with the required provisions, presents a serious risk to road safety or seriously harms the environment or seriously harms public health, it may refuse to grant the EC type-approval.

Compliance with the technical prescriptions laid down in the Directive and in the regulatory acts listed in Annex IV shall be demonstrated by means of appropriate tests performed by designated technical services.

On page 97 of the Directive a list of these ‘regulatory acts’ (Directives) for the requirements related to different ‘parts’ of the vehicle is presented. The only ‘parts’ which could be assumed to include chemical restrictions are ‘Interior fittings’, ‘Seatbelts and restraint systems’, and “Heating systems”. These are reviewed below.

The ‘general safety’ is regulated by Regulation 661/2009 which will be reviewed in the subsequent chapter.

*Review of Directive 74/60/EEC relating to the interior fittings of motor vehicles.*

The Directive states that Member States cannot prohibit sale of vehicles if these meet the requirements set out in the appendixes of the Directive. The appendixes comprise:

- Annex I: Scope, definitions, application for EC type approval etc.
  - App. 1: Information document
  - App. 2: EC type approval certificate
  - App. 3: Position of cylindrical test rod in the opening roof and window openings
  - App. 4: Symbol for driver controlled switch
- Determination of the head-impact zone
- Procedure for testing energy-dissipating materials
- Procedure for determining seat-back angles etc.
- Method of measuring projections
- Apparatus and procedure for application of ‘knee-contact devices’

The Directive focuses mainly on securing ‘physical safety’ as in the requirement “The reference zone defined in ... must not contain any dangerous roughness or sharp edges likely to increase the risk of serious injury to the occupants”. Also ‘operating

requirements' are in focus. The words 'health', 'chemical', and 'substance' are not mentioned in the Directive. No chemical requirements are included.

#### Directive on 'seat belts' and 'heating systems'

A short review of the Directives regarding seatbelts and heating systems revealed the same results – no requirements towards chemical restrictions whatsoever – the words 'health', 'substance', and 'chemical' are not mentioned. Though, in the Directive regarding heating systems, there are some requirements regarding the amount of allowed CO ( $\leq 0.1\%$ ), NO<sub>x</sub> ( $\leq 200$  ppm), and HC ( $\leq 100$  ppm) in the air. Whether these limits are set to high is not evaluated in this project. No other requirements regarding chemical restrictions seem to be included.

##### 3.10.1.1 Comitology procedure

There is no comitology in place to allow for the establishment of specific requirements including chemical limits.

### **3.10.2 Discussion of the Directive**

The Directive is a frame-Directive which links to a number of other Directives concerning different elements in motor vehicles (parking light, interior fittings, towing hooks, etc.). The Directive does not make use of the words 'chemical' or 'substance' but does state that a Member State can refuse to grant the EC type-approval if the MS feels that the product – although it complies with the required provisions – presents a risk to harm public health. Yet no further methods of when to establish this risk are included.

A review of three linked Directives most likely to include chemical restrictions (interior fittings, seat belts and heating systems) showed close to no chemical restrictions whatsoever. Only exception being the Directive regarding heating systems which introduces limit values regarding emission of CO and NO<sub>x</sub> to the air (inside the car).

However, the Directive also links to a Directive focusing on the 'general safety of motor vehicles'. This Directive may hold more restrictions regarding chemicals. This Directive is reviewed in the following chapter.

### **3.10.3 Conclusions**

The main conclusions from the review of *Directive 2007/46/EC of September 2007 on establishing a framework for the approval of motor vehicles and their intended trailers, and of systems, components and separate technical units intended for such vehicles* are:

- The words 'chemical' or 'substance' are not used in the Directive.
- A 'general' phrase of Member States being able to refuse a product if it presents a health risk is included.
- A review of three linked Directives most likely to include chemical restrictions (interior fittings, seat belts, and heating systems) showed close to no chemical restrictions whatsoever. Only exception being the Directive regarding heating systems which introduces limit values regarding emission of CO and NO<sub>x</sub> to the air (still air at 20 degrees Celsius).
- There is no comitology in place to allow for the establishment of specific requirements including chemical limits.

- I.e. there are no chemical requirements to protect consumers from the risks related to dangerous substances connected to the product group.

## **3.11 Type-approval requirements for the general safety of motor vehicles, trailers, etc.**

### **3.11.1 Description of the Regulation**

*Regulation (EC) 661/2009 of 13 July 2009 concerning type approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefore is a Non-new approach Directive.*

The Regulation is new and does not enter into force before 1 November 2011. The Regulation is meant to replace the many sub-Directives connected to the above mentioned framework Directive (2007/46/EC) for the approval of motor vehicles. The Regulation states that about 50 other Directives (including the 3 sub-directives reviewed in the previous section (Interior fittings, seat belts, heating systems) should be repealed with effect from the dates of application valid for new vehicles, i.e. from November 2014. Instead several implementing measures have been and will be adopted through different sub-regulations<sup>15</sup>.

#### *3.11.1.1 Products covered*

The Regulation establishes requirements for the type approval of motor vehicles, their trailers and systems, components and separate technical units intended therefore with regard to their safety. Tires and gear shift systems are also regulated – especially as regards to fuel efficiency, CO<sub>2</sub> emissions, rolling resistance, and noise emissions.

#### *3.11.1.2 Restrictions regarding health aspects*

The Regulation states that manufactures shall ensure that vehicles are designed, constructed, and assembled so as to minimize the risk of injury to vehicle occupants and other road users. The list of requirements comprises subjects like:

- Vehicle structure integrity
- Systems to aid the drivers control of the vehicle
- Vehicle lighting systems
- Vehicle occupant protection, including interior fittings, head restraints, seat belts, etc.
- Vehicle exterior and accessories
- Electromagnetic compatibility
- Audible warning devices
- Heating systems
- Devices to prevent unauthorized use
- Masses and dimensions
- Electrical safety
- Gear shift indicators

The words ‘health’, ‘substance’, and ‘chemical’ are not found in the Regulation.

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<sup>15</sup> [http://ec.europa.eu/enterprise/sectors/automotive/documents/directives/motor-vehicles/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/automotive/documents/directives/motor-vehicles/index_en.htm)

#### 3.11.1.3 *Associated harmonized standards*

No harmonized standards have been located for this new Regulation.

#### 3.11.1.4 *Comitology procedures*

There is a comitology procedure in place. The Technical Committee – Motor Vehicles (TCMV) is established.

Implementing measures can be adopted through different sub-regulations according to article 14 of the regulation. This means in principle that chemical requirements (e.g. for indoor air) could be established. However, in reality this is unlikely to be done as article 14 specifies that the implementing measures should be on areas like tests and technical requirements, specific safety requirements for vehicles intended for transport of dangerous goods, performance requirements of tyres, rolling resistance and rolling noise, noise levels etc.

By 1 December 2012 and every three years thereafter, the Commission shall present a report to the European Parliament and to the Council including, where appropriate, proposals for amendment to this Regulation or other relevant Community legislation regarding the inclusion of further new safety features.

### **3.11.2 Discussion of the Regulation**

The main requirement of “manufactures shall ensure that vehicles are constructed ... as to minimize the risk of injury to vehicle occupants and other road user” clearly gives the impression that the requirements in the Regulation focus on avoiding ‘physical’ health risks (injuries) rather than health risk related to exposure of dangerous chemicals. This is further supported by the subjects on the list of requirements stated (see section 3.11.1.2).

### **3.11.3 Conclusions**

No chemical requirements seem to be included in the Regulation.

## 4 Main issues identified in the review

This project has reviewed product legislation that was not already reviewed in the former project by FORCE Technology, 2010 (Chemical requirements Part I). Chemical product legislation like cosmetics, biocides, medicine, detergents, fertilizers etc. has not been reviewed as this legislation is expected to contain chemical requirements. The purpose of this review has therefore been to review legislation concerning non-chemical consumer products in order to discuss whether chemical requirements are set.

An overview of the review is given in the table below. The details are discussed under each Directive/Regulation in the former chapter.

Table 4-1: Overview of chemical requirements in the reviewed Directives/Regulations

Name of Directive/Regulation	Chemical req. in legislation	Chemical req. in standards	Comitology to establish chem. req.
Gaseous fuels appliances (NA)	No	Yes, but only for Cd, Pb and no use of asbestos-based materials	No
Pyrotechnic articles (NA)	Yes, but only for silver fumerate	Yes, for certain metal-compounds	No
Low voltage electrical equipment (NA)	No	No	No
Radio and telecommunications (NA)	No	No	No
Medical devices (NA)	Yes, but mainly through risk assessment	Yes, for sterilization residuals. Others through risk assessment.	No (but comitology to alter standards)
Packaging and packaging waste (NA)	Yes, but only for heavy metals	Yes, to some degree. (min. amount of substances classified as 'N' if released to the environment)	Only exemptions from existing metal requirements
Food contact materials	Yes, but mainly for plastics	No	Yes
Simple pressure vessels (NA)	No	No	No
Recreational crafts (NA)	No	No	No
EC-type approval system motor vehicles	Only limits for CO and NO <sub>x</sub> emissions	No	(No)*
General safety of motor vehicles	No	No	No

NA = New Approach Directive

\* In principle chemical requirements (e.g. for indoor air) could be established. It is in reality unlikely to be done as it is specified in the directive that this should be carried out on areas like tests and technical requirements, performance requirements of tyres, rolling resistance and rolling noise, noise levels etc.

Below the main issues identified during the review of the selected product legislation are presented and discussed.

### 1. Main focus seems to be on securing 'physical safety'

In general very few chemical requirements are set in the reviewed legislation (Directives/Regulations and associated harmonized standards). The main focus of the requirements is towards securing 'physical' safety (i.e. prevent accidents) by use of more general vague statements like "do not endanger (or compromise) the safety of persons". Generally it seems that the word 'safety' used in the Directives only covers 'physical safety' and not 'chemical safety'.

#### *2. Vague phrases in the Directives and a limited specification in standards*

The use of a vague statement/requirement makes it difficult to act on and therefore extremely difficult to comply with in practice – especially if the requirement is not elaborated in the associated standards by use of e.g. specification of substances to avoid, limit values to follow or positive lists of chemicals to use. The general picture is that for some standards chemical specification are made, but only for a very limited amount of chemicals. For some Directives, neither standards nor the Directives contain chemical requirements.

#### *3. Vague statements call for risk assessments which often are not possible*

These vague statements are difficult to act on as it is synonymous with the need for carrying out a comprehensive health and risk assessment of each of the substances found in the products – if it is stated that the 'health of the consumers must be protected' or similar. Furthermore, the risk assessment depends on reliable and existing data concerning the toxicity of the chemicals, information which often do not exist.

Another problem with using a risk assessment approach is that the user is given many choices and the approach requires that industry/companies are capable of performing risk assessments correctly. Furthermore, this approach gives industry a big room for manoeuvres and makes enforcement very difficult or virtually impossible. An authority can ask a manufacturer to present a risk assessment file but it would be very difficult to challenge any conclusion unless the authority conducts a risk assessment itself. Enforcement would be much easier if limits for specific chemicals were set. Then it would simply be a question about comparing legal limit values/migration limit values with the analysed values.

#### *4. Definition of 'minimizing' is lacking*

In some Directives, the wordings 'minimizing the risk' or 'minimizing the use of the substances' are used. The exact meaning of minimizing is not always clarified. As there is a lack of definition of what 'minimizing' means or how to show it in practice, it must be difficult for the manufactures to know when they have 'minimized' the risk or content sufficiently – and this of course also gives industry a big room for manoeuvres and makes enforcement very difficult or virtually impossible. Of course a solution could be to perform a classical exposure- and risk assessment, but this requires specific information (e.g. LC<sub>50</sub>-values etc.) and skills which may not be present in many companies. Actually the required data for performing risk assessments may neither be present as the knowledge of the toxicity of all chemical substances is limited (at present).

In one case – in the Packaging and Packaging Waste Directive – the word 'minimizing' has been defined in a standard as "the minimum adequate amount of a substance has to be established in relation to the functional performance or purpose of the substance". This definition is, however, useless because it allows a use of even huge amounts of a substance as long as it is argued that it is necessary to achieve the desired function (e.g. use of an endocrine disrupting plasticizer in plastic).

Therefore, the wording ‘minimization’ should not be used in standardisation, but only by legislators – and only as a guidance to establish exact strict requirements (with exact limit values). Furthermore, the requirements should be independent of any functionality to be achieved in order to avoid such loose statements as “the minimum adequate amount of a substance has to be established in relation to the functional performance or purpose of the substance”.

#### *5. In general very few chemical requirements*

The very few chemical requirements and vague statements means that in general many of the reviewed Directives do not ensure that the consumers are protected from risks related to dangerous substances in the products – or at least not all dangerous substances in the products. Exempted are the electronic and electrical equipment that are also covered by RoHS which set chemical requirements for some heavy metals and flame retardants. However, as discussed in the previous report by FORCE Technology, RoHS can also be criticized for not restricting enough relevant chemical substances in electronics.

#### *6. Accepted balance between risks and benefits*

In the Medical Device Directive an interesting balance between acceptable risks and benefits is introduced. Understandable in view of the type of products regulated. How to establish this ‘balance’ or ‘acceptable’ risk is, however, unclear and must be difficult since one has to assume that the level of ‘acceptable’ risk differs from person to person. The acceptance of this ‘balance’ can also be seen as an argument for the industry not to reduce or eliminate substances – i.e. as a *carte blanche* to accept high levels of chemicals.

Furthermore, it is not even considered to require substitute products without dangerous substances where available. An example of the use of this acceptable risk versus benefits can be found for premature born babies, where tubes used for helping the babies breathe can be made of phthalates. The requirement in the medical device Directives only requires the phthalates to be labelled on the product. A requirement in the form of a ban of use of phthalates seems much more reasonable, but the problem has been that for some of these types of products, no real alternative to phthalates has been found yet. However, a future requirement could speed up the process of finding alternatives.

#### *7. Cocktail effects not considered*

Even though a few of the reviewed Directives/regulations do set chemical requirements, the requirements are often based on a health and risk assessment of that single chemical – perhaps taking other exposures into considerations (multiple exposures), but cocktail effects are not taken into considerations when setting limits or describing methods to set limits. This is of course due to the fact that the knowledge of cocktail effects is very limited and just recently discovered. Experts are still discussing how to use this knowledge in risk assessments. However, some form of consideration towards cocktail effects seems reasonable to include when setting limits for chemical content in products.

#### *8. Use of positive lists and an overall migration limit may be useful*

In the Food Contact Materials Regulation several different ways to regulate chemicals (but mainly in plastic materials) are used:

- Positive list of substances for the content of the specific material, i.e. a list of substances that are the only ones to be used in the manufacture of the specific material/article.

- Maximum permitted quantity of a substance. Restriction of substances to be used for manufacturing of food contact materials, i.e. substances must not be used over a certain limit value (content in w/w).
- Migration limits for specific substances.
- Overall migration limit, i.e. the total migration of all chemicals allowed from food contact materials.

The use of positive lists seems to be the right way to restrict chemicals – at least seen from an idealistic health perspective – especially when the toxicological profile of all 140,000 chemicals in use today is not known (reversing the burden of proof). If there is no knowledge, no limit values can be set. By use of a positive list it can be ensured that only safe chemicals are put on the positive list.

However, the use of a positive list can only be used in areas where you know of materials/substances that are safe to use. Again this requires knowledge about chemical substances. But use of positive lists could force industry to locate/produce toxicological information faster. Of course, the major disadvantage is that today we have a rather limited knowledge of the dangerous properties of all chemicals, thus the positive list would be somewhat limited at the time being. Even though REACH will be fully implemented by 2018, there are still many years to go until we have a sufficient amount of toxicological data as REACH fully implemented does not ensure a knowledge of all toxicological data on all registered substances.

Another positive measure used in the Food Contact Materials Regulation is the overall migration limit as it ensures a maximum load of chemicals in the food and can be used as safety valve for chemicals where no migration limit has been set, e.g. because the toxicity of the chemical is unknown. It is of course important when setting such a limit to account for other sources of exposures and the limit should be set by toxicological experts.

#### *9. Lack of comitology procedures to change or set chemical requirements*

The review of the different product legislation (as well as the review performed in the previous report by FORCE Technology (Chemical requirements Part I)) shows that most Directives/Regulations do not include a comitology procedure that allows for changing or setting chemical requirements in the legislation.

The overview (Table 4-1) shows that only the Food Contact Materials Regulation (of the reviewed legislation) provides a comitology procedure that allows for changing or establishing chemical requirements. The Packaging and Packaging Waste Directive only allows for exemptions from the existing metal requirements, i.e. the comitology procedure here only allows for loosening or removing the chemical requirements set for the metals content for certain cases.

The Medical Devices Directive is special as it has a comitology procedure that allows for altering the standards. This means that as long as a general statement like ‘must not endanger human health’ is mentioned in the Directive, the necessary chemical requirements could be added to standards – and continuously altered by comitology as new information appears. However, this requires that the Member States can reach an agreement on which requirements to include in the standards and where the limit values should be set – and this could be a lengthy procedure. Normally, standards cannot be changed directly but only be challenged and it may take a long time (years) to reach an agreement.

When no comitology procedure is in place for changing the Directive, this of course means that it is a very lengthy procedure to introduce or alter the chemical requirements or the limits set (if any) as the entire Directive must be changed.

#### *10. Business controlled standard bodies do not set (strict) chemical requirements*

The review of the different product legislation (as well as the review performed in the previous report by FORCE Technology shows that most Directives/Regulations do not set chemical requirements for consumer products. In fact, the Directives only use vague requirements like “must not compromise safety”. This means that it is up to the standard bodies to establish acceptable limits (and other specific chemical requirements). As the industry is highly represented in the standard bodies and as the industry may have a tendency to weaken the requirements due to competitiveness issues, consumer interests (i.e. protection from dangerous chemicals in consumer products) are of course not properly cared for in this way as the chemical safety level may be very poor. Therefore, it is problematic if consumer protection relies on the fact that chemical requirements must be set in the harmonized standards.

The review in this report alone shows that the safety level of the associated standards is very poor. Two examples are:

- For packaging materials endocrine disrupting plasticizers can still be used as long as it is argued that it is necessary to use to achieve the desired function.
- For products in contact with drinking water there is no regulation at all on a European level on chemical substances that could migrate into the water.

For a long time, ANEC (the European consumer voice in standardisation) has called on the European standards bodies to reform their processes and procedures in order to ensure a more balanced participation and decision-making. ANEC stresses the importance of ensuring access to standardisation for SMEs, users/consumers and researchers in order to ensure a more balanced representation of stakeholders in standardisation (ANEC Position Paper, 2008).

Even the EU Parliament highlighted in the document “European Parliament resolution of 21 October 2010 on the future of European Standardisation” the weak representation of societal stakeholders (i.e. not representing business/industry) (European Parliament, 2010). Furthermore, the Parliament highlighted the following:

- “It is of the utmost importance to draw a clear line between legislation and standardisation in order to avoid any misinterpretation with regard to the objectives of the law and the desired level of protection”.
- “The European legislator must be highly vigilant and precise when defining the essential requirements in regulations while the Commission must clearly and accurately define the objectives of the standardisation work in the mandates”.
- “The role of standardisers *should be limited to defining the technical means of reaching the goals set by the legislator as well as ensuring a high level of protection*”.

This means that even the EU Parliament is of the opinion that chemical requirements should not be set in the standards, i.e. it is not up to the standard bodies to establish chemical requirements, but only technical requirements, which seems reasonable in light of the interests of the participants in the standard bodies. Therefore, the chemical requirements must be set directly in the legislation or at

least a comitology procedure should be in place making it possible to change or set new chemical requirements subsequently.

## 5 Previous and new identified gaps

In this chapter it is discussed whether the identified gaps in this report match the gaps identified in the previous report (Chemical requirements Part I) (FORCE Technology, 2010), or whether new gaps are identified in this report (“Chemical requirements for consumer products - Part II”).

This chapter therefore contains the following sections:

- Previous identified gaps from the Chemical requirements Part I report.
- Comparison with identified gaps from this report (Chemical requirements Part II).
- New gaps identified in this report (Chemical requirements Part II).
- Overall conclusion.

### 5.1 Previous identified gaps

The gaps identified in the previous report (Chemical requirements Part I) (FORCE Technology, 2010) were the following:

1. Limited consumer product regulation
2. Use of weak phrases instead of specific limit values
3. Ad-hoc based regulation
4. Only a small number of products/chemicals covered by regulations
5. Insufficient market surveillance of consumer products
6. Life cycle aspects not considered
7. Multiple exposures not considered in all cases
8. Combination effects
9. Lack of information on chemicals in consumer products
10. Nanosubstances currently not regulated properly
11. Limitations in the regulatory frame

### 5.2 Comparison

In this section the former identified gaps are discussed in view of the review performed on further regulated areas relevant for consumer products.

#### 5.2.1 Limited consumer product regulation

The review performed in this report confirms that the current European legislation framework has a very limited consumer product regulation especially when it comes to chemical requirements. Of the reviewed legislations in this report, only the Food Contact Materials Regulation sets several chemical requirements – and this only for some materials. Otherwise chemical requirements are non-existent or limited (to e.g. heavy metals).

### **5.2.2 Use of weak phrases instead of specific limit values**

The review performed in this report confirms the fact that specific chemical limit values are the exception in consumer product regulation. Instead weak phrases such as “must be safe” are used.

This is a problem for both industry and the authorities. The authorities have to prove that a chemical is dangerous for health or the environment before they can take action. This process is very resource demanding as the authorities need to carry out a comprehensive risk assessment.

Thus, the result is no action at all (or at least very limited action by both companies and the authorities because of e.g. lack of resources or competences). However, by introducing specific limit values both companies and authorities would be able to take (much easier) actions towards complying with the directives – i.e. testing the product for content of the substance in question and comparing to the limit values.

### **5.2.3 Ad-hoc based regulation**

This aspect has not been discussed in this report, but is still valid.

However, the Food Contact Material Regulation is to some degree the exception because the use of a positive list and overall migration limits are used (even though only for plastics as one of many materials).

### **5.2.4 Only a small number of products/chemicals covered by regulations**

The review performed in this report confirms the fact that only a small number of consumer products and a small number of chemicals are covered by consumer product regulations. This report has shown that consumer products in contact with drinking water are another gap in legislation (chemical substances that could migrate into water are not regulated at all on a European level).

### **5.2.5 Insufficient market surveillance of consumer products**

This aspect has not been discussed in this report, but is probably still valid.

### **5.2.6 Life cycle aspects not considered**

This aspect has not been discussed in this report, but the importance of taking into account chemical impacts from the different life cycle stages of consumer products is still valid and should be considered when chemical requirements are set in legislation.

### **5.2.7 Multiple exposures not considered in all cases**

The review performed in this report confirms the fact that multiple exposures are generally not considered. The Medical Devices Directive considers multiple exposures and the Food Contact Materials Regulations do also to some extent (through the overall migration limit – however, only for one material – plastic). The rest of the reviewed legislation either sets no chemical requirements or limits the requirements (to e.g. heavy metals).

### **5.2.8 Combination effects**

The review performed in this report confirms the fact that combination effects (cocktail effects) are not considered when setting limits or describing methods to set limits. This is of course due to the fact that the knowledge of cocktail effects is very limited and just recently discovered. Experts are still discussing how to use this knowledge in risk assessments.

### **5.2.9 Lack of information on chemicals in consumer products**

This aspect has not been discussed in this report, but is still valid.

### **5.2.10 Nanosubstances currently not regulated properly**

The review performed in this report confirms the fact that nanosubstances currently are not regulated properly. However, the new Regulation on plastic materials within the area of Food Contact Materials (that enters into force May 2011) contains an interesting clause on nanomaterials as these are only to be used if they are on an authorisation list. This is definitely a positive trend to follow in future legislation for chemical requirements!

### **5.2.11 Limitations in the regulatory frame**

The review performed in this report confirms the fact stated in the previous report that the major limitation in the regulatory frame is that the regulatory framework does not allow for adding new chemical requirements such as limit values or changing existing ones quickly by using a committee procedure (comitology). Only the Food Contact Materials Regulation has a comitology procedure that allows for adding (or changing) chemical requirements. The rest of the legislation reviewed in this report does not have a comitology procedure that allows for setting new chemical requirements.

This is of course a problem as the only way to introduce chemical requirements will be to change the legislation or by hoping that the standard bodies will introduce chemical requirements as a way of complying with the weak phrases stated in the legislation (“must be safe”). However, relying on the standard bodies, that are business controlled, to set chemical requirements will at best result in a few chemical substances being restricted, and most likely cause an overall very poor chemical safety level, seen from a consumer viewpoint. The industry may have a tendency to weaken the requirements due to competitiveness issues. It is therefore problematic if consumer protection relies on the fact that chemical requirements must be set in the harmonized standards.

## **5.3 New gaps**

When comparing the discussion of the gaps in the previous report with the discussion of the gaps in this report, it becomes obvious that it is more or less the same gaps that are discussed. Thus no new gaps have been identified in this report (Chemical requirements Part II).

However, an interesting balance between acceptable risks and benefits was found in the Medical Device Directive. The introduction of this element is understandable in

view of the type of products regulated. However, it will not be relevant for other types of consumer products and therefore this aspect is not discussed any further.

## **5.4 Conclusion**

Therefore, the conclusion is that the gaps identified in this report support the findings of gaps from the previous report. The major gaps are:

1. Limited consumer product regulation
  - a. In general very few chemical requirements
  - b. Use of weak phrases instead of specific limit values
  - c. Only a small number of products/chemicals covered by regulations
  - d. Multiple exposures not considered in all cases
  - e. Cocktail effects not considered
  - f. Nanosubstances currently not regulated properly
2. Limitations in the regulatory frame
  - a. Lack of comitology procedure for setting or changing chemical requirements
  - b. Business controlled standard bodies do not set (strict) chemical requirements
  - c. Insufficient market surveillance of consumer products
  - d. Ad hoc based regulation
3. Lack of information on chemicals in consumer products

## 6 Do the conclusions of this report alter the suggested horizontal approach?

In this chapter, it is discussed whether (and how) the result of this report supports/changes the suggested horizontal approach in the previous report (Chemical requirements Part I), (FORCE Technology, 2010).

Therefore, this chapter contains the following sections:

- The suggested horizontal approach in short (from the previous report Chemical requirements Part I)
- Comparison and discussion

### 6.1 Suggested horizontal approach in short

The horizontal approach suggested in the previous study (Chemical requirements Part I) includes in short the following elements:

- Expansion of the ERP (Energy-Related Products) Directive to include generic and specific chemical restrictions for all products. Thus, the ERP Directive should be expanded to cover all products rather than just energy related ones and to cover a multitude of environmental aspects mirroring the EU Eco-label Regulation at a somewhat lower level of ambition. This offers opportunities for synergies and efficient resource use.
- The approach for chemical restrictions may rely on positive lists, negative lists, or a combination of both.
- The generic approach for restrictions of chemicals in consumer products should be based on the definition of SVHCs in REACH (i.e. to ban substances falling in this category such as carcinogenic, mutagenic, toxic for reproduction, etc.). However, it should be further considered (in expert groups) whether further categories of chemicals should be included (as for instance sensitising substances or substances that are toxic).
- The general concentration limit of the chemicals restricted by the generic approach should be set at 0.1% (as in REACH) for any homogenous component of the product.
- It should be further discussed whether in some cases (or in which cases) the relevant type of limit-requirements should be based on migration or emission levels instead of content or concentration.
- It should be possible to allow for exemptions for certain substance in certain consumer products.
- It should be possible to establish more specific chemical requirements in special cases (like products emitting dangerous substances to our indoor

environment) or for specific groups of products (like e.g. toys addressing a certain consumer group) or specific chemical substances not covered by generic restrictions. In these cases, a risk assessment must be performed. Perhaps an extra uncertainty/safety factor could be used in order to account for the combination effects or for multiple exposures. Risk assessments including possible exemptions should be assessed by an independent scientific committee (e.g. SCHER).

- A product declaration scheme should be introduced for all consumer products. It is suggested that all chemicals classified as hazardous with a content of 100 ppm or higher should be declared. Concentration intervals should be stated.
- The legal framework should include the possibility of changing the chemical requirements by using a committee procedure.
- A systematic assessment of the occurrence of chemicals in (certain) products should be carried out.
- Establishment of an adequately funded and more efficient market surveillance system including random tests and control measurements.
- The random tests carried out by the authorities should give feedback to the process of establishing limit values for special chemical substances for special consumer products. If necessary, the special limit values could be changed or new could be adopted – again by use of a committee procedure.

## **6.2 Comparison and discussion**

The results of this report support the previous suggested horizontal approach (presented above). As discussed in this report very few chemical requirements are set in general in consumer product regulation. Typically, a use of weak phrases is used in the regulation which in some cases results in chemical requirements in the appertaining harmonized standards. However, the business controlled standard bodies do not set strict enough chemical requirements (from a consumer viewpoint) because of industry interests - if chemical requirements are set in the harmonized standards at all. It is therefore problematic if consumer protection relies on the fact that chemical requirements must be set in the harmonized standards.

For this reason, the best option for a legislation framework that includes a horizontal approach to cover chemical risks across all product groups therefore still seems to be to expand the existing ERP Directive to cover chemicals and all products.

The advantage of the ERP Directive is that it is a framework directive that gives the opportunity for issuing EU-Regulations with limit values for the energy-use of specific products. If this could be expanded to cover chemical risks as well – across all product groups, this would be a huge step forward towards protecting consumers from chemical risks from consumer products.

Furthermore, the ERP Directive uses the following structural elements that the above horizontal approach includes:

- Implementing measures that meet the criteria that “health, safety and the environment are not adversely affected”.
- Comitology procedure that ensures adding and/or changing requirements (the implementing measures) can be carried out more quickly.
- Consultation forum, represented by environmental protection groups and consumer organizations as well as industry, establishes the implementing measures.

In fact, it was already planned by DG Environment that the new ERP Directive should have been expanded to cover all products and all environmental dimensions. However, this was dismissed because of pressure by DG Enterprise.

In the table below, it is summarised how the horizontal approach presented in the previous report (Chemical requirements Part I) will account for the gaps in the chemical product legislation as pointed out in both this and the former report.

Table 6-1 Explanation of how the suggested horizontal approach will account for the identified gaps.

Identified gaps	Horizontal approach	Comments
<b>1. Limited consumer product regulation</b>		
In general very few chemical requirements	Expansion of the ERP Directive to include generic and specific chemical restrictions for all products.	An expansion of the ERP Directive to cover all products and to cover chemical requirements will ensure that more chemical requirements are set for more consumer products. A general demand about setting chemical requirements in this framework Directive will hopefully ensure that chemical requirements are set in the different sub-regulations for each product group.
Use of weak phrases instead of specific limit values	Expansion of the ERP Directive to include generic and specific chemical restrictions for all products.	When more chemical requirements are set (with exact limit values/restrictions), the use of weak phrases will be unnecessary.
Only a small number of products/chemicals covered by regulations	Expansion of the ERP Directive to include generic and specific chemical restrictions for all products.	An expansion of the ERP Directive to cover all products will hopefully ensure that more chemical requirements are set in different sub-regulations for more consumer product groups in the future.
Multiple exposures not considered in all cases	The approach for chemical restrictions may rely on positive lists, negative lists, or a combination of both.  The generic approach should be based on the definition of SVHCs in REACH and maybe further categories of chemicals should be included (sensitizing or toxic substances).	The use of positive lists seems to be the right way to restrict chemicals – at least seen from an idealistic health perspective – especially when the toxicological profile of all 140,000 chemicals in use today is not known (reversing the burden of proof).  However, positive lists are difficult to implement right now – because of lack of data. Therefore, a combination of positive lists and a general restriction of SVHC substances (and perhaps other groups of substances), i.e. a negative list with concentration limit values seems to be the best solution at the moment.
Cocktail effects not considered	General concentration limit should be set at 0.1%.  In some cases it may be relevant to set limit-requirements based on migration or emission levels instead of content.	
Nanosubstances currently not regulated	It should be possible to allow for exemptions for certain substances in certain consumer products. In contrast it should also be possible to establish more specific chemical requirements in special cases. A risk assessment could be carried out or an extra uncertainty/safety factor could be used.	Use of an extra uncertainty/safety factor could be used to account for the combination effects or for multiple exposures.
<b>2. Limitations in the regulatory frame</b>		
Lack of comitology procedure for setting or	The legal framework should include a comitology procedure.	This is suggested as a part of the expansion of the ERP Directive. This is a necessary feature to

Identified gaps	Horizontal approach	Comments
changing chemical requirements		ensure that new chemical requirement or changes to existing limit values can happen more quickly.
<b>Business controlled standard bodies</b> do not set (strict) chemical requirements	Expansion of the ERP Directive to include generic and specific chemical restrictions for all products.	In this way the chemical requirements are set by legislators and not in the business controlled standard bodies.
<b>Insufficient market surveillance</b> of consumer products	Establishment of a more efficient surveillance system including random tests and control measurements.  The random tests carried out by authorities should give feedback to the process of establishing limit values for special chemical substances for special consumer products.	To ensure a better market surveillance and a better knowledge about chemicals in consumer products for legislators, authorities and industry.  And to ensure that the knowledge is used to set “correct” chemical requirements.
<b>Ad hoc</b> based regulation	Systematic assessment of occurrence of chemicals in consumer products should be carried out.	This will ensure a higher level of knowledge about chemicals in consumer products and hopefully result in a more proactive approach towards setting chemical requirements in consumer products.
<b>3. Lack of information on chemicals in consumer products</b>		
<b>Lack of information</b> on chemicals in consumer products	A product declaration scheme should be introduced for all consumer products.	This would help create the necessary information for the systematic assessment of occurrence of chemicals in consumer products.

To conclude, the results of this project do not change the horizontal approach suggested in the previous report (Chemical requirements Part I). It is only necessary to specify that the comitology procedure of course should be able to allow for setting new chemical requirements as well as changing the existing chemical requirements.

## 7 References

4MSR, 2008. "Feasibility of developing and implementing common approval and certification practices within Europe for products in contact with water intended for human consumption". Report of the Review Group, April 2008.

<http://www.dwi.gov.uk/drinking-water-products/faqs/group.pdf>

ANEC paper, 2008. "Consumer relevant eco-design labeling and installation requirements for dedicated water heaters". 2008. X/51/2008 - 14/08/08 ANEC-PT-2008-EuP-020final

ANEC Position Paper, 2008. "Communication from the European Commission 'Towards an increased contribution from standardisation to innovation in Europe'". COM(2008) 133 final. 20 May 2008. ANEC-GA-2008-G-019.

<http://www.anec.org/attachments/ANEC%20position%20paper.pdf>

ANEC, 2010. "Revision of the Gas Appliances Directive: key issues from a consumer perspective". 2010. ANEC-DOMAP-2010-G-034final

ANEC-ECOS, 2005. "ANEC-ECOS Position Paper on the revised Packaging Standards prepared under the second Standardisation Mandate M317". ANEC2005/ENV/001. Brussels, January 2005.

[http://www.ecostandard.org/downloads/a/anec & ecos on revised packaging standards jan 2005.pdf](http://www.ecostandard.org/downloads/a/anec_%20ecos_on_revised_packaging_standards_jan_2005.pdf)

Begley, FDA CFSAN. "Migration of Perfluorochemicals from Food Contact Materials". Tim Begley, Office of Regulatory Science, Center for Food Safety and Applied Nutrition, Food and Drug Administration. *Not dated*.

[http://www.bfr.bund.de/cm/232/migration\\_of\\_perfluorchemicals\\_from\\_food\\_contact\\_materials.pdf](http://www.bfr.bund.de/cm/232/migration_of_perfluorchemicals_from_food_contact_materials.pdf)

BfR, 2006. Printing inks in foods: Health assessment not possible owing to lack of data. 06/2006. 01.03.2006. <http://www.bfr.bund.de/cd/7486>

BfR, 2010. Food packaging from recycled materials must be safe. 15/2010. 03.11.2010. <http://www.bfr.bund.de/cd/52838>

CEN/TR 13695-2, 2004. "Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging, and their release into the environment – Part 2: Requirements for measuring and verifying dangerous substances present in packaging and their release into the environment".

CLC/TC 61, 2007. Proposal of the German National Committee for an amendment to EN 60335-2-15:2002 + A1: 2005 – Particular requirements for appliances for heating liquids. CLC/TC 61/DE0605/INF, October 2007. CENELEC (European Committee for Electrotechnical Standardization).

CR 13695-1, 2000. "Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging, and their release into the environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging".

DG Health and Consumers, 2011. Food Contact Material - Legislative List. EU website of DG Health and Consumers, Food and Feed Safety, 2011.

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl\\_list\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm)

Directive 2009/142/EC of 30 November 2009 relating to appliances burning gaseous fuels.

Directive 2009/105/EC of 16 September 2009 relating to simple pressure vessels.

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:264:0012:0029:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:264:0012:0029:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:264:0012:0029:EN:PDF)

Directive 2008/98/EC of 19 November 2008 on waste and repealing certain Directives. [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:EN:PDF)

Directive 2007/46/EC of September 2007 on establishing a framework for the approval of motor vehicles and their intended trailers, and of systems, components and separate technical units intended for such vehicles. [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:263:0001:0160:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:263:0001:0160:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:263:0001:0160:EN:PDF)

Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose films intended to come into contact with foodstuffs.

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:172:0071:0082:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:172:0071:0082:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:172:0071:0082:EN:PDF)

Directive 2007/23/EC of 23 May 2007 on the placing on the market of pyrotechnic articles.

Directive 2006/95/EC of 12 December 2006 relating to electrical equipment designed for use within certain voltage limits. [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:374:0010:0019:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:374:0010:0019:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:374:0010:0019:EN:PDF)

Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:220:0018:0058:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:220:0018:0058:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:220:0018:0058:EN:PDF)

Directive 1999/5/EC of 9 March 1999 on radio equipment and telecommunication terminal equipment and the mutual recognition of their conformity. [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:091:0010:0028:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:091:0010:0028:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:091:0010:0028:EN:PDF)

Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1994L0062:20090420:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1994L0062:20090420:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1994L0062:20090420:EN:PDF)

Directive 94/25/EC of 16 June 1994 relating to recreational craft.

Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.

Directive 74/60/EEC relating to the interior fittings of motor vehicles.

DWI, 2010. "What is the progress with European testing and approval of drinking water construction products?". Frequently Asked Questions 15, Version 3a - January 2010. UK Drinking Water Inspectorate. <http://www.dwi.gov.uk/drinking-water-products/faqs/FAQ15.pdf>

EN 30-1-1, 2008. "Domestic cooking appliances burning gas - Part 1-1: Safety - General".

EN 30-1-2, 1999. "Domestic cooking appliances burning gas - Part 1-2: Safety - Appliances having forced-convection ovens and/or grills".

EN 89, 1999: "Gas-fired storage water heaters for the production of domestic hot water".

EN 549, 1994: "Rubber materials for seals and diaphragms for gas appliances and gas equipment".

EN ISO 4074, 2002: "Natural latex rubber condoms - Requirements and test methods".

EN ISO 6185-1, 2001: "Inflatable boats - Part 1: Boats with a maximum motor power rating of 4.5 kW".

EN ISO 10993-1, 2009: "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

EN ISO 10993-3, 2009: "Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity".

EN ISO 10993-07, 2008: "Biological evaluation of medical devices - Ethylene oxide sterilization residuals".

EN ISO 10993-10, 2010: "Biological evaluation of medical devices - Tests for irritation and skin sensitization".

EN ISO 10993-17, 2009: “Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances”.

EN ISO 14607, 2009: “Non-active surgical implants – Mammary implants.

EN 13427, 2004. “Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste”.

EN 13428, 2004. “Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction”.

EN 13429, 2004. “Packaging – Reuse”.

EN 13430, 2004. “Packaging - Requirements for packaging recoverable by material recycling”.

EN 13431, 2004. “Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value”.

EN 13432, 2000. “Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging”. September 2000.

EN 15947-5, 2010. “Pyrotechnic articles – Fireworks, Categories 1, 2 and 3 – Part 5: Requirement for construction and performance”.

EN 50497, 2009. “Recommended test method for assessment of the risk of plasticizer exudation from PVC insulated and sheathed cables”. Edition 2009-01-01.

EN 60335-1 Household and similar electrical appliances – Safety – Part 1: General requirements. Edition 4.2, 2006-09.

EN 60335-2-8:2002 Household and similar electrical appliances - Safety ~ Part 2-8: Particular requirements for shavers, hair clippers and similar appliances IEC 60335-2-8:2002 (Modified). Edition: 2009-07-01.

EN 60335-2-15:2002 Household and similar electrical appliances - Safety ~ Part 2-15: Particular requirements for appliances for heating liquids IEC 60335-2-15:2002. Edition: 2009-06-01.

EN 60335-2-21:2002 Household and similar electrical appliances - Safety ~ Part 2-21: Particular requirements for storage water heaters IEC 60335-2-21:2002 (Modified). Edition: 2009-08-01.

EN 60335-2-23:2003 Household and similar electrical appliances - Safety ~ Part 2-23: Particular requirements for appliances for skin or hair care IEC 60335-2-23:2003. Edition: 2009-03-01.

European Parliament, 2010. “European Parliament resolution of 21 October 2010 on the future of European Standardisation”. Procedure 2010/2051(INI). P7\_TA-PROV(2010)0384. <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0384+0+DOC+XML+V0//EN>

Foodprocessing-Technology.com, 2011. Definition found at <http://www.foodprocessing-technology.com/glossary/organoleptic.html>.

FORCE Technology, 2010. "Chemical requirements for consumer products – Proposals for regulatory measures to improve chemical safety for consumers". Study commissioned by: The Consumer Council at the Austrian Standards Institute and funded by the Austrian Ministry for Labour, Social Affairs and Consumer Protection.

Hübner, C. and Boos, R. 1998. "Emissions of Oil and Gas Appliances and Requirements in European Standards. For Austrian Standards Institute Consumer Council.

Regulation (EU) No 10/2011 of the 14 January 2011 on plastic materials and articles intended to come into contact with food. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>

Regulation (EC) 661/2009 of 13 July 2009 concerning type approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefore. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:200:0001:0024:EN:PDF>

Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:135:0003:0011:EN:PDF>

Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:086:0009:0018:EN:PDF>

Regulation (EC) No 372/2007 of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:092:0009:0012:EN:PDF>

Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:302:0028:0032:EN:PDF>

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R1935:20090807:EN:PDF>