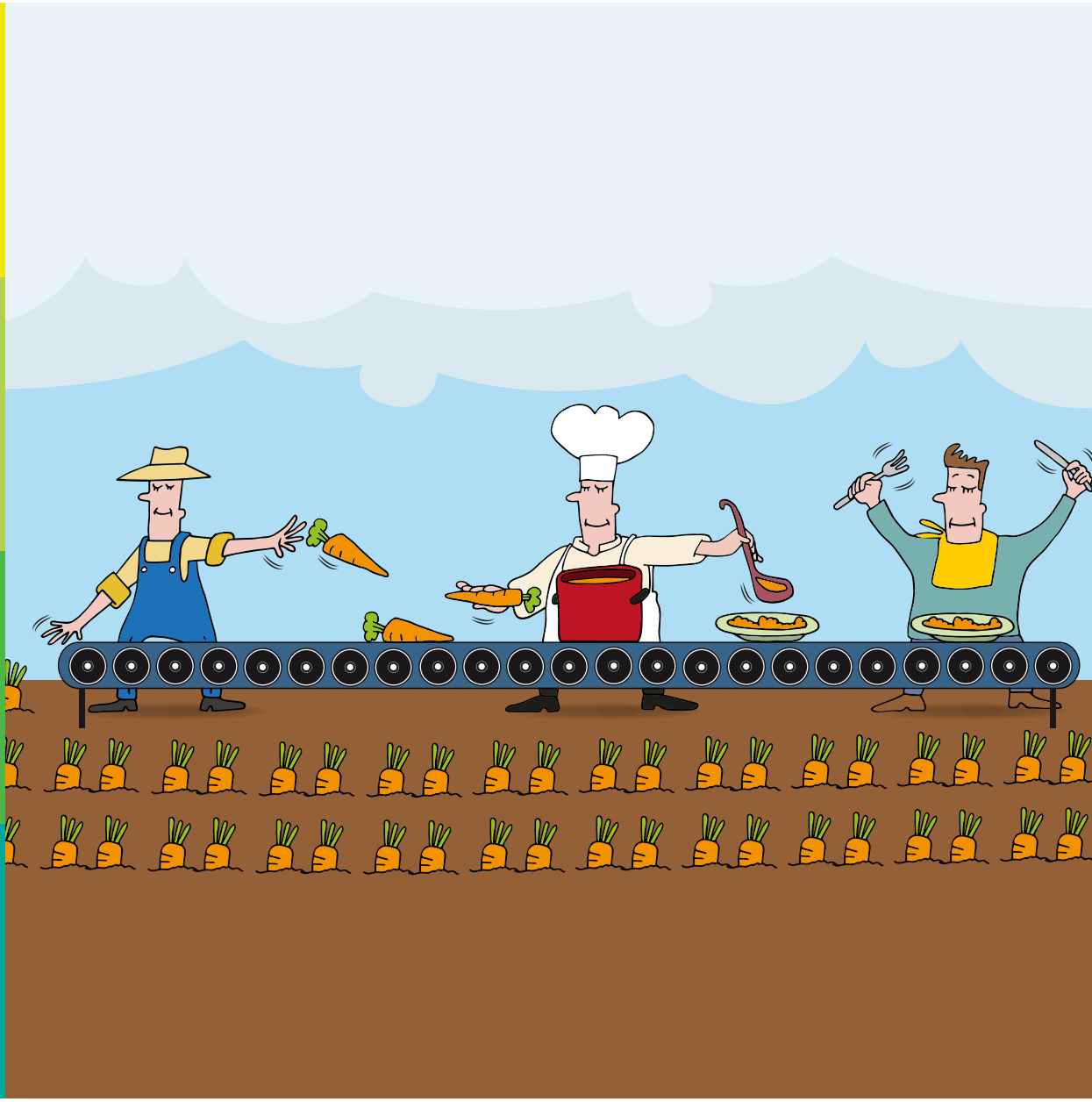
Food contact materials

Report

Common materials and their health concerns, EU legislation and recommendations towards a safer legislation



Swedish Society
for Nature Conservation

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Introduction

The aim of this report is to give a brief overview of the most common materials used in food contact, including known or potential problems, as well as current legislation within EU.

Food contact materials (FCM) are defined as all materials that are used to make food contact articles (FCA), thus *intended* to be into contact with food, such as packaging and containers, kitchen equipment, cutlery, and dishes. It also includes the equipment used for preparation and packaging of food (Regulation (EC) No 1935/2004; Geuke et al. 2014). These food contact articles can be made from a variety of materials, including glass, metal, paper, and plastics, as well as adhesives, coatings and printing inks (Simoneau 2008; EFSA 2019a), see Figure 1 for an example. The framework regulation specifies that chemicals migrating from FCM should not endanger human health at the levels present in food. However, chemicals known to be hazardous for human health are despite that allowed according to the FCM legislation. A review of the European regulation is currently ongoing (2019-2020) and welcomed by many health and environmental organisations.

Several factors can influence the migration, such as chemical properties of the material Properties of the food, e.g. fat content, acidity, and temperature, are also significant for migration. Fatty, acidic, and hot food often increases the migration from the materials. Migration can occur throughout the whole production and usage chain from farm to fork, i.e. also during food processing (Arvanitoyannis and Bosnea 2004; Livsmedelsverket 2019). Migration from food contact articles to food is considered to be a highly relevant source of chemical contamination in food, hence a considerable route for chronic human exposure to foreign substances (Geueke and Muncke 2018) and a relevant area for robust legislation to protect human health.

The available information about migration from specific materials differ as far from all chemical substances that are used in FCM have been studied. Hence it is difficult to give an overall picture. There is also a knowledge gap between the final products (what we use) and the investigated chemical substances that comprise the main part of the products. Research is often conducted on one substance at a time and not on the mixture of substances found in the final product. Also, only intentionally added substances, and known reaction products are analysed for, while non-intended added substances (NIAS) and side products goes under the radar. The lack of information about what migrates from FCM to food is one of the gaps in the legislation making it difficult to fulfil the aim of protecting human health.

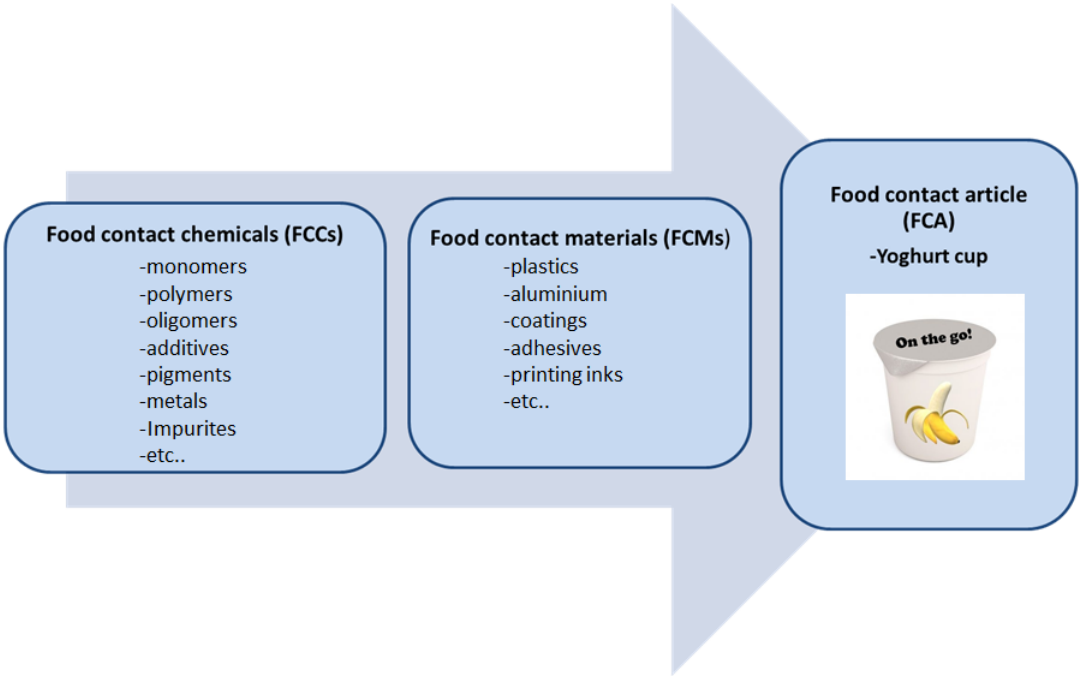


Figure 1. Illustration showing the key terms of Food contact materials (FCM). Food contact articles (FCAs), here shown as a yogurt cup, are comprised of combinations of different Food contact materials (FCMs), which consist of food contact chemicals (FCCs). Some FCCs are generated during manufacture of an FCM/FCA and some FCCs are starting substances that no longer exist in the FCM/FCA. Not all FCCs require an authorisation, and many are not subject to risk assessment (based on figure in Muncke et al. 2017).

Food contact material legislation

The legislation for food contact materials, regulates materials and articles intended or likely to be in contact with food and applies to everything from packaging, kitchenware, tableware to process machinery and farm equipment. The framework regulation, Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come in contact with food, is broad and quite general, with additional regulations on some specific materials and chemicals, as well as national regulations on non-harmonised materials (see Table 1). The main purpose of the legislation is to protect human health.

All FCMs must be manufactured in accordance with good manufacturing practice (GMP) as laid down in Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food. FCMs must be compliant with the rules laid down in the FCM legislation. This is stated in the declaration of compliance (DoC), where appropriate tests and the results thereof are reported. It is the responsibility of the business operator to provide the DoC to the next actor in the supply chain.

The European Food Safety Authority (EFSA) is responsible for the risk assessment of food contact materials and substances. The risk assessment is based on toxicological and exposure data. The European Commission (EC) is responsible for the risk management, i.e. authorisation and specific measures or conditions for the usage of substances or materials. The EC has issued authorisation for substances used in plastic FCMs, regenerated cellulose and active and intelligent materials. Some Member States have additional lists of authorised substances for the other FCMs (see table 1) (Simoneau et al. 2016).

Extract from Regulation (EC) No 1935/2004:

Article 1

Purpose and subject matter

1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

Article 3

General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
(a) endanger human health; or
(b) bring about an unacceptable change in the composition of the food; or
(c) bring about a deterioration in the organoleptic characteristics thereof.
2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Current FCM-legislations within EU

General legislation on food contact materials:

- Regulation (EC) No 1935/2004 – The framework regulation for all food contact materials
- Commission Regulation (EC) No 2023/2006 – On good manufacturing practice

Legislation of specific materials:

- Commission Regulation (EC) No 450/2009 – On active and intelligent materials and articles
- Commission Regulation (EU) No 10/2011 – On food contact plastics
- Commission Regulation (EU) 2015/1906 – On recycled plastic materials and articles
- Commission Directive 2007/42/EU – On materials and articles made of regenerated cellulose film
- Council Directive 84/500/EEC – An approximation of the laws of EU member states on ceramic articles

Legislation of specific substances:

- Commission Regulation (EU) 2018/213 – On the use of bisphenol A in varnishes and coatings
- Commission Regulation (EC) No 1895/2005 – On the use of certain epoxy derivatives
- Commission Directive 93/11/EEC – On the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers

Other legislations:

- Commission Regulation (EU) No 284/2011 – On import rules for kitchenware made of melamine or polyamine originating or cosigned from China or Hong Kong

National regulation:

- In the FCM regulation, 18 different types of materials are specified. Of them, five material types have harmonised EU-regulation, while the other 13 may have national regulation in one or more countries, see table 1 and table 4.

In-house control

Every operator in the supply chain (i.e. producer, user or trader of FCM, including raw materials/chemicals or intermediates, as well as retailers) must comply with the FCM legal requirements. In-house control is the systematic measures taken to ensure that this is fulfilled. Two important pieces of the in-house control are good manufacturing practice (GMP) and declaration of compliance (DoC).

Good manufacturing practice

The production of food contact materials and intermediates must follow good manufacturing practice, GMP, as laid down in Commission Regulation (EC) No 2023/2006. In short, GMP aims to ensure that all materials are managed in agreement with the rules and quality standards applicable for the specific material, considering the intended use. As a minimum it must be ensured that production is consistent over time and verified regularly, that staff is trained for assigned tasks, that hazard analyses are done and that all of this is well documented. In practice, quality assurance systems (QA) and quality control systems (QC) are required. This corresponds to an ISO 9000 Quality Management System.

Table 1. An overview of specified material types in the FCM-regulation.

Materials with EU-regulation	**Materials without EU-harmonised regulation, may have national regulation(s)**
Active and intelligent materials	Adhesives
Ceramics	Cork
Plastics	Elastomers and rubbers
Recycled plastics	Glass
Regenerated cellulose film	Ion exchange resins
	Metal and alloys
	Paper and board
	Printing inks
	Silicones
	Textiles
	Varnishes and coatings
	Waxes
	Wood

Declaration of compliance
Any operator trading FCM or intermediates must supply a declaration of compliance (DoC) document. The DoC states that the FCM complies with the regulations in relation to the intended use. In the supporting documentation to the DoC, details like analytic methods and detection limits are stated.

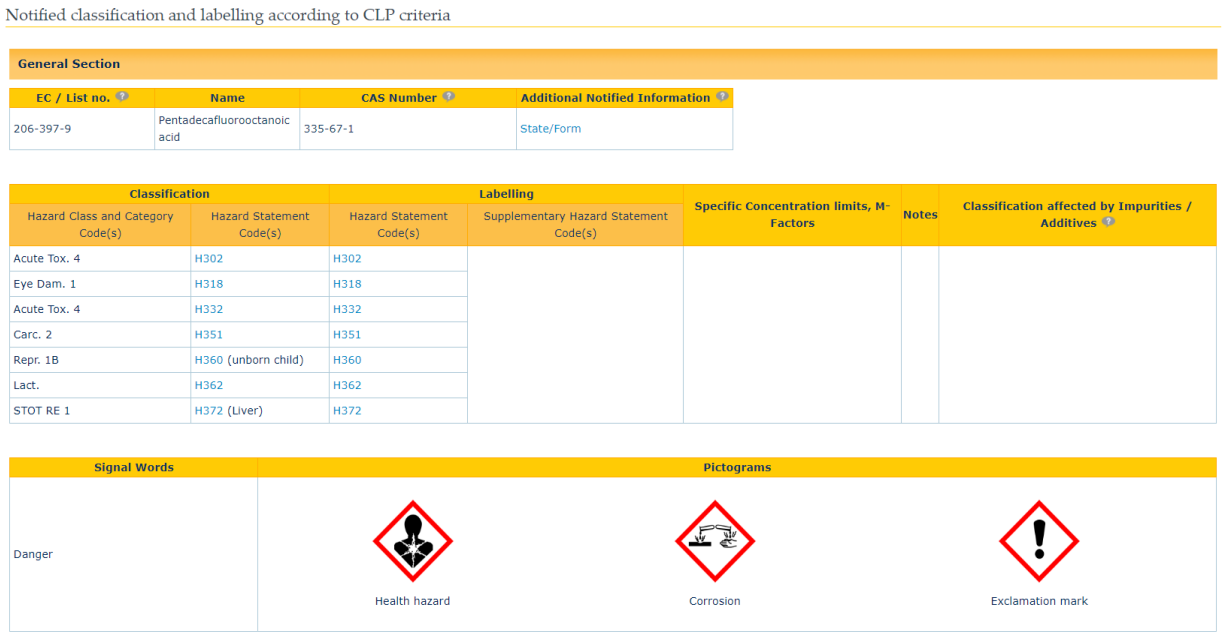
Operators using suppliers for FCM (or intermediates) must make sure that all suppliers and sub suppliers throughout the supply chain have followed GMP and provided sufficient DoC documentation. This means that all operators, importers and retailers need a systematic approach to supplier control. This may include sufficient knowledge of FCM legislation, GMP and test conditions to evaluate the reliability of the enclosed DoCs.

Relation to CLP and REACH

The FCM legislation is built on, and refers to, but is not completely harmonised with other regulations within the EU, i.e. classification and labelling of products (CLP) and the EU legislation for chemicals and mixtures, REACH. Any shortcomings in these regulations will also affect the safety of food contact materials.

CLP

Classification and labelling of products (CLP), is a central piece of regulation of chemicals within the EU legislation. Depending on the classification of a chemical or a mixture, different pieces of regulations will come into force. For example, if a chemical is classified as cancerogenic to humans, the usage will be regulated in various legislation from 'Occupational safety and health legislation' to 'Toy directive'. All chemicals and mixtures managed within the EU must be evaluated and classified according to the findings. The Hazardous Statement Codes show how hazardous a chemical is - for the hazards that have been evaluated, see figure 2.



Notified classification and labelling according to CLP criteria

General Section

EC / List no.	Name	CAS Number	Additional Notified Information
206-397-9	Pentadecafluorooctanoic acid	335-67-1	State/Form

Classification		Labelling		Specific Concentration limits, M-Factors	Notes	Classification affected by Impurities / Additives
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)			
Acute Tox. 4	H302	H302				
Eye Dam. 1	H318	H318				
Acute Tox. 4	H332	H332				
Carc. 2	H351	H351				
Repr. 1B	H360 (unborn child)	H360				
Lact.	H362	H362				
STOT RE 1	H372 (Liver)	H372				

Signal Words	Pictograms
Danger	Health hazard, Corrosion, Exclamation mark

Figure 2. Information on the substance PFOA in the C&L-database.

Unfortunately, the evaluation required is minimal and a literature search made by the producing company is enough, even though no analysis/evaluation data is found in the search. Because of this, most chemicals have one or more classification lines with 'data lacking' (see figure 3), meaning that no one knows if the chemical has that hazard or not.

According to ECHAs manual on How to prepare a classification and labelling notification (ECHA 2019), 'no classification' can be derived from one of three reasons:

- 'Data lacking', meaning that there is not enough adequate and reliable information to decide if the substance is a hazard or not.
- 'Inconclusive', meaning that there is information, but not reliable, or if the information is contradictory.
- 'Conclusive but not sufficient for classification', meaning that there is adequate and reliable information that does not fulfil the criteria for classification, or by other words, that is safe.

Therefore, it is of importance to dig into the classification files and look for the reason for 'no classification'.

Human Health hazards			
	Hazard Category	Hazard Statement	Reason for no Classification
Acute Toxicity - Oral	Acute Tox. 4	H302	
Acute Toxicity - Dermal			data lacking
Acute Toxicity - Inhalation	Acute Tox. 4	H332	
Skin Corrosion / Irritation			data lacking
Serious Eye Damage / Eye Irritation	Eye Dam. 1	H318	
Respiratory Sensitisation			data lacking
Skin Sensitisation			data lacking
Aspiration Hazard			conclusive but not sufficient for classification
Germ Cell Mutagenicity	Hazard Category	Hazard Statement	Reason for no Classification
Germ Cell Mutagenicity			data lacking
Carcinogenicity	Hazard Category	Hazard Statement	Reason for no Classification
Carcinogenicity	Carc. 2	H351	
Reproductive Toxicity	Hazard Category	Hazard Statement	Reason for no Classification
Reproductive Toxicity	Repr. 1B	H360	
Specific Effect	unborn child		
Effects on or via Lactation	Lact.	H362	
Specific target organ toxicity - Single	Hazard Category	Hazard Statement	Reason for no Classification
Specific target organ toxicity - Single			conclusive but not sufficient for classification
Specific target organ toxicity - Repeated	Hazard Category	Hazard Statement	Reason for no Classification
Specific target organ toxicity - Repeated	STOT RE 1	H372	
Affected Organs	Liver		

Environmental Hazards			
Hazardous to the aquatic environment	Hazard Category	Hazard Statement	Reason for no Classification
Hazardous to the aquatic environment - acute			data lacking
Hazardous to the aquatic environment - chronic			data lacking
Hazardous to the atmospheric environment	Hazard Category	Hazard Statement	Reason for no Classification
Hazardous to the ozone layer			data lacking

Figure 3. Classification according to CLP for PFOA from a joint notification. As can be seen, there are several hazardous that do not have sufficient data for classification, meaning that it is unknown if the substance possesses these hazards or not.

REACH

REACH, an acronym for Registration, Evaluation, Authorisation of Chemicals, is the EU legislation for chemicals and mixtures used within EU, either they are produced within the EU or imported. The main aim with the legislation is to protect human health and the environment but also to have an overview over the chemicals used within the EU. All chemicals produced or imported in quantities over 1 tonne per legal entity and year must be registered.

If a chemical is found to have unacceptable effects on human health or the environment, its usage needs to be limited. The limitation can lead to the chemical being forbidden in certain product types or only allowed with limits (restriction) or allowed but only for certain applications (authorisation).

Candidate list

The first step in the limitation chain is to identify Substances of very high concern (SVHC) and include them on the Candidate list. It is the member states or ECHA (at the request of the European Commission) that proposes a substance to be identified as a SVHC-substance. In the proposal, a dossier is submitted including the data and justification that the substance is a SVHC-substances i.e. is known or presumed to be a human carcinogen, mutagen or reproductive toxicant (CMR), or persistent, bioaccumulating and toxic (PBT), or very persistent and very bioaccumulating (vP/vB), or having an equivalent level of concern.

In Article 57 of the REACH Regulation, criteria are laid down to identify substances of very high concern (SVHCs):

- CMR cat 1A[1] and 1B[2] (article 57 a-c, criteria defined in the CLP Regulation)
- PBT/vPvB substances (article 57(d-e), criteria defined in Annex XIII of REACH)
- Substances of equivalent level of concern to CMR or PBT (article 57(f))

When a substance is on the candidate list, the manufacturer, as well as all companies in the supply chain, must pass on the information on the substance name and how to handle and dispose of the product in a safe way. Also, the consumers have the **right to know**, within 45 days after requesting, if a product contains any Candidate listed substance above 0,1 weight %.

Authorisation

It is ECHA (the European Chemical Agency) that evaluates the substances on the Candidate list and suggest further legal actions, i.e. authorisation based on the dossier submitted when the substance was proposed for the Candidate list. ECHA finalises the recommendation, considering the member state committees' opinion and the comments received during the consultation. The recommendation is then submitted by ECHA to the European Commission. The European Commission decides if the substances are to be included in the Authorisation List (Annex XIV of REACH). Companies that want to continue using a substance on the authorisation list after the sunset date (the latest date from which the placing on the market and use of a substance is prohibited) needs a granted authorisation. In the authorisation process, the ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) give their opinion on the risk versus the socio-economic effects of granting the authorisation compared to using alternatives. When the substance has been turned into a material or an article, no authorisation is needed. Materials and articles made outside the EU do not need a granted authorisation to use a substance on the Authorisation list.

Restriction

Substances on the Restriction list are not allowed in materials or articles above a certain concentration limit (Annex XVII of REACH). This applies to both EU-made and imported articles. A member states or ECHA (alone or at the request of the European Commission) and the EC can also start the restriction procedure when there are concerns of an unacceptable risk to human health or the environment. ECHA can also propose the same of substances already on the authorisation list. The dossier proposing the restriction contains background information such justifications for the proposed restrictions including the identified risks, any information on alternatives to the substance and the costs, as well as the environmental and human health benefits, resulting from the restriction. The dossier is made public for consultation and ECHA's Committee for Risk Assessment (RAC) will give its opinion. In parallel the Committee for Socio-economic Analysis (SEAC) prepares an opinion about the socio-economic impacts of the suggested restrictions. The Commission will then take a balanced view based on the two committee's opinion of benefits and costs of the proposed restriction.

[1] **Category 1A**: Known human carcinogen (H340), mutagen (H350) or reproductive toxicant (H360) based on human evidence

[2] **Category 1B**: Presumed human carcinogen (H340), mutagen (H350) or reproductive toxicant (H360) based on animal studies

The final decision is taken in a comitology procedure by the Member States and the European Parliament. Once the restriction has been adopted, industry must comply, including all manufacturers, importers, distributors, downstream users, and retailers.

Each substance authorisation or restriction evaluation takes up to a few years, hence one of the reasons why many substances on the list still awaits evaluation and further legal action. Information of which substances that are evaluated, or are awaiting evaluation, can be found on ECHAs webpage “information of chemicals”.

Food contact materials with EU-regulation

This section contains a short review on the five materials with EU-harmonised regulation (table 1), their usage, current regulations and possible health or environmental effects.

Active and intelligent materials

There are many types of active and intelligent materials and articles. Active and intelligent materials in food packaging are being developed to offer solutions for extending the shelf-life, improve and monitor food quality.

Active and intelligent food packaging are based on deliberate interactions with the food or the food environment contrary to traditional food packaging. Intelligent and active packaging products are not yet widespread in the food market but are under development and research and have the potential to reduce food waste. Active packaging is the component that takes some action, while intelligent packaging is the component that gathers and shares information.

Applications in FCM

Active materials in packaging intent to prolong the shelf life of a food product. They can be placed inside the packaging or be incorporated in the packaging materials. Oxygen absorbers is a known example, mostly based on iron oxidation but they can also be based on ascorbic acid or catechol oxidation, on enzymatic catalysis as well as on many other reactions. There are also moisture absorbers, mostly based on the adsorption of water by a zeolite, cellulose, and their derivatives etc. Another example is the use of sulphur dioxide releaser packaging for preserving grapes from mould development.

Different from active packaging, intelligent materials do not act to extend the shelf life of the food but rather monitor the quality status of a food product and communicate the conditions (to manufacturers, retailers, and consumers). One example is time temperature indicators (TTIs) that show the accumulated time and temperature history of a product. They can use e.g. enzymatic, photochemical, or microbiological principles as indicators. There are also examples of pathogen indicators, freshness indicators amongst others (Müller & Schmid 2019, Ghaani et al. 2016).

Extract from Commission Regulation (EC) No 450/2009:

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(a) 'active materials and articles' means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of 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;
(b) 'intelligent materials and articles' means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

Regulation
In the Commission Regulation (EC) No 450/2009 it is the substance responsible for the active or intelligent function that is regulated.

Health concerns
There are health concerns that include consumers ingesting sachets or other active/intelligent materials by mistake (Dainelli et al. 2008). There is also a concern about potential migration of materials from active packaging systems, the risks associated with unintended release or contact of certain substances and materials, including intelligent packaging, especially when positioned inside the primary packaging. (Ghaani et al. 2016; Dainelli et al. 2008).

Nanoparticles, such as nano silver are sometimes used in active packaging as antimicrobials. Results from studies show a low level of migration of nano silver to food. The migration of nano silver can be influenced by food composition, pH and temperatures. It is complicated and time consuming to determine the migration into real foodstuffs. The current knowledge of the effects on human health and the environment is limited and there is a need for better detection methods to determine the likelihood of migration that are adapted to active/intelligent packaging (Kuorwel et al. 2015).

Other health concerns include lower efficiency than expected of the packaging. If the materials are not performing the claimed function such as delivering antimicrobial or absorbing oxygen or not giving reliable information about bacteria presence there is a risk of consuming food that is not safe (Dainelli et al. 2008)

Ceramics

Ceramics, porcelain, pottery, earthenware, terracotta, stoneware, fine china, bone china, paper clay are various types of clay bodies, and each one has its own unique characteristics and uses. Ceramic is a general term that describes any article made of natural clay, mixed in various formulas with water and sometimes organic materials, shaped, decorated, usually glazed, and hardened by heat. The composition of the clays used, type of additives, firing temperature and duration determine the quality and the hardness of the end product. Because these variables can be widely adjusted, there are many different types of ceramic. Porcelain is a combination of clay, kaolin primary clay known for its translucency), feldspar, silica, and quartz, but other materials may be added. It is known for its white clay body used in making functional and non-functional pieces. It is traditionally fired at high fire temperatures above 1260°C (2300°F) a process that verifies the clay creating a non-absorbent surface, that are smooth, even when unglazed. The most significant identifying factor for porcelain is its translucence. Porcelain after firing becomes very white and translucent, allowing light to show through it. All other ceramics are opaque and do not transmit light

Applications in FCM
Ceramics used as food contact articles include pottery, tableware, and cooking ware. Porcelain is a common material in tableware.

Regulation

The Council Directive 84/500/EEC sets out limits for migration of lead and cadmium from the final product. This means that only intact articles are guaranteed by the regulation, and caution should be taken if the surface glaze is chapped and the underlying ceramic is exposed.

Extract from Council Directive 84/500/EEC:

Article 1:3

'Ceramic articles' means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

Article 2:4

A ceramic article shall be recognized as satisfying the requirements of this Directive if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Annexes I and II do not exceed the following limits:

- *Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm; Pb: 0,8 mg/dm2; Cd: 0,07 mg/dm2*
- *Category 2: All other articles which can be filled; Pb: 4,0 mg/l; Cd: 1,5 mg/l*
- *Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three litres; Pb: 0,3 mg/1; Cd: 0,1 mg/1*

Member states have noted that the existing migration limits for cadmium and lead do not provide a sufficient protection of exposure for consumers according to new scientific advice. The new scientific evidence state that negative health effects occur below levels currently set out in the Directive. The European Commission therefore recently published a roadmap outlining an initiative to lower migration limits for lead, cadmium and other heavy metals in ceramic, glass, and enamelled food contact materials.

Health concerns

The main concern with ceramics in contact with food are heavy metals that have been allocated in the clay or in the glazing, and that may migrate into the food. As in other materials pH, temperature and fat content may increase the risk of migration of these substances into the food. Low pH has been shown to increase the migration rate of lead and cadmium (Sheets 1999; Demont et al. 2012). According to EFSA there is no evidence for a lead threshold for negative health effects and can therefore be considered toxic at any dose. The observed negative health effects include developmental neurotoxicity (lower intelligence quotient) for which there are no safe doses and neurotoxicity in adults as well as cardiovascular effects (EFSA 2012a). Long-term exposure of cadmium can cause kidney failure and is associated with an increased risk for cancer (EFSA 2012b).

Besides of the well-studied lead and cadmium, migration of other toxic and non-toxic elements such as aluminium, boron, barium, cobalt, chrome, copper, iron, lithium, magnesium, manganese, nickel, antimony, tin, strontium, titanium, vanadium, zinc and zirconium may be a potential health hazard. A study by Demont et al. (2012) showed that both the pH ($2 < pH < 3$) but also the nature of the acid plays an important role in the migration of metals. For example, citric and malic acid seems to be more aggressive to the glaze than acetic acid except for aluminium, barium, chromium, iron and magnesium. Increasing temperature also seem to increase the migration of metals (Demont et al. 2012). When using ceramics as FCM it is important to only use products that are made for food, decorative ceramic plates have shown an even higher migration rate and a proper label regarding permissible use with food should be included.

Plastics

Plastics are a collective name for all kind of human made polymer materials. The most common plastics used in the EU are polypropylene (PP), polyethylene (PE) in various forms from low density to high density (LLDPE, LDPE, MDPE, HDPE), polyvinyl chloride (PVC), polyurethane (PUR), polyethylene terephthalate (PET) and polystyrene, common and expanded (PS, EPS).

Plastics can be made from both fossil raw materials, which is by far the most common today, and from renewable raw materials. Production from crude oil is cheaper than the equivalent for renewable raw material. However, prices of plastic from renewable raw materials will probably decrease as innovations and efficiency improvements are made.

The packaging sector has the highest share of plastics consumption in the European market of plastics with 40% in 2018 (Plastics Europe 2019). The food packaging market has the highest share of conventional packaging material from fossil raw material (non-biodegradable) (Briassoulis & Giannoulis 2018).

Regardless of the origin of the raw material, the same type of plastic may be produced. One example is polyethylene (PE) that can either be made from crude oil or from sugar. The end product will be the same, as can be seen on Arla's milk package from Tetrapack, where the plastic screw cap on the organic milk comes from renewable raw material and looks exactly like the plastic closure on other milk packaging. These two plastic screw caps, from different origins, but made to the same kind of plastic, can be recycled and are fully miscible with each other.

Bioplastics

The word bioplastic is not well-defined and can mean anything from biodegradable plastic or that the raw material is renewable to that the plastic is biocompatible and can be used as e.g. dentures in the body. Therefore, it is better to use the term ‘bio-based plastics’ for plastics from renewable resources and ‘biodegradable plastics’ for compostable plastics.

Bio-based plastics

A variety of bio-based plastics can be made from renewable raw materials such as maize, sugar cane and biomass (forest or agricultural raw material). Plastics made from starch or lactic acid (PLA) has long been available as bio-based alternative. Cellulose acetate and viscose, both from cellulose origin, are other common bio-based plastics. Also, plastics that are usually made from fossil oil can be made from renewable raw materials, fully or partially, such as polyethylene (bio-PE), polypropylene (bio-PP), polystyrene (bio-PS), polyvinyl chloride (bio-PVC) and polyethylene terephthalate (bio-PET). A benefit of bio-based plastics is that there will be less net emission of carbon dioxide. However, the production, i.e. from growing the biomass to manufacturing the products, is yet not fossil free but has the potential to be so. Some of the bio-based plastics are biodegradable, see table 2.

Biodegradable plastics

For plastics to be biodegradable, microorganisms must recognize the surface structure and be able to break the chemical bonds. At the end, the plastic is converted into biomass, carbon dioxide, methane, mineral salts, and water. Only certain plastic types, such as plastic from starch and lactic acid, meet these requirements and they are usually labelled with a composting symbol. However, the compostable plastics will only be fully decomposed within a reasonable timeframe in industrial composting with optimal conditions of humidity, heat, and oxygen, e.g. the municipality's facilities (Kubowicz & Booth 2017). In nature or in water, the decomposition takes much longer and during the breakdown process micro- and nanoplastics intermediates are formed.

Table 2. Bio-based plastics and plastics from fossil raw material, divided into their biodegradability.

	Non- biodegradable	Biodegradable
Plastics from fossil raw material	polyethylene (PE) polypropylene (PP) polystyrene (PS) polyvinyl chloride (PVC) polyethylene terephthalate (PET)	polycaprolactone (PCL) polybutylene adipate terephthalate (PBAT) polybutylene succinate (PBS) polyglycolic acid (PGA) polyvinyl alcohol (PVA) and polyvinylpyrrolidone (PVP)
Bio-based plastics	bio-PE bio-PP bio-PS bio-PVC bio-PET	starch based plastics polylactic acid (PLA) polyglycolic acid (PGA) polyhydroxyalkanoates (PHA)

Oxy-degradable plastics

Special substances can be added to non-biodegradable plastics which make the chemical bonds in the polymer less stable and thus easier to break. This type of plastic is called oxy-degradable plastic. The decomposition does not occur with microorganisms, but by sunlight and oxygen. A big disadvantage is that not all the polymer's bonds are broken, which results in micro-plastics that remain in the environment. The formation of microplastics makes oxy-

degradable plastics unsuitable for composting. Neither should it enter the recycling system since it will change the properties of recycled plastic in an unwanted way.

Plastics in an environmental perspective

From an environmental perspective, durable plastics should be used for a long time and then recycled, e.g. plastics used in building materials, cars, furniture and electronic products. While fully bio-degradable plastics (plastics that breaks down fully under the conditions prevailing in nature), should be used if the product, or its parts, can be predicted to end up in nature, e.g. plastics used in car tires, mulching films, clothing, fishing equipment and cosmetics.

The use of fossil raw materials results in a net emission of carbon dioxide. Approximately 8% of fossil oil is used for plastic production, of which half of it becomes the plastic itself and half is used as energy in the manufacture (UNEP 2014). Plastics should therefore be considered as bound carbon dioxide and recycled as many times as possible, in order to reduce carbon dioxide emissions from plastics.

There are several initiatives to make plastic usage more sustainable. EU launched a circular economy package in 2015 (COM (2015) 614 final), covering plastics but also food waste, critical raw materials, construction and demolition, as well as biomass and bio-based products. Global stakeholders are also contributing to a more holistic view on plastics. Two examples are the UNEP report from 2014 "Valuing Plastics: The Business Case for Measuring, Managing and Disclosing Plastic Use in Consumer Goods Industry" (UNEP 2014), and the OECD report from 2018 "Considerations and Criteria for Sustainable Plastics from a Chemical Perspective" (OECD 2018a) which is a first background paper in a series of papers. The OECD report extract three overarching set of principles:

1. ***Design systems holistically and use life cycle thinking.*** *This applies to the design of all sustainable chemicals, materials and products. Materials flow in dynamic environmental and economic systems. Waste from one product iteration becomes feedstock for another when designers 'design for circularity.'*

2. ***Maximize resource efficiency.*** *Resource efficiency is not just about being efficient and doing more with less. It includes the imperative to preserve natural capital Renewable resources should not be used faster than they can be regenerated. Resources that can be depleted should not be dissipated and lost to recovery, reuse and recycling. Waste is a sign of inefficiency in a system.*

3. ***Eliminate and minimize hazards and pollution.*** *Risk is a function of hazard and exposure. Reducing the inherent hazards of chemicals can be the most effective way to reduce risk from chemicals, materials and products. Hazards may also be physical. For example, litter is a form of unmanaged waste that can cause physical entrapment and be mistaken as food by wildlife when it leaks into the environment.*

Still national, regional, and global enforcements must be set and implemented, to actually make the plastic usage more sustainable. Some suggestions are outlined in the OECD environment working paper no 149 from 2019 "Policy approaches to incentivise sustainable plastic design" (Watkins et al. 2019). EU has enforced a single use plastic directive (Directive (EU) No. 2019/904) to be implemented by member states in 2021.

Microplastics in nature

Microplastics (<5 mm, including nano-plastics <0.1 µm) originate from the fragmentation of large plastic in the environment or from direct environmental emission in micro form. Microplastics are considered ubiquitous in the marine environment but the impact on ecosystems as well as human health is not yet fully understood. However, there is a growing body of literature reporting the negative effects on organisms in the aquatic environment (Ivleva et al. 2017; Law and Thompson 2014, Wright et al. 2013). Microplastics are also considered a threat to the terrestrial environment (de Souza Machado et al. 2018). The small size of microplastics enables organisms from different levels to ingest them. It can also accumulate at higher trophic levels. Negative effects in an organism come from the mechanical harming in gastrointestinal tracts and the leaching of substances shown to be cancerogenic, toxic or endocrine disrupting. It has also been shown that microplastic can be a vector or carrier of foreign species and potentially pathogenic microorganisms (Ivleva et al. 2017).

In a study by Swedish Food Agency on micro- and nanoplastics in tap water (Livsmedelsverket 2020) it was showed that there are more small plastic particles than larger. Four filter size were used, and the number of plastic particles in each of the four fractions (>100 µm, 100-30 µm, 30-10 µm and 10-1 µm) were identified by Raman microscopy. The mean value from six cities in Sweden are found in table 3. Notable is that plastic particles in the size between 1-10 µm were ranging from zero to 24 000 per litre water, with a mean value of 7400. No explanation was found for the big difference between in small plastic particles in tap water from the investigated cities.

Table 3. Plastic particles, of four different size ranges, found in tap water in Sweden. The numbers are mean values over the six investigated cities, with minimum and maximum numbers specified. (Table based on table 4 in Livsmedelsverket 2020.)

Plastic particle size (µm)	Plastic particles per litre tap water	Min and max values of plastic particles
>100	0,046	0,012 - 0,070
30-100	0,33	0,22 - 0,55
10-30	2,8	0,36 - 12
1-10	7400	0 - 24000

Applications in FCM

Plastics are used in a variety of food contact applications, from farm to fork, either as the only material or as a part in a multi material Plastics have many advantages, as it is easy to form, have good barrier properties to moisture and pathogens, is a cheap material and prints can be made directly on the plastic for information and marketing. Plastics are also durable and can be reused many times, for example as plates and unbreakable glassware used is school and preschool.

Regulation

The material that has the most detailed regulation within food contact material is plastics. The plastic regulation (Commission Regulation (EU) 10/2011) "sets out rules on the composition of plastic FCMs and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles". In the regulation plastic is defined as polymers, with or without additives, which can be formed into a solid structure. The regulation specifies around 1000 chemicals in the 'union list of authorised substances' that are allowed in plastics. Some of the chemicals have migration limits, or total content limits, or is only allowed for special use. In addition, salts of listed acids, phenols or alcohols are also allowed, as well as natural polymers with a molecular weight larger than 1000 Da. Not included in the list are colourants, non-intended added substances (NIAS), polymerisation aids but still used or found in the plastic product, and solvents used in the polymer production.

The overall migration limit of the sum of all plastic constituents is set to maximum 10 mg/dm^2 of food contact surface. Materials and articles intended to come in contact with food for infants and young children have an additional limit of 60 mg plastic constituents released per kg food simulant. This is because food packaging aimed for children often has a large surface area relative to the food content. For some chemicals there are additional specific migration limits specified in the 'union list'.

Extract from Commission Regulation (EU) No 10/2011:

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

…

(2) 'plastic' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;

(3) 'polymer' means any macromolecular substance obtained by:

(a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or

(b) chemical modification of natural or synthetic macromolecules; or

(c) microbial fermentation;

Health concerns

Even though plastic substances are highly regulated in food contact materials, the regulation is not protective enough. The main cause is that many of the approved chemicals are not yet evaluated for their toxicity. Instead the prevailing philosophy is no data = no harm. And when a chemical is found to be toxic, the FCM-legislation is not automatically updated.

For example, several substances that have been harmonised classified[3] as carcinogenic, mutagenic, or toxic for reproduction (CMR) according to CLP are still on the 'union list' of approved plastic ingredients, see table 4. Neither is REACH effective to ensure human health, as 11 of these substances are also found on the Candidate list, six on the Authorisation list and four on the Restriction list. For nine of these substances, migration limits have been set to 'not detectable' (ND). But for the others, detectable amounts are allowed to migrate, and if no specific migration limit is set, up to 10 mg/dm^2 is allowed to be released. This is worrisome.

[3] Substances and mixtures with hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers), classification and labelling should be harmonized throughout the EU to ensure an adequate risk management. Harmonized classifications are listed in Annex VI to the CLP Regulation and should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

Note that this does not apply for polymers or natural substances extracted from nature, because these groups of substances are out of the CLP scope.

Table 4. Plastic substances that have been harmonised classified as carcinogenic, mutagenic, or toxic for reproduction in CLP, but are still on the 'union list' for approved plastic ingredients for food contact materials. Migration limits set to 'not detectable' are noted as ND.

Substance name	CAS number	Used as additive or aid	Used as monomer or starting material	SML (mg/kg)	Additional limits	Harmonised CMR in CLP	Regulated in REACH
methacrylic acid, 2,3-epoxypropyl ester	106-91-2	no	yes	0,02	-	Carc 1B Muta 2 Repr 1B	-
Ethyleneimine	151-56-4	no	yes	ND	-	Carc 1B	-
Acrylamide	79-06-1	no	yes	ND	-	Carc 1B Muta 1 B Repr 2	Candidate list Annex XVII
propylene oxide	75-56-9	no	yes	ND	1 mg/kg in final product	Carc 1B Muta 1B	Candidate list
Butane	106-97-8	yes	no	-	-	Carc 1A Muta 1B	-
Butadiene	106-99-0	no	yes	ND	1 mg/kg in final product	Carc 1A Muta 1B	-
Formaldehyde	50-00-0	yes	yes	-	15 mg/kg formaldehyde in final product	Carc 1B Muta 2	-
Acrylonitrile	107-13-1	no	yes	ND	-	Carc 1B	-
Epichlorohydrin	106-89-8	no	yes	ND	1 mg/kg in final product	Carc 1B	-
perfluorooctanoic acid, ammonium salt	3825-26-1	yes	no	-	Only to be used in repeated use articles	Carc 2 Repr 1B	Candidate list
2,2-bis(4-hydroxyphenyl) propane	80-05-7	no	yes	0,05	Not to be used for the manufacture of polycarbonate drinking cups or feeding bottles aimed for infants and young children	Repr 1B	Candidate list Annex XVII
N-(2-aminoethyl) ethanolamine	111-41-1	yes	no	0,05	For indirect food contact only, behind a PET layer	Repr 1B	-
phosphoric acid, trichloroethyl ester	115-96-8	yes	no	ND	-	Carc 2 Repr 1B	Candidate list Annex XIV
di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	15571-58-1	yes	no	-	0,006 mg/kg tin in final product	Repr 1B	Candidate list
sodium tetraborate	1330-43-4	yes	no	-	6 mg/kg boron in final product	Repr 1B	Candidate list
boric acid	10043-35-3	yes	yes	-	6 mg/kg boron in final product	Repr 1B	Candidate list

vinyl chloride	75-01-4	no	yes	ND	1 mg/kg in final product	Carc 1A	Annex XVII
phthalic acid, benzyl butyl ester	85-68-7	Yes	no	30	Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae	Repr 1B	Candidate list Annex XIV Annex XVII
phthalic acid, dibutyl ester	84-74-2	yes	no	0,3	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0,05 % in the final product.	Repr 1B	Candidate list Annex XIV Annex XVII
phthalic acid, bis(2-ethylhexyl) ester	117-81-7	yes	no	1,5	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product.	Repr 1B	Candidate list Annex XIV Annex XVII
1,3-phenylenediamine	108-45-2	no	yes	ND		Muta 2	-

SML = specific migration limit

ND = not detectable

CMR = carcinogenic, mutagenic or toxic for reproduction

CLP = Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures.

REACH = Regulation (EG) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

Annex XIV = Authorisation list in REACH

Annex XVII = Restriction list in REACH

In article 13 and 14 of the FCM plastic legislation (Commission Regulation (EU) 10/2011), it is outlined that multi-layer materials and articles are not allowed to contain substances classified as CMR in the CLP-regulation, if not listed on 'the union list'. But to protect human health, no CMR substances should be allowed, indifferent of the material type. Preferable a general restriction of CMR substances should be in the main FCM-regulation document (Regulation (EU) 1935/2004) and covering all CMR-classified substances under both CLP and REACH.

Extract from Commission Regulation (EU) 10/2011:

Article 13:4 and Article 14:2

The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:
(a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council[4];
3.5 — Germ cell mutagenicity, Hazard Category 1A, 1B, H340 and Hazard Category 2, H341
3.6 — Carcinogenicity, Hazard Category 1A, 1B, H350 and Hazard Category 2, H351
3.7 — Reproductive toxicity, Hazard Category 1A, 1B, H360 and Hazard Category 2, H361

Besides the problems with the 'union list', there is an additional problem with impurities, reaction side-products and other 'non-intended added substances' (NIAS). Studies have shown that FCM-plastics can contain more than 40 different chemicals, most of them unknowns, and not on the 'union list' (Zimmermann et al. 2019). When Zimmermann et al. (2019) analysed the toxicity of different common plastic types, PET and HDPE were found to be less toxic to the cells in the test-assays, while PVC and PUR were found most toxic. LDPE, PLA, PS and PP were in between. The difference in toxicity between the samples within the same plastic type was found to be greater in some cases than between plastic types. This indicates that it is not the polymer itself but intended and unintended added substances that cause the toxicity. That can explain why PET and HDPE were less toxic, since they are known to usually have few additives. Nonetheless, only a few aspects of toxicity were studied and there may be additional effects of the chemicals leaching from plastics that remains unknown.

Since there is a knowledge gap between what the plastic producer declares and the chemicals found in the plastic, the legalisation falls short protecting human health. To circumvent this problem, analysis, and toxicological information of migrates from the final product are needed.

[4] REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Recycled plastics

In a circular economy it is desirable to reuse, and material recycle as much as possible, to spare natural resources and reduce waste. The recycling of PET-bottles in Sweden is a good example, where 84% is collected and used for material recycling. Half of the recycled PET are blended into new PET-bottles, and the other half are turned into sheets for laminate packaging, plastic ribbon and more (SMED 2019). However, to get the same mechanical properties, addition of virgin materials is always needed to compensate for the degradation of the recycled plastics. When it comes to other plastic food packaging, they are often more difficult to recycle. The plastic packaging can be made of several plastic types or consist of a plastic type that cannot be melted down and reformed into new packaging, which in both cases makes it more difficult to recycle them into new FCM-packaging. Also, the composition of additives within a plastic type (PP, PE, PLA etc) differs significantly between packaging producers, and thus the recycled plastic becomes a mixture of these, with unknown properties and chemical content. Recycling systems of well-defined plastic compositions, like the one for PET-bottles, is the preferred way towards a higher degree of material recycled plastics.

Applications in FCM

Most of the plastics used as FCM are not recycled into new food contact articles. One exception is PET-bottles that are collected and reused as material for new PET-bottles. According to The European PET Bottle Platform, nearly 60% of PET-plastic was material recycled in 2017, with end products like thermoforming sheets (40%), new PET-bottles (30%) and polyester textile (15%) (EPBP 2019). The mean content of recycled PET in PET-bottles was only 11%, with the potential to grow considerably. In Europe, leading industry has committed to achieve 25% recycled PET plastic content in PET-bottles by 2025 (The Coca-Cola Company 2018), which is the same as stipulated by the Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment. In Sweden, the average blend is 50/50 recycled and virgin PET (SMED 2019).

Regulation

As outlined in the Commission Regulation (EC) 282/2008, the recycling process must be evaluated and authorised by the European Food Safety Authority (EFSA). In theory, all kinds of plastic material can be reused, if the recycling process is authorised by EFSA. It is mostly PET that is recycled. Out of the 89 authorised recycling processes, 81 are for PET (Forrest 2016).

Extract from Directive (EU) 2019/904:

Article 6

5. With regard to beverage bottles listed in Part F of the Annex, each Member State shall ensure that:

(a) from 2025, beverage bottles listed in Part F of the Annex which are manufactured from polyethylene terephthalate as the major component ('PET bottles') contain at least 25 % recycled plastic, calculated as an average for all PET bottles placed on the market on the territory of that Member State; and

(b) from 2030, beverage bottles listed in Part F of the Annex contain at least 30 % recycled plastic, calculated as an average for all such beverage bottles placed on the market on the territory of that Member State.

Health concerns

Plastic collected for recycling may contain leftovers, mold or non-food substances from other kind of usage by the consumer then the intended one. Other health concerns are degradation products, unintentional added chemicals, by-products, and contamination of legal chemicals from non-FCM plastics (Geueke et al. 2018). In the authorised recycling processes the recycler has shown to have a regulatory system in place to avoid and deal with such concerns. To increase the possibility for recycled plastics in FCM, harmonization between FCM and REACH legislations is needed, as well as design requirements on plastic products (Watkins et al. 2019).

Regenerated cellulose film

Cellulose is a polymeric structure common in plants. Paper is the most common man-made cellulose product. Regenerated cellulose is a class of materials manufactured by conversion of cellulose to a soluble cellulose derivative that are formed to either fibre (e.g. rayon) or film (e.g. cellophane).

Applications in FCM

Regenerated cellulose film is used in twist packaging and packing windows. They are used as packaging for baked goods, ovenable and microwaveable packaging. (Tajeddin 2014). Cellulose films have high permeability to water (low barrier properties, so they are less used than the regenerated counterparts) (Bendane et al. 2015; Tajeddin 2014). They are therefore suitable for applications where protection from moisture is not required.

Regulation

The cellophane used in FCM can include several additives, listed in Annex II to Commission Directive 2007/42/EC. The film can also be coated with either derivatives from cellulose or plastics, listed in the second part of Annex II. Apart from the substances listed in Annex II, colorants and adhesives are allowed if they do not migrate into the foodstuff. Surfaces with print are not allowed to come into contact with the foodstuff.

Extract from Commission Directive 2007/42/EC:

ANNEX I
DESCRIPTION OF REGENERATED CELLULOSE FILM
Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

Health concerns

Regenerated cellulose films may contain phthalates or other hazardous chemicals additives to become more moisture proof (Gilbert 2017). A major limitation of the cellulose films in food packaging is the sensitivity to moisture as water transmission can affect the quality and safety of the food (Bendane 2015).

Food contact materials with no EU-harmonised regulation

For materials with no EU-harmonised regulation, member states may have national regulations. These are usually in the form of migration or composition limits of certain substances or lists of allowed substances. The Council of Europe (CoE) and Norden[5] are two inter-governmental organisations in EU, giving recommendations on FCM. These are not legal binding until incorporated into national legalisation.

Table 5. A list of the member states and organisations having specific measures for specific materials *(adapted from page 52 of the JRC report* (Simoneau et al. 2016)). Also, German BfR[6] have recommendations on the health assessment of FCM (not included in the table).

Material	**Positive or negative list**	**Migration limits**	**Composition limits**
Adhesives	DE, ES, FR, HR, IT, NL	ES, HR	DE, ES, FR, HR, NL
Cork	CoE, CZ, FR, NL, SK	CoE, CZ, NL, SK, HR	CoE, SK, NL
Glass	BE, (IT), SK, (HR), NL	BE, BG, CH, CoE, CZ, DE, DK, FR, HR, IT, NL, NO, SK	FR, (NL)
Ion exchange resins	CoE, ES, FR, NL	CoE, ES, NL	CoE, ES, FR
Metals and alloys	CZ, EL, FR, IT, NL, SK, AT, CH, HR	AT, (CH), CoE, FR, HR, IT, NL, NO, Norden	AT, BE, CH, CoE, CZ, EL, FR, HR, IT, NL, SK
Multi-materials	FR, IT, Norden	FR, IT	FR, IT, Norden
Paper and Board	BE, CoE, CZ, DE, (EL), FR, IT, NL, Norden, SK, (HR)	BE, CoE, DE, EE, FR, HR, IT, NL, Norden, PL, SK	BE, CoE, DE, EE, FR, HR, IT, NL, Norden, PL, SK
Printing inks	CH, CoE, DE_draft, FR, NL, SK, CZ, HR	CH, CoE, DE, (DE_draft), FR, NL	CH, CoE, CZ, FR, (HR), NL, RO, SK
Rubber	CoE, CZ, DE, ES, FR, HR, IT, NL, SK	AT, CoE, CZ, DE, ES, FR, HR, NL, RO, SK	AT, CoE, CZ, DE, ES, FR, HR, IT, NL, SK

[5] **Norden** represents a Nordic cooperation scheme that involves Denmark, Finland, Iceland, Norway and Sweden, along with the Faroe Islands, Greenland and the Åland Islands.

[6] **BfR** stands for The German Federal Institute for Risk Assessment.

Silicones	CH, CoE, CZ, DE, ES, FR, HR, IT	CH, CoE, CZ, DE, ES, FR, IT	CH, CoE, CZ, DE, ES, FR, IT
Varnishes and coatings	CoE, CZ, DE, EL, ES, FR, HR, IT, NL, SK	BE_draft, CH, CoE, CZ, DE, EL, ES, FR, HR, IT, NL	BE_draft, CoE, CZ, DE, EL, ES, FR, IT, NL, SK
Wax	DE, ES, (FR), NL	ES	CH, DE, ES, (FR), NL
Wood	FR, NL	FR, HR, NL	FR

Adhesives

Adhesives are a complex group of non-metallic chemical formulations used to glue together materials.

Applications in FCM

Adhesives typically make up less than 5% of the packaging. Direct food contact is usually not intended, although migration can occur unintentionally through seams and edges or through the packaging. Adhesives are used in a variety of applications and food packaging, such as attachment of labels and manufacturing of multilayer materials. Adhesives can be manufactured from naturally occurring materials such as starch, casein animal glue, natural rubber etc and from synthetic materials. Synthetic materials include a broad spectrum of materials, e.g. polyurethane, epoxy, acrylic and vinylic adhesives.

Regulation

Adhesives are regulated on national level in six countries (Croatia, France, Germany, Italy, the Netherlands, and Spain), with lists of authorised substances. For the other EU countries there is no specific regulation for adhesives, and the basic legal requirements for FCM apply.

Health concerns

The number of adhesive substances in use is very large and it is unlikely that all of them have been thoroughly tested and evaluated to be safe. A wide variety of compounds are used in adhesives and the composition depends on the nature of the adhesive. Research aimed to determine the migratable compounds in adhesives, studied the migration to food in 45 multilayer food packaging (various material, cardboard and paper, plastic films and combinations) with 29 different adhesives formulations (seven different adhesive types). 55 different compounds were found in the different adhesives and 57 % of the compounds migrated into a dry food stimulant even though the adhesives were not in direct contact with the food (Aznar et al. 2011). Several different substances and degradation products from adhesives have been shown to migrate into food (Nerin et al. 2013).

Cork

Cork is made from the bark of cork oak tree. Cork closures and stoppers are produced using natural and composite cork.

Applications in FCM
Cork is mainly used as bottle stoppers, especially for wine bottles.

Regulation
Five countries (Croatia, Czech Republic, France, the Netherlands and Slovakia) have national regulations for cork. The council of Europe has a policy statement concerning cork materials and articles intended to come into contact with food stuffs (ResAP(2004)2).

Health concerns
Cork components can migrate into wine after bottling (Varea et al. 2001). Little health concerns are found in the literature. Still, unregulated materials may release health hazard or unknown substances not covered by the main legislation.

Elastomers and rubbers

Rubber can be natural, i.e. latex extracted from plants, or synthetic, made from petrochemicals. Rubber is a complex material that can be made by a high number of different substances, and be named as 'rubber', 'latex', 'elastomer' or 'caoutchouc', sometimes with non-coherent definition among the member states.

Applications in FCM
The usage is mainly in food processing, where rubber is part of conveyor belts, rotating transport rollers, tubing and hoses, or in gloves used by the manufacturer. Rubber can also be used in bottle closures, baby rubber teats and soothers.

Regulation
The only EU-harmonised legislation regarding rubber, is Commission Directive 93/11/EEC on the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers. Rubber is regulated nationally in eight countries and the Council of Europe have guidant measures, with lists of authorised substances. It is estimated that over 1000 substances are considered in at least one member state (Simoneau et al. 2016). The restriction limits are usually usage dependent, i.e. children products have lower migration limits.

Health concerns
Most member states do not have measures beside the overall restrictions outlined in the main FCM-legislation. This implies that any kind of substance can be used as long as it is compliant with the main legislation. The member states that have national measures, have restrictions for the most known hazardous substances. Nevertheless, since these substances are estimated to be over 1000, bare the complexity of the material makes it difficult to evaluate if it the end product is safe.

Glass

Glass is a non-crystalline amorphous solid. In food contact material, the most common is soda-lime glass, made of silicon dioxide, sodium oxide and calcium oxide.

Applications in FCM
Glass packaging is used for a range of food products with different sealing methods e.g. plastic, metals, cork, wood etc. Glass bottles are commonly used for beverages like wine, beers, sodas and juices. Glass jars are used for e.g. spices, jams, pickled foods and baby food. Glass containers are also commonly used to store food.

Regulation
Glass is regulated nationally in twelve countries (see table 5) and includes both positive and negative lists and restrictions for migration.

Health concerns
Crystal glass contains lead oxide, which due to the higher density has a higher reflective index, and thus makes the glassware to look more brilliant. In contact with acidic food, lead can migrate from the crystal glass into the food and cause lead poisoning.

A study from 2018 measured lead and cadmium on decorated drinking glassware in the lip area. They found the presence of high concentrations of lead and cadmium in glassware both from China and Europe. The highest of concerns were the presence of both lead and cadmium in the decorative enamelling within the lip area of glassware for children due to the risk of ingestion of small quantities over an extended period (Turner 2018).

Another area of concern regarding glass jars, even though it is not the glass per se, is the migration of plasticisers from the lids of the jars into oily foods. Studies have shown that legal limits of plasticisers in oily foods are often exceeded in the EU (McCombie et al. 2015). In an analysis of plasticisers in different pesto made by "Råd och Rön", a Swedish magazine issued by the Swedish Consumers' Association (Sveriges konsumenter), 14 of the tested 15 pesto's on the Swedish market contained plasticisers DEHP (bis(2-ethylhexyl)phthalate) and ATBC (acetyl tributyl citrate) (Råd och Rön, 2019). According to the article, some of the manufacturers suspect that the lid is the leading cause, even though contamination is possible also in the manufacturing process. For more information regarding phthalates see section "substances of concern".

Ion exchange resins

Ion exchange is typically a vessel with a resin, through which a liquid flow under pressure. The resins are polymers, most common polystyrene or polyacrylate, with functional groups on the resin that binds unwanted substances (like ions or pollutants) or sorts the substances according to size.

Applications in FCM
Ion exchange resins can be used in the manufacturing process to remove unwanted substances, or to neutralise liquid food (or drinking water). Ion exchange resin is regulated nationally in three countries and the Council of Europe has recommendations, with lists of authorised substances.

Health concerns
No health concerns are found in the literature. Still, unregulated materials may release health hazard or unknown substances (e.g. NIAS) not covered by the main legislation.

Metal and alloys
A wide variety of metals are used in food contact materials. The most used are stainless steel, aluminium, and tin.

Applications in FCM
Metals and alloys are used in many types of food contact materials. They can be used as the only compartment, like in a cutely, or as part of a multi-material, like a metal layer in plastic packaging. Metals are also widely used in the manufacturing process, as it is inert and easy to clean as well as in households. For example, metals for eating and drinking utensils, kitchen knives, as well as pots and pans, coffee percolators, bread boxes and many more. Other examples are cans and foils.

Regulation
Metal and alloys are regulated nationally in ten countries with lists of authorised substances. The Council of Europe has an extensive resolution with technical guidance, and Norden also have guidance documents.

Health concerns
Metals and alloys are often covered by a surface coating, except for stainless steel. When they are not coated these food contact materials can give rise to release of metals to the food due to corrosion of the metal stainless steel does not corrode.

Studies have shown that both aluminium and stainless-steel products can precipitate metal when in contact with acidic food and beverages. Aluminium has been shown to migrate from aluminium soda cans to the soda, with concentrations increasing after time, especially in dented cans (Veríssimo and Gomes 2008). A study leading to a series of papers published have investigated and discussed the migration and health concerns with aluminium products in contact with food. The researchers investigated the migration from aluminium water bottles and stove-top mocha pots into different beverages. The migration from aluminium water bottles into an acidic beverage (apple juice in this case) may reach 87% of the TWI for adults and a child drinking tea from an aluminium bottle may exceed the TWI with 145 % (Stahl et al. 2017a). For water the limits were not exceeded. The authors estimated that a daily intake of 10 mL of lemon juice-containing marinade prepared in aluminium grill pans could contribute to up to 64% of the TWI in adults and 300% of the TWI of a child (15 kg). (Stahl et al. 2017b). They conclude that “the use of aluminium grill pans may result in an additional aluminium exposure that is not negligible for the consumer if acidic marinades are used” (Stahl et al. 2017b). Uptake of aluminium can result in risks for human health as aluminium influences different biological processes in the body, although the mechanisms of aluminium toxicity are not fully understood. It is considered to be potentially cell- and neurotoxic (Stahl et al. 2017a). Aluminium bottles or coffee pods are coated on the inside, usually an epoxy coating with BPA or BPA-analogues.

Studies investigating stainless steel cookware show that Nickel (Ni) and Chromium (Cr) leaked into tomato sauce after cooking for six hours (Kamerud et al. 2013). The concentrations differed with the grade of stainless steel and time of cooking but all the tested cookware leaked metals in different rang depending on the grade of steel. The authors conclude that stainless cookware can be an overlooked source of human exposure to Ni and Cr (Kamerud et al. 2013).

Tinplate is a metal that has high resistance against corrosion in acidic conditions that is used for containers of food (e.g. white fruit) and beverages as well as baking equipment. It has an inner layer based of steel, coated with a thin layer of tin. Migration of tin into food and beverage can occur. High concentrations of tin may irritate the gastrointestinal tract and may cause nausea, vomiting, diarrhoea, abdominal cramps, fever and headache even though the effects are considered short term and recovery is expected soon after exposure is terminated (Veríssimo and Gomes 2015).

Paper and board

Paper and board are made of cellulose fibres (approximately 99%), mainly from trees, along with naturally occurring minerals and polymers or alternately recycled from recovered materials. Additives are used in the processing to get specific properties, like bleached paper. Also, coatings are commonly used to give the surface functional properties, like water repellent. Another method to get water resistant board is to combine it with plastics in a multilayer, like in Tetra Pak®. An advantage with paper is that it is recyclable and biodegradable. However, to get the same mechanical properties, recycled paper and board are blended with virgin cellulose.

Applications in FCM

Paper and board are versatile materials and widely used to package foods. Carton board or paper board is a form of thick paper-based material used for milk and juice cartons, cereal boxes, frozen-food packages, take-away food cartons etc. Paper packaging in the form of bags can hold loose foods and e.g. flour.

Regulation

Paper and board are regulated nationally in ten countries (Belgium, the Czech Republic, Estonia, Germany, Greece, France, Croatia, Italy, the Netherlands, Slovakia), with legislation or instructions. The Council of Europe has two resolutions, including about 1100 substances, and Norden provides GMP[7] guidance. On the ESCO[8] list there are over 500 substances that are risk assessed.

Health concerns

One concern about paper and cardboard FCM is the migration of chemicals, like plasticisers, UV initiators and mineral oil hydrocarbons originating from inks used for printing on the packaging. The European Consumer Organisation (BEUC) released a report from consumer testing of food packaging such as take away coffee cups, straws and napkins originating from

[7] Good manufacturing practices
[8] European Skills, Competences, Qualifications and Occupations

European countries contain and release chemicals from inks used for printing. Aromatic amines, a suspected cancerogenic, where found in several samples and nine samples contained concentrations higher than the limit set in the EU Plastic Regulation. UV filters were found in almost all products. Some UV-filters are suspected cancerogenic and/or endocrine disrupting. 6 of the 21 of the samples further analysed showed substantial migration of the UV-filters to the food, including a box of raisins aimed for children (BEUC 2019).

Recycled paper and board often contain substances that can migrate into foods exceeding safe levels (Bidermann-Brem et al. 2016). Many of the substances potentially migrating into foods from paper packaging have not been evaluated and many not even identified (Bidermann-Brem et al. 2016). If not using virgin fibres and using recycled paper for food packaging, internal barrier such as an internal coating or a plastic bag could be used minimise unwanted substances to migrate into the food.

In 2017 several consumer organisations tested fast food packaging made from paper and board and found high levels of fluorinated compounds in the tested fast food packaging products (Forbrugerrådet taenk kemi 2017). In almost all samples the number of fluorinated compounds, Total Organic Fluoride (TOf), exceed the recommended Danish limit (0.35 µ/dm^2). The results indicate that PFAS are used intentionally for surface treatments of the paper materials despite the large concern of their safety. PFAS were found in half of the packages, several of them classified as SVHC. The most detected types of PFAS were fluorotelomer alcohols (FTOHs) and carboxylic acids, such as PFOA and its six-carbon cousin compounds perfluorohexanoate acid (PFHxA) and perfluorobutanoic acid (PFBA). PFOS was also present (Forbrugerrådet taenk kemi 2017). For more information regarding PFAS see section “Substances of concern” and for more information about paper and board in fast food containers see section “Single use products and take away containers”.

Printing inks

Inks consist of a combination of colorants, binders, solvents, and additives. In total more than 5 000 substances are associated with printing inks for food contact materials. There are different types of inks, like oleo-based or water-based, and different kinds of curing methods, like UV and electron beam.

Applications in FCM

The printings are used to give information to the consumer and to make the product packaging appealing.

Regulation

Printing inks are regulated nationally in four countries (France, the Netherlands, Slovakia and Switzerland), and the Council of Europe have policy statements with lists of authorised substances, all together considering more than 5 000 substances.

Health concerns

Inks are seldom used in direct contact with food. Nonetheless, inks may migrate through the packaging material e.g. paper or cardboard, or also via set-off migration (e.g. stacked coffee cups, beverage cartons). Printing inks include a wide variety of substances and include

substances known to be endocrine disruptive such as dicyclohexyl phthalate, carcinogenic like benzophenone and dibutyl phthalate, classified as toxic to reproduction. Recent studies suggest that exposure from food contact material has been underestimated. Only a fraction of the 5000 substances used in inks have been evaluated by EFSA, and 90% of the substances there is insufficient toxicological data, hence no possibility to assess their health risk (Beuc 2019). When consumer organisations measured the migration and presence of chemicals of concern in 76 different products of coloured paper and board food contact materials such as coffee cups, paper straws, printed napkins they found that primary aromatic amines were detected in 17% (13 samples) and 9 samples where above the limit set in the Plastic Regulation. Photo initiators and other substances that can relate to the printing inks were detected in 71 of the 76 tested packaging samples. Overall, the results demonstrate that printed paper and board food packaging materials contain and release chemicals of concern, including some that have not been risk assessed by EFSA (Beuc 2019).

Silicones

Silicones are polymers with a siloxane backbone and inert side groups.

Applications in FCM

Silicones are heat resistant and flexible and are used for a wide variety of applications from bakeware utensils to lubricants. The member countries have different definitions which classify silicone into different categories of materials.

Regulation

Silicones is regulated nationally in seven countries (Croatia, the Czech Republic, France, Germany, Italy, Spain and Switzerland), with positive lists of approved substances. The Council of Europe has a policy statement. Over 50 substances are risk assessed and on the ESCO[9] list. The CEFIC[10] sector for silicones, CES, have made a specific GMP guideline, in which it is stated that silicones most often should be considered as raw materials and not as “article and material”, and thus be excluded from the scope of Regulation (EC) No 2023/2006.

Health concerns

Migration of substances, including additives, catalysts, oligomers breakdown and reactions products, from silicone-based materials into food have been observed. For more information regarding silicones see section “Substances of concern” page 52.

Textiles

Textiles are materials made from fibres, natural or synthetic. The fibres can be held together in various ways, like fabric or knitwear. Textiles may have additives like colour and surface finish or be part of a multi-layer material

Applications in FCM

In food contact applications textiles can be used as filter, wrapping, or part of packaging, i.e. around cheese together with wax.

[9] European Skills, Competences, Qualifications and Occupations

[10] The European Chemical Industry Council

Regulation
No regulation.

Health concerns
No health concerns are found in the literature. Still, unregulated materials may release health hazard or unknown substances not covered by the main legislation.

Varnishes and coatings

Varnishes and coatings are substances or mixtures of substances applied onto another material to give it special properties or improve its technical performance.

Applications in FCM
Coatings can be used to protect the food from the packaging, like metal in food cans or fatty food from paper packaging. Coatings can also protect food from oxygen in the surrounding environment, to extend shelf life. Coatings can also be used on the non-food contact side of a package, to make the packaging more appellant (i.e. glossy) or to protect the print.

Regulation
Varnishes and coatings are regulated nationally in eleven countries, with lists of authorised substances, and the Council of Europe provide a policy statement. Together there is almost 2000 substances with measures, though less than 100 of them are common among the member states. The supply chains can be long, which requires well-functioning quality systems in all stages.

Health concerns
Since coatings and varnishes are a broad and complex kind of material, the health concerns are unclear. Two well-known hazardous substances used are epoxy derivatives of BPA used in metal coatings and PFAS used in grease and water repellent coatings. For more information regarding BPA and PFAS see section “Substances of concern”.

Waxes

Waxes are products that can broadly be categorised as natural, (e.g. beeswax, soy wax, candelilla wax), petroleum based (e.g. paraffin waxes), mineral hydrocarbon waxes and synthetic waxes.

Applications in FCM
Waxes are used in several types of FCMs as processing and production aids as well as additives. Wax is used as coating, laminate, and impregnation of materials such as paper and board in food contact. Waxes have good moisture barrier characteristics and can reduce moisture loss of food but also protect dry foods from moisture. A wax coating can also protect food stuff during transport and handling and increase shelf life. They are used as surface coatings, alone or as a component. Wax coatings of cheese are removed or peeled before consumption whilst edible waxes are used to coat apples, oranges, and other fruits to protect them during transport and handling and to give them a shine.

Regulation
Four countries have national legislation (Germany, Spain, the Netherlands, and Switzerland) with positive lists of authorised substances including maximum content, except Spain that has migration limits. France specifies the maximum content for the one authorised fungicide in waxes. There is no consolidated list of waxes.

Health concerns
There is concern that waxes and their components can migrate into food stuff, especially in direct food contact. No migration and toxicology studies are found for food-grade waxes in the literature, but that is no guarantee for it being safe. As for all unregulated materials, there may be health hazard or unknown substances not covered by the main legislation.

Wood

Wood as a material is defined as a composite of cellulose fibres (which are strong in tension) embedded in a matrix of lignin which resists compression or only the secondary xylem in the stems of trees, or it is defined more broadly to include the same type of tissue elsewhere such as in tree roots or in other plants such as shrubs (Fink et al. 2013).

Applications in FCM
Wood has been used as FCM throughout history as tools when preparing a meal, storage facilities as well as universal food contact articles for distributing food both local, regional, and global. Wood can be used as raw lumber or reconstituted wood and be painted, varnished, and lacquered. Wooden containers, crates, and baskets have been, and are still used to transport and hold a range of solid and liquid foods including fruits and vegetables, cakes and patisseries, dairy products, tea, wines, spirits, and beers. It is used both as primary and secondary packaging layers, i.e. both in direct contact with the food and not.

Wood is also used for kitchen utensils and tableware such as cutlery, cutting boards, bowls, skewers and sticks both for single and repeated use, processing and/or storage equipment such as crates pallets paddles and barrels (Fink et al. 2013; Organi trust, 2018).

Regulation
Three countries have national legislation: France, Croatia, and the Netherlands.

Health concerns
Besides from some tree species being poisonous, like the holly (*Ilex aquifolium*)can contain alkaloids and terpenes or the cherry laurel (*Prunus laurocerasus*) containing cyanogenic glycosides (Silano et al. 2019), trees can contain mineral components and extractives that consist of a large number of compounds. These low molecular weight compounds have a protective function for the tree from fungi, insects and bacteria and can therefore be toxic or sensitising. Organic extractives may have aliphatic, alicyclic, or aromatic structures and comprise mainly terpenes, fatty acids, resin acids, waxes, alcohols, sterols, stearyl esters, glycerides, and phenols. The migration and health effects of these are not yet assessed (Silano et al. 2019). In addition to the naturally occurring substances, wood can accumulate heavy metals from the soil and anthropogenic pollution (Unterbrunner et al. 2007, Clemens et al. 2002).

The main concern regarding wood as FCM has been the hygienic aspects and potential bacterial growth and most of the research conducted have aimed for these aspects. Migration of potential contaminants are less studied. Few studies are found that show migratory potential of wooden food contact materials or health effects. Still, unregulated materials may release health hazard or unknown substances not covered by the main legislation.

Substances of concern

Here follows a review of the most investigated and problematic substances used in contact with food.

Bisphenol A (BPA)

Bisphenol A is an organic compound with two hydroxyphenyl groups. At room temperature, it is a white solid that is described to have a mild phenolic odour. The synthesis of BPA was performed already in 1891 and the production of the polymer started in the 1930's (Geueke et al 2014).

Applications

BPA is used in carbonate plastics, coatings, colour developer and flame retardants. Carbonate plastics is commonly produced by a reaction of BPA and phosgene and is often used in reusable food containers and bottles because this material is shatter-proof, durable, light and transparent. BPA can also be used as coating materials in the form of epoxy resins, produced by a condensation reaction between BPA and epichlorohydrin that are further stabilized and/or modified by different cross-linking reactions. Epoxy resins are used as can coatings, both to avoid the contact between steel or aluminium and food and because they prevent corrosion of the metal can by food and protect the products taste at the same time. However, epoxy resins can also be found in food and menu trays, and the linings of caps, closures, and crown corks. BPA is also applied as colour developer in thermal papers and as a building block in the synthesis of the flame retardant tetrabromobisphenol A (Geueke et al 2014).

Migration and bioaccumulation

Different conditions such as temperature, heating time, storage time and condition as well as properties of the food will affect migration rate (Kang et al. 2003). BPA has an octanol/water partition coefficient (K_{OW}) of 3.32, which makes it to be moderately hydrophobic and have a moderate bioaccumulation capacity (Guo et al. 2017; Flint et al. 2012; Vega-Morales et al. 2010). It also has a relatively short half-life of 3–6 days in surface water under aerobic conditions at environmentally relevant concentrations (0.05 and 0.5 µg/L) (Klečka et al. 2001). However, BPA has been detected in the tissues of several different aquatic species collected from marine and freshwater systems and have shown to have a trophic transfer of BPA-derived residues from alga to rotifer indicating a potential environmental hazard, because of subsequent effects on the food chain. However, further work is needed to better understand the fate of BPA in the food chain (Guo et al. 2017; Corrales et al. 2015).

Risk and health effects

BPA is a well-studied compound but throughout history there have been controversies about the safety and negative effects. The risk assessments provided by EFSA and FDA were based on standard toxicological tests in rats and mice, and showed non-specific toxicity and identified a Lowest Observed Adverse Effect Level (LOAEL) of 50 mg/kg body weight/day and a No Observed Adverse Effect Level (NOAEL) of 5 mg/kg body weight/day. The Tolerable Daily Intake (TDI) of 0.05 mg/kg body weight/day was calculated based on these numbers applying a safety factor of 100 (Geueke, 2014 a). However, the risk assessment and exposure levels have been criticised mainly due to the low-dose estrogenic effects BPA have shown. The estrogenic effects were described already in the 1930´s by Dodds and Lawson. They showed that BPA and

related compounds exhibit estrogenic activity in ovariectomised rats (Dodds and Lawson, 1936; 1938). In 2005, vom Saal and Hughes published a review article about the observed low-dose estrogenic of BPA observed in 94 studies and the authors pointed out the need for new risk assessments due to these results (vom Saal and Hughes, 2005). This was followed by yet another article in 2009, strongly criticizing the decisions of FDA and EFSA to declare BPA safe at current exposure (Myers et al. 2009). The main critique was regarding the BPA risk assessment including the quality of the applied test systems, the investigated endpoints, the source of funding, the quality standards, misinterpreted and/or neglected results, methodological flaws, and many more (Tyl 2009; Myers et al. 2009; vom Saal and Myers 2010; Tyl 2010; Becker et al. 2009; Hengstler et al. 2011; Vandenberg et al. 2009). The critique led to numerous studies investigating the endocrine disruptive effects of BPA.

BPA is a xenoestrogen, which means that it mimics the action of estrogen but can also disturb non-estrogenic pathways. As an endocrine disrupting chemical biological effects are seen even at low-dose concentrations and with a multitude of effects (Wolstenholme et al., 2011, Bergman et al 2008). BPA effects are strongly dependent on the life stage and the tissue affected, prenatal, neonatal and (pre)pubertal life stage are especially sensitive and effects that occur at these stages are irreversible. It has also been shown that maternal exposure to BPA during pregnancy, even at low doses, induces life-long changes in the regulation of metabolic homeostasis of the progeny, affects sex steroids and thyroid hormones levels (Silva et al. 2019). Epigenetic effects (effects that are inherited but not on the DNA level) of BPA have been reported (Geueke et al 2014) including developmental neurotoxicity in zebrafish larvae (*Danio rerio*) from exposed parents (Nesan et al. 2018).

The use of BPA increases the risk of exposing both aquatic and terrestrial wildlife. Although it degrades quickly, it is pseudo-persistent in the environment because of continual inputs increasing the risk of chronic exposure to wildlife. Some invertebrate, fish, and amphibian species appear to be susceptible to low exposures of BPA. However, the endocrine and systemic effects of BPA in the environment are less well known and further studies are needed (Flint et al. 2012).

In contrast to BPA the synthesis product of BPA, BADGE (bisphenol A diglycidyl ether) is even less studied and almost no toxicological information exists. BADGE is regulated separately in Commission regulation (EC) No 1895/2005. Like BPA and other plasticisers, BADGE can cross the human placenta and reach the foetus and a recent study has shown that BADGE and its hydrolysed and chlorinated derivatives (BADGE·H_2O and BADGE·2HCl) affect placental lipid handling and modulates placental CYP19 activity (BADGE·H_2O). These results highlight the need to monitor human exposure to these compounds, at least as intensely as BPA is monitored (Marqueño et al. 2019).

Substitutions

A growing number of studies suggest that the replacement chemicals have the potential to induce adverse effects similar to those reported for BPA. A recent study of Bisphenol F (BPF) and Bisphenol S (BPS) that have been introduced as BPA substitutes results suggest that the substitute chemicals are correlated with obesity in children, like previous observations with

BPA (Jacobson 2019). Another study found that BPS and BPF affect the male spermatogenesis with persistent effects in several consecutive generations (Horan et al. 2018).
An additional study showed that BPS persists in the body longer and at higher concentrations compared to BPA. According to the authors the results suggest that replacing BPA with BPS "will likely lead to increased internal exposure to an endocrine-active compound that would be of concern for human health" (Gayrard 2019).

Regulation
BPA is regulated in the Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Commission Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials. The regulation includes a specific migration limit of 0,05 mg BPA/ kg food and no migration at all for products intended for infants and children. Business operators shall have a written declaration of compliance for products with varnishes and coatings and be able to, upon request of a national competent authority, make available appropriate supporting documentation to demonstrate compliance with the written declaration. Such supporting documentation shall be provided without delay and in any event not later than 10 days following receipt of the request. The documentation shall contain the conditions and results of the testing, calculations, including modelling, other analysis and evidence on the safety or reasoning demonstrating compliance. BADGE is regulated through Commission 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 Commission regulation ((EC) No 1895/2005).

Melamine
Melamine is a heterocyclic aromatic compound sold as white, powdered crystal and is considered a high-production volume chemical globally (Geueke et al 2014).

Applications
Melamine is used as a monomer in the production of melamine resin (or melamine formaldehyde). Melamine resin can be used as a surface coating for paper, board and beverage cans and jar lids but also blended with cellulose fibres, fillers, pigments and other additives to form moulding compounds for the production of articles including unbreakable dinner/kitchenware and electrical equipment. Melamine kitchenware was widely used in households and restaurants in the 1950s and 60s. Today melamine resin is still frequently used in tableware for specific purposes such as camping and children (Geueke et al 2014) and often presented as an "eco-friendly" alternative to plastic.

Melamine has been used in bamboo products such as reusable plates, bowls, and coffee cups. They typically consist of melamine plastic and grounded bamboo ('bamboo-melamine') or other similar constituents such as corn starch. Bamboo products such as cups cannot be made from bamboo alone and melamine-formaldehyde resin is often used to serve as glue to hold the bamboo together.

Migration and bioaccumulation
Melamine has been shown to migrate into food and food simulants from melamine formaldehyde tableware. The amount of melamine migration is dependent on temperature, acidity, contact time, and simulant used, as well as the quality of the product. According to WHO humans are exposed to melamine in food either as a result of migration from materials into food (accepted) or by intentional addition of melamine to food to pretend higher protein content, called "adulteration". However, melamine can also enter the food as degradation products of the pesticide cyromazine and disinfectants such as trichloromelamine (Geueke et al 2014).

The general overall migration of melamine into food has been estimated to less than 1 mg/kg food (WHO, 2009). Melamine has also been shown to migrate from can coatings into food, probably due to decomposition of the coating. The migration increases at higher temperature (Chien et al. 2011), while time of heating or acidity of food has less effect (Bradley et al. 2010; Bradley et al. 2011). A small biomonitoring study (n=12) showed that eating hot soup in melamine bowls significantly increased the melamine content in urine compared to hot soup in ceramic bowls indicating that that melamine migrated to the hot soup even after short contact times (Wu et al., 2013). Microwave heating increases overall migration with number of heating/washing cycles hence, microwave heating for 1–2 min in a repeated manner is of high concern for consumer health. It is therefore strongly recommended that manufacturers and suppliers of melamine articles provide clear, visible, and non-removable instructions for consumer use that the product should not be used in microwave (Poovarodom et al. 2014).

Melamine has a low accumulation rate in mammals as it is excreted with urine. The half-life is also rather low, 5 hours in rats (Yang et al. 2009), 4 hours in pigs (Baynes et al. 2008) and approximately 6 hours in humans (Wu et al. 2013). Although, gut bacteria may influence the effects as bacteria can convert melamine into cyanuric acid, thus increasing the potential of nephrotoxicity i.e. kidney stones (Zheng et al. 2013). Melamine is not easily biodegradable in activated sludge treatment systems (Xu et al. 2013).

Over the last few years concern has been raised over the migration of melamine and formaldehyde with withdrawal of products from the market, therefore. In 2019 the German consumer organisation Stiftung Warentest published an article investigating the concentration of melamine that migrates into drinks from bamboo-based, reusable cups. The organisation carried out tests on twelve reusable bamboo cups and measurements showed that seven of the twelve cups resulted in "very high amounts of melamine" in the hot beverage simulating coffee. High concentrations of formaldehyde were also found (Food packaging forum, 2019).

Regulation
Commission Regulation (EU) No 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China.

Risk and health effects

Melamine has a relatively low general toxicity with an LD50 of 3.2 g/kg in rats. The NOAELs for foetal and maternal toxicity in rats are about 400 and 1060 mg/kg body weight/day, respectively (Geueke et al 2014a).

The negative health effects of melamine were commonly acknowledged around 2007-2008 after a couple of scandals. The first public case of toxic effects of melamine occurred in 2004 when at least 6 000 cats and dogs in Asian countries died of renal failure. However, it took four years before the deaths could be related to a specific melamine-contaminated pet food factory. A similar case was revealed in 2007 in the US when pet food that was adulterated with melamine and cyanuric acid, and possibly ammeline and ammelide. The pet food was recalled from the market after serious illness and deaths of thousands of dogs and cats. In 2008 a very serious case of melamine contamination was detected, when milk powders made for human consumption of a specific brand were found to contain high levels of melamine (150-4700 mg/kg). This resulted in the illness of 300 000 people. 50 000 infants were hospitalised and sex of them tragically died (Geueke, 2014). To imitate higher protein concentrations nitrogen rich melamine was added to the milk powder. Melamine induce crystal formation in the urinary system and can be associated with kidney toxicity, nephrotoxicity. However, melamine toxicity is not limited to the urinary system additional toxicological effects of melamine including histopathological changes in testes, abnormal sperm morphology (Yin et al. 2013), neurotoxic effects of low-dose melamine exposure (Yang et al. 2012) and utero exposure of low-level melamine could post a risk on the kidneys of the pregnant mother as well as the developing foetuses, which may further increase the possibility of other health problems later in life (Chu et al. 2018).

The International Agency for Research on Cancer (IARC) has released a report classifying melamine as carcinogenic for animals and possibly cancerogenic to humans (summary of the report: Grosse et al. 2017).

Per- and polyfluoroalkyl substances (PFAS)

Per- and polyfluoroalkyl substances (PFAS) is an umbrella term including more than 4700 fluorinated aliphatic compounds (OECD 2018b). Perfluoro means that all hydrogens in the carbon chain are substituted for fluorine, while in polyfluoro compounds they are just partially substituted. The common properties of PFAS are their high water and oil repellence as well as thermal and chemical stability.

Applications

PFAS are used in various consumer and industrial products, including in food contact articles, like pizza cartoons, microwave popcorn bags, butter and dairy packaging and cookware. Its eligible properties have led to the use of non-polymeric PFAS for paper and board products since the early 1960's. Over the years, different PFAS have been used. The PFOS-based surfactant perflourooctane sulfonamido ethanol-based phosphate (SAmPaP) were widely used in food contact paper and packaging between 1974 and 2002. After that, it was replaced with short- and medium-chain substances such as perfluorobutane sulfonate (PFBS) and its derivatives. Also, the use of fluorotelomer-based polymers and phosphate mono- and diesters

(monoPAPs and diPAPs) has increased in food contact paper and board. In 2013 more than 115 PFAS with a broad structural diversity were identified to be used in FCM finishes (Geueke 2016).

Regulation
No general regulation for PFAS in FCM legislation. Some materials have restriction limits for PFOA and PFOS in some member states.

PFOS, one PFAS substance, has been restricted under the Stockholm Convention since 2009. PFOS was earlier restricted under REACH but is now moved and regulated as a persistent organic pollutants (POPs) under Regulation (EU) No 2019/1021. **PFOA** (another PFAS) was added to the Candidate List of Substances of very high concern (SVHC) in 2013. In 2017, PFOA, its salts and all PFAS that can degrade into PFOA, were added to REACH annex XVII, Restriction List. Since 2020 PFOA is restricted under the Stockholm Convention, and therefore the PFOA regulation under REACH will be replaced by a new EU POPs regulation. Other PFAS on the Candidate List for authorisation are **PFUnDA**, **PFDoDA**, **PFTrDA**, **PFTeDA** (2012), **PFNA** and its sodium and ammonium salts (2015), **PFDA** and its sodium and ammonium salts (2016), **PFHxS** and its salts (2017), **HFPO-DA** (also known as **GenX**) its salts and acyl halides (2019), and **PFBS** and its salts (under authorisation since 2020). PFHxS is currently under review for restriction under the Stockholm Convention and is under proposal for restriction under REACH. Also, Germany has submitted a restriction proposal for **PFHxA.**

Sweden and Germany jointly proposed to restrict the manufacturing and placing on the market of **six PFAS** (PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA and PFTeDA), as well as their salts and precursors, in 2017. The aim was to restrict these long-chain (C9-C14) PFAS in order to prevent the industry from using them as replacements for PFOA when the restriction of PFOA goes into effect in 2020. Both the RAC (Risk Assessment Committee) and the SEAC (Committee for Socio-economic Analysis) have agreed to the restriction proposal; public consultation on the SEAC opinion closed on 19 November 2018, and the opinion is to be decided by the commission (Echa.europa.eu).

During 2018 the european food safety authority (EFSA) published new guidelines for PFOS and PFOA and the tolerable daily intake of PFOS was lowered from 150 to 2 ng/kg body weight/day and for PFOA the reduction was even more dramatic, from 1500 to 1 ng/kg body weight/day (EFSA 2018).

The European Council of Ministers highlighted the problem with PFAS in the environment and humans and called for an action plan to eliminate all non-essential uses of PFAS in June 2019 (Council of European Union, 2019). Considering this call, the Netherlands announced in a note of 11 December 2019 from the General Secretariat of the Council to the delegations, that they want to take the lead for such restriction proposal The note also states that the competent authorities in Denmark, Germany, Sweden and Norway, and the ECHA, have indicated their willingness to cooperate. This may lead to a restriction for the usage of all PFAS in both EU made and imported products, including food contact materials.

The widespread pollution of PFAS is also found in drinking water. The EU Drinking Water Directive is currently (2019-2020) under consideration and proposed limits are of 0.1 µg/L for 16 individual PFAS, and 0.5 µg/L for all PFAS as a group.

Sweden has recently changed its regulation for companies reporting to the Swedish Chemicals Agency's product register, to include reporting on all intentionally added PFAS, regardless of the content amount. The regulation includes all chemical products, i.e. impregnation or lubrication oils, but not articles. The reason is to get a better understanding of what kind of chemical products that contain PFAS.

Migration and bioaccumulation

Migration of PFAS e.g. PFOA and fluorotelomers (FTOH), have been detected in popcorn bags, fast food wrappers, pizza boxes and similar oil-repellent and heat-resistant packaging. In addition, PFOA migration has also been detected from non-stick cookware. In non-stick cookware the polymer PTFE is often used. PTFE itself is considered to be inert in its solid form, meaning it won't react with other chemicals. PTFE has a melting point of 327 ºC and degrades above 350 ºC when it produces toxic polymer fume. Pans with PTFE have shown to reach temperatures over 350 ºC when used on induction stoves (Göteborgsposten 2012) and unattended heating and heating empty non-stick pans as well as repeated use, may increase the risk of polymer fumes and increase the migration of PFOA (Sinclair et al. 2007). What has been shown though, are that residual PFOA, used in the polymerisation of PTFE, is not completely removed during the production process, and residuals may be off-gassed when heated at normal cooking temperatures (Sinclair et al. 2007). Also, perfluoroalkyl carboxylic acids (PFCA) of different chain lengths have been detected both under normal and overheating conditions (Schlummer et al. 2015).

The normal analysis methods may however not be suitable for PFAS migration analyses. Tests have shown that addition of emulsifier to the oil, increased the migration of PFAS from paper significantly (Begley et al. 2008). Since PFAS have unique properties, and binds to proteins, analysis methods have to be developed to mimic real conditions. In another study, dairy products were shown to be contaminated with PFCA and FTOH from coated packaging used in the processing and storage. The migration of FTOH was 1000-fold higher than those of PFCA and reached levels of µg/dm^2 (Still et al. 2013).

The same properties that makes PFAS so useful in many applications, i.e. chemical and thermal stable, hydrophobic and lipophobic, also makes them persistent in the environment and bio accumulative. Biomonitoring studies of populations from around the world have reported occurrence of PFOS and PFOA in human blood sample (Kannan et al. 2004; Lau et al. 2007; Olsen 2015). Studies in Scandinavia and the US show that the levels of PFOS and PFOA have decreased during the last years, while the levels of PFBS and PFHxS remains constant or even increases (D'Eon et al. 2009; Glynn et al. 2012; Kato et al. 2011). In a study on first time mothers in Sweden between 1996 and 2016, the levels of PFOS, PFOA and PFHxS were in the ng/g serum range, while the other PFAS analysed (PFBS, PFHpA, PFNA, PFDA, PFUnDA and PFTrDA) were 10 to 100 times lower. PFOS and PFOA decreased between 1996 and 2016 while the other PFAS were increasing or constant over time (Glynn et al. 2017). Studies from the

Baltic Sea show no significant decrease of concentrations of PFAS including PFOS, in fish and birds despite being phased out in the early 2000s (Faxneld et al. 2016).

Risk and health effects

PFAS are found everywhere in the environment and they are highly persistent. They are found in indoor and outdoor environments, wildlife, and humans all across the globe. PFAS are found in virtually every human (Mamsen et al. 2019). PFAS can accumulate in and cross the placenta into the developing foetus during pregnancy (Mamsen et al. 2019). Hence, humans are born with PFAS in their bodies and further, it also shown that breastmilk is a predominant exposure route for infants (Haug et al. 2011).

Adverse health effects of PFOA and PFOS have been reported for decades and have been summarised in many scientific articles (Lindström et al. 2011; Lau et al. 2007; DeWitt et al. 2012; White et al. 2011; Olsen, 2015). Exposure to PFAS has resulted in e.g. liver malfunction (Gallo et al. 2012), testicular and liver cancers (Barry et al. 2013, Benbrahim-Tallaa et al. 2014) high levels of cholesterol (Fitz-Simon et al. 2013), ulcerative colitis (Steenland et al. 2013) and decreased immune response to vaccines (Grandjean et al. 2012). Dyslipidemia is the strongest metabolic outcome associated with PFAS exposure (Sunderland et al. 2018). The impacts of PFOA on reproduction and development have been reviewed (in e.g. Geueke 2016) showing that PFOA may reduce fecundity and foetal growth. Exposure to PFOA affects the immune system of test animals by interfering with splenocyte and thymocyte precursor cells and their maturation and by altering inflammatory responses (Geueke, 2016; Sunderland et al. 2018). The main body of toxicological data are for PFOA and PFOS, for other PFAS knowledge is less comprehensive but the body of literature is growing. However, the so called legacy PFAS are now being replaced by diverse precursors and custom molecules that are difficult/impossible to detect and with unknown (trade secret) chemical structures.

In 2015 over 120 researchers signed The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFAS) (Blum et al. 2015) calling for international cooperation in limiting the production and use of PFAS to prevent further adverse effects on the environment and human health. In 2018 over 30 scientists together with regulators published the Zurich statement where a set of needs, goals and actions were set to assess and manage PFAS stressing that the regulation is going too slowly and is not sufficient to protect human health (Ritscher et al. 2018)

Lessons learned from legacy PFAS indicate that limited data should not be used as a justification to delay risk mitigation actions for replacement PFAS (Sunderland et al. 2018). The Nordic Council of Ministers have estimated the cost of inaction on PFAS. For the three different levels of exposure (background, elevated and occupational), the total annual health-related costs was found to be at least EUR 2.8 to EUR 4.6 billion in the Nordic countries and EUR 52 to EUR 84 billion in the EEA countries (Goldenmann et al. 2019).

Silicones

Silicones are a class of polymers with a siloxane backbone $(\text{-Si-O-})_n$ and inert organic side groups. In FCM silicones are commonly used in the form of fluids, rubbers, or resins. Silicones and plastics have functional properties that are similar, they are both flexible and versatile, but

the chemical properties differ fundamentally. In general, silicones are non-reactive, thermostable, water-repellant and gas permeable. (Geueke, 2015; Mojsiewicz-Pieńkowska and Krenczkowska., 2018).

Silicones have a variety of names, depending on the polymer length. Oligomers are called siloxane or siloxane oligomer, while polymers are called polysiloxane or silicone. Silicons (in the polymer form) is not a natural substance and persistent in nature.

Silicone fluids used in FCM are made of linear and cyclic polydimethylsiloxane (PDMS). In such a mix, linear PDMS molecules are either terminated by trimethylsiloxy or silanol units, which increase their viscosity. They can also be named silicone gums. **Silicone rubbers** are formed when liquid silicones are cross-linked. This creates a network between the polymers and oligomers and gives the material its elastic properties. **Silicone resins and silicone polymers** are also made by cross-linking liquid silicone, and the main difference between silicone resins and rubbers are the mechanisms and the degree of cross-linking. Silicones that are used to produce resins contain not only di-, but also tri- and tetrafunctional siloxane units in the polymer backbone, which provide OH-groups in the backbone as branching points for cross-linking. Stable silicone material is prepared by removing all water. In FCM the formation of cyclic phenyl substituted PDMS shall be prevented by choosing suitable starting materials. Silicones are also used **as additives in polymers** to enhance the flow during manufacture and to enhance surface finish of thermoplastics. Silicones can also be used in polyurethane foams, and as anti-foaming agents in food processing. Silicones are also used as preventive towards oxidation (Geueke, 2015).

Applications
Silicones are used in the industry both during the processing as parts or lubricants in the machines, and as materials for example permanent or temporary silicone coatings prevent sticking of food or food packaging to different surfaces, e.g. conveyor belts, ovens, freezing trays, and baking tins. Tubing, conveyor belts, O-rings, stoppers, valves and milk liners in direct contact with food are often made of silicone rubbers (Geueke, 2015).

In the household kitchens silicone products are used in a variety of applications for example as baking molds, spoons, coasters, spatula, dough scrapers, brushes, containers, ice cube trays, stoppers for bottles and many more (Geueke, 2015). These can be exclusively made out of silicone or be combined with other materials such as metal or different kinds of plastic, spanning from gaskets (for e.g. pressure cookers and electric kettles), adhesive sealants (in e.g. refrigerators, catering equipment), to silicone-polyester resins found as coatings in thermally stressed appliances such as toasters, cookers and pans. As food packaging materials silicones are used in the processing of material e.g. as additives in plastics to improve processing, moulding, fire resistance, surface properties, to prevent foaming, as additives in the finishing process of paper and as de-inking substrate for paper recycling (Geueke, 2015). Silicones are also applied as liners in clear film labels on beverage bottles and other food containers as well as lining on natural corks for alcoholic beverage bottles. A large application of silicone products is also for babies and toddlers including baby soothers, feeding teats and nipple shields for breastfeeding.

Regulation
No harmonised regulation in the FCM legislation. A resolution from the Council of Europe (2004) lists chemicals allowed, and not allowed, to be used in the manufacturing of FCM silicones, and sets the overall migration levels to the same as for FCM plastics (10 mg/m^2 or 60 mg/kg food). National regulations in seven member states.

Three cyclic silicones, D4, D5 and D6, are on the REACH Candidate list and proposed for restriction. These silicones are both used as they are in various applications but may also be impurities in silicone polymers. Therefore, the impact of a restriction on the uses of D4, D5 and D6, also includes an assessment of the impact on relevant uses of silicone polymers. Restriction for D4 and D5 in wash-off cosmetic products are already in force from January 2018 and applies from January 2020 (Annex XV Restriction Report – D4, D5 and D6). D4, D5 and D6 for leave on cosmetics and other consumer products, a restriction will probably come into force by 2020.

Migration and bioaccumulation
Migration of substances, including additives, catalysts, oligomers breakdown and reactions products, from silicone-based materials into food have been observed. The migration can be directly into the food, or via the air as silicone oligomers are volatile. Migration of such volatile organic compounds is especially problematic when a silicone product is intended to be used at elevated temperatures (e.g. baking trays). Short chain silicones (low molecular weight) have a higher migration potential and silicone rubbers and silicone resins may also contain residuals catalysts that potentially migrate into food. Examples include peroxide curatives and their breakdown products, and platinum, zinc, or tin catalysts. Another possible oxidation product and migrant of silicone rubbers and resins is formaldehyde, especially at elevated temperatures. Furthermore, a higher migration rate has been observed from silicone rubbers than from silicone resins due to highly cross-linked matrix of the resins (Geueke 2015).

Migration of cyclic and linear siloxanes has been detected from food-grade silicone fluids, silicone nipples and kitchen utensils into milk, infant formula, and liquid simulants. In a cake pan, no migration into milk and infant formula was found, but a high migration into 95% ethanol was identified, indicating a potential risk of migration into fatty food (Zhang et al. 2012). This has also been shown by Helling and colleagues (Helling et al. 2009; Helling et al. 2010; Helling et al. 2012). In those studies, they investigated silicone baking moulds and teats under actual conditions of use, and analysed the migration of siloxane oligomers, volatile organic compounds, and platinum. They saw that migration into simulants for fatty foods reached high levels (35-40 mg/dm^2) when used for the first time but strongly decreased for each preparation event. They saw a general lower migration into cake (1.0-1.2 mg/dm^2), but the migration remained almost stable over 10 times of preparation. These studies also concluded that migration into fat was much higher than into other food e.g. in meatloaf the concentration in the meat itself was about 30-fold lower than in the separated fat.

In their baking experiments, the researchers observed a reverse migration of fat from the food into the silicone, which may lead to questions regarding hygienic issues when using silicone. During their long-term usage experiments the researchers discovered a migration of siloxane oligomers from pizza moulds in the range of 0.9-1.2 mg/dm^2 for the first 10 baking events and

steadily decreased over the next 1700 cycles. Interesting though was that the migrating siloxane oligomers were almost completely replaced by triglycerides originating from the food during the increase of baking event, again questioning the hygiene aspects of such products (Helling et al. 2009; Helling et al. 2010; Helling et al. 2012).

Risk and health effects

Migration of substances, including additives, catalysts, oligomer breakdown and reactions products from silicone-based materials into food have been observed. The data presented are representative and show a real tendency concerning the need of monitoring of siloxanes present in the environment. Several research studies have shown toxicity, mainly endocrine and reproductive effects in animal experiments (Geueke 2015; Wang et al. 2013; Tran et al. 2015; Kabir et al. 2015).

Phthalates (Diesters of ortho-phthalic acid)

Phthalates are esters of 1,2-benzenedicarboxylic acid (o-phthalic acid) and their chemical structure consists of one benzene ring and two ester functional groups linked with two consecutive carbons in the ring. To produce phthalates an alcohol (e.g. methanol, ethanol, tridecanol) reacts with phthalic anhydride. The hydrocarbon chains of the ester groups are obtained from the alcohol, they are either straight or branched and they are responsible for the name and the different properties among phthalates (Fernandez et al. 2011). Phthalate esters (PEs) are classified into two distinct groups according to the length of their carbon chain, long-chain and short-chain. To the group of long-chain phthalates are those with 7–13 carbon atoms in their carbon chain, for example diisodecyl phthalate (DiDP), diisononyl phthalate (DiNP), di2-propylheptyl phthalate (DPHP), diisoundecyl phthalate (DiUP) and diisotridecyl phthalate (DTDP). Phthalates with 3–6 carbon atoms in their backbone, for example dibutyl phthalate (DBP), diisobutyl phthalate (DiBP), butyl benzyl phthalate (BBzP) and di 2-ethylhexyl phthalate (DEHP), are in the short-chain group (Katsikantami et al. 2016; Fierens et al. 2012).

Applications

Phthalates are widely used in industry as plasticisers to increase softness, flexibility, elongation, and durability of rigid polymers such as polyvinyl chloride (PVC). The plasticised products include wire and cables, flooring, truck tarpaulins, wall coverings, self-adhesive films or labels, synthetic leather, coated fabrics, roofing membranes and automotive. Phthalates are also found in non-regulated food contact materials such as inks, adhesives, and surface coatings (Katsikantami et al. 2016). Food is the main route for human exposure to phthalates (Fierens et al. 2012).

Regulation

Phthalates are regulated in several EU-legislations, i.e. REACH, FCM-legislation and Directive 2009/48/EC on the safety of toys. Depending on the intended use of the FCM, it must be compliant with one or more of these regulations.

Restriction in articles under REACH

Based on the opinions of RAC and SEAC (ECHA, 2017a), the Commission concluded that the phthalates DEHP, DBP, BBP and DIBP pose an unacceptable risk to human health and introduced a restriction (Commission Regulation (EU) 2018/2005). According to this restriction, DEHP, DBP, BBP and DIBP shall not be placed on the market after 7 July 2020 in articles,

individually or in any combination of these phthalates, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article (safe some exemptions). The restriction also introduces a ban on the placing on the market of toys and childcare articles containing DIBP (placing on the market of toys and childcare articles containing DEHP, DBP and BBP under certain conditions was already banned). DINP and DIDP are restricted for those toys and childcare articles which can be placed in the mouth by children. These phthalates should not be present in concentrations greater than 0.1 % by weight of the plasticised material Childcare articles include products used to feed children.

Restriction in FCM

The phthalates DBP, BBP, DEHP, DINP and DIDP are listed and authorised in the positive list in Annex I of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. They have all restricted usages and limits of migration, nevertheless the usages and limits differ among the phthalates and no limit of the sum of all phthalates exist. Therefore, the Commission requested EFSA to evaluate whether the opinion and the authorisation under Commission Regulation (EU) No 10/2011 were still in accordance with the FCM Regulation (Regulation (EC) No 1935/2004). The EFSA CEP Panel[11] reconfirmed the same critical effects and individual TDIs (mg/kg bw per day) derived in 2005 for all the phthalates, i.e. reproductive effects for DBP (0.01 µg/kg bw per day), BBP (0.5 µg/kg bw per day), DEHP (0.05 µg/kg bw per day), and liver effects for DINP and DIDP (0.15 µg/kg bw per day each). Based on a plausible common mode of action (i.e. reduction in foetal testosterone) underlying the reproductive effects of DEHP, DBP and BBP, the Panel considered it appropriate to establish a group-TDI for these phthalates, taking DEHP as index compound as a basis for introducing relative potency factors. The group-TDI which was established to be 50 µg/kg bw per day, expressed as DEHP equivalents. For DIDP, not included in the group-TDI, dietary exposure was estimated to be always below 0.1 µg/kg bw per day and therefore far below the TDI of 150 µg/kg bw per day. These new recommendations are supposed to be enforced in 2020.

Migration and bioaccumulation

Phthalates are used to improve the plasticity (flexibility) to plastics as it fills the mesh spaces of the polymer system. And thereby imparting the plastics depending on the desired flexibility, which may go up to 70% as in flexible tubing. Phthalate plasticiser has no chemical linkage but rather a physically bound with the polymer systems and a slight change in the e.g., high or low pH, temperature and pressure, irradiation (UV, sunlight, microwaving, etc.) or contact with lipid, solvents, etc. could accelerate the migration of phthalate from the plastic embodiment into the surrounding environments. These leachates from the plastics system and other goods to food, drinks, soil, water, air (as dust and vapor), and blood (through medical devices) would pose severe damage to the environment, and the entire biota, and ultimately humans (Benjamin et al. 2017). The lipophilic properties of phthalates make it easily absorbed into human blood or fluids where they quickly are transformed into primary and secondary metabolites. Long chain phthalates (DIDP, DINP,DEHP, DnHP, DnPP, etc.) are mostly excreted through urine, sweat and feces in its glucuronidated form while short-chain phthalates (DMP, DEP, DBP, etc.) are excreted as corresponding phthalate monoesters in its non glucuronidated form, but they may circulate for briefly in plasma if conjugated. Before excretion, some of these

[11] EFSA Panel on Food Contact Materials, Enzymes and Processing Aids

metabolites would wrongly interact (xenosensing) with the endocrine molecular signalling systems in the human body (Benjamin et al. 2017).

Biological half-life of a substance coupled with duration and route of exposure (i.e., environmental conditions) influences the metabolites availability in the body. Hence, the longer biological half-life of phthalates, the greater its impact on health. Due to the hydrophobic nature of phthalates, human breast milk contains relatively more long chain phthalate metabolites compared to urine. Urine, however, contains relatively more of the secondary metabolites (formed by further oxidation, hydroxylation, and carboxylation) of long-chain phthalates and monoesters of short-chain phthalates (Benjamin et al. 2017).

Risk and health effects

Many of the health hazards posed by phthalates have been identified as hormone disrupting or impairing with the normal hormone system, known as endocrine disrupting chemicals (EDCs). Also, other negative health effects have been attributed to phthalates including various cancer forms, immune and metabolic diseases (Benjamin et al. 2017). Studies of prenatal exposure have shown correlations between in utero exposure to certain phthalates and abnormalities appeared in new-borns such as preterm birth, birth length and weight, head circumference and altered reproductive hormone levels that reflect in uterus delayed development and anti-androgen effects. Male and female new-borns appear to be affected by different phthalates and in different way indicating that phthalates are sex-specific (Katsikantami et al. 2016) Prenatal exposure has been associated with neurobehavioral disorders while exposure to phthalates during childhood have been linked to asthma and allergic symptoms, obesity, anti-androgen effects, delay of growth and puberty, and changes in systolic blood pressure. However, there are too few studies to conclude whether health impacts in children linked to phthalates are due to in utero exposure or exposure during childhood (Katsikantami et al. 2016).

Non-intentionally added substances (NIAS)

In addition to the problem of the chemical substances used intentionally, there is perhaps an even greater problem with the non-intentionally substances present in the material (Grob, 2014). Food contact materials (FCMs) and the products they constitute may contain non-intentionally added substances (NIAS), i.e. all substances that have not been added for a technical reason during manufacturing of FCMs and FCAs. NIAS can enter the supply chain of FCMs/FCAs at any level, e.g., during chemical syntheses of raw materials as well as manufacture, transport, and recycling. The awareness of NIAS as an issue of concern for food safety has grown during the last few years due to increasing sensitivity in chemical analysis and the random identification of potentially hazardous chemicals migrating from FCMs (Geueke, 2018)

The risk of NIAS is higher in material that are made from solutions with a mixture of several different chemical substances, which during the formation of the solid material undergo a variety of chemical reactions and then also form new unknown products (Grob, 2014). Sources of NIAS are grouped into side products, breakdown products, and contaminants. **Side products** are often created during the process of complex FCM when the process includ several production steps and manufacturing stage. For many processes, major side products are

known. Such NIAS can be monitored and changing the process parameters can even reduce their formation. However, currently a comprehensive prediction of all potential side products remaining in the final product is more or less impossible (Geueke, 2018).
When producing FCMs a high number of different substances are often included and the higher number of starting substances the higher potential of **breakdown products**. Both the structure-providing constituents of FCMs (e.g., polymers, fibres) as well as additives may undergo chemical reactions during manufacture and use. Such processes can be caused or accelerated by external factors such as heat treatment, irradiation, and contact with food and/or oxygen. Some types of additives form intended reaction products while fulfilling their function during use (e.g., antioxidants). These degradation products are often predictable and well-known, but nevertheless they are defined as NIAS. However, for many products and substances the degradation is not well known and together with the complexity of the manufacturing processes, it is more or less impossible to make a comprehensive prediction of all potential side products remaining in the final food contact article.

One typical group of **side products** are oligomers. Oligomers are formed during the synthesis of polymers and can strongly contribute to the overall migration from plastic FCMs. Although their presence is usually known to the manufacturer, the risk assessment of oligomeric mixtures is challenging because of their complex composition. The **breakdown** products of polymers are more complicated and, in many cases, unknown. These products have a lower molecular weight than their parent compounds, and therefore higher diffusion coefficients and increased migration potential Whether breakdown products of polymers leading to the original starting substances (e.g., bisphenol A formed via degradation of polycarbonate) shall be considered NIAS or intentionally added substances needs further specification.

According to leading researchers on the theme, most migrating substances in many cases consist of inadvertently added chemical substances (Grob 2014). It has been estimated that tens of thousands of substances can migrate from FCMs and FCAs and since many FCMs and FCAs have a high chemical complexity, it is a challenge to identify those NIAS that may be of concern and a complete characterisation of all NIAS is currently unrealistic (Geuke, 2018). Although more and more NIAS are being identified, another challenge is the risk assessment of these. Many of the known NIAS have not been risk assessed so far. Also, several NIAS may have been detected by chemical analysis but their structures remain unknown; thus, conclusions on the safety cannot be drawn. The last group of NIAS is those substances, which completely stay under the radar, because they are not detected by any of the applied analytical methods.

NIAS is introduced in the plastic FCM regulation (Commission Regulation (EU) No 10/2011) as “An impurity in the substances used or reaction intermediates formed during the production process or a decomposition or reaction products.” However, NIAS are not limited to plastics but also occur in all other non-plastic FCMs.

Examples of some special products of interest

Children products

One would believe that the FCM-legislation consider that children have higher sensibility towards hazardous chemicals than adults. Children eat and drink more in comparison to their body volume than adults. It is also known that many of the hazardous chemicals can disrupt the development, and that the chemical burden foremost comes from what we put into our mouth. Thus, it would be logical if the FCM-legislation were the toughest one when it comes to chemicals. This is not the case. Instead it is as the lawmakers thinks that children only come in contact with toys and baby bottles, and that they are safe as long as these products are regulated tough enough.

The effects from developmental exposure and high sensitivity of the foetus and young children are widely known. As a foetus and during the first years of life there is an important window of exposure causing chronic disease. If certain chemical exposures are avoided during this period, the risk for some chronic diseases can be reduced (Barouki et al. 2012). Children are therefore specially protected to some extent in the EU legislation as some substances and food contact articles are extra tightly regulated. Food contact articles intended for children include bottles, baby food and formula containers, cutlery, plates, and mugs and more. However, there are still concerns over the children's exposure from problematic chemicals in FCM.

In a recent French biomonitoring study levels of bisphenols, phthalates and PFAS in over a thousand adults and children were measured. Six **PFAS** were regularly present in both adults and children, and all samples tested positive for PFOA and PFOS. Metabolites from nine phthalates were found in over 80% of samples. The highest amounts of the contaminants were found in children's blood and urine (Santé Publique, France 2019). Also, in a recent study by the German Environment Ministry and the Robert Koch Institute found that almost all children tested, 97 %, have traces of plastic by-products in their bodies. The younger children were reported to have the highest amounts in their bodies. The researchers comment that they see an increase of exposure to substitutes for restricted chemicals and chemicals that are restricted should not be substituted with similar chemicals that have the same potential characteristics (Spiegel 2019).

Bamboo/**melamine** dinnerware sets are often marketed towards children and being labelled as “sustainable, natural and eco-friendly”, a “plastic free alternative” and “biodegradable”. The European Commission's expert working group on FCMs has published a summary of discussions regarding the use of “plastic food contact materials and articles containing ground bamboo or other similar constituents.” The working group notes that over the last few years, there has been several notifications under the Rapid Alert System for Food and Feed (RASFF) concerning bamboo-melamine articles and materials. Migration of melamine and formaldehyde high above the limits (SMLs) were found (European Commission, 2019). According to RASFF, melamine materials were the most reported in the system 2018. At least 15 of the products that were reported for migration were described as made from “bamboo filter”. In some of the notifications there were no mention of melamine as material and in others melamine was described as a “filler” (RASFF 2018).

Bisphenol A (BPA) was restricted in baby bottles in 2011 by the Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC, which later in 2011 was replaced by Commission Regulation (EU) No 10/2011. In 2018 the use of BPA in children's products was extended to drinking cups and bottles for young children and no migration is permitted from varnishes and coatings applied to materials and articles specifically intended to come into contact with formula and baby food. Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials. In Sweden amongst other countries like Belgium and Denmark, BPA is restricted in all food contact materials intended for children. In France BPA is restricted in all FCM.

In a study recently published with data from the Swedish Environmental Longitudinal, Mother and child, Asthma and allergy study (SELMA) study, the authors found that early prenatal exposure to suspected endocrine disruptor mixtures is associated with lower IQ at age seven in the studied children. The EDCs studied where; phenols, plasticisers (phthalates and non-phthalates), PFAS, and persistent chlorinated substances. The substance that was found to make the largest contribution to the mixture effect estimate was BPF, the replacement for BPA (Tanner et al. 2019).

Another result from the SELMA study was published in 2015 (Bornehag et al. 2014). Here the authors show reproductive toxicity in boys prenatally exposed to **phthalates**. Ten phthalate metabolites of DEP (diethyl phthalate), DBP (dibutyl phthalate), DEHP, BBzP (benzylbutyl phthalate), as well as DiNP and creatinine were measured in 196 boys. They show that several phthalates, including the DiNP currently often used to substitute phthalates, caused a shorter anogenital distance (AGD). A shorter AGD is used to assess reproductive toxicity and is related to male genital birth defects and impaired reproductive function (Bornehag et al. 2014).

The epidemiological analysis of the data from this cohort of mothers and children in the SELMA study showed that prenatal exposure to mixtures of EDCs is associated with various effects in children's health and development. When data from the study were used to identify EDC mixtures associated with adverse effects in prenatally exposed children sexual development, neurodevelopment and metabolism and growth were affected by the chemicals in mixtures including 13 phthalate ester metabolites of seven phthalate esters plus a metabolite of DINCH, two metabolites of two polycyclic aromatic hydrocarbons (PAHs), five metabolites of five alkyl phenols (four bisphenols and triclosan), and a metabolite of an organic phosphate esters. Further, eight perfluoroalkyl substances, 19 polychlorinated persistent aromatics and three polybrominated diphenyl ethers. (Bergman et al. 2019).

Frying pans

The material of a frying pan on the market today is not always easy to define. Ceramic frying pans can have a non-stick (PTFE or other coatings) coating but still be marketed as a ceramic pan, the same goes for cast-iron pans.

PTFE non-stick

One of the most common PFAS is polytetrafluoroethylene (PTFE), the non-stick coating used for many common cookware. This product was discovered in 1938 as the result of an unintentional polymerisation reaction of tetrafluoroethylene (TFE). In the 1940s, PTFE was patented by Kinetic Chemicals and the Teflon® trademark was registered. PTFE is also sold under other many other trade names, like Dyneon PTFE, Daikin Polyflon™, Norton® Chemfilm® and many others (McKeen 2017).

PTFE itself is inert and not itself a toxic chemical However, when heated over 350 Celsius PTFE can break down into and give rise to toxic polymer fumes. Pans with PTFE have shown to reach temperatures over 350 Celsius when used on induction stoves (Göteborgsposten 2012). Also, during manufacturing and the polymerisation of PTFE, traces of other PFAS may arise and remain in the final product. Even though the trace levels are relatively low, PFAS are extremely persistent and hence break down very slowly if at all. The health effects of PFAS are discussed in some more detail in the section about PFAS under "Substances of concern".

Cast iron

Cast iron is a group of iron-carbon alloys with a carbon content greater than 2%. Iron cast cooking ware have been used for hundreds of years but lost popularity when non-stick cookware was introduced to the market in the 1960´s and -70´s. Cast iron pans are durable but heavy, and prone to rusting if not taken care of properly.

Researchers have found that food cooked in an iron skillet has increased iron content compared to food cooked in other cookware. Acidic foods that have high moisture content, such as applesauce and tomato sauce, absorb the most iron (Brittin and Nossaman 1986). This may be beneficial for many people with iron deficiencies (Geerligs et al. 2003). Cast iron frying pans have not been associated with any health risks (note: this goes only for the cast iron pans without a non-stick coating. Non-stick coatings may contain PFAS and include other health risks).

Carbon steel

Carbon steel is mainly comprised of steel with varying carbon content up to 2% of the weight. Carbon steel has not been associated with any health risks. Carbon steel pans have similarities with cast iron pans, they need seasoning with oil to become non-stick are prone to rusting and can enrich food with iron. Carbon steel is more lightweight (note: this goes only for the carbon steel pans without a non-stick coating. Non-stick coatings may contain PFAS and include other health risks).

Stainless steel

Stainless steel is a steel alloy with a minimum of 10.5 % chromium. They have high corrosion resistance and frying pans are lightweight. They are durable and dishwasher safe but do not conduct heat as good as other alternatives. Studies have shown that both aluminium and stainless-steel products can precipitate metal when in contact with acidic food and beverages. Studies investigating stainless steel cookware show that Nickel (Ni) and Chromium (Cr) leaked into tomato sauce after cooking for six hours (Kamerud et al. 2013). The concentrations differed with the grade of stainless steel and time of cooking. The authors conclude that stainless cookware can be an overlooked source of human exposure to Ni and Cr (Kamerud et al. 2013)

however there are no available studies that show a negative health effects from using stainless steel frying pans. (Note: this goes only for the stainless-steel pans without a non-stick coating. Non-stick coatings may contain PFAS and include other health risks).

Ceramics/enamel
Ceramic coating is according to the manufacturers made mainly of silica often manufactured using nanotechnology. Negative health effects from ceramic pans can occur from migration of heavy metals if the materials are not free from such. Apart from heavy metals no reported health effects are found. The regulation for ceramics sets out limits for migration of lead and cadmium from the final product. This means that only intact articles are guaranteed by the regulation, and caution should be taken if i.e. the surface is scratched or cracked. (Note: this goes only for the stainless-steel pans without a non-stick coating. Non-stick coatings may contain PFAS and include other health risks).

An example of so called "quasi-ceramic frying pans" investigated in a study of commercially available non-stick coatings on ceramic frying pans found that the coatings contained micron- and nanosized rutile TiO_2 particles, and quartz SiO_2 embedded in a silicone polymer matrix. When the release of TiO_2 into food was investigated the results showed that intact coating released titanium in ionic form at up to 3.64 µg/L and in nanoparticulate form at up to 861 µg/L. Mechanical degradation studies showed that scratches and other types of damage to the surface from normal use may lead to significant release of particles containing titanium with a large proportion of them nanosized (Golja et al. 2017). In a chronic exposure study of TiO_2, the authors show that TiO_2 can cross the intestinal barrier and relocate to other parts of the body. Absorption of nanoparticles were found to disrupt immune disruption in both the intestine and the spleen. In addition, pre-cancer lesions in the colon were found in 40 % of the exposed animals (Bettini et al. 2017).

Nanoparticles, not only $Ti0_2$, are commonly used in food contact material as well as food additives and there is a concern over the safety of nanomaterials (Jokar et al. 2016).

Single use products and take away/fast food containers

To prevent plastics from littering the environment, EU has recently adopted Directive (EU) 2019/904, aiming to reduce or phase out plastic products that often are found in oceans, on beaches, in cities and in nature. The food contact articles that are covered are single-use plastic cups, plates, cutlery, as well as food containers and lids. They are divided into two groups, one with restriction, and one with reduction requirements, see table 6. The directive also set out requirements for percentage reused PET in PET-bottles, to 25 % in 2025 and 30 % in 2030, to increase the circularity of PET-plastics. The average recycled content in PET bottles in Europe is stable over the recent years around 11% (EPBP.org).

Table 6. The different plastic food contact articles and the requirements of restriction or reduction under the new EU directive ((EU) 2019/904) to prevent littering of the environment.

Restriction by 3 July 2021, according to article 5 of Directive 2019/4	**Reduction** (year 2026 vs 2022), according to article 4 of Directive 2019/204
Plastic plates	Plastic cups, covers and lids
Plastic cutlery	Plastic food containers
Plastic straws and stirrers	
Polystyrene food containers	
Polystyrene beverage containers	
Polystyrene cups	

Extract from the Directive:
DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 on the reduction of the impact of certain plastic products on the environment

Article 4
Consumption reduction
1. Member States shall take the necessary measures to achieve an ambitious and sustained reduction in the consumption of the single-use plastic products listed in Part A of the Annex, in line with the overall objectives of the Union's waste policy, in particular waste prevention, leading to a substantial reversal of increasing consumption trends. Those measures shall achieve a measurable quantitative reduction in the consumption of the single-use plastic products listed in Part A of the Annex on the territory of the Member State by 2026 compared to 2022.

ANNEX
PART A
Single-use plastic products covered by ***Article 4*** *on consumption reduction*
(1) Cups for beverages, including their covers and lids;
(2) Food containers, i.e. receptacles such as boxes, with or without a cover, used to contain food which:
(a) is intended for immediate consumption, either on-the-spot or take-away,
(b) is typically consumed from the receptacle, and
(c) is ready to be consumed without any further preparation, such as cooking, boiling or heating, including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets and wrappers containing food.

Article 5
Restrictions on placing on the market
Member States shall prohibit the placing on the market of the single-use plastic products listed in Part B of the Annex and of products made from oxo-degradable plastic.

ANNEX
PART B
Single-use plastic products covered by ***Article 5*** *on restrictions on placing on the market*
(1) Cotton bud sticks, except if they fall within the scope of Council Directive 90/385/EEC (1) or Council Directive 93/42/EEC (2);
(2) Cutlery (forks, knives, spoons, chopsticks);
(3) Plates;
(4) Straws, except if they fall within the scope of Directive 90/385/EEC or Directive 93/42/EEC;
(5) Beverage stirrers;
(6) Sticks to be attached to and to support balloons, except balloons for industrial or other professional uses and applications that are not distributed to consumers, including the mechanisms of such sticks;
(7) Food containers made of expanded polystyrene, i.e. receptacles such as boxes, with or without a cover, used to contain food which:
(a) is intended for immediate consumption, either on-the-spot or take-away,
(b) is typically consumed from the receptacle, and
(c) is ready to be consumed without any further preparation, such as cooking, boiling or heating, including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets and wrappers containing food;
(8) Beverage containers made of expanded polystyrene, including their caps and lids;
(9) Cups for beverages made of expanded polystyrene, including their covers and lids.

As the directive comes into force the single use plastic products likely will be replaced by reusable plastic products or products made on paper and board.

Hazardous chemicals in take away containers
Take away coffee cups and containers are often made from paper/board, and it will be more and more common with the restriction of plastic take-away articles. Paper is the second most used food packaging material after plastic (BEUC 2019). With the upcoming ban of single use plastic, it is of relevance that the paper/board packaging alternatives are safe. Unlike plastics, however, there are no specific EU regulations regarding paper/board as a food contact material

When the Danish consumer council investigated pizza boxes in 2015, they found several problematic substances that are suspected to be endocrine disrupting or cancer-causing besides from the already known PFAS. These substances include mineral oils, phthalates,

bisphenol A and nonylphenol and are according to the Danish consumer council likely to come from recycling material (BEUC 2019).

In 2017 several national consumer groups from Spain (OCU), Belgium (Test-Achats/Test-Aankoop), Italy (Altroconsumo), Denmark (Danish consumer council) and Portugal (DECO) investigated fluorinated substances in fast food packaging. They found that one third of the packaging contained fluorinated compounds including PFOA in high levels. Another 12 samples showed elevated levels of fluorinated substances although in lower levels (Forbrugerrådet taenk kemi 2017). Denmark has since then submitted a ban for all PFAS from cardboard and paper food contact materials for external review on the government's consultation portal and the National Food Authority expects the ban to take effect in July 2020 (Ministry of Environment and food of Denmark, 2019).

Recently four member states national consumer groups (Altroconsumo (Italy), Forbrukerrådet (Norway), Forbrugerrådet TÆNK (Denmark) and OCU (Spain)) analysed 76 samples of printed paper and board food packaging such as coffee cups, straws and paper napkins and found that more than one in six samples contained primary aromatic amines, some of which are suspected to cause cancer, nine of the samples exceeded limits set in the EU Plastic Regulation. Most of the samples contained UV filters, some of which are suspected to cause cancer or be endocrine disrupting. Further analysis showed that the UV filters migrate into food above the recommended levels in several products, including a children's box of raisins (BEUC 2019).

With the set of the ban of single use plastic in 2021 in the EU, safety concerns for alternatives like paper and board packaging have been raised.

Electric products

Electrical and electronic products used in food contact must be compliant with the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive, the Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (POPs Regulation), REACH (EU 2006/1907) as well as relevant parts of the FCM-legislation. The RoHS Directive regulates four metals, two groups of brominated flame retardants and four phthalates. The POPs Regulation covers persistent organic pollutants, of which PFOS and its derivatives, short chain chloroparaffins (SCCPs) and brominated flame retardants, are of relevance to electrical and electronic products, all of which are on the elimination list (Annex A).

Extract from the RoSH Directive 2011/65/EU:

Article 1
Subject matter
This Directive lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.
....
ANNEX II
Restricted substances referred to in Article 4 (1) and maximum concentration values tolerated by weight in homogeneous materials
Lead (0,1 %)
Mercury (0,1 %)
Cadmium (0,01 %)
Hexavalent chromium (0,1 %)
Polybrominated biphenyls (PBB) (0,1 %)
Polybrominated diphenyl ethers (PBDE) (0,1 %)
Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)
Butyl benzyl phthalate (BBP) (0,1 %)
Dibutyl phthalate (DBP) (0,1 %)
Diisobutyl phthalate (DIBP) (0,1 %)

Hand blenders - a case study
Handheld blenders are common kitchen appliances used to make soups, smoothies, sauces, and baby food. The hand blender is driven by an electric motor that drives the cutter blade, mounted in a bell-shaped casting at the other end of the blender through a working shaft (Yuan et al. 2017).

In 2014 a group of researchers at Stockholm University, Sweden, unintentionally found out that chlorinated paraffins (CPs) may be used in and also leaking from hand blenders, sold on the Swedish market. The discovery was made when the research team analysed cat food to investigate whether it contained organic environmental pollutants. Unexpectedly, CPs were found in the cat food, and the researcher realised that it came from the hand held blender used in the study (Icakuriren 2017). The group purchased twelve hand blenders, intended for household use and analysed them for any potential leakage of CPs into food when used for blending according to the distributor instructions. The results showed that eight out of twelve hand blenders were leaking CPs to the prepared food they were used for, and the levels can be regarded as high in five of them. This means that usage of 2/3 of the hand blenders tested will cause human exposure of CPs, i.e. exposure to a group of persistent and bio-accumulative chemicals. The presence of CPs has previously been reported in Swedish mothers' milk. Short chain CPs (SCCPs) have low acute toxicity to mammals but are classified as possible carcinogens. According to the researchers, the finding of CPs leaking out of hand blenders was unexpected. To assess the health risk from dietary exposure to the leaking CPs and to

understand how CPs leak from the hand blenders, the researchers measured CP amounts in the leakage from the hand blenders' use and estimated the background daily dietary intake using Swedish food market baskets. They also tested if the amount of CP leakage changed with usage time and dismantled all the hand blenders and compared CP patterns in the components with the patterns in the leakage to search for the source(s) (Yuan et al. 2017). This study found 5% of the tested blenders (n=16) will lead to increased exposure and that the intake of CPs for Swedish adults by using handheld blenders once a day can raise their daily dietary intake by a factor of up to 26. Also, the TDI for Swedish infants with a body weight < 7.2 kg will be exceeded. Notably is that the leakage may last several hundred times of hand blender use (Yuan et al. 2017).

As a follow up study, the Swedish journal, “Ica kuriren”, together with Stockholm University, made a new test of 21 handheld blenders in 2017. The results show that none of the tested blenders leaked CP anymore but three of them leaked a substance chemically similar to CP, but not yet identified (Icakuriren, 2017).

EFSA´s panel on contaminants in the food chain had public consultation on the scientific opinion on the draft scientific opinion on the risks posed to human and animal health from the presence of chlorinated paraffins in food and feed in 2019 (EFSA, 2019b). In the draft the CONTAM Panel “considered that the impact of the uncertainties on the risk assessment of exposure to CPs in food is substantial, and due to the limited data on occurrence of CPs in food dietary exposure is considered to be underestimated”.

Handling potential hazards in Food Contact Materials

For manufacturers and retailers

Quality management system
It is important for every and each company in the retail chain to have a quality management system in place.

Declaration of Compliance
A Declaration of compliance (DoC) and supporting documents for each product are necessary to show that FCMs are in compliance with the regulations. In a report by Norden, the business operators could present a DoC for 89% of the 280 products investigated. Only 45 % of the DoCs contained sufficient information. When further analysing plastic material in 19 food contact material samples, the frequency of violations of too high amounts of phthalates was 32% (Li et al. 2015).

Controls (to check that the information given is correct)
It is up to each and every company to ensure that the information given is correct. Random sampling and chemical analyses are probably the only way to secure that.

For consumers

Consumers right to demand information
Under the REACH legislation article 33 consumers have the right to request information from the supplier about the presence of SVHCs in a concentration higher than 0.1 % (weight/weight) in products. The supplier must provide enough information to allow safe use of the products within 45 days free of charge. The EU project AskREACH recently published a report describing the results of conducted online surveys and literature research reviewing the awareness of consumers and suppliers regarding their rights and obligations with respect to information sharing about the presence of substances of very high concern (SVHCs) in articles (Schenten et al. 2019). The survey found that 42 % of the participating companies had received "right to know requests" from consumers and half of these did not have the information for an immediate response. The authors conclude that the communication on SVHC through the supply chain is lacking. The survey shows that chemicals are one of the main environmental concerns among Europeans and an area where there is a perceived lack of information. Regarding concerns about SVHCs the main product category is children's articles, but a clear majority of respondents felt that consumers should be able to buy products in all categories that do not contain SVHCs (Schenten et al. 2019). In an online survey conducted in Germany with over 100 respondents nearly all participants considered legislators as responsible for the reduction of harmful substances in consumer products (Hartmann & Klaschka 2017). A report published by the Danish Environmental Agency in 2019 concludes that the regulation has reduced SVHC use levels in the Nordic countries. The report claims that the study "clearly indicates that regulatory action (including harmonised classification/assigning the SVHC designation) over the past decades on substances currently on the REACH Authorisation List has resulted in considerably reduced tonnages in the Nordic countries Denmark, Norway, Sweden and Finland".

Substances of Concern in Products (SCIP)-database

To increase the reuse of materials in the circular economy, it is of high importance that the chemical content in products is known at the end-of-life stage. The waste management companies need to know, at least, if any part of the product contain any regulated chemicals. In the updated Waste Framework Directive from 2018, article 9, 1 (i) and 2, on prevention of waste, the European chemical agency is assigned to develop a database for articles on the European market. The database is to include the information requirement set out in REACH Article 33, i.e. the content of SVHC-substances (> 0,1%) for each and every part of the article, as well as information on safe usage and waste management. The information is foremost aimed for waste managers, but consumers are to get access to the information in the database upon request.

The right of a consumer to the information about SVHC is not commonly known and ineffective from a consumer perspective as the information is not available at the time of purchase. In an aim to improve the communication about SVHCs, an application for smartphones has been developed by authorities and organisations in 14 EU member states. This app will help consumers learn about the risks of SVHCs and provide a space for companies to share information with consumers about SVHCs in their products. The app is to provide the missing link between consumer and producer and will strengthen consumer power with the goal to phase out all hazardous chemicals. The app has now launched in Germany, Luxembourg, and Sweden (Sveriges konsumenter, 2019) with regionally adapted apps in App Store and Google Play. Apps will successively be launched in Austria, Croatia, Czech Republic, Denmark, France, Greece, Latvia, Lithuania, Poland, Portugal and Serbia and should all be available in 2020. The long-term aim is to launch apps in most European countries (AskReach.eu).

Discussion and conclusions

The food contact material legislation does not protect human health in an adequate manner, even though it is the main purpose of the legislation. The framework legislation is from 2004, and with all the additional material, substance, and national regulations, it is more like a patchwork than a coherent and well-thought-out piece. The ongoing overview is more than welcome, and hopefully, after a profound update and harmonisation, the legislation will live up to the purpose of protecting human health. **FCM-legislation must protect human health and the environment.**

One of the main issues with food contact material is that the number of chemical substances used is enormous, over 10 000. That is about half the number of registered substances under REACH. Most of the substances used have not been thoroughly investigated regarding their health properties, and thus the health effects are unknown. Instead the prevailing philosophy is "no data - no harm". And even though the legislation states that all FCM shall be safe to use with no migration harming the health, there is a disparage between the legal requirements and really showing that what migrate do not cause any harm. This makes it impossible for the manufacturer and retailers to fulfil the requirement of only selling safe materials. The updated legislation should only allow thoroughly investigated substances that are found safe for human health, with the reason "Conclusive but not sufficient for classification" in CLP, meaning that there is adequate and reliable information that does not fulfil the criteria for classification. **Substances and materials lacking data for classification should not be allowed to be used in food contact until proven safe.**

EU's general chemical legislation, REACH, and the FCM legislation are not harmonised. Several substances under REACH that are recognised as "Substances of very high concern" (SVHC), are permitted in food contact materials. It is a blatant contradiction that substances are evaluated as safe in FCM legislation whilst they are to be phased out under REACH. **Substances of very high concern (SVHC) should not be allowed in food contact materials.**

Plastics are more regulated than other materials in food contact. For instance, multilayer materials and articles are not allowed to contain substances classified as CMR[12] in the CLP-regulation, if not listed on the union list, hence they are allowed in other material types. But to protect human health, no CMR substances should be allowed, indifferent of the material type. Preferable a general restriction of CMR substances should be in the main FCM-regulation document (EC) No 1935/2004, covering all CMR-classified substances under both CLP and REACH. We found 21 substances harmonised classified[13] as carcinogenic, mutagenic, or toxic

[12] CMR stands for carcinogenic, mutagenic, and toxic for reproduction

[13] Substances and mixtures with hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers), classification and labelling should be harmonized throughout the EU to ensure an adequate risk management. Harmonized classifications are listed in Annex VI to the CLP Regulation and should be applied by all manufacturers, importers or downstream users of such substances and mixtures containing such substances.

for reproduction (CMR) according to CLP still are on the 'union list' of approved plastic ingredients (see Table 4). Of these 11 substances are found on the Candidate list, six on the Authorisation list and four on the Restriction list. For nine of these substances, migration limits have been set to 'not detectable' (ND). But for the others, detectable amounts are allowed to migrate, and if no specific migration limit is set, up to 10 mg/dm^2 is allowed to be released. This is worrisome. **No substances that are cancerogenic, mutagenic or reprotoxic should be allowed in food contact materials.**

Per- and polyfluoroalkyl substances, PFAS, is another case example of where the FCM legislation does not protect human health. The long-term effects of exposure to many of the PFAS are still unknown. Nonetheless, more and more studies show health effects in humans and animals from exposure including cancer, damage to the liver, disruption of reproduction and immune system from several of these substances. In a recent study PFAS were found in human foetuses' liver, lungs, and brain, with levels similar to the levels in the mother's placenta, illustrating that PFAS easily cross the placenta and pose a risk for the developing foetus. PFAS are sometimes called "forever chemicals" as they break down very slowly, if at all, in the environment. The annual health and environmental related costs for PFAS exposure in the EEA are estimated by the Nordic Council to 52-84 billion respectively 10-20 billion EUR (Goldenman et al. 2019). From what is known today, it cannot be concluded that the unstudied PFAS are safe, on the contrary precautions should be applied. **PFAS should not be allowed in any food contact materials.**

Denmark is now stating an example by being the first country in the world to ban all PFAS from cardboard and paper food contact materials. The ban has been submitted for external review on the government's consultation portal and the National Food Authority expects the ban to take effect in July 2020. But it should not be up to each country to set out national regulations. A progressive, harmonised EU-legislation is the best both from a health and environmental as from an economical and circular economy perspective.

Endocrine disrupting chemicals (EDCs) are not addressed in FCM legislation (except from the isolated measures of BPA and phthalates). The harm to health from EDCs is now widely recognized (Bergman et al 2008). Experts from the WHO and UNEP together with scientists have called for action on reducing the exposure to EDCs to protect health. **EDCs should be eliminated from food contact material with a clear stipulation prohibiting EDCs.**

When FCM is manufactured from recycled materials, it is not regulated at an EU-level, except for plastic. A testing of pizza boxes by the Danish Consumer Council in 2015, found fluorinated chemicals, mineral oils, phthalates, bisphenol A and nonylphenol in pizza boxes, likely to come from recycled material The drive for circular economy and resource efficiency in the EU should not compromise human health. FCMs is considered to be quantitatively the largest source of chemical contamination in food, hence strongly contributing to "chronic" chemical exposure. However, the migration levels of many FCM substances are unknown leading to a high level of uncertainty in exposure estimation. A better harmonisation and coordination between chemical regulations and FCM legislation would contribute to consolidating the market for recycled materials and to phased out hazardous substances in all products. **Recycled materials should have the same requirements as virgin materials.**

The presence and migration of all substances (including non-intentionally added substances, NIAS) in the final food contact products should be measured, assessed and controlled. Even if they are not intentionally added, they still pose a risk for consumers and the environment which must be addressed. Absence of reliable migration data should imply presumption of full migration. Migration must be fully understood and limited to ensure a high level of protection of public health. Instead of “no data - no harm” the principle of “no data - no market” should be implemented in all aspects. **Non-intentionally added substances must be included in the legislation and measured in the final product.**

Another example of insufficient legislation is how the final product is assumed to be used. The migration of chemicals to the food from the FCM is measured on new intact articles. The migration from scratched and broken products could be higher than from the intact new articles. The ceramic regulation sets out limits for migration of lead and cadmium from the final product. This means that only intact articles are guaranteed by the regulation, and caution should be taken if i.e. the surface glaze is chapped, and the underlying ceramic is exposed. **Legislation should include used products (i.e. scratched and broken articles) to ensure human health.**

National governments must ensure effective enforcement of the FCM-legislation. **The FCM-legislation should require national authorities to establish and implement a control program to ensure that the legislative requirements are fulfilled, and if not oblige economic penalties.**

The Swedish Society for Nature Conservation (SSNC) wants legislation with a high protection of human health and the environment. All substances in FCM should have adequate safety data and substances that are already restricted in the EU, and all those meeting the REACH criteria for substances of very high concern, such as CMRs, PBTs and endocrine disruptors, should be automatically prohibited. Migration analysis of the final product should include non-intentionally added substances (NIAS).

- The food contact material legislation must protect human health and the environment, according to the precautionary principle.
- Substances lacking data for any of health classifications in CLP should not be allowed to be used in food contact until proven safe.
- The FCM-legislation should not allow any
    - Substances of Very High Concern (SVHCs)
    - CMR substances
    - EDC substances
    - PFAS substances, including polymers
- Recycled materials should have the same requirements as virgin materials.
- Non-intentionally added substances must be included in the legislation and measured in the final product.
- Legislation should include used products, like scratched and broken articles, to ensure human health.
- The FCM-legislation should require national authorities to establish and implement a control program to ensure that the legislative requirements are fulfilled, and if not oblige economic penalties.

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Annex XIV LIST OF SUBSTANCES SUBJECT TO AUTHORISATION, to REGULATION (EC) No 1907/2006

Annex XVII RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OFCERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES, to REGULATION (EC) No 1907/2006

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