ChemAgenda

Survey of the current EU regulation on food contact materials and the need for improvements

Written for and commissioned by Verbraucherzentrale Bundesverband
February 2020, updated August 2020

Gefördert durch:

Bundesministerium
der Justiz und
für Verbraucherschutz

aufgrund eines Beschlusses
des Deutschen Bundestages

Survey of the current EU regulation on food contact materials and the need for improvements

February 2020, latest revision August 2020

Written by
Sidsel Dyekjær,
ChemAgenda
www.chemagenda.dk

Survey of the current EU regulation on food contact materials and the need for improvements

Content

Abbreviations

BADGE:	Bisphenol A diglycidyl ether
BEUC:	Bureau Européen des Unions de Consommateurs, The European Consumer Organisation
BMEL:	Bundesministerium für Ernährung und Landwirtschaft, German Federal Ministry for Food and Agriculture
BPA:	Bisphenol A
BPS:	Bisphenol S
CE-marking	Certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)
CLP:	Classification, labelling and packaging (of chemicals)
CMR:	Carcinogenic, mutagenic, or toxic to reproduction (Substances that cause cancer, mutation of genetic material, or adverse effects on fertility)
DoC:	Declaration of Compliance
ECHA:	European Chemicals Agency
EDC:	Endocrine Disrupting Chemical
EEB:	European Environment Bureau
EFSA:	European Food Safety Authority
ESCO:	EFSA Scientific Cooperation
FCA:	Food Contact Articles
FCC:	Food Contact Chemicals
FCM:	Food Contact Materials
FPF:	Food Packaging Forum
GMP:	Good Manufacturing Practice
GRC	Generic Risk Considerations (also GRA – Generic Risk Assessment)
HEAL:	Health and Environment Alliance. Brussels based NGO.
IA:	Impact Assessment
IAS:	Intentionally Added Substances
JRC	The Commission's Joint Research Centre
MAF:	Mixture Assessment Factor
MS:	Member State
NGO:	Non-Governmental Organisation
NIAS:	Non-Intentionally Added Substances
OML:	Overall Migration Limit
PET	Polyethylene terephthalate
PFAS:	Perfluoroalkyl and Polyfluoroalkyl substances
RA:	Risk Assessment
REACH:	Registration, Evaluation and Authorisation of Chemicals
RoHS:	Restriction of Hazardous Substances (Directive)
SCF:	Scientific Committee for Food
SDS:	Safety Data Sheet
SML:	Specific Migration Limit
SRA	Specific Risk Assessment
SVHC:	Substance of Very High Concern
TDI:	Tolerable Daily Intake

Executive summary

There is widespread concern that the current EU legislation on food contact materials (FCM) does not protect consumers against harmful chemicals migrating from food packaging and other food contact items into our food.

Consumer safety is hampered by inadequate knowledge, missing restrictions on the migration of chemicals and a lack of harmonised safety provisions that can ensure safety in an efficient way.

The current situation is not tenable. There is a need for an overview of the substances used in FCM. There is also a need for effective legislation that can ensure the hazardous effects of chemicals used in FCM and their potential migration are measured, and clear and controllable limits are in place.

Of the seventeen types of FCM identified in the framework legislation, only four are subject to EU-wide harmonised rules.

Today, even the most harmonised area, the Plastics Regulation, only inadequately ensures public health and an intact environment. For other materials, the legislative situation consists of a patchwork of different rules in the various Member States.

It is striking that no systematic assessment or evaluation of the legislation governing FCM has been carried out since the inception in 1976[1]. Over the same period, there has been much development in other chemicals legislation, particularly the REACH Regulation from 2006. The Cosmetics Regulation[2] (2009), the Toys Safety Directive[3] (2009), and the regulations on pesticides[4] (2009) and biocides (2012) are also relatively new legislations, which may provide examples of more up to date approaches.

The regulatory system for FCM can be seen as an example of an outdated policy which relies on industries' responsibilities and actions to ensure that products are safe, while failing to provide clear information on which stakeholders are ultimately responsible for product safety. The simple safety requirement in Article 3 of the FCM framework Regulation is not supplemented with the necessary guidance, tools, and controls to make the system work in practice.

Even though the general public may be largely unaware of the problems related to the current legislative framework, the report finds that these shortcomings has for many years

[1] See section on "background and context" on the Commissions website dedicated for the evaluation on the FCM legislation: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en

[2] Regulation (EC) No 1223/2009 on Cosmetic Products: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223

[3] Directive 2009/48/EC on the safety of toys: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32009L0048

[4] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

been widely recognised within the FCM community, including the Commission, the European Food Safety Authority (EFSA), Members of the European Parliament, NGOs working for health and environment, companies marketing FCM, and Member States' Authorities.

In 2018, the European Commission took an important step by initiating an evaluation of the current legislation. A further potentially significant step towards safer FCM was taken with the European Commission's recent Farm to Fork strategy from May 2020[5]. Here, the Commission made a clear commitment to propose a revision of the FCM legislation by late 2022.

As input to the anticipated revision, this report provides an overview of the current legislation on FCM and presents a number of concrete proposals to improve the current system. The proposals are based on a summary of recent initiatives taken by different stakeholders as well as a summary of their most important concerns. Finally, the report describes good examples of tools and approaches used in other legal acts on chemicals in products, such as for example the clear placing of the responsibility for assessing safety, which is seen in the Cosmetics Regulation and the regulation concerning Registration, Evaluation and Authorisation of Chemicals (REACH), the clear procedures for gathering and exchanging information on chemicals as also seen under REACH, and different provisions to avoid unacceptable hazards, of which there are several examples. In addition, there are other examples of urgent issues that need to be addressed in all EU legislations on chemicals. These are related to concerns for endocrine disrupters and mixture effects and to the need for assessing and regulating chemicals in groups. There is an urgent need to develop a mechanism to facilitate the identification and regulation of endocrine disruptors in the FCM legislation as well as in the legislation governing many other products.

Based on its findings, the report recommends a full review of the current legal framework on FCM, including the following key elements:

- Clear obligations for all actors in the supply chain to supply and share data
- Harmonised measures for all materials and usable guidance for industry
- Risk Assessments related to the final articles and based on the "foreseeable use"
- Mechanisms to take account of the cocktail effect and the mixture effect
- Efficient enforcement
- A basic aim for minimising exposure in line with the precautionary principle

[5] Commission Communication on the Farm to Fork Strategy: https://ec.europa.eu/food/farm2fork_en

Introduction

On the way from farm to fork, our food comes into contact with a whole range of different materials from food storage containers, factory equipment, packaging, kitchen utensils and cookware. These items are food contact articles (FCA) made of food contact materials (FCM), which may contain thousands of different food contact chemicals (FCC), including substances that are harmful to human health (figure 1).

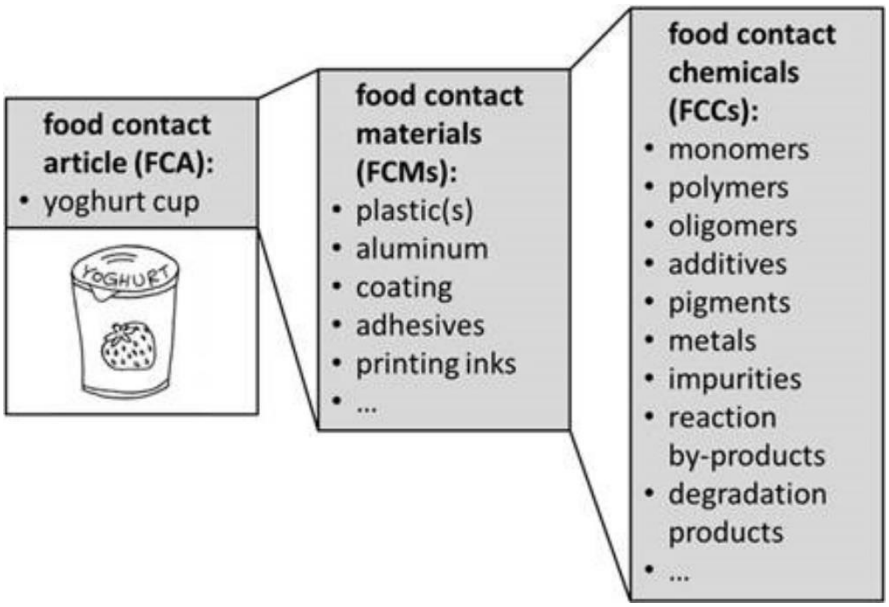

Figure 1: Explanation of some key terms. Food contact articles (FCAs) are combinations of different FCM, which consist of food contact chemicals (FCCs) (for example, a yogurt cup made of polystyrene with printing inks and a coated aluminium cover glued on with adhesives). Food contact materials consist of mixtures of many FCCs.[6]

It is well known that chemical substances are able to migrate from food contact material into our food and, as we eat food that has been in close contact with FCM every day, our food represents a significant potential source of chemical contamination of our bodies.

In order to support future work on the safety of food contact materials, the Federation of German Consumer Organisations, vzbv, has commissioned this report to provide an overview and updated information about the current status of the EU legislation on FCM as well as the need for improvement. The report has been compiled in a period from January to February 2020 and updated in August 2020.

[6] Muncke, J. et al.,2017: Scientific challenges in the risk assessment of Food Contact Materials, Environ Health Perspect., 2017 Sep 11;125(9):095001. doi: 10.1289/EHP644, https://pubmed.ncbi.nlm.nih.gov/28893723/

1 EU's legislation on chemicals in consumer products - with special focus on food contact materials

Hazardous chemicals in consumer products may constitute a health risk to consumers or a problem for the environment. In order to control these risks, the EU has developed a comprehensive framework of legal acts to provide protection. These laws are developed and maintained by three different Directorates-General (DG) in the European Commission and the corresponding ministries in the Member States (MS).

The overall aim of EU's legislation on chemicals in consumer products is to have a coordinated and coherent system in place to ensure public health and a healthy environment while also protecting the internal market. However, there are still both gaps and overlaps in the system, which need to be addressed.

There are two legislative acts which govern most chemicals on the market: Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (the CLP regulation)[7] and Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[8]. These two legal acts provide basic rules to ensure the safety of chemicals in consumer products, the environment, and the workplace. The CLP Regulation sets out the criteria for classification, labelling and packaging of hazardous chemicals and mixtures. The REACH Regulation demands that all producers and importers of chemicals provide basic information about the hazardous properties of their chemicals before they are placed on the market. These two basic regulations are complemented with a large number of directives and regulations laying down specific rules for different consumer products such as for example cosmetics, toys, electronics, and detergents (annex 1). In addition to this, there are comprehensive rules for the protection of for example workers' health, the environment and for food safety. This also includes the regulation of materials and articles that come into contact with food, the food contact material (FCM).

The Commission's Directorate-General for Health and Food Safety (DG SANTE)[9], is responsible for the EU policy on food safety related laws, including FCM, while the Directorate-General for Environment (DG ENV)[10] and the Directorate-General for the Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)[11] are in charge of the chemicals in most other consumer products.

---

[7] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Read more about the CLP regulation at the European Chemicals Agency, (ECHA)'s, website. https://echa.europa.eu/regulations/clp/understanding-clp

[8] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Read more about REACH at the European Chemical Agency, (ECHA)'s website: https://echa.europa.eu/regulations/reach/understanding-reach

[9] Directorate-General for Health and Food Safety: https://ec.europa.eu/knowledge4policy/organisation/dg-sante-dg-health-food-safety_en

[10] Directorate-General for the Environment: https://ec.europa.eu/environment/index_en.htm

[11] Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs: https://ec.europa.eu/growth/index_en

When seeking to achieve an overview of the overall EU legislation on harmful chemicals in consumer products it is important to be aware that EU legislation has been developing – and is still developing - since the EU was established. It is also important to have in mind that – from a chemical point of view - consumer products basically consist of chemical *substances*, that may be mixed or combined to produce *mixtures* or *materials,* and these may again be incorporated into *articles*. The individual laws governing harmful chemicals differ in the sense that some legal acts address chemical substances and mixtures, other legal acts address material and articles, and some cover all. Moreover, EU's chemicals legislation also reflects that some products are more "obviously" representing a risk to human health or the environment than others. The need to develop harmonised laws and safety requirements for products representing a specific risk seem to have been clear to the legislators already in the early days of the EU. Examples of products for which such EU-legislation has been developed are pharmaceuticals, pesticides and biocides, cosmetics, detergents, toys, food contact materials, and electronics.

Finally, it should be noted that the Toys Safety Directive and Restriction of Hazardous Substances in electrical and electronic equipment Directive (RoHS) are examples of legal acts that contain provisions on chemicals but belong to a different legal umbrella. These products are covered by the legislative framework for the Internal Market for Goods and are to a large extent regulated based on standards, and they require certification that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (CE-marking)[12].

EU's legislation on chemicals for different kinds of products often consists of several legal acts that work together and refer to each other. The legislative system for FCM, which is the focus of this report, also has its own specific legal framework (figure 1). The system is described in summary below:

[12] Commission's website on Single Market Goods https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

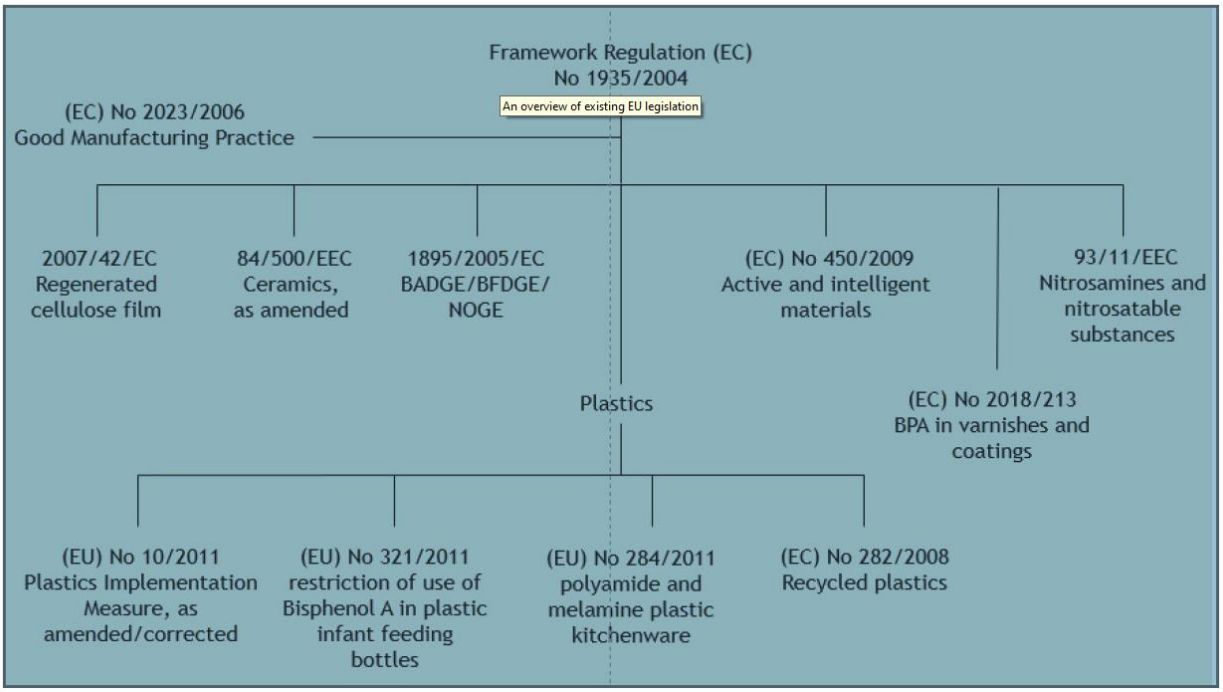

Figure 2. Overview of the EU legislative system for FCM[13].

1.1 The FCM framework Regulation (EC) No 1935/2004

The Commission Regulation (EC) No 1935/2004[14] is the basic framework legislation for FCM. The purpose of this regulation is to ensure the effective functioning of the internal market for materials and articles intended to come into contact directly or indirectly with food and to secure a high level of protection of human health.

The FCM framework Regulation sets out general safety requirements for all FCM as well as a general obligation on Good Manufacturing Practice (GMP), whose specifics are also spelled out in a separate regulation[15] (section 1.2).

A simple basic safety requirement, which applies to all food contacts materials, is laid down in article 3 of the framework regulation:

"*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;

[13] Published by; UK Food Standard Agency, June 2019, Biobased materials for use in Food contact applications https://www.food.gov.uk/sites/default/files/media/document/bio-based-materials-for-use-in-food-contact-applications.pdf

[14] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R1935

[15] Commission Regulation (EC) No 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R2023

or (b) bring about an unacceptable change in the composition of the food;
or (c) bring about a deterioration in the organoleptic characteristics thereof."

In addition, the FCM framework Regulation sets out rules on traceability during the entire supply chain and adequate labelling. It also foresees the development of more detailed rules (specific measures, section 1.3) for ensuring the safety for one or more of seventeen individual types of FCM:

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

1.2 The GMP Regulation, (EC) No. 2023/2006

The GMP Regulation[15] applies to all FCM at all stages of production, apart from the manufacture of starting substances. It provides general rules on Good Manufacturing Practice, such as the establishment of quality assurance and quality control systems and the adequate documentation of those systems. Moreover, specific requirements for printing inks applied on the non-food contact side of FCM are set up, including an obligation to ensure that inks are not transferred to the food-contact side.

1.3 Harmonised measures for four materials

As mentioned above, the FCM framework Regulation, adopted in 2004, made room for the legislators to follow up with further development of more comprehensive implementing measures or specific measures for the individual types of FCM materials and articles. Such specific measures may be rules and specifications for individual types of food contact materials and may contain for instance a list of authorised substances (a positive list), with corresponding migration limits for its constituents and methods for compliance verification.

Materials for which such specific EU measures exist are generally called the 'harmonised' food contact materials. Today, only four out of the seventeen materials are regulated via specific measures at EU level. For the thirteen remaining materials, including paper and cardboard, coatings, inks, rubber, metal, glass, glues etc. no specific measures have been developed. This means that the general safety requirements, as set out in FCM framework and GMP Regulations, are– largely – the only rules applicable at EU level.

There is no risk-based reason for the choice of materials that are subject to specific harmonised measures, apart from plastics being a logical choice for detailed measures as this is the most commonly used FCM. When the framework legislation was adopted, the Commission chose to start with plastics (section 1.3.1) and was expecting to move on to more materials. In 2004, active and intelligent materials and recycled plastic materials were chosen for harmonisation. However, no initiative has been taken to harmonise other widely used materials such as paper and cardboard. The explanation for these choices in the past may be that legislators, in the absence of any agreed prioritisation approach, just assumed they should prioritise new products, thinking older products were more well-known[16].

1.3.1 The regulation on plastic food contact materials and articles

Regulation (EU) No. 10/2011 on FCM plastic materials and articles intended to come into contact with food[17] is by far the most comprehensive regulation establishing specific measures for food contact material. The regulation applies to single-layer plastic materials, multilayer plastic materials and plastic layers in multi-material multilayer products. Plastic coatings on lids of cans, as well as printed or coated plastic materials are also within the scope.

The Plastics Regulation is based on a **positive list.** Monomers, additives, and other *starting substances* may only be used in the manufacture of plastic FCM if they are listed in Annex I to the regulation (the Union List). About 1000 chemicals have been authorised by The European Food Safety Authority (EFSA, section 1.10.1)1.10.1 for use in food contact plastics. Other manufacturing substances may be used in the plastic under a "functional barrier", however, provided their migration remains below a limit of 0.01 mg/kg, and provided they are not CMR (Carcinogenic, Mutagenic, or toxic to Reproduction. i.e. Substances that cause cancer, mutation of genetic material, or adverse effects on fertility).

The regulation sets an **Overall Migration Limit** (OML) of 10 mg of substance/dm² of the food contact surface for the sum of all substances that can migrate from food contact materials to food. However, for infants and young children, the overall migration limit is expressed as 60 mg/kg food. For the individual substances, the Union list may set out **Specific Migration Limits** (SML) and other specifications for use which has been

[16] CHEM Trust, 2019: Minutes from a workshop looking at the gaps between the EU laws on chemicals in Food Contact materials and REACH, April 2019: https://chemtrust.org/workshop-fcm-reach/
[17] Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R0010

established by EFSA on the basis of a toxicological evaluation and a default exposure assumption.

Plastic food contact materials all contain substances other than those included in the Union list. The Plastics Regulation exempts several substances from regulatory scrutiny as the requirement for authorisation does not apply to the actual coatings, adhesives, or printing inks, although they all may be an integral part of the plastic material. Ion exchange resins, rubber and silicon, as well as colourants and solvents and aids to polymerisation are also excluded from the demand for authorisation along with a potentially large amount of contaminants, impurities, and reaction and decomposition products generated in the manufacturing or extraction process or in the material during storage (The NIAS see section 3.2.2).

1.3.2 Active and intelligent materials

Active and intelligent materials are designed to extend the shelf life by maintaining or improving the condition of packaged food by releasing or absorbing substances to or from the food or its surrounding environment. Thus, the packaging deliberately interacts with the food or the environment. The specific measures for these materials provided in Commission Regulation (EC) No 450/2009, address their specific purpose, for example absorption of substances from food packaging interior such as liquid and oxygen, release of substances into the food such as preservatives, and indication of expiry of food through labelling that changes colour when maximum shelf life or storage temperature is exceeded. However, if their capacity is exhausted, there is a risk of contamination. Since the ingredients are not labelled, consumers do not know which products are already using active substances[18].

Intelligent packaging is still not widely used due to the high costs per packaging unit. However, intensive research is being carried out on it, so these materials may well become more common in the future.

1.3.3 Ceramic FCM

The current Council Directive 84/500/EEC[19] on ceramic food contact articles is from 1984 i.e. long before the framework regulation. The directive sets lower limits for migration of lead and cadmium in ceramic FCM. However, updated scientific information, including opinions from EFSA, indicate that the current exposure to several metals, particularly lead and cadmium, released from these FCM, is of concern, and the Commission is considering lowering the migration limits for lead, cadmium and other metals[20].
In May, 2019, the Commission published a roadmap with a public consultation. The policy options included appropriate protective migration limits for lead, cadmium and possibly

[18] Read more about active and intelligent materials at vzbv's website: https://www.verbraucherzentrale.de/wissen/lebensmittel/lebensmittelproduktion/intelligente-verpackungen-7065
[19] Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic food contact articles: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31984L0500
[20] Commission website on ceramic and vitreous FCM: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/ceramic-and-vitreous-fcms_en

other heavy metals, in ceramic and vitreous food contact materials. However, the roadmap also mentions the option to include derogations for traditional and artisanal production.

The next step will be the preparation of a more detailed impact assessment, which will be published and subject to a 12-week open public consultation. This would happen simultaneously with the developments related to the overall FCM legislation.

1.3.4 Regenerated cellulose film

Commission Directive 2007/42/EC[21] relates to materials and articles made of regenerated cellulose film - a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton - intended to come into contact with food. This directive establishes a list of approved substances, accompanied by limits to the quantities to be used. The directive also prohibits contact between printed surfaces of regenerated cellulose film and the food, and for the two softeners, diethylene glycol and monoethylene glycol, the directive establishes a total amount that may be present in food after it has been in contact with the film.

1.4 Other harmonised measures for FCM

In addition to the harmonised measures for four specific food contact materials, there are additional harmonised rules related to individual substances and other issues[22]. Two important issue, authorisation of recycled plastic and restrictions on bisphenols are shortly explained below.

1.4.1 Rules on recycled plastic

Using recycled plastic for FCM may entail a risk of unknown hazardous chemicals in the materials. According to the regulation EC No. 282/2008 on recycled FCM plastic materials and articles[23] recycled plastics should only be used in FCM if they are obtained from processes which have been assessed by EFSA and authorised by the Commission.

Since this regulation entered into force, EFSA has published scientific opinions for approximately 140-150 processes which are still awaiting authorisation by the Commission. 95 percent of these processes describe the recycling of polyethylene terephthalate (PET), the remaining five percent refer to the recycling of polyolefins[24]. When EFSA has published all its opinions, the Commission and Member States will decide whether or not to grant authorisation to all the processes at the same time. After that recycled plastics in FCM may only be obtained from authorised processes. In the

[21] Commission Directive on regenerated cellulose film intended to come into contact with foodstuff: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32007L0042

[22] [22] The harmonised measures for FCM are summarised at the Commission's website: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en

[23] Commission Regulation 282/2008 on recycled FCM materials and articles: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32008R0282

[24] B. Geueke et al., 2018. Food packaging in the circular economy: Overview of chemical safety aspects for commonly used materials. Journal of Cleaner Production 193. https://www.foodpackagingforum.org/news/food-packaging-in-the-circular-economy

meantime, recycling of PET for food contact has become a widely used practise, which is accepted as long as the authorisation process has still not been finalised.

1.4.2 Rules on bisphenols

The use of the well-known hormone-disrupting chemical bisphenol A (BPA), is controversial, and this substance is one of the most debated substances used in consumer products (see also section 3.7). In 2018, the Commission amended the food contact Plastics Regulation by setting a new limit of 0.05 mg/kg food for the migration of BPA from plastic FCM (Regulation (EU) 2018/213). This regulation also extended this specific migration limit to varnishes and coatings. Additionally, migration of BPA shall not occur from plastic FCM, varnishes and coatings that are in contact with baby food and products specifically intended for young children.

Other than that, there are only few regulations that are related to bisphenols in FCM. In 2005 specific migration limits were set for bisphenol A diglycidyl ether (BADGE) and its derivatives (Commission Regulation EC 1895/2005). These substances can be formed during the production of BPA-based epoxy can coating and have been shown to migrate into food.

1.5 The duty to produce a Declaration of Compliance (DoC)

Article 16 of the FCM framework Regulation states that materials and articles which have been covered by specific measures shall be accompanied by a written Declaration of Compliance (DoC) to state that they comply with the rules. Annex IV contains a list of points that must be covered by the Declaration.

The DoC is a basis for exchange of information between the different business operators in the FCM supply chain, and the objective is to prove to the downstream users (the professional customers using the FCM for their products) that self-compliance assessments have taken place by producers of FCM.

However, the substantiated information on which the DoC is based, such as information on compliance work received from upstream users, conditions and results of migration tests, the composition of the material, toxicological data on the substances present in the material, and other analyses and evidence used in the risk assessment or reasoning demonstrating compliance shall only be recorded in “supporting documents”. The information in the supporting documents does not have to be included in the DoC, and all this background information is often not available in the supply chain.

Article 16 of the FCM framework Regulation states that in the absence of specific measures, Member States (MS) may adopt national provisions for DoCs, and such national

requirements for DoCs are in place in at least thirteen EU Member States[25], but the detailed requirements are not the same in the different MS.

1.6 The regulatory situation for the non-harmonised materials

The legal landscape for the non-harmonised materials is characterised by a mixture of soft law with numerous guidance documents combined with different national legislations in the MS for different materials. The Council of Europe (section 1.8) also provide guidance that MS can use to transpose into national law. Different industry sectors have produced guidance documents for their members, but there is still much confusion as to how safety should be ensured.

More information about the situation for the non-harmonised materials can be found in sections 1.6, 1.8, 2.2.1 and 3.1.

1.7 National provisions

In 2016, the Commission's Joint Research Centre (JRC) published a comprehensive report on the non-harmonised FCM aiming, amongst other things, to establish an overview of national provisions[26]. Annex 2 and 3 of this report are simple copies of tables provided in the JRC report to provide an overview. The table in Annex 2 shows the distribution of countries with measures or national norms specific to different materials, while the table in Annex 3, vice versa, shows national rules and tools related to each material. These tables reflect the fact, which is also highlighted in the report, that the legislative system for FCM in the EU has become a patchwork of different rules for which it is virtually impossible to gain a clear overview. Some countries only have measures for one or two materials. For the remaining materials they rely in principle on EU regulation and "mutual recognition" of rules in place in other countries. In most Member States, the national legislation does not set out detailed requirements[26]. The measures are mainly based on lists of authorised substances (and negative lists) with limits being the most common associated tool. The study further revealed that three main legal systems can be observed based on different type of measures in operation at national level:

- System of authorised substances and migration limits comparable to the Union list. This system has been applied for example in the Netherlands.
- System of recommendations for substances to be used in the final material or article. This system is applied in Germany.
- System of no specific legislation but with an industry code of practice defining the due diligence of business operators. This is used in the United Kingdom.

Below a few examples of additional significant national provisions are mentioned.

[25] Belgian Packaging Institute, IBE:BVI, 2017: DOSSIER: FCM in de EU: The declaration of compliance and its supporting compliance work https://ibebvi.be/src/Frontend/Files/Labo/5/files/DOC_EN_1ad_fr.pdf
[26] C. Simoneau et al., Non-harmonised food contact materials in the EU: Regulatory and market situation, 2016, EUR 357 EN; doi:10.2788/234276: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study

French ban on BPA in all FCM.
Since January 2013, BPA has been banned in France in FCM intended for use by children up to three years of age (Law 2010-729).The French law is not harmonized with the European legislation on FCM as BPA is authorised in the EU to be used as a monomer for the production of plastic with a specific migration limit of 0.6 mg/kg food. The French national law was later amended, and since 2015, the use of BPA is prohibited in all packaging, containers, and utensils intended to come into direct contact with food in France.

The Swiss Printing Inks Ordinance
Although not an EU Member State, Switzerland is the only country in Europe that currently has legislation in place specifically regulating food packaging printing inks. This Swiss Ordinance[27] has become an important standard by which many companies evaluate printing inks in the EU, in the absence of harmonised EU law.

Danish restriction on Per- and Polyfluoroalkyl substances (PFAS) in paper and board
Per- and polyfluoroalkyl substances (PFAS),which are a large group of very persistent chemicals (section 3.7), have often been highlighted as a particular problem in FCM, particularly in paper and board. For this reason, Denmark has introduced a national ban on PFAS in paper and board which took effect from July 2020. This new order restricts food contact material made of cardboard and paper if any PFAS have been used. The substances are only allowed –for example in recycled paper – if a functional barrier is in place to prevent the substances from migrating into the food.

This step is particularly interesting as this law makes Denmark the first country in the world to ban the entire group of PFAS in a product type. In this way, this ban can be seen as promoting the concept of *grouping* (section 4.3.3).

More steps towards more widely regulation of the PFAS are presented in section 2.5.3. and proposals for new national rules on FCM in Germany are presented in section 2.5.

1.8 Guidance documents published by the Council of Europe

The Council of Europe[28](CoE), founded in 1949, is a regional intergovernmental organisation of 47 countries. Unlike the EU, the CoE cannot emit binding laws. The CoE is devoted mainly to the protection of human rights, democracy, and rule of law. However, the CoE has also been an important player in providing guidance for industry on the safety of FCM. The Council produces guidelines and technical documents which – in the absence of national regulations - can be used as reference documents to show the harmlessness of

[27] Specifically, Annex 10 of the Ordinance of the FDHA on materials and articles intended to come into contact with foodstuffs. https://www.blv.admin.ch/blv/en/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln.html
[28] Council of Europe's website on FCM: https://www.edqm.eu/en/food-contact-materials

an FCM. These documents[29] require a total or partial transposition in national law to become binding.

The goal of the CoE is to have separate guidelines for all non-harmonised materials, which can be seen as a back-up plan if no harmonisation is implemented at the EU level[16].

1.9 Industry self-regulation

Industry self-regulation exist in varying extents in all sectors for individual materials. According to the JRC report on the Non-harmonised materials (section 1.6) different FCM sectors have developed their own guidances in the absence of guidance from authorities. These sectorial guidelines sometimes mention national measures or CoE resolutions (section 1.8) and seem fairly consistent with national laws while also focusing on where gaps are present in the context of national measures.

Sector guidelines range from highly detailed documents to descriptions remaining generic in nature. Some sectors have developed dedicated guidelines on DoCs and supporting documents which may include lists of substances authorised or banned (negative lists) that are relevant to the sector. These are taken from relevant national measures not only from the EU, but also often from, for example, Japan or the United States.

Sectors with strong guidance include adhesives, inks and coatings, and paper and board including multi-sectorial joint guidance with the sectors of flexible plastics and chemicals, while sectors with a single guidance document include those of metals and alloys, cork, and silicones. The report furthers claims that sectors with an absence of sector-specific guidance include ion exchange resins, waxes, ceramics, glass, and rubber[26].

1.10 Authorities responsible for Risk Assessments

1.10.1 The European Food Safety Authority (EFSA)

EFSA was established under the General Food Law Regulation (EC)178/2002[30] in 2002 following a series of food crises in the late 1990s to be a source of scientific advice and communication on risks associated with the food chain.

EFSA is responsible for performing risk assessments and for communicating its scientific findings to the public. EFSA produces scientific opinions and advice that form the basis for European policies and legislation. EFSA's 10 scientific panels of experts are responsible for the bulk of EFSA's scientific assessment work. Areas in EFSA's remit are food and feed safety, nutrition, animal health and welfare, plant protection and plant health. EFSA may give advice on, for example, food borne diseases, food poisoning, pesticides, health claims on food, and finally, EFSA is responsible for assessing risks of chemicals in FCM. The Scientific Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) evaluates

[29] List of FCM document on the CoE website: https://www.edqm.eu/en/resolutions-policy-statements
[30] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32002R0178&from=EN

the safety of chemical substances added to food or used in food packaging and related processes. The Panel's work mainly concerns substances and processes evaluated by EFSA before their use can be authorised in the EU.

EFSA works mostly on harmonised materials. However, EFSA can work on all materials covered by the framework regulation[14]. EFSA's CEP panel responds to requests for advice on the safety on non-plastic materials on an ad hoc basis, and the Food Ingredients and Packaging (FIP) unit's Scientific Network on Food Contact Materials, the FCM Network, is a platform for further cooperation between EFSA and Member States focusing on the non-harmonised materials. The network aims to enhance collaboration between scientists involved in risk assessment of FCM. The FCM Network[31] was initiated in October 2013 for a period of three years and later it was proposed to maintain the network for further three years. In November 2019, the panel decided to submit a request for a new mandate to continue the work to EFSA's management board.

EFSA's website[32] provides information on opinions on substances to be used in food contact materials as well as minutes from scientific meetings and other publications on a wide variety of issues related to food and food safety, within their remit.

1.10.2 German Federal Institute for Risk Assessment (BfR)

All MS have national agencies providing risk assessments on FCM. Amongst them, particularly the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR[33]) has provided much guidance related to safe use of FCM. The BfR is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL). The main task is to provide opinions on potential risks from food, consumer articles and chemicals, and to offer scientific advice to the federal government and ministries for their policy decisions. The Agency has developed recommendations for a number of non-harmonised FCM such as paper, cardboard, rubber, and silicone.

[31] Link to minutes of meetings of the FCM network: https://www.efsa.europa.eu/en/events/advanced-search?start_date=1009839600&f%5B0%5D=im_field_event_participant%3A70072&f%5B1%5D=im_field_event_participant%3A70176&sort_type=published&sort_order=desc
[32] EFSA's website: http://www.efsa.europa.eu/
[33] BfR website: https://www.bfr.bund.de/en/home.html

2 Recent Initiatives from different stakeholders

In recent years, there has been increasing focus on the inefficiency of the current legislation in protecting public health (Chapter 3). Below a number of significant reports and initiatives from the Commission and other stakeholders are listed. These initiatives may be seen as key developments leading to the Commission's recent significant step of committing to put forward a proposal for a revision of the FCM legislation by late 2022 (section 2.2.3).

2.1 Scientific reports on risks related to FCM

2.1.1 ESCO report on non-harmonised materials

Early warnings about the problems with the non-harmonised materials were published in 2012 in a report published by EFSA and written by a Scientific Cooperation Working Group (ESCO, EFSA Scientific Cooperation), which was set up with an aim to collect information present at Member State level on non-plastic food contact materials for which no harmonised risk assessment was available. The report highlighted that only 230 substances used in non-plastic FCM had been risk assessed at national level since publication of SCF[34] Guidelines in 1991.

An inventory list, containing 2800 entries used in the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork, was established and strategies for prioritisation of the evaluations of substances and for providing preliminary advice in case of urgent need were proposed. The report's summary pointed out that:

"These materials are not covered by a specific regulation and thousands of substances used to manufacture them have not been evaluated for their safety at the EU level"[35]

2.1.2 EFSA opinion on risk assessments

In 2016, EFSA published an opinion on developments in risk assessment[36], examining the safety assessment of chemicals in food and impact on evaluating FCM, concluding that more focus was needed on the *finished materials and articles* as well as the so-called NIAS (Non-Intentionally Added Substances. See section 3.2.2) generated through the manufacture of FCM.

Moreover, a recent joint Statement from 33 scientist has further confirmed that concern for consumer safety requires an urgent reform of the regulatory framework for FCM (Section 2.4.3).

[34] The Scientific Committee on Food (SCF) was established in November 1974, and transferred to the European Food Safety Authority (EFSA) in May 2003
[35] EFSA, 2012: Report of ESCO working group on non-harmonised materials: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2011.EN-139 (page 3)
[36] EFSA, 2016: Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials: https://www.efsa.europa.eu/en/efsajournal/pub/4357

2.2 Initiatives of the Commission

The Juncker Commission (2014 - 2019) had much focus on analysing existing laws on chemicals. A large number of REFIT analyses[37] (and less concrete policy development) was produced in that period, but today it is clear that some significant initiatives and steps have been taken, particularly as related to the FCM, as described below.

2.2.1 JRC Study on Non-harmonised materials

In January 2017, the Commission's Joint Research Centre (JRC) published its the comprehensive baseline study about the "Non-harmonised food contact materials in the EU" . This report estimated that more than 8.000 different chemicals are used in FCM in the EU, and it revealed how numerous national rules, lack of clear provisions, and different national approaches to how risks should be assessed has led to a chaotic legal situation with unclear and varying safety provisions and inefficient control of chemicals in the non-harmonised materials.

More information and overviews derived from this report can be found in sections 1.7 and 1.9 as well as in annex 2 and 3.

2.2.2 Commission evaluation of the legislative framework for FCM

In September 2018, the Commission initiated an evaluation of the legislative framework for FCM engaging an external consultant to assess to what extent the current EU legislative framework for FCM is fit for purpose and delivers as expected.

The evaluation process included two stakeholder workshops in September 2018 and September 2019, as well as an open public consultation, which ended in May 2019, and a series of processes with industry stakeholders. The responses to the open public consultation of 2019 from a wide range of different stakeholders have been uploaded to the Commission's Better Regulation Portal[38].

The agenda for the first evaluation workshop on 24 September 2018 can be found at the Commission's website dedicated for the evaluation[39]. The website provides links to different stakeholders perspectives, including a joint presentation by BEUC, CHEM Trust, HEAL and Client Earth. In addition, more detailed reporting from the event has been published by CHEM Trust[40] and the Swiss-based Science Research Organisation Food Packaging Forum (FPF)[41].

---

[37] See Commission's REFIT platform: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

[38] Consultation document and responses to the Commission's public consultation on the FCM legislation can be found at the Commission's Better Regulation website: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/public-consultation_en

[39] Commission website on the evaluation of FCM: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en

[40] CHEM Trust blog about the first stakeholder workshop, October 2018: https://chemtrust.org/eu-fcm-review-conference/

[41] EU starts evaluation on FCM regulation, 1st stakeholder event: https://www.foodpackagingforum.org/news/eu-starts-evaluation-of-fcm-regulation-1st-stakeholder-event

The second workshop on 9 September 2019 revealed a significant agreement amongst all stakeholders on the need for more harmonisation and better enforcement[42].

In July 2020, the final evaluation report[43] was made publicly available at the Commission's website dedicated for the evaluation[39].

The evaluation is based on the Commission's general evaluation criteria, which are also used in other REFIT projects:

- **Effectiveness** of the approaches, processes and tools set up by the FCM Regulation and its associated and implementing measures in relation to the original objectives of the regulation;
- **Efficiency** of the approaches, processes and tools set up by the FCM Regulation and its associated and implementing measures in relation to the resources used;
- **Relevance** of the regulation in relation to current scientific and technological developments in the field of FCM, and stakeholders' needs and expectations;
- **Coherence** internally and with other related interventions at national, European, and international level;
- **EU added value** of regulating at the EU level compared to what could have been achieved by Member States or otherwise.

The evaluation report[43] provides information about selected views of different stakeholders and acknowledge several gaps in both the legislation and its implementation including lack of adequate resources for enforcement, problems related to the NIAS, combination effects, multiple sources of exposure, and lack of harmonised measures for many materials.

According to the evaluation study, the framework regulation provides a basis for securing a high level of protection of human health regarding individual materials, with benefits estimated to outweigh costs. The EU positive list approach is effective in contributing to the functioning of the internal market. However, the study finds that it is very unlikely that it will be possible to establish positive lists of authorised substances for all FCM.

In addition, the report found that declarations of compliance, traceability, and labelling requirements also contribute positively to the functioning of the internal market, but the overall performance of the EU FCM legislative framework is weakened by the lack of harmonised measures and not completely satisfactory due to insufficient availability of resources and important gaps in implementation and enforcement.

[42] CHEM Trust (2019) blog about Commission's 2nd stakeholder workshop: https://chemtrust.org/debate-eu-laws-packaging/

[43] European Commission, 2020: Study supporting the evaluation of Food Contact Materials (FCM) legislation – regulation (EC) no. 1935/2004: https://op.europa.eu/en/publication-detail/-/publication/3ae0294b-bc0c-11ea-811c-01aa75ed71a1/language-en

The report was not accompanied with any supplementary document from the Commission to indicate how the Commission would react to the findings. However, the Commission has given some indications about envisaged next steps (section 2.2.3 and 2.2.4)

2.2.3 A clear commitment to revise the FCM legislation

In December 2019, the new von der Leyen Commission published a Communication on the new European Green Deal[44] including plans for several further detailed strategies with possible relevance for the FCM. A Circular Economy Action Plan[45] was published in March 2020 as one of the main blocks of the Green Deal. Another important element will be the Chemicals Strategy for Sustainability, which is expected in September 2020. The Commission consulted stakeholder on the roadmap for this strategy in June 2020[46].

Most important, however, is the Commission's Farm to Fork Strategy from May 2020 as this strategy provides a clear commitment from the Commission to revise the food contact legislation. With reference to circular economy and waste issues, which are also raised in the Circular Economy Action Plan, the Commission states that:

"Food packaging plays a key role in the sustainability of food systems. The Commission will revise the food contact materials legislation to improve food safety and public health (in particular in reducing the use of hazardous chemicals), support the use of innovative and sustainable packaging solutions using environmentally-friendly, re-usable and recyclable materials, and contribute to food waste reduction[47]"

In an annex to the strategy, it is revealed that a "*Proposal for a revision of EU legislation on Food Contact Materials to improve food safety, ensure citizens' health and reduce the environmental footprint of the sector*" is planned to be published in the 4th quarter of 2022[48].

2.2.4 Envisaged next steps from the Commission

In February 2020, at a conference on FCM arranged by Chemical Watch[49], a representative of DG Sante presented a tentative timeline[50] for the next steps towards developing new

---

44 Commission Communication on the European Green Deal, December 2019: https://ec.europa.eu/info/publications/communication-european-green-deal_en

45 Commission's Circular Economy Action Plan for a cleaner and more competitive Europe, March 2020: https://ec.europa.eu/environment/circular-economy/

46 The roadmap and responses to the consultation can be found at the Commission's website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12264-Chemicals-strategy-for-sustainability-

47European Commission, 2020: Farm to Fork Strategy, for a fair, healthy and environmentally friendly food system, page 13: https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf

48 ibid, page 22.

49 Link to chemical Watch FCM conference programme: https://events.chemicalwatch.com/77006/food-contact-regulations-europe-2020/programme

50 Presentation by Legal Officer Bastiaan Schupp, DG Sante, at conference on FCM, February, 2020; Partly described in Chemical Watch: https://chemicalwatch.com/93912/eu-commission-may-delay-fcm-report-by-nearly-two-years

FCM-legislation. When combined with new information from the Commission[51] the following timeline is envisaged:

1. Inception Impact Assessment: A short 4-5 week's public consultation on policy options and problem definition to be launched in September 2020
2. Impact Assessment: A more detailed assessment of policy options. A public consultation of 12 weeks is planned for the first part of 2021.
3. Publication of the results of the Impact Assessment (probably beginning of 2022)
4. Proposal for new harmonised FCM legislation from the Commission in the 4th quarter of 2022.

According to the presentation in February, the policy options to be assessed may range from no changes to the current system to a (thorough) revision of current legislation.

2.3 Initiatives by the European Parliament

The EU Parliament has voiced concern about chemicals in FCM in recent years, and has also called on the Commission to act on this issue on several occasions:

2.3.1 Parliament Study on FCM, 2016

In March 2016, the European Parliament published a comprehensive study on the Implementation of the FCM Regulation[52]. The study was based on a survey conducted between December 2015 and February 2016, which documented stakeholders' positions on the functioning of the regulation. The report concluded that the lack of specific measures at EU level for some FCM negatively impacted both the functioning of the internal market and food safety. It also stated that many stakeholders across businesses, consumers, environmental and health-focussed Non-Governmental Organisations (NGO), researchers, as well as Member States' competent authorities are in favour of more specific measures at EU level for those FCM that are not yet harmonised at EU level.

2.3.2 Parliament Resolution on FCM, 2016

In October 2016 the European Parliament sent a clear signal to the Commission and EU governments in a resolution[53] based on the abovementioned study, which called for the Commission to draw up measures for the non-harmonised materials paper and cardboard, metals and alloys, printing inks and adhesives. It also called for a ban on BPA in all food contact material and listed the need for many other substantial improvements to the regulatory system. The EU Parliament was concerned that FCM are a significant source of human exposure to harmful chemicals, which may affect not least babies and young children.

[51] Personal Communication with Policy officers in DG Sante.
[52] Parliament Implementation Assessment Study on the FCM Regulation, 2016,: https://www.europarl.europa.eu/RegData/etudes/STUD/2016/581411/EPRS_STU(2016)581411_EN.pdf
[53] EU Parliament Resolution on FCM 2016: https://www.europarl.europa.eu/doceo/document/TA-8-2016-0384_EN.html?redirect

2.3.3 Parliament Resolution on endocrine disrupting chemicals (EDC), 2019

In April 2019, the European Parliament reacted to the Commission's communication on endocrine disruptors from November 2018[54] by adopting a "Resolution on a comprehensive European Union framework on endocrine disruptors"[55]. The resolution's point 8 calls for increased focus on endocrine disrupting chemicals, EDCs, in different legislative acts as the Parliament:

" Calls on the Commission to revise Regulation (EC) No 1935/2004 no later than June 2020 in order to effectively reduce the content of hazardous substances therein, with specific provisions to substitute the use of EDCs"

2.3.4 Parliament resolution on the European Green Deal

In January 2020, the European Parliament adopted a resolution[56] on the European Green Deal, which reiterates the demands from April 2019 concerning food contact materials. The resolution's point 62 and 80:

"[...] stresses that legislation on food contact materials and maximum residue levels of pesticides should be revised and be based on the latest scientific findings [...]"

"[...] calls for an ambitious legislative proposal by June 2020 to tackle endocrine disruptors, especially in cosmetics, toys and food contact materials, and an action plan that provides a comprehensive framework with targets and deadlines to minimise citizens' exposure to endocrine disrupting chemicals [...]"

2.3.5 Parliament resolution on the Chemicals Strategy

In July 2020, the European Parliament further adopted a resolution concerning the planned Chemicals Strategy for Sustainability[57]. This Resolution clearly demonstrates a continued - or even intensified - interest in FCM among the member, as it states in points 66 - 70 that the Parliament:

Stresses that the legislation on food contact materials should be revised in line with CLP and REACH in order to ensure a coherent, protective approach to the safety of materials and products that come into contact with food;

Insists in particular on the need for comprehensive, harmonised regulation of all FCMs, which should be based on the precautionary principle, the principle of 'no data, no market', comprehensive safety assessments that address all the relevant safety and

---

[54] The Commission's Communication on a comprehensive framework for endocrine disrupting substances. November, 2018: https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF

[55] European Parliament Resolution of 18. April, 2019 on a comprehensive European Union framework on endocrine disruptors: https://www.europarl.europa.eu/doceo/document/TA-8-2019-0441_EN.html

[56] Parliament Resolution on the European Green Deal, 15. January 2020: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0005_EN.html

[57] Parliament resolution on the Chemicals Strategy for Sustainability, July 10 2020: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.html

health endpoints and are based on the latest scientific data for all chemicals used in FCMs, effective enforcement and improved information to consumers;

Calls for a phasing out of substances of very high concern in FCMs; Suggests that an inventory be swiftly devised collating the best practices of FCMs regulation at Member State level, including national measures to tackle exposure to endocrine disruptors and fluorocarbons, and

Calls on the Commission to ensure proper linkage between the revision of FCMs regulation, and the Farm to Fork Strategy and the Beating Cancer Plan;

2.4 Initiatives by Non-Governmental Organisations (NGOs)

Several EU based NGOs have been actively communicating about the problems related to the current FCM-legislation and calling for a reform. NGOs have worked both individually and jointly.

2.4.1 Five key principles for future FCM policy

Soon after the Commission initiated its evaluation process (section 2.2.2), a group of NGOs decided to cooperate to assess the most important problems with the current legislation and to provide constructive proposals for the future legislation. The group consisted of CHEM Trust, HEAL, EEB, Client Earth, ChemSec, The Danish Consumer Council, US Breast Cancer Prevention Partners, together with BEUC and the Food Packaging Forum. Together, these organisations developed *five key principles* which they suggest should be the basis for any future legislation[58].

These five key principles constitute a short and condensed description of what is missing from the current EU legislative framework on FCM (Chapter 5).

2.4.2 BEUC Position on FCM

The European consumer organisation BEUC has produced a number of reports and position papers on FCM. The latest report, "Time is ripe to repackage food safety. BEUC position on the regulation of Food Contact Materials" from December 2019[59] calls for an urgent reform of the legislative system and insists on the following seven demands for a reform of the FCM legislation:

- **Regulate all FCM**, including novel materials such as bamboo or palm leaves. New rules to control all migrating chemicals are required, while existing legal limits should be revisited to better protect consumers.
- **Establish a precautionary approach to risk management**. Substances of high concern, such as endocrine disruptors or chemicals that may cause cancer,

[58] Blog on the 5 key principles for the future EU regulation on chemicals in food contact materials: https://chemtrust.org/5-key-principles-fcm/
[59] BEUC, 2019: Time is ripe to repackage food safety. Position on the regulation of Food Contact Materials, December 2019: https://www.beuc.eu/publications/beuc-x-2019-096_time_is_ripe_to_repackage_food_safely.pdf

change DNA, or harm reproductive health should be automatically prohibited in FCM.

- **Make FCM labels work for consumers.** The obligation for manufacturers to provide instructions for safe and appropriate use of FCM needs to be clarified to ensure that risk assessments correspond to actual consumer behaviour.
- **Shift the burden of proof** by requiring manufacturers to perform and notify safety assessments of their food contact materials. Member State authorities must rigorously police the accuracy and reliability of safety assessments.
- **Ensure effective enforcement**. Member States must dedicate sufficient resources for official controls of FCM, while the European Commission should promote a systematic enforcement strategy to ensure that EU FCM policy translate into real consumer protection.
- **Improve transparency** to enable informed consumer choice. Clear and readily accessible information about chemicals present in or migrating from FCM is essential to facilitate identification, traceability, and handling of exposure sources.
- **Guarantee the same, high level of protection** for FCM made from virgin and recycled materials. A successful circular economy can only be achieved if consumers are confident that secondary raw materials are safe.

2.4.3 A Declaration of Concern based on scientist's Consensus Statement

In the beginning of March 2020, more than thirty scientists working on developmental biology, endocrinology, epidemiology, toxicology, and environmental and public health published a Consensus Statement expressing deep concern about the impacts of food contact chemicals on public health[60]. The statement was based on more than 1200 peer reviewed studies and urge decision makers to improve legislation on food contact materials and articles to ensure protection of public health.

The scientists' Statement was soon followed by a "Declaration of Concern and Call to Action regarding Plastics, Packaging and Human Health"[61], signed by more than 170 civil society groups from Europe, the U.S. and Asia and calling on regulators to upgrade regulatory frameworks. Based on the scientists' findings, the Declaration calls on lawmakers to:

- Ensure full disclosure and traceability of chemicals used in packaging throughout the supply chain,
- Restrict the use of hazardous chemicals in food packaging (and products), and prevent regrettable substitutions, and,
- Adopt policies that support the transition towards safe, reusable, and refillable packaging.

[60] Muncke. J.et al.,2020: Impacts of food contact chemicals on human health: a consensus statement: https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-0572-5

[61] Zero Waste Europe, Gaia Asia-Pacific, Gaia US and Upstream (2020) Declaration of Concern and Call to Action regarding Plastics, Packaging and Human Health, https://zerowasteeurope.eu/library/declaration-of-concern/

2.5 Initiatives from Member States

This section provides a few examples of initiatives towards new laws from the MS.

2.5.1 German restriction on printing inks

In July 2016, Germany notified the Commission of their intentions to introduce national rules in the form of a Printing Inks Regulation ("Twenty-first Regulation amending the Consumer Goods Regulation")[62] on printing inks for FCM. This draft regulation would generally apply to printed FCM and articles such as packaging, napkins, cardboard cups, and paper plates. The draft regulation established a positive list of substances permitted for use in printing inks for printing food contact materials and articles, including specific migration limits (SML). To be included in the positive list, substances should have undergone a health assessment, or have been proven not to migrate to food from the printing inks. CMR substances (Substances that cause cancer, mutation of genetic material, or adverse effects on fertility) would be banned unless a safety assessment justified their use.

This legal act would approve 535 substances, which can be considered a limited number compared to the European Printing Inks Association's estimate of about 6,000 substances actually used[63].

Later, Germany suspended its work on the regulation, in response to an announcement by the Commission in November 2016 that it planned to develop a harmonised EU measure on printed FCM. It picked up on the legislative process in May 2020.

2.5.2 German Mineral Oil Regulation

Wastepaper consists of newspapers, magazines, catalogues and other graphic papers, and packaging papers. It is quite common to use recycled paper and cardboard for food packaging, but in recent years awareness of the many possible chemical contaminants in these recycled materials has increased significantly. Such contaminants may originate for example from printing inks, adhesives, and coatings. Mineral oil hydrocarbons are one of the most prominent examples measured at high concentrations in many fibre-based packaging materials and in the food[64].

The German Federal Institute for Risk Assessment (BfR) has advised that the use of mineral oil should be minimised[65]. In March 2017, the German Federal Ministry of Food

[62] German Notification on national regulation for printing inks: Twenty-First Regulation amending the Consumer Goods Regulation (2016): https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2016&num=333&mLang=EN
[63] Various information about printing inks was found at https://www.packaginglaw.com/special-focus/printing-inks-europe-%E2%80%93-caught-time-warp and https://www.therecycler.com/posts/eu-to-adopt-printing-ink-legislation/
[64] Food Packaging Forum,2017 Dossier on mineral oil hydrocarbons: https://www.foodpackagingforum.org/food-packaging-health/mineral-oil-hydrocarbons
[65] BfR website information on Mineral Oil: https://www.bfr.bund.de/de/fragen_und_antworten_zu_mineraloelbestandteilen_in_lebensmitteln-132213.html

and Agriculture (BMEL) sent a proposal for draft Regulation on mineral oil[66] for written consultations to the federal states of Germany and to industry associations.

The Regulation provided a specific migration limit for mineral oil aromatic hydrocarbons and recommended the introduction of functional barriers to reduce the migration of chemicals from recycled paper and board used in contact with food. This proposal came shortly after the European Commission had adopted a recommendation[67] that Member States should monitor the presence of mineral oil hydrocarbons in food and FCM during 2017 and 2018. That recommendation followed a petition from the NGO foodwatch[68] following a laboratory study showing contamination of dry foods packaged in paper or board with mineral oils and asking the Commission to act on mineral residues in food. This petition attracted more than 100,000 signatures from people in France, Germany, and the Netherlands.

Later, in September 2019, the European Commission gave a mandate[69] to EFSA to carry out a rapid assessment[70] on the risks related to the presence of mineral oil aromatic hydrocarbons in infant milk substitutes. This emergency measure followed the detection by foodwatch[71] of the substances in baby milk substitutes in, Germany, France, and the Netherlands.

2.5.3 Emerging plans for regulating PFAS

In recent years, there has been increasing focus on problems related to the use of Per- and polyfluoroalkyl substances (PFAS, section 3.7) which are widely used in a number of different product, including paper and board used as FCM.

In the Council conclusions on a sustainable chemicals policy strategy for the EU released from the meeting of the Environment Council in June 2019[72] the ministers from Member States underlined amongst other things:

"... the increasing health and environmental concerns posed by highly persistent chemicals; notes in specific the growing evidence for adverse effects caused by exposure to highly fluorinated compounds (PFAS), the evidence for wide spread occurrence of PFAS in water, soil, articles and waste and the threat this may cause to our drinking

[66] German proposal for national draft regulation on mineral oil, March, 2017 (in German): https://www.bmel.de/SharedDocs/Downloads/DE/_Verbraucherschutz/Produktsicherheit/MineraloelVO_Entwurf.pdf?__blob=publicationFile&v=3

[67] Commission recommendation from 2017 to monitor mineral oil: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2017.012.01.0095.01.ENG

[68] The original petition is not available, but it was reported by the Food Packaging Forum: https://www.foodpackagingforum.org/news/update-foodwatch-mineral-oil-petition

[69] Commission Mandate to EFSA on mineral oil, October 2019: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00691

[70] EFSA ,2019: Rapid risk assessment on the possible risk for public health due to the contamination of infant formula and follow-on formula by mineral oil aromatic hydrocarbons (MOAH) http://www.efsa.europa.eu/en/supporting/pub/en-1741

[71] Foodwatch press release on mineral oils, October 2019: https://www.foodwatch.org/en/news/2019/foodwatch-laboratory-tests-suspected-carcinogenic-mineral-oil-residues-in-baby-milk/

[72] Council conclusions on a Sustainable Chemicals Policy Strategy, June 2019 (point 14): http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf

water supplies; calls on the Commission to develop an action plan to eliminate all non-essential uses of PFAS."

At the following council meeting in December 2019, the EU ministers for environment continued their discussions[73] on the problems with PFAS in all sectors and the Netherlands informed of their intention to draft a REACH[8] restriction proposal on all non-essential uses of PFAS. This work has since been initiated in cooperation with Germany, Denmark, Sweden, and Norway[74]. At the same time, the Commission's Action Plan on PFAS is planned to be part of the Chemicals strategy for Sustainability (section2.2.3) indicating a general focus on the need for safer use of these chemicals amongst regulators.

The scope of REACH restrictions generally do not cover the FCM, but if the foreseen restriction on PFAS would cover all "non-essential uses", the FCM should be included. This presumption was supported at the council meeting, as the Minister for the Environment and Housing, van Veldhoven, asked the following question:

"*Are we really willing to risk our health and environment for the fact that the cheese on the pizza does not stick to the box. Let's start with these low-hanging fruits first*"

[73] The Environment Council discussion is public. https://video.consilium.europa.eu/en/webcast/da0bab77-93ce-42b6-b85c-77a6162bf290 (NL talk on PFAS starts at minute 27)
[74] Five European states call for evidence on broad restriction proposal, ECHA, 2020: https://echa.europa.eu/da/-/five-european-states-call-for-evidence-on-broad-pfas-restriction

3 Problems related to the current legislation on FCM

This chapter presents a summary of the basic deficiencies and problems identified as related to the current legislative framework for FCM in the EU.

3.1 Lack of harmonisation

There are no specific harmonised rules at the EU level for harmful chemicals in commonly used FCM such as paper, cardboard, coatings, inks and glues (section 1.6), and the current regulatory situation for these non-harmonised materials seems chaotic. This lack of harmonisation can be seen as one of the main reasons why thousands of chemicals that may migrate into our food are used in FCM without proper rules for safety assessment.

For all the non-harmonised materials, and for those chemicals in plastics that are exempted from the authorisation requirement, there is only the basic safety provision of the framework regulation in place. The lack of harmonisation is criticised by both industry organisations and NGOs as it disrupts the internal market and provides inefficient protection of public health and the environment[43]. The absence of harmonised EU rules allows Member States to maintain or adopt their own national measures, but the Member States have not done so in any consistent manner (section 1.7, 2.1.1 and annex 2 and 3). As shown in the study from the Commission's Joint Research Centre (JRC)[26], there is a patchwork of different national schemes for risk assessment, chemical safety, compliance documentation, and other regulatory approaches, and there may be either no legal guidelines or different national guidelines and rules for how to comply with the basic safety provision of the framework regulation.

The JRC study identified around 8.000 substances regulated at national level, some of which are regulated by many Member States, others only by a few. These differences imply that consumers are not guaranteed a similar level of protection against harmful chemicals across Europe.

3.2 Lack of adequate safety provisions

The data that would be required for any kind of safety assessment is often not available. Instead of having specific authorisations and migration limits, which are based on trusted risk assessments to rely on, the actors in the supply chain must firstly rely on the self-assessment done by their suppliers and secondly do their own self-assessment, and decide what information is needed and what procedures must be in place.

Even for the plastic FCM, where detailed harmonised specific measures are in place, the provisions are inadequate, as explained below.

3.2.1 Information is lost in the supply chain

According to the JRC baseline study[26], the system of DoCs (section 1.5) is a pillar of food safety. At the same time, the implementation remains an issue of concern, especially for non-harmonised materials. National requirements for the DoC vary between Member

States and many Member States do not require DoCs for non-harmonised materials. In addition, the definition of supporting documents varies, and their acceptance fluctuates from Member State to Member State. This situation is complex for those companies, who must deliver the DoC, and is clearly not effective in achieving the uniform high level of health protection, which was the original intention of the framework regulation.

The JRC baseline study and others[16] point out that the risk assessment of the chemicals in the final food contact article is often hampered by the lack of transfer of safety-related information along the supply chain. The transfer of information seems to get more difficult with the complexity of the supply chain or the FCM itself (for example multi-material FCM).

A control campaign in the harmonised plastics sector found that virtually no data was available on substances used other than the specifically regulated monomers and additives, and none about reaction products and impurities. Hence, the safety of these migrations was not shown[75]. It is clear that if the compliance documentation is not transferred, then downstream users will not know whether the suppliers' declared compliance is well supported and how they could use it for their own compliance work.

Another important issue is that the main focus of the DoC and the supporting compliance work is still on the substances used in the manufacturing of the *starting material*. It is much less on the substances actually present in or migrating from the *final food contact article*, which are both the intentionally added substances (IAS) and the non-intentionally added substances, (the NIAS, see section 3.2.2 below).

3.2.2 The Non-Intentionally Added Substances – NIAS

In addition to the chemicals that are deliberately used in the original material, there are also a large number of non-intentionally added substances in FCM. These are for example reaction products formed after the production of a material, or they can be impurities in the starting material. Final food contact articles, consisting of harmonised or non-harmonised materials, or both, may contain numerous substances that are unknown both as regards to hazards and amounts. NIAS can make up the majority of substances that migrate from plastics, and a study from 2006 showed that 97 percent of substances that migrate from can-coatings can be NIAS for which the chemical identity is largely unknown. This study further claimed that the level of migrating substances from packaging material including the NIAS may well exceed other contaminants in the food by a factor of 100 - 1000[76].

[75] McCombie, G. et al., 2016: Compliance work for polyolefins in food contact: Results of an official control campaign. Food Control 59

[76] Grob, K. et al., 2006: Food Contamination with Organic Materials in Perspective: Packaging Materials as the Largest and Least Controlled Source? A View Focusing on the European Situation, (46:529-35):https://www.researchgate.net/publication/6836185_Food_Contamination_with_Organic_Materials_in_Perspective_Packaging_Materials_as_the_Largest_and_Least_Controlled_Source_A_View_Focusing_on_the_European_Situation

The basic situation is that a complex mixture of IAS and NIAS migrate from FCM into our food in significant volumes, and there is frequently little information on the nature and toxicity of these substances. According to Article 3 of the FCM framework Regulation and Article 19 of the Plastics Regulation, the FCM manufacturers are obliged to ensure NIAS' safety, which means that in principle they have to be assessed. However, there is much concern that NIAS are not properly evaluated and that in practise it is not possible for the FCM suppliers to meet the basic requirement of the framework regulation to ensure that substances which may endanger human health will not migrate from the FCM into the food[6, **Fehler! Textmarke nicht definiert.**,43].

There is an obvious need to intensify the efforts both to gain knowledge and to find measures to avoid migration of harmful NIAS into food.

3.2.3 Inadequate risk assessments

There are concerns amongst stakeholders about the risk assessment method used under FCM legislation [6,77]. Of particular concern are the endocrine disrupting chemicals (EDC) that interact with the endocrine system and contribute to the development of various diseases. These kinds of effects are often insufficiently covered under the current risk assessment paradigm which is used for both plastics and other materials. At low migration levels, only few standard tests are required. The purpose of these tests is to assess the property of a chemical to cause or contribute to the generation of cancer. However, endocrine disrupting chemicals are also known to have possible harmful effect at low concentrations, and exposure to harmful chemicals at low levels has also been associated with higher risks for chronic diseases such as cardiovascular and metabolic diseases as well as diseases related to the nervous and immune systems.

3.2.4 Lack of adequate safety provisions for substances of very high concern

In line with the considerations above (section 3.2.3), there has been increasing acknowledgement amongst scientists and experts in national competent authorities in recent years that for the most harmful substances we know, such as CMR substances, EDCs and other substances of very high concern (SVHC), safety can only be ensured by simply preventing their use in FCM irrespective of the envisaged migration (see section 4.2.2). That is because the uncertainty of the specific risk assessments that aim to determine protective levels in the form of TDIs (Tolerable Daily Intake) and SMLs (Specific Migration Limits), is more crucial for substances with serious and irreversible effects. It is important to acknowledge that the concept of a "safe level" often does not make sense for *non-threshold substances* i.e. substances that can still have adverse effects even in extremely low concentration.

3.2.5 Risk assessments do not take account of mixture effects

Today, we are exposed to numerous chemicals from multiple sources, including food and drinking water, consumer products, and household dust. However, current safety

[77] Food Packaging Forum (2019) Position paper by Food Packaging Forum on the European food contact regulation. F Delivered as response to the Commission's open public consultation on the FCM legislation: https://www.foodpackagingforum.org/fpf-2016/wp-content/uploads/2019/05/FPF-Position-Paper-May-2019.pdf

assessments across the board of the EU chemicals legislation still mainly focus on one single substances at a time. This practice is used although it is well known that combined exposure to many chemicals can lead to unacceptable effects even if each substance in the mixture is below the safe level. The issue of mixture effects is much discussed[78] primarily as related to the EDCs, as there is a need to address the reality of multiple exposure to chemicals as a standard approach in EU chemicals risk assessment and risk management, including, in particular, in the safety provisions for FCM (se also section 4.3.2).

3.3 Lack of enforcement

When there is no clear guidance and rules as to what shall be done to ensure safety, enforcers can only control companies' self-assessment as to whether they comply with Article 3 of the FCM framework Regulation, and if there are no provisions demanding DoCs or few rules for its content, it clearly becomes difficult to enforce the basic safety requirement.

Moreover, in the JRC study[26] Member States highlighted a significant lack of resources needed for controls (personnel for the inspections, analytical equipment, facilities, etc.). They also reported that local inspections are not adequate for checking compliance with a supply chain spanning the entire world.

At the Commission's first stakeholder workshop on the FCM evaluation (section 2.2.2)) a presentation[79] by a representative of the food inspection of Zurich explained how the current enforcement of FCM rules in both the EU and Switzerland is mostly not working due to several key flaws:

- No European level working group concerning enforcement
- Too many substances
- Lack of allocated resources for FCM controls
- Lack of knowledge on risks associated with migration from FCM
- Lack of adequate sanctions

In line with the above, the Commission's evaluation report emphasizes the national enforcement of the FCM legislation as a key area in need of improvement[43].

3.4 Lack of coherence with REACH

There seems to be a lack of coherence between the current FCM legislation and Articles 14,5 and 56,5b of the REACH Regulation[8]. These are the only two articles in the regulation referring to FCM. According to REACH Article 14,5 the risk assessment performed by a REACH registrant, and covering most other uses of a chemical, does not have to include

[78] CHEM Trust, 2019: The chemical cocktail: new research on mixture effects call to urgent need for action https://chemtrust.org/chemical-cocktail-mixture-effects/
[79] Presentation by Gregor McCombie, evaluation workshop, 24 September 2018: Enforcements perspective: https://ec.europa.eu/food/sites/food/files/safety/DoC/cs_fcm_eval-workshop_20180924_pres07.pdf

assessment of health effects related to the use in FCM, only the effects on the environment must be assessed. Furthermore, REACH Article 56,5 exempts the use in FCM from the authorisation requirement for those substances of very high concern that are included in the list of substances which require a specific authorisation before they can be used in the EU. These exemptions in REACH do not seem warranted as long as the legislation in place for FCM does not provide comparable and equal safety for the consumers. Similarly, it seems important to ensure that the scope of any REACH restriction only exempts the use in FCM if these are irrelevant for the restriction in question, or alternatively, if similar restrictions are already in place in the FCM legislation.

3.5 Lack of understandable labelling and guidance for consumers

The international symbol for "food safe" material is a wine glass and a fork symbol (figure 3). The symbol indicates that the material used in the product is considered as being safe for food contact. The symbol is mandatory for products sold in the EU according to the FCM framework Regulation along with specific use instructions 'if necessary'. This rule is applicable to any product intended for food contact, but not yet containing food, whether it is made of metals, ceramics, paper and board, or plastics, including food and water containers, packaging materials, cutlery etc. The use of the symbol is more significant in products which should be explicitly identified whether safe for food or not, or if there is an ambiguity whether the container could be used to hold food. The symbol is also used in North America, Europe, and parts of Asia.

Figure 3: The Glass and Fork Symbol

However, according to the policy paper on FCM from the consumer organisation BEUC[59] even though most consumers may be familiar with this symbol itself, their understanding of its detailed meaning is low, consumers may not be aware that they should look for this symbol before using a container for storing food, and the practical value of the symbol as a communication tool appears limited.

There may also be need for better communication and labelling related to those packaging items that the consumer buy with their food. This is because the migration of chemicals from food contact material is affected by many factors. These factors include temperature, storage time and the chemistry of both the food contact article and the food, the thickness

of the food contact layer, and the packaging size. The framework regulations prescribe that if an authorisation scheme is in place, then the assessment of safety shall be based on the concept of 'intended use'. Thus, in principle, authorised chemicals in FCM have only been shown to be safe if the food contact article is used as intended by the manufacturer. But for the average consumer it is generally not clear from the packaging that it is intended for some uses, and not for others. This may lead to risky consumer practices. For example, if a consumer stores hot or fatty food in a single-use ice cream container then the migration of certain chemicals may be different than foreseen in the safety assessment. As a result, the EU FCM regime may systematically underestimate health risks since actual consumer behaviour is not explored and accounted for.

3.6 Hazardous chemicals may hamper aims for Circular Economy

The European Green Deal commits the Commission to ensure that all packaging on the EU market is reusable or recyclable in an economically viable manner by 2030[44, 45]. While it is an important objective to promote circular economy, it should be borne in mind that recycling of packaging into new FCM can increase both the possible sources of contamination and the amount of chemicals that can migrate from packaging into foods[80].

If the transition to circular economy gains momentum as planned in the coming years, there will be an increasing need for more focus on how to avoid the recycling of hazardous chemicals, particular for the more sensitive uses as the FCM in order to avoid a contradiction between aims for consumer protection and aims for better waste management. Currently, the FCM legislation does not have sufficient specific measures in place, such as the measures for recycled plastic (section 1.4.1), to guarantee a high level of protection for FCM made from recycled materials.

3.7 Substances of concern

This section provides brief information about some of the substances of particular concern in FCM (See also section 2.5.2 for information on mineral oils).

Perfluoroalkyl and Polyfluoroalkyl substances (PFAS)

The PFAS (Perfluoroalkyl and Polyfluoroalkyl substances) is a group of more than 4.000 different chemicals. They are highly persistent, degrade very slowly – if at all – in the environment, and are known to accumulate in the food chain. Due to their persistence, they are often referred to as "the forever chemicals"[81], and several have been banned under the Stockholm convention[82], which bans the most harmful chemicals in the world.

[80] B. Geueke et al., 2018: Food packaging in the circular economy: Overview of chemical safety aspects for commonly used materials. Journal of Cleaner Production 193. https://www.foodpackagingforum.org/news/food--in-the-circular-economy

[81] CHEM Trust,2019: PFAS, the forever chemicals: https://chemtrust.org/wp-content/uploads/PFAS_Brief_CHEMTrust_2019.pdf

[82] Website of the Stockholm Convention: http://www.pops.int/Implementation/IndustrialPOPs/PFOS/Overview/tabid/5221/Default.aspx

PFAS are used in the manufacture of a vast array of products such as water-resistant clothing, cosmetics, and firefighting foams. In spite of serious and well-known concerns, PFAS are still widely used in non-harmonised FCM such as non-stick cookware, and paper and cardboard food packaging. They are popular due to their grease-resistant properties and are found in pizza boxes, compostable bowls, and greaseproof paper, for example around takeaways chips.

As seen from in section2.5.3, there is increased focus on PFAS among the Member States and NGOs both in the EU and US.

Phthalates

Many phthalates are EDCs and known to be developmental and reproductive toxicants. There are indications that phthalates may impact genital development, semen quality, libido, children's neurodevelopment, male genital development, thyroid function, onset of puberty in females and that they could possibly cause respiratory problems.

Phthalates are used in a variety of consumer products, including food packaging, food processing (such as conveyer belts and tubing) and food preparation (such as gloves used in restaurants). For certain phthalates (DEHP, DBP and DIBP) food is thought to be the main exposure source due to the substances migrating from FCM into food[83].

In 2017, the presence of four phthalates was restricted in most consumer goods under the REACH Regulation, based on their ability to cause reproductive harm and endocrine disruption. Following up on this, EFSA published a scientific opinion in December 2019 assessing whether the authorised use of five phthalates in plastic FCM is still in accordance with the FCM legislation[84]. The results of this evaluation, which did not include all relevant data, did not lead to any changes in the current Specific Migration Limits (SML). Instead, a new group Tolerable Daily Intake (TDI) for four of the five phthalates (DBP, BBP, DEHP and DINP) based on their effects on the reproductive system was established. The fifth phthalate DIDP was given a different TDI. These TDI were set on a temporary basis due to uncertainties, and they may be revised once new toxicological data are included as the European Commission soon acknowledged a need to provide a new mandate for EFSA to conduct a more comprehensive risk assessment[85].

Bisphenol A (BPA) and other bisphenols

BPA is a highly controversial chemical which is used in a number of food contact applications. It is used to make polycarbonate plastic, which is hard and durable and is therefore produced for articles that are intended to be reused, such as cookware, liquid

[83] Food Packaging Forum (2012) on phthalates: https://www.foodpackagingforum.org/food-packaging-health/phthalates
[84] EFSA news on phthalate risk assessment, December 2019: https://www.efsa.europa.eu/en/news/faq-phthalates-plastic-food-contact-materials
[85] Chemicals Watch, December 2019: https://chemicalwatch.com/87078/efsa-to-look-again-at-phthalates-in-plastic-FCM

containers, plates, mugs and other plastic containers. It is also widely used for coatings of food and drink cans[86].

It has been known since the 1930s that bisphenol A mimics estrogen, and bisphenol A has been identified by the European Chemicals Agency (ECHA) as being toxic to reproduction and having EDC properties[87]. Many toxic effects, including neurological, immunotoxic, cardiovascular, and metabolic effects have been related by research to the exposure to BPA. It is well known that BPA migrates into our food and that BPA migration from food cans strongly contributes to the overall human BPA exposure[88], which makes its continued use very problematic.

Another issue of concern is the fact that there are many bisphenols available which are similar to bisphenol A. Thus, it may be important to address all bisphenols when taking legal action to restrict the use[89]. This concern was clearly documented by ECHA after a restriction of BPA in thermal paper recently implemented under REACH[90]. Market research conducted by ECHA showed that BPA was to a large degree substituted by another similar substance, Bisphenol S (BPS)[91]. According to ECHA, the wide use of BPS in thermal paper raises concern, as BPS is suspected to affect human reproductive and hormonal systems. Such widespread regrettable substitution entails that the legal action to restrict BPA has in practice not reduced the risk to the extent envisaged by the legislators. The concept of grouping (section 4.3.3) which could have led to the inclusion of a wider group of bisphenols in the restriction for thermal paper would have been useful to overcome this problem.

[86] EFSA website. FAQ on BPA: http://www.efsa.europa.eu/en/topics/topic/bisphenol
[87] ECHA website. Substance information on BPA: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133
[88] EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) 2015, Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Executive summary, https://www.efsa.europa.eu/en/efsajournal/pub/3978
[89] CHEM Trust,2018: From BPA to BPZ: a toxic soup? How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them: https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf
[90] Commission Regulation (EU) 2016/2235 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.337.01.0003.01.ENG&toc=OJ:L:2016:337:TOC
[91] ECHA,2020: The use of bisphenol A and its alternatives in thermal paper in the period 2014 – 2020: https://echa.europa.eu/da/-/bisphenol-s-has-replaced-bisphenol-a-in-thermal-paper

4 Good examples from other EU legislation

There may be good reasons to examine existing regulations on chemicals to see whether other legal acts can provide useful examples of new solutions and legislative tools, which could serve as inspiration for the coming revision of the FCM legislation. The existing EU chemicals legislation is largely built on a number of recurring principles, tools, and procedures used in different ways and in different combinations. There may also be good principles which are used only in one or few legislations. As may be deducted from the previous chapters, some important basic demands that should be in place in a legal system in order to achieve a situation which is both workable for businesses while also ensuring public safety, are for example:

- Clear allocation of the responsibility for assessing safety
- Clear procedures for gathering and exchanging information on chemicals
- Strong provisions to avoid unacceptable hazards
- Public right to information and participation
- Regular reviews

This chapter presents good examples of legislative tools and procedures that could be solutions to some of the problems described in the previous chapters. These include legal acts, such as the REACH regulation, where the principles above seem to have been clearly present in the mind of the legislators when designing the legislation.

No position is taken here as to whether the examples mentioned below are sufficient to ensure adequate protection. On the contrary, all EU legislation on chemicals would certainly benefit from improvement, and as described below, there are basic problems related to society's current use of chemicals which are not solved in any EU legal acts.

4.1 Information is a key

The REACH Regulation was based on a clear understanding amongst regulators that sufficient reliable data on chemicals' hazardous properties is a key requisite for any legislation on chemicals to be able to provide public safety. Consequently, the REACH Regulation provides clear information requirements which have undoubtedly contributed significantly to protecting human health and the environment from hazardous chemicals.

4.1.1 The "No data, no market" principle

The most important basic approach of REACH is that all manufacturers and importers of chemicals are obliged to provide testing data for assessing safety of use. The data requirements increase with increasing volume, and the sanction for not providing the data is clear: "No market".

If this principle should be transposed to the FCM legislation, it should preferably cover data on both the starting substances of FCM as well as on the chemicals in the migrating mixture from the final food articles.

Under REACH, the massive amount of information to be provided by industry was pragmatically required over a period of 10 years in a stepwise approach via a phase-in system with three clear legal deadlines[92]. These deadlines were mainly dependent on the tonnages produced or imported - as a proxy for exposure - but there was also an early deadline for chemicals with certain hazardous properties, regardless of tonnage. A similar but adapted phase-in approach might work to gradually introduce data requirements for FCM starting with the most important materials such as paper, cardboard and inks, and the most important chemicals, such as endocrine disrupting chemicals (EDC) and other substances of very high concern (SVHC).

Other examples of how the responsibility for ensuring safety is placed on the manufacturer is the Cosmetics Regulation, which identifies the producer of the product as the "responsible person". The responsible person must ensure that the cosmetic product has undergone a safety assessment, and that a safety report is set up, which must be updated in case any further relevant information is received after distribution has started. A different approach is seen in the Toys Safety Directive, which is under the Internal Market umbrella**Fehler! Textmarke nicht definiert.**. This directive requires manufacturers inside or outside the EU to carry out a safety assessment including chemical hazards, and to go through self-assessment (documenting that the toy is in conformity with harmonised standards), or use third party verification before drawing up a Declaration of Conformity to enable CE-marking of the toy.

4.1.2 IT-systems for sharing data on hazards and risks

The REACH-IT system and ECHAs comprehensive databases of registered chemicals[93], and probably also the databases on biocides[94] and pesticides[95], are examples, which show that it is possible to make massive amounts of data publicly available in a useful way.

If a similar customised system should be established for FCM, it would be important to not only make basic hazard data publicly available, but also to provide access to the presumptions behind the risk assessments for the materials and articles. The information currently found in the supporting documents for DoCs would probably be relevant in this context , possibly with a possibility for claiming some information confidential for business reasons. A clear obligation to update data would be indispensable, if such a system should be useful.

Different stakeholders have proposed different models for databases on chemicals in FCM. One proposal is for example to establish "document collection centres" for DoCs and supporting documents[96] The industry organisation PlasticsEurope is working on a

[92] Read about REACH registration at ECHA's website: https://echa.europa.eu/da/reach-registrations-since-2008
[93] ECHA's website. Registered substances: https://echa.europa.eu/information-on-chemicals/registered-substances
[94] ECHA's website. Information on biocides: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances
[95] Database on pesticides: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
[96] Grob, K.,2017: The European system for the control of the safety of food contact materials needs restructuring: a review and outlook for discussion, Food Additives &

proposal for a database for chemicals in FCM[97], and some regulators also see some form of a joint EU-wide database as a possible beneficial tool for chemicals in food contact materials and/or food contact articles[16].

A new database on substances of concern in articles and products (the SCIP database)[98], which is going to be established by ECHA, and which will contain obligatory information on substances of very high concern (SVHC) in articles, is also an example of a new initiative, recently taken under the Waste Framework Directive. The aim is to ensure that information on SVHCs shall be available in the whole lifecycle of a product, including the waste stage. This database will also cover SVHC in food contact articles, but as only information on SVHC in concentrations above 0.1 percent in the article is required, it may not be of much relevance for the FCM.

4.1.3 A workable system for supply chain information

REACH has a significant potential in managing risks by bringing together the knowledge of the manufacturer and the knowledge of the downstream user in the supply chain. The basic obligation to assess the risk of using a chemical is placed on the manufacturer or importer. These actors must register their information and also use it for developing the safety data sheet which accompanies the chemicals throughout the supply chain. However, as manufacturers do not know all of their customers' uses, REACH includes a provision that the customers throughout the supply chain (the downstream users) can report their uses to the registrants. At the same time, it is unlawful for downstream users to use a substance in a way which has not been identified and assessed by the registrant unless the downstream user makes their own risk assessments. Thus, under REACH in principle any specific use of a hazardous chemical in volumes above 10 tonnes per year without a risk assessment is unlawful. Such a system with clear obligations to assess chemicals and communicate about hazards and exposures placed on both the initial producer and the downstream users may be a good example to follow.

Unfortunately, the basic REACH system is mainly useful for substances and mixtures. The risk assessments made under REACH, generally "lose track" of the substances when they are incorporated into an article (including food contact articles and materials). Thus, there is a need for the FCM legislation to "take over" the safety provisions from REACH at the point of incorporation of a chemicals into a food contact material.

Formal documents may in principle work well for information exchange. In the same way as Safety Data Sheets (SDS) are the well-known formal tool for sharing hazard information in the supply chain for hazardous chemicals and mixtures under REACH, the Declarations of Compliance (DoCs) are the formal tool for sharing information in the FCM supply chain.

Contaminants: Part A, DOI: 10.1080/19440049.2017.1332431Koni Grob (2017): The European system for the control of the safety of food contract
materials needs restructuring: a review and outlook for discussion, Food Additives &
Contaminants: Part A, DOI: 10.1080/19440049.2017.1332431

[97] Marcel Bosma, SABIC and PlasticsEurope. Presentation at annual workshop of the Food Packaging Forum,October 2019: https://www.foodpackagingforum.org/events/workshop2019

[98] Information on the SCIP database on ECHA's website: https://echa.europa.eu/de/scip-database

The DoCs have been criticised for not being very detailed and for not providing sufficient background information about how the conclusions about safe use was derived (section 3.2.1). This report cannot provide any in-depth discussion on the current usefulness of the DoC information as these documents are not publicly available. But it is worth noting that:

- Some stakeholders question the value of the DoCs[16,26,], and some enforcers claim the information requirements are impossible to enforce (section 3.2.1)
- However, a good number of Member States have national rules requiring DoCs for the non-harmonised materials, indicating these documents are considered to be of some value (section 1.5).

4.2 Restricting hazardous chemicals

In the EU chemicals acquis, there are two basic approaches to risk management often used in combination[99]. One leads to restrictions (or definition of acceptable levels) of certain named substances while the other approach comprise predefined restrictions of chemicals as soon as certain hazardous properties are identified.

The first approach is based on Specific Risk Assessments (SRA) and the second on Generic Risk Considerations (GRC) or -Assessment (GRA). The main difference between these two approaches is the point in time when the exposure assessment is considered, and the specificity of the exposure assessment. When risk management is based on SRA as is the general situation for FCM, then risk management measures are based on assessments of the hazard of the individual substance. When risk management is based on GRC, the potential exposures and risks are considered prior to the adoption of legislation. The GRC-approach may be built into a legislation in the form of an automatic trigger of pre-determined risk management measures (which is often in the form of a restriction, but it can also be packaging requirement, communication requirement etc.). With the GRC, the predefined measure take effect when (as soon as) the hazardous properties of the chemical are established, without the need to assess and consider specific exposure levels for a specific situation or use.

Most legal acts under the EU chemicals legislation are based on SRA, but in recent years the GRA approach has been increasingly introduced. Moreover, as can be seen in the next section, a combination of the two approaches in the same legal act is not uncommon.

4.2.1 Acceptable levels for specific substances - based on Specific Risk Assessment

List of acceptable levels for individual substances are well known and exist in many regulations in different forms. These can be in the form of negative lists where the acceptable level is often very low or close to zero, or positive lists/authorisation lists where substances may be accepted, but under certain conditions or below certain concentrations or migration levels. Some examples are:

[99] Staff Working Document; Non-REACH Fitness check,2019: https://eur-lex.europa.eu/resource.html?uri=cellar:e7eb0a70-9757-11e9-9369-01aa75ed71a1.0001.02/DOC_1&format=PDF

REACH' annex XVII[100] is a continuously updated list of currently (August 2020) 70 entries that restrict marketing or use of different substances in different uses and products, including consumer products.

The **Cosmetics Regulation**[2] includes an annex (II) of 1379 substances or groups that may not be used, and a further annex (III) of 287 substances that may only be used under certain conditions, such as concentration limits and specific labelling.

The MRL Regulation pesticides in food (396/2005)[101] sets harmonised Maximum Residue Levels for pesticides in all agricultural products for food or animal feed based on safety assessments by EFSA. In addition, a general default value of 0.01 mg /kg is applicable where no specific MRL has been established.

The Toys Safety Directive[3] bans 19 so-called 'heavy elements' like mercury and cadmium beyond certain limits in the parts of the toys that are accessible to children. The directive also restricts allergenic fragrances and nitrosamines, and finally, migration of bisphenol A is restricted.

Similarly, harmonised restrictions are in place for certain substances in **electrical and electronic equipment** under the RoHS Directive[102] and for phosphates in detergents under the **Detergents Regulation**[103].

4.2.2 Generic Risk Considerations – Avoiding substances of certain properties

As mentioned above, the Generic Risk Consideration (GRC) approach has been implemented in several chemicals legislations in recent years. This approach protects consumers against the most hazardous chemicals which may have harmful effects even at extremely low concentrations (non-threshold substances). In practice the names of substances identified via GRC may be published on a list after some kind of scrutiny procedure. For example REACH provides a fast track Committee Procedure for restriction of CMRs as soon as they are classified, while the identification of a substance as an SVHC immediately triggers a number of obligations related to its use[104]. Restrictions based on generic risk considerations is seen in the regulation of toys and cosmetics, and under the

[100] An updated list of substances restricted under REACH, Annex XVII can be found at ECHA's website: https://echa.europa.eu/substances-restricted-under-reach
[101] Commission website about the MRL regulation: https://ec.europa.eu/food/plant/pesticides/max_residue_levels/eu_rules_en
[102] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0065
[103] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on Detergents: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0648
[104] Summary of obligations resulting from inclusion of SVHCs on the candidate list. ECHA's website: https://echa.europa.eu/candidate-list-obligations

Pesticides Regulation a number of active substances will not receive authorisation in the future due to new cut-off criteria for CMRs and aquatic toxicity.[105]

Although the provisions in these other legislations could certainly still be improved, it is striking that the GRC approach does not seem to be in focus for FCM (except for a ban on CMRs in plastics in absence of a functional barrier). This can be seen as one of the most serious backlogs of the current lack of harmonisation, and a main demand in the 5 NGO principles for the future legislation (chapter 5) is that identification or regulation of substances of concern under other EU laws, such as substances identified as SVHCs under REACH, should automatically trigger a restriction – or at least a mandatory evaluation – of its use in FCM.

4.2.3 Positive lists and authorisation

There are several legal acts in the EU based on positive lists similar to the Union list for plastic FCM (section 1.3.1).

The Cosmetics Regulation includes positive lists specifically for colorants, UV filters and preservatives. **The Biocides Regulation** requires that biocidal products and the active substances must be authorised before being placed on the market. There are certain exceptions, including active substances in the Review Programme, which can be marketed (subject to national laws) pending the final decision on the approval of the active substance. **The Pesticides Regulation** is based on an EU-wide authorisation list for the active substances while the final pesticide product must be approved in each Member State, and finally, the authorisation scheme under **REACH** demands authorisation for use of substances of very high concern (SVHC)[106], which may be seen as a combination of negative listing and positive listing. The first step is to place a substance on a list of substances of very high concern that requires authorisation. The next step is then for those companies who intend to continue the use, to apply for authorisation.

Finally, it has recently been agreed that **The Drinking Water Directive** should be recast[107] giving ECHA the task to compile and manage an EU positive list of chemicals that can be safely used in materials that come into contact with drinking water[108].

ECHA's work will be done in close collaboration with EFSA due to the close links with food contact materials. The first positive list is expected to cover around 1.500 chemicals and should be adopted by the European Commission by 2024, (although the actual recast has now been postponed due to the COVIC-19 crisis).

---

[105] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

[106] ECHA's website about the authorisation scheme under REACH: https://echa.europa.eu/substances-of-very-high-concern-identification-explained

[107] Commission's press release about a recast of the Drinking Water Directive (December 2019): https://ec.europa.eu/commission/presscorner/detail/en/ip_19_6830

[108] Press Release from ECHA about the positive list to be compiled for materials that come into contact with drinking water, January 14, 2020: https://echa.europa.eu/-/echa-starts-work-on-making-drinking-water-safer

It has been suggested that a similar approach could be an efficient way of establishing positive lists for those FCM[109] for which there are currently no harmonised rules. This could be more efficient compared to the process used today for the plastic FCM where all applications by industry have to be assessed individually by a scientific committee.

4.3 Concerns related to EDCs and mixtures

Two highly topical, urgent, and partly interlinked issues that still need to be addressed in all EU chemicals legislations are the issues of 1) how to identify and manage endocrine disrupting substances and 2) how to handle the reality of mixture exposure. These issues are also closely linked to the need for developing more advanced legislative safety measured based on GRC (section 4.2.2). As these issues are basically unsolved, there are fewer good examples in existing legislation, but some developments and experience from recent years is considered worth noting here.

4.3.1 Provisions to identify and avoid endocrine disruptors

Although the concern for the harmful effects of EDCs on humans and the environment has been omnipresent for decades, it is only very recent that basic criteria to identify EDCs have been established. These criteria were initially introduced into the Pesticides and Biocides Regulations. The Biocides Regulation has had criteria for identifying EDCs since June 2018, and for pesticides criteria were in place from November 2018. REACH includes EDCs as substances of very high concern (SVHC), and the data requirements for REACH registration are currently being updated to support the identification of EDCs.

Under the Cosmetics Regulation, the Commission's Scientific Committee has compiled a priority list of 28 potential EDCs to be further risk assessed[110].

In November 2018, the Commission published a Communication[111] updating the EDC strategy from 1999. The strategy included a roadmap[112] to launch of a cross cutting fitness check analysing the coherence of the rules on EDCs across the EU legal framework. Later the roadmap[46] for the chemicals strategy also predicted new measures to minimise exposure to EDCs, which may coincide the abovementioned EDC strategy.

As can be seen from previous chapters, several stakeholders, including Scientists, NGOs, Members of The European Parliament, and some Member states are concerned that the EUs actions on EDCs are too few and too late. There is an urgent need to develop a cross-sectoral overarching mechanism to facilitate identification and regulation of endocrine disruptors under the FCM legislation as well as in legislation governing all other relevant products. Such a mechanism must account for possible low-dose effects and the scientific

[109] Michael Warhurst, presentation at Chemicals Watch Conference, February 12th, 2020. How to modernise Europe's regulations on chemicals in FCM: https://chemtrust.org/wp-content/uploads/warhurst-cw-fcm-feb20.pdf
[110] Information about identification of EDCs in cosmetic products. Commission website: https://ec.europa.eu/growth/sectors/cosmetics/products/endocrine_en
[111] Commission Communication on endocrine disrupters. November , 2018: https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF
[112] Commission's consultation page on the EDC roadmap: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2142-Fitness-Check-on-endocrine-disruptors

uncertainties around the question of whether safe thresholds for endocrine disruptors can be determined.

4.3.2 Provisions to handle mixture effects

When establishing acceptable exposures, it is important to consider aggregate and cumulative exposures from chemicals with similar harmful effect as the toxicity may increase when we are exposed to several chemicals with the same or similar toxicity. This concerns exposure to the same chemical from multiple sources as well as to other similar chemicals from multiple sources combined. As chemicals in FCM migrate directly into our food, it is particularly important that the reality of mixture exposure is considered for these products.

The Commission's NON-REACH REFIT report highlighted the issue of addressing combination effects of different hazardous as an important area for future improvement[99].

In December 2018, a restriction of four phthalates was adopted under REACH. This restriction can be seen as a first attempt to restrict chemicals based on considerations of mixture effects. The reasoning behind the Danish restriction proposal was the need to address the combined effects of the four phthalates in articles.

The MRL Regulation for pesticides in food highlights the importance of further work to develop a methodology to take into account cumulative and synergistic effects. A mandate was given to EFSA and in response to this, the agency has undertaken a programme of work on mixtures risk assessment[113]. However, generally, the EU legislation on chemicals is not able to handle the reality that consumers and the environment are exposed to many toxic chemicals during their daily life, and that some of these have harmful effects that accumulate.

Recently, Sweden and the Netherlands asked the Commission and MS to (re)consider the introduction of a Mixture Assessment Factor (MAF) in risk assessments under REACH[114]. If an adequate generic MAF was introduced, for example as part of the coming chemicals strategy for sustainability (section 2.2.3), this might be a significant step in the protection of consumers and the environment. Particularly, if the approach was also applied for FCM.

4.3.3 Grouping to avoid regrettable substitution

The new concept of grouping[115], which is increasingly discussed amongst NGOs, the Commission, and Member States, and which ECHA has committed to use more systematically in the future, is an approach to make it less common that companies replace a restricted harmful chemical with a very similar chemical with the same harmful effects. The term "regrettable substation" is used for cases where a harmful chemical is replaced

[113] EFSA's website on mixture assessment: http://www.efsa.europa.eu/en/topics/topic/chemical-mixtures
[114] Food Packaging Forum has reported on the discussion on MAF among regulators: https://www.foodpackagingforum.org/news/eu-discusses-application-of-mixture-assessment-factor
[115] See for example articles published by CHEM Trust https://chemtrust.org/regulating-substances-as-groups/ and ECHA https://newsletter.echa.europa.eu/home/-/newsletter/entry/want-to-know-about-grouping-substances-to-manage-risks-of-chemicals-

with a similar and equally harmful substance, either because the harmful effects of the substitute are not known, or simply because a restriction does not cover the substitute (section 3.7).

In May 2020 ECHA published its annual report for the integrated regulatory strategy[116] focussing on their work to review data for groups of substances, thus focussing mainly at *assessing* substances in group. However, even if the move towards assessing more chemicals in groups may well speed up regulatory action, it is important to also focus on *regulating* substances in groups with actual *group-restrictions*. Substances such as the phthalates, the bisphenols and the PFAS (section 3.7) would be good candidates for future group restrictions.

4.4 Third party certification system

In 2017, the Commission revealed that is was contemplating a new certification system for FCM printing inks involving so-called "designated bodies" responsible for certifying compliance work[117]. Amongst the different legal acts presented in this chapter, the mandatory third party verification system is only used in the Toys Safety Directive as such verifications are more common under the New Approach framework**Fehler! Textmarke nicht definiert.**.

There is some scepticism towards the approach both within industry and among regulators and NGOs. It is clear that such a system could only improve the current situation if it would increase resources for compliance checks, and if it was accompanied by clear rules for data requirements and risk assessment procedures. Otherwise the new independent assessor would be as much in the dark as to when a safety assessment is sufficient, as suppliers and enforcers are today. An ambitious aim for such a system, could be to have a possibility for independent authorisation of the final food contact article including assessment of the migrating mixture in all cases of "foreseeable use".

4.4.1 Transparency and participation

According to the Commission, a key principle and objective of the EU's Better Regulation programme is to ensure that decision-making is open and transparent, and that citizens and stakeholders can contribute throughout the policy- and law-making processes. The Commission also acknowledges that stakeholders' (including industry, NGOs, academics, experts and citizens) access to relevant data and ability to be part of the decision-making process, especially during key stages of hazard and risk assessment/management processes, is essential for the effective chemicals risk management. Thus, there is room for improvement regarding participation in legal processes relating to FCM. There seems to be a need for a more balanced approach towards stakeholder participation, as EFSA is known to communicate much more with industry than with the civil society. However, changes may be underway as the Agency has recently set up a new Stakeholder Forum and is

[116] ECHA,2020: press release and link to ECHA's integrated regulatory strategy annual report, 2019: https://echa.europa.eu/-/grouping-of-chemicals-speeds-up-regulatory-action
[117] EC's proposal for regulating Printing inks. News release from Food Packaging Forum (July 2017): https://www.foodpackagingforum.org/news/ecs-proposal-for-regulating-printed-fcms

further in the process of implementing new requirements for transparency under the food law[118] .

A particular important participatory process under REACH is the process of developing guidances on how the comprehensive and complicated legal text should be interpreted in practice. Under REACH, ECHA has coordinated the development of such guidance for almost all aspects of this legislation in cooperation with different ad-hoc stakeholder groups[119]. The REACH guidance documents are detailed, and their status is high, as all Competent Authorities in the Member States, including enforcers, refer to them when establishing how the legal text should be interpreted in different situations. In that way, ECHA has successfully combined the aims of providing practical guidance for companies and providing harmonised interpretation of the legal text for enforcers and other regulators in the MS.

4.4.2 Regular review

According to the Commission, no systematic assessment or evaluation of the basic provisions on FCM has been done for over 40 years[120]. It is not viable that legislation for products with high risk of consumer exposure, such as FCM, is not reviewed regularly. In contrast, the whole REACH Regulation is subject to detailed review every 5 years.

[118] Commission website about the transparency regulation: https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en
[119] Guidance documents at ECHA's website: https://echa.europa.eu/support/guidance
[120] See the Commission's evaluation page (background and context) https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en

5 Possibilities for improvement of the EU legislation on FCM

As stated in section 2.2.3, the Commission has committed to take forward a proposal for a revision of EU legislation on Food Contact Materials by 2022, and has further indicated an aim to consult stakeholders on policy options prior to presenting the final proposal (section 2.2.4).

In view of the above, and as a contribution to the coming policy discussions, this chapter presents possible elements, and tools which could be useful in the future legislative framework for FCM. The proposals presented here are based on 5 key principles developed by a group of NGOs (section 2.4.1) including CHEM Trust, HEAL, EEB, Client Earth, ChemSec, The Danish Consumer Council, US Breast Cancer Prevention Partners in cooperation with BEUC and the Food Packaging Forum.

The NGO-group's five key principles states that a new EU regulation of chemicals in food contact materials must ensure:

1. A high level of protection of human health
All substances used in food contact materials should have adequate safety data, provided by industry, and should be regularly reviewed for this use by public authorities. The presence of substances that are already restricted in the EU, and those meeting the REACH criteria for substances of very high concern, such as CMRs, sensitizers or endocrine disrupters, should be automatically prohibited.

2. Thorough assessment of chemicals in materials and final articles
The presence in, and migration of, chemicals in food contact articles – including non-intentionally added substances (NIAS) – should be measured, assessed, and controlled. Absence of reliable migration data should imply presumption of full migration. Assessments of migration should include mixture effects and take a precautionary approach to exposures from non-FCM sources. Both industry and regulators should ensure that any migration is understood and limited to ensure a high level of protection of public health.

3. Effective enforcement
National governments must ensure effective enforcement, including checks on both imported and EU-manufactured finished articles using the best available analytical methods. Producers and importers of chemicals used in FCM should always be responsible for providing adequate analytical standards and analytical methods to regulators and test laboratories. In the event of contamination of products with problematic chemicals, producers should be obliged to notify the regulators.

4. A clean circular economy based on non-toxic material cycles
As the EU's transition to a circular economy gains momentum, it is vital that the EU's efforts to encourage recycling do not perpetuate the use of harmful chemicals in FCM.

Adequate regulation and enforcement of all types of recycled FCM is required to ensure that recycled food contact materials are never less safe than virgin materials.

5. Transparency and participation
Supply chains and final consumers should have a "right to know" the identity and safety information on chemicals used in, and migrating from, food contact materials. Regulatory and policy processes should as a minimum adhere to the same standards of openness and stakeholder participation that have been established in REACH.

5.1 Three possible levels of change

Although the findings of this report clearly point towards a need for a thorough revision of the EU FCM legislation, it may still be that "do nothing" or "almost nothing" is seen by the Commission as a viable possibility (section 2.2.4), and such an approach may be included as a policy option for the coming impact assessment.

In this report, the proposals for improvement are divided into three groups according to the level of change to the current legal system, that the proposal would require. The purpose of this segregation is to create an overview of the level of ambition associated with each proposal.

1) **A minimum level of change** could consist of new processes and procedures which could be implemented without - or before – any revision of the legal text is in place (section 5.1.1.).

2) **A medium level of change** could encompass new harmonised measures for some, but not all, currently non-harmonised materials in combination with additional measures which might require only a recast[121] of the current legal text (section 5.1.2.)

3) **The full review** (section 5.1.3) requires a proposal for a new legal text from the Commission to be negotiated and agreed between the European Council and the European Parliament. This approach should be combined with complementing tools and procedures presented under section 5.1.1. and 5.1.2.

5.1.1 Improved procedures and processes

In this section some important measures, which could be adopted without changes to EU legislation are presented:

Research: Both companies and consumers could benefit from more public resources allocated to assessments and research on for example the mixture of chemicals migrating

[121] An explanation of recast of legislation can be found at Client Earth' website: https://www.clientearth.org/eu-recast-procedure-used/

from final articles, including the NIAS, as well as on hazardous substances in recycled materials, or possibilities for substitution of harmful chemicals in FCM.

Guidance: Clear and updated guidance is a key to adequate safety assessment and compliance. Companies could benefit much from more adequate, univocal, and preferably common guidance provided by the authorities in EU Member States.

Handle the FCM under Restrictions introduced REACH: Legally, it is fully possible to restrict the use of harmful substance in FCM under REACH.

Participation: Balanced participation should be ensured by inclusion of equal numbers of NGOs as compared to industry stakeholders in meetings and processes run by EFSA and the Commission.

Enforcement: More resources should be allocated to enforcement in the Member States and better cooperation between enforcers in the different MS should be encouraged.

Ceramics: It is important to continue the on-going work to develop harmonised rules for the migration of toxic metals from ceramic materials, glass, and enameled metals. These must ensure adequate protection and consumer information for these products, including for artisanal and traditional products.

5.1.2 Possible elements with a medium level of change?

This section provides proposals for change which could be included in a theoretical a medium level of change.

Harmonised measures for more materials: Implementing measures for the non-harmonised materials could be introduced in a stepwise approach. It would be logical to start with those materials that are most problematic such as paper, cardboard, coatings, printing inks and glass and ceramics as mentioned above.

Authorisation of recycling processes: There is increasing need for measures to control hazardous chemicals in recycled materials. These could include authorising schemes for the recycling processes for more materials. For example paper and cardboard.

Third-party verification: In order for this to be successful, there would at least need to be full access to adequate data on hazard and exposure, clear guidelines for risk assessment and compliance, and a possibility for subsequent further control and enforcement.

5.1.3 What could be achieved with a full review?

As stated above, there is an urgent need for a thorough revision of the current legal framework in order to ensure safety for the consumers in the EU. The findings of this report show the need for a strong and ambitious approach to create new FCM legislation

based on the precautionary principle and aiming to minimise the exposure rather than searching for toxicological limits.

Important elements to include in the future EU legislation on FCM would be:

Harmonisation: The new legislation should introduce harmonised rules for all FCM materials, including any new materials such as grass and bamboo. This should be supplemented with useful guidance for all actors in the supply chain.

Obligations to provide data: The FCM legislation could take inspiration from the "no data, no market" approach under REACH and demand that industry provides useful data on chemical hazards and migration. This could be combined with the establishment of a database.

Obligations to share data in the supply chain: Harmonised DoCs with clear demands for the content, which should include sufficient supporting documentation, could enable all actors in the supply chain to perform sufficient safety evaluation of their products.

Risk Assessment related to the final article: The new legislative system should include measures to ensure safety assessment of the mixture migrating from the final article, including the NIAS.

Coherence and generic risk considerations: The new legislative system should include measures (for example in the form of a general mandate on the responsible Agency) to ensure that substances restricted or identified as being for concern under other legislations, such as SVHC substances identified under REACH, must be evaluated before being used in FCM.

Negative lists based on grouping: The new legislation could include lists of substances to be banned in FCM, such as PFAS, bisphenols and phthalates. For such substances it would be relevant to use the concept of grouping to the widest extent possible.

New approach to positive lists: The new approach for developing a positive list for drinking water contact materials could be an inspiration for improving the FCM legislation.

Taking account of multiple exposure: The new legislation should take into account that consumers and the environment are exposed to hazardous chemicals from many sources. The introduction of Mixture Assessment Factors in risk assessments may be useful in this context.

Take account of consumers foreseeable use: Risk assessments should be more clearly based on consumers' foreseeable use and expectable re-use of food packaging rather than only on the use which is "intended" by the manufacturer[122].

Address all relevant health effects: Risk assessments for chemicals in FCM should include evidence regarding all relevant health effects including endocrine disrupting properties, as well as for example neurotoxicity and immunotoxicity.

In addition to the points listed above, the Federation of German Consumer Organisation (vzbv) has developed a detailed policy summary calling for new EU legislation on FCMs and also presenting additional proposals for the revision**Fehler! Textmarke nicht definiert.**.

The Commission's recent commitment to propose a revision of the legislation provides that there is now a genuine chance to change the legislative system for FCM from being one of the most backward and dysfunctional areas of legislation to being one of the most modern.

An ambitious approach to the revision would be the best solution for the citizens of Europe and for the environment. It would probably also be beneficial to most businesses providing and using FCM as it would create a clear level playing field, make obligations clear to all parties, and create more trust between producers, downstream users, retailers, food producers and consumers.

If the legislation on FCM would be developed to provide both efficient safety for consumers and a workable system for the suppliers, then this legislation might serve as the good example for other legislation in the future.

[122] vzbv Consumer Report, 2019: Sicherheitslücken von Produkten, die für den Kontakt mit Lebensmitteln bestimmt sind, Ergebnisse einer Online-Befragung, https://www.vzbv.de/sites/default/files/downloads/2020/09/25/20-08-20_befragung_lebensmittelkontaktmaterialien_ergebnisse_1.pdf, 25.09.2020.

Annex 1: Selected EU legal acts on chemicals

	Type of product covered	**Basic elements included**	**Aims**
The REACH Regulation 1907/2006	Substances and mixtures. Articles to limited extent	Registration Evaluation Authorisation Restriction	Basic law to provide data and manage risks while enhancing competitiveness and the internal market
The CLP Regulation 1272/2008	Substances and mixtures for professional and consumer use	Classification Labelling and Packaging of hazardous substances and mixtures	Protection of human health and the environment and free movement of substances, mixtures, and articles
Cosmetics Regulation 1223/209	Final cosmetic substances and mixtures for consumers	Positive list and negative list. Responsible person for safety assessment	Ensure safety of the product and promote the internal market
Pesticides Regulation 1107/2009	Pesticide product	Authorisation scheme	Protection of human and the environment and improve the functioning of the internal market
MRL Regulation 396/2005	Food and feed	Maximum levels of pesticides in food	Consumer protection and harmonised provisions
General Food law Regulation 178/2002	Food and feed	General principles and requirements	Consumer protection and well-functioning internal market
Toy Safety Directive 2009/48	Articles and mixtures in the form of toys	Internal market, New approach Directive	Ensure safety of toys and a well-functioning internal market
RoHS Directive 2011/65/	Electrical and electronic equipment	Restriction of certain substances	Protection of human health and the environment, sound recovery and disposal of waste EEE.
Detergents Regulation 648/2004	Detergents and surfactants for detergents	Demands for labelling, biodegradability of surfactants and phosphate content	Movement on internal market while protecting environment and health

Annex 2. Summary of the presence of legislation or standards for non-harmonised materials[123]

The table shows the distribution of countries with measures or national norms[124] specific to different materials. CoE[125], Norden[126], Switzerland and Norway are included.

MS	Adhesives	Printing inks	IERs	Varnishes	Waxes	Ceramics	Glass	Metals and alloys	Cork	wood	Paper and board	Rubbers	Silicones	SM or OM generic to all FCMs	reference
France	multiple	multiple + norm	x +norm	multiple	x		x	multiple + norm	x	multiple	multiple	multiple	x	x (metals)	multiple
Netherlands	x	x	x	x	x	x	x	x	x	x	x	x		x	Com Act
Croatia	x	x		x		x	x	x	x	x	x	x	x		NN125-2009
Czech Republic		x		x		x	x	x	x		x	x	x		V 38/2001
Germany	xx	(x)		multiple +norm	x	norms	norm				multiple + norms	multiple + norm	x		BfR Rec.
Italy	x	x (DoC)		x			x	multiple	norm		multiple	x	x	x	DM 73 ++
CoE		x	x	x			x	x			x	x			
Slovakia		x		x			x	x	x		x	x			1799/2003
Spain	x		x	x	x		norm					x	x		RD 847/2011
Switzerland		x			x		x	x					x		ord 817
Belgium				(x)			x	x			x				AR 1992
Austria						x		x				x			BGBl 258
Greece				x				x			x				Food code
Norden								x	x		x				
Poland						norm	norm				x (norm)				*only norms*
Denmark						norms	norm								*BPA*
Norway						x	x								
Portugal							x norm		norms						*only norms*
Romania		x										x			
Bulgaria							x								*only glass*
Finland						x								x (metals)	268/1992
Sweden								norm							
Cyprus															
Estonia															
Hungary															49/2014
Ireland															n/a
Latvia															
Lithuania															
Luxembourg															
Malta															
Slovenia															uses CoE
United Kingdom															

[123] The table is a copy of table 4, page, 51 of the JRC Baseline report[26]
[124] National Norm: The table shows the distribution of countries with measures or national norms specific to different materials
[125] CoE: Council of Europe is a regional intergovernmental organisation of 47 countries.
[126] Norden is a geographical region consisting of Denmark, Finland, Iceland, Norway, and Sweden, along with the Faroe Islands, Greenland and the Åland Islands. The region has an extensive cooperation scheme.

Annex 3: Overview of material-specific national rules and tools[127]

Material	Positive list	Negative list	SML	OML	Limits for substance quantity	Details on GMP	DoC & supporting docs	Basis for sanctions	Basis for enforcement
Adhesives	DE, ES, FR, HR, IT, NL		ES, HR	ES, HR	DE, ES, FR, HR, NL			ES	ES, HR, IT
Ceramics			AT, CZ, DE, DK, FI, HR, NL, NO, PL	NL			AT, CZ, NO		CZ, DE, NL
Cork	CoE, CZ, FR, NL, SK	CoE, (NL)	CoE, CZ, NL, SK	CoE, HR, NL	CoE, SK, NL				CoE, HR
Glass	BE, (IT), SK	(HR), NL	BE, BG, CH, CoE, CZ, DE, DK, FR, HR, IT, NL, NO, SK	BE, NL	FR, (NL)	(SK)	IT		BG, CZ, DE, DK, FR, IT, NO
Ion exchange resins	CoE, ES, FR, NL		CoE, ES, NL	CoE, ES, NL	CoE, ES, FR	CoE	NL	ES	CoE, (ES)
Metals and alloys	CZ, EL, FR, IT, NL, SK	AT, CH, HR	AT,(CH), CoE, FR, HR, IT, NL, NO, Norden	FR, NL	AT, BE, CH, CoE, CZ, EL, FR, HR, IT, NL, SK	(IT)	CoE, FR, IT	IT	AT, CoE, FR, HR, IT, NO
Multimaterials	FR, IT, Norden	Norden	FR, IT	FR, IT	FR, IT, Norden				FR
Paper and Board	BE, CoE, CZ, DE, (EL), FR, IT, NL, Norden, SK	CoE, DE, EL, (HR), Norden	BE, CoE, DE, EE, FR, HR, IT, NL, Norden, PL, SK	BE, DE, FR, NL, Norden	BE, CoE, CZ, DE, EL, FR, HR, IT, NL, Norden, SK	(HR), Norden	IT, Norden	IT	CoE, DE, EE, FR, HR, IT, Norden, PL
Printing inks	CH, CoE, DE_draft, FR, NL, SK	CoE, CZ, HR	CH, CoE, DE, (DE_draft), FR, NL	FR	CH, CoE, CZ, FR, (HR), NL, RO, SK		DE_draft, FR, IT, Norden, RO	DE_draft, IT	CoE, Norden
Rubber	CoE, CZ, DE, ES, FR, HR, IT, NL, SK	CZ, DE, HR, SK	AT, CoE, CZ, DE, ES, FR, HR, NL, RO, SK	CoE, DE, ES, FR, HR, NL, RO	AT, CoE, CZ, DE, ES, FR, HR, IT, NL, SK	CoE	FR, IT, RO	ES	AT, CoE, DE, (ES), FR, HR, IT
Silicones	CH, CoE, CZ, DE, ES, FR, HR, IT	CoE, CZ, HR	CH, CoE, CZ, DE, ES, FR, IT	CH, CoE, DE, ES, FR, HR, IT	CH, CoE, CZ, DE, ES, FR, HR, IT			ES	(ES), FR
Varnishes and coatings	CoE, CZ, DE, EL, ES, FR, HR, IT, NL, SK	FR, HU, HR	BE_draft, CH, CoE, CZ, DE, EL, ES, FR, HR, IT, NL,	BE_draft, CoE, EL, ES, FR, HR, IT, NL	BE_draft, CoE, CZ, DE, EL, ES, FR, IT, NL, SK	CoE	BE_draft, EL	ES, IT	BE_draft, DE, (ES), HR, IT, NL
Wax	DE, ES, (FR), NL		ES	ES	CH, DE, ES, (FR), NL			ES	(ES)
Wood	FR, NL	FR, (NL)	FR, HR, NL	NL	FR				FR, HR

[127]The table shown here is a copy of Table 5, Page 52 of the JRC Baseline Report (2016)[26]