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EVALUATION

of the

legislation on food contact materials - Regulation (EC) No 1935/2004

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Glossary

Acronym	*Meaning or definition*
ADC	Azodicarbonamide. Used as a foaming agent in plastic gaskets that are used to seal metal lids to glass packaging.
AIM	Active and intelligent food contact materials (FCMs). Active FCMs extend the shelf-life or maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food. Intelligent materials and articles monitor the condition of packaged food or the environment surrounding the food.
BADGE, BFDGE and NOGE	Bisphenol A diglycidyl ether (BADGE), bisphenol F diglycidyl ether (BFDGE) and novolac glycidyl ethers (NOGE) result from the polimerisation process of epoxy resin out of bisphenol A (BPA), bisphenol F (BPF) or novolac and monomers that are not fully chemically bound may migrate into food.
BfR	Bundesinstitut für Risikobewertung (German Federal Institute for Risk Assessment).
BPA	Bisphenol A. A monomer used in the manufacture of polycarbonate plastic and epoxy coatings.
CEN	European Committee for Standardization is an association that brings together the National Standardization Bodies of 34 European countries.
CMR	Carcinogenic, mutagenic and reprotoxic chemicals. They make up the first and most toxic category of the toxicity classes into which hazardous chemicals can be subdivided, according to EU legislation.
CoE	Council of Europe.
DoC	Declaration of compliance. This is a written declaration stating that FCMs comply with the specific rules applicable to them as per Article 16 of Regulation (EC) No 1935/2004.
EFSA	The European Food Safety Authority is responsible for risk assessment in the area of food safety.
EURL-FCM	European Union Reference Laboratory.
FCMs	Food contact materials are all materials and articles which are intended to come into contact with food including those which are already in contact with food and those which can reasonably be expected to come into contact

	with food or transfer their constituents into food under normal or foreseeable conditions of use as per Article 1(2) of Regulation (EC) No 1935/2004.
FTE	Full-time equivalent. It is a unit to measure employed persons in a way that makes them comparable although they may a different number of hours per week. The unit is obtained by comparing an employee's average number of hours worked to the average number of hours of a full-time worker.
GMP	Good Manufacturing Practice.
ISO	The International Organisation for Standardisation is an international standard-setting body composed of representatives from various national standards organisations. It promotes worldwide proprietary, industrial, and commercial standards.
JRC	The Commission's Joint Research Centre.
LOQ	Limit of Quantification. It is the smallest amount of a substance that can be measured with stated and acceptable imprecision and inaccuracy (e.g. the smallest concentration of a chemical that can be measured with sufficient precision in a millilitre of water).
NIAS	Non-intentionally added substances. These are impurities in the substances used to manufacture FCMs or reaction intermediates formed during the production process or reaction products or impurities through decomposition.
NGO	Non-governmental organisation. NGOs are usually non-profit and independent of governments (though often funded by governments) that are active in humanitarian, educational, health care, social, human rights, or environmental causes.
NRL	National Reference Laboratory. It is required to implement quality assurance and is often the main laboratory where official controls are undertaken.
OML	Overall Migration Limit. This applies to the sum of all substances that can migrate from the FCM into food (or food simulant). The OML is a measure for the inertness of the material.
PET	Polyethylene terephthalate (PET or PETE) is a general-purpose thermoplastic polymer.
PVC	Polyvinyl chloride, a synthetic plastic polymer.
RASFF	Rapid Alert System for Food and Feed. A key tool to ensure the flow of information to enable swift reactions when risks to public health are detected in the food chain.

RCF	Regenerated cellulose film. Materials manufactured by the conversion of natural cellulose to a soluble cellulosic derivative and subsequent regeneration, typically forming either a fibre (e.g., rayon) or a film (e.g., cellophane).
REACH	REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals, which is provided for by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006.
SCF	Scientific Committee for Food. The Committee carried out risk assessment work on FCMs prior to the establishment of EFSA.
SC-PAFF	Standing Committee on Plants, Animals, Food and Feed.
SD	Supporting Documentation. It must demonstrate that FCMs, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of legislation. It contains the conditions and results of testing, calculations including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance.
SME	Small, medium and micro-sized enterprise defined by staff headcount, turnover or balance sheet total[1].
SMC	Semicarbazide is formed from the breakdown of azodicarbonamide.
SML	Specific Migration Limit. The amount of substance allowed to migrate into food from the FCM.
TDI	Tolerable daily intake. A TDI is an estimate of the amount of a substance in air, food or drinking water that can be taken in daily over a lifetime without appreciable health risk. TDIs are often calculated based on laboratory toxicity data to which uncertainty factors are applied.
VCM	Vinyl chloride monomer, used to manufacture polyvinyl chloride (PVC).

[1] https://ec.europa.eu/growth/smes/sme-definition_en

1. INTRODUCTION

Food contact materials (FCMs) are all materials and articles which are intended to come into contact with food, including those that are already in contact with food and those that can reasonably be expected to come into contact with food or transfer their constituents into food under normal or foreseeable conditions of use – in accordance with the principal basic act Regulation (EC) No. 1935/2004[2] (hereafter also referred to as the 'FCM Regulation'). FCMs include food packaging, kitchenware and tableware as well as items used in professional food manufacturing, preparation, storage and distribution.

FCMs are manufactured using a wide variety of different materials, including plastics, paper and board, metals, rubber, ceramic and glass; natural materials such as wood and other plant based materials, as well as components used widely in packaging such as coatings, adhesives and inks. FCMs contribute directly to the safe production, processing, transport, sale and ultimately consumption of all foodstuffs placed on the market in the EU.

No FCM is completely inert and substances are present in final articles, including those used in their manufacture, those formed from chemical reactions during their manufacture or those present as breakdown products and impurities. They may transfer to food, resulting in exposure of humans consuming that food. Therefore, since 1976 EU legislation has placed basic requirements on businesses concerning the safety of FCMs and substances migrating from them with the aim of securing a high level of protection of human health and the interests of consumers, whilst ensuring the effective functioning of the internal market.

The FCM Regulation sets out the modalities for the authorisation of substances used to manufacture FCMs, which must be followed in cases where a specific measure establishes a list of authorised substances for the manufacture of certain FCMs. Further specific measures may then include compositional and testing requirements and restrictions such as the amount of substance allowed to transfer into the food. The FCM Regulation also provides rules on labelling, compliance documentation, traceability as well as inspection and controls. It is complemented by a Regulation on requirements for good manufacturing practices (GMP)[3].

The current main EU-specific measure concerns plastic FCMs[4], which includes a list of authorised substances that may be used in their manufacture. A number of other specific measures also exist, on ceramics, recycled plastics, active and intelligent materials (AIM) and certain specific substances[5] (see also annex 7). In the absence of EU-specific measures, Member States may maintain or adopt their own national provisions on FCMs as per Article 6 of Regulation (EC) No. 1935/2004; such national legislation is in place in many Member States.

The current FCM Regulation does not contain requirements addressing hygiene, environmental concerns or waste management.

[2] http://data.europa.eu/eli/reg/2004/1935/oj
[3] http://data.europa.eu/eli/reg/2006/2023/oj
[4] http://data.europa.eu/eli/reg/2011/10/oj
[5] https://ec.europa.eu/food/food/chemical-safety/food-contact-materials/legislation_en

1.1. Purpose and scope of the evaluation

Although the EU legislation on FCMs was never formally evaluated prior to this exercise, informal monitoring of the legislation has taken place over many years by way of feedback and dialogue on its practical management and implementation, in working group meetings as well as correspondence with EU Member States experts[6], with industry associations and other stakeholders. This dialogue together with increasing experience with the functioning of the legislation in practice raised several fundamental issues with the existing approach to regulating FCMs at EU level. These encompass the risk assessment and risk management processes, in particular the authorisation of starting substances; the compliance of final articles, information flow in the supply chain, enforcement, as well as coherence with other legislation.

Furthermore, the lack of EU-specific rules beyond mainly plastic FCMs is considered by most stakeholders to negatively impact the functioning of the internal market and possibly, the safety of FCMs. In 2017, the Commission's Joint Research Centre (JRC) published a study (JRC 'baseline' study)[7] setting out detailed information on the different FCM supply chains and national measures in Member States. It analysed the effectiveness of such measures on the safety of FCMs and coherence as well as the possible burden of national instruments on Member States and businesses.

This evaluation assesses the EU FCM legislation in all EU Member States at the time of its undertaking (i.e. including the UK) as well as its application in EEA countries and Switzerland. This includes the main elements introduced in the first Council Directive 76/893/EEC[8] and maintained in the current FCM Regulation (EC) No 1935/2004, such as basic requirements on safety. It also includes elements that were introduced in 1976, such as the role of the European Food Safety Authority (EFSA) and the approaches taken by the specific measures to regulating FCMs, including assessment and authorisation of substances – primarily in plastic FCMs.

As Member States can maintain or introduce national measures in the absence of EU-specific rules according to the FCM Regulation, the evaluation also considers the impact of the presence of national measures.

2. BACKGROUND TO THE INTERVENTION

The size of the European FCM market is estimated to be around EUR 100 billion per annum[7], with more than half of this value coming from the plastic as well as paper and board industries. The glass, metal and machinery sectors are also considerable in value, with a significant number of businesses producing and transforming other materials critical to the manufacture of FCMs, including silicones, rubbers, wood, ceramics, coatings, adhesives and inks. Table 2 in annex 5 summarises the distribution of different sized businesses and annual revenue for several sectors. Figure 6, annex 5 provides a generalised overview of the FCM supply chain.

[6] https://ec.europa.eu/food/food/chemical-safety/food-contact-materials/fcm-document-library_en
[7] https://publications.jrc.ec.europa.eu/repository/handle/JRC104198
[8] http://data.europa.eu/eli/dir/1976/893/oj

Imports make up a considerable portion of the EU market. Although the value of all imports including raw materials is difficult to accurately quantify, as the Combined Nomenclature (CN) codes for imports are not sufficiently detailed, they play a significant role in bringing kitchenware and tableware into the EU, with an estimated value of around EUR 340 million[9].

2.1. Description of the intervention and its objectives

The EU started to legislate FCMs in 1976 with Council Directive 76/893/EEC in recognition of the potential risks to human health from FCMs and potential problems concerning the functioning of the internal market. Since then the legislation has been revised twice; once in 1989 by way of Directive 89/109/EEC[10] and again in 2004 when the current FCM Regulation was adopted.

The **general objectives** pursued by the legislation on FCMs since 1976 are twofold:

1. Provide the basis for securing a high level of protection of human health and the interests of consumers;
2. Ensure the functioning of the internal market.

To support these general objectives, the regulation contains a **principle legal requirement** (Article 3) which states that "*materials and articles [FCMs] must be manufactured in compliance with good manufacturing practice, so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.*"

The **specific objectives** aim to ensure the following:

1. FCMs are manufactured to a high-quality standard by requiring the application of GMP for all materials and articles and specific measures on information flow in the FCM supply chain through a declaration of compliance (DoC) and supporting documentation;
2. the interests of consumers are addressed, concerning information on the correct and safe use through labelling requirements such as the wine glass and fork symbol (see right) and prohibition of misleading labelling, advertisement or presentation;

3. enforceability including the removal of non-compliant products from the market through official control and traceability throughout the FCM supply chain;
4. transparency of the safety assessment procedures of FCMs and to ensure accountability and dependency of the authorisation processes;
5. technological progress is taken into account by setting out rules for materials that intentionally change food in accordance with the food law.

[9] Wood; table and kitchenware (HS Code 441900) imports into EU in 2019. World Integrated Trade Solution.
[10] http://data.europa.eu/eli/dir/1989/109/oj

Annex 8 provides the intervention logic of the original needs, objectives of the intervention and actions taken, as well as the outcome and anticipated impacts with a particular focus on the points above introduced in 2004.

The EU legislation on FCMs fits into the wider EU policy on food, chemicals and consumer protection. In particular, following the farm to fork approach governing the General Food Law, it complements Regulation (EC) No 178/2002 (the General Food Law)[11] concerning the safety of foodstuffs, which does not cover transfer from FCMs into food. Official controls on FCMs are within the scope of the food and feed control Regulation (EU) 2017/625[12].

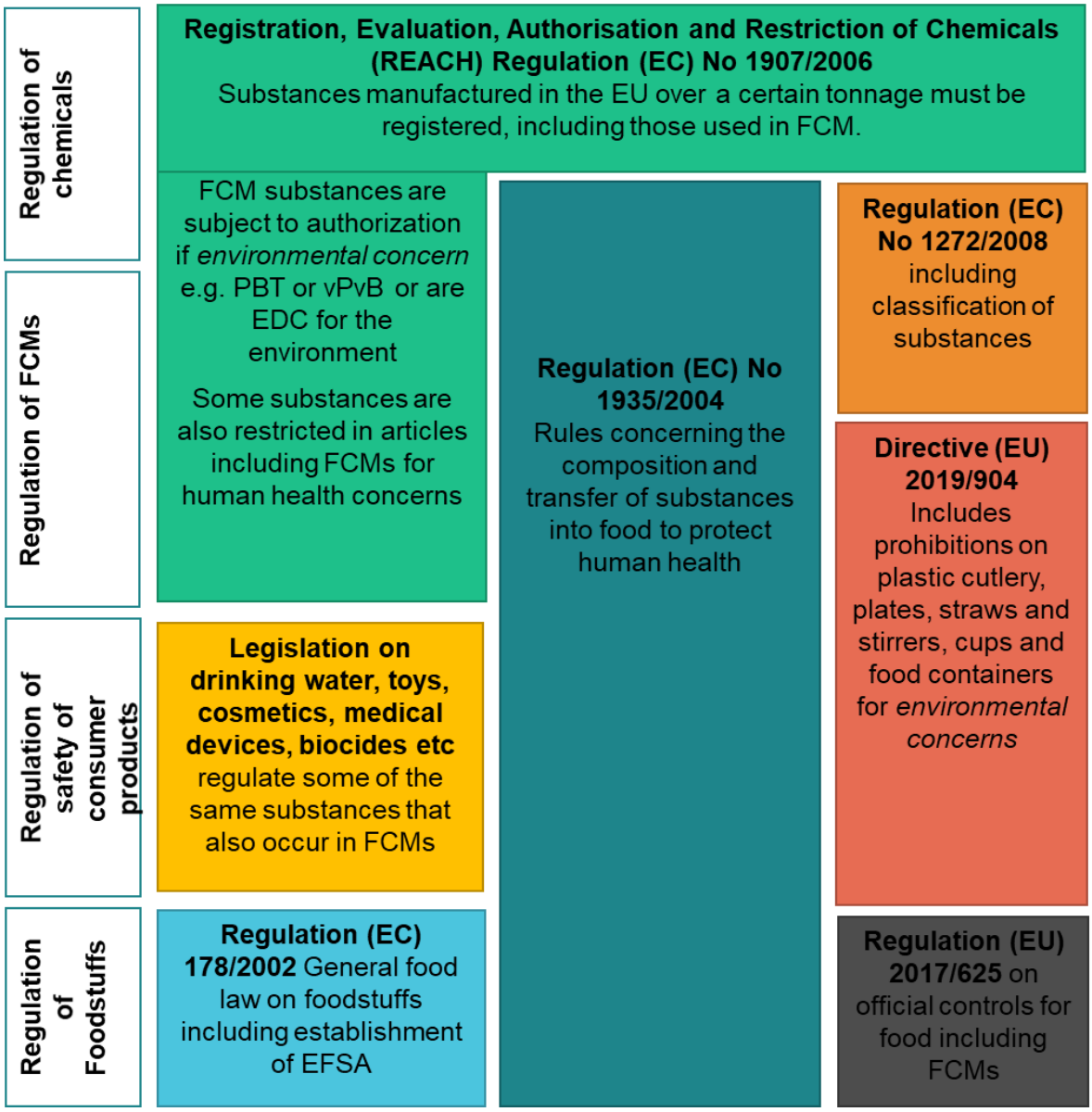
Other relevant legislation concerning the risk management of chemicals and the protection of citizens include those related to drinking water[13], medical devices[14], toys[15], cosmetics[16] and the general product safety legislation[17], in which substances found in FCMs may also be regulated (such as phthalates), although there is no direct link between the legislation.

Substances used in the manufacture of FCMs are subject to registration requirements under the main chemicals Regulation (EC) No 1907/2006[18] concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), depending on the tonnage used. Additionally, where risks may be identified from substances to the environment as opposed to human health, authorisation of certain substances, including those used in FCMs, may be required. As an alternative risk management approach, a limited number of substances are subject to restrictions set out in Annex XVII to that Regulation, including their presence in FCMs.

Of more recent relevance are interactions with major Commission policies on the circular economy (recycling) and the plastic strategy (e.g. the single use plastics Directive[19]), which bans the use of certain single use FCMs such as plastic straws.

[11] http://data.europa.eu/eli/reg/2002/178/oj
[12] https://eur-lex.europa.eu/eli/reg/2017/625/oj
[13] https://eur-lex.europa.eu/eli/dir/2020/2184/oj
[14] http://data.europa.eu/eli/reg/2017/745/oj
[15] http://data.europa.eu/eli/dir/2009/48/oj
[16] http://data.europa.eu/eli/reg/2009/1223/2019-08-13
[17] http://data.europa.eu/eli/dir/2001/95/oj
[18] http://data.europa.eu/eli/reg/2006/1907/2020-08-24
[19] http://data.europa.eu/eli/dir/2019/904/oj

Figure 1: Relationship between the FCM legislation and other legislation on chemicals, food and consumer products



2.2. Baseline and other points of comparison

In general, the evaluation uses the situation before the introduction of EU rules as a point of comparison. Although some individual rules existed in Member States as far back as 1912, work on FCMs started to develop in the 1950s and 1960s as the use of more synthetic materials began to grow in importance. Some countries such as Germany and the Netherlands introduced specific lists of positive authorised substances, including limits on those substances per polymer type, taking account of the specific technological properties of each material. A more toxicological approach prevailed in several other Member States including Italy, France, Belgium and Luxembourg.

In the late 1960s, the Council of Europe (CoE) took steps to design a harmonised approach addressing FCMs by designing a draft Resolution for plastic FCMs. Despite these efforts, many differences amongst the then Member States remained unresolved.

For assessing the effectiveness of specific EU measures, primarily plastic FCMs, a comparison has been made with the situation for sectors that to date do not have specific EU measures (sometimes referred to as "non-harmonised") areas. Where possible, a comparison is made with other EU measures regulating chemicals (see section 4.1), as well as legislation in third countries.

3. IMPLEMENTATION/STATE OF PLAY

The FCM Regulation is directly applicable to all businesses involved in the manufacture, import, processing and distribution of FCMs on the EU market including food businesses selling packaged food. In addition to laying down its scope and providing certain definitions, it sets out basic requirements on safety and changes to food, as described in Article 3 of the FCM Regulation, labelling to ensure the safe use of FCMs by consumers (Article 15) and traceability (Article 17) in the supply chain.

All FCM businesses manufacturing FCMs in the EU must comply with rules on GMP, which aim to support compliance and conformity of FCMs throughout the entirety of the manufacturing processes rather than simply at the end.

The Commission is empowered to adopt specific measures for the 17 material types presently listed in Annex I of the FCM Regulation, normally in accordance with the Regulatory Procedure with Scrutiny ("PRAC"), following consultation with the toxicological safety section of the Standing Committee on Plants, Animals, Food and Feed (SC-PAFF).

The main specific EU measure regulates the composition of plastic FCMs and features a Union list of substances authorised for use in the manufacture of plastic FCMs. Restrictions for these substances used in FCMs are also often introduced to ensure safety, including limits on the content in the final material or for their transfer into food, commonly known as specific migration limits (SMLs).

3.1. Establishment of authorised substances

Building on work already done by Member States, early scientific risk assessments at EU level to inform on the authorisation of substances was undertaken by the Scientific Committee for Food (SCF), an advisory body set up by the Commission in 1974. This was initially achieved for regenerated cellulose film (RCF) in 1983[20], which currently exists as Commission Directive 2007/42/EC[21] and eventually by the start of the 1990s, a first list of monomers and other starting substances ('building blocks' for plastic), authorised for use in the manufacture of plastic FCMs, was established.

Since the introduction of the FCM Regulation, the functions of risk manager and risk assessor have been separated to ensure transparency of the safety assessment procedures of FCMs and to ensure accountability and dependency of the authorisation processes. Consequently, the scientific risk assessment work has been conducted by EFSA which replaced the former SCF. The current FCM Regulation lays down specific procedures for the application process for the

[20] http://data.europa.eu/eli/dir/1983/229/oj

[21] http://data.europa.eu/eli/dir/2007/42/oj

assessment and authorisation of a substance subject to authorisation, including specific provisions on public access to applications for authorisation, supplementary information from applicants and opinions from EFSA.

In order to have a substance assessed, a business operator must compile a dossier of scientific information in accordance with EFSA guidelines[22], published in accordance with Article 9(2) of the FCM Regulation. The dossier is sent to EFSA via any Member State competent authority and should be assessed by EFSA within six months, subject to the need for supplementary information. EFSA then publishes an opinion indicating whether the substance is safe for its intended use, the conditions under which it can be used as well as restrictions of use for the evaluated substance and/or the [plastic] FCM in which it is used.

Taking into account the opinion of EFSA, the Commission may authorise the substance and set out any necessary restrictions for its use, including an SML. Thereafter, any business operator may use the authorised substance in the [plastic] FCM and must comply with any condition or restriction attached to such authorisation. Furthermore, business operators must inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, EFSA then reviews the assessment.

Commission Regulation (EU) No 10/2011 on plastic FCMs ("the plastics Regulation"), includes a Union list of about 900 starting substances and additives authorised for use in the manufacture of plastic FCMs, including specifications and restrictions on their use. No other substances may be used, unless there is a derogation, until they have been assessed and authorised. The plastics Regulation consolidated and simplified the previous two decades' worth of EU legislation on plastic FCMs, and adapted to technological developments by including rules for plastics used in combination with other materials in so called multi-material multi-layers, such as adhesives or inks, acknowledging the shift in FCMs on the market, and rules on documentation that must accompany the FCMs and how to verify compliance with the rules (e.g. testing).

The Regulation also provides certain derogations, for example for substances that catalyse reactions during the manufacturing process. Such 'aids to polymerisation' are used in minute amounts and are not intended to remain in the final polymer. They are therefore subject to a risk assessment by the business operator, rather than requiring a full application and assessment by EFSA and authorisation by the Commission. Substances from chemical reactions or degradation may also be formed during the production of plastics – otherwise known as non-intentionally added substances (NIAS). Although they are relevant for the risk assessment, it is not practically possible to list and consider all reaction and degradation products in the authorisation and therefore they must similarly be risk assessed by the business operator according to international rules.

Other substances including polymer production aids and macromolecules obtained from microbial fermentation may be included in the list of authorised substances but may also be used without an authorisation, subject to the businesses' own risk assessment or national law.

[22] https://www.efsa.europa.eu/en/applications/foodcontactmaterials/regulationsandguidance. NB. Significant changes to this system have since entered into force in March 2021 as a result of the Transparency Regulation.

Such exemptions are laid down in the plastics Regulation and there is no scope for businesses to apply for derogations for those substances for which an authorisation is compulsory, i.e. monomers, other starting substances and additives, excluding colorants.

3.2. Other EU FCM legislation

In order to take account of the provisions for waste reduction and thus the need to prioritise recycling, it is necessary to control potential incidental contamination from substances originating from misuse, cross contamination or from the presence of materials that were intended or used for non-food purposes. Therefore, Commission Regulation (EC) No 282/2008[23] sets out rules for plastic recycling processes and requires the adoption of authorisation decisions addressed to individual recyclers, following an EFSA assessment of their recycling processes.

At the time of this evaluation, the Commission was in the process of repealing and replacing the current Regulation[24] and thereafter authorising recycling processes based on applications assessed by EFSA. In the meantime, recycled food contact plastics have been allowed subject to national rules, existing only in a few Member States.

Technological developments in the area of food packaging intended to monitor the condition of the packaged food or influence its composition through the release of substances prompted the need to derogate from the general requirements on inertness set out under the FCM Regulation. Regulation (EC) No 450/2009[25], sets rules for the establishment of a Union list of authorised substances for active and intelligent materials (AIM) and adopts specific provisions on labelling of AIM, declaration of compliance and supporting documentation. Whereas EFSA has undertaken assessments of substances for use in AIM, the authorised list for AIM has not been established.

Although both recycling and AIM Regulations are in force, neither has been fully implemented yet for reasons further discussed in section 5.4.

Directive 84/500/EEC[26] harmonised the rules on ceramic FCMs at the EU level for the release of lead and cadmium, and sets out conditions for testing the migration of these metals. However, as exposure to lead and cadmium remain too high, considerable reductions in the current limits to safeguard health are needed although many businesses would consequently face difficulties, in particular small or micro artisanal companies, as well as medium sized companies using traditional manufacturing techniques. These considerations are subject to a separate impact assessment process and in general, ceramics and vitreous materials been considered as part of this evaluation process.

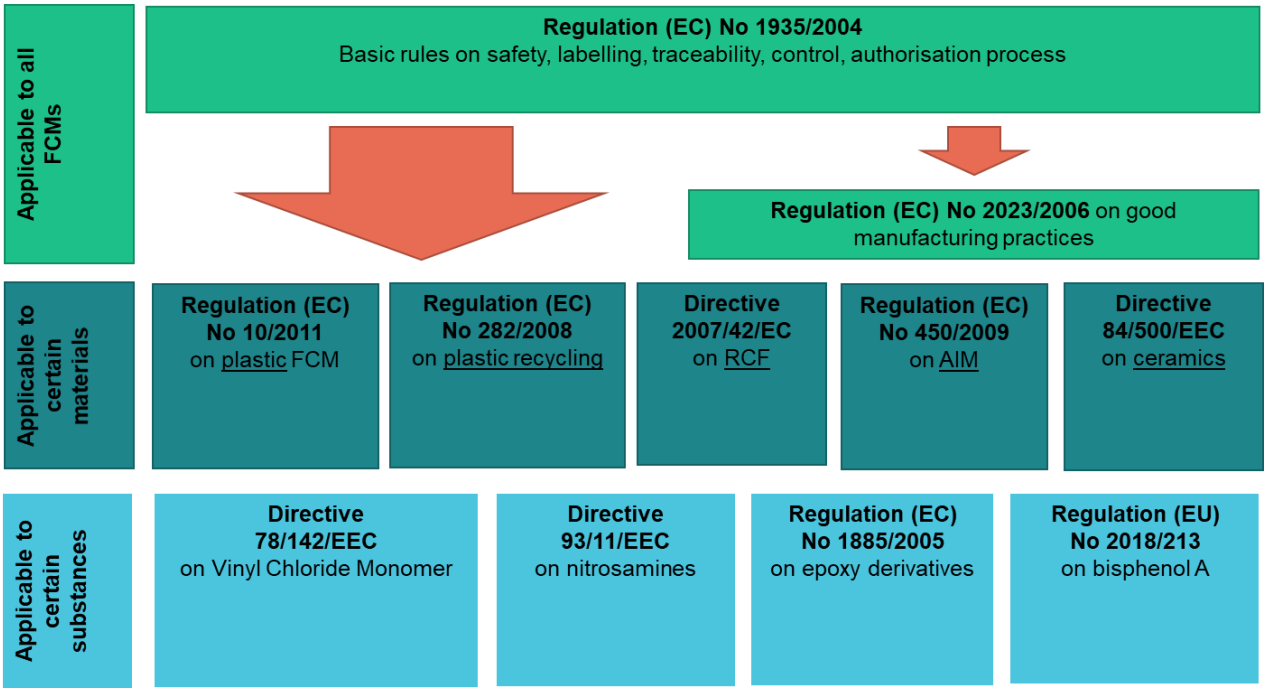
In addition to the main specific legislation at EU level mentioned above, several additional measures exist, addressing specific substances. These have been introduced following specific concerns or scientific output, including measures on vinyl chloride monomer (VCM)[27], N-

[23] http://data.europa.eu/eli/reg/2008/282/oj
[24] https://ec.europa.eu/transparency/comitology-register/screen/documents/079492/3/consult?lang=en
[25] http://data.europa.eu/eli/reg/2009/450/oj
[26] http://data.europa.eu/eli/dir/1984/500/oj
[27] http://data.europa.eu/eli/dir/1978/142/oj

nitrosamines and nitrosatable compounds in rubber teats[28] as well as bisphenol A (BPA)[29] and epoxy derivatives[30] in materials other than plastic. Guidance documents have also been introduced in addition to EU legislation, in particular to support understanding and compliance of the plastics Regulation.

Figure 2 below gives an overview of all the specific rules and measures in place. Annex 7 contains a description of all specific measures in place at EU level and relevant supporting guidance documents.

Figure 2: All specific measures in place for FCMs under Article 5(1) of the FCM Regulation



3.3. Documentation requirements

All EU-specific measures require that FCMs to which they apply must be accompanied by a written declaration (declaration of compliance or 'DoC') stating that they comply with the rules applicable to them. Appropriate documentation must also be made available to demonstrate such compliance. For plastic FCMs, these rules apply at all of the marketing stages other than the retail stage, including final articles, products from intermediate stages of manufacturing and for the substances intended for the manufacturing of those materials and articles. The information requirements include the identity of the business operator, the materials and substances used and limitations of the use of the material such as the temperature to which the materials can be subjected.

The written DoC must confirm that the products comply with the rules and should be supplemented by appropriate documentation to demonstrate compliance, such as conditions

[28] http://data.europa.eu/eli/dir/1993/11/oj
[29] http://data.europa.eu/eli/reg/2018/213/oj
[30] http://data.europa.eu/eli/reg/2005/1895/oj

and results of testing, calculations including modelling, other analyses, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in the plastics Regulation.

3.4. National legislation

In the absence of specific measures at EU level, Article 6 of the FCM Regulation allows Member States to maintain or adopt national provisions. The 2017 'baseline' study[7] by the Commission's JRC sets out a comprehensive overview of the current national legislation on FCMs in each Member State and identifies multiple pieces of legislation across the majority of Member States, covering most of the materials for which there are currently no EU-specific measures.

Some Member States have also introduced national measures on BPA, although there are EU-specific rules, under the safeguard measure provided for in Article 18 of the FCM Regulation. Further risk assessment is currently being carried out by EFSA to determine action at EU level. The impact of the national measures are examined in this evaluation.

The FCM Regulation requires Member States to carry out inspections and official controls in order to enforce compliance with the Regulation and to lay down effective, proportionate and dissuasive sanctions in case of non-compliance. Official control work must be carried out in accordance with relevant provisions of Union law relating to official food and feed controls (Regulation (EU) 2017/625). The work is supported by the EURL-FCM[31] at the JRC. Amongst other activities, it develops testing methods, organises inter-laboratory comparison exercises and conducts training courses for the benefit of National Reference Laboratories (NRLs) and experts from developing countries. It also produces guidance documents to support compliance and enforcement work.

In contrast to some other EU rules on food, no international regulatory framework currently exists for FCMs such as the *Codex Alimentarius*. The Council of Europe (CoE) has continued to publish non-binding policy statements on a number of FCMs including metals and alloys and paper and board[32]. International standards also exist for ceramics, both at the level of CEN and ISO, and standards for glass are often available in combination with ceramics. Table 3 in annex 5 gives an overview of the different national measures and materials to which they are applicable.

4. METHOD

4.1. Short description of methodology

The Commission published a roadmap[33] setting out the approach for this evaluation exercise in November 2017. Feedback on the roadmap was received from 26 stakeholders, which was taken into account. A supporting study was commissioned and launched in 2018, undertaken by an external contractor. Additional work to complement the contractor's report also provides essential input to the evaluation. This includes the JRC 'baseline' study[7] as well as

[31] https://ec.europa.eu/jrc/en/eurl/food-contact-materials
[32] https://www.edqm.eu/en/publications-food-contact-materials-and-articles
[33] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1212-Evaluation-of-Food-Contact-Materials-FCM-

two supplementary studies done by DG SANTE on controls and information in the supply chain[34].

The analysis further draws on a number of parallel and related EU initiatives on other sectorial or horizontal legislation undertaken recently by the Commission. These include the Fitness Check on General Food Law[35], the REFIT evaluation work on the mutual recognition (MR) principle[36], on which FCMs rely, and the Fitness Check on the most relevant chemicals legislation[37]. In addition, EFSA published an opinion on developments in risk assessment[38], which has also provided evidence that has contributed to the evaluation.

Stakeholders participated throughout the entire process, sharing experiences and views on the scope and the approaches set in the FCM Regulation, as well as to help identify any positive or negative effects. The consultation process included a strong representation of scientific and technical expertise from both public (e.g. national authorities) and private sectors (e.g. businesses including SMEs and professional associations) as well as adequate representation from consumer and civil society organisations, including NGOs. Activities included a 12-week public consultation, workshops, an SME Panel Survey and focus group activities. Further details are available in the annexes and on the Commission's website[39].

4.2. Limitations and robustness of findings

As the original intervention was introduced almost 45 years ago, the reconstruction of the baseline prior to 1976 is largely descriptive and does not readily provide information as points of comparison in order to assess the evaluation criteria, for example impact on costs or health. Similarly, EU-specific measures have been introduced since the early 1980s without impact assessment work, to establish the situation at that time and to provide a quantitative baseline. Nevertheless, the implementation of national legislation in the absence of EU-specific measures beyond mainly plastics has provided a useful baseline, as well as quantitative points of comparison to evaluate the impact of EU-specific measures, in particular on plastic FCMs.

It has been difficult to comprehensively quantify costs due to lack of robust data. The scientific studies and the contractor's report include some relevant data, but stakeholders, especially businesses, were not always willing or able to share information on compliance costs, which are considered confidential. Industry also confirmed particular difficulties in estimating all costs from presence of different national measures. Henceforth, in order to allow a quantitative comparison, surrogate figures or best estimates have been used based on the best available data. To compensate for the lack of hard data, the work encompassed several consultation exercises, including one-to-one interviews, case studies, focus groups and an SME Panel questionnaire, in addition to the 12-week public consultation and workshops. Ad hoc contributions have also been taken into account.

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[34] https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en
[35] SWD(2018) 37 https://ec.europa.eu/food/safety/general_food_law/fitness_check_en
[36] SWD(2017) 475 https://ec.europa.eu/docsroom/documents/26975
[37] SWD(2019) 199 https://ec.europa.eu/info/publications/fitness-check-most-relevant-chemical-legislation-excluding-reach_en
[38] https://doi.org/10.2903/j.efsa.2016.4357
[39] https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en

The quantification of health benefits could not be properly established due to the lack of available information which is sufficiently robust to establish a causal relationship between the introduction of EU rules on FCMs and health outcomes. However, attempts have been made to investigate the impact of an intervention, such as a restriction or prohibition for a specific substance together with an estimation as to the extent to which the measure may have been beneficial to health. Further analyses have been made to try to gauge the extent to which the legislation may have contributed positively to health, in order to facilitate understanding of the efficiency.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

In order to carry out the evaluation, 10 questions were prepared covering the five evaluation criteria; effectiveness, efficiency, relevance, coherence, and EU added value.

5.1. Effectiveness

To what extent has the FCM Regulation and subsequent implementation achieved its objective of (Q1) *providing the basis for securing a high level of protection of human health and the interests of consumers* and (Q2) ensured the effective functioning of the internal market in relation to the *placing on the market in the EU* in relation to FCMs?

5.1.1. Scope of the FCM Regulation, definitions and labelling

The FCM Regulation covers materials intended for and already in contact with food but also those which can reasonably be expected to come into contact with food or transfer their constituents into food. Information collected from the consultation work with stakeholders indicates that the scope of the regulation is clear concerning the first two cases (Article 1(2)(a) and (b)). However, around 40% of consultation respondents questioned the clarity of what constitutes "normal and foreseeable conditions of use"[40] (Article 1(2)(c)) including almost all NGOs. The difficulty of fully predicting consumers' behaviour and to take into account all possible ways they may use or re-use FCMs (see section 5.3 on relevance) was also highlighted in one of the focus groups.

Typical examples include paper towels deployed in the kitchen setting and paper napkins used during the consumption of food (see case example 1, annex 6), where views differ on their status as an FCM. Products not considered to fall within the scope of the FCM Regulation are governed by general product safety or REACH, which do not take into consideration risks arising from the transfer of substances into food. They are also not subject to control under the Regulation (EU) 2017/625 on official controls. Thus if used for food contact they may pose a risk to health as indicated in case example 1.

While the wine glass and fork symbol (see section 2.1) should inform consumers about the suitability of an article for food contact, the public consultation shows that 30% of consumers are unclear or unsure of the meaning of that symbol[37]. Although not statistically significant, a larger sample size (>1000 consumers) taking part in a 2019 survey conducted by the

[40] Ecorys report: public consultation, Part II. Full results available at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/public-consultation_en. Factual summary report published July 2019 https://ec.europa.eu/food/system/files/2019-07/cs_fcm_20190616_summary-report.pdf

Federation of German Consumer Organisations (vzbv)[41] put this figure at over 50%, similar to the understanding of the AIM symbol (annex I of Commission Regulation (EC) No 450/2009) determined during the public consultation. Earlier survey work on silicon articles on the German market[42] found that when use instructions were given exclusively in the form of pictograms without further wording, those were rarely self-explanatory and often difficult to read because the imprint was blurred and in the same colour as the product. Identification and communication of information to consumers therefore seems partly unclear, which is also identified under the chapter on relevance.

In contrast, the wine glass and fork logo is often seen on types of packaging for which it is difficult to re-use with food in any context, such as carton-board packaging, and therefore cannot be aimed at consumers. It raises the possibility that the symbol may be used as a quick and easy way for businesses to indicate legal compliance in the supply chain.

The majority of respondents from the public consultation[37] consider that the definitions in Article 2 of the FCM regulation are sufficient and clear, with the exception of NGOs, most of whom perceive the current definitions provided by the legislation as not sufficient, although it is not clear on what basis this opinion is formed. However, it may be that the definitions are clear from the perspective of the respondent, but that respondents would not necessarily agree on their meaning. As regards specific measures, discussions frequently occur on definitions of different material types, for example on whether certain elastomeric products fall under the definition of 'plastic' in Regulation (EU) No 10/2011, or may rather be considered as 'rubber', which are not in the scope of the plastics Regulation. Generally, therefore, it can be concluded that although definitions appear clear, their interpretation depends strongly on the perspective of the stakeholder, leading to possible confusion and different applications of the legislation.

5.1.2. Traceability

FCMs should be traceable throughout the distribution chain up to the raw materials to ensure effective action in terms of non-compliance. During the public consultation, almost three-quarters of businesses indicated that they consider traceability requirements to be sufficiently detailed whereas less than half of public authorities agreed with this[37]. In addition to the FCM Regulation, industry associations have provided guidance that defines requirements to ensure traceability with examples[43]. The Nordic Council of Ministers has developed a traceability checklist on FCMs[44]. Conversely, the evidence from audit and fact-finding missions, as well as discussions with Member States, indicate some general difficulties with accessibility of information across the supply chain, particularly where different businesses operate in different Member States, where coordination between different competent authorities is challenging and where documents are only available in paper format.

As well as guidance, stakeholders indicate that traceability is enhanced when a DoC and supporting documentation (SD) is required, in the case of plastic FCMs for example, since

[41] https://www.vzbv.de/sites/default/files/downloads/2020/09/25/20-08-20_befragung_lebensmittelkontaktmaterialien_ergebnisse_1.pdf
[42] https://www.verbraucherzentrale.de/sites/default/files/migration_files/media235769A.pdf
[43] https://www.apeal.org/wp-content/uploads/2015/04/1.-Industrial-Guidelines-Traceability-Jan2006.pdf
[44] http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A702301&dswid=1800

these documents contain information such as the name and address of the legally responsible business. In the absence of these specific requirements, there is an indication that traceability may be compromised since businesses must make specific efforts to provide traceability, rather than simply filling in a DoC. However, no examples or evidence have been found of specific problems that have led to major difficulties, for example, in withdrawing or recalling FCMs from the market. Some Member States such as Denmark, Spain (with a reference to an industry guideline), Poland, Slovenia, Estonia and Norway have requirements for registering businesses, which helps as regards traceability. This is touched on again in section 5.1.7 concerning inspections and controls. Overall, there appears to be room for improvement in EU traceability requirements, which are currently supplemented by self-guidance (i.e. standards set by industry bodies) or information in a DoC.

5.1.3. General requirements on safety

The general legal requirement on safety laid down in Article 3 of the FCM Regulation has acted to a certain extent as a driver for pushing safety standards and improving the protection of human health. This includes the EU-specific measures in place in addition to the main safety requirement in Article 3 of the FCM Regulation. Member States have introduced national specific rules which support the achievement of safety. Output from EFSA has also helped to facilitate the understanding of safety and compliance[22] concerning the migration of substances that can be applied regardless of whether substances are subject to authorisation at EU level. Numerous industry guidelines have also been introduced, which have been designed to ensure safety and facilitate businesses in demonstrating compliance, such as the CEPI Food Contact Guidelines for the Compliance of Paper and Board Materials and Articles[45].

It should be noted that some of these benefits may have materialised even in the absence of Article 3, but not necessarily consistently throughout the EU and to varying degrees. For example, prior to 1976, some Member States had already started to introduce specific rules on FCMs and this appears to be the case for FCMs not subject to specific EU rules. Article 3 in isolation is insufficient to be effective at achieving the aims of the legislation, since it does not define the level of safety expected, how this should be achieved or how it can be demonstrated. Since safety is not absolute and views differ between stakeholders on how to define levels of safety and demonstrate compliance, some stakeholders, in particular industry, find that Article 3 on its own is not effective at providing a level playing field across the EU to support the functioning of the internal market[46]. Others, including NGOs, argue that gaps exist concerning the safety of FCMs[47]. Further analysis on this is carried out in section 5.1.5.

The effectiveness of the requirements concerning the effect of FCMs on the organoleptic qualities of food appears questionable because of a lack of agreement and definition of what constitutes a "deterioration in the organoleptic characteristics" of food. There have been unsuccessful attempts at solving issues with sensory science on an EU level, including a JRC workshop in 2011[48]. Furthermore, a key issue identified during the workshop was the lack of

[45] https://www.cepi-eurokraft.org/wp-content/uploads/2019/04/Food-Contact-Guidelines_2019.pdf
[46] Stakeholder perspectives Cross-Sector Group, inaugural workshop 24 September 2018
[47] Stakeholder perspectives NGOs, inaugural workshop 24 September 2018
[48] https://ec.europa.eu/jrc/sites/default/files/Simat-presentation-FCM-sensory-workshop-20111129.pdf

harmonised EU standards or guidance on testing procedures. As noted by the JRC 'baseline' study[7], the extent of approaches is different between different Member States, with some having internal standards, while others following CEN/ISO standards. Case example 2 in annex 6 outlines some practical problems on this topic.

Little information is available on the effectiveness of Article 3(2) which prohibits misleading of consumers, aside from recent cases involving so-called 'eco-friendly' FCMs[49]. Very few RASFF notifications have been raised on incorrect labelling or advertising of FCMs, which in any case may also relate to safety concerns and therefore non-compliance with Article 15. This may indicate that the requirement is effective at dissuading businesses from misleading advertising, or perhaps reflects the lower priority given to its enforcement.

5.1.4. Specific EU rules introduced under Article 5 of the FCM Regulation

Union lists of authorised substances including risk assessment

The requirement to generate scientific data, the risk assessment by an independent EU scientific body and corresponding risk management measures introduced by the Commission and agreed upon by Member States has ensured a well-established, well-defined and agreed level of safety that has been achieved for starting substances and additives used in the manufacture of plastic FCMs at EU level. Most stakeholders agree that this process is effective in ensuring their safety, including businesses and Member States according to the public consultation. Indeed, Member States also use the scientific guidance[22] provided by EFSA for risk assessment as a basis for their own risk assessment work[50]. The approach has therefore been generally effective at ensuring the safety of starting substances and additives in plastic FCMs.

There is a consensus, particularly from businesses involved in the plastic FCM supply chain, that the approach is effective in contributing towards the smooth functioning of the internal market[40, 51]. The approach means that rules on the use of starting substances are the same throughout the EU and thus contribute effectively to the functioning of the internal market. The list of authorised substances has provided legal certainty to businesses on what substances can be used, which in turn has facilitated business investments and exchange in the supply chain. The impact appears positive compared with the situation prior to the establishment of the list and in particular in comparison to sectors that trade FCMs for which there is no EU authorised list, as these sectors face different national contexts both at the stage of risk assessment of substances and in their use in plastic FCMs.

Development of a Union list has also led to rules on the technical quality and purity of substances, general restrictions such as an overall migration limit (OML) and specific restrictions such as SMLs. These are particularly important mechanisms to ensure exposure to substances stays below a safe level and usually reflect a health-based guidance value such as a tolerable daily intake (TDI) established by EFSA, below which a risk is considered not to be present. In setting an SML, the Commission also takes into account other possible sources of exposure to the substances where information indicates it is necessary. This recognises that

[49] https://www.beuc.eu/publications/beuc-x-2021-050_towards_safe_and_sustainable_fcm._report.pdf
[50] Ecorys report: Focus group 5 "Risk assessment and risk management"
[51] Ecorys report, annex 2: Case study 1 "From application to market"

consumers may also be exposed to the same substances that are present in other products as well as their presence in the environment including the air. Consequently, these restrictions complement the authorisations and enhance consumer protection.

The effectiveness of the approach is however limited in several ways. Currently, over 900 substances are authorised for use in the manufacture of plastic FCMs. This represents no more than around 10% of the overall number of substances used in FCM manufacture, which is broadly estimated to be around 10 000 (although plastic accounts for the greatest proportion of all FCMs on the market[6]). Not all these substances are toxicological relevant, but the current approach does not automatically focus on those substances with the highest risks. The lack of specific rules beyond mainly plastics is, according to stakeholders, a major problem – either because it does not guarantee safety of other materials or because trade in other materials is hampered by a lack of consistent rules on how compliance to ensure safety should be achieved.

The approach is weakened because new scientific knowledge is not reflected in a timely manner in the authorisations. Such knowledge on many substances has become increasingly available over the years, generated for example by REACH requirements, independent scientific research or reviews by other assessment bodies. This is particularly pertinent given that a significant number of the substances that are authorised were assessed decades ago. While a mechanism for update exists that must be triggered by any user of the substances, or can be started by Member States or the Commission, this mechanism does not work.

In recent years, the Commission has asked EFSA to re-assess phthalates[52] and styrene[53], and various requests were received from Member States to re-assess certain substances authorised in plastic FCMs, such as phenol[54]. There is a legal obligation under the FCM Regulation for applicants or users of a substance to report new relevant data, although this has happened very infrequently. While industry has provided new data together with existing data in REACH registrations, FCM dossiers have not been updated at the same time. A possible reason may be that while there is a dedicated applicant for authorisation, once a substance is authorised, there is no authorisation holder; the original applicant may cease to exist and consequently there is a limited responsibility for the update of the substance. Other sectors such as plant protection products[55], have a built in renewal or review period for the approval of active substances not lasting more than 15 years. Case example 3 in annex 6 provides a practical example.

NGOs as well as the European Parliament[56] have expressed concerns that the current approach in the risk assessment and management of FCM substances does not sufficiently take into account vulnerable populations, unlike other sectorial legislation as identified in the EU Chemicals Fitness Check[37]. According to a 2016 opinion by EFSA[38], a more refined risk assessment of substances is necessary but is not feasible with the current risk management approach due to the consequential demand on resources and practical complexities, such as multiple SMLs for the same FCM. EFSA also considers that the final FCM or article should

[52] https://doi.org/10.2903/j.efsa.2019.5838
[53] https://doi.org/10.2903/j.efsa.2020.6247
[54] https://doi.org/10.2903/j.efsa.2013.3189
[55] http://data.europa.eu/eli/reg/2009/1107/oj
[56] Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004) (2015/2259(INI))

be evaluated for its safety rather than the starting substances. However, the Regulation is drafted on the premise that it is possible to determine the safety of the final material based on its starting substances. The approach used in the plastics Regulation would therefore require fundamental changes to accommodate for this.

A number of stakeholders and in particular NGOs are concerned that the current legislation is not sufficiently effective at taking into account the possible combination effects of substances migrating from FCMs, in particular that the toxicity of combinations of substances could be larger than that of individual substances[57]. Although such phenomena have, for the moment, been observed only in a few cases[58], it is acknowledged in the EU Chemicals Fitness Check[37] as a gap and area in which there is the need for dedicated studies. In 2019, EFSA published guidance for the assessment of this phenomenon (EFSA 2019)[59]. This will help in contributing to the risk assessment of the combination effects of migrants released by FCMs.

Substances for which a derogation applies and that are not subject to authorisation

The effectiveness of the legislation on plastic FCMs is also weakened by several derogations that exist for the assessment and authorisation of substances at EU level. Historically, information has been readily available on monomers and additives that are used in higher concentrations. The process has excluded substances such as polymer production aids, colorants, solvents and aids to polymerisation, which are either used in smaller quantities or not intended to remain in the material. Often, the substances are subject to national legislation and self-assessment, which has led to differences in actions taken across Member States and industry.

This is exemplified in the limits and testing methods for colorants set by Member States despite the existence of the CoE Resolution AP 89(1)[60]. The Dutch Warenwet[61] and German BfR Recommendations[62] II and VII require a positive listing for aids to polymerisation, but according to industry, when production is sourced outside these countries, it is difficult to receive information on the status of these substances. In the public consultation[40], public authorities and businesses expressed the opinion that to provide more effective protection of public health, the Union list for plastics should also include these substances currently covered by derogations.

The plastics Regulation focuses on substances used to produce plastics under the assumption that the reacted polymer is substantially less toxic than its starting substances. To manage other substances available in the final product in addition to the overall migration limit, all substances in plastic FCMs including NIAS that do not require an authorisation should be assessed using "*internationally recognised scientific principles on risk assessment*". Assessment of NIAS has therefore been the responsibility of industry, which has published

[57] https://chemtrust.org/wp-content/uploads/ct-additionalevidence-ecorys-sep19.pdf
[58] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6135635/
[59] https://doi.org/10.2903/j.efsa.2019.5634
[60] https://rm.coe.int/16804f8648
[61] Dutch Consumer act Warenwet, 2017, English version: http://www.adfopack.nl/assets/dutch-packagings-and-consumer-articles-regulation-from-january-2017-(20122016).pdf
[62] https://www.bfr.bund.de/en/bfr_recommendations_on_food_contact_materials-1711.html

recommendations and guidance documents addressing the evaluation of NIAS (ILSI 2016[63], CEPE 2018[64], EuPIA 2019[65]).

In more recent times, EFSA has started to assess NIAS as far as possible, recognising that they too may present a risk that needs to be assessed. EFSA has provided some partial recommendations on possible ways to assess them[38], but a lack of clear and comprehensive EU rules appears to hinder the adoption of a single harmonised approach by all stakeholders. The discovery of cyclo-di-badge[66] as a NIAS in coatings has recently led to challenges because of differences in interpretation between industry and Member States.

Despite scientific improvements[67,68], identification and assessment of all possible NIAS are still very challenging, if not impossible in practice. Whilst EU rules require NIAS to be considered, many participants in the consultation work consider that there is insufficient information or guidance agreed upon at EU level. Furthermore, almost 90% of the companies asked[40] reported that they do not receive adequate information on NIAS from suppliers and therefore information flow on NIAS is lacking. Case example 4 in annex 6 provides an illustration of the NIAS issue. In conclusion, clearer EU rules and delegation of responsibilities in the supply chain on substances that are subject to derogations are needed to improve effectiveness and to better ensure the safety of final FCMs.

Rules for verification of compliance

The plastics Regulation is supplemented by guidance documentation, including the EU Guidance on the application of the plastics Regulation[69] with further supplementary guidance on information exchange in the supply chain[70] and testing guidelines developed by the EURL-FCM[71]. According to stakeholders, this guidance is essential to being able to fulfil their compliance work, which in turn ensures safety. Given the constraints of the legal text, these guidance documents have proved popular with industry stakeholders and in particular Member States' authorities[40,72] who consider them helpful in understanding the Regulation, which is technically complex and demanding to understand and ensuring compliance. Further work on migration testing guidelines by the EURL-FCM is ongoing and eagerly awaited by stakeholders. Specific EU guidance therefore complements the legal requirements enhancing effectiveness in achieving the objectives.

A survey on DoC and SD undertaken by DG SANTE[73] in 2017 in which 227 businesses, 59 trade and business associations and 230 public authorities participated, showed that the documentary system based on DoCs and SD has become common practice within the FCM sectors, with the use of DoCs even for FCMs for which there are no EU-specific measures.

[63] https://ilsi.eu/wp-content/uploads/sites/3/2016/04/2015-NIAS_version-January-2016.pdf
[64],https://www.cepe.org/wp-content/uploads/2018/05/TSC33-NIAS-GUIDELINES-May-2018-v1.7.4.pdf
[65] https://www.eupia.org/fileadmin/Documents/Risk_Assessment/2019-02-21_EuPIA_NIAS_Guidance.pdf
[66] Cyclo-di-badge is a reaction product formed from BPA and BADGE during epoxy resin production
[67] https://fcm.wiv-isp.be
[68] https://doi.org/10.1080/19440049.2019.1664772
[69] https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf
[70] https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_reg_en.pdf
[71] https://ec.europa.eu/jrc/en/eurl/food-contact-materials/technical-guidelines
[72] Ecorys report, annex 2: Case study 3 "Compliance along the supply chain"
[73] https://ec.europa.eu/food/system/files/2022-04/cs_fcm_eval_btsf_20220419_controls-sum.pdf

Businesses report that they usually receive DoCs from their suppliers but that obtaining adequate supporting information through the whole of the supply chain is more difficult, citing confidentiality issues and a lack of knowledge, particularly among SMEs. Checks are mainly limited to visual identity checks with only 11% of business operators analytically checking SMLs/OMLs and the authorisation status of substances.

The analysis of DoCs provided shows that most contain basic information and mention compliance with the FCM Regulation and the plastics Regulation. The main shortcomings were in referencing rules on GMP, clear identification of substances used, dual use additives, functional barriers and specifications on the adequate use. Few provided the identity of upstream suppliers. Overall, many DoCs were incorrectly filled-in and incomplete.

Trade business associations represent an important channel for information, providing industry guidelines, information and advice on compliance work and legislation to their members. Most mentioned issues in the functioning of information in the supply chain, frequently mentioning the lack of a common structure for DoCs, lack of capacity of SMEs, lack of clarity of responsibilities and varying degrees of knowledge on FCMs along the supply chain. An overview of the main difficulties mentioned in the public consultation has also been summarised[40]. A study by enforcement authorities[74] has also underlined that following a request by Member States, the chemical industry could not provide adequate supporting documentation showing that they comply with the FCM Regulation.

Although it is accepted that downstream users are better placed to estimate likely consumer exposure, they do not currently have access to necessary information that is contained in confidential documentation supporting DoCs of the chemical industry. A mechanism that would relax the confidentiality of this supporting documentation could "*contribute to improved assessment of the compliance of the FCM put on the market by downstream FCM users*" (Grob 2019). Case example 5 in annex 6 describes a situation concerning a lack of transfer of information in the supply chain.

Overall, it can be concluded that some gaps exist in the flow of information along the supply chain and in enforcement by control authorities that undermine the effectiveness ensuring compliance and safety of FCMs.

5.1.5. FCMs not subject to EU-specific rules and/or subject to national rules as provided for by Article 6 of the FCM Regulation and mutual recognition

According to the JRC 'baseline' study[7], some materials are regulated by many different Member States, such as metals or paper and board. However, legislation differs somewhat across the EU. Although there is extensive use of lists of substances, which are either authorised for use or considered safe, which cover close to 8000 substances, less than 20% of substances are in common in three or more Member States (table 4, annex 5).

Differences between Council of Europe and Member States' lists of substances suggest a limited transposition of Council of Europe Resolutions. Where the same substance is regulated in different Member States, the type of restriction (migration, compositional limits,

[74] McCombie G, Hötzer K, Daniel J, Biedermann M, Eicher A, Grob K. 2016. Compliance work for polyolefins in food contact: results of an official control campaign. Food Control. 59:793–800.

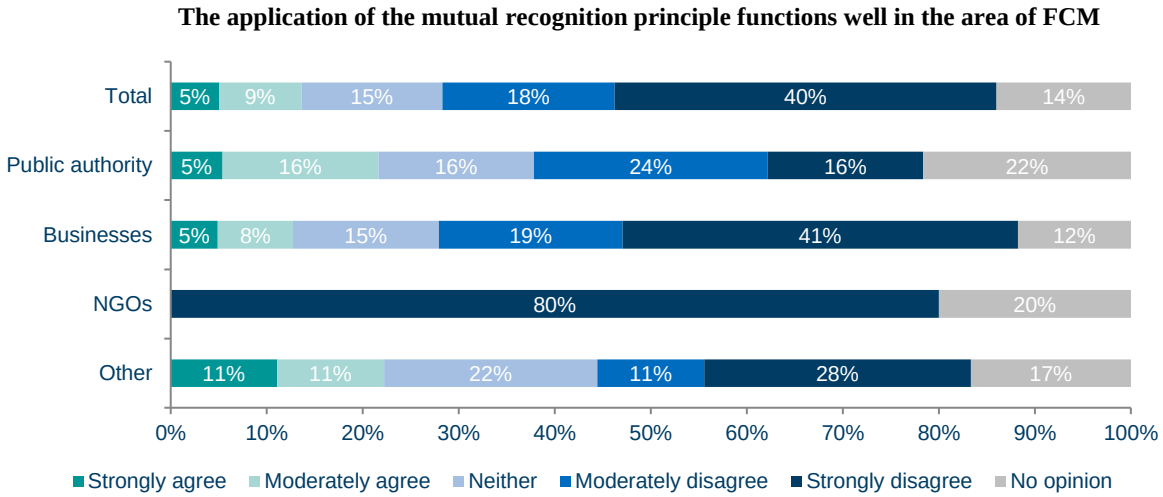
quantity in materials) also varies. For example, 11 Member States have legal provisions for varnishes and coatings, but these have common requirements for only 88 out of 1720 substances, and may differ in terms of the definition of use and their categorisation.

Less than half of substances regulated nationally are in lists that EFSA has previously found to be adequately risk assessed[75]. National risk assessment schemes and requirements for the authorisation of substances are not the same in all Member States and often differ from that of EFSA. Their access is limited and often it is not possible to determine in detail how conclusions have been reached, in contrast to the transparency of EFSA' work.

These aspects, together with difficulties reported by businesses to access information and their availability only in national languages, are considered a large burden for industry and barriers to trade. It leads industries to seek external legal advice, which results in lengthier authorisation processes and delayed market access. It also results in greater focus on certification and accreditation systems at industrial level. According to various sectors, they have increasingly tended to seek global food contact compliance in non-EU legislation to overcome the lack of coherent rules at EU level. The results are substantiated by the findings of the supporting study including the public consultation[40] and specific difficulties for the rubber sector are set out in one case study[76].

Where no specific EU rules exist, the mutual recognition principle[77] should apply to ensure market access for products that are not subject to EU harmonisation. However, there is a widely shared view among FCM industry representatives that the mutual recognition system is not working properly in the sector (see figure 3 below), which constitutes a barrier to the functioning of the internal market. In many cases, rules in one Member State may differ from those in another since according to EU law, justification can be given based on overriding reasons of public interest and which are proportionate to the aim pursued.

Figure 3: Opinion on the application of the mutual recognition principle[40]



[75] https://doi.org/10.2903/sp.efsa.2011.EN-139
[76] Ecorys report, annex 2: Case study 2 "Effect of lack of EU specific rules and application of national specific rules"
[77] http://data.europa.eu/eli/reg/2008/764/oj

The application of the mutual recognition principle has always been challenging and typical barriers to effective mutual recognition stem from Member States' application and knowledge of the principle, and from companies' lack of awareness of the principle[78]. The staff working document (SWD) on the evaluation of mutual recognition[79] also highlights the need for more reliable monitoring tools and better data on the functioning of the mutual recognition system. Both the evaluation and impact assessment for a new regulation[80] concluded that the interrelationship between the FCM Regulation and the mutual recognition Regulation (EC) No 764/2008[81] was not clear to economic operators, in particular in terms of the principles and scope of application of the latter and its ability to facilitate compliance with specific national rules. Case example 6 in annex 6 gives an overview of some practical examples where additional costs and burdens to industry have been experienced.

Since the evaluation of the mutual recognition principle, a new Regulation 2019/515[82] has been adopted and has applied since 19 April 2020. It has sought to address the problems established by the evaluation, including the assessment procedure to be followed by competent authorities when assessing goods as well as a business-friendly problem solving procedure, based on SOLVIT[83], that includes the possibility of an assessment from the Commission on the compatibility of a decision restricting or denying market access with EU law. This should help FCM businesses, but the impact of these changes will need to be assessed in time.

Overall, the situation created by a lack of EU-specific measures beyond plastic FCMs, and a multitude of national measures has created legal uncertainty, barriers to businesses and may create confusion over required or acceptable levels of safety.

5.1.6. Good Manufacturing Practice (GMP)

Many stakeholders consider that the current EU rules on GMP are not sufficiently detailed in the legislation to enable FCMs to be manufactured to a high standard, particularly Member States' authorities and most NGOs[40]. However, the introduction of basic rules has prompted industry to address GMP in different sectors, and only in very specific cases has EU intervention been necessary, in particular in the case of preventing migration of printing ink[23]. Since 2006, sectorial GMP guidelines have been introduced by industry, that are better adapted to the specific supply chain situation and needs and with specific expert knowledge.

Examples of such sectorial GMP guidelines include those issued by the ink[84] and paper and board[45] industries. Indeed, the most comprehensive GMP guidance documents appear to be those for paper and board, which also include guidance from Nordic countries[85] and which are considered useful in helping to ensure GMP for this sector. The Swiss Packaging Institute

[78] http://ec.europa.eu/DocsRoom/documents/13381/attachments/1/translations/en/renditions/native [27.10.2019]
[79] https://ec.europa.eu/info/publications/evaluation-mutual-recognition_en
[80] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2017:0471:FIN [27.10.2019]
[81] http://data.europa.eu/eli/reg/2008/764/oj
[82] http://data.europa.eu/eli/reg/2019/515/oj
[83] https://ec.europa.eu/solvit/index_en.htm
[84] https://www.eupia.org/key-topics/food-contact-materials/good-manufacturing-practice-gmp
[85] Norden guidelines on paper and board "Paper and Board Food Contact Materials", (TemaNord 2008:515)

(SVI) has developed and revised a checklist for industry to assess DoC[86], which is used by inspectors for controls.

However, it is not always clear whether these guidelines are used in practice by the members at national and local level, especially among SMEs. There are references to GMP in a number of Member States and a full guidance has recently been developed by Italy[87], although it has not been possible to evaluate the extent to which this is effective.

Sector specific guidelines are also provided by some Member States, although these are often conceptual and require further elaboration by industry. Stakeholders including NGOs and some interviewed business associations have expressed a preference for integrating GMP requirements into specific measures rather than having a separate GMP Regulation, i.e. that GMP is not sector specific enough at present to be sufficiently effective[88].

Moreover, stakeholders (from all categories) mention difficulties in ensuring that, in the case of products imported from third countries, the manufacturing process is in line with GMP requirements. Results from the public consultation, across all categories, show that most respondents are concerned about the application of GMP in third countries[40]. In conclusion, the basic requirements on GMP have stimulated industry to implement self-guidance on GMP with more sector specific rules. However, there is some uncertainty on the extent to which GMP guidelines are taken up and used in practice.

5.1.7. Inspection and official controls by Member States' competent authorities

The Regulation (EU) 2017/625 on official controls explicitly captures the manufacture and use of FCMs: FCM operators are explicitly included. Controls should be undertaken on products, substances and materials that may influence food safety, including food processing equipment and packaging. Official controls should include an examination of compliance already established by the business operators and procedures on GMP. Member States' competent authorities must take account of previous records on compliance as well as the reliability and results of businesses' own controls that have been performed by themselves, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance. Member States' competent authorities must draw up and keep up-to-date a list of FCM business operators. Non-compliances are typically reported via the Rapid Alert System for Food and Feed (RASFF) or the Administrative Assistance and Cooperation (AAC) system.

Typically, RASFF notifications on FCMs make up a small proportion of all RASFF reports[89]. To some extent, this may reflect priorities set by Member States on controls. However, the findings are also generally limited by a significant lack of accredited methods for authorised substances in plastic FCMs because of the large number of substances and combination of those substances with plastic matrices, conditions of use, etc. This is also discussed later in

[86] CH- SVI - Bewertung von Konformitätserklärungen.
[87] IT- Guidelines for the application of the Regulation 2023/2006. Rapporti Istisan 11/37- CAST project: ISSN 1123-3117.
[88] https://chemtrust.org/wp-content/uploads/chemtrust-fcm-position-paper-may19.pdf
[89] https://webgate.ec.europa.eu/rasff-window/portal/?event=searchForm&cleanSearch=1 Over the period 2010-2018, FCM-related RASFF notifications (n=1,764) accounted for 6% of the total number of food alert notifications in the RASFF database (n=25,704), compared with 7% for feed and 87% for food)

section 5.3 on relevance. Member States' competent authorities are therefore in reality enforcing only a very small number of the SMLs set for different substances (<5%) that have high visibility and/or for which dedicated measures exist or are easy to test for. Member States are therefore able to carry out inspections and controls in a very limited capacity.

Performance of Member States

Commission visits and audits of 22 national control systems[90] between 2007 and 2011 found that many (mainly new) Member States had only just started implementing controls and further efforts were needed to develop the control systems, like an elaboration of specific guidelines, upgrading of laboratories and specific training. Moreover, competences were not sufficiently clear, resulting in either a lack – or an overlap – of official controls. Risk-based official controls at FCM manufacturing level were not well established and staff was lacking sufficient training on FCM related issues, such as assessments of documentation, traceability systems and GMP principles.

Follow-up audits in 2017 and 2018[91] together with two workshops confirmed that deficiencies remained, with the following conclusions:

- Official controls on FCMs in Member States are in general weak, not sufficiently effective and considered a low priority.
- Controls are often limited to the verification of the presence of the DoC, with inspectors rarely having the expertise to verify its content.
- Businesses involved in the FCM chain can only be identified to a limited extent.
- Underlying problems identified include:
  - Lack of regular dedicated inspections;
  - Lack of expertise and experience at the front-line control level;
  - Inability to identify all relevant businesses;
  - Lack of comprehensive checklists;
  - Lack of guidance documentation, including on the evaluation of DoCs;
  - Lack of effective training for inspectors;
  - Laboratories have neither the resources nor the ability to perform analytical checks on samples not foreseen by established control plans;
  - Enforcement measures and/or sanctions are not systematically imposed;
  - Poor documentation of controls and few records of cases of non-compliance hampers future risk-based planning;
  - Industrial equipment is often overlooked during official controls.

Overall, the current systems of official controls cannot adequately or fully enforce the requirements of the legislation, although this does not imply that FCMs are unsafe.

One key problem, the lack of a systematic registration system for businesses, currently only in place in eight Member States, is expected to be helped through Article 10(2) of Regulation 2017/625 on official controls (which entered into force on the 14th December 2019)

[90] https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm
[91] https://ec.europa.eu/food/audits-analysis/overview_reports/act_getPDF.cfm?PDF_ID=1732

introducing a more systematic registration of businesses, which should allow competent authorities to better plan inspections and controls for all relevant companies.

5.2. Efficiency

Q3. What are the *quantifiable benefits*, taking into account resources (cost, time, etc.) to stakeholders, including:

- **Consumers (e.g. health benefits);**
- **Businesses, including specifically for SMEs and microbusinesses (e.g. in demonstrating compliance, market access);**
- **Member States' competent authorities (e.g. in ensuring safety and control of FCMs)?**

5.2.1. Human health benefits

There is some available literature supporting adverse health effects from exposure to a limited number of hazardous substances that have been found to migrate from FCMs, for which rules have been introduced, such as phthalates. However, these adverse health effects occur from long-term exposure, where exposure also occurs from other sources such as environmental or other consumer products and where other interventions may have occurred. This makes it impossible to directly link possible health benefits of specifically regulating FCMs and to quantify the overall health benefits of the FCM Regulation.

However, an attempt has been made to estimate the magnitude of some plausible health benefits from a limited number of substances regulated under FCM legislation for which information is available. FCMs are known to be a contributing source and even where the contribution from FCMs to overall exposure is assumed to be very small (~1%), the magnitude of health cost benefits for these substances is likely to run into hundreds of millions of euros. Based on reasonable assumptions, the same estimations may be applied for a number of other substances that migrate from FCMs, although the extent of the health benefits will vary, and many will have less hazardous properties or migrate in smaller amounts resulting in lower exposure.

Lead has long been used in ceramic ware, both in glazes and in decorations. However, it is a toxic substance that can cause a wide range of diseases, affects reproduction and the nervous system, as well as the (cognitive) development of children.[92] A study from 2013 estimates that the health costs caused by exposure to lead amount to some USD 970 billion (EUR 820 billion) annually in low and middle-income countries (LMIC), compared to USD 55 billion (EUR 45 billion) in Europe[93]. This translates to approx. USD 170 (EUR 144) per capita in LMIC, compared to less than USD 110 (EUR 93) in Europe. The differences between the costs attributed to stricter legislation in the EU, extrapolating the per capita difference to the EU population, overall implies health benefits stemming from EU legislation of approx. USD 31 billion (EUR 26 billion) per year.

[92] https://wedocs.unep.org/bitstream/handle/20.500.11822/27635/LeadRev.pdf
[93] Attina/Trasande (2013), Economic Costs of Childhood Lead Exposure in Low- and Middle-Income Countries, Environmental Health Perspectives 121(9).

Human exposure occurs mainly via food and water, with minor amounts via air, dust and soil[94]. Although a significant proportion of exposure via food is likely to occur due to environmental contamination, it is known that lead can migrate in high amounts from ceramic ware and EU legislation exists setting limits on the amount of lead that may migrate from ceramic FCMs. An estimate of the exposure to lead from FCMs accounting for around 1% of total exposure was considered reasonable, which in turn would equate to approximately USD 310 million, or EUR 285 million per year in cost savings from the legislation. This indicates that the health benefits from restricting lead in FCMs could range in the hundreds of millions of euros, particularly over the period since the rules were introduced.

Phthalates have long been used as softeners or plasticisers in plastic. The study on the cumulative health and environmental benefits of chemical legislation estimates that restrictions on phthalates resulted in benefits for reproductive health of approx. EUR 130 billion between 1996 and 2008 cumulatively, or about EUR 11 billion annually[95]. These values are based on the lower bound reported by the study. While the study was not able to establish a causal relationship, the authors note that the reduction in health costs from diseases possibly caused by exposure to phthalates occurred at the same time as increased regulatory activity. Given that FCMs are one significant source of exposure of consumers to phthalates, it is likely that a significant share of the benefits reported above can be traced back to restrictions on the use of the substances in FCMs. For example, even if legislation on FCMs contributed only 1% to the estimated health benefits, this would imply health benefits of about EUR 110 million annually for this group of substances.

A report published recently by ECHA on the costs and benefits of REACH restrictions proposed between 2016 and 2020[96] also gives clues as to the possible impact of restrictions for the same substances restricted in FCMs, even if the restrictions are not comparable. Three of the four phthalates restricted under REACH are also restricted, albeit to a lesser extent, by the FCM plastics Regulation. According to the ECHA report, monetised benefits of restricting bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) (the four phthalates) are estimated to outweigh the costs by more than 10 times. The benefits are estimated at EUR 235 million while the costs are about EUR 17.6 million per year in the worst-case scenario.

Vinyl chloride monomer (VCM) is produced industrially, primarily to make polyvinyl chloride (PVC); PVC is used to make a variety of plastic products, including pipes, wire and cable coatings, and packaging materials. Exposure to VCM is associated with an increased risk of a rare form of liver cancer (hepatic angiosarcoma), as well as brain and lung cancers, lymphoma, and leukaemia. In the mid-1970s, VCM was also identified as a contaminant of foods packaged in PVC material[97]. In 1978, the EU introduced a restriction on the presence of vinyl chloride monomer in, and possible migration from, FCMs prepared with vinyl chloride polymers or copolymers. In turn, more stringent manufacturing specifications for PVC were

[94] https://doi.org/10.2903/j.efsa.2010.1570
[95] Commission (2017), Study on the cumulative health and environmental benefits of chemical legislation, p.114ff.
[96] https://echa.europa.eu/documents/10162/13630/costs_benefits_reach_restrictions_2020_en.pdf
[97] Rösli, M. et al. Rückstände von Vinylchlorid-Monomer in Speiseölen [Residues of vinyl chloride in edible oils]. Mitteilungen aus der Gebiete der Lebensmitteluntersuchung und Hygiene, 66: 507-511 (1975).

implemented and such contamination decreased substantially; as a result, VCM has not been identified in food, pharmaceuticals or cosmetic products in recent years[98].

Whilst it is not possible to quantify the health savings from the EU intervention, a report prepared for the Commission in 2011 on possible impacts of amending EU legislation on VCM for workers, indicates that health savings run into hundreds of millions of euros. Whilst the risks to workers are greater than they are to the average consumers, workers represent a sub-section of the population, whereas all EU citizens are consumers who may otherwise have been exposed to VCM from food packaging over the years subsequent to when the EU intervention was introduced. Therefore, a reasonable assumption is that restrictions on VCM may also have resulted in health savings of hundreds of millions of euros in the last 40 years.

Prevention, control and reaction in Member States

To estimate the health benefits in a semi-quantitative way, a composite index was developed[99]. This index is based on three factors, which are considered to contribute to the protection of consumer health in Member States: prevention, controls, and reaction. Further, table 5 in annex 5 reports on the results of the analysis.

The score for prevention is based on the share of FCMs covered by national legislation (excluding harmonised materials). The results indicate that 14 out of 25 countries have a good overall score, meaning that they got at least 70% of the potential weighted score, while 12 countries received an overall weighted score of below 70%. However, for some of them the information available is very limited. Data availability was too limited for three countries to yield meaningful results. The analysis found a good weighted score for five countries only, reflecting those with measures in place covering many material types. These scores are likely to be conservative, as they do not account for the potential contribution of one Member States rules to another.

The control score captures whether Member States have the resources, expertise, analytical equipment and procedures in place to perform sufficient controls. Scores are mixed, with good scores in just above half of Member States, suggesting that the benefits yielded from controls remain limited, at least in some countries. A common obstacle pointed out across audit reports is the limited number of controls performed each year. In addition, inspectors often lack adequate training to perform controls.

The reaction scores indicate that there are good structures in place in all Member States except one, which enables them to react swiftly to RASFF notifications, all notifications are answered, and sanctions are applied that should motivate compliance with the legislation. These aspects provide benefits for consumers by ensuring the protection of human health, and non-compliant FCMs will be quickly removed from the market.

Overall, the exercise indicates that health benefits stemming from the EU Regulation on FCMs are not maximised.

[98] WHO (1999) *Vinyl Chloride* (Environmental Health Criteria 215), Geneva, World Health Organization
[99] Ecorys report, Annex 4 Methodological Annexes - Composite Index

5.2.2. Economic benefits for consumers

The harmonisation of rules under the FCM Regulation and subsequent material-specific legislation likely yields economic benefits for consumers too. Harmonisation should reduce barriers to trade within the EU and, consequently, lower production prices for packaging and other FCMs. This may translate into lower prices for consumers. While the cost and price reduction are likely to be very small for an individual product, they may account for a sizeable sum when aggregated at EU level. An attempt was made by the contractor to collect evidence to indicate a positive (or negative) effect of the FCM legislation on consumer prices, but none could be found.

5.2.3. Benefits for businesses

The public consultation[40] results showed that difficulties in placing FCMs on the EU market appear far less frequent for FCMs subject to specific EU measures (plastic FCMs) than for FCMs that are not, indicating that further harmonisation of FCM legislation has a positive effect on intra-EU trade. Similarly, about two-thirds of respondents to the SME survey[100] indicate that further harmonisation would enhance the functioning of the internal market. Furthermore, trade data was examined and showed a correlation between the introduction of EU rules on plastic FCMs and an increase in intra-EU trade[101], although no firm conclusions can be drawn since factors other than the legislation might also affect trade at the same time as the legislation was introduced, such as demand and economic viability of manufacturing plastic.

Harmonised risk assessment work at EU level has also saved industry costs, which have been estimated by the number of times the application would need to have been filed with Member States. Based on the JRC 'baseline' study[7], an average of 3.7 Member States perform risk assessments per material group[102]. The *administrative* costs to prepare a dossier are estimated to be approximately EUR 60 000 per dossier on average[103], taking into account its preparation, translation, etc. These are taken as the basis to estimate cost savings.

Table 6 in annex 5 illustrates total costs savings for the 95 dossiers assessed at EU level by EFSA between 2014 and 2018. This shows that total cost savings could be anywhere up to EUR 15.4 million or EUR 162 000 per dossier. This does not take into account the costs for scientific work required for the assessment, which are several folds higher. It is assumed that applicants would be able to re-use the toxicity studies and analytical testing, although in some cases additional tests or criteria may need to be fulfilled. Member States have in some cases diverging requirements, which also results in re-doing studies or generating new ones. The true savings for a harmonised EU system may therefore be much greater.

Further cost savings have been identified insofar as the Union list of authorised substances is not applicant specific and reduces the costs for businesses as they can use substances without generating risk assessment data and submitting applications of their own. As discussed in one

[100] Ecorys report, SME panel consultation: 25 February 2019 – 20 April 2019. Factual summary report of the SME Panel questionnaire: https://ec.europa.eu/food/system/files/2019-07/cs_fcm_20190616_summary-report-sme-panel.pdf
[101] Source: Ecorys based on Eurostat data
[102] Ecorys calculations based on JRC 'baseline' study.
[103] Source: Ecorys based on assessment of costs provided for EQ4

of the focus groups of the evaluation, this is particularly important for SMEs as they otherwise lack resources to determine compliance without such legal certainty, compared with larger industry players.

Evidence also remains inconclusive when the analysis is undertaken at the country-level. In September 2017, the German BfR published new recommendations on paper based FCMs[104]. This "intervention" was used to explore imports of paper based FCMs into Germany from other EU countries in the months before and after the publication of these recommendations. However, it was not possible to identify a clear effect on the trade of these products.

Overall, cost savings from the EU legislation are limited and relate to the existence of specific measures, in particular for plastic FCMs.

5.2.4. Benefits for Member States' competent authorities

According to EFSA, it spends an average of around EUR 430 000 to EUR 450 000 per year on risk assessments[105]. This covers the three categories of FCMs for which risk assessments are currently actively performed at EU level (and for which authorisation is required or foreseen – plastic, recycled plastic and AIM). Three scenarios and estimates are provided in table 7 in annex 5 and from this, estimates suggest that cost savings from harmonised risk assessments range between EUR 450 000 and EUR 1.2 million per year for Member States who otherwise undertake their own risk assessment work.

The harmonisation of provisions on FCMs at EU level requires cooperation and exchange of information among competent authorities in the Member States. For example, authorities meet regularly in the scope of PAFF meetings to exchange views and direct risk management actions. The EURL-FCM contributes to the improvement and harmonisation of methods of analysis through its network with national reference laboratories. However, it is not possible to quantify or even monetise the benefits of this enhanced cooperation and knowledge sharing. Among others, the following organisations facilitate exchange and cooperation:

- **ESCO**: The EFSA Scientific Cooperation working group is composed of experts from a selected number of Member States. The EFSA Scientific Cooperation working group supports the collection of information on non-harmonised FCMs across the EU;
- **FCM network**: The Scientific Network on Food Contact Materials is a permanent group of representatives of Member States. EFSA oversees the organisation of the group. It comprises all Member States, as well as the Commission including the JRC (EURL-FCM), Council of Europe, with EEA countries as observers.

Overall, cost savings for Member States from harmonised risk assessment currently appear limited.

Q4. What are the *quantifiable burdens*, taking into account resources (cost, time, etc.) to stakeholders and are there aspects that could be simplified to improve efficiency?

[104] https://bfr.ble.de/kse/faces/resources/pdf/360.pdf.
[105] Ecorys report, interviews with stakeholders

5.2.5. Burdens for stakeholders

The estimate from this evaluation suggests annual costs to industry linked with the FCM legislation in the region of EUR 3.1 billion per year (or around 3% of turnover)[106]. This is detailed further in table 8 in annex 5. The dimension of costs varies greatly depending on the position of businesses in the value chain and the type of the material. Based on the input received from stakeholders[40,104] and previous research, the cost items were grouped and categorised in line with the framework developed in the Commission's better regulation toolbox[107]. Two types of costs are considered in the analysis: (1) compliance costs, including dossier preparation, GMP, and analytical testing, which are borne principally by manufacturers and convertors and (2) administrative costs.

It should be noted that compliance and administrative costs here are assumed to be linked with the FCM legislation. However, the business-as-usual (BAU) factor, which describes the share of activities that companies would have performed (and thus costs they would incur) even if the EU legislation on FCMs had not been introduced, is likely to account for some of this. Certain activities and production standards are desirable for companies anyway, due to self-regulation in the sector and because business partners along the value chain ask for certain information. For example, even though DoCs are not mandatory for FCMs without specific EU measures, several industry associations developed similar documents for their sectors to ensure transparency and the information flow along the value chain.

Plastics FCM industry

Overall, estimates developed during the evaluation suggest that the total costs of the FCM legislation for the plastics sector amount to 0.2% to 2.9% of the sector's turnover[106]. An interview with representatives of the sector supports the upper bound, reporting costs amounting to 3% to 4% of turnover, or in the region of EUR 1 billion. Table 9 in annex 5 illustrates the overall estimated costs for the plastics sector. Specifically for compliance costs, the upper bound estimate is in the region of EUR 650 million annually, which represents around 2% of the turnover. An interview with industry representatives to discuss the estimates suggests that the actual value is indeed likely to be closer to the upper bound.

Table 10 in annex 5 reports specifically on the cost estimates for dossier preparation, which were collected from different sources for triangulation. PlasticsEurope provided cost estimates ranging between EUR 200 000 and almost EUR 2.2 million for a dossier, including the administrative costs to prepare a dossier. This correlates with the findings of the REFIT Evaluation of the General Food Law[35]. The association also provided a breakdown of costs among the key cost items of dossiers – toxicity testing, analytical testing, and additional resources. This breakdown suggests that toxicological tests are the key cost driver but vary significantly depending on the degree of testing required, with requirements and thus costs increasing the more a substance is likely to migrate. The costs reported by industry are generally supported by other estimation techniques, except for case study 1 (see annex 2), which used older cost estimates.

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[106] Ecorys report, Annex 3 Methodological Annex and Quantification of costs

[107] https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox/better-regulation-toolbox-0_en

From when the plastics Regulation entered into force until 2019, 97 applications for the authorisation of substances have been received for substances specifically to be used in plastic[108]. This equates to approximately 12 dossiers per year and therefore between EUR 2.4 million and EUR 26.4 million per year on dossiers. On average, this equates to EUR 14.4 million per year.

According to the SME Panel questionnaire[100], the majority of SMEs do not have sufficient resources to apply for authorisation of a new substance in plastic FCMs. Not surprisingly, the SME panel questionnaire results show that the smaller the size of the enterprise, the lower the resources to prepare applications. A review of the EFSA register of questions shows that in the plastics sector, only a small fraction of all applications is submitted by SMEs - out of approximately 100 applications since 2011, only two (in 2018) have been identified to be submitted by SMEs.

Establishing GMP and analytical testing account for the largest share of compliance costs for producers of plastic FCMs. The evaluation has estimated that these two cost elements account for 69% to 72% of overall costs. Within the scope of case study 3 (see annex 2), 16 companies provided detailed information on the costs linked to the FCM legislation and cost estimates for industry were based on these. Table 11 in annex 5 presents the costs per company and its size, differentiating between a minimum, average, and maximum amount. In total, estimates suggest annual costs of EUR 54 million to more than EUR 280 million for establishing GMP, and some EUR 93 million to almost EUR 350 million for analytical testing. As mentioned before, interviews with the industry suggest that the actual annual costs are likely to be close to the maximum estimated above, suggesting total costs close to EUR 630 million for industry per year.

In the case of the FCM legislation, key administrative cost items are the cost for producing a DoC and SD. Companies employ between 0.1 and 6 full-time equivalents (FTEs)[106] on administrative tasks linked to reporting requirements. The number depends on the size of the company. Table 12 in annex 5 reports on the minimum and maximum number of FTEs employed per company, broken down by company size. As for the compliance costs, numbers for small businesses had to be extrapolated based on information available for medium and large companies. Using a weighted average[109], these estimates can be translated into costs for companies. This suggests that administrative costs range between a minimum of EUR 3600 per year for a small company and a maximum of almost EUR 215 000 per year for a large company. This translates into total annual costs ranging between EUR 59 million and close to EUR 230 million. In relative terms, administrative costs stemming from FCM legislation account for less than 1% of turnover. They account for about a quarter of the overall costs of the FCM legislation for the plastics sector.

According to the plastics industry (direct correspondence with the Commission), the duration of the process of risk assessment and moreover, risk management in the authorisation of substances leads to lost market time. This is significant given the investment it puts into dossiers. It points to long periods of time in particular in the inclusion of new monomers and

[108] Between 2011 and 2018, based on EFSA Register of Questions, retrieved on 21/05/2019.
[109] Average labour costs in industry, weighted by the distribution of plastic packaging producers in the EU-28.

additives in the Union list, which is often in contrast with the time taken to market substances on the US market.

Non-plastic FCM industry

The evaluation examined burdens to industry sectors not subject to specific harmonised EU measures to compare with the impact of EU-specific rules. Table 8 in annex 5 gives an overview of these costs compared with the plastics industry. Information was mostly available on compliance costs, which, like the plastics sector, appear to account for up to 2% of turnover for many sectors. However, depending on the sector concerned, there appears to be some variation, which is likely to reflect presence or absence of national requirements.

For certain sectors, companies do not have to produce a DoC for their products or are not subject to specific testing requirements, which may reduce costs. On the other hand, resources spent on compliance costs for certain sectors including metals and alloys (5% of turnover), paper and board (4%) and printing inks (10%) are considerably higher. It was not possible to gather data to elaborate in detail on why these sectors' costs are so high but are likely in part to relate to multiple national requirements, and three examples are given below. Additionally, industry confirmed that while certain costs are easily quantifiable (such as testing and dedicated human resources), other costs are unpredictable, making their assessment complicated. Such costs mainly relate to market and development opportunities that are missed in EU Member States' markets with different national legislation, or when entering competition with harmonised materials (especially plastics).

Rubber FCM industry

According to national legislation, approximately the same number of substances are registered and used as for plastic (~900), which makes for a useful comparison. According to industry, diverging individual national approval schemes, containing a list of safety requirements and related tests to be applied to the final FCM article, increase costs[110]. It argues that the lack of a homogeneous approval scheme and positive lists, in combination with the absence of mutual recognition across Member States, is also creating an unjustified burden for companies, most of which are SMEs. Costs for certifying product conformity or authorising the use of new substances are, according to them, multiplied for each country where products are commercialized. The cost for certifying a single product is at least EUR 5000. Whereas an inventory of existing "positive lists" of monomers and other compounding ingredients for rubber FCM from the Council of Europe Resolution on rubber products[111] exists, it has not been implemented by most EU Member States, perhaps providing a lost opportunity for reducing costs.

Using the example from table 13 in annex 5, zinc di(benzothiazol-2-yl) disulphide, the estimated costs from administrative preparation of the dossier for authorising the substance is EUR 60 000 in four Member States which equals EUR 240 000 compared with EUR 60 000 for one single dossier preparation at EU level. Therefore, the additional cost incurred is EUR 180 000. It is not known for any of these substances what additional costs may have incurred

[110] Resolution AP (2004) 4 on rubber products intended to come into contact with foodstuffs.

[111] https://www.edqm.eu/sites/default/files/policy_statement_concerning_rubber_product_products_intended_to_come_into_contact_with_foodstuffs_v1_june_2004.pdf

for different studies or data and testing requirements across the four Member States, and so the additional costs to the rubber industry may be significantly higher.

FCM printing inks

Germany has recently prepared legislation to introduce a positive list for inks[112]. In the accompanying impact assessment (page 90 onwards of the draft), it explores the effects and costs of the ordinance on authorities, as well as industry. It is estimated that the introduction of the ordinance would create costs of about EUR 18 million for the inks industry in Germany (EUR 900 000 per company) as one-off costs, with another EUR 2 million (EUR 100 000 per company) in ongoing or annual costs. Based on the input from the ink industry in Germany, authorisation processes can be expected to add another EUR 2 million per year. Costs for the whole value chain are estimated to be significantly higher, at about EUR 660 million one-off costs for the implementation of the ordinance. The impact assessment does not provide an estimate of the recurrent costs for the whole value chain nor the costs if printing inks would be regulated at EU level. Industry has argued that the legislation is disproportionate, increases barriers to the commercial success of innovation and drives up consumer prices, which is not supportive of on-going economic recovery[113].

Safeguard measures on BPA

The use of BPA in food and beverage cans is particularly significant, as the majority of cans (around 80%) utilise the BPA based epoxy-resin technology as a coating. Around 50 billion beverage cans and 20 billion food cans are produced in the EU each year; in the latter case, the estimated value of this market in 2010 was EUR 30 billion in the EU. Specific requirements laid down by the safeguard measures adopted by French legislation have had a knock-on impact throughout the EU and in wider Europe since production and distribution methods have been developed for the EU market as a whole. Costs derive not only from the research and development time of either replacement substances or alternative packaging materials, but also as a consequence of reformulation, testing, trial periods before marketing and questions over the effectiveness of replacements, leading to possible food waste and therefore additional costs. Overall costs to industry are high and in 2015, industry estimated such costs at up to EUR 1.5 billion[114].

Burdens on SMEs

Almost a third of SMEs report that costs linked to the FCM legislation are not proportionate to the size of companies, whereas a fifth of respondents to the SME survey[100] state the opposite. Companies did not provide a reasoning for this judgement. However, there are certainly costs that are independent of the size of the business. The tests and evidence companies must produce is independent of the size of the company. As a result, these requirements can be particularly burdensome for smaller businesses.

SMEs heavily rely on associations and service providers to get them the information they need as they do not have internal resources with knowledge of national systems across EU

[112] Einundzwanzigsten Verordnung zur Änderung der Bedarfsgegenständeverordnung vom 2. Dezember 2021 (BGBl. I S. 5068)
[113] Stakeholder correspondence to DG SANTE, 2018
[114] Stakeholder correspondence to DG SANTE, 2015

Member States. As discussed with industry representatives, the specific consequences for SMEs in monetary terms cannot be measured, but SMEs may not be able to understand or afford to meet the different requirements in national laws, which means they can be excluded from markets. The costs of additional testing are a burden, especially for small companies which cannot absorb such costs, or they simply have to decide where to sell in advance and test accordingly, which is restricting their access to the internal market. Case example 6 in annex 6 highlights some practical issues.

Overall, costs to industry are estimated to be around 3% of the total turnover, with the majority of those costs spent on compliance (~2%) and a smaller proportion (~1%) spent on administrative costs. For certain sectors where there are no EU-specific measures, costs may be even higher (up to 10%). Safeguard measures adopted by Member States pursuant to Article 18 of the FCM Regulation or other unilateral action can significantly increase costs. Costs for SMEs may be proportionality higher where the same requirements exist; national measures are even more burdensome.

Burdens on Member States

Overall, cost estimates for Member States are reported in table 14 in annex 5, although there were significant data gaps and large variations in the costs between Member States. On average, each Member State spends between EUR 500 000 and 800 000 per annum on FCMs. The majority of costs come from controls, including both costs for FTEs and budget allocated to control activities in Member States. Resources spent on controls generally increase with the size of a country's population, which would be expected, with the majority being costs for resources such as physical sampling and analysis, and costs for staff contributing around one-third.

Competent authorities incur costs of about EUR 2.4 million to EUR 3.2 million in implementing harmonised (EU) legislation each year, about half of which are estimated to be staff costs. These numbers are estimates, based on the information from interviews with Member States and the JRC 'baseline' study[7], which together covered about half of the Member States. Estimates suggest that in total about 36 to 39 FTEs work on the implementation of harmonised legislation in Member States (about 1.4 FTE per Member State). This varies depending on the Member State, which perhaps reflects their priority on FCMs. Costs for Member States for the implementation of the national legislation on FCMs are less than for the EU legislation. In some Member States, there is no national specific legislation and consequently, these Member States incur no such costs. Estimates suggest that there are about 20 to 24 FTEs working on the implementation of national legislation across the EU (just under 1 FTE per Member State).

Burdens on EU institutions and agencies

In total, EFSA spent about EUR 3.4 million between 2014 and 2019 on FCM related activities, around EUR 600 000 per year including both resources for risk assessment and costs for FTEs, which were on average just under 6 FTEs annually. This does not take into account experts and members of the Panel on Food Contact Materials, Enzymes and

Processing Aids (CEP), who contribute with their scientific expertise to the risk assessment work.

According to its register of questions, EFSA has received 569 applications related to FCMs since 2004[115]. This includes substances for plastic, AIM and recycling processes. At the time of the research, 430 applications have been completed with just over 100 either not accepted or withdrawn. On average, EFSA needs 392 days between acceptance of an application and the adoption of an opinion. However, EFSA reaches a conclusion in less than 300 days in more than half of all cases, and the median duration is 280 days, or about 9.5 months. However, this is longer than the six months foreseen in the legislation, which may indicate the complexities of the risk assessment work, need to establish further information or resources available to EFSA.

On average, the Commission spends around EUR 2.3 million per year on tasks related to FCMs. This is based on costs calculated to be almost EUR 10 million spent by DG SANTE since 2010. Of these costs, about EUR 5.7 million are attributable to FTEs who undertake risk management of the legislation and policy coordination, and the remaining EUR 4.3 million has been spent on other resources, including Better Training for Safer Food (BTSF) activities, external meetings, studies and audit work. An additional EUR 1.3 million per year is spent by the JRC on operational costs related to FCM technical work and support in the context of their work as the EURL-FCM, although this does not include the cost of new equipment.

Q5. Taking into account the answers to questions 3 and 4, how efficient is the FCM Regulation and its implementation tools in ensuring the safety of FCMs?

5.2.6. Overall efficiency of the FCM Regulation

Despite efforts to gather relevant information for this evaluation, it has not been possible to quantify health benefits stemming from the EU FCM legislation. Therefore, no comparison can be made with the estimated cost of the legislation to conclude on overall efficiency. The evaluation has looked at specific examples of substances, the restrictions of which may contribute to health benefits in the region of hundreds of millions of euros; whereas the overall cost of the legislation is estimated to be in the region of EUR 3 billion. This includes annual costs for competent authorities, EU institutions, and costs for industry.

Hypothetically, if the same potential health benefits of regulating the substances analysed in this evaluation are realised for all regulated substances, the monetary value of the health savings is likely to exceed the costs of the legislation. It should be acknowledged that the substances for which estimates of health benefits are given in this report are examples where adverse health effects of exposure to those substances are substantial and easily identifiable, e.g. lead, and the corresponding restriction is therefore likely to result in higher cost savings for health. Still, even if the health savings for other individual substances were less substantial, the health benefits are overall still expected to exceed the costs.

Efficiency of the legislation itself is difficult to estimate because not all actions taken are necessarily a result of the FCM Regulation. Self-regulation by industry is likely to have taken place even without the FCM Regulation; Member States are likely to have introduced national

[115] EFSA Register of Questions, as of 21/05/2019

rules even without Article 6 of the FCM Regulation. Therefore, to a certain extent, actions taken by industry and Member States are likely to have contributed positively to cost savings for health, even in the absence of EU rules.

For some sectors for which there are no EU-specific rules, the cost estimates are either the same or less than for the plastics sector, i.e. compliance costs are estimated to amount to about 2% of turnover. The glass and ceramics sectors are both estimated to face compliance costs which are significantly below the average of 2%. This may largely be explained by the approach both at EU level and national level, where relatively few substances are regulated, lowering the burden to industry of ensuring compliance.

For other sectors such as paper and board, costs appear to be greater than for sectors for which EU-specific rules apply. As no additional health benefits can be attached to these extra costs, the efficiency for these sectors, which combine the general requirements of the FCM Regulation and national rules, appears less than the efficiency provided by EU-specific rules. Since certain stakeholders also consider that there is inadequate health protection for materials for which no specific rules exist, this inefficiency may be even greater.

Although the evidence itself is not always clear, there are unanimous calls from industry for greater harmonisation of EU-specific rules across sectors beyond plastic. More than 9 out of 10 respondents to the public consultation[40] indicate that they consider harmonised material specific legislation better than regulating materials at a national level, often pointing to efficiency gains for industry. There is clear logic that greater efficiency comes from EU-specific rules: resources spent on regulation and compliance ensure access to the whole EU market and a high level of human health protection across the EU, following a thorough and transparent risk assessment from EFSA, with follow up risk management agreed across all EU Member States. It avoids potential duplication of assessments, legislation and testing rules across different Member States.

Other inefficiencies can be seen in the approach to regulating plastic FCMs. While significant resources are put into ensuring safety of the monomer or additive in its intended use in plastic, the same approach for other materials and the remaining 9000 additional substances used in FCMs that are not specifically regulated at EU level is impractical. Based on current resources, EFSA is capable of processing between 25 and 50 applications for risk assessment each year with the current approach, depending on the complexity of the dossier. This implies that with current resources, EFSA would need between 140 and 360 years to perform risk assessments for all substances used in FCMs. This calculation does not yet include time for the preparation of dossiers, risk management or the legislative process to establish the legal basis to perform risk assessments for all material groups.

So far, plastic FCMs and RCF are the only materials for which authorised lists of substances exist at EU level. EFSA takes responsibility for the risk assessment of new applications, while the Commission is responsible for risk management in collaboration with Member States. The Union list in effect since 2011 is based on extended harmonisation efforts of the EU and the Member States in previous decades. The compilation of a Union list of substances authorised for use in the manufacture of plastic FCMs has taken more than 30 years, with the continued need to update and modify both the list and associated rules. As discussed in section 5.1, this represents only 10% of substances known to be used in the manufacture of all FCMs.

Many substances, such as those used to manufacture polymers, are not only used to make plastic but also other materials such as synthetic rubbers, silicones and coatings. Whereas the

chemistry involved in production of the resulting polymer often differs as well as the potential for migration and generation of NIAS, the toxicology of the starting substance remains the same. Yet, risk assessment and risk management of the same substances used in coatings are not in place at EU level. This raises questions on the efficiency of the approach of regulating plastics alone and that potential health benefits, compared with the costs, are not fully realised.

Another inefficiency has also been identified in the lack of prioritisation of substances. Whereas the authorised list approach dictates that substances used to manufacture an FCM must first be assessed and authorised before they are used, these substances may in fact be more benign than other substances for which either an EU authorised list does not exist or where they may be present anyway and migrate as NIAS.

The current approach to the EU risk assessment dictated by EFSA recognises differences that may exist in the potential risk from a substance due to its migration potential, and this is reflected proportionality in the resources and efforts required to generate toxicology data. However, resources at both the EU risk assessment and risk management level are focused on starting substances subject to an authorised list, regardless of their potential hazardous properties, rather than on substances with known hazardous properties that may be present and potentially migrate into food.

Compared with similar approaches to the risk assessment and risk management of chemicals in other EU legislation, the costs for industry for the risk assessment of plastics materials are low compared with other EU legislation. As for active substances used in plant protection products, companies do not have to pay a fee for the submission of dossiers to include substances in the positive list of plastic FCMs. In comparison to this, companies have to pay fees under REACH and the biocides Regulation (EU) No 528/2012[116] (see table 1 below).

The cost for preparing a dossier for biocides products is 6 to 10 times higher than for FCMs; the approval of an active substance for the use in plant protection products is up to 80 times higher than the dossier for substances to be used in plastic FCMs. Compared to the REACH registration system, costs appear higher for the FCM sector. Including application fees, an average application under FCM costs about 30% more than under REACH. Yet, these comparisons need to be treated with caution. The complexity of dossiers and the tests required for each of them vary greatly across policy fields.

However, it is noteworthy that almost all studies required for an application under the plastics Regulation are also required for the registration of substances under REACH. Therefore, in theory, companies would not have to redo toxicological studies for submissions under the FCM legislation if the substance is registered. However, in an interview, industry representatives pointed out that this is not necessarily the case. In particular, an applicant seeking the authorisation of a substance for the use in plastic materials needs to provide also tests and studies on potential impurities. However, the applicant usually does not have access

[116] http://data.europa.eu/eli/reg/2012/528/oj

to these studies, and therefore needs to reach out to the Substance Information Exchange Forum (SIEF)[117], requesting access, and might have to redo a study if access is not granted.

Table 1: Comparison of costs for industry for the inclusion of substances in positive lists

Application costs	Regulation on plastic FCMs	Plant protection products[118],[119]	Biocide products[120]	REACH
Fees (EUR)	0	0	50,000 – 150,000[121]	1,739 – 33,699[122]
Dossier preparation (EUR)	500,000	2,000,000 to 40,000,000	3,000,000 to 5,000,000	153,195[123]

5.3. Relevance

Q6. What are the needs, interests and expectations of (a) consumers and their representative organisations; (b) businesses including food businesses and (c) Member States' competent authorities and to what extent does the current legislation address them?

Over the last decade or so, consumers' relationship with food appears to have shifted, with concerns that food should be safe taking an increasingly important role. A 2005 Eurobarometer[124] survey showed that consumers associated food mainly with taste and concerns over food health risks were low (11%). However, a Eurobarometer held in 2019 showed in addition to taste, food safety was among the most important factors for European consumers. Consumers are also increasingly concerned about the effect of chemicals on health. The same Eurobarometer survey in 2019 revealed that EU citizens are aware of issues potentially related to FCMs, with around half of the respondents saying they have heard about traces of materials that come into contact with food (51%) and micro plastics found in food (48%). Consumer safety concerns are reflected in the willingness to accept higher prices in order to have safer food packaging or kitchenware (66%).

For consumers and consumer representatives, safety remains one of the first priorities when it comes to FCMs. Replies to the public consultation[40] shows 96% of consumers consider it very important that FCMs are safe and chemical substances do not contaminate the food.

[117] http://www.sief-it.com/. The aim of SIEF is to facilitate the exchange of information between potential registrants necessary for the registration of the same substance in order to avoid duplication of studies and to agree on the classification and labelling (C&L) of the substance. The SIEF also serves as a platform for data holders to share their substance data/studies. Moreover, when the available information is not sufficient for registration, a SIEF collectively identifies the need for further studies

[118] European Commission (2018), Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)

[119] Estimates reported for the application of approval of a new active substance

[120] COM(2009) 773 final

[121] COM(2018) 342 final. https://ec.europa.eu/health/sites/default/files/biocides/docs/com2018342_en.pdf

[122] http://data.europa.eu/eli/reg_impl/2015/864/oj (depending on volume/type of submission and company size, with reductions for SMEs)

[123] European Commission 2017, Impacts of REACH Authorisation. Average dossier preparation includes registration fees

[124] https://www.gesis.org/en/eurobarometer-data-service/home

Equally, 97% of EU citizens responding to the public consultation consider it important that FCMs do not alter the taste, texture or smell of food, indicating the continued relevance of Article 3(1)(c) of the FCM Regulation. The public consultation showed citizens trust the safety of FCMs to a reasonable (38%, 84 respondents) or to a large extent (35%, 76 respondents), with 66% of EU citizens responding to the public consultation believing that the level of safety of food packaging sold in the EU has increased over the last 10 years. On the other hand, NGOs raised concerns related to the presence and migration of hazardous substances, such as substances of very high concern (SVHCs) under REACH, CMRs, substances with endocrine disrupting properties (EDs), neurotoxic and NIAS substances and to the sustainability (e.g. disposal, recycling, reuse) of FCMs as consumer waste (e.g. packaging).

Labelling is another important aspect that is specifically relevant for consumers' needs as it enables them to use the FCM safely and appropriately. However, section 5.1 describes difficulties in the understanding of simple pictograms, including the wine glass and fork logo. Specific instructions for safe use also appear relevant but may be absent in situations where all conditions of use or re-use are not or cannot be foreseen by the FCM business. One example is the storage of hot or fatty foods in single-use ice cream containers, as confirmed by public consultation[40] results and illustrated in the 2019 survey undertaken by vzbz[41], although it should be noted that this does not necessarily demonstrate that such re-use is unsafe.

However, public authorities and business reiterated the difficulties of realistically assessing all possible uses and reporting them on the label – as demonstrated by the more novel practice of cooking whole beer cans together with hot, fatty foods. The practice has nevertheless become much more common over recent years, promoted by celebrity chefs with hundreds of 'recipes' available online[125].

While specific needs differ depending on the position along the supply chain, overall, the needs of businesses have not changed significantly over time. Their needs relate to their ability being able to produce, sell and trade their products across the EU with minimal burden and meeting their customers' needs. This requires clear rules and guidance, and that information along the supply chain is exchanged effectively to ensure compliance and the safety of the final article or material. The JRC 'baseline' study[7] demonstrates commonalities in the production and distribution of FCMs on the EU market and from the consultation activities and discussion in earlier sections, it is clear that the more harmonised rules are, the more relevant this is for businesses. Overall, there has been an *expectation* from industry stakeholders that more EU-specific rules would follow those already introduced primarily for plastic FCMs.

Although current specific EU rules are more relevant to business operators than more generic rules or diverging specific rules between Member States, they appear more relevant for businesses at the start of the supply chain, rather than convertors or manufacturers of final FCMs, including the majority of SMEs, because they are focussed on starting substances and lack more detail on intermediate and finished articles. This leaves a potential gap as regards

[125] https://www.simplyrecipes.com/recipes/beer_can_chicken/

the needs of actors further along the supply chain who have responsibility for intermediate and final materials. For example, convertors reported problems related to the flow of information and burdens due to the necessity to adapt and perform migration tests for multiple articles. In this sense, the specific EU rules are less relevant for actors further along the supply chain.

Targeted consultation of 700 SMEs[100] showed that assessing the needs of SMEs is difficult as the smaller the business gets, the less they are aware of FCM legislation, let alone what the requirements and their responsibilities are, and what their own needs might be. Although SMEs consider that the current FCM legislation places disproportionate burden on them, most SMEs consulted do not report having any issues to market or sell FCMs. The smaller the business, the less burden they reported, with 67% of self-employed respondents reporting no burden at all. Overall, awareness of the rules and ease of understanding them appears to be low for SMEs.

Around 65-70% of responding SMEs replied being sufficiently familiar with safety requirements under FCM legislation. This drops to below 50% for self-employed individuals. Most SMEs replied being fairly familiar with basic requirements of the FCM Regulation regarding safety, GMP, labelling and traceability. Their degree of knowledge was lower for specific legislation and rules, and, in particular, on compliance documentation and migration limits (for plastics). This is not necessarily due directly to the legislation itself but indicates a possible opportunity to address better the needs of SMEs, who may find the requirements simply too complex without further assistance.

As with industry stakeholders, it is apparent from consultation activities such as case study 2 (see annex 2) as well as proactive correspondence to the Commission that Member States desire further EU-specific rules for materials beyond mainly plastics and have anticipated this for several years. Enforcement of FCMs without specific EU rules is perceived as particularly challenging and controls tent to be lax or even absent. Member States may rely on BfR Recommendations, other national legislation, resolutions from the Council of Europe or even US legislation, but argue that it is difficult to enforce based on recommendations and resolutions, as they are not “hard legislation”. Where national legislation exists, it is difficult to access and use by inspectors, and it is often available only in national languages, whereas inspectors in particular require clear rules in the own language. A lack of controls also implies a lack of findings by competent authorities and a failure to identify potential problems and prioritise FCM controls, which ultimately has the potential to affect safety of FCMs.

The capacity of Member States to enforce legislation based on physical sampling and analysis is limited; costs are high and methods are not readily available. Consequently, there is a need to have access to adequate and timely information on compliance undertaken in the supply chain, including a DoC and SD. However, there are no requirements for DoC and SD are at EU level beyond specific materials including plastics, RCF and ceramics, and Member States or industry are free to define their own approaches, which can vary or may be absent. According to Member States’ experience, compliance documentation is often lacking or at least not readily available on request. Stakeholders have repeatedly asked for a common DoC

and SD requirements beyond plastics, including a specific request made under the Commission's REFIT platform[126] as per the opinion following a request by the Danish Business Forum[127].

Audits and fact-finding by the Commission point to insufficient training on controls, including those on documentation checks and implementation of GMP. Many Member States indicate a need for more capacity to train staff and interest and participation in BTSF training by Member States' competent authorities continues to be strong. In addition to this gap in expertise, there has been a lack of coordinated and systematic enforcement strategies with few exceptions. This has left Member States to prioritise controls individually, whereas problems are likely to be common across the EU, as demonstrated by the prevalence of non-compliant melamine tableware in recent years. A recent exercise to coordinate controls[128] has proved successful and well received by Member States, indicating further scope for more coordination in the future.

Q7. To what extent has Regulation (EC) No 1935/2004 [the FCM Regulation] and its subsequent implementation allowed for evolving science, prioritisation and innovation?

There are elements of the FCM Regulation and its implementation that have been supported by evolving scientific understanding. For example, the JRC in its capacity as EURL for FCMs provides scientific and technical assistance to the Commission and the Member States. It organises inter-laboratory comparison exercises and conducts training courses for the benefit of NRLs as well as experts from developing countries, helping them to apply new methods of analysis. It has developed guidelines for testing and compliance work, which ultimately help in supporting the work of the Member States on controls as well as helping to keep requirements set on testing approaches in the EU up-to-date. Therefore, support exists in the implementation of the legislation as regards the development of analytical methodology.

Similarly, part of EFSA's mandate includes identifying emerging risks, including substances migrating from FCMs. An EFSA Scientific Cooperation (ESCO) Working Group was set up in 2010 in order to collect the information and make proposals to anticipate emergency situations linked to the presence of substances released by non-plastic FCMs in food. Strategies for prioritisation of the evaluations of substances and for providing preliminary advice in case of urgent need were proposed[75], although to date no need has been identified. They included toxicity and exposure assessment tools, such as read-across approaches from structural similar substances or approaches based on human exposure thresholds correlated to the chemical structure of the substance. Following this, a network of experts was set up[129] to enhance collaboration between scientists involved in risk assessment of FCMs to support and harmonise risk assessment practices in this area and continues to date.

The introduction of EU-specific measures focussing on the safety of substances used in AIM and to that ensure plastic FCMs are sufficiently decontaminated during recycling, reflected a growing use of AIM and recycling of plastic for food contact use. At the time, the approaches

[126] https://op.europa.eu/webpub/com/refit-scoreboard/en/policy/9/9-13.html
[127] https://ec.europa.eu/info/sites/default/files/opinion_health_food_1a.pdf
[128] http://data.europa.eu/eli/reco/2019/794/oj
[129] https://www.efsa.europa.eu/sites/default/files/assets/fipnonplasticsnetworktor.pdf

used in the regulations were considered appropriate in order to protect consumers and address the needs of businesses. However, to date, neither the authorisation of substances assessed for use in AIM nor the authorisation of processes for recycling have been successfully implemented, whereas stakeholders have indicated in particular that the measure on recycled plastics is urgently needed to support the overall reduction in plastic waste.

The untimely implementation of these regulations in part reflects the difficulties in keeping pace with evolving science and has raised questions on the practicalities of the approaches originally foreseen. For AIM, EFSA has been evaluating AIM systems as a whole, whilst the regulation requires authorisation of individual substances, which has presented a significant difficulty in the implementation.

Similarly, the initial phase of risk assessment and risk management for the authorisation of processes under Commission Regulation (EC) No 282/2008 has focussed on recycling of poly(ethylene terephthalate) (PET) and has fallen short in addressing other types of plastic, other materials or newer scientific technologies such as chemical recycling, leaving a gap in an ever-expanding market and to address evolving priorities[130]. These new types of recycling technologies are seen as key to providing for future needs and challenges that cannot be addressed altogether with more traditional, mechanical recycling.

There is a growing interest among consumers in the impact our consumption patterns have on our environment, in particular on how we produce, consume and dispose of consumer goods and waste we produce[131]. Similarly, these concerns are reflected well in the results from the public consultation[40], where most EU citizens considered it important that FCMs are recyclable with minimum packaging as well as a general preference to see packaging that is reusable, biodegradable or made from "natural" materials. In turn, there is clear evidence that the production of FCMs and in particular food packaging, is evolving with new and innovative types of material being used and introduced onto the market, including those that are either bio-based, possess more biodegradable properties than traditional packaging materials[132] or use nanomaterials[133].

Yet, these trends are not well accommodated in the current FCM legislation, which favours risk assessment and risk management of well-established chemistry, with a focus on defined starting substances to produce synthetic polymers in order to manufacture plastics. While bio-based polymers are specifically addressed under the plastics Regulation, there are still clear gaps for materials for which no EU-specific measures have or even can be introduced, including biodegradable materials. These gaps must be filled in the context of initiatives introduced under the European Green Deal[134], including legislation on Single Use Plastics and Waste, Packaging and Packaging Waste in order to ensure that new products entering the market are safe for consumers to use as well as being more sustainable and better for the environment.

[130] Ecorys report, annex 2: Case study 6 (based on focus group 6) "External coherence of the FCM legislation"
[131] 2020 Eurobarometer on Attitudes of EU citizens towards the environment
[132] https://onlinelibrary.wiley.com/doi/full/10.1111/1541-4337.12715
[133] https://link.springer.com/article/10.1007/s13197-018-3266-z
[134] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

As noted in section 5.1 on effectiveness and 5.4 on coherence, the current approach also fails to sufficiently prioritise the most hazardous substances, rather focussing on starting substances regardless of their hazard properties, whether they are present in or migrate from the final article and is primarily applicable for plastic FCMs. Information generated under REACH legislation and hazard assessments done under Regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures[135] (the CLP Regulation), for example remains untapped, whereas in reality some of the data may be relevant to use in the prioritisation and regulation of FCMs. Similarly, new scientific developments in risk assessment have been identified by EFSA in 2016, including the need to better address vulnerable population groups (see section 5.1.4) and with more focus on the final article. However, a new approach to regulating specific materials would first be required to address these findings since the current approach is poorly compatible, e.g. requiring multiple migration limits for the same article.

Furthermore, very few notifications have been made to the Commission from applicants or businesses with new scientific or technical information, which might affect the safety assessment of the authorised substance, as required by the legislation. In contrast, several examples have recently come to light where new information has been made available, for example data generated under REACH, prompting the Commission to proactively request re-assessments, including a recent request to prioritise substances with no SML[136]. Failure to automatically generate such re-assessments may be caused by a lack of incentive or knowledge on the part of the applicant or business operator in the absence of a legal deadline to review the substance, or moreover, simply imply that the substance is no longer used. Therefore, risk assessments fail to keep pace with science, which in turn are not incorporated into risk management.

Innovation also appears to be hampered by the current Union list approach. Once authorised, a substance may be used by anyone else, promoting the status quo, i.e. the use of already listed substances, rather than innovation and new FCMs that may be beneficial to industry and consumers alike. As identified in section 5.2.5, only a very small fraction of all applications for substances are submitted by SMEs. The current system therefore appears biased towards larger businesses, in part possibly because they can afford the costs linked to the development of the substance and application for its authorisation but also losses in terms of competitiveness. This is likely to discourage innovators, especially smaller operators, and is in contrast with the US FDA Food Contact Notification system, where authorisations are only granted to applicants.

Some businesses also mentioned the length of the risk assessment procedure as a hurdle to more innovation in the field. The public consultation[40] results showed that 45% of businesses consider that the duration of the assessment and authorisation process does not support innovation. The perception of businesses is that the requirements for safety assessment of substances have increased and it incentivises them to use approved substances rather than substituting them with new ones. Whereas EU guidelines for the assessment of substances

[135] http://data.europa.eu/eli/reg/2008/1272/oj
[136] https://doi.org/10.2903/j.efsa.2020.6124

have been updated based on new knowledge and understanding, such perception may also be based on the length of time taken from the development of a substance to authorisation at EU level – in particular the latter part of the process which industry feels is too long (see section 5.2.5).

5.4. Coherence

Q8. To what extent is the FCM Regulation *internally* coherent, including all of its implementing acts?

5.4.1. Internal coherence

In general, there is a broad consensus among consulted stakeholders that the FCM Regulation itself and the specific EU rules adopted under that regulation are generally coherent and function as intended as supported by stakeholders during the consultation activities. This includes the GMP Regulation as well as the plastics Regulation. These pieces of legislation deploy the use of the procedures set out in the FCM Regulation concerning assessment and authorisation of substances and processes.

However, inconsistencies – mainly gaps – also exist, which generate uncertainties and may compromise the two aims of the FCM Regulation of ensuring safety and functioning of the internal market. In line with the views of stakeholders concerning the existence of national measures[40,76,137] it can be concluded that the main incoherence stems from Article 6 of the FCM Regulation, which enables Member States to adopt or maintain their own national rules. As described earlier in section 5.1.5 on effectiveness, Member States' approaches and national legislations often differ and in part contradict each other, which act against efforts for a common consensus on safety and functioning of the internal market for FCMs for which no EU-specific measures exist.

These issues were repeatedly raised by stakeholders during many of the consultation activities. In the replies to the public consultation[40], 70% of public authorities, 60% of business associations and 100% of NGOs who reported a gap in the legislation identified the presence of national measures/lack of EU-specific measures as a main reason for the gap. As well as creating barriers to the smooth functioning of the internal market, the situation also creates distrust by consumer organisations and raises concerns about the way that public health is protected.

Another inconsistency identified within the FCM legislation itself concerns the lack of analytical methods which have been assessed and validated sufficiently to control authorised substances and ensure compliance and enforcement of restrictions, such as SMLs. This in part is caused by the complexity and diversity of plastic FCMs, their chemical constituents, who then come into contact with multiple different food types. Accreditation of analytical methodology is burdensome, expensive and requires regular testing/use of those methods. EFSA, which is tasked with making the assessments of the methods according to the FCM Regulation, does not have the full capacity to do so, even though analysts are appointed in its assessment work. DoCs are made on real materials, which may be inconsistent with the model materials evaluated by EFSA, as they may give rise to a different migration pattern. This also

[137] Ecorys report, Focus Group 4 "Effects of the lack of harmonisation"

causes a challenge for enforcement bodies and not all possible migration scenarios are comprehensively accounted for.

Contrary to the requirements of the FCM Regulation, it is not within the remit of EFSA to assist in developing technical guidance on sampling and testing. The EURL-FCM, (the Commission's JRC), which has the competence and the capacity, is now struggling to supply the network of national reference laboratories with suitable analytical methods; in part, because this information may be 'hidden' in confidential documentation submitted with the application to EFSA, or because the relevant data dating from before the establishment of EFSA are frequently missing.

The complex rules regarding multi-material multi-layer articles in the plastics Regulation also weaken internal coherence according to some stakeholders[76]. Difficulties arise when such articles contain substances that are not on the Union list for plastics and substances (see figure 7, annex 5) but which are present in other materials, but where it is not possible to verify from which material or layer the non-listed substance originates. DoCs may relate only to part of the article and where SMLs do not apply because of the presence of non-plastic material.

In the absence of clear rules and given the complexity of ensuring compliance, businesses (often at retail stage) often request compliance with their own national law for materials without specific EU measures. This is similar to the situation prevailing before the entry into force of specific EU measures. The complexity of the rules may thus hinder mutual recognition, while the first objective of the FCM Regulation is related to the effective functioning of the internal market.

Gaps also currently exist in the implementation of existing specific EU measures for AIM and recycled plastic FCMs, as described in section 5.3.

Q9. To what extent are the FCM Regulation and its subsequent implementation including the risk assessment and risk management approaches taken, externally coherent with other relevant legislation and policies?

5.4.2. External coherence

FCM legislation is complementary to other legislation designed to protect consumers from hazards arising from exposure to chemicals through food. In particular, it has ensured coherence with the basic provisions of General Food Law[11], which cover food and feed. The REFIT Evaluation of the General Food Law (GFL)[35] also supports the coherence of the systematic application of the risk analysis principle in all EU secondary food legislation, including FCMs and the EU level risk assessments provided by EFSA. Furthermore, specific rules in FCM legislation take into account situations where the same substance may be assessed and authorised under other specific food laws, such as components of AIM. FCM legislation is therefore coherent with other EU food laws.

Similarly, the FCM Regulation is complementary to other legislation designed to protect citizens from chemicals to which they may be exposed in the environment or via other consumer products. Whereas many substances, including those used in FCMs, need to be registered under REACH, further risk assessment and risk management taken under REACH are not specific to FCMs; and with the exception of substances requiring authorisation under REACH because of environmental concerns, assessment and management of substances that may pose a risk to human health through exposure from FCMs are carried out only under the

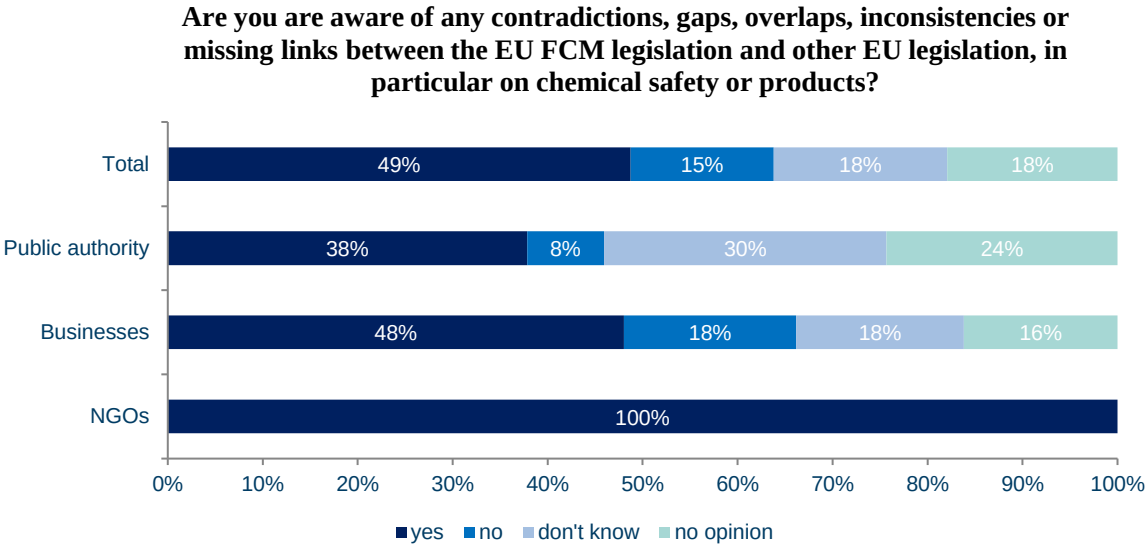
FCM Regulation. Largely, therefore, the two pieces of legislation have complementary tasks to protect citizens.

However, nearly half (49%) of respondents to the public consultation[40] report that they are aware of contradictions, gaps, overlaps, inconsistencies or missing links between the EU FCM legislation and other EU legislation, relating particularly to chemical or product safety, while only 15% indicate that they are not aware of such issues (see figure 4 below). The most frequently reported issue concerns coherence and consistency between the FCM Regulation and REACH. In particular, NGOs express the view that substances identified as CMR under the CLP Regulation or as being of 'Very High Concern' (SVHC) under REACH should not be authorised for use in FCMs, regardless of migration potential, exposure and specific risk assessment.

Specific risk approach (SRA) and generic risk approach (GRA)

The main difference identified between the FCM Regulation and other legislation is the approach taken to risk assessing and risk managing certain substances. FCM legislation takes a specific risk approach (SRA), where the specific use in plastic FCMs, exposure to consumers via that route and possible health risks to humans are taken into account before an authorisation is given. Other legislation applies a generic risk approach (GRA), which focuses more on the intrinsic hazard properties of a substance. The GRA-based approach is built into some legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.).

Figure 4: Stakeholders' opinion regarding external coherence. Source: public consultation *(Q23)*[40]



Examples of EU legislation using the GRA approach, at least in part for the most hazardous substances, include EU legislation on cosmetics, where any substance classified as CMR categories 1A/B and 2, are banned from use (subject to strict derogations). This is based on the generic consideration that direct exposure of humans takes place through the application of a cosmetic product on the external parts of the human body (or mouth). Thus, BPA for example, is prohibited for use in cosmetics but not in FCMs. Similar approaches have been taken for CMR substances in toys.

The REACH Regulation typically deploys the GRA in the authorisation process, since inclusion in its Annex XIV (list of substances subject to authorisation) is based firstly on hazard. Additional prioritisation is given to substances with high volumes and wide dispersive uses. The restriction procedure in Article 68(2) gives a simplified restriction procedure for CMRs, cutting out the detailed risk assessment and socio-economic assessment that is part of the normal restriction process.

Few substances subject to authorisation in Annex XIV, particularly because of human health concerns, are authorised for use in plastic FCMs, with notable exceptions of certain phthalates. The incoherence in practice concerning the same substances subject to authorisation under REACH and permitted in plastic FCMs are therefore currently very small. Furthermore, substances may still be authorised or exempt from authorisation for a specific use under REACH (e.g. phthalates in the packaging of medicinal products), which may lead to a similar outcome as for FCMs.

Classification of CMR does not necessarily mean that there is a risk when the substance is used in a certain application. The plastics Regulation authorises some reactive monomers, which have been classified as CMR in REACH. In the 1990s, these substances were recognised as CMRs in the safety assessment by the Scientific Committee on Food (SCF). Nonetheless, they were authorised because they are highly reactive, and they are no longer present after polymerisation; safety assessments verified that they are not present (not detectable) in the final FCM. Consequently, these monomers are listed in the Union list for plastic FCMs. In addition, it is often possible to establish safe levels of exposure to certain carcinogens, for example, and therefore even if trace amounts remain, exposure is such that no risk is identified.

This is exemplified by a recent study[138] that compiled a list of monomers listed in Annex I of the plastics Regulation, their classification as CMR substances according to the CLP Regulation, and their maximum concentration/migration limits permitted in toys. It lists 20 substances authorised for use in plastic FCMs, for which a non-detect (ND) requirement is set in the plastics Regulation for each substance that has been identified as CMR category 1A or B. An exception to this is formaldehyde (Carc1B), for which the main route of exposure does not arise from FCMs but is nevertheless currently under discussion within the FCM Expert Working Group and BPA (Rep1B), which is discussed later in this section.

Despite this, and although the Fitness Check of the most relevant chemicals legislation (excluding REACH) (see section 4.1) concluded that there are advantages and drawbacks to both the SRA approach and the GRA approach, the different approaches, especially for the most hazardous substances including CMRs, persistent and bioaccumulative toxins (PBTs) and very persistent and very bioaccumulative toxins (vPvBs), are seen by some stakeholders, particularly NGOs as a major inconsistency. The issue is compounded for non-plastic FCMs for which no risk assessment or specific risk management measures exists for known or potential CMRs in these materials, at least at EU level.

[138] CMR substances in consumer products: from food contact materials to toys. Ariane Lenzner, Bärbel Vieth & Andreas Luch. Archives of Toxicology volume 92, pages1663–1671(2018).

As well as CMRs, incoherence also exists as regards the approach to regulating substances that have endocrine disrupting properties (EDs). Although substances identified under separate legislation as having endocrine disrupting properties are specifically risk assessed when used to manufacture plastic FCMs, which may in turn take into consideration these properties, the legislation does not specifically mention or prioritise them and consequently does not define them. On the other hand, legislation on plant protection products and biocidal products set scientific criteria with automatic consequences, i.e. a ban unless a justification for exemption can be made. Other pieces of legislation also contain provisions that specifically addresses endocrine disruptors, including REACH and medical devices legislation.

The absence of horizontal criteria for the identification and classification of endocrine disruptors across relevant EU legislation has also been criticised by a number of different stakeholder groups including both NGOs and industry, as well as national authorities and was identified as an area for action in the EU's 7th Environment Action Programme. Endocrine disruptors have recently been subject to a cross-cutting Fitness Check[139], which identified some incoherence in the horizontal approach across legislation and in data requirements and possible gaps in addressing vulnerable populations. Despite differences in risk management approaches, however, it found no cases of inconsistent risk management for specific substances based on the lack of a horizontal approach to the identification of substances or any other consideration specific to endocrine disrupting properties, limited as it was by the small number of substances examined.

Issues specific to REACH

Most chemicals used to manufacture products (whether or not FCMs) are subject to the REACH registration process, as they are often produced in high volumes. In accordance with the REACH Regulation, FCM substances that have been placed in Annex XIV of REACH (list of substances requiring authorisation) due to their human health hazards are exempt from authorisation requirements for food contact use because the FCM legislation specifically controls health risks. They remain subject to REACH authorisation with respect to occupational or environmental risks.

By way of example, the plastics Regulation authorises perfluorooctanoic acid (PFOA) following an opinion from EFSA concerning its specific use in FCMs (non-stick coating), which leads to a negligible dietary exposure and is considered safe for human health. On the other hand, ECHA has identified it as toxic and highly persistent in the environment. Consequently, PFOA was restricted in Annex XVII of REACH entry 68[140] and subsequently transferred to Regulation (EU) 2019/1021 on Persistent Organic Pollutants[141]. This restriction includes its presence in FCMs, but as emphasised in the focus group on coherence[142], withdrawal from the Union list is not possible under the FCM Regulation, since there is no mechanism in place to do this, only following an opinion by EFSA. The continued listing of

[139] {COM(2020) 667 final} - {SWD(2020) 225 final} - {SWD(2020) 247 final} - {SWD(2020) 248 final} - {SWD(2020) 249 final} - {SWD(2020) 250 final} https://ec.europa.eu/info/policies/endocrine-disruptors_en
[140] http://data.europa.eu/eli/reg/2017/1000/oj
[141] http://data.europa.eu/eli/reg/2019/1021/oj
[142] Ecorys report, focus group 3 “Risk assessment and REACH-FCM interaction”

PFOA in the plastics Regulation is likely to cause confusion for FCM producers and suggests a need to ensure better coherence.

Annex XVII of REACH also includes restrictions for substances that pose an unacceptable risk to human health and the environment that are not adequately controlled and that must be restricted at EU level. There is no general exemption for FCM substances unless a specific exemption is stated in the corresponding entry in Annex XVII (such as that for lead).

Occasionally, restrictions on substances in Annex XVII of REACH include their presence in FCMs, such as PAHs in plastic drinking utensils or phthalates in childcare feeding articles. However, national measures may exist for PAHs in FCMs in accordance with Article 6 of the FCM Regulation and indeed do exist for phthalates in plastic FCMs under the plastics Regulation. This appears to present an overlap and has the potential to cause confusion among stakeholders.

Overall, the main difference between FCM legislation and other EU legislation such as REACH is the approach taken to the management of the most harmful chemicals, where the latter also deploys a more hazard-based approach as well as specific risk assessment. Some overlaps have also been identified where both sets of legislation regulate FCMs, which may lead to confusion amongst businesses. Specific EU rules applicable to FCMs are inconsistent in a limited number of cases, where authorisation of a substance under the FCM Regulation continues despite action taken under REACH on environmental grounds. An increase in recycling and re-use of materials under sectorial legislation must also be taken into account in the FCM legislation to ensure safety.

Cooperation of EU Agencies

The ECHA-EFSA memorandum of understanding[143] sets the framework for cooperation between the two EU agencies, including scientific collaboration and information exchange, hazard and risk assessment of chemical substances and exchange of scientific data and experience in developing scientific IT and support tools. This is highlighted in the Fitness Check of the GFL.

Although both agencies consult each other, where possible and appropriate, when delivering scientific advice and risk assessments that concern the safety of chemicals in food, there is still scope for greater coherence in the approach to risk assessment. The findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH)[37] highlighted the complexity of assessment procedures, which represents a specific challenge for authorities and stakeholders and can lead to inconsistencies, slow procedures, inefficient use of resources and unnecessary burdens. Interviewed stakeholders and those participating in the public consultation[40] demonstrate a consensus on the potential for stronger synergy between REACH and FCM Regulation, as they collect information on similar materials. This should be facilitated following the adoption of the Memorandum of Understanding between both agencies.

Possible inconsistencies with other EU legislation

[143] https://www.efsa.europa.eu/sites/default/files/assets/mouecha.pdf

An example of incoherence also exists between the FCM Regulation and the EU Regulation on medical devices. This is exemplified by feeding tubes used for administering foods for special medical purposes, which are both medical devices and FCMs according to the respective regulations. However, the Regulation on medical devices does not necessarily have the same approach to migration of chemical substances as the FCM Regulation, since there could be other issues to consider for the patients' safety. For example, some tubes for feeding premature babies require a composition that makes them sufficiently soft, so they don't perforate the stomach of the children. Rules on the content of phthalates in these tubes to plasticize them differ from the rules in the plastics Regulation. Although the benefits of using devices for medical purposes in most scenarios are likely to outweigh the possible risks from migration of substances from the medical device, legal clarity could be improved.

Overlaps also now exist in the case of biocidal substances used in plastic FCMs. A small number of substances used as biocides are still subject to national rules[144] in accordance with the plastics Regulation, whereas since 2012, use of biocidal substances in biocidal products incorporated into FCMs has required approval and authorisation respectively under Regulation (EU) No 528/2021. This has also led to confusion amongst stakeholders as demonstrated by correspondence to the Commission, requesting clarification on whether an application requires an assessment under the FCM Regulation, Regulation (EU) No 528/2012 or both.

Some questions have been raised on the coherence between the FCM Regulation and the recently updated waste management legislation (Directive (EU) 2018/851 on waste[145]). This Directive sets requirements for FCM producers to increase recycling rates. On the other hand, Regulation (EC) No 282/2008 places a major emphasis on food safety when new FCMs are made from post-consumer recycled FCMs. The objectives of the two pieces of legislation do not contradict each other but may create challenges to one another, since the need to ensure safety can hamper the recycling of certain materials that contain hazardous substances.

Post-consumer recycled materials may be contaminated with various chemicals. Although many processes for PET recycling allow contaminants of concern to be efficiently removed, not all polymers can be purified and recycled into new materials equivalent to virgin polymers compliant with FCM rules. EFSA guidance is provided for applications on processes to decontaminate plastic FCMs during the recycling process, depending on the polymers, the processes, and the intended uses. However, current recycling processes do not enable a purification of polyolefins and removal of contaminants of concern, although polyolefins have an important market position and their recycling is necessary to achieve recycling targets.

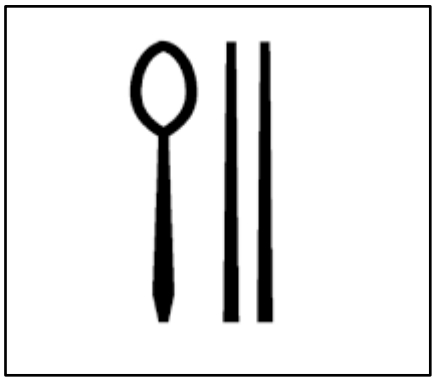
Global regulation of FCMs

There are no common global standards for FCMs as there are for other sectors, such as pesticides and contaminants under *Codex Alimentarius*. The main system that differs from the EU is that of the US FDA. Whilst there are parallels between the EU and the US FDA system, the main difference is that authorisation is exclusive to the manufacturer or supplier. As noted in section 5.2.5, the authorisation process is also generally quicker than in the EU.

[144] https://ec.europa.eu/food/system/files/2016-10/cs_fcm_legis_additives-prov-list.pdf
[145] http://data.europa.eu/eli/dir/2018/851/oj

The approach also differs insofar as the US permits certain exemptions including substances at low exposure or because they are food additives or are "Generally Recognised As Safe (GRAS)". In contrast, the EU approach requires at least a basic toxicological evaluation of the listed substances, regardless of exposure.

On the other hand, many FCM regulators across the world have, by and large, been evolving their systems broadly based on the approach taken by the EU. This includes the switch from a negative list system in Japan to one comprising positive lists[146] and most notably, a replication of the EU general requirements and regulatory framework system (GB 4806.1-2016), including requirements for a DoC and labelling with symbols representing more common utensils in China (see right). The system in China also deploys the use of an authorised list of additives (GB 9685-2016), using similar restrictions such as SMLs (see figure 8 in annex 5). Work has now progressed in China and legislation incorporates additional requirements on plastic as well as rubber, inks, coatings and adhesives.



Although the EU and Chinese systems have a similar structure and approach in a number of aspects, feedback from interviews indicates that there is more room for coherence. Future trends in packaging and other FCMs may also drive regulators in the same direction, in particular in areas such as vulnerable populations and regulation of more novel materials as well as paying greater attention to "chemicals of concern" and recycling of FCMs[147]. This could potentially pave the way for enhanced synergies between global regulators.

5.5. EU added value

Q10. What is the EU added-value of the FCM Regulation in relation to its main objectives?

The EU legislation has brought value in ensuring the safety of FCMs and the functioning of the single market through common principles, language and regulatory approach, and harmonised specific rules for some materials. This includes setting the ground for harmonised rules for listed materials, a defined assessment and authorisation procedure for ensuring substances used in making those materials are safe, rules regarding labelling and traceability for consumers and businesses along the supply chain, and controlling and enforcing the legislation. Further benefits include the introduction of an EU risk assessment process centred around EFSA and the formation of the EURL-FCM and network of NRLs, which facilitate a coherent approach to method development and guidance on ways to ensure compliance.

The FCM Regulation did not completely transfer responsibility to the EU level. The powers to control and enforce remain with the Member States. The key provision providing Member

[146] https://www.ul.com/news/japan-adopts-positive-list-system-manage-food-contact-materials-fcm

[147] Future trends in global food packaging regulation. lJ.S.Baughan. Global Legislation for Food Contact Materials Woodhead Publishing Series in Food Science, Technology and Nutrition, 2015, Pages 65-74. https://doi.org/10.1016/B978-1-78242-014-9.00003-6

States with the autonomy to act independently is Article 6. It allows them to maintain or adopt national provisions in the absence of specific measures.

The clearest added-value brought about by EU intervention is the progressive *harmonisation* and provision of more *specific rules* over the last four decades. Significant milestones include the introduction of EU lists of substances authorised for use in plastic FCMs and the replacement of the Member State authorisation provision (article 4 of Directive 89/109/EEC) with the Union authorisation process.

In particular, the EU-specific rules in the plastics Regulation, including a Union list of authorised starting substances, additional compositional requirements, restrictions including SMLs and rules on verification of compliance and documentation in the supply chain have had positive effects on both the effectiveness and efficiency of regulating FCMs. These positive effects were further solidified in 2011 with the inclusion of multi-material multi-layer plastics. According to stakeholders, these specific rules have brought an increased level of consumer protection, enhanced cooperation and controls amongst Member States and provided greater legal certainty to businesses. These effects are enhanced at EU level because they help to define what is required in order to ensure compliance with Article 3 of the FCM Regulation and avoid differences that occur as a result of national legislation.

So far, the EU added-value has been limited. Over 30 years after the entry into force of Directive 89/109/EEC, which set provisions for introducing specific rules for specified materials, specific measures are in place for only four materials (plastics and recycled plastics, ceramics, AIM, and RCF). This 'incomplete implementation' has a negative impact on the overall performance and the added-value of the EU legislation on FCMs.

For materials not subject to specific EU rules, different national approaches remain in the absence of EU-specific legislation, hampering trade on the internal market. Reliance on national measures also raises doubts about the safety of some non-plastic materials, creating uncertainty and barriers to trade for businesses. Companies are required to invest in additional tests and to provide documentation in order to meet national requirements and varying client requirements. It also makes controls and enforcement more difficult, due to the complexity and cross-cutting nature of the topic and lack of resources and expertise in Member States but also among businesses.

The EU's mutual recognition principle appears to be correctly applied to a limited extent and the difficulties encountered are higher for SMEs. As illustrated in section 2 of the JRC 'baseline' study[7], supply chains are set up to supply the EU market, rather than being country specific and this may also explain the difficulties encountered with multiple rules in different EU Member States.

There is a consensus among Member States, citizens and other stakeholder categories that EU intervention is necessary and of great added-value. Member States, citizens and stakeholders confirmed in all of the consultation activities that further action at EU level is needed. For Member States, and in particular in the smaller countries, harmonisation helps to implement the legislation at lower costs. For NGOs, harmonisation is considered a way to improve consumer protection and ensure that it is equal for all EU citizens. For companies, harmonisation guarantees the functioning of the internal market. It is particularly the case for SMEs as illustrated in figure 9, annex 5. Finally, for consumers, results from the consultation[37] show that the level of trust regarding safety issues is the highest for EU authorities.

6. CONCLUSIONS

Increasing experience with the functioning of the FCM Regulation over many years has stimulated discussion and reflections between the Commission, EU Member States and stakeholders; not only on the anticipated impacts and outcomes but moreover on several fundamental issues with the existing approach to regulating FCMs at EU level. The purpose of this exercise was therefore to formally evaluate and document, with supporting evidence, the functioning of the FCM Regulation in relation to its original objectives, whilst acknowledging that no previous assessments or monitoring of the FCM Regulation have taken place as well as the difficulties in collecting information from stakeholders and generating quantitative data.

The evaluation has found that EU FCM Regulation is partly effective in fulfilling its two main objectives. The scope of the Regulation is generally clear, although there are differences in the interpretation of the status of some items that may come into contact with food, leading to legal uncertainty. There are questions about the full effectiveness of labelling and communication to consumers, including the use of symbols or pictograms. Definitions are generally clear, but difficulties may arise in delineating between similar material types including those made from synthetic polymers. No specific issues were identified concerning traceability within the FCM supply chain, although Member States' competent authorities face challenges in the absence of compliance documentation and lack of business registration.

Article 3 of the FCM Regulation concerning the safety of FCMs has set a clear legal requirement that has promoted several specific initiatives, including EU-specific ('harmonised') measures, national measures and industry standards. A similar approach has been successful in stimulating industry guidance on GMP. The main 'harmonised' approach has largely ensured the safety of starting substances used to manufacture plastic FCMs, based on a transparent EU risk assessment and provides legal certainty for industry. Businesses are generally clear on their roles and responsibilities and do not face different national requirements, allowing good access to the EU market. Member States rely on specific rules and have also adopted their own similar approaches for regulating other materials at national level. The EU rules are technically complex however and have required supplementation with guidance, which stakeholders have welcomed although may still be beyond the routine understanding of SMEs, taking into account their normal resources.

The development of a Union list of authorised substances has nevertheless been restricted to plastic FCMs as well as RCF; on the whole, no such assessments, authorisations and associated restrictions have been introduced for other materials. The effectiveness for plastic FCMs is compromised by derogations for some substances such as colorants and so-called non-intentionally added substances (NIAS). Risk assessment and management of authorised substances is not always assured in part because the most up-to-date science is not routinely incorporated into the regulatory process and questions have also arisen over whether vulnerable populations and combinations of substances are sufficiently addressed. Exchange of safety and compliance information in the supply chain is also relatively poor and overall, the evaluation points to uncertainty and insufficient rules on how to ensure the safety of the final FCM sold to consumers.

In contrast to the specific complexities of the plastics Regulation, on its own, Article 3 of the FCM Regulation does not define the level of safety or quality expected for many other materials, which may differ amongst stakeholders. Further, it does not state how safety should

be achieved or how it can be demonstrated. Many national measures have therefore been introduced by Member States but are often incoherent across the EU for the same materials or the same substances. This creates confusion over required levels of safety and legal uncertainty for businesses, particularly SMEs, who may be faced, for example, with multiple testing regimes, increasing costs or leaving large parts of the EU market inaccessible. The mutual recognition principle does not appear to have so far improved the situation. The legislation has therefore generally been ineffective for most materials other than plastics.

Member States are able to carry out inspections and controls only in a very limited capacity and the current systems of official controls, as implemented, cannot adequately or fully enforce the requirements of the legislation. Inspection and official controls are hampered by the lack of specific EU rules on which to base controls, lack of resources and prioritisation of FCMs, lack of validated methodology and inability to identify FCM businesses. On the other hand, specific EU rules on plastic FCMs are complex requiring high level expertise, which is often lacking in Member States. Work on methods of analysis is supported by the EURL-FCM and NRL network but this is complex and resource intensive for the number of substances that are authorised and need to be checked. Validated test methods are absent except for a small sub-section of substances, which compromises the ability to verify restrictions.

The presence and quality of declarations of compliance (DoC) and supporting documentation (SD) were found to be insufficient in the supply chain, which also makes Member States' controls additionally challenging. Gaps have been identified in the flow of information along the supply chain and there is a clear need to standardise, simplify and clarify rules on compliance documentation, improve the quality and exchange of information along the supply chain and reinforce the system of enforcement.

Overall, the efficiency of the FCM legislation appears to be sub-optimal although health benefits are still expected to exceed the costs. A relatively qualitative analysis suggests that specific EU restrictions for certain substances have led to significant health benefits that may run into hundreds of millions of euros from the time the intervention was made until the present. However, the extent of the health benefits will vary depending on the risk that is being controlled i.e. exposure to a given substance. The efficiency of enforcement of the FCM legislation and subsequent benefits to consumers appears to be below its potential.

Trade data does not provide clear evidence of enhanced intra-EU trade due to FCM legislation. There is some evidence that harmonisation has a positive effect on intra-EU trade at industry level, including savings on the preparation of dossiers for risk assessment. Similarly, estimates suggest that there are some cost savings for Member States from EFSA risk assessments. However, overall, cost savings from the EU legislation are limited and relate to the existence of specific measures, in particular for plastic FCMs.

Overall, costs to industry are estimated to be around 3% (EUR 3 billion) of the total turnover; the majority of those costs are spent on compliance (~2%), with a smaller proportion (~1%) spent on administrative costs. Costs vary depending on the sector involved and the role of the business in the supply chain. Compliance costs are borne principally by manufacturers and convertors, including dossier preparation, GMP and analytical testing.

Annual costs spent by EU Member States, through either implementation of EU rules or national measures are estimated at less than EUR 1 million per Member State. Costs are made up of staff time, annual control costs as well as some risk assessment work that is done at

national level. Annual costs spent by EU institutions are approximately EUR 3.4 million. This includes the risk management done by the Commission on EU legislation as well as training and audits; method development and support to Member States on controls and risk assessment work undertaken by EFSA.

For certain industry sectors, for whom there are no EU-specific measures, costs may be even higher (up to 10%) due to multiple national requirements. Unilateral action by Member States under safeguard measures provided for by the legislation has significantly increased costs. SMEs do not have the resources to submit dossiers to EFSA and many consider that costs linked to the FCM legislation are not proportionate to the size of companies.

On the other hand, the EU system of authorising starting substances in plastic FCMs also suffers from inefficiencies. This includes the time taken for authorisation to be given, taking into account the costs and resources to industry of the data generation and application process. EU resources needed for the plastics Regulation, including EFSA as risk assessor and the Commission as risk manager are unavailable for other material types, using the same approach. Efficiency gains could be made with a less specific approach as many substances are used in more than one material type. Moreover, the current approach is potentially sub-optimal, as it does not address the most hazardous substances migrating from all materials. Doing so could lead to greater efficiency through enhanced health gains whilst making use of existing relevant information such as that generated under the REACH Regulation.

Rules to protect consumers from potential risks arising from the migration of substances from FCMs remain relevant with citizens, who show an increased interest in food safety issues including those relating to FCMs. Trust in FCM safety standards appears reasonable to consumers but views from NGOs indicate that there is scope for further improvement. Evidence suggests that in some cases unintended use or reuse of FCMs is relevant for consumers, whereas appropriate labelling may be unclear or absent.

Businesses continue to need a consistent and predictable regulatory platform on which to produce, sell and trade their products across the EU with minimal burden whilst meeting their customers' needs. This is somewhat hampered in the absence of EU-specific rules beyond mainly plastic FCMs, which many stakeholders have anticipated. However, even for plastic FCMs, it can be concluded that actors further along the supply chain require more clarity as regards the safety of final FCM articles. Familiarity and understanding of the FCM legislation decrease with the size of the business, indicating a need for greater support for SMEs.

The evaluation points to a need for clearer, simpler rules that are more commensurate with Member States' resources, an emphasis on improving access to compliance documentation and increased training and transfer of knowledge. Further coordinated controls at EU level would also seem welcome.

New and evolving science are partially addressed, including support from the EURL-FCM in the implementation of the legislation and the development of analytical methodology. Similarly, EFSA has also worked on identifying emerging risks, including substances migrating from FCMs, and set up a network of experts to enhance collaboration between scientists involved in the risk assessment of FCMs to support and harmonise risk assessment practices.

Yet questions remain over the relevance of and need for all substances still authorised from risk assessment and management carried out decades ago; whether new and improved FCMs may be more forthcoming in an environment that better supports innovation. Furthermore, if

older substances are still used, it is likely that in many cases information generated under other EU chemicals legislation could be used in the prioritisation and regulation of substances in FCMs.

The EU FCM regime is also currently geared towards risk assessment and risk management of well-established chemistry, with a focus on defined starting substances to produce synthetic polymers to manufacture plastics. This approach has proved problematic in the implementation of legislation on AIM, where considerations beyond simply substances are needed. And while bio-based polymers are specifically addressed under the plastics Regulation, there are still clear gaps for materials for which no EU-specific measures have or even can be introduced, including materials used from more natural sources or that are more biodegradable – and in turn, potentially less inert.

Legislation concerning safe recycling of plastic FCMs does not yet fully address evolving technologies and needs to recycle not only other types of plastic and other types of materials, but also different approaches to recycling, including chemical recycling. Such technology is key to provide address future needs and challenges that cannot be addressed altogether with more traditional, mechanical recycling.

Such future needs are linked to growing consumer interests in environmental concerns and EU policy itself that pushes not only recycling but also the use of materials that are considered more environmentally friendly, such as those that are bio-based or possess enhanced biodegradable properties compared with more traditionally produced plastics.

The FCM Regulation itself and the specific EU rules adopted under it are generally internally coherent and function as intended. The main 'incoherence' exists between the objectives of the Regulation and Article 6, which has allowed Member States to introduce or maintain national measures that are often divergent and create uneven standards for protecting consumers and creating difficulties for trade on the internal market.

Inconsistencies also exist between EU-specific measures and the feasibility of ensuring compliance and enforcing the rules. The capacity for EFSA to evaluate a test methodology that is applicable in practice for all combinations of FCMS and food is limited. Furthermore, the EURL-FCM does not have the capacity to fully develop and supply a methodology to NRLs commensurate with the large number of substances for which SMLs are set. Accreditation of analytical methodology, which is burdensome, expensive and requires regular use of those methods is an even greater challenge.

For plastic FCMs, rules on multi-material multi-layer articles present problems, where some specific rules apply to plastic whereas national rules or no specific rules apply to other parts of the article. Complications arise from determining where NIAS has originated from, and which business operator has responsibility for ensuring compliance.

Concerning links with non-FCM legislation, the FCM Regulation is generally coherent with the General Food Law, including definitions and the use of risk analysis principles. It is also complementary to other EU legislation such as REACH, which aims to protect citizens from exposure to potentially harmful chemicals, but which is not specific enough to ensure that the presence and migration from FCMs is sufficiently risk assessed and risk managed. Similarly, the FCM Regulation complements EU legislation on other consumer products such as toys and cosmetics as well as medical devices, protecting citizens from many of the same chemicals and contributing to the overall limitation of exposure to certain chemicals where necessary.

Differences do exist in the approach taken under the FCM Regulation compared with approaches taken under REACH or other sector specific legislation such as cosmetics and toys. Whilst under the FCM Regulation, substances are assessed specifically for their use and migration from FCMs taking into account the estimated exposure, (specific risk approach (SRA)), many other pieces of EU legislation prioritise substances based on their hazard properties. REACH includes a more generic risk approach (GRA) with certain hazardous properties that are automatically prioritised for risk management. Although incoherence in practice is limited, the main consequence of this is a lack of *prioritisation* of safety matters in the FCM approach.

Regulation of substances under the FCM Regulation and the REACH Regulation may be confusing for stakeholders, as illustrated by restrictions on substances introduced in the latter because of environmental concerns, that cannot be taken into account in the former and continue to be authorised. Provisions introduced in the REACH legislation intended to regulate substances due to environmental concerns cannot currently be reflected in the FCM legislation. Given the risk assessment and management of many substances falling under both FCM legislation and the REACH Regulation, there is greater potential for stronger synergy between these regulations and work between the two EU Agencies.

Although no evidence exists per se that the current measures on FCMs are incoherent with the waste management legislation, the evaluation has identified that recent EU policies and requirements for the industry to increase recycling and reduce waste will create increased challenges to ensure the safety of FCMs through recycling and use of new materials. This will need to be monitored and it is likely that a future FCM policy will have to be designed with this in mind to ensure safety.

Apart from the system in the US, regulation of FCMs in the EU is relatively coherent with third countries, which in general have followed a similar approach to that of the EU. However, differences also exist and synergy gains could be made concerning key issues in future regulation of FCMs, such as chemicals of concern and regulation of more novel materials.

There is considerable EU added-value from regulation of FCMs at EU level compared with the situation at national level. In particular, the EU-specific rules in the plastics Regulation, including a Union list of authorised starting substances, additional compositional requirements, restrictions including SMLs and rules on verification of compliance and documentation in the supply chain have had positive effects on both the effectiveness and efficiency of regulating FCMs. They have provided equal protection of health for consumers across the EU as well as a level playing field for businesses.

Conversely, in the absence of EU-specific rules building on the basic requirements of the FCM Regulation and progressing harmonisation, non-plastic sectors appear to have struggled, which are discussed in both sections on effectiveness and efficiency. In the absence of EU-specific measures, national measures raise doubts about the safety of some non-plastic materials, create uncertainty and barriers to trade for businesses. Companies are required to invest in additional tests and to provide documentation in order to meet national requirements. The benefits of the EU's mutual recognition principle appear to be limited and the difficulties are higher for SMEs.

Annex 1: Procedural information

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

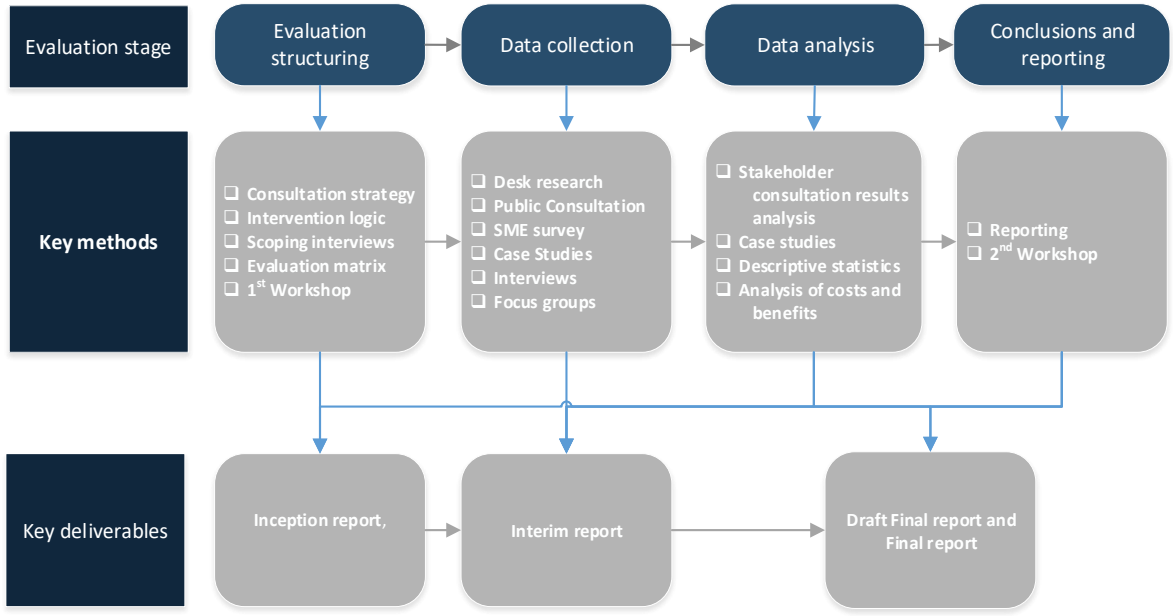
DG SANTE, PLAN/2016/436

2. ORGANISATION AND TIMING

During a 4-week period 28 November – 26 December 2017, all interested stakeholders were able to provide feedback on the FCM Evaluation Roadmap[148]. This was the first step of the consultation in order to receive feedback on the general consultation approach to the evaluation.

A tender for a supporting study was published in 2018 and a contractor was appointed. An overview of the organisation of their work is summarised in figure 5:

Figure 5: Overview of the organisation of the supporting study



The consultation period was launched in September 2018 with a stakeholder workshop and the open public consultation[37] for the evaluation followed on 11 February 2019. The consultation activities were carried out September 2018 – September 2019.

[148] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en

Within the Commission, an inter-service steering group (ISSG) was set up, including DG SANTE, DG ENV, DG GROW, SG, DG RTD, DG AGRI, DG TRADE, JRC and EFSA. Four meetings were held between February 2018 and September 2019 to appraise and discuss the progress of the supporting study as well as the final output. A final meeting to discuss this staff working document was held on 8 June 2021, which was also subject to an inter-service consultation in March 2022.

3. EXCEPTIONS TO THE BETTER REGULATION GUIDELINES

None

4. CONSULTATION OF THE RSB

Yes

5. EVIDENCE, SOURCES AND QUALITY

The evaluation relies largely on the following sources:

- Supporting study including all consultation activities described in annex 2;
- JRC baseline study;
- BTSF Workshop report on strengthening Member States' response to Union audits on FCMs;
- Study on the use of compliance documentation in official controls and in the supply chain;
- Correspondence and evidence submitted independently to the Commission prior to the start of the evaluation exercise;
- Other relevant evaluations and Fitness Checks carried out by the Commission, as referenced.

Annex 2: Stakeholder consultation

Prior to the start of the supporting study, a consultation strategy was developed, and stakeholders were mapped to identify relevant groups and to identify suitable consultation activities to reach out to these groups. A draft consultation strategy was published in the FCM Evaluation Roadmap. This was the first step of the consultation in order to receive feedback on the general consultation approach to the evaluation. A total of 26 stakeholders responded, including business organisations and NGOs, mostly related to issues with the legislation.

The objective of the consultation was to collect information, data, knowledge and opinions. Many participants of the consultation shared their experiences with the implementation of the regulation and provided additional supporting evidence. Information was collected on all five evaluation criteria: effectiveness, efficiency, relevance, coherence, and EU added-value. The main consultation activities consisted of the following:

- **A 12-week internet based public consultation** took place 11 February 2019 – 6 May 2019 to ensure transparency and accountability and gave all interested parties the possibility to contribute. The questionnaire was made available in all official EU languages;
- **An SME panel consultation** also took place 25 February 2019 – 20 April 2019 which collected the views of micro, small and medium enterprises (SMEs) on the FCM legislation;
- **Interviews** were undertaken with various key stakeholders and represented a main data collection source for the study. Approximately 40 organisations from Member States' competent authorities, NGOs (including consumer organisations), EU professional associations and experts were contributed to help build a comprehensive picture of the functioning of the FCM legislation;
- **Six Focus Groups** were organised aimed at gathering views from actors who are involved in the implementation of the provisions of the FCM Regulation, including representatives from Member States' competent authorities as well as Commission policy officials. The groups focussed on various topics ranging from enforcement and official controls of the legislation through to risk assessment, risk management approaches and coherence with other legislation;
- A number of **case studies** were also carried out, which fed into the analysis of the evaluation questions, providing illustrations of specific and real-life situations. These included applications for EU authorisation of substances, impacts of the EU legislation on SMEs and effects of national legislation in place of EU-specific rules.
- **Two workshops** also dovetailed the consultation activities, the first to introduce the process to stakeholders and the second to conclude it. All main stakeholders

attended including profession business associations, NGOs, Member States' competent authorities, scientific experts and other professionals involved in FCM regulatory compliance.

Public consultation[40]

The public consultation ran on the Europa website from 11 February 2019 to 6 May 2019. It was open to any interested individual and available in the 24 official languages of the EU. The consultation targeted citizens, experts and people with prior knowledge of the FCM legislation within and outside the EU. The final number of responses to the public consultation was 503.

The public consultation questionnaire was structured into three sections. The introduction section explored the general information of the respondent. Part I of the public consultation was addressed only to citizens, while Part II was targeted at experts or those with prior knowledge of the FCM legislation and working in the field. A factual summary report was prepared and published in July 2019[149].

Respondents live in more than 27 countries. The majority of replies were submitted by respondents from Belgium (74 responses that correspond to 15%), followed by France (13%) and Germany (13%) (figure 1 of the factual summary report). Of all the replies, 5% are from respondents in non-EU countries (Norway, Switzerland, Other). Out of 503 respondents, 97 are registered in the Transparency Register.

Overall, citizens represented the largest number of respondents to the public consultation (219; 44%), followed by businesses (204; 41%) and public authorities (37, 7%). Concerning the distributions of the organisations by size, most organisations identified themselves as "Large" (35%, 98), followed by "Medium" (23%, 64), Micro (22%, 61) and "Small" (20%, 56).

The first part of the public consultation targeted citizens (both EU and non-EU). Citizens were asked if they trust the safety of food contact materials, including food packaging, kitchenware, and tableware, sold in the EU (figure 4 of the factual summary report). The responses show a high level of trust. Most citizens trust the safety of FCMs to a reasonable (38%, 84 respondents) or to a large extent (35%, 76 respondents). Only 4% (8 respondents) of citizens do not trust the safety of FCMs sold in the EU.

Despite high trust in the safety of FCMs on the EU market, out of 210 respondents, most EU citizens responding (66%) do not know which authority is responsible for addressing complaints in cases of concerns about the safety of FCMs. Regarding citizens' perception of the development of food safety, 60% of EU citizens believe that the level of safety of

[149] https://ec.europa.eu/food/system/files/2019-07/cs_fcm_20190616_summary-report.pdf

food packaging sold in the EU has increased over the last 10 years (figure 5 of the factual summary report). Only 10% of respondents believe that the safety has decreased.

56.4% of responses received to the public consultation were from experts. Within the group of experts, businesses represent the largest group of respondents (72%). Besides businesses, this section of the consultation received contributions from public authorities (13%), NGOs (7%) and other experts (8%).

On average, 71% of respondents agreed that the scope of the FCM Regulation is generally clear and they indicated that it is obvious whether a product is an FCM or not (figure 6 of the factual summary report). NGOs are slightly less positive as majority of NGOs neither agreed nor disagreed with the statement (58%). Generally, experts consider the definitions provided by the FCM Regulation as sufficient and clear (figure 7 of the factual summary report). Majority of NGOs (89%), however, perceived the current definitions provided by the legislation as not sufficient.

Moreover, results show that the majority of businesses (71%) believe that in general it is not possible to demonstrate compliance with the general safety requirements set out in Article 3 of the FCM Regulation without having access to significant resources.

Finally, the majority of businesses, NGOs and public authorities are aware that the EU FCM legislation presents contradictions, gaps, overlaps and inconsistencies. A large majority of respondents (94% of the total number of respondents, across all categories) indicated that more harmonisation at EU level is desirable, compared to individual Member State legislation.

SME Panel consultation[100]

701 SMEs from 21 Member States provided their input via a dedicated survey. A factual summary report was prepared and published in July 2019. The majority of the respondents originate from four Member States: Poland (161 SMEs), Italy (103), Romania (86) and France (81). Four types of companies were involved in the survey: self-employed (45 replies representing 7% of the total number of responses), micro enterprise (223 replies, 33% of the total), small enterprises (212 replies, 31% of the total) and medium-sized enterprises (195 replies, 29% of the total).

The largest number of SMEs that responded to the survey declared to be active in the plastics, and paper and board industry (respectively, 67 and 64% of SMEs), followed by the glass, and metals and alloys industry (34 and 25%)[150]. Respondents were also asked to classify the sector in which they operate. A majority of SMEs that replied to the questionnaire classified themselves as food business operator - processor or manufacturer

[150] Multiple answers possible

of food products (42%). The second largest sector in which SMEs responding to the survey were active is as manufacturer of final articles or convertor (19%).

Participants were asked questions regarding their familiarity with the FCM Regulation. In total, the 38% of the SMEs declared to be fairly familiar with general safety requirements of the food contact material legislation, 24% very familiar, 22% a little familiar and 12% not at all familiar. Overall, 48% of SMEs indicated that they did not experience any difficulties in complying with the FCM legislation or in selling FCMs on the EU market in the past. 21% of respondents reported having encountered difficulties to comply with the regulation (9% rarely, 9% occasionally and 3% frequently).

Regarding the administrative costs stemming from the FCM Regulation for SME businesses, 79% of respondents indicated that the FCM Regulation represents less than 2% of their total administrative costs. The overall administrative burden stemming from the FCM Regulation appears to be rather small (none or less than 1%) across all SME types.

On average, 39% of respondents believe that the needs of their business are sufficiently addressed ('fairly' to 'very well') by the current FCM Regulation. The results show that medium-sized enterprises are slightly more positive (50% 'fairly' to 'well') than smaller businesses. When looking at the needs of different types of businesses, 47% of 'Food companies' and 46% of 'multi-stage entrepreneurs' believe that their business' needs are sufficiently reflected by the current FCM Regulation. This number is slightly lower for FCM providers with 37%.

Finally, a large majority of respondents indicated that more harmonisation at EU level would ensure better functioning of the EU internal market and could help to achieve higher and more uniform safety standards across Member States (respectively, 74 and 65%).

Focus groups[151]

Six Focus Groups were organised in the context of this study, aimed at gathering views from representatives from Member State competent authorities, the Commission, and policy officials from competent authorities and inspectors from enforcement authorities who are involved in the implementation of the provisions of the FCM Regulation. These are published on the evaluation webpage. The six topics covered were:

1. *Enforcement of the FCM legislation*

[151] Documents that were used or produced during some Expert Working Groups of the Member States on FCM to support some of the focus group activity is published on the evaluation webpage: https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en

A focus group on enforcement directly involved enforcement activities staff, such as inspectors and laboratory officials. Participants highlighted that the FCM legislation generally enables the authority to perform official controls on FCMs. However, there are several limitations and pitfalls that limit the effectiveness of the enforcement by Member States. Firstly, FCMs subject to specific EU measures (plastics in the first place) appear to be the most controlled sectors, in that precise limits are available for inspectors. On the other hand, non-harmonised sectors tend to be less subjected to control.

Other issues mentioned by participants were a general and widespread lack of resources, different backgrounds of inspectors, language barriers in the documentation (both provided by business operators and legal texts) and difficulties in controlling imported FCMs (including control of GMP). Finally, there is a consensus as regards the effectiveness of the JRC guidelines on kitchenware.

2. Official Controls in Member States

This workshop aimed at discussing findings and issues identified in the course of recent audits and to discuss common problems, good practices and methods for official controls in the FCM sector. The participants were asked to validate some of the findings from the public consultation. In the context of such consultation activity, competent authorities could express their views as regards the number of controls performed, resources and expertise, access to analytical methods and sanctions. Twenty competent authorities took part in the public consultation, and the results of five selected questions on enforcement were discussed during the workshop.

Although not statistically significant, the exercise provided a useful qualitative assessment of the agreement of the two groups on selected topics. Overall, the results of the group exercise largely overlap with those of the public consultation, depicting a general lack of resources for the enforcement of the FCM legislation, insufficient controls and inspections and inconsistencies of sanctions across Member *States.*

3. Internal coherence of FCM legislation and coherence with REACH

This focus group was organized with the aim of reflecting on the aspects related to internal coherence of the FCM legislation, as well as coherence with REACH. All participants agreed that the separation between risk management and risk assessment for FCMs is appropriate and necessary. Aspects related to size and capacity were identified as the root causes for not having risk assessment procedures in place in all Member States. Broadly speaking, risk assessments carried out at national level are usually aligned with the work done by EFSA; however, it has been reiterated that the different Member States approaches should be more aligned with each other's and with EFSA's approach. On this point, participants concluded that EFSA could provide some "guidance" for risk assessment done at Member State level in non-harmonised sectors, to enhance alignment.

As regards the publication requirements for risk assessments, most countries are in favour of a more transparent approach. EFSA's approach was considered appropriate by some of the participants, but not stringent enough for the others. It was mentioned once that guidance on the risk assessment from OECD (Organisation for Economic Cooperation and Development) is incomplete for FCMs. On the coherence with REACH, there was a consensus among participants on the importance of using data generated under REACH for FCMs [risk assessment]. However, all the groups agreed that the two regulatory systems are based on different principles (risk vs hazard based, migration vs tonnage) possibly bringing a different endpoint.

4. Effects of the lack of harmonisation

This focus group examined the effects of non-harmonisation and the implications of the absence of harmonised measures. As regards the achievement of both aspects of the legislation, there was no consensus among participants. In fact, whereas some participants agreed that the lack of EU-specific measures could hamper the achievement of both objectives, the rest argued that objectives are met even in the lack of harmonised measures, thanks to national legislation and other tools like industry self-regulation. Main reasons for not having national measures in place mentioned by participants are linked to limited knowledge, capacity and resources. This is especially the case for smaller Member States. Enforcement in non-harmonised sectors is perceived as particularly challenging by participants. In fact, if there is no specific legislation in place, controls tend to be lax or even absent. In absence of national legislation, Member States usually rely on BfR (German Federal Institute for Risk Assessment) recommendations, resolutions from the Council of Europe, the US legislation or legislation by other Member States. However, for enforcement purposes, it has been reiterated that is difficult to use such recommendations and resolutions, as they are not "hard legislation". Moreover, most of the national legislation is available only in national languages, and is sometimes not easily accessible and workable for inspectors.

As regards the application of the mutual recognition principle, participants showed reservation towards finding evidence that a product is legally marketed in another Member State, hence hampering the application of the principle. As a matter of fact, participants underlined that checking the compliance of FCMs in other Member States creates too much burden, due to the issues discussed above (e.g. language barrier, inspectors not trained in all Member State legislation, difficulty to access the legal text).

5. Risk assessment and risk management

This focus group aimed at discussing risk assessment and risk management procedures at EU and national level with representatives from Germany, Belgium, France and Netherlands, as well as with the Commission. As regards toxicological data requirement and exposure assessment, EFSA Note for guidance is generally followed in all countries participating in the focus group, albeit with some modification on a case-by-case basis.

The focus of the risk assessment has been debated: participants agreed that more focus should be given to the final article, yet recognizing the technical hurdles stemming from such approach. As regards transparency and publication of risk assessment outcomes, participants have different procedures in place, but it is generally recognized that more transparency would increase trust in the risk assessment outcome. Limited resources and expertise to carry out risk assessment has been highlighted as a limiting factor for the evaluation and re-evaluation of substances.

As regards risk management, timelines and procedures may differ among participants, and it has been recognized as a lengthy phase due to the involvement of stakeholders. A more effective exchange of information among countries, but also among risk assessment and management bodies within the same country has been recognized as a tool to improve effectiveness and efficiency of both processes.

6. External coherence of the FCM legislation

This focus groups explored the coherence of the FCM legislation with officials from the Commission, i.e. representatives from DG ENV, DG JUST, DG SANTE and SG.

The items discussed covered a review of the outcomes of the Public Consultation related to coherence and the overall coherence of the provisions of the FCM Regulation with other legislations, with a review article by article under the point of view of coherence (i.e. gaps, inconsistencies with other legislation).

Results of this focus group fed into the Case study on Coherence, in that the focus group represented a substantial basis for the above-mentioned case study.

Targeted interviews

Interviews encompassed all relevant stakeholders from EU Member States, as well as other relevant countries including Switzerland and Norway. An overview of the stakeholders interviewed can be found listed below:

Stakeholder type	Stakeholder
EU institutions	1. EFSA
	2. ECHA
International bodies and third countries	3. China
	4. Zürich Laboratory
	5. FDA
	6. Council of Europe
MSCA	7. Greece
	8. Ireland
	9. Netherlands
	10. Belgium

Stakeholder type	Stakeholder
	11. Slovakia
	12. France
	13. Italy
	14. Germany
	15. Denmark
FCM associations	16. CEPE and MPE
	17. Flexible Packaging
	18. FEICA
	19. CEFIC
	20. FEC
	21. MPE + Cross Sector Group
	22. CEPI
	23. EuPC
	24. ECMA
	25. ETRMA
	26. APPLIA
	27. Plastics Europe
	28. SME United
	29. FoodDrinkEurope
	30. Eurocommerce
Experts	31. Laurence Castle
	32. Maria Rosaria Milana
	33. Karla Pfaff
NGO	34. HEAL
	35. BEUC
	36. ChemTrust
Compliance laboratories and law firms	37. Smithers Pira
	38. Intertek
	39. Steptoe
	40. Keller & Heckman

Overall, 40 interviews have been performed, excluding those performed in the scope of the case studies. Questionnaires for interviews have been customised for each interview, thus allowing to focus on the most relevant topics for each interview.

Nine Member State competent authorities were interviewed. The lack of resources allocated to FCMs has been recognised, thus possibly hampering the implementation of the legislation in Member States. Issues related to enforcement (e.g. inspections and

controls, enforcement of FCMs with no specific EU measures, sanctions, etc.) have been extensively discussed with competent authorities, as well as the occurrence of national legislation and its effects on both the internal market and the protection of human health. Differences in terms of approaches, resources and priority have been identified among Member States.

Professional associations generally recognised the positive developments brought by the FCM legislation, especially in harmonised sectors. However, business operators often complained that the lack of harmonisation could represent a burden to companies, due to multiple national legislation comply to. The mutual recognition principle has been a recurrent topic for discussion, and business operators often pointed out that such principle is often not applied. However, only a few cases of non-application of the principle have been reported during interviews.

NGOs interviewed remarked that the lack of harmonised measures in all FCM sector represents a gap that negatively impact the protection of human health. Issues like the cocktail effect and multiple sources of exposure have been recalled, as missing in the current approach. Moreover, the need for more instructions and information for consumers and information has been mentioned.

Workshops[152]

Two workshops were organised in the context of the study. The first introductory workshop was held on 24th September 2018 and it brought together representatives from Member State and EFTA competent authorities, the European Institutions, and policy officials from governmental and non-governmental organisations, European Professional Associations and regulatory consultancies. Different stakeholders (NGO and industry representatives) and professional associations outlined diverse positive and negative aspects of the FCM legislation. The lack of harmonisation was identified as the main issue. Other aspects of the FCM Regulation that should be improved and addressed are its coherence with the circular economy initiative and REACH information, the lack of resources for FCM controls and the clarity of the analytical methods and tests.

The second workshop was held on 9th September 2019 and represented an occasion to present and discuss the preliminary findings of the draft final report with relevant stakeholders. Around 140 participants were present at the workshop, including representatives from 19 Member States as well as Norway and China, from the Commission including the JRC (EURL-FCM), EFSA and representatives from professional associations, NGOs and regulatory support businesses.

[152] Documents supporting the workshops including a recording of the inaugural workshop can be found on the evaluation webpage https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en

Overall, participants agreed with the preliminary findings of the study and they welcomed the conclusions. However, it has been highlighted that some of the numbers presented in the efficiency section require additional verification and overall traceability of findings shall be enhanced. The workshop also represented a last call for data and evidence; as a matter of fact, participants were given the possibility to provide last feedbacks both during and in written form after the workshop.

Case studies[153]

Six case studies were performed within the scope of this study, entailing different data collection tools and consultation activities (i.e. interviews, desk research, focus groups). Notably, synergies have been sought among case studies and focus groups, to enhance triangulation of data and findings. As an example, findings of the focus groups on enforcement and coherence fed into the related case studies. Moreover, inputs from the public consultation as well as from the SME survey have been considered.

Case study "From application to market"

Two companies were interviewed for this case study. Due to confidentiality matters, the identity of the companies is not disclosed.

Case study "Lack of harmonisation"

This case study mainly relied on desk research. An interview with the German Rubber Association (Gesamtverband Kunststoffverarbeitende Industrie e.V.) was performed.

Case study "Compliance along the supply chain"

For the plastic and paper subcases, a written questionnaire was distributed to individual companies via the pertinent EU professional associations. For plastics, this included PlasticEurope and EuPC (European Plastic Converters Association).

For the subcase on kitchenware and appliances, a business operator replied to the written questionnaire and two professional associations were interviewed (FEC (Federation of European manufacturers of Cookware and cutlery) and APPLiA (Home Appliance Europe).

Case study "Enforcement"

Several competent authorities have been consulted in the course of these case studies through interviews as well as a written questionnaire (see focus group on enforcement).

[153] Details of case studies are also published in annex 2 to Ecorys' report, available at https://op.europa.eu/en/publication-detail/-/publication/ccbd784d-bc0c-11ea-811c-01aa75ed71a1

Country	Authorities
Belgium	Federal Public Service/Health, Food chain safety and Environment
Croatia	Ministry of Health/Directorate of Sanitary Inspection
Denmark	Danish Veterinary and Food Administration (DVFA)
EU	Council of Europe, European Directorate for the Quality of Medicines & HealthCare (EDQM)
Germany	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Greece	Hellenic Food Authority (EFET)
Hungary	National Food Chain Safety Office
Ireland	Food Safety Authority of Ireland
Italy	Ministry of Health/Direzione generale per l'igiene e la sicurezza degli alimenti e la nutrizione
Lithuania	Ministry of Health/Nutrition and Physical Activity Division
Poland	Chief Sanitary Inspectorate
Spain	Agencia española de Consumo, Seguridad alimentaria y Nutrición (AESAN)
Switzerland	Kantonales Labor Zürich
UK	Fera Science

Case study "Small and Medium Enterprises"

Two SMEs were interviewed in the context of this case study. Findings from interviews have been complemented with inputs from the SME survey

Case study "Coherence of the FCM Legislation"

Inputs for this case mainly came from desk research, inputs from the public consultation and the related focus group with participants from DG ENV, DG JUST, DG SANTE and SG. Inputs from DG GROW were also taken into account.

Annex 3: Methods and analytical models

A detailed description of the methods used to derive cost and benefit estimates made for this evaluation have been published as part of the supporting study (Ecorys study) as Annex 3 Methodological Annex and Quantification of costs[154] and Annex 4 Methodological Annexes - Composite Index[155].

Quantification of costs

Due to data limitations, the use of different estimation techniques was necessary. The combination of a bottom-up and top-down approach to assess costs for businesses was applied.

For the bottom-up approach, the Standard-Cost model was used. While the main purpose of the model is to assess administrative costs, its core formula and elements were applicable to any type of direct costs.

$$Cost = \sum P * Q$$

According to the core equation of the model, costs are the sum of all prices (P) times the quantity or number (Q) by which these prices occur. Where sufficient data was available, this equation is used to estimate costs linked to the FCM legislation.

As data availability did not always allow to assess costs this way, a top-down approach was also applied. This usually tried to derive the costs linked to FCM legislation from a cost estimate that was already available from previous research. The analysis then tried to assess the share of costs that could be linked to FCM legislation.

$$Cost = C_R * S_{FCM}$$

The costs are the product of reported costs (C_R) multiplied by the share of these costs attributable to the FCM legislation (S_{FCM}). This share was obtained from research, interviews with stakeholders and other consultation activities, notably the surveys and case studies.

The assessment of costs was undertaken for different industry sectors (plastics, glass, ceramics, others) and looked in particular at the following cost categories:

- Compliance costs
- Implementation costs

[154] https://data.europa.eu/doi/10.2875/045961
[155] https://data.europa.eu/doi/10.2875/028503

- Dossier preparation
- Administrative costs

Composite index

Benefits were mostly not quantifiable in a systematic and uniform manner in the present context. Product and substance specific studies did not offer possibilities for meaningful generalisations that would clearly link changes to the FCM Regulation. However, (mostly) qualitative information was available in audits reports, research reports and institutional memories. These were combined and the resulting qualitative information and existing quantitative data were aggregated through a set of composite indices.

The regulation has two key objectives:

1) Protect consumer health and the interests of consumers, and
2) Facilitate the functioning of the single market.

The composite index was used to get a better understanding of the first of the two objectives, which forms the upper level of the composite indices. A second level is made of sub-indices. These were derived from the intervention logic and a clear definition of the ideal implementation of the FCM Regulation. Finally, each sub index was constructed from a set of specific criteria.

The criteria were used as proxies to measure beneficial effects of the regulation. Based on information available from reports and consultation activities, a score was assigned for each of the criteria. Based on this, weighted scores were generated per Member State per sub-index and composite index. This approach allows a detailed assessment of the performance of individual Member States to identify the benefits of the FCM Regulation as well as areas where the regulation did not deliver as expected.

Three factors contributed to the protection of consumer health: prevention, controls, and reaction. These three factors formed the sub-indices for this objective and could be split into several criteria. Preventive factors were the existence of a positive list that only authorised the use of substances proven not to be harmful as well as authorisation mechanisms that test substances for their properties. Aspects linked to the enforcement of the FCM Regulation, namely controls helped to ensure that industry is compliant. Mechanisms to swiftly react to identified risks to consumer health also contributed to ensure the benefits of the FCM Regulation.

The analysis was performed for each Member State. The analysis and aggregation of the composite indices consisted of several steps:

Step 1: Scoring criteria

A reasoned score was attributed based on the operationalisation of the criterion. The judgement was based on the evidence collected from the specified sources. Scores were in the range between 0 and 5. If there was no information available for a given criterion,

no value is assigned, and the criterion is taken out of the assessment. Member States where information is very limited were excluded from the analysis.

Step 2: Weighting of scores

The formula used to calculate the weighted country indices:

$$I_i = \sum C_{in} M_{in}$$

I denotes the corresponding index, *C* the criterion, *M* the multiplier, *i* the Member State and *n* the ID of the criterion.

Step 3: Interpretation of scores

The weighting of sub-indices yielded the final index value per Member State. The higher the final score, the greater the benefits of the regulation were expected to be. A high score indicated that the regulation contributed significantly to the protection of the health of consumers, while a value of 0 indicated that the regulation had not generated benefits in the particular country. A score of at least 70% of the possible score was considered "good". A score below 60% suggested that the benefits for human health are limited.

Annex 4: Overview of costs and benefits identified in the evaluation

		Citizens/Consumers		Businesses		Administrations	
		Qualitative	Quantitative/monetary	Qualitative	Quantitative/monetary	Qualitative	Quantitative/monetary
Benefit: human health	Continual health benefits from reduction in exposure to hazardous substances via food, expected	Not possible to quantify but for certain substances likely to be in the magnitude of hundreds of millions of Euros					
Benefit: Dossier preparation	Costs savings by having EU level authorisation			Increased legal certainty and intra-EU trade	Based on the average number of risk assessments needed at national level, EUR 162,000 per dossier or EUR 15.4 million 2014 - 2018	Enhanced cooperation and exchange of information among competent authorities in the Member States	Between EUR 450,000 and EUR 1.2 million per year for Member States who otherwise undertake their own risk assessment work
Cost: FCM	Annual costs to				Compliance costs		

		Citizens/Consumers		Businesses		Administrations	
		Qualitative	Quantitative/monetary	Qualitative	Quantitative/monetary	Qualitative	Quantitative/monetary
plastics industry	plastic FCM businesses				(dossier preparation, testing, GMP) up to ~ EUR 650 million Administrative costs up to ~ EUR 230		
Cost: FCM businesses	Annual costs to all FCM businesses				~ EUR 3.1 billion		
Cost: Controls and inspections	Annual costs to Member States for controls and inspections, expected						Up to EUR 23 million, including staff costs and resources to undertake controls
Cost for EFSA	Annual cost for EFSA to undertake risk assessments						~ EUR 600,000, including staff costs
Cost for EC	Annual cost for risk management and technical support						~ EUR 2.3 million including staff costs, BTSF activities and operational costs by JRC

Annex 5: Supporting tables and diagrams

Figure 6: Simplified structure of the organisation of an FCM supply chain

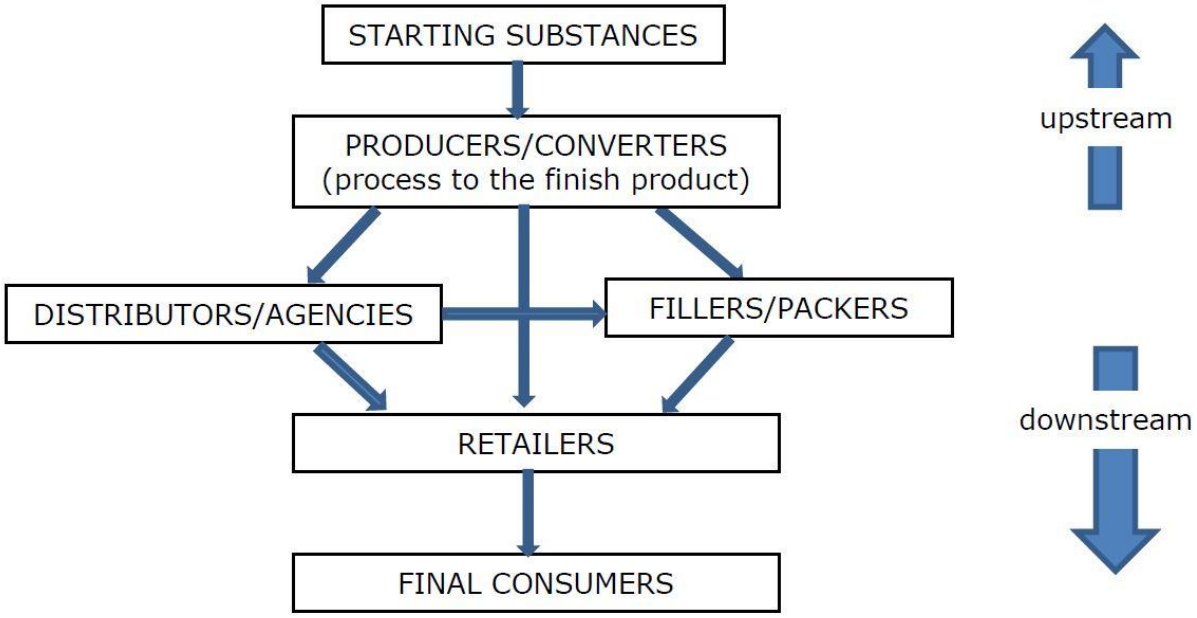


Figure 7: Representation of a Multi-material Multi-layer presented by the Industry Cross Sector Group.

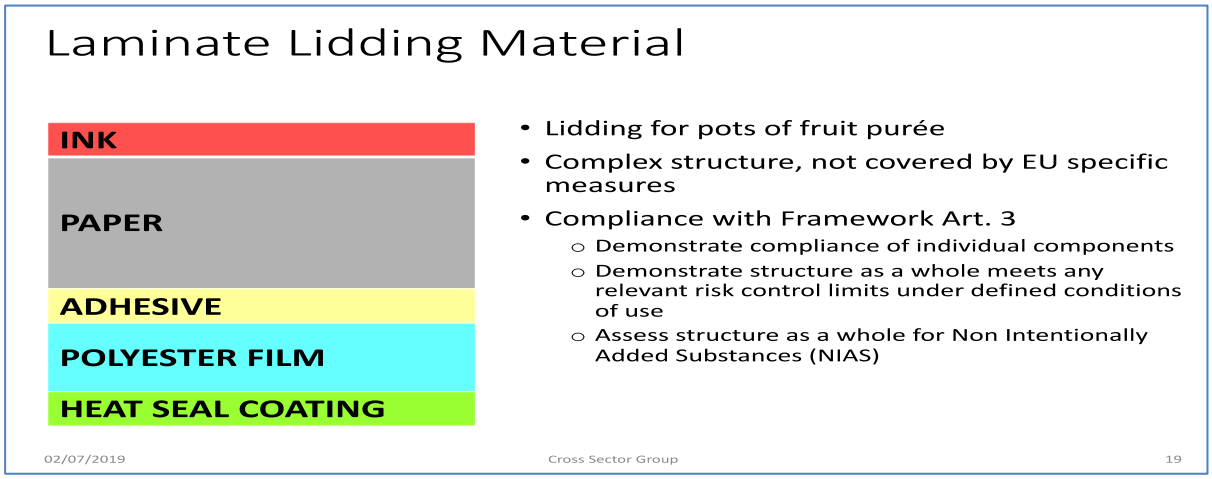


Figure 8: GB 9685-2016 Standards for Uses of Additives in FCM. Updates on FCM Standards: Developments in China. 5th Symposium for safety of food contact material

Appendix B Total Specific Migration Limit (SML(T))

SML(T) group restriction No.	CAS No.	Substance name	SML (T) (mg/kg)	group restriction Specification
1	75-07-0	乙醛	6	以乙醛计
	105-38-4	丙酸乙烯酯		
2		硬脂酸与乙二醇的酯	30	以乙二醇计
	107-21-1	乙二醇		
	111-46-6	二甘醇		
3	108-31-6	顺丁烯二酸酐 (又名马来酸酐)	30	以马来酸计
	110-16-7	马来酸 (又名顺丁烯二酸)		
4	105-60-2	己内酰胺	15	以己内酰胺计
	2123-24-2	己内酰胺钠盐		
5	77-62-3	2,2′-亚甲基二[4-甲基-6-(1-甲基环己基)]苯酚	3	以物质之和计
	4066-02-8	2,2'-甲亚基双(4-甲基-6-环己基苯酚)		

Figure 9: SME opinion regarding harmonisation at EU level

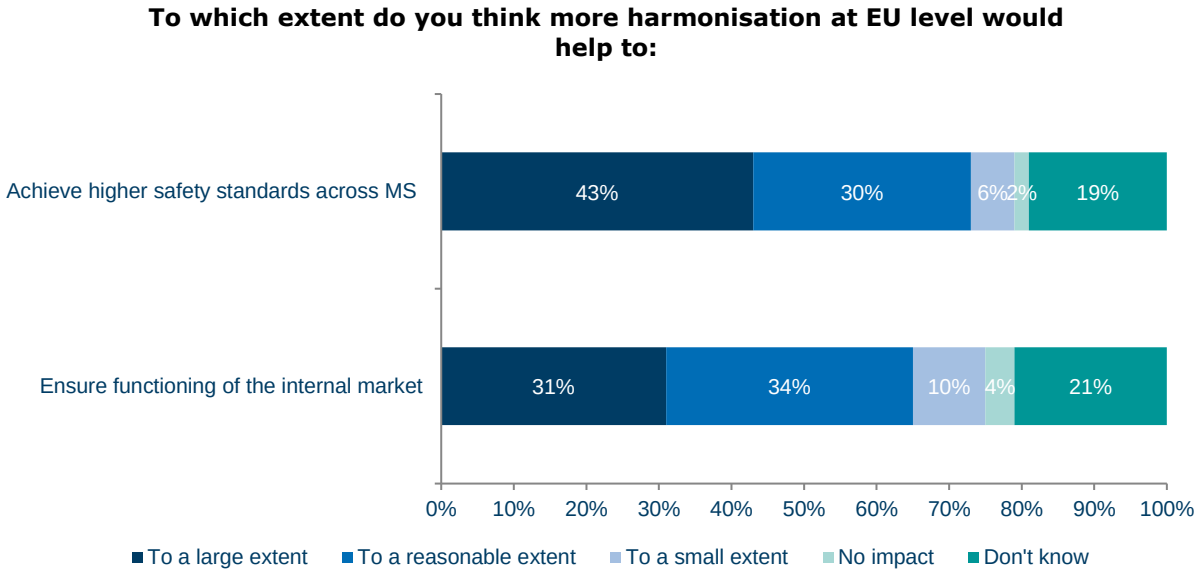


Table 2: EU manufacturing sales per annum of different packaging materials, cutlery and FCM machinery and revenue share by size of enterprise. SME shares may also include micro enterprises. JRC 'baseline' study.

Material	EUR Million	% EUR Small enterprises	% EUR Medium enterprises	% EUR Large enterprises	Source
Plastic	30 029	26	41	33	Pira 2013
Paper	26 713	30	35	35	Pira 2013
Glass	7157	13	19	68	Pira 2013
Metals	7068	16	42	26	Pira 2013
Printing inks	1300	6	14	80	EuPIA
Cork	1216	69	21	10	Pira 2013
Adhesives	1200	35	15	50	FEICA
Ceramic & porcelain	915	43	19	38	Pira 2013
Wood	713	74	17	9	Pira 2013
Rubber	500	35	15	50	ETRMA
Varnishes & coatings	400	5	0	95	CEPE
Cutlery	202	50	30	20	Pira 2013
General purpose machinery	11 134	24	33	43	Pira 2013
Special purpose machinery	12 572	27	32	41	Pira 2013

Table 3: Overview of material specific national rules and tools. From JRC 'Baseline' report[6]. CoE means Council of Europe.

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
Multi-materials	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

Material	Positive List	Negative list	SML	OML	Limits for substance quantity	Details on GMP	DoC & supporting docs	Basis for sanctions	Basis for enforcement
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

Table 4: Common substances regulated by different Member States: JRC 'baseline' study.

Material	No. of substances regulated in national rules	Substances in common ≥ 3 Member States
Adhesives	1323	9 (0.7%)
Printing inks	5214	34 (0.6%)
Ion exchange resins	387	0
Varnishes	1721	88 (5%)
Cork/wood	168	19 (11%)
Paper & board	1710	147 (9%)
Rubbers	1028	185 (18%)
Silicones	336	37 (11%)

Table 5: Overview of country performance on the composite index on health benefits +: Score above 70%; 0: Score above 60%; -: Score below 60% of potential score *Assessment based on a limited number of data points. From Ecorys report, methodological annex 4, composite index[95].

Country	Prevention	Control	Reaction	Score
C 1	+	+	0	72%
C 2	+	-	+	65%*
C 3	-	+	+	66%
C 4	-	0	+	70%
C 5	-	+	+	74%
C 6	+	+	+	76%
C 7	-	0	+	63%
C 8	-	+	+	72%
C 9	-	-	+	44%*
C 10	-	-	+	57%
C 11	-	+	+	71%
C 12	-	+	+	64%*
C 13	-	0	+	62%
C 14	-	+	+	62%*
C 15	-	+	+	75%
C 16	-	+	+	71%
C 17	-	0	+	53%*
C 18	-	+	+	78%
C 19	-	+	+	73%
C 20	+	0	+	72%
C 21	-	-	+	65%
C 22	-	-	+	44%*
C 23	-	+	+	70%
C 24	-	+	+	79%

Country	Prevention	Control	Reaction	Score
C 25	+	+	+	80%

Table 6: Estimated cost reduction for industry due to harmonised risk assessments Source: Ecorys. Data on the number of applications for specific measures submitted to EFSA is taken from EFSA's Register of Questions from 2014 – 2018. From Ecorys report, methodological annex 3, quantification of costs[106].

	Scenario 1	Scenario 2	Scenario 3
Avg. admin cost of dossier	EUR 60 000		
Total number of applications	95		
Multiplier	1	2	3.7
Total cost	EUR 5.7 million	EUR 11.4 million	EUR 21.1 million
Total cost savings	**None**	**EUR 5.7 million**	**EUR 15.4 million**

NB. Scenario 1 represents the administrative cost for submission of one dossier, either to a Member State or in the case of substances used in plastic FCMs, to EFSA. The cost is the same in cases where one Member State assesses and authorises a substance and all other Member States accept that assessment, including those who do not have specific rules on the substance. No specific examples were identified in this scenario. The total administrative cost of submitting the 95 dossiers to EFSA for substances used in plastic between 2014 and 2018 is estimated to amount to approximately EUR 5.7 million.

Scenario 2 represents the situation where industry must submit data for the assessment of a substance twice, for two Member States to authorise the same substance. In this case, the administrative costs are therefore double and costs savings amount to EUR 60,000 per substance assessment or EUR 5.7 million over the period 2014 – 2018 for 95 substances by having one EU risk assessment. Scenario 3 uses the average of 3.7 Member States who perform risk assessments per material group and therefore represents the average scenario when applicants wish to market their product in the EU, in the absence of EU-specific rules (i.e. for non-plastics). Administrative costs for submitting a dossier are assumed to multiply by 3.7 and costs savings amount to EUR 162,000 per substance or EUR 15.4 million over the period 2014 – 2018 for 95 substances by having one EU risk assessment.

Table 7: Overview of estimated cost savings for Member States' competent authorities for risk assessments. From Ecorys report, methodological annex 3, quantification of costs[106].

	Scenario 1	Scenario 2	Scenario 3
Number of risk assessments	1	2	3.7
Total costs for authorities	EUR 450 000	EUR 900 000	EUR 1.6 million
Cost savings	None	EUR 450 000	EUR 1.2 million

Table 8: Overview of estimated costs and extrapolated estimates for the industry overall. *For cork, wood, and machinery, it was assumed that compliance costs amount to 2% of turnover. **JRC baseline Report. From Ecorys report, methodological annex 3, quantification of costs[102].

Sector	**Turnover ****	**Compliance costs**		**Administrative costs**		**Total costs**	
	EUR million	Share of turnover	EUR million	Share of turnover	EUR million	Share of turnover	EUR million
Plastics	30 000	2.1%	650	0.9%	230	3%	878
Ceramics	915	0.001%	0.01	0.009%	0.08	0.01%	0.09
Glass	20 000	0.1%	7.5	0.04%	4	0.1%	11
Adhesives	1450	2.0%	29	*N/A*	*N/A*	*N/A*	29
Printing inks	1700	10.0%	170	*N/A*	*N/A*	*N/A*	170
Metals & alloys	10 000	5.0%	500	*N/A*	*N/A*	*N/A*	500
Paper & board	26 713	4.0%	1069	*N/A*	*N/A*	*N/A*	1069
Rubber	500	2.0%	10	*N/A*	*N/A*	*N/A*	10
Coatings	400	2.0%	8	*N/A*	*N/A*	*N/A*	8
Other sectors*	25 600	2.0%	512	*N/A*	*N/A*	*N/A*	512
Total	**117 000**	**2.5%**	**2,955**	***N/A***	***N/A***	**2.7%**	**3 187**

Table 9: Overall estimated compliance costs for plastics sector. From Ecorys report, methodological annex 3, quantification of costs[106].

Costs	**Lower bound**	**Upper bound**
Compliance costs	154 300 000	650 000 000
Administrative costs	58 500 000	227 900 000
Total	**212 800 000**	**877 900 000**
Share of turnover	**0.7%**	**2.9%**

Table 10: Overview of strategies to calculate dossier costs. *Surrogate data from PlasticsEurope. From Ecorys report, methodological annex 3, quantification of costs[102].

Source	PlasticsEurope	Case study 1	Own computation	Expert example
Cost items	EUR	EUR	EUR	EUR
Toxicity testing				
Lower bound	150 000		21 000	50 000
Central estimate			447 000	155 000
Upper bound	2 000 000		1 080 000	1 750 000
Analytical testing				
Lower bound	30 000		*30 000**	80 000
Upper bound	80 000		*80 000**	100 000
Resources				
Lower bound	20 000		*20 000**	9000
Upper bound	100 000		*100 000**	50 000
Total dossier				
Lower bound	200 000	300 000	71 000	139 000
Upper bound	2 180 000	400 000	1 260 000	1 900 000

Table 11: Estimates of costs for compliance activities (excl. dossier preparation) by company size. * Since the sample of companies only contained medium and large companies, it was necessary to extrapolate estimates for small companies. **Based on the number of plastic packaging companies in the EU-28. From Ecorys report, methodological annex 3, quantification of costs[102].

Compliance cost	Small	Medium	Large	Total**
Establishing GMP				
Min EUR	*2000**	40 000	40 000	**54 100 000**
Max EUR	*23 500**	100 000	100 000	**281 300 000**
Analytical testing				
Min EUR	*7500**	31 000	64 000	**93 300 000**
Max EUR	*31 000**	100 000	150 000	**347 100 000**

Table 12: FTEs and costs per company by size, and total annual costs for industry. From Ecorys report, methodological annex 3, quantification of costs[102]. Weighted average labour costs = EUR 35,790

Administrative costs	Small	Medium	Large	Total
Numbers				
Min FTE	0.1	0.6	2.6	---
Max FTE	0.6	1	6	---
Costs				
Min EUR	3600	21 500	93 100	58 500 000
Max EUR	21 500	35 800	214 700	227 900 000

Table 13: Some of examples of substances authorised at national level for rubber FCM (Ecorys report).

Substance	Authorisation
Acrylic acid	DE, F, I
zinc di(benzothiazol-2-yl) disulphide	DE, F, I, NL
Benzothiazole-2-thiol	DE, NL, F
5-vinylnorborn-2-ene	NL, F
Dibenzyldithiocarbamic acid, zinc salt	NL, F
Dibenzolyl peroxide	NL, F
Diphenylamine, styrenated	DE, NL, F

Table 14: Overall costs of FCM legislation for the EU-28. From Ecorys report, methodological annex 3, quantification of costs[102]

	Lower bound	Upper bound
Implementation of EU rules	EUR 2.4 million	EUR 3.2 million
Implementation of national legislation	EUR 1.3 million	EUR 1.8 million
Controls	EUR 10.0 million	EUR 18.0 million
Total	**EUR 13.7 million**	**EUR 23 million**

Annex 6: Case examples

Case example 1

An example of problems encountered on the scope of FCMs

The discussion is relevant for both safety as demonstrated by studies showing migration of hazardous substances from paper napkins[156,157] as well as the functioning of the market. The latter is exemplified by a case presented to the Commission from a business affected by competitors who were not taking steps to ensure that paper napkins were food contact safe. In this example, different interpretations from businesses and Member States' competent authorities were therefore demonstrably creating conditions of inequality as regards placing FCMs on the EU market. Many examples have been highlighted by businesses and Member States in recent years, including questions over the need for compliance documentation for plastic table mats as well as more novel products, such as food grade colorants intended to be used in homes printers in order to apply patterns or decoration to cakes.

Case example 2

An example of deterioration of organoleptic characteristics

In 2018, Denmark performed sensory tests of drinking bottles and cups - 22 samples of drinking bottles (for water) and 3 samples of cups. The DVFA enforcement laboratory test for organoleptic changes was based on standards for testing (ISO 13302:2003, Nordic Committee on Food Analysis NMKL procedure no. 19). The test conditions (food simulant, contact time and temperature) reflect the conditions of use of the material. The result of the testing showed deterioration of organoleptic characteristics of water in contact with plastic bottles from the Netherlands. This led to withdrawal from the market of the product.

The manufacturer provided a DoC and results from a sensoric test for three other bottles (considered to be representative for the tested bottle). The test method applied was comparable to the DFVA test but included 5 and not 8 participants in the panel. Furthermore, the scale for assessing if the product was compliant was different from the approach of the DFVA. The manufacturer referred to the Regulation (EC) No 764/2008 on the mutual recognition of goods lawfully marketed in another Member State and claimed that the lack of a standardised method for testing organoleptic characteristics was creating uncertainty.

Case example 3

Ageing of the Union list of authorised substances

The only legal requirement to update assessments and authorisations is placed on industry,

[156] https://www.bfr.bund.de/cm/349/primary-aromatic-amines-from-printed-food-contact-materials-such-as-napkins-or-bakery-bags.pdf
[157] https://www.tandfonline.com/doi/full/10.1080/19440049.2016.1184493?scroll=top&needAccess=true

who must inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance. However, only two such notifications have been made to the Commission in recent years whereas scientific information has become available on substances such as phthalates and styrene and on which, following requests from the Commission, EFSA has given updated opinions.

Another example is that of 'untreated wood flour and fibres' (FCM No 96), which is presently authorised as an additive in plastic FCMs. The substance was included in the list of additives for plastic FCMs by Directive 95/3/EC[158], based on the assumption that it is inert. However, recently it has not been possible to establish the basis for this conclusion and doubts could not be resolved over which plant species and plant parts may be considered as wood and would therefore be in the scope of this authorisation, as well as over the actual inertness of untreated wood flour and fibres when added to a plastic. Therefore, the Commission provided EFSA with a mandate to address these questions, and to assess in particular whether the authorisation of untreated wood flour and fibres would still be in accordance with the FCM Regulation.

The opinion adopted by EFSA concludes that wood cannot be considered inert per se, and considers that presently available information is insufficient to support that the authorisation of this substance is in accordance with the FCM Regulation. EFSA also concluded that given the chemical differences in composition of wood materials, the safety of migrants from these materials must be evaluated on a case-by-case basis, considering beyond species also origin, processing, treatment to make it compatible with the host polymer and assessment of the low molecular weight constituents migrating into food.

Case example 4

An illustration of the NIAS issue

The issue of NIAS can be illustrated by the historical case of azodicarbonamide (ADC) from the early 2000s. ADC had been authorised as a blowing agent of PVC in Directive 2002/72/EC[159], the precursor of the plastics Regulation. Prior to its authorisation, several known degradation products of ADC had been evaluated for their safety. One degradation product, semicarbazide (SMC) was not known to the evaluators at the time, and therefore it was not included in the evaluation. Consequently, when SMC was detected by an enforcement laboratory, its origin was not known, which in turn caused concern, including in mainstream press[160]. This case illustrates the importance of having available full information - communicated by the chemical industry - on the stability and of the reactivity of the starting substance for the evaluation of NIAS. If the full pattern of reaction products of ADC had been known, there would have been no ADC crisis. However, often the formation of reaction products cannot be anticipated, as it frequently depends on many parameters in the production process of polymeric materials. This remains a major obstacle to ensuring compliance of the final FCM with Article 3 of the FCM Regulation and therefore hampers the effectiveness of

[158] http://data.europa.eu/eli/dir/1995/3/oj
[159] http://data.europa.eu/eli/dir/2002/72/oj
[160] http://news.bbc.co.uk/2/hi/health/3194284.stm

the legislation.

Case example 5

Lack of transfer of information in the supply chain

'Glymo' is a substance authorised in plastic FCMs, but its use is severely restricted based on a 2017 EFSA opinion[161] as the substance has genotoxic potential. This means that basic *in vitro* tests show it can damage genetic information and may cause mutations leading to cancer. Under REACH this is being further addressed in order to conclude on the genotoxicity of Glymo[162].

Glymo belongs to a group of very similar epoxy silanes and is used to provide a chemical bond between inorganic materials and polymers. In the authorised application for plastics the substance reacts with the surface of the glass fibres and with the polymer. Therefore, a very strong bond is formed between the glass fibre and the plastic. EFSA considered this use safe, because the residue of unreacted Glymo on the fibre is negligible, and it is added to low diffusivity plastics.

However, the publication of the EFSA opinion stimulated awareness of this substance and its genotoxic potential. There are many more applications of Glymo, such as in adhesives, coatings and other multi material materials, to bind a polymer to an inorganic substrate. However, such use is not automatically safe as it is in the authorised use in glass fibres.

A meeting between the Commission, Member States and industry on 2 May 2019 confirmed wide use of the substance, with migration exceptionally peeking well above its detection limit of 10 ppb. On the basis of the presently available information, the migration of the substance and its reaction and decomposition products should be well below 0.15 ppb in accordance with current EFSA guidelines on risk assessment.

A producer of the substance said it first became aware of its potential genotoxic nature around 2000, but it only acted recently "on the basis of the EFSA opinion". Based on the reactions from the industrial users of Glymo, sufficient information in the supply chain was lacking. In some cases, the users only had just become aware of its presence in their products. The example demonstrates a lack of information being passed on in the supply chain.

Case example 6

Mutual recognition issues

- Additional specific tests are required in Italy to show that FCM paper and board comply with Italian legislation, although the supplier is able to demonstrate the paper complies with rules in the origin Member State and in all other Member States. The costs of the testing amount to approximately EUR 700, which is relatively low for the company involved but may be prohibitively high for small businesses. This example shows that the requirement for additional testing does not

[161] EFSA Journal 2017;15(10):5014; Safety assessment of the substance [3-(2,3-epoxypropoxy)propyl]trimethoxy silane, for use glass-fibre-reinforced plastics in food contact materials (CAS No 2530-83-8, FCM No 01068)
[162] https://echa.europa.eu/documents/10162/928e3cb7-726b-4eae-0888-8b2450b6a02b

come directly from the authorities, but rather from the customers of the producing company. As confirmed by an organisation, which represents large, medium and small chemical companies across Europe during this study, this is by no means an exception. It should be noted that this is not a problem of mutual recognition per se since the barrier does not result from a Member State action but from private requirements.

- Also in Italy, a laboratory provided an example of pans manufactured in the US, which are sold everywhere in EU, but were not approved for sale in Italy pursuant to national legislation on metal FCMs.
- A third example concerns difficulties for a company to place water filter cartridges on the Italian market, although they were legally marketed in another Member State. A lack of agreed EU rules and diverging standards in Member States increased costs for the company to access the Italian market and resulted in a formal complaint to the Commission and legal challenge by a business operator before Italian courts. A follow up complaint was also made concerning information guidelines on water treatment systems for human consumption.
- National rules are a particular challenge for complex and large machines in contact with food. For example, if a company in Spain produces a rubber product (e.g. conveyer belt) and delivers it to a machine producer in Italy the national legislation of both countries will have to be respected when producing the FCM. However, since the final product will be sold in Germany, the rubber composition also needs to be compliant with rules in Germany, which may not be known to the producer in Spain. As consequence, when a Member State is applying different rules in a specific area, it leads to different costs for companies (e.g. test report describing the proof of compliance (or DoC) of a certain product with food application purposes).
- In Belgium, there is a national legislation on coatings, and it is the responsibility of the industry to communicate compliance throughout the supply chain. If the industry does not comply with the national legislation and they do not state that they comply with another Member State's legislation, then this is considered a case of non-compliance. In case that industry complies for instance, with the Dutch legislation, the mutual recognition principle is applied. However, Member States' participants in the focus groups also shared that it was hard to produce evidence that a product is legally marketed in another Member State.

Annex 7: Overview of main specific measures on FCMs that are currently applicable at EU level and their implementation

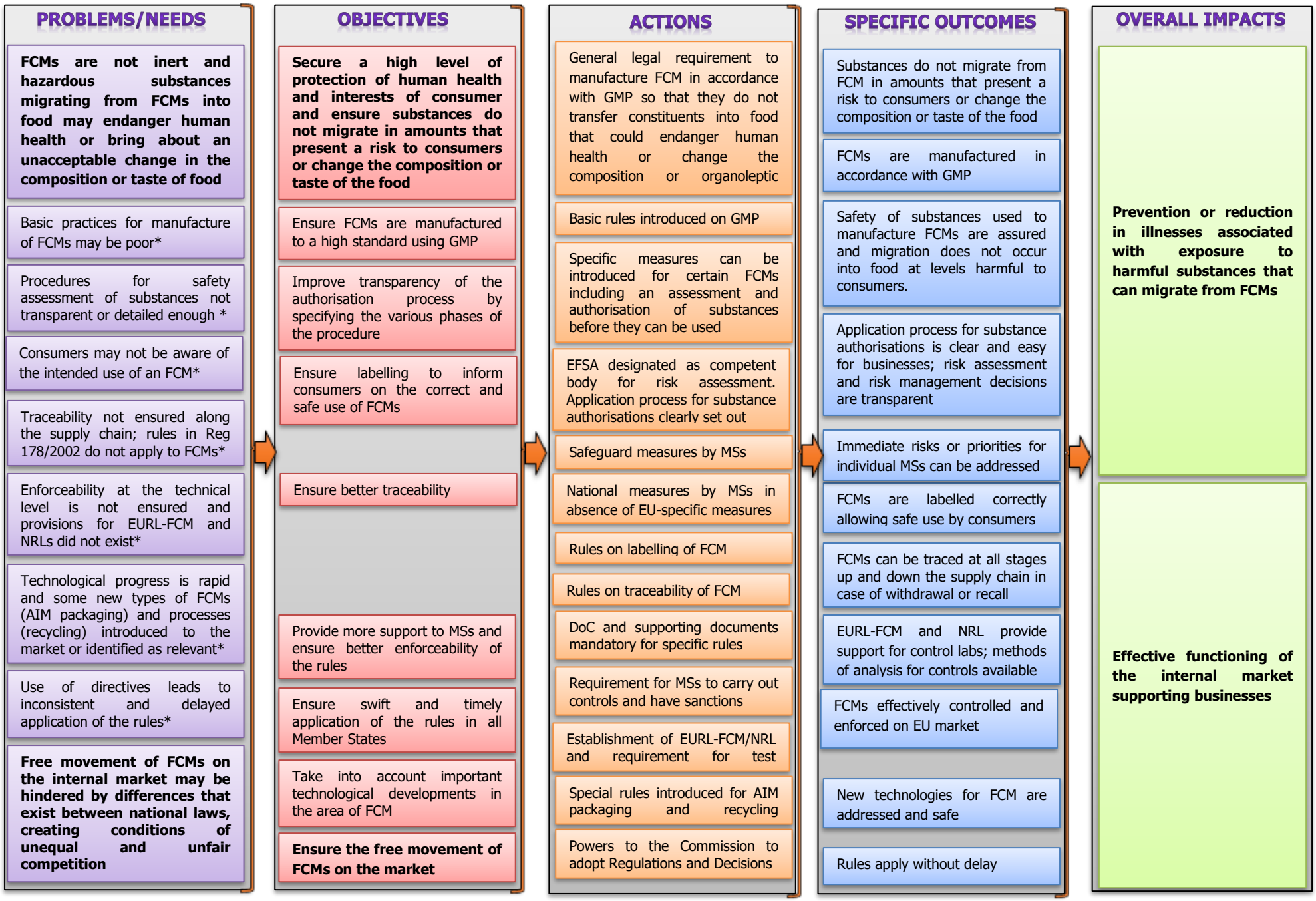
Legislation	Description and state of play on implementation
Commission Regulation (EC) No 2023/2006	**Rules on Good Manufacturing Practice (GMP)**, including the need for quality assurance systems, quality control systems and documentation. Directly applicable to all businesses manufacturing materials and articles in the EU from 1 August 2008.
Commission Regulation (EU) No 10/2011	**Specific rules concerning plastic FCMs**, including their composition, testing requirements and a list of authorised substances to be used in their manufacture. The majority of the regulation was directly applicable from 1 May 2011, but it was an updated version of legislation that had evolved since 1990. The regulation is regularly amended to authorise new substances, modify restrictions on existing substances or further clarify rules or testing methods. The regulation is supported by two guidance documents: EU Guidance on Regulation (EU) No 10/2011 and EU Guidance on information in the plastics supply chain. These are tools available for both business operators and Member State competent authorities that have been translated into all languages of the EU.
Commission Directive 2007/42/EC	**Specific rules concerning regenerated cellulose film (RCF)**, which is more commonly recognised as Cellophane when converted into film. The Directive, which includes a list of authorised substances to be used in the manufacture of RCF is a codification of Commission Directive 93/10/EEC and its amendments. This latter directive itself repealed the original Council Directive 83/229/EEC, which Member States were required to implement by 1 January 1985.
Commission Regulation (EC) No 282/2008	**Specific rules concerning recycled plastic used as FCM**, including a list of processes authorised to carry out recycling of plastic for FCMs. The Commission is currently in the process of replacing this regulation. Until then, processes used for recycling of plastic for use as FCM are subject to national rules.
Commission Regulation (EC) 450/2009	**Specific rules concerning active and intelligent FCM (AIM)**. Since these materials are by their nature not inert, they are exempt from the general FCM rules concerning inertness. This regulation provides for the establishment of a Union list of substances permitted for the manufacture of AIM but has not yet been established. Whereas EFSA has assessed several applications for such substances, the conversion of this work into an EU list of authorised substances requires additional consideration and currently, substances used in AIM are subject to national rules. Some elements of the regulation are however applicable, including the need for labelling.

Legislation	Description and state of play on implementation
Council Directive 84/500/EEC	**Specific rules concerning heavy metals from ceramic FCMs**. This directive was introduced in the mid-1980s and aims to adverse effects of lead and ceramic, which can be present in ceramic ware and transfer into food. Limits were therefore established with test methodology that Member States had 3 years to implement. Recent opinions by EFSA on lead and cadmium, indicate a significant reduction in the current limits is required.
Commission Regulation (EU) 2018/213	**Specific rules on the use of bisphenol A (BPA) in varnishes and coatings and plastics**. BPA has been authorised for use in plastic FCMs since the establishment of a Union list of substances together with an SML. Increasing scientific output on the toxicology of BPA and scrutiny by Member States led to re-evaluation work being undertaken by EFSA and national measures being introduced under Article 18 of the FCM Regulation concerning safeguard measures. Regulation (EU) 2018/213 was introduced, with the aim of avoiding the barriers on the EU market caused by national measures and updating restrictions and applying them to varnishes and coatings in recognition of the wide-spread use of BPA in these materials, in addition to plastic.
Commission Regulation (EC) 1895/2005	**Specific rules on the use of certain epoxy derivatives in FCMs**. Rules on the use of certain epoxy derivatives were first introduced in 2002 by Directive 2002/16/EC[163] to avoid risks to human health and barriers to the free movement of goods. Following an assessment by EFSA, Regulation (EC) 1895/2005 replaced that directive. The rules were updated and are applicable to plastics, coatings and adhesives and in particular, prohibit two substances known as BFDGE and NOGE.
Commission Directive 93/11/EEC	**Specific rules on the release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers**. These were introduced following an assessment by the then SCF, which identified that n-nitrosamines and endogenous precursors n-nitrosatable substances can migrate from these rubber materials in particular, during oral contact. Member States were required to implement the directive from 1 April 1994.

[163] http://data.europa.eu/eli/dir/2002/16/oj

Legislation	Description and state of play on implementation
Commission Regulation (EU) No 284/2011	**Specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong**. Following an increase in the incidence of non-compliance with EU legislation concerning certain types of plastic FCMs from China and Hong Kong, this measure was introduced to increase checks and controls of such consignments entering the EU. It was introduced under Article 48 of Regulation (EC) No 882/2004 on official controls, which has since been replaced by Regulation (EU) 2017/625. The regulation requires Member States to record and report on the controls, including rates of compliance, every three months. Two sets of related guidance have been introduced: EU Guidelines concerning Commission Regulation (EU) No 284/2011 as well as Technical Guidelines concerning polyamide and melamine, which contain practical information on sampling, migration testing and methodologies prompted by the introduction of the Regulation (EU) No 284/2011.
Commission Recommendation (EU) 2019/794	This Recommendation sets out a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food. Controls were carried out by Member States 2019 – 2020.
Commission Recommendation (EU) 2017/84	This Recommendation coordinates efforts to investigate the occurrence of mineral oil hydrocarbons in food and in FCMs.

Annex 8: Intervention logic



*** New elements introduced in 2004**

- **To take into account technological developments in the area of FCMs**, Regulation (EC) 1935/2004 introduced an updated list of materials for which specific measures can be adopted, as well as specific provisions on active and intelligent materials (AIM) and recycling processes, foreseen as new technological solutions in the field of food packaging production.
- **To ensure transparency of the safety assessment procedures of FCMs** and **to ensure accountability and dependency of the authorisation processes**, the functions of risk manager and risk assessor were separated under the regulation. EFSA was designated the competent body to undertake risk assessment on FCMs replacing the former SCF. The regulation established specific procedures for substance authorisation and specific provisions on public access to applications for authorisation, supplementary information from applicants and opinions from EFSA.
- **To ensure traceability throughout the FCM supply chain**, a requirement for traceability was introduced to facilitate self-control for businesses, the recall of defective products, consumer information and the attribution of responsibility. Under the FCM Regulation FCMs must be traceable by means of labelling, relevant documentation and adequate information provided to the supply chain.
- **To ensure that the rules on FCMs are enforced and sanctions in place**, the FCM Regulation introduced requirements for Member States to carry out official controls on FCMs and take all measures necessary to ensure that sanctions are implemented and are effective, proportionate and dissuasive. The JRC was subsequently established as the EU Reference Laboratory (EURL-FCM) for FCM to assist Member States through their National Reference Laboratories (NRLs) in controlling FCMs and support high quality and uniformity of analytical results.
- Council Directive 89/109/EEC had already introduced an obligation for FCMs governed by specific rules to require a **declaration of compliance (DoC)** to attest compliance with specific EU rules. An obligation for appropriate **supporting documentation (SD)** to be made available to Member States was added to complement the DoC and provide the detailed reasons for compliance of the FCM and matters such as testing results.
- As regards the **interests of consumers,** a legal requirement was also introduced prohibiting labelling, advertising and presentation of FCMs to mislead consumers.