Discussion document for the second workshop on the Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)

9 September 2019

Thon Hotel EU
Rue de la Loi 75, Brussels

Objectives of the workshop

The workshop is organised by Ecorys within the Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004), its objective is to present and validate the preliminary findings of the study. Participants to the workshop include stakeholders involved in the FCM sector (NGOs, business operators, consultants, Member States Competent Authorities, EC officials). The workshop is the final occasion to provide inputs for the study.

The workshop is organised in four main sessions corresponding to the evaluation criteria (effectiveness in session 1, efficiency in session 2, relevance and coherence in session 3 and EU added value in session 4). Each session will start by a presentation of the preliminary findings followed by feedback sessions, to gather last inputs which can be included in the study.

The preliminary findings are included in the document. During the workshop, they will be briefly introduced by Ecorys and discussed by workshop participants in small groups. Feedback will be reported in plenary sessions.

The main starting question to be discussed in the group discussions are:

1. Do you agree with the key findings presented? Why or why not? Is there evidence contradicting any of these results?
2. Are there any aspects linked to {effectiveness, efficiency, relevance, coherence, EU added value} that are missing from these findings?

Agenda

08:30 – 09:30	**Registration and coffee/ tea**
	Welcome and introduction
09:30 – 10:00	welcoming remarks and objectives (DG SANTE)
	Presentation of the agenda and objectives of the workshop (Ecorys)
	Presentation of the evaluation study approach and main outcomes of the consultation (Ecorys)
	Session 1: Effectiveness
10:00 – 10:15	Presentation of the key findings
10:15 – 10:40	Table discussions
10:40 – 11:00	Reporting in plenary
11:00 – 11:30	**Tea and coffee break**
	Session 2: Efficiency
11:30 – 11:45	Presentation of the key findings
11:45 – 12:10	Table discussions
12:10 – 12:30	Reporting in plenary
12:30 – 13:30	**Lunch break**
	Session 3: Relevance and coherence
13:30 – 13:50	Presentation of the key findings
13:50 – 14:30	Table discussions
14:30 – 15:00	Reporting in plenary
15:00 – 15:30	**Tea and coffee break**
	Session 4:EU added value and concluding comments on all evaluation questions
15:30 – 15:50	Presentation of the key findings
15:50 – 16:15	Table discussions on EU added value
16:15 – 17:15	Reporting in plenary (EU added value and all findings of evaluation questions)
17:15 – 17:30	Final remarks and wrap up (Ecorys)

Purpose of the evaluation

The purpose of this evaluation is to assess whether the current EU legislative framework for Food Contact Materials (FCM) is fit for purpose and delivers as expected. The evaluation was officially launched on 28 November 2017 with the publication of the a roadmap that describes the purpose, content and scope of the evaluation and its main evaluation criteria. The Roadmap indicates the five evaluation criteria to be addressed:

(1) Effectiveness of the approaches processes and tools set up by the FCM Regulation and its associated and implementing measures in relation to the original objectives of the Regulation;
(2) Efficiency of the approaches, processes and tools set up by the FCM Regulation and its associated and implementing measures in relation to the resources used;
(3) Relevance of the Regulation in relation to current scientific and technological developments in the field of FCMs, and stakeholders' needs and expectations;
(4) Coherence internally and with other related interventions at National and European; and
(5) EU added-value compared to what could have been achieved by Member States or otherwise without regulating FCMs at EU level.

The objective of the study undertaken by Ecorys is to provide the Commission with factual, quantitative and qualitative data and a comprehensive analysis to help answer the 10 evaluation questions. The study will help to support a Commission Staff Working Document (SWD) on the evaluation including evidence-based conclusions and a prioritisation of the areas of the current legal framework for FCM that require action. The evaluation of FCM legislation will provide a basis on which to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCMs in the EU.

Study approach and consultation strategy

The study has been implemented in four evaluation stages: structuring (evaluation design), data collection, data analysis, conclusions and reporting.

Consultation strategy and activities

The consultation process aimed to engage all relevant stakeholders and to collect supporting information, data and knowledge on the functioning and application of Regulation (EC) No 1935/2004 and its associated and implementing measures. Consultation activities intended to seek stakeholders' experiences and views on the scope and the approaches set in the Regulation, as well as to identify any positive or negative effects, including unexpected impacts, and any emerging issues as a consequence of the current legislation.

Workshops

Two workshops have been organised during the course of the study. Whereas the first workshop kick-started the consultation process, presenting the approach and the methodology for the study, this second workshop aims at validating the preliminary results from the study.

Targeted interviews

40 Interviews have been performed in the scope of the study, encompassing all relevant stakeholders groups and covering EU Member States, as well as from third countries (i.e. Switzerland, China and USA). The main purpose of the targeted interviews was to investigate, clarify, substantiate and analyse the evidence provided by key stakeholders in the practical implementation of FCM Regulations.

Focus Groups

Six Focus Groups have been organised in the context of this study, aimed at gathering views from actors who are involved in the implementation of the provisions of the Regulation. These are representatives from Member State Competent Authorities, the Commission, and Policy Officials from Competent Authorities and inspectors from enforcement authorities.

Case Studies

Six case studies have been implemented in the context of this study, aimed at gathering data and facts on several aspects related to the FCM legislation. Findings from the case studies fed into the analysis of the evaluation questions, providing illustrations of specific and real-life situations.

Open Public Consultation (OPC)

A 12-week consultation using the EU survey tool has been performed in line. It aimed at collecting the views of citizens as well as experts on the existing legislation on Food Contact Materials (FCM) in the European Union. The overall number of responses submitted was 503. A Factual Summary Report gives an overview of the responses received.

SME panel consultation

A specific questionnaire targeting SMEs, which was distributed to the SME panel of the Enterprise Europe Network and managed by DG GROW. The questionnaire was focused on exploring the needs and challenges faced by SMEs in the context of the FCM legislation. The overall number of responses submitted was 701, from 21 Member States. A Factual Summary Report provides an overview of the responses received.

Session 1: preliminary results of the study - effectiveness

EQ 1: To what extent has Regulation (EC) No 1935/2004 and subsequent implementation achieved its objective of providing the basis for securing a high level of protection of human health and the interests of consumers in relation to FCM?

Key finding	Methodology and data source	Limitation of the findings
1. The subject matter in Article 1 and definitions in Article 2 of the FCM Regulation are generally clear and encompassing in order to achieve the objective. However, there are differences in the interpretation and understanding of some concepts such as 'normal or foreseeable conditions of use', which may lead to differences in the level of the protection of human health.	Desk research Public consultation Focus group on Risk Assessment and Risk Management Interviews	-
2. The positive authorised listing approach offers an effective way of ensuring that the main substances used to manufacture FCMs do not pose a risk to human health. However, the approach has several limitations. For example, it focusses only on starting substances and the same level of risk assessment and management is not applied to non-intentionally added substances (NIAS) formed from reaction and degradation products and impurities and which may be present in the final FCM. Moreover, the lack of systematic review of the substances on the list as well as the derogation for certain types of substances (i.e. colorants, solvents, aids to polymerisation) undermine the effectiveness of the positive list approach in protecting the human health. Finally, the lack of assessment of combination effects and multiple routes of exposure leaves a gap in the capacity of the positive list to ensure a high level of protection of human health.	Desk research Public consultation Interviews Case study on compliance	There is no robust data on the impact on human health of regulating starting substances in FCMs either before or after the introduction of the intervention

3. The FCM symbol (*glass&fork*) is an effective vehicle of information, as the vast majority of consumers is aware of its meaning. However, the derogation of labelling requirements for certain articles (as provisioned by in Art 15(2)) could hamper the effectiveness of the labelling requirements, in that it could create uncertainty in consumers and control authorities alike. Aside of the FCM symbol, consumers need more instructions on the appropriate use of FCM, in that the lack of clear instructions could cause uncertainty for consumers, and a mismatch with the so-called *normal or foreseeable conditions of use*, against which FCM are tested by manufacturers and controlled by Competent Authorities. As regards they AIM (active and intelligent materials) symbol, there is a lower degree of understanding among consumers, showing that consumers are not yet familiar with this kind of articles.	Desk research Public consultation Interviews	The results of this Evaluation questions are largely based on the results of the OPC, hence do not capture a representative sample of EU consumers
4. GMP play a crucial role in ensuring the safety of the final FCM. In fact, focusing on the process and being implemented in *day-to-day* practice, they usefully complement compositional provisions, such as the positive list approach. However, there is a lack of clarity and guidance as regards controls of GMP performed by Competent Authorities, which hampers their enforcement and, consequently, undermine their effectiveness in ensuring the safety of the final FCM. Moreover, the use of private standards appeared to be not sufficient to cover all the GMP requirements. Finally, there are reservation on the application of GMP during the manufacturing of FCM imported from third countries.	Desk research Public consultation Case study on compliance Interviews	Lack of data of non-compliance to GMP requirements in MS.
5. There are doubts about whether the system of Official Controls adequately enforces the requirements of the FCM legislation. This can mainly be attributed to: lack of resources and expertise at MS level, differences among MS, uncertainty in the enforcement of non-harmonised materials, lack of a registration system of business operators and lack of systematic data records of cases of non-compliance. The insufficient level of enforcement makes it difficult to reach firm conclusions on the performance of the legislation in protecting human health.	Desk research Public consultation Interviews Case study on enforcement Focus groups on official controls and on enforcement	Lack of centralized enforcement data at MS level, due to the fact that control activities are often handled at local-regional level.

EQ 2: To what extent has Regulation (EC) No 1935/2004 and subsequent implementation ensured the effective functioning of the internal market in relation to the placing on the market in the EU of FCMs?

Key finding	Methodology and data sources	Limitation of the findings
1. The purpose, subject matter, and definitions of the Regulation (Articles 1 and 2) generally provide a good basis to the effective functioning of the internal market. Compared to the previous Directives, Regulation (EC) No 1935/2004 clearly states the objective to ensure the effective functioning of the internal market. In addition, there appears to be a consensus among stakeholders that the scope of the Framework regulation is sufficiently clear. In line with that, the study did not reveal major issues with regards to the scope of the legislation. At the same time, some definitions are in need of greater clarity. A lack of definition for the 'deterioration in the organoleptic characteristics' and 'normal or foreseeable conditions of use' lead to different interpretations among Member States. This creates obstacles to the free movement of FCMs across borders, as companies have to comply with different criteria and conditions.	Desk research Public consultation Interviews RASFF notifications database	-
2. The EU positive list approach for plastic FCMs contributes to the functioning of the internal market. It provides companies with a defined list of substances safe for their use in FCMs. While a positive list restricts companies in the number of substances that can be used, it provides certainty that companies need to produce their FCMs. EFSA has limited capacities to keep the positive lists up to date. In addition, while foreseen, there are no positive lists for active and intelligent materials and for recycled plastic materials yet. These aspects undermine the beneficial effect of positive lists on the functioning of the internal market.	Desk research Public consultation Interviews SME panel	A serious limitation to the findings on the positive list is that it is not possible to quantify the benefits of the existence of the positive list on plastic FCMs. The same is valid for the positive lists currently existent on national markets.
3. From an industry perspective, overall traceability along the FCM supply chains is generally considered to be ensured and contributes to the effective functioning of the internal market. The introduction of traceability requirements Regulation (EC) 1935/2004 (Art.17) has led to improved transparency of information flows among different supply chain actors. Compared to larger companies, SMEs face	Desk research Public consultation Interviews SME panel	-

greater challenges in terms of awareness and ensuring traceability as they usually do not have the time, resources, and most importantly the bargaining power to get the information along the supply chain. The longer the supply chain, the greater the challenge to ensure traceability. Short supply chains facilitate the direct exchange among the individual actors within it. This is not possible if several intermediaries are involved. The problem is particularly pronounced if supply chains extend to outside the EU.		
4. The labelling requirements of the Framework legislation further facilitate transparency in the supply chain. Industry considers the labelling requirements as clear. Hence, the requirements do not create obstacles to the functioning of the internal market, but rather facilitate it. Industry only raised minor issues that could further improve the beneficial effect of labels, e.g. clarity on whether a FCM manufacturer needs to mention a batch number or the production date on the material itself.	Desk research Public consultation Interviews SME panel RASFF notifications database	No estimation has been provided on the costs related to labelling and the findings are based on reports only by a few industry stakeholders.
5. Similarly to the framework regulation, the GMP regulation provides a direction for ensuring quality practices in manufacturing without being prescriptive. It does not directly ensure safety, or contributes to the functioning of the internal market. However, ensuring that manufacturing processes are performed correctly provides an indirect positive effect on the functioning of the market as common standards are followed by businesses across the EU. The majority of businesses consider the objectives and rules on GMP as sufficiently detailed and effective in ensuring that FCM are manufactured to a high standard. NGOs and some of the interviewed business associations have expressed a preference for an integral FCM Regulation rather than having a GMP regulation separately. This is seen as a way of strengthening harmonisation and linking GMP with risk assessment. Two issues with the current GMP system is that the certification of businesses on compliance with GMP is costlier to SMEs as compared to larger companies and that ensuring GMP implementation in the EU is functioning much better than in third countries.	Desk research Public consultation Interviews SME panel	No hard data is available to illustrate the difficulties of SMEs and companies in third countries to ensure GMP compliance.
6. Declarations of compliance are an important innovation of the Framework Regulation that enhances transparency and trust. It provides users of materials with a detailed description of the materials' properties and thus increases certainty for companies. At the same time, DoCs are not mandatory for all but only for harmonised materials. In addition, some Member States require DoCs for other materials as well, or there is industry guidance. This creates a patchwork of rules and requirements, leading to misunderstanding along the supply chain. Where national rules differ, companies are forced to re-do work and to prepare	Desk research Public consultation Interviews SME panel	No hard data has been identified to illustrate the following issues: misunderstanding along the supply chains; the guidance on the DoC and SD content is insufficient; different level of knowledge on DoC/SD along the

several DoCs. This is particularly challenging for smaller companies and companies lacking an in-depth knowledge of the legislation. Incomplete DoC due to lack of knowledge, differences in requirements, and insufficient enforcement of the rules lead to obstacles of the free movement of FCMs.		supply chain; incomplete DoCs; SMEs are in a disadvantaged position in terms of meeting the DoC requirements; and information in the DoCs may be difficult to trace for imported FCMs.
7. The lack of a well-functioning mutual recognition system undermines the objective of Regulation (EC) 1935/2004 to ensure the effective functioning of the internal market. According to industry stakeholders national requirements lead to: (1) obstacles to trade and delayed market access; and (2) additional tests and the need to provide documentation in order to meet national requirements places an extra burden on businesses. These effects are more pronounced with SMEs that do not have the resources to counter incorrect application of the mutual recognition principle. National rules and lack of mutual recognition is also a challenge for the use of complex and large machines that are in contact with food.	Desk research Public consultation Interviews SME panel	There is no hard data to illustrate the extent to which the mutual recognition principle is applied or not applied. Also no quantification is possible on the effects of the existence of national requirements on trade and delayed market access. Thus, the analysis relies on a few examples for illustration purposes.

Session 2: preliminary results of the study - efficiency

EQ 3: What are the quantifiable benefits, taking into account resources (cost, time, etc.) to stakeholders, including consumers, businesses, and Member States' Competent authorities?

Key finding	Methodology and data source	Limitation of the findings
1. Benefits for consumers mostly stem from stricter rules. Compliance with these rules reduces exposure of consumers to hazardous substances and thus renders FCMs safer. Based on an assessments of the beneficial effects of substance restrictions, human health benefits are likely to range in the billions annually. These benefits include cost savings from (e.g. health treatments avoided, etc.) as well as avoidance of adverse effects on individuals' life expectancy, productivity, etc. Since the estimates only cover some causal challenges via which the health of consumers might be affected, the estimates are likely to significantly underestimate the beneficial effects of the FCM legislation. Results of a composite index assessing the performance of Member States on the enforcement of the FCM legislation indicate that the enforcement activities remain below their full potential. Only 14 out of the 25 Member States assessed perform well on the index for health protection. Therefore, there is still room to further improve health protection and to further increase health benefits for consumers.	Literature review Interviews Public consultation Statistics (Eurostat)	The assessment is based on a small number of identified channels through which specific substances affect the health of consumers. The estimates provided are therefore likely to underestimate the actual cost-savings/ benefits for consumers to a large extent. In general, establishing causality is extremely challenging, which limits the amount of research that has focused on the impacts of FCMs on health, not to mention potential effects of FCM legislation on health protection.
2. The harmonisation of the Framework Regulation and material-specific legislation yielded benefits for the industry as well. Estimates suggest that the harmonised risk assessments could reduce costs for industry by about EUR 10 million to EUR 25 million per year over the last 10 years. With a smaller number of	Desk research Interviews Public consultation	Cost savings for active and intelligent materials and recycled plastics are based on information obtained for the plastics sector. The assessment of

applications filed for active and intelligent materials, as well as for recycling processes for plastics materials, annual cost savings are likely to decrease in future. Generally, the harmonisation avoids duplication of work and increases predictability for companies. While data suggest an increase in year-on-year growth rates of FCM trade among the EU-28 after implementation of the FCM legislation, it is not possible to establish causality. Still, companies indicate far less problems with placing products on another market for harmonised FCMs compared to non-harmonised FCMs.	Statistics (Eurostat)	quantifiable benefits remains limited. Potential cost savings, e.g. from harmonised production standards, reporting requirements, etc. could not be assessed due to limited data availability.
3. Estimates suggest that annual cost savings for Authorities due to harmonised risk assessments exceed EUR 1 million. Member States appear to maintain deviating mechanisms for risk assessment for materials which are not regulated at EU-level. While they cannot be quantified or even monetised, there are additional benefits to Member States arising from knowledge sharing and enhanced cooperation among Member States and with EU institutions.	Desk research Interviews Public consultation Focus groups	

EQ 4: 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?

Key finding	**Methodology and data source**	**Limitation of the findings**
1. Compliance costs for industry are at least in the tens of millions for industry each year. Based on estimates for producers of three different materials (glass, ceramics, and plastics), costs for material producers are estimated to amount to some EUR 50 million annually. For the three cited sectors, costs linked to the FCM legislation are equivalent to between 0.03% to 0.1% of the sectors' production values. Risk assessments for plastics, recycled plastics, and active and intelligent materials created annual costs of approximately EUR 7 million to EUR 45 million over the last 10 years.	Desk research Public consultation Interviews Case studies Statistics	Costs have been quantified based on a limited number of data points. Most information has been available for plastic materials. The overall assessment of costs for material producers is based on extrapolations for three sectors and should be seen as an indicative value, rather than an actual

Costs for downstream users of the materials (e.g. fillers, distributors, etc.) are not included. However, interviews and responses to the public consultation suggest that costs for these downstream users are significant as well. Administrative costs are estimated to represent from about 2% to 8% of total administrative costs, depending on the material. Evidence suggests that the costs of FCM legislation disproportionally affect SMEs compared to large enterprises.		estimate of overall costs. Note that due to the focus on material producers, the compliance costs are systematically underestimated. It has not been possible to gain intuition for the factor by which the values are underestimated.
2. Extrapolations suggest that costs for Competent Authorities in Member States range between EUR 17.5 million and EUR 26 million per year. Controls and enforcement account for about EUR 13.5 million to EUR 21 million. Member States allocate approximately EUR 2.5 million to EUR 3 million to the implementation of harmonised legislation. Another EUR 1.5 million to EUR 1.8 million is allocated to the implementation of national legislation. These costs include budget and resources for personnel. In total, it is estimated that work on FCM related tasks in Member States corresponds to 166 to 183 FTEs. About 20% of this work relates to implementation of harmonised legislation (26 to 39 FTEs) and 13% to the implementation of national legislation (20 to 24 FTEs). Work on controls and enforcement represents around two thirds of the workload (110 to 120 FTEs).	Desk research Interviews Statistics	Only about half of the Member States provided information on their budget allocated to and/ or FTEs working on FCM related activities. The breakdown of the costs follows the same approach as the JRC report to maximise the number of data points available. Estimates that are presented for the EU overall are extrapolated based on available data. To increase the validity of the estimates, ranges are provided and several extrapolation techniques have been employed.
3. The annual budget of EFSA for FCM related activities is estimated at between EUR 500,000 and EUR 600,000, which includes costs for personnel. Over the last couple of years, the budget allocated to FCM related tasks in EFSA has decreased, although the number of staff engaged in FCM related activities increased to about 6.3 FTE in 2018. Within the European Commission, FCM related tasks represent approximately 2 FTEs working, which represents a cost of about EUR 330,000 per year.	Desk research Interviews	The estimates reported remain yet to be validated by EFSA and the European Commission. In particular, information on applications for risk assessment submitted needs to be confirmed by EFSA. JRC costs are not taken into account.

EQ 5: Taking into account the answers to question 3 and 4, how efficient is Regulation (EC) No 1935/2004 and its implementation tools in ensuring the safety of FCMs?

Key finding	Methodology and data source	Limitation of the findings
1. The benefits for human heath arising from the safety of FCM, as assured by FCM legislation and partly monetised under EQ3, are estimated to far outweigh the costs of the legislation for industry. Here, the analysis compared the estimated cost-savings stemming from restrictions on the use of selected substances in FCMs with the overall costs of the legislation for all stakeholders (industry, Member States, and EU institutions). This assessment holds true even if costs to industry were underestimated e.g. by a factor of 10. They would nonetheless remain much lower than estimated benefits to human health. Given that not only costs, but also benefits are systematically underestimated, it is safe to assume that the benefits by far outweigh the costs of the legislation. In terms of this trade-off, the legislation can be considered efficient in ensuring the safety of human health.	Desk research	Estimates are systematically underestimating both costs and benefits. However, since the benefits outweigh costs by a very large factor, it is likely that the assessment remains valid even if costs are underestimated by far.
2. The study does not reach a conclusion on the efficiency of the legislation from the perspective of strengthening the internal market. There is insufficient evidence on the benefits of FCM legislation for the internal market to make a sound assessment of its efficiency. Simply comparing identified benefits to costs for industry suggests that the legislation has created costs, rather than reduced costs. However, it is unclear which part of these costs would be business as usual costs. In addition, it was not possible to establish an overall estimate for cost savings and benefits for the industry under EQ 3. Nonetheless, input from the public consultation and the strong consensus in the business community calling for greater harmonisation suggest that internal market benefits from FCM legislation outweigh their costs. Due to these contradicting findings, a final assessment is not possible.	Desk research Public consultation SME survey Interviews	Data availability is too limited to come to a definite conclusion. There is unfortunately not even a consensus among stakeholders on the efficiency of the FCM legislation vis-à-vis the functioning of the internal market.

3. Following from the previous point, the available evidence suggests that a harmonised approach using EU FCM legislation is more efficient than national-level legislation or an absence of legislation. There are several material groups where in the absence of harmonised legislation several pieces of national legislation co-exist. Oftentimes, criteria and conditions differ across countries or contradict each other. This leads to a multiplication of resources spent by authorities as well as industry. Further, the absence of any legislation does not necessarily lead to lower costs for industry either, as there appears a tendency to self-regulate standards and procedures to facilitate production and trade. However, as noted, the lack of information necessary to evaluate the economic benefits of FCM legislation means that a full assessment of harmonised versus non-harmonised approaches cannot be made.	Desk research Interviews	Qualitative assessment, since a quantification of the counter-factual situation is not possible.
4. Costs for the risk assessment for plastic FCMs are relatively low when compared to other legislation. In particular, costs for risk assessments of plant protection products and biocides appear to be higher than those for the authorisation of substances used in plastic materials. Yet, the evidence suggests that e.g. risk assessments under REACH are less costly than the assessment for plastic FCMs. Whereas registration fees under REACH help to (partly) finance the risk assessments ECHA performs, EFSA has not the same option under the legislative framework for FCMs.	Desk research	

Session 3: preliminary results of the study – relevance and coherence

EQ 6: What are the needs, interests and expectations of the following stakeholder groups and to what extent does the current legislation address them?

Key finding	Methodology and data source	Limitation of the findings
1. Regulation (EC) 1935/2004 reflects the needs of consumers for protection of human health and preservation of organoleptic properties of food. While consumers have relatively high awareness of the FCM symbol, there is a need for consumers to be better informed in order to improve their understanding of FCM labelling and instructions and restore their confidence in the (packaged) food on the EU market. There is a growing consumer interest in environmental issues. Although the current FCM legislation does not address protection of the environment, it is a topic that is covered in other comparable pieces of legislation, such as REACH and the Waste Directive.	Desk research Public consultation Interviews	Results rely mainly on stakeholders consultation activities.
2. Overall, Regulation (EC) 1935/2004 reflects the needs of business operators. While needs of companies have not changed much since the entry in force of the legislation, business operators active in non-harmonised sectors indicate a desire for measures covering all FCM, either in the form of a Union list and/or harmonised guidelines. The FCM legislation is more reflective of the needs of larger business operators; i.e. the proportion of medium sized firms that indicate that FCM legislation is adequate for their needs is higher for medium-sized enterprises than for smaller ones.	SME survey Interviews Focus group	/
3. Many Member State authorities indicate a need for more capacity and expertise to carry out inspections and controls. Likewise, there appears to be a lack of access to analytical methods for verifying compliance with compositional requirements.	Public consultation Focus groups	/

EQ 7: To what extent has Regulation (EC) No 1935/2004 and its subsequent implementation allowed for evolving science, prioritisation and innovation?

Key finding	Methodology and data source	Limitation of the findings
1. Regulation (EC) 1935/2004 does not provide sufficient flexibility when it comes to considering new scientific knowledge and technological developments. This rigidity is mainly linked to the fact that the Regulation neither foresees a periodic revision of existing specific measures nor provides a mechanism for the revision of the legislation.	Desk research Public consultation Interviews	/
2. Even though Regulation (EC) 1935/2004 provides a basis for the uptake of new scientific information that might affect the safety of human health, it does not put a mechanism in place to prioritise the handling of certain substances of health concern. The mechanism relies on business operators flagging up new scientific findings, while excluding other relevant stakeholders.	Desk research Public consultation Interviews Focus groups	Results are largely based on stakeholder consultation activities.
3. It is unclear to what extent Regulation (EC) 1935/2004 stimulated and allowed for innovation and research. Nevertheless, business operators have called for actions for better protection of intellectual property that would allow for more innovation.	Desk research Public consultation SME survey Case studies	No hard data provided to demonstrate barriers to innovation for business operators.

EQ8: To what extent is Regulation (EC) No 1935/2004 internally coherent, including all of its implementing acts?

Key finding	Methodology and data source	Limitation of the findings
1. The Framework Regulation and specific regulations co-act as intended. However, the absence of EU specific measures for many FCMs means that the current (harmonised) legal framework is incomplete, with national rules applying to many FCM. Companies indicate that the gaps in coverage of the Regulation create a burden, as it can be complex to ensure that materials comply with different legal requirements in different Member States. The most frequently cited materials for which there is a need for EU-level specific harmonised measures are coatings, inks, adhesives and paper and board. Both NGOs and business operators worry about the complexity of the application of the plastics legislation to certain situations, such as multilayer multi-materials. NGOs report two additional gaps in the Regulation: (i) the Regulation is based on evaluation of isolated starting substances, while cocktails of migrating substances released by the final FCM articles could lead to non-evaluated synergistic effects, and (ii) the absence of specific measures for Substances of Very High Concern (SVHC). When substances raising concerns for human health are authorised in the plastics Regulation (EU) No 10/2011, severe restrictions always apply: e.g. their migration into food must be non-detectable or their residual concentration in the final FCM must be extremely low.	Desk research Public consultation Interviews Focus groups and case study on coherence	The assessment could not include an exhaustive review for all substances. The burden is not quantified.
2. An area that is considered not sufficiently covered by the Regulation concerns requirements to establish harmonised recommendations for final articles. The lack of standards and methods creates difficulties in demonstrating compliance and, also, creates problems for enforcement.	Public consultation Interviews	
3. Overall, the EU specific measures on plastics and on regenerated cellulose are coherent with Regulation (EC) 1935/2004. For plastics, coherence may be challenged in the case of multi-layer multi-materials which may have to comply with both harmonised (EU) and national regulations. For active and intelligent materials and articles, and for recycling processes, although EFSA has published many positive advices, there are delays in the publication of the Union lists of approved applications. On the EU market, active	Desk research Public consultation Interviews	

substances evaluated positively are in competition with substances produced outside EU, which have not been submitted to applications and not been evaluated by EFSA.	Focus groups and case study on coherence	
4. The coherence of Regulation (EC) 1935/2004 with national provisions is an area of concern. The development of national provisions could challenge efforts to reach common rules for non-harmonised FCM. Consumers' and NGOs' perceptions of coherence are negatively affected when disagreements arise between risk assessors, and when national agencies challenge EFSA opinions.	Desk research Public consultation Interviews	The study could not provide an exhaustive assessment of all national provisions

EQ9: To what extent are Regulation (EC) No 1935/2004 and its subsequent implementation including the risk assessment and risk management approaches taken, externally coherent with other relevant legislation and policies?

Key finding	**Methodology and data source**	**Limitation of the findings**
1. Although some stakeholders criticise the external coherence of the FCM legislation, the analysis suggests that perceived inconsistencies between the Regulation and other relevant legislation are not always genuine incoherence. In most cases, the conclusions of ECHA and of EFSA concerning the assessment of hazards to humans are consistent with each other. Differences in risk management decisions under REACH and under FCM can be explained by differences in the objectives of the Regulations and of the corresponding risk assessment approaches. Many of such differences relate to environmental risk assessment, which is not within EFSA's remit for FCM. This can result in situations where a given substance can be submitted to different restrictions, depending on its use and on the objectives of the legislative framework.	Desk research Public consultation Interviews Focus groups and case study on coherence	The assessment could not include an exhaustive and detailed review for all substances.
2. Overall, the FCM and the REACH Regulations do not overlap. However, exchange of data between EFSA and ECHA could be improved, with each agency able to use data collected by the other one. Collaboration could be initiated at an early stage using the RMOA procedure of ECHA.	Desk research Public consultation Interviews	

There is consensus among all categories of consulted stakeholders that coherence of FCM and the REACH Regulations should be ensured, especially for Substances of Very High Concern (SVHC). The Classification and Labelling Inventory (CLI) held by ECHA could become a source of information for assessment of NIAS and of chemicals in the non-harmonised FCM area, despite current weaknesses and inconsistencies, underlined in the Chemicals Fitness Check.	Focus groups and case study on coherence	
3. There are gaps in the methods used to set acceptable limits of migration of "dual use substances" (food additives and flavourings also used as FCM substances);	Case study on coherence	
4. There are some contradictions between the regulation on recycled plastic FCM and the waste management legislation. The safety requirements of Regulation (EC) No 282/2008 on recycled plastics contradict the objectives of the Directive (EU) 2018/851 on waste, which targets increased recycling rates. Similar safety requirements limit the recycling rate of post-consumer used paper and board.	Public consultation Interview Case study on coherence	

Session 4: preliminary results of the study – EU added value

EQ10: What is the EU added value of Regulation (EC) No 1935/2004 in relation to its main objectives?

Key finding	Methodology and data source	Limitation of the findings
1. The harmonisation introduced by Regulation (EC) 1935/2004 provides EU added value but its amount is reduced by incomplete implementation. Positive developments mainly relate to the coherent framework provided by the legislation, in which measures can be taken at EU and national levels to cover all FCM. The Regulation (EC) 1935/2004 provides a basis for securing a high level of protection of human health regarding individual materials, with benefits estimated to outweigh costs. The EU positive list approach is effective in contributing to the functioning of the internal market. Declarations of compliance, traceability, and labelling requirements also contribute positively to the functioning of the internal market. The overall performance of the legislation is weakened by gaps in implementation, due to the combined effect of the absence of specific measures for many substances and of the poor functioning of the mutual recognition system. The persistence of national requirements for non-harmonised substances creates a burden for companies. SMEs are in a disadvantaged position compared to larger companies. There are also gaps in enforcement, with official bodies having difficulties to effectively undertake controls. Finally, there are reservations concerning the focus on assessment of starting substances instead of final articles, together with concerns about exposure of EU consumers to NIAS, combination effects of multiple migrating substances, and to multiple sources of exposure.	Previous EQs	The burden of national requirements for non-harmonised substances could not be quantified.
2. Regulation (EU) 10/2011 has brought considerable added value and has enhanced the regulatory framework for plastic materials. Harmonisation has reinforced the functioning of the internal market by removing barriers to trade and the positive list approach provides more legal certainty for business	Previous EQs	A full assessment of harmonised versus non-harmonised approaches could not be made.

operators. Moreover, collected evidence suggests that harmonised legislation is more efficient than following a non-harmonised approach. This positive assessment contrasts with that of Regulation (EC) 450/2009, for which EU added value is considered to be low due to the absence of authorisation of active and intelligent materials.		
3. There is a consensus among Member States, EU authorities, citizens and other stakeholder categories that EU intervention is of great added value. For Member States, harmonisation reduces the cost of implementing FCM legislation. For NGOs, harmonisation better protects consumers and should contribute to better addressing consumer concerns about multiple exposure and cocktail effects of migrating substances. For companies, harmonisation positively contributes to the functioning of the internal market.	Public consultation SME survey Interview	