



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food and Feed Safety, Innovation
Food Processing Technologies and Novel Foods, Unit E2

DG SANTE introductory workshop to support the evaluation on Food Contact Materials (FCMs) legislation

Workshop document

Background

Food Contact Materials (FCMs) 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. FCMs include many different types of articles including food packaging, kitchenware and tableware and items used in professional food manufacturing, preparation, storage and distribution. It incorporates a wide range of materials such as glass, metal, paper, plastics but also adhesives, printing inks and coatings used in the finishing of the final articles, as well as composite materials.

Adoption of the first FCM [Directive 76/893/EEC](#) in 1976 was done so on the basis of two main principles. The first principle is that substances in FCM may endanger human health or bring about unacceptable change in the composition or taste of food and secondly, that regulating FCMs at national level may hinder the free movement of FCMs, creating conditions of unequal and unfair competition.

These principles are today reflected in the objectives of the current [Regulation \(EC\) 1935/2004 of the European Parliament and of the Council](#), set out in Article 1 i.e.:

- 1. To provide the basis for securing a high level of protection of human health and the interests of consumers;**
- 2. To ensure the effective functioning of the internal market in relation to the placing on the market in the EU of materials and articles intended to come into contact directly or indirectly with food.**

Regulation (EC) No 1935/2004 provides a harmonised legal EU framework for FCMs. It requires FCMs to be manufactured using Good Manufacturing Practice (GMP) so that they do not endanger human health nor bring about an unacceptable change in the composition or deterioration in the organoleptic properties of the food. It further provides the power to enact specific EU measures for specified materials and articles. The current Regulation built on the previous Directives by introducing procedures for performing safety assessments of substances used to manufacture FCM as well as rules on labelling, compliance documentation and on traceability. It also introduced rules to take into account technological developments in the area of FCM, such as active and intelligent packaging.

A series of measures relating to specific materials and substances have been established within the legal framework of Regulation (EC) No 1935/2004, comprising legislation on plastic FCMs including recycled plastic; regenerated cellulose film; ceramics and on active and intelligent packaging materials. Specific rules on substances relate to the use of bisphenol A in varnishes and coatings, the use of certain epoxy derivatives and the release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers. Further

rules also apply on GMP to all stages in the manufacturing chain of FCM except starting substances, to ensure their manufacture is well controlled.

In the absence of specific measures at EU level, Article 6 of the Regulation allows Member States to maintain or adopt national provisions if they comply with the rules of the Treaty. The application of national measures by Member States therefore requires the effective implementation of the [mutual recognition principle](#), so as not to hinder free movement of FCM and create barriers to the correct functioning of the internal market.

An intervention logic on the legislation can be found in annex 1.

Context and rationale for the evaluation

The size of the European FCM market is estimated to be around €100 billion per annum. More than half of this value comes from the plastic and paper and board sectors; followed by considerable value in the glass, metal and machinery sectors. However, a significant number of business operators produce other materials critical to the supply chain, including adhesives, inks, resins, waxes, ceramics, wood, rubbers, silicone, coatings and others materials. Some of these materials are used as the main material in final articles, while other materials are combined during various manufacturing stages. Whilst many FCMs are manufactured in the EU, significant quantities of intermediate and finished articles are also imported from third countries. The FCM rules apply equally once a material or article is placed on the EU market.

There are no requirements to monitor Regulation (EC) No 1935/2004 and no evaluation of EU FCM legislation has been carried out to date by the European Commission since the inception of its basic provisions set out over 40 years ago in 1976. Additionally and on the basis of evidence gathered so far, including the sources referred to above, it appears that:

- Several fundamental issues are present in the existing approach to regulating FCMs at EU level;
- Difficulties exist as regards ensuring the safety of FCMs and the correct functioning of the internal market due lack of EU harmonised rules.

Information that will contribute towards this evaluation already exists.

A [JRC baseline study on non-harmonised FCM in the EU](#) was published in January 2017 and provides a comprehensive picture on the state of play concerning both FCM regulation and FCM markets in Europe. The study maps current FCM supply chains and provides detailed information on the existing national measures in Member States. It assesses the effectiveness of such measures on the safety of FCMs by taking into consideration risk assessment schemes, compliance of FCMs and enforceability of the provisions. Furthermore, it examines the burden of national instruments carried by both Member States and businesses.

Evidence collected through the study identifies around 8000 substances regulated at national level, some of which are regulated by many Member States, some others only by a few. The study found that even if some materials such as paper and board, metals and glass are regulated by many Member States, differences exist in terms of national schemes for risk assessment, general requirements on chemical safety, requirements on compliance documentation, number and type of authorised substances, as well as ways to regulate them. Such differences, together with the lack of concerted strategies for the monitoring of FCMs can be perceived as a grey area for the systematic assurance of food safety.

Evidence on the implementation of GMP, shows that requirements are mostly not material specific and lack practical guidance. Sectorial guidelines on GMP are adopted by industry in some cases, but it is not clear whether these are adopted and applied consistently and equally by all members and from large enterprises to Small and Medium enterprises (SMEs) and micro enterprises. According to the study, both harmonised and non-harmonised FCM sectors present flaws in GMP systems as there is a lack of communication and provision of adequate portfolios of documents, from the Documents of Compliance to well defined criteria and quality checked supporting documents, with accompanying sanctions.

As regards possible barriers to trade, the JRC study identifies an incomplete or incorrect application of the mutual recognition principle by some MSs within the EU. Extra costs for the acquisition of external advice and laboratory services, as well as long authorisation processes and delayed market access place an additional burden on businesses, particularly SMEs. Industry self-regulation may be adopted to overcome these barriers. Nevertheless, if not under EU Guidelines, industry self-regulation can limit the access to markets particularly for SMEs. According to the JRC study, sectors increasingly tend to seek compliance with non-EU FCM legislation to find a solution to the lack of specific rules at EU level, for example work undertaken by the CoE, standards from third countries or industry guidelines.

The JRC study concludes that the lack of specific measures at EU level for some FCM negatively impacts the functioning of the internal market for the relevant material or article and its food safety. According to the report, without EU specific measures for some FCM, the general FCM safety requirement established by the Regulation cannot be fully achieved and enforced.

In addition, a number of position papers and correspondence have been submitted by Member States' Government Authorities, industry associations, NGOs and consumers organisations to the Commission, including feedback on the roadmap published on 28 November 2017 regarding the FCM evaluation. These comments place further emphasis on issues such as lack of specific measures for many materials at EU level, functioning of the current approach, coherence with other EU legislation and information flow along the supply chain.

Recent work undertaken by the Commission on other sectorial or horizontal legislation indicates issues with the current FCM legislation. For example, the [Fitness Check on General Food Law](#) identifies shortcomings in authorisation procedures foreseen in other secondary legislation e.g. FCMs other than plastics; the [Single Market Strategy](#) cites the need to strengthen the [single market for goods and improve the Mutual Recognition principle](#) whilst [the study supporting the Fitness Check on the most relevant chemicals legislation \("Fitness Check +"\)](#) highlights issues on coherence of data, science, and risk management procedures and measures, between different regulatory areas including those relating to FCM.

EFSA has recently published [an opinion on developments in risk assessment](#), examining the safety assessment of chemicals in food and impact on evaluating FCMs, concluding that more focus is needed on the finished materials and articles as well as non-intentionally added substances (NIAS) generated through the manufacture of FCMs.

In March 2016, the European Parliament published a [European Implementation Assessment Study on FCM Regulation \(EC\) No 1935/2004](#). The study is based on a survey conducted between December 2015 and February 2016, which documents stakeholders' positions on the functioning of the Regulation. The report concludes that the lack of specific measures at EU level for some FCMs negatively impacts the functioning of the internal market and food safety and many stakeholders across businesses, consumers, environmental and health

NGOs, researchers, as well as Member States' Competent Authorities are in favour of specific measures at EU level for the FCMs that are not yet harmonised at EU level.

The information gathered so far provides a partial understanding of the functioning of the EU legislation on FCMs. However, further evidence is required to reinforce and substantiate the understanding so far and provide concrete evidence to fully assess how the Regulation is performing in relation to its main objectives.

Objectives

The overall purpose of this evaluation is to assess to what extent the current EU legislative framework for FCMs is fit for purpose and delivers as expected. It will assess the overall effectiveness, efficiency, relevance, coherence including coherence with other chemicals and food legislation, and EU added value of the FCM Regulation.

The objective of the accompanying study is to provide the Commission with factual, reproducible, quantitative and qualitative data and a comprehensive analysis to be able to answer all 10 evaluation questions (annex 2). The study will feed into a Staff Working Document (SWD) containing the evaluation work including evidence-based conclusions and any possible recommendations for the improvement of the current legal framework for FCM delivered by the Commission services.

The study will cover all the evaluation criteria of effectiveness, efficiency, relevance, coherence and the EU added value of the EU legal framework on FCMs. The analysis will evaluate how the approaches, procedures and processes established by the Regulation and implementation contribute to securing a high level of protection of human health as well as the effective functioning of the internal market for FCM.

The study aims to establish whether the EU FCM legislation has delivered expected benefits, and whether this has been achieved at proportionate costs. In addition, the study shall assess whether the objectives and the tools set out in the FCM legislation remain relevant and coherent, in light of recent technological progress in FCM sectors as well as legislative developments in other relevant fields (e.g. food, chemicals, etc.).

Chronologically, the scope of the evaluation includes the basic requirements, implementation and the functioning of Regulation (EC) No 1935/2004 from its entry into force on 23 November 2004 but also the period concerning the general rules that have been maintained since the introduction of the earliest FCM legislation in 1976, including those in the current Article 3.

It includes subsequent implementing measures and the concepts and ways in which these measures regulate FCMs, including risk assessment and risk management processes, authorised lists of substances, document requirements, Good Manufacturing Practices (GMP), traceability and enforcement. It also covers the situation concerning FCMs for which no specific EU measures exist but may exist at national level, as set out in Article 6.

The scope of the evaluation will not include analysis of the detailed rules and requirements contained within the specific harmonised EU legislation, for example whether a particular substance should be authorised or not, specific restrictions or testing methodologies

The study will aim to include any unexpected or unintended positive or negative effects of the legislation, and explicitly mention such effects when addressing the evaluation questions. 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.

Timeline

The duration of the study in support of the FCM regulation evaluation is 14 months, starting in August 2018 and finishing in October 2019. Overall, the study is structured into four phases, which are illustrated below:



Figure 1 Timeline of the study

Evaluation questions

Ten evaluation questions covering the effectiveness, efficiency, relevance, coherence and EU added-value of the FCM legislation have been defined for this evaluation. These are provided in annex 2 to this document.

Consultation strategy

The starting point for this evaluation was a [roadmap](#) published in November 2017 to inform citizens and stakeholders about the Commission's plans including the consultation strategy and to allow them to provide feedback on the intended initiative as well as to participate effectively in future consultation activities. The feedback provided can be found in annex 3.

The consultation process aims 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 intend 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

The consultation strategy encompasses all five evaluation criteria: effectiveness, efficiency, relevance, coherence, and EU added value. While consulting stakeholders, triangulation is important to generate robust results. This means that the study will aim to cover all relevant stakeholder groups on a given aspect. However, this does not mean that all stakeholder groups are consulted on all aspects of the regulations. Rather, the goal is to engage stakeholders on those aspects where they can be expected to have information or an opinion.

Consultation activities

Workshops

Two workshops will be organised during the course of the study. This first workshop will kick-start the consultation process. The aim of this workshop is to engage stakeholders in the process and to finalise the inception phase by collecting stakeholder views on the proposed approach, and methodology for the study. A second workshop will be organised towards the end of the study to validate preliminary results from the study.

Targeted interviews

Interviews will encompass all relevant stakeholders from EU Member States, as well as Switzerland and Norway. Stakeholders from third countries whose business is relevant to the

placing on the market of FCMs in the EU will also be taken into account. The main purpose of the targeted interviews is to investigate, clarify, substantiate and analyse the evidence provided by key stakeholders in the practical implementation of FCM Regulations. Among other topics, interviews will address risk assessment and management processes, positive authorised listing approach, application of the GMP and enforceability of the Regulations.

Focus Group discussions

Focus groups will be organised in Brussels to gather expert representatives from all stakeholder groups to cover some key elements of the legislation. Focus group meetings will integrate stakeholders' knowledge on the main issues of interest linked to the application of Regulation (EC) No 1935/2004. Each focus group will consist of a half day meeting with approximately eight persons. During the focus group, participants will be asked to contribute as individual experts.

Open Public Consultation (OPC)

A 12-week consultation using the EU survey tool is foreseen. The OPC aims to collect opinions from various stakeholders as well as citizens. The OPC will be available in all official EU languages, to enable citizens from across the EU to participate in the survey. The OPC is planned for the period December 2018 to February 2019.

Plenary discussion session

Objective: Collect the initial views of key stakeholder groups on the functioning of the FCM legislation against the evaluation criteria

The results of the discussions may be used as an input for the evaluation questions. However, the main purpose is to obtain ideas of stakeholder perceptions on the overall performance of the legislation and to get a better knowledge of the most challenging issues related to the legislation. The workshop is also an occasion for stakeholders to bring to the attention of the study team their experiences regarding the implementation of the Regulation.

Below, stakeholders can find general 'starter' questions to consider and give their feedback on during the plenary session of the stakeholder workshop.

Effectiveness

- To what extent does the legislation meet the two major objectives on health and functioning of the internal market?
- What are both the main positive and negative aspects of the legislation at each level of the implementation chain?

Efficiency

- What are the quantifiable benefits and burdens of the legislation and how can these be quantified / weighted?

Relevance

- Have the scope and applicable rules been relevant to stakeholders, including consumers and businesses and do they remain so today?

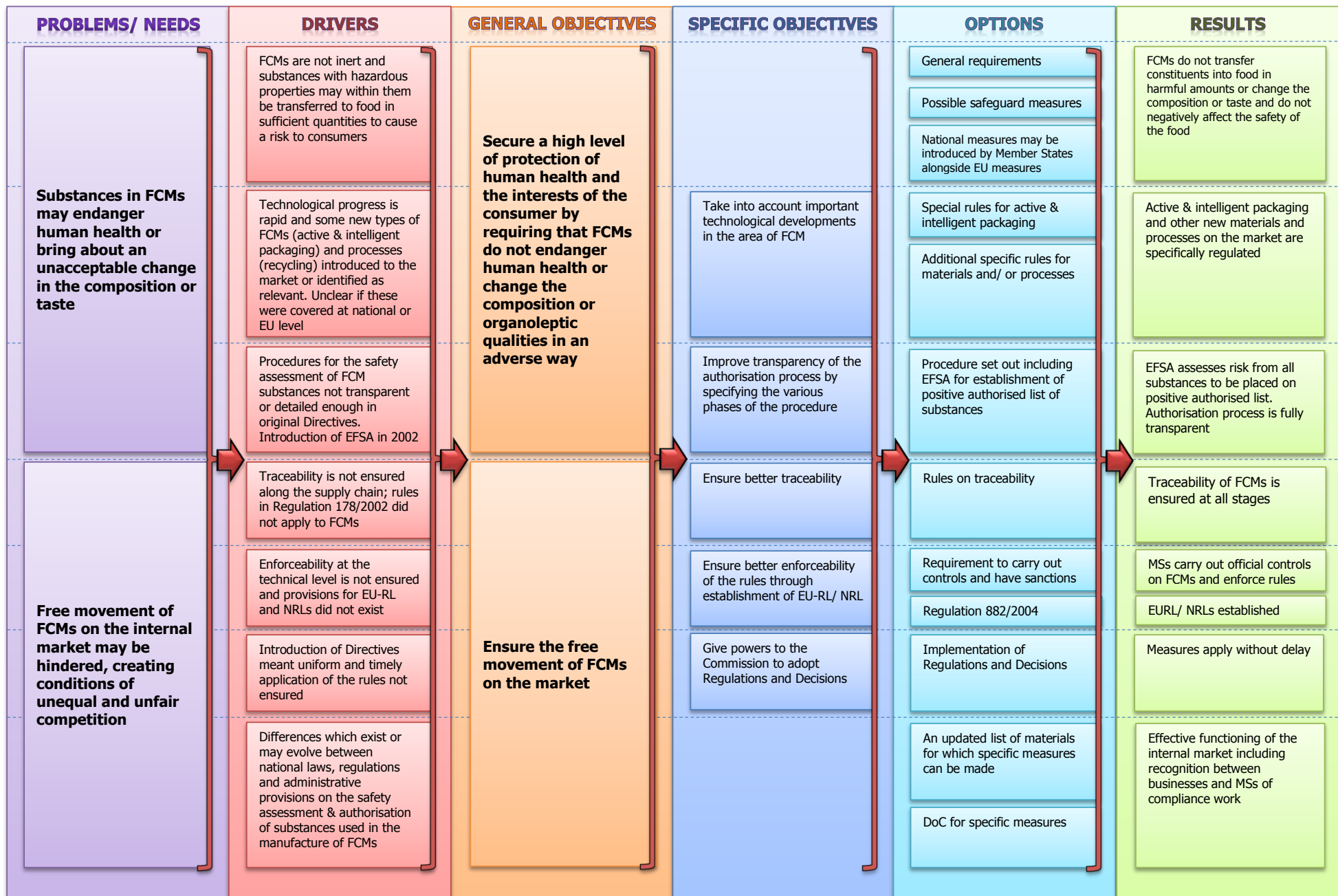
Coherence

- Which parts are coherent and which parts are not coherent within the legislation itself and other relevant rules or practices?

EU Added Value

- Has it been better to have the legislation at EU level or alternatively at national level?

Annex 1 – Intervention Logic



Annex 2 – Evaluation questions

Effectiveness

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?
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?

Efficiency

3. What are the quantifiable benefits of the FCM legislation, taking into account resources (cost, time, etc.) to stakeholders?
4. What are the quantifiable burdens of the FCM legislation, taking into account resources (cost, time, etc.) to stakeholders and are there aspects that could be simplified to improve efficiency?
5. Taking into account the answers to questions 3 and 4, how efficient is Regulation (EC) No 1935/2004 and its implementation tools in ensuring the safety of FCMs?

Relevance

6. What are the needs, interests and expectations of the following stakeholder groups and to what extent does the current legislation address them?
 - a. Consumers and their representative organisations;
 - b. Business operators including food business operators and;
 - c. Member States' Competent Authorities?
7. To what extent has Regulation (EC) No 1935/2004 and its subsequent implementation allowed for evolving science, prioritisation and innovation?

Coherence

8. To what extent is Regulation (EC) No 1935/2004 internally coherent, including all of its implementing acts?
9. 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?

EU Added Value

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

Annex 3 – Feedback on the FCM evaluation roadmap

Organisation: ENFIT e.V. Internationaler Tankreinigungsverband

Feedback: Aus unserer Sicht besteht ein dringender Klärungsbedarf bei der Frage, ob Silofahrzeuge, die zum Transport von Schüttgütern in Pulver- oder Granulatform beim Lebensmitteltransport für z.B.: Zucker, Milchpulver, Mehl, Gries, Getreide, etc., eingesetzt werden, diese aus Aluminium sein dürfen.

Derzeit sind mindestens 99,5% aller Silo-Transportbehälter aus Aluminium gefertigt. (Tankwagen, ISO Container und IBC's im Bereich des Transportes flüssiger Lebensmittel sind in der Regel aus Edelstahl gefertigt).

Aluminium wurde bereits vor Jahren in der Lebensmittelproduktion- und -verarbeitung weitestgehend durch Edeltäle ersetzt. Grund dafür war und ist die hohe Aluminium-Migration in das Lebensmittel. Eine hohe Migration tritt dann auf, wenn das Kontaktmaterial sauer oder alkalisch ist (bei Flüssigkeiten).

Nun könnte man vermuten, dass Schüttgüter, Pulver und Granulate ph-neutral wahren und somit keine Gefahr beim Transport von Schüttgütern gegeben ist.

Das muss man deutlich verneinen. Denn, Lebensmittel-Transportbehälter, zu denen auch die Silo-Transportbehälter gehören, werden mehr oder weniger regelmäßig gereinigt und desinfiziert. Reinigungsanlagen verfügen bisher nicht über das erforderliche Know how zu wissen, dass Aluminium-Silo-Transportbehälter besonders empfindlich auf saure oder alkalische Reinigungsmittel reagieren.

Daher werden diese Transportbehälter oftmals falsch bei der Reinigung behandelt.

Beim Einsatz von üblichen Reinigungs- und Desinfektionsmitteln wird die Oberfläche des Aluminiumbehälters angegriffen (man kann den Alu-Abrieb leicht mit einem Tuch abwischen).

Das bedeutet, dass besonders nach einer ungeeigneten Reinigungsprozedur ein besonders hoher Aluminium-Übertrag in das nächste Ladegut stattfindet.

Dies gilt besonders für Transporte von Milchpulver das für die Herstellung von Babynahrung eingesetzt wird.

Nach unserer Erkenntnis machen sich bereits einige große Lebensmittelproduzenten darüber Gedanken, wo die hohe Kontamination mit Aluminium in deren Rohstoffen herkommen könnte. Das die Ursachen durch den Transport in einem Aluminiumbehälter herrühren könnten, ist bisher kaum jemanden bekannt. Die meisten Unternehmen gehen davon aus, dass Silo-Transportbehälter, wie beim Transport von Flüssigkeiten, ebenfalls aus Edelstahl wären.

Als Verband, der sich besonders auch mit dem Thema Lebensmittelsicherheit in der Supply Chain beschäftigt, ist es uns ein Anliegen, diesen Sachverhalt aufzuklären und Lösungen zu finden, die die hohe Aluminium-Migration verhindern können (Andere Behältermaterialien, Beschichtungen, etc.).

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F7916_en

Organisation: ClientEarth

Feedback:

- We welcome the plan to identify unexpected impacts or issues as a consequence of the current Regulation, but the benefits of the regulations for public and environment safety should be taken into account as well.
- We welcome the content on the table describing the intervention logic, but would like to note that it is missing a measure or 'cut off' which would drastically help to improve the FCM regulatory framework: a legal presumption resulting in the ban, by default, of substances with hazardous properties in FCM. This legal presumption could be overturned only when there is strong evidence that leachates cannot happen and that safe recycling is possible despite the presence of hazardous properties in the material.
- This would be essential for two reasons.
 - First, for public health, as 1) a safety threshold cannot not be found for every substances, 2) food consumption habits vary drastically between individuals 3) vulnerable populations, such as children, are particularly exposed to packaged foods.
 - Second, to ensure a safe circular economy, which requires FCM that can be safely recycled.
- We welcome a reinforced traceability requirement, but note that traceability should also involve traceability of hazardous substances in FCM in order to facilitate safe end-of-life, including recycling. This would also ensure coherence with the agreement newly reached under the circular economy package obliging suppliers to send information to ECHA on the presence of hazardous substances in the products they sell in order to make this information available to waste operators as well as consumers.
- We urge the Commission to take better into account the health costs of not properly controlling hazardous substances in FCM, including EDCs.
- We emphasise the need to make public all the evidence used and collected in the process of the evaluation, and to include civil society in a meaningful way. This means to organise consultations before decisions are made, to give equal attention to inputs from the industry and from civil society and to provide clear and precise explanation of how the comments were, or not, taken into account.
- We finally urge the Commission to take into account the latest knowledge on chemical risks, including the risks caused by EDCs, by non-intentionally added substances and by the additive and synergistic effects between various chemicals.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8349_en

Organisation: The Alliance for Beverage Cartons and the Environment (ACE)

Feedback: ACE members support the general direction and intention of EC's roadmap to evaluate Food Contact Materials (FCM) and wish to highlight some points as set out below:

1. ACE members appreciate that the roadmap recognizes the importance of the free movement of FCMs.
2. ACE members would welcome a systematic assessment of EU 1935/2004.
3. In "Drivers" first row of the Annex, there is the sentence which sets out that: "FCMs are not inert and substances with hazardous properties may within them be transferred to food in sufficient quantities to cause a risk to consumers." This definition seems to observers (e.g. consumers) like a general suspicion that FCM are in general unsafe. Therefore, we would welcome a more correct wording, as for instance: "FCMs are not inert and substances within them may be transferred to food. If hazardous and in sufficient quantities, this could cause a risk to consumers."
4. Several non-EFSA-evaluated substances are used in the production of FCMs. EFSA's capacity to evaluate new substances is limited. To avoid putting more burdens on EFSA, EFSA and DG SANTE could recognize already approved substances, like chemicals positive listed by BfR and FDA.
5. The heading "Identified problems (pre-2004)" leaves room for interpretation. ACE members wish to point out that problems that may not have existed pre-2004, but which are existing today, should be addressed. Traceability is an example for such a problem. It is not governed by measures to ensure that FCMs are traced at all stages.
6. The operation of Good Manufacturing Practice (GMP) is an essential part of the process of producing safe Food Contact Materials (FCM). This is recognised in article 3 of Regulation (EC) No 1935/2004 – "Materials and articles ... shall be manufactured in compliance with good manufacturing practice so that ...". Regulation (EC) No 2023/2006 is an important part of the legislative framework and should be explicitly included in the evaluation Roadmap
7. In "Drivers" fourth row, there is an assumption that the safety assessment of FCM substances will be achieved through an EFSA assessment of the risk of all substances and the creation of positive lists. This is possible for Intentionally Added Substances. The Roadmap should acknowledge that Non-Intentionally Added Substances (NIAS) are also present in FCM. These cannot be risk assessed by EFSA and placed on a list. There is a need to raise the issue of industry self-assessment of NIAS and how this can be done in a way that is effective and transparent.
8. A barrier to the extension of harmonised measures is the sheer number of substances that require assessment and the limited resources of EFSA to do this. Industry self-assessment of substances is also a possible solution for this issue.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8342_en

Organisation: European Printing Ink Association (EuPIA)

Feedback: EuPIA, the European Printing Ink Association, represents the manufacturers of printing inks and related products in Europe.

We welcome the European Commission's initiative to review the current legislation on food contact materials. We would like to point out that many of the issues listed in the Annex (Intervention logic) were raised already in the Commission's Roadmap of 2012 (Food Contact Materials - Specific provisions for materials other than plastics – implementing measure), and answers were provided by us and many other trade associations at that time. We reiterate our call for European harmonized legislation for the reasons set out in our 2012 reply to the Commission. In doing so, we are convinced that inflexible approaches such as currently required for plastic food contact materials are no longer contemporary, and modern approaches for risk assessments should take precedent and be implemented in future FCM legislation. Finally, EuPIA would like to stress that the envisaged Roadmap activities should not jeopardise a timely development of the EU measure on Printed Food Contact Materials. The Commission announced a timely adoption of this measure in response to the TRIS notification of the "Printing Ink Ordinance" by Germany who said they would restart work on this ordinance if the development of EU legislation were considerably delayed.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8365_en

Organisation: Center of Global Consciousness

Feedback: These are my recommendations:
<https://www.youtube.com/watch?v=7kQZ6TIGBHU>

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8089_en

Organisation: FEFCO

Feedback: Dear FCM team, We would like to thank you for the opportunity to send feedback on the European Commission Roadmap on the Evaluation of Food Contact Materials (FCM).

We understand the need to assess the effectiveness, efficiency and added value of the existing EU legislative framework on FCM and appreciate the efforts of the Commission to bring improvements. The food contact materials and their supply chain represent a significant part of the EU market which could only benefit from clear and coherent EU legislation.

Our particular feedback relates to “Annex I – Intervention logic” from the Roadmap. The first basic problem identified by the Commission as “Substances in FCM may endanger human health or bring about an unacceptable change in the composition or taste” is probably the main reason for the existence of FCM legislation at EU and National level. We all, as individuals and consumers, want to make sure that our food is safe for consumption. At the same time we all, as producers, want to make sure that our FCM would not contaminate the food or endanger human health. So, we all want to have a sustainable solution for all FCM, including those that are not yet harmonised.

However, the first tool suggested to solve that problem, namely “National measures may be introduced by Member States alongside EU measures” creates a paradox. The reason is that the suggested tool already describes the existing legislative situation in EU, and is also identified by the Commission as the main driver for the second problem, specified as “Free movement of FCMs on the internal market may be hindered, creating conditions of unequal and unfair competition”.

We believe that having fragmented National measures alongside EU measures is not only hindering the internal market of FCM and packaged food but it also creates difficulties for the national competent authorities to ensure compliance and enforcement.

Therefore, our proposal would be to delete or adapt the first tool suggested as a possible solution to the first problem.

We recognise that this might create challenges and we are prepared to work together with the Commission for a sustainable solution regarding paper & board as FCM.

Thank you in advance for your kind consideration.

Best regards, Krassimira Kazashka-Hristozova, Technical Director, FEFCO

This position is sent on behalf of the following associations, part of the paper & board supply chain:

FEFCO: the European Federation of Corrugated Board Manufacturers that represents the producers of corrugated board packaging.

ETS (European Tissue Symposium): the European Tissue Paper Association with members representing about 90 % of the total European tissue production.

CEPI Eurokraft: the European Association for Producers of Sack Kraft Paper for the Paper Sack Industry and Kraft Paper for the Packaging Industry.

EUROSAC: the European Federation of Multiwall Paper Sack Manufacturers that represents the producers of industrial paper sacks.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8479_en

Organisation: I&P Europe - Imaging and Printing Association

Feedback: The following comments should be taken in the context of our interest as the trade association Imaging & Printing Europe, representing suppliers of digital inks, toners and pressroom chemicals for the packaging industry.

- We welcome the evaluation of the frame-work regulation.
- The absence of EU regulations for other FCM beside plastic has a negative ef-fect on the market of FCM.
- Framework regulation is in principle good, but problem is that this is not fol-lowed up by the implementation of regulations on different FCM.
- We support that additional regulation has to be implemented and we have ad-vocated for years to have one developed concerning packaging inks used in indirect food contact applications.
- The problem that these additional regulations do not exist lies according to our information in the fact that there is not enough manpower in relevant EU au-thorities to develop regulations. Is this correct and how could this be resolved?
- EFSA has problems with evaluating substances in a reasonable timeframe for addition on the positive list (6 months as given in framework) and with devel-oping standard test methods.
- European Union reference laboratories that act under EFSA might solve the problem.
- National reference laboratories might give problems with non-uniform ap-proach.
- If EU Regulators can not implement clear decisions, regulations, tools and test methods to support industry to be in compliance with FCM regulation, this will lead to non-uniformisation within the European Union, which will possible cre-ate confusion and distrust by the consumer, which is not beneficial for both EU and industry.
- GMP would imply good traceability, so if good GMP guidelines are in place, the situation will be improved.
- Industry associations already have developed tools and guidance to support companies with their FCM compliance, due to lack of existing support from au-thorities.
- It is the responsibility of industry to ensure compliance.
- FC laboratories are forced to develop their own test methods due to lack of standard test methods from authorities, which results in different approaches and results for FCM.
- Difficult to judge on enforceability at technical level if insufficient EU rules are in force.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8456_en

Organisation: Cerame-Unie / FEFP

Feedback: The European Federation of Ceramic Table- and Ornamentalware (FEFP) is a member association of Cerame-Unie (The European Ceramic Industry Association). It was founded in 1959 and its secretariat is based in Brussels. Its membership currently covers producers in 9 countries: France, Germany, Italy, United Kingdom, Spain, Portugal, Poland, Romania and Croatia.

All our members, which are national associations and some direct companies, are working on articles/materials intended to come into contact with food (FCM). With regard to FCM, the majority of our members manufacture tableware & kitchenware and bakeware. Some members also manufacture food & beverage packaging ceramics materials. All FEFP members are manufacturers based in the EU and a vast majority of products are made in the EU. The sector employs around 25,000 skilled people with a majority of small and medium sized enterprises.

The European Commission is revising the Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs (the “Ceramic Directive”) and to reduce the limits for lead and cadmium in the coming months. Future limits have to be scientifically justified and achievable without creating disproportionate burden and costs for the industry. FEFP holds the opinion that the current European plans are too strict and would have a severe negative impact on European Industry.

FEFP wishes to provide comments to the current Evaluation of Food Contact Materials roadmap, specifically on the main relevant criteria. FEFP wishes to highlight the impacts of the current regulation and our expectations with regards to the revision.

TRADE CONCERNS

The original objectives, laid down in framework Regulation 1935/2004, still correspond to real needs. However, on the one hand, our internationally operating members have to respect the judicial requirements incl. food contact legislation of other markets, and on the other hand ceramic tableware and kitchenware imported to the EU are not subject to the same level of manufacturing controls in the EU. We would like to point out that more than 75% of products placed on the market are imported to the EU from third countries.

The current EU FCM rules are still relevant to the original objectives. However, it is not clear to what extent the existing rules have been well enforced at customs and if the same level of enforcement can be met across different member states and on products coming from third countries.

Legal regulation should be implemented and FCM products placed on the EU market should be effectively controlled. Effective traceability and market surveillance should be assured. When a product is non-compliant, it should be made possible to trace it back to the manufacturer and at the same time the product should be removed from the EU market and its re-entry should be prohibited.

RISK ASSESSMENT

DG SANTE and the EURL – European Reference Laboratory – are currently taking account of the available research on food contact materials. Both DG SANTE and EURL and have been engaged with the industry via conferences e.g. JRC Ceramic Workshops in Ispra or through bilateral information sharing.

However, when work to review the Council Directive 84/500/EEC started (in early 2012) the research conducted by EU policy-makers was at the time relying on internet sources to research the use of materials without consulting with industry. A prior consultation before

starting a discussion at EU level on FCM for ceramics, would have allowed for a more accurate information and expertise to feed into discussions.

In the meantime, the industry has compiled a list of available scientific resources, conducted tests and shared this information and testing results with the EU as well as national policy makers. We do not have a clear overview of the expertise exchanges at national level. However, we recommend that EU and national policy-makers take into account the expertise available at company or associations level.

FEPF recognises that limits need to be modified and made stricter. However, new limits must be realistic, possible to achieve and be able to be monitored in a cost-effective way.

New FCM rules at EU and national levels should, in our opinion, take into account available international test methods and technologies in order to avoid any duplication that may result in undue costs. In this regards the adoption of more stringent values currently implemented in California (Proposition 65) could be a good reference for the revision of the new FCM limits in the EU. The current limits under discussion by the EURL and DG SANTE would pose severe aesthetical limitations that would diminish creativity and innovation from an artistic point of view which is what characterises artisanal and artistic production.

There are many problems which should be discussed at length before new limits are imposed. The setting of new limits must be accompanied by a complete impact assessment (environmental, economic and social) taking into account both industrial and artisanal/artistic productions. There are local artistic productions spread throughout the EU that must be considered for their excellence and tradition.

SUBSTANCES

Lead and cadmium are relatively well researched but scientific knowledge still needs to be further developed to ensure it is sufficient for decision making. Additional substances researched by the EURL (as reported at a previous Ceramic Stakeholder meeting in Ispra) are less well researched than lead and cadmium.

It seems that some substances are targeted as a matter of principle without real studies actually proving their harmful effects. Furthermore, the analytical methods do not sufficiently take into account in particular the reduction of the leached metals after several uses. Consequently greater scientific knowledge is required before it can be considered sufficient.

TRACEABILITY

Although there is a requirement for a declaration of conformity, a rule is not in place to ensure that ware is marked with the brand or the name of the manufacturer. This seriously undermines traceability. As a minimum there should be the requirement to mark ware with a manufacturer's or distributor's name and/or brand so that the consumer can trace items.

One challenge to the implementation of traceability rules is the variance in approach by different countries as the diverse requirements can make it very complex for companies to comply. Moreover it's worth underlining that some imported products are characterised by incorrectly fired decoration and quality standards well below the current performance levels achieved so far by the European companies and legislation.

GOOD MANUFACTURING PRACTICE (GMP)

We understand that some companies in our sector have established GMP and conduct controls regarding food contact and ensure traceability, e.g. raw materials from their suppliers.

In some European countries a process is under way to develop national guidelines of GMP at company level. The current EU and sector-specific GMP rules are sufficient to ensure safety of the articles and materials.

With regard to the fulfilment of GMP and 1935/2004 EU, testing costs can be significant, particularly for smaller companies or companies offering a high number of decoration options. Some companies offer individual decoration options. Although such offer is an essential part of their business model, it results in high compliance costs.

ENFORCEABILITY

There should be a consistent approach to the control of all food contact materials placed on the EU market.

We are aware of the various national judicial requirements for ceramic food contact materials such as lead and cadmium (see LUCIDEON's (formerly CERAM) publication about national judicial requirements for ceramic FCM in different countries). Our members comply with national and international legislations lead and cadmium. However, we are not aware of a list of "authorised" substances.

The "compliance costs" generated by the current EU FCM rules and national FCM rules are generally High to Very high costs mainly due to testing and related equipment. It is impossible to differentiate for each country.

We understand that the compliance practices may differ country by country. In some countries, the very availability of Declaration of Compliance and appropriate documentation is not sufficient and a testing in an accredited laboratory is necessary.

The cooperation with Member States' competent authorities is generally positive. However, authorities may have different requirements levels and may execute more control than guidance.

IMPLEMENTATION CHALLENGES

Firstly, there is not a consistent approach across the EU. Some Member States implement the current EU FCM rules to the full extent, whereas others only partially implement / do not implement. In other countries, the check and controls may go beyond the current legislation in force.

Regular checks carried out in European companies seem to be rather effective but the absence or lack of controls on products from third countries does not consider that security is ensured for consumers. The lack of a 'watchdog' limits the benefits EU FCM directive could deliver.

In order to guarantee a sustainable compliance with the current FCM rules, new structures had to be built up. This created high costs. The future challenge will be to find a reasonable way for all stakeholders (consumers and companies) on national, as well as on international, level.

In conclusion:

- FEPF recognizes that limits need to be modified and made stricter. However, new limits must be realistic, possible to achieve and be able to be monitored in a cost-effective way.
- The setting of new limits must be accompanied by a complete impact assessment (environmental, economic and social) taking into account both industrial and artisanal/artistic productions. There are local artistic production spread throughout the EU that must be considered for their excellence and tradition.

- The delay in involving relevant industry representatives in the review from an early stage could have had a significant negative impact on the sector across Europe. Any future work must involve the relevant experts at the outset.
- The review of the Directive commenced with a sense of urgency and then stalled, but regained speed in late 2017. However, the completion will most likely take place in 2020 at the earliest. This has created costs and uncertainty for businesses.
- The delay in completing the review of the Directive has led to some Member States to start implementing new rules and regulations in anticipation. This is creating complexity and uncertainty for businesses.
- Even before the Directive was reviewed, it was not being consistently implemented throughout Europe. More should be done to ensure uniform enactment.
- It is important to ensure surveillance of the existing and any future revision requirements. The requirements should be clear, realistic and burden of compliance should not only be on European companies (which tend to be controlled more often) but equally on all producers placing FCM on the EU market.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8480_en

Organisation: Health and Environment Alliance (HEAL)

Feedback: The Health and Environment Alliance (HEAL) welcomes the possibility to comment on the European Commission roadmap for the evaluation of food contact materials (FCM).

In HEAL's view, such an evaluation is long overdue, since the legislation has been in place since 1976. Many of the synthetic chemicals involved in packaging and storing the food we eat can leak into it, and researchers have alerted to potential harm to long-term health for three reasons: 1) consumers are exposed to known toxicants; 2) hormone production-disrupting chemicals, such as bisphenol A (BPA), tributyltin, triclosan and phthalates, can also be present in FCMs and 3) the number of known chemical substances intentionally used in FCMs is over 4,000. (1) This evidence combined with the JRC's recent assessment and other studies demonstrates that the regulation falls short of meeting its two main objectives: the high level of protection of human health and the interests of consumers on the one hand, and the effective functioning of the internal market on the other hand.

PROBLEMS WITH THE CURRENT LEGISLATION

HEAL's most immediate concerns relate to the lack of adequate provisions in the current regulation to achieve the protection of human health. We regret that the context description included in the roadmap does not highlight this aspect prominently and we call on the European Commission to ensure that the protection of human health is a guiding aspect of the upcoming evaluation. This is particularly critical, when we know that vulnerable groups such as babies, young children, pregnant or breast-feeding women are most at risk from the adverse health effects of an inadequate regulation (for instance because of loopholes for certain toxic substances in food packages). Unwanted chemicals present are routinely found in various food packages, without consumers knowing it and regulatory bodies acting upon those findings to fully ban those substances from food contact materials. (2) On the contrary, addressing food contact materials in a health-protective way will benefit citizens, workers in the food packaging sector and contribute to significant economic savings. (3)

Our concerns about the regulation's inadequacy to protect human health add to and overlap with the inadequacy of the regulation to ensure the functioning of the single market. This is because member states currently adopt different regulations to fill in the gaps of the European framework. In practise, this means that citizens are not protected equally across Europe from the risks arising from the presence of chemicals used in food packaging. Moreover industries have to abide by different standards depending on the countries in which they sell their products and workers in the food packaging industry are also exposed to different risks depending on the country of their workplace.

The European Parliament 2016 resolution on food contact materials (4) identified severe shortcomings on the functioning of the current regulation and clear demands for how the European Commission could improve the current legislation and its enforcement. HEAL regrets that the present roadmap does not acknowledge this resolution and strongly supports that it should be an important basis for the evaluation to come, in addition to the JRC report already referenced in the roadmap.

HEAL'S VIEW ON WHAT THE UPCOMING EVALUATION SHOULD DELIVER

In HEAL's view, it is urgent for the European Commission to identify the existing loopholes in the regulation that currently put citizens' and workers' health at risk and draw on the most protective regulatory frameworks that might already exist in individual member states in order to overhaul the European framework. Doing so will benefit citizens' and workers' health and translate into higher regulatory certainty for businesses so that they can operate in better

conditions. Finally this will stimulate innovation towards safer alternatives, giving the EU industry a competitive advantage over the rest of the world and an opportunity to set a golden standard in terms of regulation for others to follow.

In HEAL's view, the biggest regulatory gaps (4) that the evaluation should cover include the following:

- Most materials currently used for food packaging are not covered by the current regulation. Only five materials are covered: these are ceramics, regenerated cellulose film, active and intelligent materials, plastics, recycled plastics. Widely used materials such as paper and boards are overlooked.
- Many chemicals are not assessed for safety by public authorities, the so-called non-intentionally added substances (NIAS) that are present as impurities or by-products of manufacturing processes.
- Numerous chemicals harmful to human health are overlooked – including substances identified as of very high concern (SVHC) under the REACH legislation.
- Endocrine disrupting chemicals are not addressed at all.
- Recycled inputs are not assessed for their adverse health effects.
- The real-life exposure conditions to chemicals as well as the additive effects between the various chemicals used in one single food package are overlooked in the current risk assessment process.
- The current regulatory process for FCM is not transparent enough and suffers from an unbalanced stakeholder access, with limited access for civil society groups.
- By not being aligned with the REACH regulation, the FCM regulation is not delivering on the better regulation objectives set by the European Commission itself.

In HEAL's view, the evaluation of the regulation should allow to take measures in order to achieve the following:

- Regulate all types of food contact materials in a health-protective way;
- Contribute to a toxic-free circular economy;
- Prohibit or phase out "Substances of Very High Concern" (or SVHCs) as identified under the REACH legislation;
- Ban all endocrine disrupting chemicals (or EDCs) from FCMs;
- Address the cocktail effect of chemicals when assessing the safety of the substances present in FCMs;
- Support innovation for safer and less resource intensive materials and health-protective alternatives.

HEAL'S VIEW ON THE EVALUATION PROCESS

In terms of the proposed evaluation logic:

- The current regulation's failure to protect human health and the need to change this situation should be the departing point of the intervention logic. The presence of substances with health-adverse effects in food packages currently sold on the European market should be acknowledged.

- Likewise the failure of the risk assessment process to address the cocktail effect of chemicals and the potential toxicity of the mixtures present in packages should be acknowledged.
- Finally and related to the previous point, the intervention logic should shift away from the sole focus on food contact materials in order to also integrate the finalised food packages (that composed of different materials). Both individual materials and final packages should be assessed for safety.

In terms of the process for the evaluation to be carried out, particular attention should be given to the following points:

- Ensure full transparency throughout the entire evaluation process (who is being consulted, how, when, by whom, on which points);
- Ensure balanced consultation between public interest and industry stakeholders in order to guarantee that the evaluation fairly reflects on how the regulation performs on both of its objectives. The protection of human health should not be considered as a secondary objective when compared to the functioning of the single market.
- All the data mentioned in the 'data collection and methodology' box (including the information held 'concerning audit and fact-finding work carried out by DG SANTE' and 'information on the use of compliance documentation in the supply chain' should be made publicly available.

Notes:

(1) Journal of Epidemiology and Community Health
<https://www.medicalnewstoday.com/articles/272910.php>

(2) See for instance <http://kemi.taenk.dk/bliv-groennere/fast-food-packaging-contains-unwanted-fluorinated-substances>; <http://kemi.taenk.dk/bliv-groennere/test-chemicals-plastic-food-containers-migrate-warm-fatty-foods>; <http://kemi.taenk.dk/bliv-groennere/test-unwanted-chemicals-found-pizza-boxes>; <http://www.env-health.org/resources/press-releases/article/two-thirds-of-food-can-linings>

(3) See for instance: https://ehp.niehs.nih.gov/wp-content/uploads/2017/09/EHP644.alt_.pdf; <http://www.chemtrust.org/wp-content/uploads/chemtrust-foodcontactchemicals.pdf>

(4) <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2016-0384>

(5) Details about HEAL's views on the gaps in the existing regulation and our recommendations are detailed here: http://www.env-health.org/IMG/pdf/15022016_-_heal_briefing_fcm_final.pdf

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8338_en

Organisation: FoodDrinkEurope

Feedback: FoodDrinkEurope, representing the European food and drink manufacturing sector, welcomes the Roadmap as this exercise would be beneficial for the safety of consumers and the function of the internal market.

The food and drink industry is a key player in the food contact supply chain, as we place pre-packed food products on the market. Therefore we commit to provide input during the targeted consultation phase.

We would be interested to know the outcome of the recent survey conducted by the European Commission (EC) regarding the use of compliance documentation in the supply chain, prior to the result of the Roadmap evaluation.

We advocate that this initiative does not delay on-going pieces of EC work which are important to ensure a level playing field in the EC and a proper function of the internal market, in particular the authorisations of the plastic recycling processes, the revision of the ceramic directive, the monitoring work on mineral oils and the new measure on printed food contact materials.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8320_en

Organisation: Der Grüne Punkt - Duales System Deutschland GmbH

Feedback: Lebensmittelrechtliche Zulassung von Post-consumer-Rezyklaten für die Herstellung von Lebensmittelverpackungen

Ausgangslage

Gemäß EFSA-Empfehlung (Scientific Opinion, EFSA Journal 2011;9(7):2184) sind Kunststoffrezyklate dann für den Einsatz bei der Herstellung von Lebensmittelverpackungen geeignet, wenn sie in einem zugelassenen Herstellverfahren dekontaminiert und zweitens aus Rohstoffen hergestellt worden sind, die nachweislich zu 95% aus Lebensmittelverpackungen bestehen.

Die zweite Vorgabe ist ganz offensichtlich nur mit entsprechend geeigneten Sammelsystemen einlösbar und steht im offenen Konflikt mit Bestrebungen, das Spektrum der in Getrenntfassungssystemen gesammelten Produkte eher zu erweitern denn einzuschränken. Am besten geeignet sind Pfandsysteme, die eine zielgenaue Eingrenzung der Erstanwendungen ermöglichen. Die in einer Reihe von europäischen Ländern bis heute praktizierte Einschränkung der Sammlung auf den Verpackungstyp „Flasche“ unterstellt, dass nach einer Separierung der HDPE-Gebinde die verbleibenden PET-Flaschen nach wie vor derart von Getränkeflaschen dominiert werden, dass die Einhaltung der 95:5-Regel ohne große Anstrengung gewährleistet werden kann.

Inwieweit das bei der europaweiten Stagnation des Marktes für Erfrischungsgetränke und bei gleichzeitigem Wachstum des PET-Einsatzes im Non-food-Sektor auf längere Sicht absicherbar sein wird, ist nicht recht klar, gegenwärtig stellen Recycler die Einhaltung der Regelung gegebenenfalls über manuelle Nachsortierung sicher.

Die Problematik des steigenden Anteils an Non-food-Anwendungen für PET-Verpackungen wirkt sich in der deutschen Sammel-Infrastruktur besonders dramatisch aus: In der Verpackungsabfall-Sammlung durch Duale Systeme fehlen die befandeten Flaschen für Erfrischungsgetränke, der Anteil der Non-food-Verpackungen aus PET macht damit von Haus aus einen höheren Anteil an den erzeugten PET-Rezyklaten aus. Obwohl diese Rezyklate sich, wie mehrfach nachgewiesen, hinsichtlich der aus Verbraucherschutzsicht relevanten Kontaminationen nicht von food-grade-Rezyklaten unterscheiden, sind sie unter gegebenen Umständen nicht zulassungsfähig.

Neben den Erfrischungsgetränke-Verpackungen aus PET stellen in einigen Ländern Europas allenfalls noch Milchflaschen aus HDPE eine in vergleichbarer Weise eindeutig zuordnenbare Fraktion dar, die die Einhaltung der genannten 95:5-Regel via Mono-Rücknahme oder manuelle Nachsortierung ermöglicht. In Ländern mit entsprechend anderen Konsumgewohnheiten wie z.B. Deutschland, ist die Einlösung der EFSA-Vorgaben mit der gegebenen Sammelinfrastruktur für HDPE und andere Polymere außer PET nicht vorstellbar. Zusätzlich ist einzuräumen, dass die technische Abreinigung problematischer Kontaminationen (Dekontamination) aus polyolefinischen Rezyklaten technisch deutlich schwieriger ist als aus PET. Die unter aktuellen Voraussetzungen nicht gegebene Zulassungsfähigkeit für Post-consumer-Rezyklate in Lebensmittel-Direktkontakt-Anwendungen außerhalb des Sekundärrohstoff-Sektors PET-Getränkeflaschen behindert den Rezyklateinsatz in Verpackungsanwendungen generell auf zweierlei Weise:

Zwei Lösungswege

- Weg 1 „arrangiert“ sich mit dem Faktum der unterbrochenen Informationskette an der Schnittstelle Abfall und stellt sich den Anforderungen der Produktsicherheit durch aufwändige, statistisch abgesicherte Analytik.

- Weg 2 sichert die Rückverfolgbarkeit durch die Schnittstelle Abfall „hindurch“ indem über zweifelsfrei zuordenbare, sensor-„lesbare“ Materialmarkierungen hinter der Schnittstelle Abfall die sortiertechnische Selektion von Rohstoffen vorgenommen werden kann, deren Herkunft zweifelsfrei belegbar ist (Stichwort „Polymark-Projekt“). Neben noch zu klärenden technischen Fragen ist hier die Kooperation aller relevanten Player längs der Wertschöpfungskette erforderlich. Die strukturellen, kommunikativen und wirtschaftlichen Herausforderungen hierbei liegen auf der Hand.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8354_en

Organisation: ETRMA

Feedback: ETRMA - The European Tyre & Rubber Manufacturers Association - welcomes the publication of the Road Map Evaluation of Food Contact Materials (FCM) particularly the announcement to address the situation to materials for which there are no EU specific measures and are subjected to national measures. Indeed, rubber materials in contact with food suffer from different implementation measures of the FCM regulation across EU Member States. ETRMA offers its full support, commitment and collaboration to the European Commission to put forward the Road Map "Evaluation of Food Contact Materials (FCM)"

Annex I of the Food Contact Materials Framework Regulation (1935/2004/EC), FCM, lists 'Rubbers' and 'Silicones' among the groups of materials and articles which may be covered by specific measures. However, not specific measures have been set for rubber materials in contact with food. Additionally, implementation of article 3 of the FCM - that states that food contact materials shall be manufactured in compliance with good manufacturing practice provisions - has resulted in a Non-homogenous individual national approval schemes, containing a list of safety requirements and related tests to be applied to the final article.

Additionally, some countries (such as France, Germany, Italy, The Netherlands, Spain) have adopted specific positive lists of chemicals that are permitted to be used in rubber food contact applications. The content of the positive lists varies from country to country (for instance the German BfR Recommendation on rubber lists elastomers, vulcanization aids and additives whereas, the French "Arrêté du 9 Novembre 1994" comprises monomers, vulcanization aids and additives) and chemicals could be differentiated by categories related to food, contact time, contact area and/or specific shapes. The lack of 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 SMEs. Costs for certifying product conformity or to authorize the use of new substances are now multiplied for each country where products are commercialized. SMEs. Costs for certifying product conformity or to authorize the use of new substances are now multiplied for each country where products are commercialized.

Industry needs an internal market for rubber materials in contact with food. Therefore, we encourage the Commission to include in the Road Map provisions that clearly address the concerns raised on rubber products, particularly:

- Provisions to work towards a horizontal European legislation to regulate rubber components (raw materials and finished goods) in contact with food.
- Criteria for including new substances in (a possible single harmonized) positive list – that should be based on the same risk assessment methodologies defined at European level, taking into account the specific characteristics of the different materials and applications.
- The assessment of an eventual ad-hoc legislation on rubber materials that address the unique properties of such materials in terms of chemical composition and physical properties.

More information and references are available at the [attached document](#).

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8368_en

Organisation: Food Contact Additives - a Cefic Sector Group

Feedback: FCA, a Cefic Sector Group, is the European Food Contact Additives professional organisation representing the manufacturers of additives used in the production of Food Contact Materials (FCM) – (For further details about FCA – including its members - please refer to: <http://fca.cefic.org/>). In response to the Commission public consultation on the “Roadmap on the evaluation of the FCM legislation” we would like to offer the following general comments, specifically on the intervention logic included in Annex I of the roadmap:

We would like to reiterate our call for fully EU harmonised regulations for all those food contact materials (FCMs) that are not already covered by specific measures. We believe that setting harmonised provisions for all FCMs will further contribute to ensuring the same high safety standards across the whole of the EU. This would in turn allow the free circulation of FCMs in Member States. As a result of the creation of a single European market for all FCMs, innovations in food contact materials developed in one country would be available across the EU as a whole. We therefore would strongly recommend to consider the development of EU harmonized measures as the “Tool” to pursue, and to abandon the approach suggested in the document of having “national measures alongside EU measures”.

In addition, we would like to highlight that several of the items mentioned in the document are already currently in place, e.g. there are already detailed processes for the risk assessment by EFSA, where we would support the risk assessment process allowing for new concepts like TTC, QSAR, read across, etc, where feasible.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8386_en

Organisation: European Plastic Converters

Feedback: The European Plastics Converters Association (EuPC) has been advocating for many years in favour of a new holistic approach to the Food Contact Materials (FCM) legislation, which would possibly adopt common and modern risk assessment tools for ruling all FCMs. We believe that the most recent scientific advancements in this field make the current legislation ripe to be modernised, not because we consider the present legislation not protective enough for the consumer, but because we believe that the principles on which it was built are now outdated, and in such a scenario the risk from plastic FCM is largely overestimated. Being that the legislation was developed over 40 years ago, it adopts unrealistically overprotective tools to address the potential risk from FCMs, and it focuses almost entirely on plastics.

EuPC welcomes the announced new approach, with the hope that the risk assessment tools that have been developed, of which it has contributed (such as Exposure Principles, Threshold of Concern etc.) are taken into account in the context of the specificity of each FCM. We think in particular that involvement and consultation of all stakeholders, and in particular industrial stakeholders, will be of great help for the EU Commission to understand and balance the legitimate needs that would help the European FCM industry to grow, create jobs, and continue to maintain the highest standard of consumer protection. We at EuPC have experience, skill set and concrete proposals to provide a contribution to the evolution of the FCMs legislation.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8396_en

Organisation: CVUA-OWL

Feedback: Überwachung von Bedarfsgegenständen

Evaluierung des EU-Lebensmittelkontaktmaterialienrechts

Sehr geehrte Damen und Herren,

zur Evaluierung des EU-Rechts bei Lebensmittelkontaktmaterialien habe ich folgende Anmerkungen:

1. Keramik

Die derzeit noch bestehenden Höchstmengen für die Blei- und Cadmiumlässigkeit bei keramischen Gegenständen, die in der RL 84/500/EG genannt sind, genügen schon seit vielen Jahren nicht mehr dem technischen Stand und insbesondere nicht den aktuellen toxikologischen Bewertungen. In Einzelfällen können sich durch Keramikartikel Aufnahmemengen von Blei und Cadmium, aber auch Cobalt und anderen Elementen ergeben, die nicht mehr als konform zu den Anforderungen des Artikel 3 (1a) der Verordnung (EG) 1935/2004 anzusehen sind.

Beispiele findet man aktuell bei Frühstücks-Sets für Kinder mit auffälligen Dekoren (z.B. Film-Motive).

Die Diskrepanz von den derzeit noch „legalen“ Abgabemengen zu den toxikologisch vertretbaren Mengen wird durch die Auflistung in der Tabelle deutlich:

Unter der Annahme, dass ein Erwachsener pro Tag jeweils 1 kg eines Lebensmittels verzehrt, das mit dem zu beurteilenden Material in Kontakt gekommen ist (in Anlehnung an das „Würfelmodell“ bei Kunststoffen) würde für keramische Gegenstände eine „Höchstmenge“ für den Stoffübergang ins Lebensmittel von 0,04 mg/kg für Blei und 0,02 mg/kg für Cadmium als tägliche duldbare Aufnahmemenge für einen Erwachsenen resultieren.

Grenzwerte / Elemente	Hohlgefäß	Hohlgefäß	Flacher Gegenstand	Flacher Gegenstand
	Blei mg/L	Cadmium mg/L	Blei mg/dm ²	Cadmium mg/dm ²
nach RL 84/500/EG	4,0	0,30	0,8*	0,07*
abgeleitet vom TDI-Wert (für 60 kg Körpergewicht)	0,04	0,02	0,008*	0,004*

* Umrechnungsfaktor von 5 (= 5 dm² stehen mit 1 Liter Flüssigkeit in Kontakt)

Die Gegenüberstellung der duldbaren Aufnahmemengen von 1984 und heute (EFSA 2009 und 2010) zeigt, dass die in der RL 84/500/EG genannten Grenzwerte i.S. des gesundheitlichen Verbraucherschutzes nicht mehr akzeptiert werden können.

Herstellungstechnisch können

a. über die Rohstoff-Auswahl (z.B. keine Verwendung von Cadmium-haltigen Pigmenten und Ersatz von Bleioxid als Flussmittel) und

b. technische Steuerung des Brennprozesses

Maßnahmen zur Qualität und Konformität ergriffen werden.

Diese Maßnahmen sind im Rahmen einer "Guten Herstellungspraxis" nach der GMP-Verordnung (EU) Nr. 2023/2006 in Verbindung mit Artikel 3 Abs.1a der Rahmenverordnung (EG) Nr. 1935/2004 für Unternehmen (Hersteller/Importeure) verpflichtend, denn sie sind für alle Lebensmittelbedarfsgegenstände rechtsverbindlich.

Doch bei den Unternehmen fehlt häufig das Verständnis für diesen globalen Regelungsansatz. Selbst im Rahmen einer DIN-Norm wurden bisher keine Aktualisierungen

vorgenommen. Die Prüfung von Keramik nach DIN / CEN umfasst nur die Blei- und Cadmiümlässigkeit, andere Elemente werden nicht berücksichtigt. Die Unternehmen verhalten sich abwartend.

Dies zeigt, dass für Keramik dringend konkrete, detaillierte EU-Reglementierungen (zu diversen Elementen) erforderlich sind, um den grundsätzlichen Anforderungen der Verordnung (EG) 1935/2004 zu genügen und ein hohes Schutzniveau für die menschliche Gesundheit zu erreichen.

2. Emaille

Die allgemeinen Anforderungen nach GMP-VO Nr. 2023/2006 und nach Artikel 3 der VO (EG) 1935/2004 sind für alle Lebensmittelkontaktmaterialien und -gegenstände rechtsverbindlich.

Damit ist z.B. auch die Festlegung von Spezifikationen für Rohstoffe und die Prüfung von Endprodukten verbunden. Ohne konkrete Detail-Vorgaben durch nationale oder EU-Reglementierungen werden diese Aspekte aber nicht von allen Unternehmen berücksichtigt.

Bei Emailierungen werden z.B. Cobalt- oder auch Nickel-Verbindungen für den Haftungsgrund zwischen Metall und Emaille-Beschichtung verwendet, sowie Lithiumsalze als Flussmittel. Eine Überprüfung der Freisetzung dieser Elemente unter Prüfbedingungen, die auch das Kochen und Braten von Lebensmittel einbeziehen wurde bisher nicht oder nur selten vorgenommen. Dass es hier auch Probleme mit Kontaminanten wie Arsen geben kann, zeigt der „Bericht zum Monitoring-Programm 2015 „Elementlössigkeiten von füllbaren emailierten oder keramikbeschichteten Gegenständen zum Kochen/Braten/Backen/Grillen“ (siehe Seite 70ff)

http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/01_Im_mon_dokumente/01_Monitoring_Berichte/archiv/lmm_bericht_2015.pdf

Da sich emailierte Koch-, Back- und Bratgeräte derzeit in großer Vielfalt auf dem Markt befinden, sollten auch für diese Material- / Produktgruppe konkrete EU-Regelungen erlassen und Grenzwerte für diverse Elemente auf Basis toxikologischer Betrachtungen festgelegt werden.

Mit freundlichen Grüßen

i.A.

Helma Haffke

(Dezernentin für Bedarfsgegenstände)

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8410_en

Organisation: European Tube Manufacturers Association (etma)

Feedback: “Article 3 of Regulation (EC) No 1935/2004 specifically says that “Materials and articles ... shall be manufactured in compliance with good manufacturing practice so that ...”. GMP is an essential part of the process of producing safe food contact materials. Regulation (EC) No 2023/2006 on good manufacturing practice is hence an important part of the legislative framework and should be explicitly included in the evaluation roadmap.”

Information about the responsibilities and transmission of information along the supply chain is another aspect which is missing. Analogous to the format in the annex of the EC document, the issue could be presented in the following way:

Basic Problem	Drivers (why problems exist)	Policy Objectives	Tools	Anticipated results
Transmission of information through the FCMs supply chain is not fluent	Business operators are not prone to pass out information because of confidentiality issues	Place food safety and consumers’ health protection before confidentiality issues	Major legal protection to B2B NDAs to protect IP (by a general NDA template provided by EC?)	More fluent information exchange
	Responsibilities are not clearly defined in legislation and guidelines are not able to state further actions, not stated in the legislation	Every link in the supply chain has their responsibilities concerning compliance work clearly defined	Rules on compliance assessment concerning every link of the supply chain	FCMs put in the market are compliant with the legislation, securing food safety and enhancing internal market functioning
	Greatest part of the costs linked to the compliance work lies on the business operator who puts the final article on the market	Compliance work is carried out as a common task through the supply chain	Rules on compliance assessment concerning every link of the supply chain	Enhanced food safety and enforceability through the supply chain

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8417_en

Organisation: Center for International Environmental Law (CIEL)

Feedback: CIEL welcomes the possibility to comment on the European Commission roadmap for the evaluation of food contact materials (FCM).

The FCM legislation regulation has been in place since 1976 and is long due an assessment to reflect the many evolutions in food packaging design and use, human health impacts and requirement of a truly circular economy.

There have been several indices that current regulation¹ fails to provide the basis for “securing a high level of protection of human health”². We call on the revised framework to consider those shortcomings. We also call on this revision process to specify that one of the main objectives of the regulation is to “guarantee a high level of protection of human health” rather than the current objective of “providing the basis for securing”³ such high level of protection.

We know that vulnerable groups such as babies, young children, pregnant or breast-feeding women are most at risk from the adverse health effects⁴ of a number of chemicals, which are currently routinely found in various food packages⁵. It is also established that a number of these chemicals hinder the possibility of recycling or participate in re-circulating toxic substances onto the market via a phenomenon usually referred to as “toxic recycling”.⁶

The European Commission must identify the existing loopholes in the regulation that may currently put citizens’ and workers’ health at risk, and design a regulatory framework that provides an equivalent high level of protection of human health for all citizens across Europe.

In CIEL’s view, it is crucial that the future regulation on FCM takes into account the latest knowledge on chemicals risks, including the risks caused by

- Endocrine Disrupting Chemicals (EDCs),
- Nanomaterials,
- Non-intentionally added substances,
- All additives, and
- Synergistic effects between various substances to which consumers and workers are exposed.

In that respect, CIEL recommends that the revised regulatory framework for FCM makes use of all sources of available information (including REACH list of Substances of Very High Concern, and REACH candidate list, as well as other tools identifying toxic substances such as the SIN List) to establish a by-default ban on the presence of all and any hazardous substances in FCM.

The re-drafting of the FCM regulation should pay particular attention to addressing exposure to EDCs as such substances interfere with hormone signalling and are linked to major and irreparable impacts on human health, especially when exposure occurs at early stages of development. All identified and suspected EDCs should thus be banned from all FCMs. EDCs should be addressed in a coherent manner with other legislations developed to limit exposure of consumers and workers to such substances.

Nanomaterials use in food packaging is growing (whether in traditional uses such as inks or to develop food packaging with novel properties)⁷. However, the risk profile of most of these nanomaterials (including those already present on the market) still contains large knowledge gaps.⁸ The revised FCM regulation should take into consideration the specificities of nanomaterials, including future materials currently in development so as to “future-proof” the

regulation and effectively protect the health of current and future generation.

The European Union is currently leading in developing a coherent circular economy package that recognizes the need to ensure full and safe recyclability of all products coming on to the market to respond to XXIst century challenges. The revised FCM regulatory framework must be fully integrated with the circular economy objectives and ensure full recyclability of all FCM. A by-default ban of all hazardous substances from FCM is the only way to reach such objective in a cost efficient manner while providing the EU industry a chance to establish a gold standard and market advantage in that respect.

Finally, we emphasise the need to create a fully transparent and participative process for this revision. In that respect, we call on the Commission to make public all the evidence used and collected in the process of the evaluation, and to allow civil society's participation in a meaningful way, including by:

- Organising consultations before decisions or major orientation are adopted,
- Giving equal attention to inputs from the industry and from civil society, and
- Providing clear and precise explanation of how the comments are taken into account or not.

1 Regulation (EC) No 1935/2004 (FCM Regulation)

2 Ibidem, Article 1.

3 Ibidem.

4 <http://www.who.int/ceh/risks/en/> and <http://www.who.int/ceh/risks/cehchemicals/en/>

5 <http://www.tandfonline.com/doi/full/10.1080/19440049.2014.931600?scroll=top&needAccess=true>

6 <http://www.foodpackagingforum.org/news/toxic-chemicals-in-recycled-materials>

7 <http://www.foodpackagingforum.org/food-packaging-health/nanomaterials>

8 See for example: <http://www.ciel.org/reports/toxicity-of-engineerednanomaterials/>, <http://www.ciel.org/reports/factsheet-risk-assessment-nanomaterials-regulatorycontext/>, http://www.ciel.org/wp-content/uploads/2017/02/IOM-Analysis-of-OECD-dossiers_Full.pdf

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8435_en

Organisation: UEAPME

Feedback: UEAPME and its members welcome the launch of the inception impact assessment by the European Commission regarding the Regulation (EC) No 1935/2004 Food Contact Material (FCM).

UEAPME would like to raise the main concerns from the side of SMEs:

- Related to food contamination by Mineral Oil Saturated Hydrocarbon (MOSH), Mineral Oil Aromatic Hydrocarbon (MOAH), Polyolefin Oligomeric Saturated Hydrocarbons (POSH), and Polyolefin Oligomeric Aromatic Hydrocarbons (POAH), in particular with regard to the concept of “indirect food security”. In practice, the need to reconcile the European strategy for the recovery of secondary raw materials with the safety requirements of FCM would impose a considerable sensitivity by the European Commission on the “emerging risks” which have to be evaluated quickly and have to receive regulatory responses in a short time. At present, as regards the volatile minerals indicated above, this has not occurred. Food business operators face many difficulties and many complexities deriving from a lack of harmonization, and from a large number of guidelines, draft technical regulations, national laws and restrictive judicial readings of food safety.
- The concept of “food security” contained in the Regulation is not clear, as it is not easy to understand whether secondary and tertiary packaging (which present the problem of potential assignment of the substances) are or not included in the scope of the Regulation. At the same time, it is not easy to define derogations (for example, food crust materials which do not fall under the scope of the Regulation, with notable exceptions).
- The conformity statement should be systematically made available to the SMEs. As it stands FCM suppliers often don't deliver the conformity statements and even when they do, the results have to be verified. The small food businesses are wholly reliant on their suppliers. That is not to say, that FCM producers in Europe do not comply. However, where FCM are supplied from outside the EU, e.g. China, Vietnam, etc., the traceability and reliability of FCM is questionable.

As such the main issue with the effectiveness of the Regulation is the clear structuring of supply from outside the EU. In terms of practicality, having to record and preserve all conformity statements for any FCM in their business is a heavy administrative burden for small businesses. This burden should not be increased but rather lightened. An alternative might be a digital solution.

UEAPME concludes that to raise the effectiveness and the efficiency of the Regulation, the European Commission should review the legislation focusing on

1. The clarification of its field of application
2. Its definitions and the activities related to its management and its implementation
3. Making systematically available the conformity statements.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8415_en

Organisation: CHEM Trust

Feedback: CHEM Trust welcomes the fact that the European Commission has published a draft roadmap for the "Evaluation of Food Contact Materials", and we welcome the chance to comment on this road map.

We have been highlighting deficiencies in the EU's regulation in this area for over three years, including writing to the previous Health Commissioner in July 2014 , and publishing a detailed briefing on the subject in January 2016 .

CHEM Trust also set up a detailed multi-stakeholder discussion on the links between laws on chemicals in food contact materials and the REACH chemicals law in March 2016 ; officials from both DG Health and DG Environment participated. However we have found it almost impossible to engage with, and participate in, policy discussions in this area, as DG Health - which is responsible for legislation in this area – focusses on organising industry-only stakeholder processes .

We hope that this evaluation will provide an opportunity for the Commission to modernise and improve regulations in this area, as they are currently grossly inadequate. This new evaluation must be done in an open, transparent and participative way. It is clear that the secretive approach applied until now has been one of the reasons for the lack of proper examination of the effectiveness of regulations in this area.

Specific points:

- see attached file or online here" <http://www.chemtrust.org/wp-content/uploads/chemtrustfcmroadmapcomments-dec17.pdf>

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8421_en

Organisation: Flexible Packaging Europe

Feedback: Flexible Packaging Europe represents manufacturers of flexible packaging in Europe. We welcome this proposed review of food contact legislation and would wish to provide input during the consultation phase.

At this stage, we make the following points:

1. The operation of Good Manufacturing Practice (GMP) is an essential part of the process of producing safe Food Contact Materials (FCM). This is recognised in article 3 of Regulation (EC) No 1935/2004 – “Materials and articles ... shall be manufactured in compliance with good manufacturing practice so that ...”. Regulation (EC) No 2023/2006 is an important part of the legislative framework and should be explicitly included in the evaluation Roadmap.
2. In “Drivers” first row, there is the sentence: “FCMs are not inert and substances with hazardous properties may within them be transferred to food in sufficient quantities to cause a risk to consumers.” This seems to imply that the majority of FCM are inherently unsafe – which is not true. We suggest an alternative wording: “FCMs are not inert and substances within them may be transferred to food. If hazardous and in sufficient quantities, this could cause a risk to consumers.”
3. In “Drivers” fourth row, there is an assumption that the safety assessment of FCM substances will be achieved through an EFSA assessment of the risk of all substances and the creation of positive lists. This is possible for Intentionally Added Substances. The Roadmap should acknowledge that Non-Intentionally Added Substances (NIAS) are also present in FCM. These cannot be risk assessed by EFSA and placed on a list. There is a need to raise the issue of industry self-assessment of NIAS and how this can be done in a way that is effective and transparent.
4. A barrier to the extension of harmonised measures is the sheer number of substances that require assessment and the limited resources of EFSA to do this. Industry self-assessment of substances is also a possible solution for this issue.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8436_en

Organisation: Consiglio Nazionale dell'Ordine dei Tecnologi Alimentari

Feedback: I tecnologi alimentari sono l'anello di congiunzione tra gli operatori MOCA (Materiali Oggetti a Contatto con Alimenti), i loro clienti e le normative, in quanto si preoccupano di tradurle in seno l'organizzazione a livello operativo.

Nonostante in Italia il quadro normativo sui MOCA sia presente e copra diversi ambiti, grazie al DM 21/3/73 ed i numerosi aggiornamenti nel corso degli anni, ad oggi manca la consapevolezza negli operatori che si occupano di FCMs di essere parte attiva del settore alimentare.

Manca in loro questa cultura e le piccole medie imprese, tessuto produttivo caratterizzante il territorio nazionale, ad oggi, nonostante il Reg. CE 1935 sia entrato in vigore dal 2005, non conoscono cosa ci sia da fare per implementare i manuali GMP ed il sistema di tracciabilità e la loro importanza. Ma non sono consapevoli neanche delle specifiche delle materie prime che lavorano/assemblano e cosa significhi documentazione di supporto. Il flusso di informazioni lungo tale catena è carente, e non si hanno dati in merito alle materie prime, che cambiano molto spesso e non sono standardizzate.

In questo quadro, la visione plasticocentrica attuale non aiuta coloro che lavorano altre tipologie di materiali; esitano norme italiane, ma servono leggi armonizzate. Per chi opera nel settore è di fondamentale importanza capire quali siano le cessioni/migrazioni/controlli analitici da effettuare con limiti di riferimento da seguire per comprendere la conformità o meno del materiale e la rispettiva matrice alimentare. Inoltre servono metodiche analitiche armonizzate, perché attualmente i laboratori propongono metodi differenti e l'organizzazione non sa di chi fidarsi.

Fortunatamente essendo giunto quest'anno il decreto sulle sanzioni, le aziende di MOCA si sono "svegliate" dal torpore ed al contempo hanno preso coscienza della materia. Vista la presa di coscienza occorre fornire loro strumenti chiari per poter lavorare in serenità e garantire la sicurezza al cittadino.

Nondimeno per favorire la libera circolazione sul mercato interno di prodotti e servizi, un adeguato riferimento normativo, sia obbligatorio che volontario sui MOCA, potrebbe consentire alle imprese del settore di operare, comunicando nelle transazioni che procedure si adottano per garantire livelli di sicurezza e controllo anche ulteriori ai requisiti.

Chi si occupa di stampaggio di materiali, si trova a discutere con i fornitori d'inchiostri, che sono toccati indirettamente solo dal 1935: occorre una norma che li disciplini, di modo da favorire il flusso d'informazioni lungo la catena.

I NIAS sino ad ora non sono normati, e questo genera preoccupazione per la salute dei consumatori.

Il consumatore finale italiano, inoltre, allo stato attuale non è per nulla a conoscenza dei MOCA, del loro corretto utilizzo, delle contaminazioni che potrebbe lui stesso creare trattando in modo scorretto un'attrezzatura o un cibo nel suo contenitore: si rende quindi necessaria, in parallelo, un'educazione in materia da affiancare ai progetti di educazione alimentare, che sono anch'essi purtroppo non armonizzati e coordinati

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8458_en

Organisation: FEVE - European Container Glass Federation

Feedback: FEVE – the European Container Glass Federation – welcomes the possibility to comment on the European Commission roadmap for the evaluation of food contact materials (FCM). As the Federation of European manufacturers of glass containers and machine-made glass tableware, our members produce over 20 million tonnes of glass per year, of which approximately 95% is for food contact applications.

According to our consumer research [Insites Survey, 2014] personal health conditions and food safety are among the top daily life worries of Europeans. 66% of European consumers are highly worried about food contamination or migration of harmful chemicals from the packaging into the food product. 8 out of 10 European believe these chemical interactions are a risk to human health. This shows the importance of maintaining a high level of ambition when it comes to food contact material safety in the European Union.

The European Parliament 2016 resolution on food contact materials identified several shortcomings on the functioning of the current regulation and formulated clear demands for how the European Commission could improve the current legislation and its enforcement. In particular, it urges the European Commission to make use of all the available resources at its disposal to put forward harmonised legislation for the remaining 13 food contact materials not yet regulated at EU level.

FEVE supports developing legislation for glass in order to ensure effective functioning of the internal market by establishing one set of harmonized testing methods for glass. In the absence of clearly defined EU regulations, some customers are requesting glass container producers to conduct multiple tests to meet the specific requirements of different Member States. In some instances, glass articles are even being tested according to regulatory test protocols developed for other types of food contact materials (e.g. plastics or ceramics), even though these test protocols are not intended or appropriate for glass containers because they require testing of elements that simply do not exist in glass.

In addition, one of the biggest regulatory gaps that should be addressed in the new legislative framework for food contact materials is the impact of recycling on the health and safety of consumers, as unintentional impurities might contaminate the materials during the collection and recycling processes. Especially in the context of increased recycling targets in the Packaging & Packaging Waste Directive, there is a risk that more substances of concern enter material streams that end up as food contact applications. This should be addressed in the European Commission's further work.

FEVE is interested to collaborate with DG SANTE on these aspects and will seek to contribute throughout the consultative process.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8459_en

Organisation: Food Packaging Forum

Feedback: The Food Packaging Forum welcomes the opportunity to provide comments on the draft roadmap for the «Evaluation of Food Contact Materials». Our work is dedicated to providing scientific information pertaining to chemicals in all kinds of food contact materials (FCMs) and articles (FCAs), and their impact on health.

This evaluation offers the opportunity to reflect on the existing regulation from the perspective of most current scientific understanding. With more than 8'000 substances used in the manufacture of FCAs (<http://www.foodpackagingforum.org/news/eu-study-on-non-harmonized-fcms-published>), and likely more than 10'000 substances present in finished FCAs as non-intentionally added substances (<https://www.ncbi.nlm.nih.gov/pubmed/16954061>) we see the need for innovative approaches for protecting public health from harmful chemical exposures to individual food contact chemicals (FCCs), but also to mixtures of overall migrants. We are especially concerned about the effects of migrating FCCs on the hormone, nervous and immune systems. Harmful effects can occur at very low doses, and especially developing fetuses are vulnerable. We would welcome regulatory approaches to protect this population group in particular.

We have recently published a detailed analysis of the scientific challenges in the risk assessment of food contact materials in form of a peer-reviewed scientific article (<http://www.foodpackagingforum.org/news/risk-assessment-of-fcms-overview-of-key-scientific-challenges>). This analysis shows that current EU regulatory approaches and requirements do not adequately address actual chemical exposures from finished FCAs. One of the challenges relates to the current regulatory focus on starting substances. These compounds undergo significant transformation during FCA manufacture, so that the focus in terms of population-wide human exposure is better placed on those FCCs that migrate from the finished FCAs, since the average citizens are mostly exposed to these.

We trust that this evaluation will be carried out in a transparent way that invites input from all experts and stakeholders, and places a high value on independent scientific information. Our organization is open to providing input that may be of use to the European Commission in this evaluation process.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8461_en

Organisation: Anonymous

Feedback: The symbol reproduced in Annex II of Regulation 1935/2004 (for products not yet in contact with food when placed on the market) might generate confusion among products intended to: 1) contain food while eating 2) cook food 3) store food. They are 3 very different usages and imply different temperatures and contact duration. Some objects might be suitable for all 3 usages, but more likely, most objects are suitable only for one of these 3 functions. Having 3 different symbols might help using them correctly and providing helpful information to consumers.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8472_en

Organisation: SAFE - Safe Food Advocacy Europe

Feedback: Due to the evolution of scientific knowledge, changes in practices, new materials emerging, experience acquired in the last decades, and more consumers' awareness, it is time to update the Regulation 1935/2004 to answer current questions and gaps and to face future challenges.

SAFE considers that the Commission must address the legal issues arising from the current regulation: while the general principle for FCMs is that it can be found in food under a certain risk quantity (scientifically determined), common standards on these risk quantities are not uniform in the EU for all FCMs, leading to dangerous doubts and gaps that hamper the internal market and the interests of consumers. Supporting the findings of the European Parliament, SAFE recommends the adoption of specific EU rules for non-harmonized materials.

SAFE is also worried about shortcomings in traceability, enforcement and controls. Deeper harmonisation is required on enforcement controls, still differing across Member States. SAFE believes better framework rules, helping Member States to perform regular monitoring and in situ controls more efficiently as well as ensuring that they have the necessary staff trained to do such controls, will result in a safer food for consumers.

The fact that some essential rules, such as the standards to draft declarations of compliance, mostly remain at the Member States' discretion, does not allow to secure a high level of protection of human health and the interests of the consumers. SAFE believes that the Commission should engage in benchmarking and harmonising to develop single EU standards (especially for FCMs analytical testing).

Furthermore, any improvement in the FCMs' regulation's functioning should impact EFSA, whose capacity to effectively control FCMs is not optimal. The general task of evaluating substances intended to be used for and additional risk assessments in relation to FCMs are carried out by the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), which is also responsible to answer to ad-hoc requests from the Commission to review FCMs in the light of new scientific information and/or changing conditions and/or use. Therefore, CEF's capacity to perform independent analyses and to coordinate more the activities of national authorities is essential for the good performance of an independent scientific assessment.

Going into more details on the scientific assessment, SAFE supports the findings of the CES Scientific Opinion of December 2015, in which it is clearly stated that the tiered approach recommended by the SCF in 2001 is updated based on scientific progress. There is the need, SAFE believes, for new guidelines, foreseeing more accurate analyses and new research. SAFE supports CEF's suggestion to perform new screenings on toxicity data related to the expected human exposure level (higher exposure, greater risks). This is very important in areas, such as recycled materials, Cocktail Effects and NIAS, that have not been sufficiently investigated yet.

SAFE believes that there is a necessity for the FCMs' legislation to propose clear, general legal criteria defining endocrine disruptors (ED), together with a comprehensive policy response to it. A holistic approach towards food contaminants should be envisioned. Given that EDs are found in FCMs, therefore potentially in consumed foods, any FCMs legislation not assessing them will threaten the EU's precautionary principle whereas the latter should however be the prime focus of this legislation. With EDs still under investigation, SAFE believes this is an opportunity for deeper research, including EDs in the FCMs deeper researches advised by CEF.

Finally, SAFE argues that better coordination between the various legislative texts, in particular regulations on FCMs and REACH, should be foreseen. Consequently, agencies involved in assessing in each regulation (EChA, EFSA) need to cooperate.

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8464_en

Organisation: Chemisches und Veterinäruntersuchungsamt MEL

Feedback: Überwachung von Bedarfsgegenständen

Evaluierung des EU-Lebensmittelkontaktmaterialienrechts

Sehr geehrte Damen und Herren,

zur Evaluierung des EU-Rechts bei Lebensmittelkontaktmaterialien haben wir die folgenden Anmerkungen:

Konformitätserklärungen

In Artikel 16 Absatz 1 der Verordnung (EG) 1935/2004 heißt es:

In den in Artikel 5 genannten Einzelmaßnahmen ist vorzuschreiben, dass den Materialien und Gegenständen, die unter die betreffenden Einzelmaßnahmen fallen, eine schriftliche Erklärung beizufügen ist, nach der sie den für sie geltenden Vorschriften entsprechen.

Daraus folgt, dass das Mitführen von Konformitätserklärungen nur für solche Materialien und Gegenstände verpflichtend ist, für welche Einzelmaßnahmen existieren. Für nicht spezifisch geregelte Materialien und Gegenstände, wie z.B. dem im Lebensmittelkontakt vielfältig genutzten Papier und Karton, müssen dementsprechend keine Konformitätserklärungen ausgestellt werden.

Sowohl aus Sicht des Verbraucherschutzes als auch aus Gründen der Handhabbarkeit erscheint es sinnvoll, die Pflicht zum Mitführen von Konformitätserklärungen für alle Materialien und Gegenstände verbindlich zu regeln. Derzeit ist – vor allem zum Zeitpunkt der Probenahme durch die zuständige Behörde – nicht immer eindeutig festzustellen, bei welchen Gegenständen eine Konformitätserklärung notwendig ist oder nicht (Beispiele: TPE (Thermoplastische Elastomere), Unterscheidung zwischen Kunststoffen und Coatings, aus mehreren Materialien zusammen gesetzte Gegenstände).

Die Konformitätserklärungen sollten immer die Angaben der für die Konformität relevanten Stoffe – incl. NIAS (not intentionally added substances) – sowie die der Prüfung zugrunde gelegenen Migrationsbedingungen mit den Schlussfolgerungen auf die mögliche Verwendung enthalten.

Gute Herstellungspraxis (GMP)

Die gute Herstellungspraxis im Sinne von Art. 3 a der Verordnung (EG) Nr. 2023/2006 sieht vor, dass Materialien und Gegenstände in konsistenter Weise hergestellt und überprüft werden, damit ihre Konformität mit den für sie geltenden Regeln gewährleistet ist und sie den Qualitätsstandards entsprechen, die dem ihnen zugedachten Verwendungszweck angemessen sind.

Im Sinne von Art. 4 der GMP-VO wird der Unternehmer verpflichtet sicherstellen, dass Fertigungsverfahren, Qualitätskontrolle und Dokumentation in Übereinstimmung mit den allgemeinen Regeln für GMP gemäß den Artikeln 5, 6 und 7 durchgeführt werden.

Diese Verpflichtung mündet bei Nichteinhaltung aber ausschließlich bei Materialien und Gegenständen aus Kunststoff in ein Verbot. Bei anderen Materialien führt es nicht zu Konsequenzen, wenn ein Unternehmer die Konformität seiner Erzeugnisse nicht nachweisen kann, noch nicht einmal dann, wenn die Ermittlungen der Untersuchungseinrichtungen bei einem Gegenstand den Verdacht auf Nonkonformität ergeben (z.B. Untersuchungsbefund innerhalb der Messunsicherheit eines Beurteilungswertes).

Um die GMP-Verordnung zu einem wirksamen Instrument des Verbraucherschutzes zu machen, wäre es sinnvoll, ein Verkehrsverbot für Gegenstände aus allen Materialien vorzusehen.

Positivlisten

Das klassische Konzept der Positivlisten, wie es für Materialien und Gegenstände aus Kunststoff existiert, hat sich bewährt. Die spezifischen Migrationsgrenzwerte sind konkret, sodass sich Industrie und Überwachung danach richten können. Die Werte basieren auf toxikologischen Bewertungen oder Expositionsbetrachtungen, die tolerierbaren täglichen Aufnahmemengen wurden von einem wissenschaftlichen Gremium evaluiert, und die spezifischen Migrationsgrenzwerte sind verbindlich und justiziabel.

Für Materialien und Gegenstände, die derzeit noch nicht spezifisch geregelt sind (z.B. Druckfarben), wäre es trotz des hohen Aufwandes wünschenswert, wenn Regelungen auf der Basis dieses Konzeptes erlassen würden.

Mit freundlichen Grüßen

gez. Dr. Heitmann

Link to feedback: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429/feedback/F8468_en