Food Contact Materials (FCMs)

Feedback to the European Commission's Evaluation and Fitness Check Roadmap

Document addressed to the European Commission by SAFE – Safe Food Advocacy Europe ASBL

Introduction

The following feedback paper was drafted by SAFE – Safe Food Advocacy Europe.

SAFE is a non-profit independent organisation based in Brussels whose main objective is to ensure that consumers' health and concerns remain at the core of the EU's food legislation. SAFE monitors the EU's food legislation process and cooperates with EU legislators and its stakeholders, to draft comprehensive food regulations.

The work of SAFE is supported by its members, which are consumer, food health, obesity and overweight-affected patients', vegan and vegetarian associations, as well as individual members such as independent research scientists, doctors (including oncologists) and nutritionists, spread across Europe (9 EU Member States). To date our membership collectively represents the voice of over 1.050.000 European consumers.

SAFE's missions are:

- to strengthen the voice of civil society in the EU debate concerning the future of EU food regulation, thereby reinforcing participatory democracy in the EU. Since its creation, SAFE considerably developed its lobbying and advocacy activities, by taking part in several WG of the DG SANTE such as the Advisory Group for the Food Chain and Animal and Plant Health. SAFE also participated in several meetings and events organised by EFSA and has become an official EFSA stakeholder.
- to increase public awareness and information on food safety issues *via* training programmes and seminars, to allow ordinary citizens to make informed decisions on the food they eat. SAFE regularly organises conferences on EU food law gathering independent experts, European Commission's officials, NGOs and Foundations, as well as in-school training courses on how to read food labels for sugars and food additives.
- to identify priority areas for research and raise funds for independent research on food components with direct consequences on consumers' health, and on which SAFE builds its advocacy and information material, such as:

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- the information materials aimed at consumers on excessive sugar consumption, food colourings and acrylamide;
- the feedback on the delegated regulation on total diet replacement for weight control;
- the position paper on the Declaration of iodized salts' ingredients and iodized salt's exemption;
- the position paper on the endocrine disruptors and on the Draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products;
- the position paper on the Draft Regulation on acrylamide in food.

1. What are Food Contact Materials (FCMs)?

Food Contact Materials, also referred to by their acronym FCMs, are **all the materials and articles that are intended to be put into contact with food, and beverages, or will presumably be in contact with food, or beverages**[1]. This includes food packaging and containers, kitchen equipment, tableware, etc. It also includes machinery used in processing food and objects that are used to transport food. All these items can be **made from a variety of materials** including plastics, rubber, paper and metal. The current European regulation for food contact materials also covers materials that contact water intended for human consumption (bottles). On the contrary, fixed public or private water supply equipment is specifically excluded from the scope of the legislation, since its main purpose is not to carry a "beverage". The current legislative framework also excludes "covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits", since those materials "form part of the food and may be consumed together with this food"[2].

Since it was adopted in 2004, the current legislation has included "active and intelligent food contact materials and articles". Those two types of FCMs included[3]:

- in case of "active" FCMs, "materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food", Art. 2 (2)(a);

[1] Regulation (EC) 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, art.1 (2): "This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:
(a) are intended to be brought into contact with food; or
(b) are already in contact with food and were intended for that purpose; or
(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use".

[2] Art.1 (3)(b).

[3] Art.2 (2).

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- in case of “intelligent” FCMs, “materials and articles which monitor the condition of packaged food or the environment surrounding the food”, Art. 2 (2)(b).

The different materials included in the FCM definition are therefore **intended to be in contact with food and beverages, but not to be consumed**. Since those materials behave differently depending on their composition and properties, the issue at bay is **how materials’ constituents and chemicals emanating from FCMs, are transferred to food and beverages, and if they can constitute a danger for human health or do change the composition of the foodstuffs in a way that alter significantly the products that consumers eat or drink**. While this means that FCMs in food can be found under a certain risk quantity since chemicals will migrate from the materials into the food and beverages, the level of FCMs must therefore be evaluated according to the threat they can pose to consumers. The safety of consumers therefore depends both from the in-depth knowledge of scientific processes and the capacity to perform adequate tests on a regular basis.

2. What is the regulatory framework?

FCMs are regulated at EU level by the **Regulation (EC) 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC** (hereafter the Regulation (EC) 1935/2004), which defines FCMs (see point 1 of this paper) in its scope, and lays down **general safety requirements for all FCMs**.

Therefore, to be considered as safe for consumers, FCMs must “be manufactured in compliance with good manufacturing practices”, so that any potential transfer to foods does not raise safety concerns, change the composition of the food in an unacceptable way or have adverse effects on the taste and/or the odour of foods[4].

The general principle stated above is to be understood with the premise that FCMs, and the food they are applied to, are “under normal or foreseeable conditions of use”. This means for example that a particular FCM that is foreseeably exposed to higher or lower temperatures (e.g. it is used in cooking or refrigerated) cannot change composition in a way that could led to a “transfer [of its] constituents to food in quantities which could (…) (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof”[5]. The regulation also specifies that “labelling, advertising and presentation of a material or article shall not mislead the consumers”, therefore preventing that consumers misunderstand the use they can do of FCMs[6].

[4] Art. 3 (1).
[5] Same article.
[6] Art.3 (2).

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An important feature of Regulation (EC) 1935/2004 is that it allows Member States to adopt specific measures[7], if no binding measures exist at EU level. Since regulation (EC) 1935/2004 has led to **specific legally binding provisions for only four FCMs**, out of a list of seventeen[8], all other FCMs remain at the Member States' discretion. This subsequently creates different legislations depending on each country and different standards for product safety. At the moment, the four FCMs falling under specific binding provisions are: plastics (and recycled plastics), ceramics, regenerated cellulose and active and intelligent materials. All other FCMs are only subjected to the regulation's general safety requirements, as well as to the precaution principle, in the EU, but may be regulated by more strict provisions in some Member States.

Finally, according to articles 7, 9, 10 and 11 of Regulation 1935/2004, the European Food Safety Authority (EFSA) has a role to play in the legal framework established for FCMs. In conformity with its role as an independent authority at EU-level, its task is to give an opinion regarding new FCMs in the internal market, once it is referred by a Member State's authority. While its EU-level evaluation suggests an important coordination role with authorities at Member States' level[9], it is clear that the responsibility for the legal enforcement, as well as the scientific expertise[10], is vested in the "competent national authority or authorities"[11].

3. What are the current issues?

Nearly thirteen years after the adoption of Regulation (EC) 1935/2004, the Commission started the evaluation of this piece of legislation, which "has never been systematically assessed since the inception of its basic provisions set out in 1976"[12].

a. Legal issues

There are several issues in Regulation 1935/2004 concerning the effective functioning of the internal market as well as the effective functioning of the legal framework established by the regulation. In particular, in the European Parliament reports[13], MEPs have flagged up several shortcomings in the areas of traceability, enforcement and controls.

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[7] Art.6.

[8] Identified in **Annex I of Regulation (EC) 1935/2004**: 1.Active and intelligent materials and articles; 2.Adhesives; 3.Ceramics; 4.Cork; 5.Rubbers; 6.Glass; 7.Ion-exchange resins; 8.Metals and alloys; 9.Paper and board; 10.Plastics; 11.Printing inks; 12.Regenerated cellulose; 13.Silicones; 14.Textiles; 15.Varnishes and coatings; 16.Waxes; 17.Wood.

[9] In particular Art. 9.

[10] Articles 9 and 10 foresee that EFSA examines the dossier's administrative validity, and two technical issues: if the examined FCM respects the general safety requirements; if the analytical method proposed is appropriate.

[11] Art. 13.

[12] As stated in the Evaluation Roadmap published by the Commission.

[13] *European Parliament Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*, of 18th July 2016 (http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-

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i. Effectivity in the functioning of the legal framework

MEPs have pointed out that enforcement controls differ across Member States, and advised that a deeper harmonisation would be beneficial for the effective functioning of any FCM legislative framework as well as securing a high level of protection of human health and the interests of the consumers. It was also noted that regular monitoring is not always carried out, therefore Member States should perform controls more efficiently, and ensure that they have the necessary staff trained to do so. However, this proves to be difficult when there are no common standards or reliable guidelines, on which authorities can benchmark practices.

A deeper harmonisation of administrative procedures, control and enforcement practices, and of regulatory standards is an important issue for the evaluation and refit of Regulation (EC) 1935/2004, as manufacturers rarely submit detailed official information on their activities to public registers. To support enforcement, companies should always submit a certified full declaration of compliance (DoC). This document should confirm that their FCMs meet regulatory standards. However, this is not always performed in such a way that would secure an optimal level of protection of the interests of consumers, due to the mechanism created by articles 16 and 17 of Regulation 1935/2004. Indeed, following those two articles, there is little control on the accuracy of DoCs or on how they are established, and the burden of the proof heavily relies on the Member States' authorities[14].

Any improvement in the functioning of the legal framework should have an impact on EFSA, whose capacity to effectively control FCMs is not optimal. Since the entry into force of Regulation 1935/2004, EFSA was left in charge to publish "detailed guidelines concerning the preparation and the submission of the application"[15]. As the general task of evaluating substances intended to be used for use and additional risk assessments in relation to FCMs are carried out by the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), this was done only four years later, in 2008, and had to be corrected in November 2009[16]. In the meantime, the issue was left under the "Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation", which date back to 2001[17], and are still

2016-0237&language=EN) and *European Parliament Report on the initiative on resource efficiency: reducing food waste, improving food safety*, of 28th April 2017 (http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2017-0175+0+DOC+XML+V0//EN); see also *European Parliament resolution on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*, of 6 October 2016 (http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2016-0384).

[14] It is useful to remember that in the last months, multiple debates arose in the EU following either too scarce controls (such as in the case of fipronil, since July 2017), either too high costs to perform public, independent research (as has been said in the case of glyphosate).

[15] Art. 9 (2).

[16] Available here: https://www.efsa.europa.eu/en/efsajournal/pub/717.

[17] Note under Art. 9 (2), Official Journal of the European Union, 13 November 2004, p. L 338/9; the guidelines are available here: http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf.

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used for "old" FCMs, i.e. the ones listed in Annex I of Regulation 1935/2004 (except for "active and intelligent packaging and processes for recycling plastic used in food contact materials", for which EFSA developed a specific guidance for the submission of applications).

In the recent months, EFSA has come under scrutiny by the European Parliament[18], and MEPs have asked[19] whether EFSA could not have a better role in scientific assessment and risk analysis. This would require the strengthening of its capacity to perform independent analyses; yet it would be an important step considering that EFSA's CEF Panel also responds to ad-hoc requests from the European Commission to review certain food contact materials in the light of new scientific information and/or changing conditions and/or use[20].

ii. Internal Market

As already stated in point 2 of this paper, harmonised rules have been enacted for only four FCMs (active and intelligent materials, plastics -whether recycled or not-, ceramics, and regenerated cellulose) out of seventeen recognised FCMs in Annex I of Regulation (EC) 1935/2004 -therefore fragmenting the internal market in the case of adhesives, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, printing inks, silicones, textiles, varnishes and coatings, waxes, and wood. It is an assumed fact that such a divergence in rules creates uncertainty, and it is also contrary to a seamless market.

The European Parliament has already[21] called upon the Commission to address gaps in the EU legal framework for FCMs in order to draft proper safety regulations for chemicals in all food contact materials. At this occasion, they recommended the adoption of specific EU rules for non-harmonized materials and asked for specific EU legislation. This follows numerous written and oral questions by Members of the European Parliament (MEPs), from diverse political backgrounds, to the Commission and to the Commissioner in charge of Health and Food safety. MEPs acknowledged that Regulation (EC) 1935/2004 is a solid legal basis, but they also considered as a priority for the Commission the drafting of specific measures regulating EU-wide "on chemical non-plastic FCMs", especially when those materials reasonably constitute a risk to human health. This was underlined to be the case[22] when FCMs are consisting of paper and cardboard, varnishes and coatings, metals and alloys, inks and adhesives.

[18] The President of the European Parliament and a delegation of MEPs from the ENVI Committee visited the EFSA headquarters on the 18th and 19th December 2017 to discuss EFSA's strategic perspective, the scientific decision-making process, transparency and specific aspects of EFSA's scientific work. The discussions went on topics such as glyphosate, endocrine disruptors (EDs) and crisis preparedness.

[19] European Parliament Reports *on the implementation of the Food Contact Materials Regulation (…)* and *on the initiative on resource efficiency: reducing food waste, improving food safety*, and European Parliament resolution *on the implementation of the Food Contact Materials Regulation (…)*.

[20] See EFSA website.

[21] European Parliament Reports *on the implementation of the Food Contact Materials Regulation (…)* and *on the initiative on resource efficiency: reducing food waste, improving food safety*, and European Parliament resolution *on the implementation of the Food Contact Materials Regulation (…)*.

[22] *European Parliament Report on the implementation of the Food Contact Materials Regulation (…)*.

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Finally, it is important to recall that as the rules for the submission of DoCs mostly remain at the Member States' discretion, there are different legislations and safety standards depending on each country. This is both a burden for companies that are rightfully considering the EU as a seamless market, as well as an issue jeopardising consumers' health. Different standards can hamper legal certainty for all stakeholders involved; hence, a deeper harmonisation is required. This was noted also by many MEPs, which suggested to the Commission[23] to develop a single EU standard for analytical testing of FCMs: it would be followed by companies and competent authorities across the EU -thus both reducing costs inside the common market and creating better controls.

b. **Uncertainty on chemical elements**

Human exposure to chemical substances mainly happens through food contact. In the case of FCMs, scientists call this phenomenon "migration" (i.e., from the packaging to the foodstuff). It is foreseen that FCMs must not transfer their chemical components to foods in unacceptable quantities. However, there are (according to a European Parliament report[24]) currently no less than 15.000 materials that are used in packaging, the majority of which is not known enough.

Consequently, even if such materials may also have some impact on health, there is a real lack of legislation and scientific studies regarding such materials. It is therefore important both to raise awareness on the hazards that constitute those materials and to implement proper regulation on the chemicals within them.

i. Scientific evolution: changes in knowledge

In the last decades, science evolved, both with the creation of more performing materials, including FCMs, and in the analysis techniques. In its December 2015 Scientific Opinion, EFSA's Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) noted that "[r]egarding the identification and evaluation of all substances that migrate, experience gained over the years has shown that more focus is needed on the finished materials and articles, including the manufacturing process used"[25].

In the aforementioned Scientific Opinion, CEF supported changes in the applicable guidelines (which date back to 2001[26]) as well as in the analysis methods.

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[23] *European Parliament Report on the implementation of the Food Contact Materials Regulation (…)*.

[24] European Parliament Reports *on the implementation of the FCMs Regulation (…)* and *on the initiative on resource efficiency: reducing food waste, improving food safety*, and European Parliament Resolution *on the implementation of the Food Contact Materials Regulation (…)*.

[25] EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) - *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, adopted on the 2nd December 2015, EFSA Journal 2016, 14(1):4357, pp.3-5.

[26] CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, p.3: "current guidelines on this risk assessment process and the corresponding data requirements from applicants date back to the Scientific Committee on Food (SCF) guidelines from 2001".

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On the former, CEF considers that "the tiered approach recommended by the SCF in 2001 is updated based on scientific progress"[27]. The European Commission opened discussions with authorities in Member States for risk management, and to send its findings on the necessary levels of protection for consumers to EFSA in order for the latter to develop new guidance on data requirements for applications for the safety assessment of substances in food contact materials.

On the latter, considering that there are now more accurate analyses, new research and more data, CEF suggests performing new screenings considering that "toxicity data needed should be related to the expected human exposure level, in accordance with the principle that the higher the exposure, the greater the amount of data required. Considering human exposure to determine the data needed may allow more efficient use of resources and contribute to reducing the use of experimental animals without loss in the safety assessment".[28]

Finally, CEF warned in its Scientific Opinion that "FCM are one sector for potential use of nanotechnology and nanomaterials", as well as of new materials (including new recycled materials), whose "specific properties (…) may affect their toxicokinetic and toxicology profiles"[29]. CEF advised to perform new analyses and to continue research as, in some cases, "the availability of data to cope (…) may depend on the specific properties of the nanomaterials and on the likely impact of the matrix in which they are dispersed"[30].

ii. Changes in practices

As part of a change of habits, consumers use more food that was put into contact with recycled materials, whether for its preservation, preparation, transport, distribution or use. While this ecological shift has very positive purposes, in particular in the field of environmental preservation, it is still not enough investigated in the area of human health safety. In fact, new research found that thousands of chemicals are being used in paper and board packaging without having their safety properly assessed[31].

In addition to mineral oils (MOH and MOAH), which are a new issue (see below), some recycled FCMs used in packaging, such as recycled paper packaging may contain more than 250 other potentially dangerous substances. Unfortunately, in lack of conclusive toxicological

[27] CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, p.4.
[28] CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, pp.4 and 5.
[29] CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, p.5.
[30] *Idem.*
[31] European Parliament Reports *on the implementation of the FCMs Regulation (…)* and *on the initiative on resource efficiency: reducing food waste, improving food safety*, and European Parliament Resolution *on the implementation of the Food Contact Materials Regulation (…)*.

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studies on all substances that could migrate from food packaging to food products, it is still impossible to assess the health risks associated with exposure to these chemicals, which could pose serious threats to human health. It is therefore important to conduct new studies and foster research.

c. Endocrine disruptors (EDs)

Our nutritional habits and general living conditions have, in little less than a century, changed in so many ways that exposition of our bodies to EDs has drastically increased. EDs are inherent to food contamination: they are present in everyday substances from packaging to pesticides that have been linked to an array of illnesses including cancer, infertility, obesity, diabetes, birth defects and reproductive problems.

Packaging[32] is an important element in the food industry to prepare, transport, distribute and use food while preserving its safety for the consumer. The amount of food packaging has increased in recent years, due to legal obligations, practicability, convenience. Furthermore, food is the only product most commonly consumed at least three times per day by consumers, which necessarily intensifies food packaging. Despite this, much packaging is unnecessary and only used once, although in recent years many food providers adopted eco-responsible practices and recycled products for their packaging (see the previous sub-point).

Therefore, EDs must be included in the evaluation on Regulation 1935/2004.

i. Definitions

According to the World Health Organisation (WHO)[33], endocrine disruptors (ED)[34] are chemical substances, naturally or artificially present in some food products but usually not inherent to the human body, that can affect people's endocrine system and have a negative impact on their health and on the health of their future children. These effects can take time –sometimes decades– before being tangible, but the more a person is in contact with one or several EDs, and the younger they are when it happens, the more likely they are to develop problems later in life, or to pass them on to their descendants[35].

The scientific criteria endorsed by the Commission, based on the WHO's definition of EDs, came in the form of two drafts aimed at amending legislation on plant protection products

[32] According to Commission Decision 2005/270/EC of 22 March 2005 establishing the formats relating to the database system pursuant to Directive 94/62/EC of the European Parliament and of the Council on packaging and packaging waste, packaging is defined as "*any material which is used to contain, protect, handle, deliver or present goods*"; this includes items like glass bottles, plastic containers, aluminium cans, food wrappers, timber pallets and drums.

[33] http://www.who.int/ceh/risks/cehemerging2/en/

[34] Sometimes known as Endocrine-Disrupting Chemicals (EDCs).

[35] WHO report from 2012 on "Endocrine disrupters and child health - Possible developmental early effects of endocrine disrupters on child health": http://www.who.int/ceh/publications/endocrine_disrupters_child/en/.

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(EC 1107/2009) on the one hand, and legislation on biocidal products (EU 528/2012), as well as a Communication and an Impact Assessment. Those new criteria should complete FCM legislation, but gaps remain. Indeed, there is no general legal definition of endocrine disruptors has been established at EU level and there is not a comprehensive policy response to it.

The list of EDs that were found in FCMs, particularly in some plastic food containers (therefore potentially in consumed food products) is as large as that of their assumed threats to health. Phthalates, adipates, styrene or Bisphenol A[36], to name only a few, are increasingly believed by members of the scientific community to be key explaining factors of the ever-growing number of citizens suffering from Type-2 diabetes, obesity, reproduction troubles and some types of cancer. As the WHO noted in a report on EDs' effects on humans published in 2013[37], there may be other EDs that scientists could yet be unaware of, as well as other potential effects for those already on the list.

As only some aspects of EDs-related issues are addressed in legal texts such as the Waste Framework Directive[38] and the Packaging and Packaging Waste Directive[39]. An urgent action to deal with such challenges becomes necessary, also to help the EU reach the goals agreed in the major international conventions, such as Rio + 20 and COP21 and to ensure the minimization of adverse effects of chemicals on human health (as well as on the environment).

ii. State of play

The situation is evolving fast, especially since the adoption of the 7th Environment Action Programme by the EU which, under the priority 3 "*to safeguard the Union's citizens from environment-related pressures and risks to health and well-being*", highlighted that by 2020 all relevant substances of very high concern (SVHCs), "including substances with endocrine-disrupting properties", must be placed on the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) candidate list. The MEPs' Report of July 2016[40] also aimed to include the REACH which is not impervious to the legislative texts on

[36] Bisphenol A, a chemical found in many plastic items that come into contact with food and that consumers may ingest, can lead to an increase in oestrogen feedback and the development of precocious puberty. In the EU, baby bottles made with Bisphenol A are banned; France went further with a law (January 2015) banning Bisphenol A's use in all food packaging. EFSA's re-evaluation of Bisphenol A concluded that there were no health risks in any age group if exposure to Bisphenol A is under the tolerable daily intake (TDI), but researchers have shown that in high doses it may cause liver and kidney damage in humans.

[37] WHO/UNEP Report on "State of the science of endocrine disrupting chemicals, 2012 - An assessment of the state of the science of endocrine disruptors prepared by a group of experts for the United Nations Environment Programme (UNEP) and WHO", available here: http://www.who.int/ceh/publications/endocrine/en/.

[38] Officially the "Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives".

[39] Officially the "Directive 94/62/EC of 20 December 1994 on packaging and packaging waste".

[40] *European Parliament Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*, of 18th July 2016 (http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2016-0237&language=EN), point 29 and 30.

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FCMs. In fact, and the European Parliament confirmed it[41], both regulations are intrinsically linked and cannot be conceived separately.

Therefore, the Commission should ensure "better coordination and a more coherent approach between REACH and FCM legislations", in particular for substances classified as SVHCs under REACH, and to ensure that harmful substances phased out under REACH are also phased out in FCMs (there are currently no automatic restrictions on their use on FCMs). Consequently, the two agencies involved in assessing chemicals under both laws, the European Chemicals Agency (EChA) and the European Food Safety Authority (EFSA), need to cooperate.

d. New issues arising

Other complex issues were pointed out in the last years. Following the CEF Scientific Opinion in December 2015, EFSA recommended refining the safety assessment of substances used in FCMs based on a review of advances in science and the experience of applying existing EU guidelines for the previous decade.

While recent scientific developments have cast doubts on the current estimation of consumer exposure to substances migrating from food contact materials, the tiered approach to their safety assessment, toxicological data requirements and the combination of different substances (under the authorised limits when analysed singly) present new challenges. It is useful here to streamline three of them: "Cocktail effects", NIAS, and MOH and MOAH.

i. "Cocktail effects"

"Cocktail effects"[42] occur when there is an exposition to different chemical substances simultaneously. Even though exposure to certain doses of a single chemical does not in itself constitute a risk of effects, there could be a risk if there is simultaneous exposure to other substances at the same time. To avoid this, the testing of finished food contact articles is required. This means investing in research and development to improve biological testing methods.

ii. Non-Intentionally Added Substances (NIAS)

According to the CEF Report of December 2015, "Substances used in the manufacture of plastic materials or articles may contain impurities originating from their manufacturing. Moreover, during manufacturing and use, reaction and degradation products can be formed, of which oligomers can be the dominant class"[43]. These substances are known as "Non-

[41] *European Parliament resolution on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*, of 6 October 2016 (http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2016-0384).

[42] See CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in FCMs*.

[43] CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, pp.4 and 5.

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Intentionally Added Substances" (NIAS), and are of concern because, "[w]hether their presence is intentional or not, it is necessary to evaluate the safety of all migrating substances and not just of the starting substances (…) and the guidelines should be updated to account more fully for this more comprehensive approach". This paradigm shift, where the focus is on the finished FCM and its use, reflects the will for a better evaluation of the safety of food, as well as a shift towards taking more into account the consumers' perspective. This however will need "an adjustment of the present system of listing substances in order to render transparent what has been evaluated".

While "new rules are provided in Regulation (EU) No 10/2011", in the case of testing for migration using food simulants, "the use of mathematical migration models has developed significantly in recent years, including proper validation for some of the most common types of plastics". While taking into account NIAS, "the same approach as that used for authorised substances should be applied for their toxicological assessment, as the same degree of safety should be warranted for all migrating substances".[44]

iii. Mineral Oil Hydrocarbons (MOH) / Mineral Oil Aromatic Hydrocarbons (MOAH)

Another related health concern regards the presence of mineral oil hydrocarbons (MOH) in foods, whose major sources include food packaging and additives. Possible risks posed by the most dangerous type of MOH, mineral oil aromatic hydrocarbons (MOAH), include the potential carcinogenicity and their ability to alter genetic material and disrupt the hormonal system. Since no level of consumption of MOAHs can be considered as 'safe', EFSA established that any exposure to it through food presents a potential health risk. In its "*Scientific Opinion on Mineral Oil Hydrocarbons in Food*"[45], EFSA estimated that in Europe MOAH exposure ranged from 0.03 to 0.3 mg/kg b.w. per day, with higher exposure in children. After comprehensive scientific assessments, EFSA concluded that background exposure to MOAH via food was a potential concern: under specific circumstances, foodborne MOAH may be mutagenic and carcinogenic.

4. Why should the existing regulation be updated, and how?

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

On legal issues that arose from the current legislative framework, SAFE considers that the review of the FCMs Regulation cannot leave those aside. While the general principle for FCMs

[44] CEF *Scientific Opinion on Potential impact on the safety assessment of substances used in food contact materials*, pp.4 and 5.
[45] CEF *Scientific Opinion on Mineral Oil Hydrocarbons in Food*, June 2012.

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is that it can be found in food under a certain risk quantity, which is to be scientifically determined, it appears common standards on these risk quantities are not uniform in the EU for all FCMs, leading to dangerous scientific doubts and to 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 and asks for specific EU legislation.

SAFE also supports the position, in the review of the FCMs Regulation, of the shortcomings in the areas of 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. In this area too, 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, in order to develop single EU standards (especially for analytical testing of FCMs).

Furthermore, any improvement in the functioning of the FCMs' legal framework should have an impact on EFSA, whose capacity to effectively control FCMs is not optimal. SAFE reminds that 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 European Commission to review certain food contact materials 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 of performing new screenings on toxicity data related to the expected human exposure level (higher the exposure, greater risks). This is even more important in the areas, such as recycled materials, "cocktail effects" and NIAS, that have not been sufficiently investigated yet.

Finally, SAFE believes that there is a necessity for the future 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. Giving the fact that EDs are found in FCMs, therefore potentially in consumed foods, any FCMs

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legislation not assessing them will threaten the EU's precautionary principle whereas the latter should however be the prime focus of this legislation. As EDs are still under investigation, SAFE believes this is an incredible opportunity to perform more research, and to include EDs in the FCMs' deeper researches advised by CEF. To this purpose, SAFE argues that better coordination between the various legislative texts, in particular regulations on FCMs and REACH, should be foreseen. Consequently, the two agencies involved in assessing in each regulation (EChA and EFSA) need to cooperate.

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