

# Revision of EU rules on FCM

## Contribution to the IIA- Ares (2020)7731375

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We thank the Commission for the opportunity to provide comments on this initiative. We applaud DG SANTE's manifest commitment to the goals of the Green Deal as set, in particular, in the Chemicals Strategy for Sustainability and the Circular Economy Action Plan.

We agree with the problems listed in the Inception Impact Assessment, and welcome a majority of the solutions proposed. However, we note that most of the problems identified are symptoms rather than the root causes of the lack of safety in Food Contact Materials (FCM). DG SANTE needs to rectify this in the next step, because treating the symptoms can only be a short-term solution.

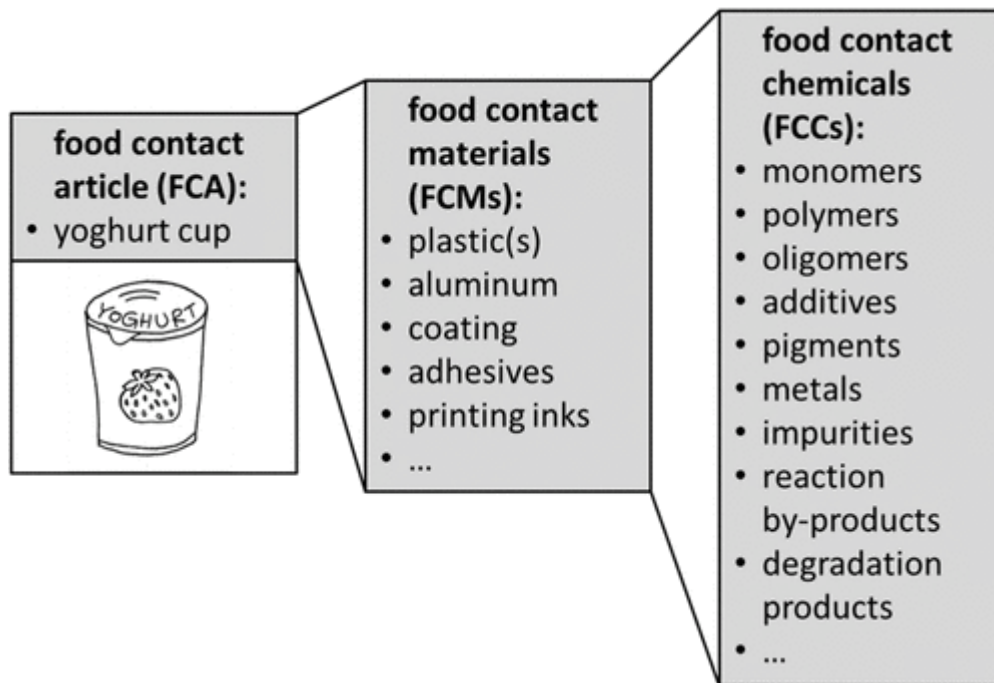
We list below the root causes of the FCM Regulation's failures. As the issues are structural, only **Option 2** described in the Roadmap – a full overhaul of the regulatory framework – can solve them. We also offer high-level recommendations on the way forward.

### **Root cause 1 – The mismatch between the aims and the tools**

#### The current situation

The supply chain of most products, in particular synthetic products, runs across three interconnected sectors: chemicals, materials, and articles. Muncke et al. created a useful visual to represent this reality in the Food Contact Material sector.

Figure 1, taken from Muncke et al.<sup>1</sup>



For the final article to be safe from eco-toxicity risks, the whole supply chain needs to be involved. This is as true for FCM as it is for Toys or any other products made with, composed of or containing chemicals.

The two core questions to solve in this context are therefore:

- Which actor in the supply chain must hold the ultimate responsibility for safety?
- Which mechanisms can be created to help the holder of this obligation mobilise its suppliers so the entire supply chain contributes to the agreed aim?

When the safety of a product is at stake, the solution adopted in EU law is to make the manufacturer or the importer – the entity placing the product on the market under its trademark – responsible for its safety as explained in the Blue Guide on the implementation of EU product rules<sup>2</sup>. EU product law also creates related obligations for the distributor.

This system has several advantages:

- It concentrates responsibility on one pre-identified and visible actor, which creates legal and behavioural accountability.

<sup>1</sup> Jane Muncke, Thomas Backhaus, Birgit Geueke, Maricel V. Maffini, Olwenn Viviane Martin, John Peterson Myers, Ana M. Soto, Leonardo Trasande, Xenia Trier, and Martin Scheringer, 2017, [Scientific Challenges in the Risk Assessment of Food Contact Materials](https://doi.org/10.1289/EHP644), Environmental Health Perspectives 125:9 CID: 095001 <https://doi.org/10.1289/EHP644>

<sup>2</sup> 2016 version, see [https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0\\_en](https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en)

- It makes it possible to think about the product holistically, for example by considering the design implications of limiting its health as well as its environmental and social impacts across its entire life-cycle

Given the nature of chemical risks, product regulation acknowledges that a product's manufacturers might not be equipped to understand its chemicals properties. This is why chemical safety is usually addressed by attaching legal consequences to the identification of dangerous substances under chemical law and/or by drawing up a list of banned or restricted chemicals.

This approach has advantages as it considerably eases compliance and enforcement by setting a clear definition of chemical safety. But it also has drawbacks. It leaves knowledge and safety gaps in practice, as the substances considered are:

- only those used intentionally;
- only those captured under chemical law, whose scope does not necessarily cover all substances relevant for the sector; or
- mainly the most known and studied substances, while making it difficult to develop knowledge on substances which are newly used or unintentionally created.

Chemical law uses another approach. Its goal is to create knowledge on the substance on the market and to control those which are harmful. It focuses on individual substances or groups of substances, mostly intentionally used. For substances which pose a potential risk because of their properties and/or the exposure their use leads to, processes for restriction and authorisation are created. The common approach is a process of pre-marketing authorisation, relying on an analysis of the properties of the substance to be placed on the market, to determine the conditions under which it may be used.

The Food Contact Materials Regulation is supposed to address *materials* (the centre of Figure 1), but it has the aim of a *product* regulation (the left of Figure 1) and uses mostly the tools of *chemical* regulation (the right of Figure 1). This confusion has resulted in a triple failure: the regulation does not address the safety of food-contact articles, addresses the safety of food contact materials only indirectly and the system it created does not have the capacity needed to address the safety of the FC chemicals (i.e. chemicals).

## The Roadmap

We welcome the Roadmap's recognition of the need to focus more on the final article to address NIAS and of the importance of looking at the sustainability of the product in addition to its safety.

We call on the Commission to recognise that the tools and approach used in the current system cannot, by design, deliver the goal of the FCM Regulation. **The only logical conclusion is therefore that Option 2 must be the way forward.**

In the next step, the Commission must aim in particular to:

- Refocus on FC materials and articles, using the Blue Guide on EU products rules as a basis, as well as the recommendations of the Non-Toxic Environment Study<sup>3</sup> on the regulation of materials. This should include the creation of a database containing the support documentation notified by

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<sup>3</sup> NTE, sub-study b) "Chemicals in products and non-toxic material cycles", Okopol, 2017.

the FC materials manufacturers, with a view to create a taxonomy of sub-materials, their uses and their properties. The standardisation of key materials could be considered in a second step.

- Change the approach to FC chemicals in order to address all substances across all sectors, starting with a better articulation of chemical and FCM rules. A better articulation could for example consist of ensuring that a Safety Data Sheet and a Chemical Safety Report are systematically provided by FC chemical manufacturers and importers, and prioritised for evaluation by ECHA/EFSA.
- Seize the opportunity of creating a system focused on materials and articles to adopt a more holistic approach that includes their sustainability as well as their safety. The potential of a life-cycle analysis approach should be considered,<sup>4</sup> as well as the hierarchy of consumption behaviour.<sup>5</sup>

Such an approach would have several consequences:

- abandon the current narrow focus on human health;
- focus on actions that serve both safety and sustainability, for example: the reduction of the diversity of FC chemicals and materials, the simplification of FC materials, the phase out of substances of concern, and the promotion of materials and uses that enable recyclability, longevity and versatility of (re)uses, etc.

The recognition of a potential need to consider sustainability in the Roadmap is very welcome.

## **Root cause 2 – Accountability cannot be achieved without allocating precise and targeted responsibilities in the supply chain**

### **The current situation**

The current FCM regulations (General and Plastic) do not designate any entity as the main entity responsible for the safety of the food contact product (be it the food contact material or the food contact article). They set a common obligation for all the actors in the extremely diverse supply chain, which is as a result vague. This is the biggest weakness of the existing system.

Giving one actor the ultimate responsibility for safety is indispensable for creating legal and social accountability. It eases enforcement by creating one focus point and structures compliance efforts by identifying the critical stage for ensuring safety and sustainability. It can even address power dynamics in

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<sup>4</sup> As per the recommendations of the Sustainable Market Actors Horizon 2020 research project E. Maitre-Ekern, M. Taylor, F. and M. van der Velden, Towards a Sustainable Circular Economy: SMART Reform Proposals, 8 May 2020, SSRN <https://www.jus.uio.no/english/research/areas/companies/publications/research-papers/200508-towards-a-sustainable-circular.html>

<sup>5</sup> Maitre-Ekern E, Dalhammar C. Towards a hierarchy of consumption behaviour in the circular economy. Maastricht Journal of European and Comparative Law. 2019;26(3):394-420. doi:10.1177/1023263X19840943

the supply chain if the law gives the responsible entity enforceable rights to require key information from its suppliers.

Identifying key roles in the supply chain and setting targeted obligations is a common tool in EU law. It can be found in EU products rules as well as in chemical law.

In the FCM sector, the manufacturer of the final product put on the market (FC material and/or FC article) needs to be made responsible for its safety. Distributors and FC chemical manufacturers also need to be subject to specific obligations corresponding to their control over the safety of an FC material or article.

## The Roadmap

The Roadmap remains silent on this root cause, which needs to be fixed at the next step.

The Blue Guide on EU product rules details the allocation of responsibility in EU product rules between manufacturers, importers and distributors and so could be the basis of the new system.

### Examples of what the core rights and obligations could be:

- Manufacturers/Importers of FC chemicals
  - Systematic and enforceable obligation to provide a Safety Data Sheet (SDS) and Chemical Safety Report (CSR) as defined under REACH.
- Manufacturers of FC materials
  - Right to require SDS/CSR from manufacturers/importers of FC chemicals, obligation to include their provision in contracts with FC chemical suppliers
  - Obligations designed on the basis of the obligations detailed in the Blue Guide on EU product rules for manufacturers, with detailed essential requirements that:
    - cover both intentional and non-intentional substances, with, at a minimum, an obligation to know and disclose the full composition
    - are adapted to the specifics of the type of materials concerned (synthetic/natural, organic/inorganic) as well as to the type of use
    - include negative and potentially positive FC chemical lists
  - Obligation to respect good manufacturing practice, including the application of a quality-control system covering all essential requirements
  - Obligation to submit a declaration of compliance and supporting documents to a centralised EU database.
- Manufacturers of FC articles (if different from FC materials)
  - Obligations that build on those of the materials' manufacturer, proportionate to the changes made to the products
- Importers of FC materials and/or articles
  - Obligations that build on the obligation of FC articles' and materials' manufacturers

- Distributors/professional users
  - Obligations that build on the Blue Guide – obligation to buy FC materials and articles from manufacturers that follow the rules and provide full evidence that they do so.
  - An enforceable right to access the declaration of compliance and supporting documentation.

## **Root cause 3 – Any migration into foods = food contamination**

### The current situation

The safety obligation set by the current regulation assumes that migration is not per se an issue. However, the Food Contaminant Regulation defines a contaminant as “any substance not intentionally added to food which is present in such food as a result of the production (...) manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination”<sup>6</sup>, which applies neatly to the reality of FC chemicals migrating into food.

The goal of the regulation is to keep the level of contamination as low as can be reasonably achieved from farm to fork; the FCM Regulation should pursue the same goal considering that FC chemicals are a significant source of food contamination.

### The Roadmap

The Roadmap recognises the commitment made by the Chemicals Strategy for Sustainability to exclude the most dangerous groups of substances, including CMR, PBT, vPvB and EDCs, from consumer products. This is a considerable progress compared to the current system.

Aligning the FCM regulation further with the aim of the food contaminant regulation would require to include in the essential requirements:

- Phase out the most problematic materials, such as PVC, polystyrene, polyurethane and polycarbonate
- An automatic exclusion of the CMRs classified under CLP (and in the future the PBT, VPVB and EDCs identified by the same process once CLP is amended) as well as the substances on the REACH candidate list. Derogations could be considered if verifiable justifications prove that there is no migration or that, for CMRs, a safe level may be set.
- An obligation to substitute the substance self-classified as CMRs (and once CLP is amended, as PBT, vPvB and EDC)
- An obligation to minimise migration as much as reasonably achievable and to respect an overall migration limit of 30 ppm

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<sup>6</sup> COUNCIL REGULATION (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

## Root issue 4 – Self-regulation does not work

### The current situation

The obligation to manufacture and use safe FC materials and articles has existed for long enough to conclude that, considering the current level of non-compliance, self-regulation does not work.

Precise rules are needed, as well as incentives in the form of support, monitoring and sanctions. Considering the limited resources of the Member States, both actors in the supply chain and third parties must be empowered to contribute to monitoring and enforcing compliance.

### The Roadmap

The Roadmap recognises the importance to facilitate enforcement, including by creating a digitalised platform for compliance documents, but it also seems to place a lot of faith in self-regulation mechanisms.

In the next step, the Commission must consider the development of a sophisticated multi-process and multi-actor compliance and enforcement system, featuring the following:

- An obligation to create an internal-quality system
  - A detailed obligation as to good manufacturing practice and an obligation to document its application
  - An obligation to develop a declaration of compliance justified by supporting documentation including a Bill of Materials and a Bill of Substances
  - An internal audit system to check the conformity assessment. A role could be granted to private standards to set out the conformity assessment process and potentially to check its correct application, but the application of the standard can never shield the actor from responsibility where a violation of an essential requirement is detected.
- An enforcement mechanism targeting suppliers
  - An obligation to integrate the provision of SDS/CSR or DoC/supporting documentation in contractual provisions
  - An obligation to disclose violations to public authorities
- An enforcement mechanism targeting manufacturers
  - An enforceable right for NGOs to access the documentation and to complain about a violation of essential requirements.
  - An enforceable right to obtain detailed information on the intended use
- Sanctions
  - A clear taxonomy of sanctions per type of non-compliance, with sanctions inspired by the GDPR regime for violation of essential requirements.
  - EU-wide sanctions


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