Food Contact Materials – Position Paper

28 October 2020

SAFE would like to express its view on the raising concern about hazardous food contact materials which 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.

This position paper aims at drawing attention on various health problems caused by FCMs such as endocrine disruptive effects and increased chemicals found in the human body on account of chemical components migrating from food packaging into food. Recycled plastic is also a growing preoccupation because of harmful chemical substances that are integrated during the recycling process.

Having all that in mind, SAFE would like to urge the European Commission to revise the current FCMs Regulation to ensure properly the safety of European citizens' food and health.

1. A FAVOURABLE POLITICAL CONTEXT

Revising the **Regulation (EC) 1935/2004 of 27 October 2004** on materials and articles intended to come into contact with food is of utmost importance within the **context of the European Green Deal**. Indeed, the issue of FCMs touches many different topics such as chemicals toxicity, recycled plastics and other food packaging, healthy food and safeguarding human health which are considered to be at the top of the political agenda set up by the new European Commission. Due to its transverse nature, the topic of FCMs is raised in several documents that are related to the Green Deal such as the **new Action Plan for a Circular Economy** in terms of FCMs' recycling and the forthcoming **strategies on Chemicals** which is part of a zero-pollution ambition for a toxic-free environment and **the Farm to Fork**.

Furthermore, on the point 62 of its resolution on the European Green Deal, **the European Parliament "stresses that legislation on food contact materials** and maximum residue levels of pesticides **should be revised** and **be based on the latest scientific findings**".

Finally, as the outcomes of the evaluation process launched by the European Commission about the FCMs regulation should be disclosed during the first quarter of 2020, this new political context is particularly favorable for a new FCMs regulation that should provide a comprehensive assessment process of food contact articles to fill the current unsafe gaps.

2. AN URGENT NEED FOR A NEW FCMs LEGISLATION

As highlighted by the European Commission itself in its Evaluation roadmap, since the inception of basic provisions set out over 40 years ago with Directive 76/893/EEC, the EU legislation on Food Contact Materials has never been systematically assessed. Considering the evolution of scientific knowledge,

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changes in practices, the emergence of new materials, the experience acquired in the last decades and the raising awareness of consumers, SAFE believes in the necessity of a new FCMs legislation designed to address the impairments of the current one and to face future challenges.

The Framework Regulation requires FCMs to be manufactured in a way that *"they do not transfer their constituents to food in quantities which could endanger human health"* with the aim to secure a high level of protection for human health and consumers' interests. However, the current legislation on FCMs does not effectively achieve these objectives given that legally binding provisions have only been adopted for four materials (namely, plastics, ceramics, regenerated cellulose and active and intelligent materials) out of a list of seventeen. Therefore, the rules regulating the manufacturing of most FCMs remained at the discretion of Member States which resulted in a **plurality of legislations across the EU as well as in different standards for product safety**. Those differences hamper the consumers' interest to have a uniform and effective legislation on materials which can potentially affect the composition of foodstuffs and therefore jeopardize the **right of European consumers to benefit the same level of protection across the EU**.

Moreover, many materials largely used as FCMs (such as paper, ink, adhesive or glues) are not controlled by harmonised EU-level laws. Even though those materials are commonly used in Europe, they are unregulated and their safety has not been evaluated by any national authority.
In addition to that, there is a mismatch between the European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the FCMs Regulation. Substances of Very High Concerns (SVHC) are defined under the REACH Regulation. Nevertheless, those chemicals with proved adverse effects on human health can be found in food contact articles in Europe. Therefore, the Commission should ensure better coordination between REACH and FCMs legislations to guarantee that harmful substances phased out under REACH are phased out in FCMs as well.

Lastly, there is a severe lack of information given to European consumers regarding the identity and the safety of chemicals used in Food Contact Materials. Plus, regulatory processes should include stakeholder participation as it is in the REACH Regulation. The new FCMs regulation should advocate for a greater openness and give the right to know to consumers.

Consequently, SAFE recommends the adoption of specific rules for those non-harmonizing regulated materials and encourages the Commission to adopt a legally binding legislation which includes all FMCs to ensure a higher level of protection for EU consumers.

3. EFFECTIVE ENFORCEMENT AND IMPLEMENTATION

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As enforcement controls differ across Member States, a deeper harmonization of administrative procedures, control and enforcement practices would be beneficial for the effective functioning of any FCM as well as securing a high level of protection of human health and interests of consumers. Indeed, effective enforcement is an important issue for of Regulation (EC) 1935/2004, as regular monitoring is not always carried out.

According to the articles 16 and 17 of Regulation 1935/2004, companies should always submit a certified full declaration of compliance (DoC) which confirms that their FCMs meet regulatory standards. However, it is not always performed in such way that would secure an optimal level of protection of interests of consumers because there is little control on the accuracy of DoCs or on how they are established, and the burden of proof relies on the Member States' authorities.

Since the submission of DoCs mostly remains at the discretion of the Member States, there are legislation and safety standards depending on each country. Member States should therefore perform controls more efficiently both imported and EU-manufactured finished articles and ensure that they have the necessary staff trained to do so. The European Commission should also promote a systematic enforcement strategy to ensure that EU FCM policy translate into real consumer protection.

Consequently, new regulations must be enforceable and sufficient resources for compliance control must be made available to authorities. As different standards can hamper legal certainty for all stakeholders involved, SAFE believes a single EU standard for analytical testing of FCMs is required.

4. MIGRATION IN FCMs

According to EU legislation, all FCMs should be safe, inert and manufactured in a way that "*they do not transfer their constituents to food in quantities which could endanger human health*" with the aim to secure a high level of protection for human health and consumers' interests.

However, current safety assessment of food contact chemicals is ineffective at protecting human health, not only because it is not sufficiently harmonised at European level, but also because even legally binding food contact materials regulations do not take sufficient account of scientific research on chemicals migration.
There is indeed clear scientific evidence that chemicals can transfer from food contact materials and articles into food. Scientific research expresses that approximately 12,000 hazardous chemicals are used in packaging and other forms of food contact materials, that migrate into our food and that are hazardous for human health.

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Many of the chemicals that are intentionally used in the manufacture of food contact articles have not been tested for hazard properties, or the available toxicity data are limited. In addition, more and more non-intentionally added substances (NIAS), including those with evidence for migration, have been detected by modern analytical methods, but many remain unidentified due to prevailing limitations in structure elucidation.

The main problem is that toxicity and exposure information is available only for few of the intentionally used chemicals and that risk assessment of unknown chemicals is not possible under the current regulatory approach. Consequently, scientists see a need for revising how the safety of migrating chemicals is assessed, using current scientific understanding and SAFE stresses that the presence and migration of chemical substances in food contact articles must be measured, evaluated and controlled.

5. RECYCLED PLASTICS

Recycled plastics can be defined as plastic packaging having been through a mechanical recycling process which includes cleaning, grinding, remelting and regranulating steps. Recycled plastics may have also had a chemical recycling process which consists of depolymerise plastics into monomers which are subsequently used for repolymerisation of virgin-like material.

The main issues concerning the recycling of plastic into FCM are the increased migration of chemicals from FCM into foods, the increased possibility of contamination due to-previous misuse by consumers, cross-contamination from waste disposal and environmental contaminants and the sorting machines-products prohibited from being recycled into FCM are being recycled on a significant scale such as Waste Electric and Electronic Equipment (WEEE). Plus, as recycled plastics are part of the solution for reducing packaging waste, it is the right time to ensure a safe and chemical-free waste recycling process.

Even though plastic recycling used for FCMs is regulated rather strictly, it is considerably more difficult to control recycled plastic's safety than it is for virgin plastic. The exposure of hazardous substances to humans is of great concern from a human health perspective. A risk of cocktail effect may rise on account of the simultaneous exposure to different substances through FCM and the lack of research concerning the effect of chemical mixtures on human health. Consequently, better risk assessment and testing should be put in place to reduce safety risks brought on by non-intentionally added chemicals (NIAS) leakage from FCMs to food. A large percentage of investigated recycled plastic FCM is not compliant with FCM regulations. A Brazil and Spain-based study of the Universities of Campinas, São Paulo and of Zaragoza investigated post-consumer PET packaging submitted to cleaning processes for recycling into FCM. Tests detected migration of non volatile and inorganic residual compounds (i.a.

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silicon, calcium, sodium, iron, magnesium, aluminium, zinc) which are contaminants not allowed by Brazilian and EU Regulations were identified even in deep cleaning samples.

In addition, the presence of NIAS should be systematically monitored in recycled food contact materials. NIAS can reach higher levels in recycled food packaging on account of the materials intended for recycling that may contain intrinsic contaminants such as dyes, additives and their degradation products. Furthermore, packaging may be degraded with a greater number of chemicals that are accumulated when materials are recycled several times. Previous use and misuse of plastic packaging may also contribute to the presence of unwanted and unexpected contaminants, and non-food grade materials may enter the recycling stream.

Many types of plastics absorb chemicals during waste management which are difficult to remove during the recycling process. For instance, it is a challenge to introduce sorting systems that separate food contact materials from non-food grade plastics. There are also some examples showing the deliberate recycling of non-food plastics into new food packaging. A research from the Institute for Testing and Certification in Czech Republic analysed ten black polymeric food-contact articles purchased on the European market. 7 out of 10 samples contained a bromine level exceeding the authorized one. Typical elements used in electronic equipment and present in Waste Electric and Electronic Equipment (WEEE) were detected either at trace level or at elevated concentrations. Brominated samples contained flame retardants have regularly been found in plastic items intended for food contact materials, which is a clear indication that waste electric and electronic equipment (WEEE) has been used in the process which is prohibited. Another study conducted by Turner & Filella in 2017 analysed a range of plastic consumer products (i.a. coffee stirrers, thermo cup lids). Bromine was detected in 18% of 789 analyses performed on non-electronic samples. Better enforcement is needed to improve this situation.

Within the framework of the circular economy, the demand for recycled plastics, and more generally, recycled food packaging, will be growing which will lead to an increased exposure to harmful chemicals found in recycled containers. On March 11th, the European Commission published a new Circular Economy Action Plan in which they commit themselves to "*seek standardisation and the use of quality management systems to assure the quality of the collected waste destined for use in products, and in particular as food contact material*". The adopted policies should support the transition towards reusable packaging while guarantee consumers safety as a first priority. Notwithstanding, the new regulation should restrict the usage of hazardous chemicals in food packaging, ensure a better control of recycling system and promote sustainable, risk-free alternative to recycled plastics such as glass containers or bulk materials.

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6. ENDOCRINE DISRUPTORS

Endocrine disruptors (EDs), known as substances that interfere with humans' hormonal systems, are inherent to food contamination as they are present in every day substances, from foodstuffs' packaging to pesticides. The list of EDs that were found in FCMs includes a variety of chemicals such as phthalates, adipates and Bisphenol A. In particular, the latter was identified by the European Chemical Agency as a substance of very high concern due to its adverse effects on human and animal reproductive system.

EDs are considered as Food Contact Chemicals that can cause adverse effect to human health. As a matter of fact, a recent statement, written by a group of 33 eminent scientists and based on more than 1,200 peer-reviewed studies, raised the issue of the hazardous effects of endocrine disrupting chemicals found in food contact materials. Indeed, chemicals migrating into food are not subject to any endocrine disruptive effects' assessment. Furthermore, the fact that Non-Intentionally Added Substances (NIAS) are found in FCMs leads to a mix of chemicals with toxic properties that are neither taken into account. Last but not least, low level of exposure to some chemicals - that might be endocrine disruptors - are not tested because exposures to them are considered to be below the toxicologically established no-effect level. These above-explained loopholes in the current FCMs Regulation should be considered to set up a new assessment process to ensure that FCMs do not contain any endocrine disruptors.

We fully support the European Parliament, which in its resolution of 15 January 2020 on the European Green Deal, "calls for an ambitious legislative proposal by June 2020 to tackle endocrine disruptors, especially in cosmetics, toys and food contact materials, and an action plan that provides a comprehensive framework with targets and deadlines to minimise citizens' exposure to endocrine disrupting chemicals (EDCs)".

7. CONCLUSIONS

In light with the important push for a greener and sustainable lifestyle encouraged by the European Green Deal, SAFE takes this opportunity to highlight the urgent need for reopening the Food Contact Materials Regulation.

Several loopholes have been listed regarding the assessment process of FCMs that does not ensure a complete safety, the limited scope of the current legislation that do not cover the numerous hazardous chemicals migrating into food and the new innovative materials such as recycled glass or plastics which have been proven to contain harmful chemicals.

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Even if we highly appreciate the Commission's efforts in approaching a new Circular Economy Action Plan, we call the attention for the importance of a strong concern towards the presence of NIAS in the recycled plastic in FCMs. As these substances are harmful for consumers, there should be a strong regulation which pays special attention to the use of recycled plastics. In that sense, we endorse for the need of an independent scientific research on this matter.

Revising the FCMs Regulation is essential to provide a safe and healthy legal framework that would be applied uniformly and with high standards in all EU Member States in order to guarantee a maximum protection of European citizens' food, health and environment.

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