

May 2019

## **The European framework for food contact materials is outdated and does not ensure safety.**

### **The legislation should be revised based on 5 new key principles**

CHEM Trust has been calling for a revision of the legislation on food contact materials (FCM) for nearly 5 years<sup>1</sup>, and we genuinely welcome the Commission's initiative to evaluate the framework regulation including the further aim to consider what possible steps need to be taken in the future concerning the regulation of FCMs in the EU<sup>2</sup>.

The original concept of a framework regulation<sup>3</sup> supplemented by positive list for substances used in specific types of FCM in combination with overall and specific migration limits has been recognised as insufficient by many stakeholders<sup>2</sup>. Just recently a EU Parliament resolution has called on the Commission to revise the Regulation on Food Contact Materials substances no later than June 2020 to effectively reduce the content of hazardous substances therein, with specific provisions to substitute the use of EDCs<sup>4</sup>. The need for reform is also evident on the basis of a comprehensive baseline report from the EC Joint Research Center<sup>5</sup> which showed massive safety gaps related to non-harmonised food contact materials. The alarming fact is that thousands of deliberately used chemicals as well as a wide range of reaction products and impurities are present in FCM and can migrate into our food. Many of them are known to have harmful properties and many more are suspected to have similar effects. The situation is unacceptable and reforming the current ineffective system must be a key priority for the next Commission. In this consultation response, we highlight some of the most important problems with the current system and call for new updated legislation based on 5 new key principles. In addition, we further recall the need for full alignment of the FCM regulation with the REACH<sup>6</sup> regulation and provide examples of how a new legislative system for FCMs could be developed.

Our response has the following sections:

1. Problems with the current system
2. Call for new legislation based on five key principles
3. Proposals for way forward taking inspiration from REACH and other chemicals legislations

### **1. Problems with current legislation**

#### **Hazardous chemicals are found in FCM sold to European consumers**

In recent years, there have been several examples of hazardous chemicals detected in food contact material that were on the market and sold to consumers:

- In 2017, 5 consumer organisations from Denmark, Spain, Italy Portugal and Belgium found high levels of fluorinated compounds (PFAS) in one third of tested fast food packaging<sup>7</sup>. These compounds can be highly persistent, and some accumulate in animals and humans. Several are suspected of being endocrine disrupting chemicals, carcinogens and are harmful to the immune

system. It is well-known that PFAS can migrate into food, but a harmonised ban is not established at EU level and some are authorised for use in FCM<sup>8</sup>. Retailers of the tested products did not know that these chemicals were in their products<sup>9</sup>. This situation is particularly worrying in light of the fact that a recent risk assessment on perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) made by EFSA conclude that humans can tolerate 808 times less PFOA and 175 times less PFOS than previously thought<sup>10</sup>. Following this, Denmark is working on a national ban and could become the first – and only - country in the world to ban the entire group of organic fluorinated compounds in cardboard and paper FCM<sup>11</sup>

- A test in Norway, published in 2018, showed that reusable water bottles leach phthalates, bisphenols, flame retardants, lead and other dangerous chemicals into their content<sup>12</sup> – the levels were below current limit values, but these findings illustrate the need to assess to what extent FCM contribute to the consumers' total exposure to harmful chemicals.
- Swiss authorities checked 78 packaging items, including cups, pizza boxes, bread packaging. 14% had residues of photo initiators, plasticisers, or chlorinated substances at concentrations exceeding recommended limits. 62% had elevated mineral oil saturated hydrocarbons, 20% elevated mineral oil aromatic hydrocarbons. Only 43% had proper self-assessment documentation<sup>13</sup>

It is particularly unacceptable that substances with harmful effects are found in food contact material, as these materials – due to their physical contact with our food - constitute a high risk of exposure. The examples above, and other - sometimes scandalous - findings from recent years<sup>14,15,16</sup> illustrate how the legislation does not properly protect consumers from harmful chemicals. Below, more information and discussion is provided about the gaps and deficiencies in the current legislation on FCM.

### **Harmonisation is long overdue**

The recitals of the framework regulation<sup>3</sup> indicate that the original intention in 2004 was to establish harmonised rules for all relevant food contact material. However, this has still not happened and today only four FCMs<sup>17</sup> out of the seventeen listed in Annex I of the framework regulation, are regulated at the EU level. For the thirteen materials left, including paper and card, can coatings, inks and glue, only the general safety requirements set by the FCM<sup>3</sup> (and GMP<sup>18</sup>) regulations are applicable. This lack of harmonised legislation for chemicals in all these important materials is leaving the consumers at a higher risk and industry in a big uncertainty challenge.

### **The regulatory situation for the non-harmonised materials is chaotic**

The landscape of non-harmonised materials is characterised by a mixture of soft law with numerous guidance documents combined with different national legislation in the MS for different materials. The Council of Europe provides guidance that MS can use to transpose into national law. Different industry sectors have produced guidance documents for their members, but there is still much confusion as to how safety should be ensured.

The baseline report from JRC<sup>5</sup> clearly showed how the current regulatory situation as regards the non-harmonised materials is unacceptable. As mentioned above, in the absence of common rules, MS have chosen to lay down national rules for different materials which creates a fragmented and chaotic system. The report particularly highlights that there is a lack of common guidelines and transparency in undertaking risk assessment work across Member States. Moreover, the national measures can be difficult to access and are not always consistently structured or sufficiently detailed. In particular, lack of clear provisions and standards related to Good Manufacturing Practise (GMP) and the declaration of compliance (DoC) and supporting documents was reported, and the baseline report call for a better link to sanctions and to provisions for traceability along the supply chain. Moreover, it was highlighted that testing methods are lacking for both enforcement and compliance work, making it difficult to ensure safety.

### **Numerous substances are used**

The rules for plastic food contact materials are harmonised in the EU<sup>19</sup> and about 1000 chemicals have been authorised by EFSA for use in plastics. In addition, close to 8000 substances have been reported as used in non-harmonised food contact materials<sup>5</sup>. and it has been estimated that e.g. more than 5000 substances are used in inks alone<sup>20</sup>.

### **Unknown and unassessed substances are accepted without proper scrutiny?**

In addition to the chemicals that are deliberately used, there are also a large number of so-called NIAS, Non Intentionally Added Substances, in FCM. The NIAS can be e.g. reaction products formed after the production of a material, or they can be impurities in the starting material. Final food contact articles, consisting of harmonised or non-harmonised materials, or both, may contain numerous substances that are unknown, both as regards hazards and amounts. For example, 97% of substances, that migrate from can linings can be NIAS<sup>21</sup>. NIAS can also make up the majority of substances that migrate from plastics and the level of migrating substances including the NIAS can be 100-1000 higher than you could have pesticide residue in the food<sup>21</sup>.

Researchers have expressed concern that in practise it is not possible to comply with the general requirement of the framework regulation, which says that FCM “must not endanger human health” or the limited requirement of the plastic regulation to risk assess NIAS<sup>21,22,23</sup>. EFSA has recently published an opinion concluding that more focus is needed on NIAS migrating from the finished materials<sup>24</sup> and there is an obvious need to intensify the efforts both to gain knowledge and to find measures to avoid these substances.

### **EDCs are not properly addressed**

Consumers are exposed to low levels of substances from FCM throughout their entire lives. The effects of these compounds are assessed with a focus on mutagenicity and genotoxicity. This approach however neglects integrating toxicological findings, like endocrine disruption, mixture toxicity, and developmental toxicity<sup>25</sup>. Endocrine disrupters are of particular concern as recent science has associated these substances with various diseases and conditions such as hormonal cancer, reproductive problems, metabolic disorders (diabetes, obesity) asthma and neurodevelopmental conditions.

However, the new scientific insights on potential long term and delayed effects, the increased uncertainties for setting thresholds for these substances due to low doses and non-monotonic dose response curves as well as combination effects have so far not led to significant regulatory steps to protect consumers from these substances in FCM. Isolated policy measures have been taken on bisphenol A (but not other bisphenols with similar properties, such as Bisphenol S) and are hopefully underway for phthalates, but in general the existing legislation does not address the health risk posed by endocrine disrupting chemicals<sup>26,27</sup> and unlike several other EU legal acts on different consumer products, there are no provisions that lay down criteria or define any substances of such high concern that they should be fully avoided in FCM.

### **Lack of Information in the FCM supply chain**

In order to ensure safety, it is imperative that the company doing a risk assessment of a food contact material knows how the substances is used and likewise that the company, that uses a FCM to assemble a final food contact article knows which chemicals are present in the material as well as their potential hazards. However, the transfer of safety-related information from one actor to the next in the manufacturing chains presents flaws, both as regards chemicals content and hazardous properties for both harmonised and non-harmonised FCM<sup>5</sup>. Documents from upstream supplies are often too superficial to ensure appropriate risk management,

and the downstream users do not have access to the calculations behind Declarations of Compliance<sup>28</sup>.

### **Lack of enforcement**

There is a lack of clear provisions related to the actual content of key elements in the FCM legislation (GMP, DoC, Risk assessment methodology) which serve to establish whether the basic safety requirement is met. This makes the provisions difficult to enforce<sup>5</sup> and this situation, in combination with few resources in MS, have created a situation with very low enforcement intensity<sup>29</sup>.

In conclusion the current legislation on FCM does not provide appropriate safety for the consumers and there is an urgent need for amending this situation. This is the background for our call for new legislation based on 5 key principles.

## **2. Call for new legislation based on five key principles**

Since the beginning of the evaluation period, CHEM Trust has been cooperating with a group of organisations (ChemSec, Client Earth, HEAL, Danish Consumer Council, EEB, US Breast Cancer Prevention Partners, as well as BEUC and the science research organisation Food Packaging Forum) to pinpoint the main problems with the current system and propose solutions. As a result, we have developed 5 new key principles that we believe should guide the future legislation on food contact material to ensure consumer protection<sup>30</sup>.

The new EU regulation of chemicals in Food Contact Materials must ensure:

### **1. A high level of protection of human health**

All substances used in food contact materials should have adequate safety data, provided by industry and should be regularly reviewed for this use by public authorities. The presence of substances that are already restricted in the EU, and those meeting the REACH criteria for Substances of Very High Concern, such as CMRs, sensitizers or endocrine disrupters, should be automatically prohibited.

### **2. Thorough assessment of chemicals in materials and final articles**

The presence in, and migration of, chemicals in food contact articles – including Non-Intentionally Added Substances (NIAS) – should be measured, assessed and controlled. Absence of reliable migration data should imply presumption of full migration. Assessments of migration should include mixture effects and take a precautionary approach to exposures from non-FCM sources. Both industry and regulators should ensure that any migration is understood and limited to ensure a high level of protection of public health.

### **3. Effective enforcement**

National governments must ensure effective enforcement, including checks on both imported and EU-manufactured finished articles using the best available analytical methods. Producers and importers of chemicals used in FCM should always be responsible for providing adequate analytical standards and analytical methods to regulators and test laboratories. In the event of contamination of products with problematic chemicals, producers should be obliged to notify the regulators.

### **4. A clean circular economy based on non-toxic material cycles**

As the EU's transition to a circular economy gains momentum, it is vital that the EU's efforts to encourage recycling do not perpetuate the use of harmful chemicals in FCM. Adequate regulation and enforcement of all types of recycled FCM is required to ensure that recycled food contact materials are never less safe than virgin materials.

### **5. Transparency and participation**

Supply chains and final consumers should have a right to know the identity and safety information on chemicals used in, and migrating from, food contact materials. Regulatory and policy processes should as a minimum adhere to the same standards of openness and stakeholder participation that have been established in REACH.

### **3. Proposals for way forward taking inspiration from REACH and other chemicals legislations**

In recent years, CHEM Trust has been seeking to promote discussions amongst stakeholders about the coherence between the FCM legislation and REACH. In addition, we believe it would be beneficial to look at regulatory measures already in place under other regulations, that might serve as inspiration for possible new approaches for food contact materials. In the following we provide a list of examples, which could serve as input to further discussion about the future both during and after the evaluation period.

#### **Substances of high concern should be phased out**

As established in Key Principle 1, we call for a generic risk assessment provision to prevent the further use of certain substances of concern (irrespective of migration as a condition). That is because specific risk assessments that aim to set protective levels for substances with serious and irreversible effects, like the Substances of Very High Concern (SVHCs) identified under REACH, have high uncertainties and are generally not applicable for non-threshold substances.

A generic approach is used in several existing legislations today: It is prohibited to sell CMRs in mixtures consumers according to REACH annex XVII entry 28-30. CMRs are also restricted in toys<sup>31</sup>, cosmetics<sup>32</sup> and pesticides<sup>33</sup> and recently also in textiles<sup>34</sup>. Without taken a stand on whether these measures are sufficient for CMRs and - more importantly - stressing that provisions for endocrine disrupters are still missing<sup>27</sup>, we would stress that a generic approach in FCM are long overdue and these should be broader and cover not only CMRs but also EDCs and other substances of high concern.

#### **Cumulative risk assessment**

When establishing acceptable exposures, it is extremely important to consider aggregate and cumulative exposures from chemicals exerting similar adverse outcomes. This concerns exposure to the same chemical from multiple sources as well as to other chemicals from multiple sources combined. As chemicals in FCM migrate directly into our food, it is particularly important that the reality of combined exposure is taken into account for these products.

In our view, the need to fully implement a coherent cumulative risk assessment approach based on grouping of substances with similar hazards combined with a generic restriction of substances of high concern is one of the most important tasks for regulators of all chemicals' legislations across the board.

#### **A phase-in system could create overview**

A main aim of the REACH regulation from 2006, was to establish an overview of the potentially hundreds of thousands of industrial chemicals on the market in EU. This was done via a phase-in system with clear deadlines for industry to register and deliver data. The deadlines were mainly dependent on tonnage, as a proxy for exposure, but there was also an early deadline for certain hazards, irrespective on tonnage. A similar phase-in approach, shortened and adapted to the different situation, might work to gradually introduce harmonised rules for the currently non-harmonised FCM starting with the most important materials such as paper and board and the most important chemicals, the SVHCs, DNTs<sup>35</sup> and EDCs including

bisphenols, phthalates and fluorinated substances which should be addressed as groups.

### **Create a database of industry assessments etc.**

In order to ensure transparency and avoid double work, it could be beneficial if the information produced by industry on hazards, migration at different conditions, risk assessment, and proposed risk management was stored in a publicly accessible database. Data from authorities and scientific agencies about risks from substances in harmonised and non-harmonised material should also be public.

Here, inspiration from the REACH-IT system and ECHAs comprehensive databases and standard reporting formats could be taken, including, importantly, the obligation on industry to update their registration when new information is available, and with a view to establishing a new No data – No market approach for FCM.

### **Ensure coherence with REACH**

There is a lack of coherence between REACH articles 14,5 and 56,5b and the FCM legislation which need to be addressed. These exemptions in REACH does not seem warranted as long the FCM framework does not provide similar safety. Similarly, it is important to ensure that the scope of any REACH restriction only exempts FCM if they are irrelevant for the restriction in question, or if similar restrictions are already in place in the FCM legislation.

### **Review the legal system regularly**

It is not viable that the legislation for products with high risk of consumer exposure, such as FCMs, is not reviewed regularly. In contrast, the whole REACH regulation is reviewed every 5 years. We propose a similar review clause in the new FCM legislation.

Finally, we can only reiterate our call for new legislation. The FCM legislation is 40 years old and no evaluation has been carried out by the Commission since the basic provisions were put in place in 1976<sup>2</sup>. The Commission has acknowledge that “difficulties exist as regards ensuring the safety of FCMs”<sup>2</sup> and decisive regulatory changes are needed for a better protection of consumers from the exposure to harmful chemicals in food contact materials.

*“Doing the right thing is sometimes used as the last resort”  
(Nicken Malmström, Fenno-Swedish writer)*

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<sup>1</sup> See CHEM Trust’s website: <https://chemtrust.org/food-contact/>

<sup>2</sup> DG SANTE introductory workshop to support the evaluation on Food Contact Materials (FCMs) legislation. Workshop document [https://ec.europa.eu/food/sites/food/files/safety/docs/cs\\_fcm\\_eval-workshop\\_20180924\\_wd.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_eval-workshop_20180924_wd.pdf)

<sup>3</sup> Regulation (EC) No 1935 of 2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

<sup>4</sup> European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors (2019/2683(RSP)) [http://www.europarl.europa.eu/doceo/document/B-8-2019-0241\\_EN.html](http://www.europarl.europa.eu/doceo/document/B-8-2019-0241_EN.html)

<sup>5</sup> C. Simoneau et al (2016) Non-harmonised food contact materials in the EU: Regulatory and market situation, EUR 28357 EN; doi:10.2788/234276 <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study>

<sup>6</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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- <sup>7</sup> N. Søndergaard, Danish Consumer Council (2017) Fast food packaging contains unwanted fluorinated substances [/fast-food-packaging-contains-unwanted-fluorinated-substances](#)
- <sup>8</sup> B. Geueke, Food Packaging Forum (2016) Dossier – Per- and polyfluoroalkyl substances (PFASs), [https://www.foodpackagingforum.org/fpf-2016/wp-content/uploads/2016/07/FPF\\_Dossier10\\_PFASs.pdf](https://www.foodpackagingforum.org/fpf-2016/wp-content/uploads/2016/07/FPF_Dossier10_PFASs.pdf)
- <sup>9</sup> S. Müller, Danish Consumer Council (2017) Test: kemi i emballage til fastfood. In Danish. <https://kemi.taenk.dk/bliv-groennere/test-kemi-i-emballage-til-fastfood>
- <sup>10</sup> EFSA panel on contaminants in the food chain (CONTAM) 2018. See <https://chemicalwatch.com/72934/efsa-panel-lowers-tolerable-intakes-for-pfos-and-pfoa>
- <sup>11</sup> Chemical Watch, February 2019, Denmark target ban on all fluorinated chemicals in FCM <https://chemicalwatch.com/74124/denmark-targets-ban-on-all-fluorinated-chemicals-in-fcms>
- <sup>12</sup> Norwegian Consumer Council (2018) Drinking bottles leach chemicals <https://www.forbrukerradet.no/side/drinking-bottles-leach-chemicals>
- <sup>13</sup> Chemical Watch, 1st May 2018, Swiss project finds excessive hazardous chemical levels in FCMs <https://chemicalwatch.com/66493/swiss-project-finds-excessive-hazardous-chemical-levels-in-fcms>
- <sup>14</sup> N. Søndergaard, Danish Consumer Council (2015): Unwanted chemicals found in pizza boxes, <https://kemi.taenk.dk/bliv-groennere/test-unwanted-chemicals-found-pizza-boxes>,
- <sup>15</sup> J. Samsonok and F. Pyupe (2013) Occurrence of brominated flame retardants in black thermo cups and selected kitchen utensils purchased on the European market. Journal of food additives and contaminants part A: volume 30, 2013. Issue 11. <https://www.tandfonline.com/doi/abs/10.1080/19440049.2013.829246#.VYp4uVWWGMU>
- <sup>16</sup> See e.g. ref 27 for more examples.
- <sup>17</sup> Virgin and recycled plastics, ceramics, regenerated cellulose and active and intelligent materials
- <sup>18</sup> Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
- <sup>19</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
- <sup>20</sup> B. Geueke (2015) Food packaging and chemical safety today, overview of scientific challenges for tomorrow. Cited in CHEM Trust (2016) Chemicals in food contact materials: a gap in internal market, a failure in public protection. [www.chemtrust.org](http://www.chemtrust.org)
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- <sup>27</sup> Commission communication to the European Parliament, the Council, the European Social Committee and the Committee of the regions on endocrine disrupting chemicals, Towards a comprehensive European Union framework on endocrine disruptors COM(2018) 734 final <http://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF>
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- <sup>29</sup> CHEM Trust blog (2018) Finally, a review of Europe’s ineffective laws on chemicals in food contact materials has begun: <https://chemtrust.org/eu-fcm-review-conference/>
- <sup>30</sup> CHEM Trust blog (2019) Five Key principles for future EU regulation of chemicals in food contact material: <https://chemtrust.org/5-key-principles-fcm/>
- <sup>31</sup> Directive 2009/48/EC of the European Parliament and of the Council of 18. June 2009 on the safety of toys
- <sup>32</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
- <sup>33</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
- <sup>34</sup> Regulation (EU) 2018/1513 on 10 Oct 2018 amending REACH Annex XVII restricted substances list and restricting certain substances classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B (CMR substance) in apparel, footwear and other textile consumer products.
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