May 2019

For a healthy food chain

ClientEarth's contribution to the public consultation on the evaluation of "food contact materials"

ClientEarth welcomes the initiative of the European Commission (the Commission) to review the EU rules[1] on "food contact materials" (FCM) and the opportunity to provide its views in the public consultation. If this regulation exists, it is to ensure, first and foremost, a high level of protection for human health[2,3]. This evaluation should therefore focus on this objective.

The flaws and weaknesses of the FCM legal framework have been known for many years[4], and translate into unacceptable risks to public health as well as obstacles to the circular economy. ClientEarth would like to take the opportunity in this public consultation to emphasise two elements that make the protection of human health under the FCM Regulation weak and unsatisfactory:

- Lack of harmonisation for all FCM, meaning different levels of protection against dangerous chemicals present in FCM, depending on the Member State
- Lack of adapted provisions to prevent harm from chemicals classified as carcinogenic, mutagenic or toxic for reproduction (CMRs), and endocrine disruptors (EDCs)

Lack of harmonisation endangering public health

According to Article 6 of the FCM Regulation, Member States are allowed to adopt specific provisions on FCMs, if no binding measures exist at EU level. Currently, only four FCM[5], out of seventeen listed in Annex I, are regulated at the EU level. This means that, for the thirteen materials left, Member States have full discretion to set the level of safety they see fit. Indeed, as only the general safety requirements set by the FCM Regulation are applicable in that case, the level of protection can be set at different levels depending on each country and their interpretation of an acceptable risk. This creates different safety standards for products.

[1] 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 (OJ L 338 13.11.2004, p. 4) (FCM Regulation) and other regulations adopted to implement the FCM Regulation.
[2] The environmental concern that these materials can raise is covered by other EU rules: Regulation (EC) No 1907 of 2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), (OJ L 396 30.12.2006, p. 1) (REACH Regulation).
[3] Article 1 of the FCM Regulation.
[4] See a comprehensive briefing by ChemTrust (2016), *Chemicals in food contact materials: A gap in the internal market, a failure in public protection*. Available at: https://www.chemtrust.org/wp-content/uploads/chemtrust-foodcontactchemicals.pdf (last access 29th April 2019).
[5] Virgin and recycled plastics, ceramics, regenerated cellulose and active and intelligent materials.

Moreover, in the absence of harmonised rules at EU level, the principle of mutual recognition applies[6]. This means that products sold lawfully in one Member State cannot be prohibited from sale in another. Therefore, if an article is lawfully produced in a Member State where very lax safety standards apply, it can be sold in other EU countries, even though these Member States have stricter rules. This can lead to a race to the bottom that jeopardises public health.

For instance, regarding paper and board - to which no harmonised rules exist at EU level - there are only nine Member States (Belgium, the Czech Republic, Germany, France, Greece, Croatia, Italy, the Netherlands and Slovakia) that specifically regulate the chemical content of this type of FCM. An estimated total of about 1700 substances were found in national[7] measures and, of these, 147 (9 %) substances were common to two or more Member States. Within these 147 substances, 74 substances have no convergence on restrictions applied by different Member States. If we consider the example of the Glutaraldehyde (CAS 111-30-8)[8], such a fragmented regulatory framework led to a situation in which two Member States set two different specific migration limits and others set no restrictions[9]. In practice, if glutaraldehyde is used in a country where no restriction on it applies, it can not only be used in FCM in that country, but it can also be legally exported and sold to another country with stricter safety standards on that specific substance. This way, the principle of mutual recognition, while avoiding trade barriers within the internal market, promotes also the lowest common denominator.

The FCM Regulation needs to be amended to fill these gaps and stop this race to the bottom.

Lack of adapted provisions to prevent harm from chemicals classified as carcinogenic, mutagenic or toxic for reproduction (CMRs), and endocrine disruptors (EDCs)

Pursuant to Article 3 of the FCM Regulation, under normal or foreseeable conditions of use, materials and articles must not transfer their 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.

[6] Cassis de Dijon ruling, judgment of the Court of Justice of 20 February 1979, Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein, Case 120/78. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:61978CJ0120&from=EN (last access 29th April 2019).
[7] Sometimes national measures refer to "supranational" standards, such as those developed by the Council of Europe. For instance, on the basis of known substances that are or were used in FCM, Belgium has created a database of substances known by Member States of Council of Europe. This database is available at: https://fcm.wiv-isp.be/Default.aspx (last access 26th April 2019).
[8] Information on the substance are available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.003.506 (last access 26th April 2019).
[9] C. Simoneau, B. Raffael, S. Garbin, E. Hoekstra, A. Mieth, J. A Lopes, V. Reina (2016), JRC Science for Policy Report, *Non-harmonised food contact materials in the EU: regulatory and market situation*, P. 68-70. Available at: 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 (last access 26th April 2019).

In application of these "general requirements", as stated in Article 8, no substance can be authorised to be used in food contact materials and articles, unless it has been demonstrated that the amount of the substance released into food does not endanger human health or change composition/organoleptic characteristics of food.

When business operators wish to use a certain substance in a FCM, they have to submit an application for authorisation to the competent national authority that will transmit the application to the European Food Safety Agency (EFSA). At the end of this process, the dossier will be sent to the Commission, who will take the final decision. The authorisation, if granted, can be limited to special conditions of use.

The whole approach relies on the concept of "migration", namely the release of a specific substance from food contact materials into food. The current regime accepts (i) that migration of the chemical from the FCM into food can happen and (ii) the chemical can be used in FCM even when it is classified as hazardous (for example, carcinogenic), as long as the "quantities" are not so high that it "could endanger human health". In other words, this regulation assesses safety by asking "how much exposure to a dangerous chemical (for example capable of causing cancer) is too much?".

This approach does not ensure a high level of protection of human health. Considering the seriousness of their hazardous properties, CMRs and EDCs should not be allowed to be present and used in food contact materials in the first place. The FCM Regulation should be amended in order to introduce a "cut-off", preventing the use of CMRs and EDCs in FCM.

The case for a cut-off approach on CMRs

In the FCM Regulation, there are no specific provisions on CMRs nor any link made to their identification as "substances of very high concern" under the REACH Regulation. This means that, even when a substance has been already identified as a CMR[10], the Commission will be able to authorise its use in food contact materials.

Even when there are harmonised rules for a specific type of FCM - such as in the case of plastic food contact materials[11] - there are no cut-off for CMRs. The only limitations to their use is that the concept of "functional barrier"[12] does not apply to them[13]. On the one side, this means that a company cannot argue that a CMR can be used without authorisation because it is separated from the food thanks to a "functional barrier". On the other side, it still means that a CMR can be used in plastic FCM, as long as it is granted an authorisation, which will assess "how much is too much".

[10] In application of Regulation (EC) No 1272 of 2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).
[11] Regulation (EU) No 10 of 2011 on plastic materials and articles intended to come into contact with food (OJ L 012 15.1.2011, p. 1) (Plastic FCM Regulation).
[12] Article 15(3) Reg. (EU) No 10 of 2011 defines it as "a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935 of 2004 and with the provisions of this Regulation".
[13] Article 13 of the Plastic FCM Regulation.

Such a regulatory framework is not protective enough as it means that, after a risk assessment has been carried out and an authorisation has been granted, even CMR substances are allowed to be used in FCM, despite the fact that they may migrate into our food. The only way to fully protect citizens from this hazard class is a "cut-off" criterion, that would not only save resources and time for public authorities, but would also send a clear signal to the market, redirecting innovation towards safer solutions.

Such a cut-off principle exists for CMRs when used in "plant protection products" (i.e. pesticides)[14]. Pesticides rules and FCM rules are worth comparing because they both try to address, notably, the risk of consumers exposed to chemicals via food: the former looking at residues in food, the latter at chemicals that can migrate into food from the packaging or other materials with which it enters into contact. Both systems function with an approval mechanism: under the pesticides rules, companies need to apply for the approval of their active substance, while FCM rules set out a positive list of authorised chemicals, which can be expanded when companies apply for an authorisation. It is, then, quite surprising to see that pesticides rules follow a more protective approach. Indeed, in principle, no approval is possible if the chemical is identified as a CMR. There is no reason to not apply the same logic to materials coming into contact with food.

The case for a cut-off approach on EDCs

The relevance, urgency or level of strictness required when regulating EDCs should depend on the seriousness of the health threat that they pose. The difficulty to predict a "safe level" of exposure and thus the difficulty to anticipate accurately and control the risk should also play a role in the risk management decision.

Health impacts of EDCs are evidently extremely serious: reproductive and fertility problems, hormone-related cancers, neurological impairment, obesity and diabetes and other severe adverse effects[15]. Biomonitoring studies[16] have shown that the general European population is exposed to many different EDCs via food, dust and water, absorption through the skin, and by transfer from pregnant women to the fetus or child via the placenta or breast milk. Moreover, "the effects of EDC exposures are not limited to the generation exposed because of intergenerational and transgenerational epigenetic inheritance"[17]. It is also clear that "given the scientific knowledge on specific actions of [endocrine disruptors] (low dose effects, possible non-monotonic dose

[14] Regulation (EC) No 1107 of 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 (OJ L 309, 24.11.2009, p. 1) (Pesticides Regulation).
[15] See for more information on endocrine disruptors: https://www.endocrine.org/topics/edc (last access 29th April 2019).
[16] See e.g. EU Biomonitoring project DEMOCOPHES. Available at: http://www.eu-hbm.info/democophes (last access 24th April 2019).
[17] See the 2019 Editorial *EDCs: regulation still lagging behind evidence*, The Lancet. Diabetes & Endocrinology, Vol. 7, p. 325. Available at: https://www.thelancet.com/action/showPdf?pii=S2213-8587%2819%2930114-7 (last access 29th April 2019).

responses, cumulative effects often expected from combined exposure and vulnerable periods of exposure) it is unlikely that safe levels can be set"[18].
Under the current FCM Regulation, there is no specific provision on EDCs, or reference to their identification as a "substance of very high concern" under the REACH Regulation. Not even the specific Plastic FCM Regulation gives particular attention to protect human health from the hazard of EDCs. In practice, a chemical identified as an EDC (for example, under REACH) can be legally included in the authorised list of chemicals in plastic FCM, on the basis of an assessment that tries to set a "safe level" threshold, or, in other words, to define "how much is too much".

In addition, the risk assessment for granting authorisation to use chemicals in FCM is not adequate to identify EDCs and may not cover all EDCs' relevant endpoints. Indeed, in order to obtain an authorisation for a specific substance, food business operators have to present an application for authorisation, which comprises a "technical dossier". The information in the technical dossier includes: structural information on the substance with purity and impurities; physical and chemical properties (boiling point, solubility etc.); intended application of the substance; conditions of contact; regulatory status in other countries; data on migration; data on residual content of substance in FCM, microbiological properties of substance; toxicological data. However, there is no reference at all to the notion of endocrine disruption, or to criteria to identify them.

Similarly to CMRs, pesticides rules are also more protective than FCM rules when it comes to EDCs, as in principle no approval is possible if the chemical is identified as EDC[19]. As mentioned previously, on the FCM side, there is no reference to EDCs, no reference to their identification under other laws (e.g. REACH), and no legal mechanism to prevent their inclusion in the authorised list, once identified as such on the basis of scientific criteria. It is a case-by-case assessment, aiming to set a "migration limit", under which its presence in food is considered "safe". As a result, looking at the authorised list of chemicals in plastic FCM, ClientEarth found, with specific migration limits, 5 "official" EDCs for human heath - meaning substances identified as of very high concern under REACH due to their endocrine disrupting properties, including BPA and DEHP.

EDCs, should instead be regulated, taking into account the seriousness of their potential impact on human health and the difficulty that exists to set maximum levels under which exposure can be considered "safe". A cut-off criterion, preventing any kind of exposure, is the only regulatory response that is capable of preventing harm.

A "cut-off" approach is an effective regulatory response, proportionate to the seriousness of EDCs' adverse effects as well as to the difficulties in anticipating – and thus, controlling - the risk from exposure. It would also save public resources and time, by avoiding a long and complex assessment in an attempt to predict "how much is too much". Finally, it would ensure more legal certainty and would incentivise industries to innovate and invest in safer and long-term alternative chemicals, materials or technologies for producing or packaging our food.

[18] See scientific report commissioned by the PETI Committee of the European Parliament (2019) titled *Endocrine Disruptors: from Scientific Evidence to Human Health Protection*, p.80. Available at: http://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU(2019)608866_EN.pdf (last access 29th April 2019).
[19] Pesticides Regulation, Annex I 3.6.5.

Conclusions

ClientEarth calls on the Commission to propose to amend the FCM rules in order to ensure that:

The new regime regulates all types of FCM across the EU;

The new regime prevents the use and presence of CMRs and EDCs in FCM;

The new regime ensures synergies with the REACH Regulation and, in particular, with the process of identification of substances of very high concern.

May 2019

Alice Bernard
Lawyer (Juriste), Chemicals Project Lead
60 Rue du Trône (Box 11)
Brussels, 1050
+32 (0) 28 08 8015
abernard@clientearth.org
www.clientearth.org

Lara Fornabaio
Law and Policy Advisor
60 Rue du Trône (Box 11)
Brussels, 1050
+32 (0) 28 08 3471
lfornabaio@clientearth.org
www.clientearth.org

ClientEarth is a non-profit environmental law organisation based in London, Brussels and Warsaw. We are activist lawyers working at the interface of law, science and policy. Using the power of the law, we develop legal strategies and tools to address major environmental issues.

ClientEarth is funded by the generous support of philanthropic foundations, institutional donors and engaged individuals.

Brussels
Rue du Trône 60
5ème étage
1050 Bruxelles
Belgique

London
274 Richmond Road
London
E8 3QW
UK

Warsaw
ul. Żurawia 45
00-680 Warszawa
Polska