

The Consumer Voice in Europe

REFORM EU FOOD PACKAGING RULES TO BETTER PROTECT CONSUMERS

BEUC comments to the Food Contact Materials REFIT evaluation



Contact: Pelle Moos – safety@beuc.eu

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • consumers@beuc.eu • www.beuc.eu
EC register for interest representatives: identification number 9505781573-45



Co-funded by the European Union

Ref: BEUC-X-2019-029 – 01/05/2019

Why it matters to consumers

On its way from farm to fork, our food comes into contact with many different materials and products, such as food processing machines, plastic packaging or paper wraps, kitchen aids and ceramic tableware. While these materials are essential to how we store, handle, transport, preserve, and ultimately consume our food, they may also negatively impact the quality and safety of foodstuffs. Chemicals migrating from packaging can for example contaminate our food, thereby potentially creating risks for consumer health. Existing EU legislation is meant to safeguard consumers against such risks; however, the current rules are deficient and therefore provide insufficient protection of consumers.

Recommendations

While the current EU food contact material (FCM) regime is meant to safeguard the health and interests of consumers, neither is adequately achieved today; in fact, the deficiencies of the current system are widely acknowledged. As such, a reform of the EU regulatory framework is urgent.

BEUC, the European Consumer Organisation insists that a reformed FCM regime must

- **Achieve comprehensive, harmonized regulation of all FCMs.** New rules to control all migrating chemicals are required, while existing legal limits should be revisited to better protect consumers.
- **Establish a precautionary approach.** Substances of (high) concern, such as endocrine disruptors, should be automatically prohibited, unless industry can demonstrate that their presence in FCMs does not present a risk to human health.
- **Shift the burden of proof.** Business operators should be required to perform and notify safety assessments of their food contact materials. Member State authorities must rigorously police the accuracy and reliability of safety assessments.
- **Ensure effective enforcement.** Member States must ensure sufficient resources for official controls of FCMs, while the Commission should promote a systematic enforcement strategy to ensure that EU FCM policy translate into real consumer protection.
- **Improve transparency to enable informed consumer choice.** Greater transparency about chemicals present in or migrating from FCMs is essential to facilitate identification, traceability, and handling of exposure sources.
- **Guarantee the same, high level of protection for FCMs made from virgin and recycled materials.** A successful circular economy can only be achieved if consumers are confident that secondary raw materials are safe.

Do the EU rules on food packaging keep consumers safe?

Food contact materials¹ (FCMs) are of high societal importance because they protect food from physical damage, soiling, and microbial spoilage, thereby reducing food waste. But FCMs can also impact the quality and safety of food throughout the entire food chain. Chemicals present in food contact materials are known to migrate into, and thus contaminate foodstuff, thereby potentially creating risks for consumer health.²

According to existing EU legislation,³ all FCMs should be safe and inert – that is, not influence the food in a negative way. With the exception of plastic food contact materials, harmonized EU rules to determine compliance with these generic provisions have however not been established. Consequently, demonstrating that food safety is consistently achieved for materials other than plastics has proven difficult, as illustrated by several food contamination scares⁴ originating from food packaging such as cardboard.

Existing EU rules on plastic materials⁵ meanwhile focus primarily on starting materials, such as monomers and additives used in the manufacture of products, largely neglecting the potential migration of substances formed during manufacture and use, such as impurities, degradation or reaction products (collectively known as non-intentionally added substances or NIAS⁶). Regulators therefore lack adequate tools to establish whether chemical mixtures migrating from plastic materials could endanger human health.⁷

The exact number of potential food contaminants from FCMs is unknown, but it is enormous: thousands of chemicals are used in the production of various FCMs, while migrating impurities and reaction products are counted in the tens of thousands, only a fraction of which have been identified.⁸ The risk that a few of these unknown substances are toxic is correspondingly significant. Chemicals migrating from food packaging may thus be the largest and least controlled source of food contamination, exceeding other sources such as pesticides or environmental pollutants by a factor 100.⁹

The current EU FCM regime is meant to safeguard the health and interests of consumers, e.g. in relation to information, comfort, food preservation, or reuse. Neither is however adequately achieved today; in fact, the deficiencies of the current system are widely

¹ Food contact materials are all materials that come into contact with food including packaging as well as every-day items such as kitchen and table ware and those used in professional food manufacturing, preparation, storage and distribution.

² See J. Muncke *et al.* 2017. Scientific Challenges in the Risk Assessment of Food Contact Materials. *Environmental Health Perspectives* 125(9).

³ Specifically, Regulation (EC) No 1935/2004 (the FCM Regulation) stipulates that these materials shall not transfer their components into food in quantities that could endanger human health or change the composition, or organoleptic properties of the food.

⁴ For example, in 2005, reports emerged in Italy that liquid baby milk had been contaminated with isopropyl thioxanthone (ITX), a chemical used in the printing process of the milk cartons. The producer, Nestlé subsequently had to recall the products from the market. In 2009, hundreds of boxes of noodles were withdrawn from sale in Germany after levels of benzophenone almost three times above the European legal limit were found to have migrated from the packaging.

⁵ Commission Regulation (EU) No 10/2011.

⁶ NIAS are not limited to plastics however but occur in all other FCMs as well.

⁷ J. Muncke *et al.* 2017. Scientific Challenges in the Risk Assessment of Food Contact Materials. *Environmental Health Perspectives* 125(9).

⁸ J. Muncke *et al.* 2017. Scientific Challenges in the Risk Assessment of Food Contact Materials. *Environmental Health Perspectives* 125(9).

⁹ K. Grob *et al.* 2006. Food Contamination with Organic Materials in Perspective: Packaging Materials as the Largest and Least Controlled Source? A View Focusing on the European Situation. *Critical Reviews in Food Science and Nutrition* 46.

acknowledged, including by the European Commission and the co-Legislator.^{10, 11} In 2012, the then Commission department for health and consumers, DG Sanco, for example emphasised¹² that “materials on the market are not safe”, while the lack of harmonized EU rules acts as a barrier to the smooth functioning of the internal market. In 2016, the European Parliament likewise concluded¹³ that the lack of uniform EU measures is detrimental to public health. Parliament therefore urgently called on the Commission to revise the current regulatory framework.

Against this background, the Commission announced in November 2017 a REFIT evaluation to assess whether the current EU legislative framework for FCMs is fit for purpose and delivers as expected. BEUC, The European Consumer Organisation welcomes the review as a long overdue opportunity to achieve better consumer protection. Combined with our response to the public consultation (see annex), this paper outlines our recommendations for a reform of the EU FCM regime.

From a consumer perspective, it is imperative that the review delivers credible answers to known deficiencies. We insist on the need to adopt a more precautionary approach to risk management, combined with a shift in the effective burden of proof from public regulators to industry and improved transparency for consumers. As a first, overarching point, we however emphasize that political will on behalf of the Commission and the Member States is a fundamental precondition to ensure that a reformed EU FCM regime delivers better protection of consumers against harmful chemicals.

The EU FCM regime: a regulatory patchwork

Unlike other EU food and chemicals laws, the EU FCM Regulation has never been systematically assessed since the inception of its basic provisions in 1976.¹⁴ Over the past two decades, EU chemicals legislation has in contrast been modernized. As such, crucial contradictions exist *between* the current FCM regime and other EU laws governing chemical safety.

Recent reviews¹⁵ have moreover highlighted that the incomplete implementation of the FCM Regulation for materials other than plastics gives rise to significant contradictions *within* the EU FCM regime. Consequently, the EU FCM regime suffer from severe gaps in the framework meant to protect consumers against harmful chemicals. Current national and EU legislation has thus failed to establish sufficient parameters to ensure compliance with the objective of a high level of human health protection.

We here highlight three major thematic failings of the current EU FCM regime that urgently needs to be addressed by the REFIT evaluation.

¹⁰ European Parliament. *Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*. 2015/2259(INI). July 2016. Available at: www.europarl.europa.eu/doceo/document/A-8-2016-0237_EN.pdf

¹¹ Joint Research Centre. *Non-harmonised food contact materials in the EU: regulatory and market situation. Baseline study*. January 2017. 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>

¹² European Commission. *Roadmap: Food Contact Materials – Specific provisions for materials other than plastics – implementing measure*. July 2012.

¹³ European Parliament. *Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*. 2015/2259(INI). July 2016.

¹⁴ European Commission. *Roadmap: Evaluation of Food Contact Materials (FCM)*. November 2017.

¹⁵ See e.g. Joint Research Centre. *Non-harmonised food contact materials in the EU: regulatory and market situation. Baseline study*. January 2017.

Gaps within the FCM regime leave consumers exposed to toxic chemicals

The disparity between detailed EU rules for some FCMs, notably plastics, and the absence of harmonized rules for other materials gives rise to severe gaps in consumer protection across the EU. To illustrate, in 2017, five BEUC members found¹⁶ high levels of fluorinated compounds in one third of 65 tested fast food packaging. In 2018, a test¹⁷ by our French member, UFC-Que Choisir found similar results. These compounds, known as PFAS, are problematic for the environment, but are also suspected to have adverse effects on human health, such as cancer, infertility, obesity. Consequently, scientists call¹⁸ for limits to the production and use of PFAS; nonetheless, our members' results indicate that fluorinated compounds are used *intentionally* for surface treatment of paper materials. Absent detailed EU rules for paper and board FCMs, the safety of these compounds remains however essentially unregulated.

The FCM Regulation allows Member States to maintain or adopt their own national measures in the absence of harmonized EU rules. As highlighted by a 2017 JRC baseline study,¹⁹ the result is a patchwork²⁰ of different national schemes for risk assessment, chemical safety, compliance documentation, and regulatory approaches. Evidence collected through the JRC study for example identified around 8000 substances regulated at national level, some of which are regulated by many Member States, some others only by a few. According to the report, without specific EU measures, the general safety requirement laid down in the FCM Regulation cannot be fully achieved and enforced.

These differences imply that European consumers are not guaranteed the same level of protection against harmful chemicals depending on where they live. The distinction between harmonized (e.g. plastics) and non-harmonized sectors (e.g. paper and board) meanwhile implies that the same chemical may be regulated in some sectors, while its use is unrestricted in others, even though the exposure potential may be similar or even higher. In February 2018, the Commission for example adopted new restrictions²¹ on the release of the endocrine disrupting chemical, Bisphenol A from plastics, varnishes and coatings. Comparable EU restrictions for other FCMs, such as paper and board, are however missing even though BPA is likely present, especially in recycled materials.²²

In parallel, the protective standards set for the harmonized sectors are largely insufficient and partly outdated. Although the 1984 Ceramics Directive²³ for example commits the Commission to revisit the migration limits for cadmium and lead, two toxic heavy metals, by 1987, this has not happened to date. Research has however shown that these metals are much more toxic than was known in 1984. Consequently, the EU has set strict limits for the presence of lead and cadmium in relevant consumer legislation other than FCMs. In opinions published between 2009 and 2012, the European Food Safety Authority (EFSA) concluded that exposure cannot be regarded as safe at any level. Available evidence thus

¹⁶ BEUC news, [Harmful substances found in fast food packages across Europe](#), March 2017.

¹⁷ UFC- Que Choisir, [Fast-food – Des emballages qui font tache](#), March 2018.

¹⁸ See e.g. The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs). Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC4421777/

¹⁹ Joint Research Centre. *Non-harmonised food contact materials in the EU: regulatory and market situation. Baseline study*. January 2017.

²⁰ National legislation is in place in 19 Member States with divergent scope setting up more or less detailed requirements. No Member State covers all materials. For the majority of Member States, national legislation does not set out detailed requirements. Limits set out in national legislation are divergent, in particular for migration of heavy metals.

²¹ Commission Regulation (EU) 2018/213.

²² See e.g. K. Pivnenko *et al.* 2016. Material Cycles and Chemicals: Dynamic Material Flow Analysis of Contaminants in Paper Recycling. *Environmental Science & Technology* 55(22).

²³ Council Directive 84/500/EEC.

indicates the need for a significant reduction in the migration limits for lead and cadmium by a factor of 400 and 60, respectively, to achieve an acceptable level of exposure.²⁴

The plastics regulation meanwhile exempts a number of substances from regulatory scrutiny, including solvents, colourants, aids to polymerization and non-intentionally added substances. Many of the authorized substances listed in Annex I have never undergone sufficient and regular scrutiny in light of new evidence *e.g.* on their endocrine disrupting properties. Taken together, this situation is unacceptable, and calls for an overhaul of the FCM regime to ensure better protection of all EU consumers.

Insufficient regulation of chemical migrates misleads consumers

Despite the significant number of chemicals potentially migrating from FCMs into food, regulation lags far behind the standards reached in other sectors. Article 3 of the FCM Regulation stipulates that FCMs shall not transfer their components into food in quantities that could endanger human health. Absent specific parameters against which to evaluate safety, this approach *de facto* implies that migration of contaminants into food is legal as long as no specific health risk can be shown. For most FCMs, such parameters have yet to be established, and control authorities are therefore rarely in a position to ensure compliance.

For example, our members in Belgium, Italy, and Spain last year found²⁵ high level of mineral oil hydrocarbons (MOH) in various food samples, such as pasta, rice, breakfast cereals and chocolate. These contaminants likely originated from recycled paper and board packaging, although batching and/or lubricating oils used during food production is another potential source. Despite a 2012 EFSA scientific opinion²⁶ which concluded that exposure to certain MOH is of potential concern to human health, including a potential cancer risk, the presence of MOH in FCMs escapes effective control. While the Commission recommends that Member States monitor MOHs in food and FCMs,²⁷ regulation to reduce human exposure to MOHs through food remains entirely insufficient.

This situation notably clashes with EU food legislation²⁸ which applies the principle of strict minimization: for most food contaminants, producers must seek to avoid contamination, even if there is no detectable health risk. While the EU for example has established strict pesticide registration procedures and maximum residue levels in food, chemicals migrating from food contact materials tend to be considered inert by default. By sheer probability, however, among the thousands of chemical migrates there will be some with a toxicological profile worse than would be acceptable for pesticides – and possibly at higher concentrations.²⁹ Current limit for pesticides is moreover significantly lower than the generic threshold established for migrates from packaging materials.

While insufficient control does not necessarily imply a health risk, it does highlight the inconsistent approach towards this significant source of food contamination. Moreover, this inconsistency severely misleads consumers: most consumers want to avoid food contaminants even if they present no detectable health risk. Many consumers for example

²⁴ European Commission. *Discussion note on a regulatory approach concerning, ceramic, glass, and enamelled metal materials following the completion of the JRC Research project towards suitable tests for the release of metals from ceramic tableware*. November 2017.

²⁵ See AltroConsumo, Scivolati sull'olio, *Inchieste* N°332. February 2018.

²⁶ EFSA. 2012. Scientific Opinion on Mineral Oil Hydrocarbons. *EFSA Journal* 10(6).

²⁷ Cf. Recommendation EU 2017/84.

²⁸ Cf. Regulation (EC) No 178/2002.

²⁹ K. Grob *et al.* 2006. Food Contamination with Organic Materials in Perspective: Packaging Materials as the Largest and Least Controlled Source? A View Focusing on the European Situation. *Critical Reviews in Food Science and Nutrition* 46.

prefer organic over conventionally produced foods to reduce their potential intake of pesticide residues, without realising that the packaging itself is far more likely to contaminate their food. Few consumers would expect, little less accept that substances similar to pesticides may migrate from packaging materials into organic food.³⁰ Better control of food contamination from food contact materials, consistent with the standards achieved in other sectors, is needed.

A regulatory relic

Over the past two decades, EU chemicals legislation has been modernized; the FCM regulation is however a regulatory relic firmly rooted in the approach instituted in 1976. Risk management under the EU FCM regime is based on cumbersome, often iterative processes of repeated risk assessment of chemicals of known concern (e.g. BPA) which neglects substances of potential concern (e.g. BPS, BPF).³¹ Unlike other EU chemical laws, the FCM Regulation further establishes insufficient vertical links with the CLP Regulation: since the 2001 White Paper on a strategy for a future EU chemicals policy,³² generic bans on chemicals which may cause cancer, change DNA or harm reproductive health (CMRs) have been introduced in EU product laws, such as cosmetics or toys. The REACH Regulation meanwhile provides for a semi-automatic ban on sale to consumers of CMR substances.

In contrast, the use in FCMs of classified CMRs remains unrestricted, unless a specific risk assessment can demonstrate an unacceptable risk to human health. At present, EFSA however suffers backlogs in its work which affect the proper functioning of the system and the sustainability of the model as a whole, as recently highlighted by the Court of Auditors.³³

This is both inefficient and unacceptable as it leaves consumers exposed to chemicals of known concern long after they are banned in other consumer goods. Last year, the EU for example decided to restrict the presence of four phthalates – plasticizers linked to reproductive harm and endocrine disruption – in most consumer goods. Although the restriction proposal³⁴ estimated that up to 75 per cent of exposure to one of these phthalates, DEHP, is attributable to food intake, the four phthalates can nonetheless still be found in FCMs. The FCM Regulation in short lacks an automatic trigger for risk evaluation of chemicals of known concern, such as CMRs.

Current risk assessment and management practices tend to focus on substances and additives used in the production of FCMs. Final food contact materials and articles however contain novel compounds, such as impurities and reaction products that are not sufficiently assessed.³⁵ According to one estimate,³⁶ starting substances only constitute 3 per cent of the migrating material from coatings, with the chemical identity of the remaining migrates largely unknown. This serious disconnect between legal requirements and the reality of

³⁰ See K. Grob *et al.* 2006. Food Contamination with Organic Materials in Perspective: Packaging Materials as the Largest and Least Controlled Source? A View Focusing on the European Situation. *Critical Reviews in Food Science and Nutrition* 46.

³¹ See CHEM Trust. *From BPA to BPZ: a toxic soup?* March 2018. Available at: www.chemtrust.org/wp-content/uploads/chemtrust-toxicoup-mar-18.pdf

³² COM/2001/0088 final.

³³ European Court of Auditors. *EU food safety policy protects us but faces challenges*. Special Report. January 2019.

³⁴ ECHA. *Annex XV restriction report – four phthalates*. April 2016. Available at: <https://echa.europa.eu/documents/10162/63d36637-750b-390c-3410-d0dea806869d>

³⁵ J. Muncke *et al.* 2017. Scientific Challenges in the Risk Assessment of Food Contact Materials. *Environmental Health Perspectives* 125(9).

³⁶ K. Grob *et al.* 2006. Food Contamination with Organic Materials in Perspective: Packaging Materials as the Largest and Least Controlled Source? A View Focusing on the European Situation. *Critical Reviews in Food Science and Nutrition* 46.

consumer exposure to unknown chemicals, calls the current regulatory approach and risk assessment practices into question.

The concept of 'intended use' moreover implies that products are only safe, if they are used as intended by the manufacturer. But the intended use is often not clear to consumers, who may for example store hot or fatty foods in single-use ice cream containers. The 'Glass and Fork' symbol may in parallel mislead consumers to believe that the safety of FCMs has been adequately assessed and that they do not contribute to food risks/contamination, *cf.* above. A failure to accurately account for consumer behaviours, thus means that risks may be systematically underestimated.

This issue is in part about raising consumer awareness; nonetheless, manufacturers also bear a significant responsibility. A market survey by five German consumer associations for example found³⁷ that use instructions were given exclusively in the form of pictograms without further wording. The pictograms were however rarely self-explanatory and often difficult to read because the imprint was blurred and kept in the same colour as the product. Control authorities need to focus more on such insufficient, ambiguous, or missing labelling, while the obligation for business operators to provide instructions for safe and appropriate use of FCMs urgently needs to be clarified to ensure that risk assessments corresponds to actual consumer behaviour.

A reform of the EU FCM regime is urgent

From a consumer perspective, it is imperative that the REFIT evaluation delivers credible answers to known deficiencies, including on non-intentionally added substances, combination effects, and new and emerging risks, such as endocrine disruptors. BEUC recommends that a reformed FCM regime draws inspiration from extant EU product laws, such as on cosmetics, to achieve a more coherent and protective approach to the safety of food contact materials and articles. We insist in particular on the need for comprehensive, harmonized regulation of all FCMs based on a precautionary approach, combined with a shift in the effective burden of proof from public regulators to industry, better enforcement and improved transparency for consumers.

Achieve a harmonized EU FCM regime

A reformed FCM regime must address current inconsistencies to ensure that food contact materials are safe for consumers. In line with the recommendations³⁸ of the European Parliament, BEUC insists on the need for harmonized EU rules, including strict limits and criteria for all FCMs to assess and ensure compliance with the FCM Regulation's general safety provisions.

Focus moreover needs to shift towards assessment and regulation of chemical mixtures actually migrating from finished food contact materials and articles rather than starting substances.³⁹ A similar level of safety for starting materials and non-intentionally added substances must be ensured. Consistent with EU food safety legislation, requirements to control migrating materials should therefore be introduced, while existing legal migration

³⁷ Verbraucherzentrale. "HEISSE" KÜCHENUTENSILIEN? Bundesweiter Marktcheck der Verbraucherzentralen zur Kennzeichnung von Lebensmittelbedarfsgegenständen aus Kunststoff. July 2015. Available at: www.verbraucherzentrale.nrw/sites/default/files/migration_files/media235769A.pdf

³⁸ European Parliament. *Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004)*. 2015/2259(INI). July 2016.

³⁹ See J. Muncke et al. 2017. Scientific Challenges in the Risk Assessment of Food Contact Materials. *Environmental Health Perspectives* 125(9).

limits should be revisited to achieve coherence with other sectors. As recently observed by EFSA,⁴⁰ such an approach would achieve better protection of consumer health.

Progress on finding methods to better control – and minimize – food contamination from food contact materials consistent with the standards achieved in other EU food laws is further urgent. Last year, our Norwegian member, Forbrukerrådet, for instance showed⁴¹ that reusable plastic bottles leach dangerous chemicals such as phthalates, bisphenols, flame retardants and lead into their content. Disturbingly, bottles marketed to kids were the worst performers in the test. Fortunately, none of the examined bottles give rise to a health hazard seen in isolation. Taken together with all other products that surround us, however they contribute towards a total exposure to problematic chemicals that is worrisome. Ultimately, a political decision by the Legislator on the acceptable degree of food contamination similar to e.g. EU pesticides legislation is therefore needed.

A precautionary approach to chemicals present in or migrating from FCMs

Given the enormous number of chemicals potentially migrating into food, we need to rethink the risk management approach to food contact materials. A reformed FCM regime thus needs to move towards risk management based on generic risk considerations:⁴² in particular, substances classified as CMR cat. 1 and cat. 2 under the CLP Regulation should be automatically prohibited for use in FCM (subject to strict derogation criteria, cf. e.g. article 15(2) of the Cosmetics Regulation). The plastics regulation to some extent already includes an element of this approach, but such a mechanism needs to be implemented for all FCMs to achieve better consumer protection.

For substances of (high) concern, such as endocrine disruptors, a presumption of migration should be introduced to allow regulation of their *presence* in FCM in the first place, unless industry can demonstrate according to predefined criteria that their presence does not present a risk to human health. Equally, an explicit mandate for performing mixture risk assessments needs to be introduced in the FCM Regulation. Such a mandate has in part already been established under other EU laws, e.g. on pesticide residues, but needs to be significantly strengthened for FCMs based on clear rules for deriving acceptable exposure and risk levels.⁴³ This mandate should also promote a more holistic and coherent approach to risk assessment: where health concerns are raised in one sector or for one product, it should automatically trigger risk evaluation across legislative 'silos' to fully assess the impact of cumulative exposures.

Ultimately, a more precautionary approach is needed to better protect the health of consumers in situations where scientific evidence is insufficient, inconclusive or uncertain. While the precautionary principle has in the past been invoked e.g. to prohibit the use of BPA in polycarbonate infant feeding bottles,⁴⁴ it remains underutilized by EU risk managers. Similar to General Food Law, the precautionary principle should therefore be enshrined in the legal text of the FCM Regulation as the basis for risk identification, assessment, and management. This would provide a mandate to risk managers to better protect consumers against chemicals of concern in the face of scientific uncertainty.

⁴⁰ EFSA. *Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials*. January 2016. Available at: www.efsa.europa.eu/en/efsajournal/pub/4357

⁴¹ Forbrukerrådet, *Drinking bottles leach chemicals*, August 2018.

⁴² That is, risk management measures automatically triggered by a hazard classification under the CLP Regulation, without further assessment of the risk. See M. Postle *et al.* *Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation. Evaluation Report*. January 2017.

⁴³ See A. Kortenkamp and M. Faust. 2018. Regulate to reduce chemical mixture risk. *Science* 361(6399).

⁴⁴ Commission Directive 2011/8/EU.

Shift the effective burden of proof

Industry not the public must bear the burden of proof for the products that are on the market. A reformed FCM regime must therefore shift the effective burden of proof from public regulators to industry. The general principle embodied in EU chemicals legislation is that chemical risks should be controlled, mitigated, or justified by their creators. For this reason, the REACH Regulation introduced the principle of 'no data, no market' requiring manufacturers to demonstrate safe use of their chemicals through a chemical safety report. FCMs – and cosmetic products – are however exempted⁴⁵ from this obligation – as according to the Commission proposal – these uses are 'adequately addressed by other EU legislation' (*i.e.* the FCM Regulation and the Cosmetics Directive⁴⁶); nonetheless, the Cosmetics Directive was reformed in 2009 in large part to strengthen the obligation for producers to perform a safety assessment prior to placing a product on the market. The FCM Regulation in contrast does not sufficiently compensate for this 'gap'. This situation results in a serious disconnect between legal requirements and the data that are generated by manufacturers along the supply chain.⁴⁷

While the FCM Regulation and its implementing measures introduces traceability and documentation requirements to various degrees, experience to date demonstrates severe shortcomings in the information available to control authorities, in the supply-chain and to the public.⁴⁸ A control campaign in the plastics sector for example found⁴⁹ that virtually no data was available on substances used other than the specifically regulated monomers and additives, and none about reaction products and impurities. Hence, the safety of these migrates was not shown. Five German consumer associations found⁵⁰ a similar pattern of incomplete documentation in an inspection of eight declarations of conformity for plastic films. In no single statement were all mandatory entries completed, while a majority failed to provide information needed to ensure safety during subsequent production stages. This lack of information is unacceptable, and urgently need to be addressed.

A reformed FCM regime should introduce obligations for business operators to perform a global safety assessment of their food contact materials and articles, including of the chemical mixtures actually migrating from finished articles. These requirements should be established as a joint supply-chain obligation based on a duty to transfer safety-related information from one actor to the next in the manufacturing chains. Such requirements would not only increase the available information in the supply chain but would likely also incentivize industry to reduce the current significant number of substances and processes used to fewer, but better evaluated, ones.⁵¹

Documentation should be included in product files available to the relevant actors in the supply-chain as well as to authorities for a pre-defined period of time, *e.g.* 10 years, to enable systematic spot checks. Specific quality criteria (*e.g.* accuracy, completeness and hence reliability) related to product files and compliance documents need to be established in legislation and linked to sanctions to ensure adequate quality and traceability of the

⁴⁵ According to the Commission proposal (COM/2003/0644 final), the use of chemicals in FCM and cosmetics are adequately addressed by other EU legislation; this is incorrect. For cosmetics, this 'oversight' was addressed by the 2009 Cosmetic Product Regulation (1223/2009).

⁴⁶ Council Directive 76/768/EEC.

⁴⁷ J. Muncke et al. 2017. Scientific Challenges in the Risk Assessment of Food Contact Materials. *Environmental Health Perspectives* 125(9).

⁴⁸ Joint Research Centre. *Non-harmonised food contact materials in the EU: regulatory and market situation. Baseline study.* January 2017.

⁴⁹ G. McCombie et al. 2016. Compliance work for polyolefins in food contact: Results of an official control campaign. *Food Control* 59.

⁵⁰ Verbraucherzentrale. [Kunststoffverpackungen bei Lebensmitteln: Sicherheit und Transparenz](#). Bundesweite Herstellerbefragung eine Gemeinschaftsaktion der Verbraucherzentralen. December 2014.

⁵¹ See K. Grob. 2017. The European system for the control of the safety of food-contact materials needs restructuring: a review and outlook for discussion. *Food Additives & Contaminants: Part A* 34(9).

information transferred along the supply-chain.⁵² Finally, mandatory registration of business operators and an obligation to notify the Commission and Member States prior to placing FCMs on the market should be introduced.

Ensure effective enforcement

Enforcement of EU FCM legislation remains inadequate, as recently highlighted by the European Court of Auditors.⁵³ While the new Official Controls Regulation⁵⁴ (OCR) is expected to bring some improvements, *e.g.* in relation to import controls, further efforts are needed to bridge the gap between legal requirements and the reality of consumer exposure to chemicals migrating from FCMs in to food.

As foreseen by the OCR, Member State must in particular entrust their authorities with *sufficient* powers, resources and knowledge to effectively enforce the FCM legislation. Given the significant number of largely unknown chemical substances originating from FCMs, Member States should further prioritize official controls of food contact materials and articles in line with the risk-based approach prescribed by the OCR. This must also entail a commitment to address known shortcomings, such as coordination problems between competent authorities and between competent authorities and control laboratories, as well as an insufficient number of official controls of food contact materials on the market and compliance issues in FCM supply chains.^{55, 56} New obligations for business operators to perform and notify safety assessments of their food contact materials would greatly facilitate official controls, *cf.* above.

Consumer organisations play an essential role in informing consumers about their rights and protecting their interests. To strengthen enforcement of the FCM Regulation, we therefore encourage Member State competent authorities to promote systematic cooperation with consumer organisations inspired by the approach and principles set out in the revised CPC Regulation.⁵⁷

Given the limited resources available to authorities, official controls should be shared, coordinated and streamlined throughout Europe, including through the development of agreed functional procedures (*e.g.* on how to perform controls or how to access documentation). This could also help avoid that the same (or similar) product is controlled repeatedly, whereas others are not controlled at all. The European Union Reference Laboratory (EURL) could support this development and provide corresponding education.⁵⁸

The Commission should finally take a much more prominent role on enforcement of EU FCM legislation. In particular, the Commission should encourage Member States to develop a systematic enforcement strategy to ensure that EU FCM policy translate into real consumer protection. Inspiration could for example come from the current REACH

⁵² See further K. Grob. 2017. The European system for the control of the safety of food-contact materials needs restructuring: a review and outlook for discussion. *Food Additives & Contaminants: Part A* 34(9).

⁵³ European Court of Auditors. *EU food safety policy protects us but faces challenges*. Special Report. January 2019.

⁵⁴ Regulation (EU) 2017/625.

⁵⁵ Joint Research Centre. *Non-harmonised food contact materials in the EU: regulatory and market situation. Baseline study*. January 2017.

⁵⁶ G. McCombie *et al.* 2016. Compliance work for polyolefins in food contact: Results of an official control campaign. *Food Control* 59.

⁵⁷ Regulation (EU) 2017/2394.

⁵⁸ See J. Daniel *et al.* 2019. Conclusions from a Swiss official control of the safety assessment for food contact polyolefins through the compliance documentation of the producers. *Food Additives & Contaminants: Part A* 36(1).

enforcement indicators⁵⁹ as a tool to enable benchmarking of national enforcement activities. In parallel, a special working group for FCM control authorities (similar to PEMSAC in the cosmetic area) should be convened to enable knowledge exchange of the practical aspects of FCM official controls, ultimately with a view to ensure a coherent and consistent approach to the presence of dangerous chemicals in FCMs. As foreseen by the OCR,⁶⁰ the Commission may set rules on uniform practical arrangements for the performance of official controls, including minimum frequency of official controls. We strongly encourage the Commission to actively explore how such rules could be implemented in practice.

Improve transparency for consumers

The public's right to know is core principle of EU chemicals policy.⁶¹ Still, information on substances of concern migrating from FCMs remains woefully incomplete. For example, five in six manufacturers surveyed⁶² by German consumer associations provided no information on the composition of their plastic materials, while the remaining manufacturers gave only general information and no information on additives. This situation *de facto* curtails the right to know for consumers, while also hampering risk management of chemicals of concern.

A reformed EU FCM regime needs to improve transparency on chemicals present in and migrating from food contact materials. In parallel, we strongly encourage the Commission and Member States to invest in awareness raising campaigns to educate consumers about labels and chemicals in FCMs, so they better understand the correct use of specific food contact materials and articles (*e.g.* repackaging, use in microwaves, *etc.*). Comprehensive guidance further needs to be developed to clarify the obligations for business operators to provide instructions for safe and appropriate use of FCMs, similar to comparable ECHA guidance documents.⁶³

Clear and readily accessible information about substances of concern is essential to facilitate identification, traceability, and handling of exposure sources. Consequently, FCM manufacturers and suppliers should be required to declare the chemical contents of all materials and articles sold to consumers. Improved transparency could influence what retailers choose to buy, and hence what materials and articles would become available for consumers, including pregnant women and parents with small children. Consumer organisations and other NGOs could further contribute to disseminating information about chemicals in food packaging in a way that is understandable to consumers. Finally, public access to this information would greatly facilitate efforts to identify chemicals of emerging concern through scientific research.

Greater transparency about chemicals present in and migrating from food contact materials and articles would thus facilitate informed consumer choices. Above all, however, we emphasise that improved transparency under no circumstance should shift responsibility to the consumer for avoiding exposure. Only regulatory measures as set out above are an acceptable solution to protect consumer health and safety.

⁵⁹ See *e.g.* European Commission. REACH and CLP enforcement - Summary of available information from Member States and through public consultation on enforcement. September 2018. Available at: <https://ec.europa.eu/docsroom/documents/32823>

⁶⁰ *Cf.* Article 19 of Regulation (EU) 2017/2394.

⁶¹ See *Council Conclusions on the protection of human health and the environment through the sound management of chemicals*. December 2016. Available at: <http://data.consilium.europa.eu/doc/document/ST-15046-2016-INIT/en/pdf>

⁶² Verbraucherzentrale. *Kunststoffverpackungen bei Lebensmitteln: Sicherheit und Transparenz*. Bundesweite Herstellerbefragung eine Gemeinschaftsaktion der Verbraucherzentralen. December 2014.

⁶³ *Cf. e.g.* ECHA. Guidance on requirements for substances in articles. June 2017. Available at: https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

EU FCM rules: unfit for the Circular Economy

As the transition to a more circular EU economy gains momentum, fixing the governance of chemicals in FCMs assumes new urgency. Recycling of packaging wastes into new food contact materials presents particular challenges: the use of recycled materials for food packaging may increase both the possible sources of contamination and the amount of chemicals that can migrate from packaging into foods. The presence of non-intentionally added substances can often reach higher levels in recycled food packaging, since recirculated materials may contain intrinsic contaminants, such as dyes or additives, while previous use of the packaging or sourcing of non-food grade materials may contribute to the presence of unwanted and/or unexpected contaminants.⁶⁴

Last year, a report for example documented⁶⁵ the presence of a banned, suspected endocrine disruptor (decaBDE) in 46 per cent of 109 tested consumer products, including kitchen utensils made of recycled plastics. Our Danish member, Forbrugerrådet TÆNK, has likewise documented⁶⁶ the presence of chemical contaminants, such as mineral oils, bisphenol A, phthalates, and nonylphenol, in pizza boxes, likely originating from recycled materials.

The Commission's Plastics Strategy, and the recent decision to ban certain single use plastics, such as plastic cutlery, plates and straws, is set to further exacerbate these concerns as business operators switch to alternatives for which adequate EU rules are not in place, such as paper and board or bamboo. Last year, Öko-Test for example documented⁶⁷ that single-use table wear made of plastic alternatives, such as palm tree leaves, can contain traces of the banned pesticide DDT along with biological contaminants such as mold and mite excrements. In addition, the test found that many items emitted an unpleasant smell. While we fully support⁶⁸ the initiatives to reduce the amount of single use plastics, developing in parallel new, stringent EU rules for materials other than plastics is crucial to prevent consumer exposure to harmful chemicals migrating from new plastic alternatives.

A successful circular economy can only be achieved if consumers are confident that secondary raw materials are safe. A scandal, such as a toxic substance recycled into food packaging, could both create unacceptable health risks and do tremendous damage to consumer confidence in the safety of recirculated materials. From a consumer perspective, it is therefore paramount that an ambitious framework is established that prevents chemicals of concern from being reinjected into the economy. This means accepting that certain products and materials should not – and cannot – be recycled.⁶⁹ It also requires new, stringent controls on 'recirculated' materials to prevent food packaging from contaminating our food.

Before closing the loop on a circular economy, the EU needs to close the regulatory gaps that could afford chemicals of concern a second lease of life in food and especially its packaging. Whether made from recovered or virgin materials, the EU needs to ensure the same level of protection for human health. More lenient standards for recycled materials

⁶⁴ See B. Geueke *et al.* 2018. Food packaging in the circular economy: Overview of chemical safety aspects for commonly used materials. *Journal of Cleaner Production* 193.

⁶⁵ Straková *et al.* *Toxic Loophole. Recycling Hazardous Waste into New Products*. October 2018. Available at: https://ipen.org/sites/default/files/documents/TL_brochure_web_final.pdf

⁶⁶ Forbrugerrådet TÆNK Kemi. *Unwanted chemicals found in pizza boxes*. October 2015.

⁶⁷ Available at: www.oekotest.de/bauen-wohnen/20-Einweggeschirr-aus-nachwachsenden-Rohstoffen-im-Test_111087_1.html

⁶⁸ See BEUC. *How to bring down the use of single-use plastics?* October 2018. Available at: www.beuc.eu/publications/beuc-x-2018-086_beuc_position_on_single_use_plastic.pdf

⁶⁹ See BEUC. *How to detoxify the Circular Economy*. July 2017. Available at: www.beuc.eu/publications/beuc-x-2017-084_how_to_detoxify_the_circular_economy.pdf

will in contrast counteract the transition to a successful circular economy: while risks may be managed in virgin materials during first use, when it comes to end-of-life and reincorporation into future goods, risks become increasingly unpredictable as there is little effective control of where recycled materials end up. Above all, EU decision makers need to pursue a clean circular economy through policies that respect the fundamental commitments of EU food and chemicals policies.

ENDS



This publication is part of an activity which has received funding under an operating grant from the European Union's Consumer Programme (2014-2020).

The content of this publication represents the views of the author only and it is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

BEUC would like to thank the European Environment and Health Initiative (EEHI) for providing funding for the development of this publication.