Food packaging: safety first

Towards toxic-free and future-proof packaging

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Contents

Background

EU rules and policies are widely recognised as the most strict and ambitious in the world. But ambition and regulation worldwide for chemicals is rather low, and therefore we still need to assess how effective existing laws are in addressing chemical pollution in order to actually fulfil their goal: to protect human health and environment.

The failure to address some chemical pollution sources are the key reasons for the limited progress towards the EU's zero pollution targets. Learning from the past, we must show extra firmness in tackling chemicals of concern. The coming years up to 2030 will be critical in terms of establishing a regulatory and legislative foundation to reduce long-term chemical risks[1].

Inconsistencies in the current *Food Contact Materials (FCMs) Regulation* – mainly gaps – exist and compromise its aims of ensuring chemical safety and functioning of the internal market.[2] Food packaging and other food contact materials (FCM) can release a variety of chemicals into food and drink, and represent a considerable source of human exposure to hazardous chemicals. Ironically, the EU rules on chemicals in food contact materials chemicals are less protective than other EU chemical regulations, i.e. hazardous substances restricted from other applications (for example bisphenol A in thermal paper) are still allowed for food packaging uses. **The focus on plastic packaging is prominent, but harmonised EU rules are lacking for most other materials where harmful chemicals can be** found, for example in food packaging made of paper and board, metal, multi-materials and other FCMs.

Despite increased attention being paid to the sustainability and principles of circular economy, there is a general lack of holistic approaches towards materials' circularity and the critical aspects of chemical safety.[3] In parallel, scientists working on developmental biology, endocrinology, epidemiology, toxicology, and environmental and public health, are concerned that public health is insufficiently protected from harmful exposures to food contact chemicals. **A more coherent EU policy on consumer safety issues** is not only highly desirable, but human biomonitoring data on harmful chemicals detected in the entire EU population show that **it is urgently needed**.

[1] "Chemicals and Health — European Environment Agency." www.eea.europa.eu/publications/zero-pollution/health/chemicals
[2] "EUR-Lex - 02004R1935-20210327 - EN - EUR-Lex." eur-lex.europa.eu/eli/reg/2004/1935/2021-03-27
[3] "Marrying Safety with Sustainability in Food Packaging." Zero Waste Europe. Accessed 4 July, 2023. www.zerowasteeurope.eu/library/marrying-safety-with-sustainability-in-food-packaging

Unfortunately, a **revision of EU legislation on Food Contact Materials is facing further delays**, and it is very unsure when and what changes to the current system will be proposed. Revision of the *Registration, Evaluation and Authorization of Chemicals (REACH)* regulation has been delayed as well.

- **MAY 2020** (Farm to Fork Strategy) and **OCTOBER 2020** (Chemicals Strategy for Sustainability) promise revision of FCM legislation
- **DECEMBER 2020:** the European Commission kicks off a revision of EU FCM law (with indicative planning for Q4 2022)
- **JUNE 2022:** Evaluation of the FCM Regulation completed - a number of shortcomings are identified
- **DECEMBER 2022:** New deadline "2024 and beyond"

Fortunately, **the *Packaging and Packaging Waste Regulation* provides an excellent opportunity to** regulate not only sustainability aspects of food packaging, but also **improve and harmonise at EU level the rules on substances of concern in packaging materials and articles**. This is also in agreement with the *EU's Chemicals Strategy for Sustainability*, which calls for complementary and coherent approaches to assess and manage chemicals in sectorial legislations, especially those that regulate consumer products. Importantly, further harmonisation of EU legislation will have a positive effect on intra-EU trade and will support that technological progress regarding chemicals and materials used in food packaging is adequately considered.

"Ongoing and emerging health and environmental concerns call for a strengthening of the legal framework to rapidly respond to scientific findings, making it more coherent, simple and predictable for all actors. In particular, the REACH and CLP Regulations should be reinforced as EU's cornerstones for regulating chemicals, and be ***complemented by coherent approaches to assess and manage chemicals in existing sectoral legislation, especially that regulating consumer products".***
European Commission, Chemicals Strategy for Sustainability[4]

"While the current proposal for a new packaging and packaging waste regulation mentions minimising and cutting out hazardous substances in packaging materials at the outset of the product cycle as a general ambition, ***clear measures to achieve this are shockingly absent. Human health is not something to be bargained with****."*
Euroconsumers' checklist for a regulation fit for consumer[5]

[4] "Chemicals Strategy., European Commission - Directorate-General for the Environment. Accessed 4 July, 2023. environment.ec.europa.eu/strategy/chemicals-strategy_en

[5] "Reducing Packaging Waste Euroconsumers' Checklist for a Regulation Fit for Consumers." Euroconsumers. Accessed 4 July, 2023. assets.ctfassets.net/iapmw8ie3ije/4Lf7MZbicVJ7iuC8JUux3C/228c9c089c1efec91050646a5b13f106/Reducing_packaging_waste_-_Euroconsumers___checklist.pdf

Introduction

Regulation of food packaging is subject to a complex interplay of different laws, and the most relevant regulatory requirements on chemicals, applying to food packaging, have been illustrated in Figure 1. More detailed analysis of efficiency of the current legislative framework for chemicals in food packaging in the EU has been done in the next section of this briefing.

In Europe, some 8,000 substances[6] can be used in food packaging and other food contact materials (FCM), with 388 different chemicals that have been classified as the most harmful chemicals according to the EU Chemicals Strategy for Sustainability's (CSS) criteria because they are carcinogenic, mutagenic, toxic to reproduction (CMRs), persistent and bioaccumulative, and/or endocrine-disrupting chemicals (EDCs).[7]

Importantly, many of these chemicals may migrate from food packaging and thus become a significant source of contamination in food and eventually the consumer's body. Food packaging is one of the most significant sources of exposure to endocrine disruptors such as bisphenol (BPA) and phthalates in children and adults, and a growing number of different hazardous chemicals is found in human blood and body tissue.[8] **A high number of food contact chemicals have been associated with harmful impacts on human health,**[9] and the recent extensive EU human biomonitoring data on harmful chemicals show that **a lot more needs to be done to protect the general population from health impacts due to chemical exposure**. For many substances, such as BPA, phthalates and PFAS chemicals, action is long overdue.[10]

[6] Simoneau Catherine; Barbara Raffael; Simone Garbin; Eddo Hoekstra; Anja Mieth; Lopes João Filipe Alberto; and Vittorio Reina. 2017. "Non-Harmonised Food Contact Materials in the EU: Regulatory and Market Situation: BASELINE STUDY: Final Report." JRC Publications Repository. January 17, 2017. publications.jrc.ec.europa.eu/repository/handle/JRC104198.

[7] Zimmermann, Lisa, Martin Scheringer, Birgit Geueke, Justin M. Boucher, Lindsey V. Parkinson, Ksenia J. Groh, and Jane Muncke. 2022. "Implementing the EU Chemicals Strategy for Sustainability: The Case of Food Contact Chemicals of Concern." Journal of Hazardous Materials 437 (September): 129167. doi.org/10.1016/j.jhazmat.2022.129167

[8] HBM4EU. Accessed 4 July, 2023. www.hbm4eu.eu

[9] Muncke, Jane, Anna-Maria Andersson, Thomas Backhaus, Justin M. Boucher, Bethanie Carney Almroth, Arturo Castillo Castillo, Jonathan Chevrier, et al. 2020. "Impacts of Food Contact Chemicals on Human Health: A Consensus Statement." Environmental Health 19 (1). doi.org/10.1186/s12940-020-0572-5

[10] "April 2022 HBM4EU Newspaper European Human Biomonitoring Initiative." Accessed 4 July, 2023. www.hbm4eu.eu/wp-content/uploads/2022/05/HBM4EU-Newspaper.pdf.

Examples of harmful chemicals used in food packaging and their impact on human health

Bisphenol A, which is found in the lining of food and beverage cans, can act at low doses to significantly increase risk of breast and prostate cancer[11] (these two cancers account for a quarter of the total cancer burden in Europe).[12] Human exposure to the BPA in Europe is widespread, and data on bisphenol S and bisphenol F showed that median levels of urinary BPA alternatives are increasing in all European regions.

Phthalates, used to make plastic food packaging soft and flexible, and may lead to infertility[13] (from 1973 to 2011, the total sperm count of men in Western countries dropped by 59%) and impair development,[14] including increasing risks for child learning, attention, and behavioural problems, with the costs related to neurodevelopmental disease and IQ loss in the EU reaching EUR 157 billion per annum.[15] Studies on 10 phthalates and DINCH (a substitute for some phthalates) demonstrated that nearly all children and teenagers tested throughout the EU are exposed to these substances.

Perfluoroalkyl and polyfluoroalkyl substances (PFAS), used in paper and cardboard food packaging, impact our nervous and immune systems[16] (for example, multiplying up to 4 times the likelihood of children falling ill). Over 14% of European teenagers show levels of several PFAS in their bodies that, when combined, exceed assumed safe levels set by the European Food Safety Agency.

Equally worrying is that for many of the chemicals present in / leaching from food packaging, we simply lack a safety assessment. Moreover, microplastics are an emerging pollutant also generated from the normal use of plastic food packaging and have recently been found in human blood,[17] breast milk,[18] lungs,[19] liver,[20] and in the placentas of unborn babies.[21]

[11] "Impact of EDCs on Hormone-Sensitive Cancer." Endocrine Society. Accessed 4 July, 2023. www.endocrine.org/topics/edc/what-edcs-are/common-edcs/cancer#:~:text=In%20women%2C%20EDC%20exposure%20is

[12] "Europe." International Agency for Research on Cancer, World Health Organisation. Accessed 4 July, 2023. gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf.

[13] "Shanna Swan: 'Most Couples May Have to Use Assisted Reproduction by 2045.'" 2021. The Guardian. March 28, 2021. www.theguardian.com/society/2021/mar/28/shanna-swan-fertility-reproduction-count-down

[14] Engel, Stephanie M., Heather B. Patisaul, Charlotte Brody, Russ Hauser, Ami R. Zota, Deborah H. Bennet, Maureen Swanson, and Robin M. Whyatt. 2021. "Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children." *American Journal of Public Health* 111 (4): 687–95. doi.org/10.2105/ajph.2020.306014

[15] Beans, Carolyn. 2021. "News Feature: How 'Forever Chemicals' Might Impair the Immune System." *Proceedings of the National Academy of Sciences* 118 (15): e2105018118. doi.org/10.1073/pnas.2105018118

[16] Beans, Carolyn. 2021. "News Feature: How 'Forever Chemicals' Might Impair the Immune System." *Proceedings of the National Academy of Sciences* 118 (15): e2105018118. doi.org/10.1073/pnas.2105018118

[17] Carrington, Damian. 2022. "Microplastics Found in Human Blood for First Time." The Guardian. March 24, 2022. www.theguardian.com/environment/2022/mar/24/microplastics-found-in-human-blood-for-first-time

[18] Carrington, Damian. 2022. "Microplastics Found in Human Breast Milk for the First Time." The Guardian. October 7, 2022. www.theguardian.com/environment/2022/oct/07/microplastics-human-breast-milk-first-time

[19] Carrington, Damian. 2022. "Microplastics Found Deep in Lungs of Living People for First Time." The Guardian. April 6, 2022. www.theguardian.com/environment/2022/apr/06/microplastics-found-deep-in-lungs-of-living-people-for-first-time

[20] Horvatits, Thomas, Matthias Tamminga, Beibei Liu, Marcial Sebode, Antonella Carambia, Lutz Fischer, Klaus Püschel, Samuel Huber, and Elke Kerstin Fischer. 2022. "Microplastics Detected in Cirrhotic Liver Tissue." *EBioMedicine* 82 (August): 104147. doi.org/10.1016/j.ebiom.2022.104147

[21] Carrington, Damian. 2020. "Microplastics Revealed in the Placentas of Unborn Babies." The Guardian. December 22, 2020. www.theguardian.com/environment/2020/dec/22/microplastics-revealed-in-placentas-unborn-babies

Even if the full health impact of exposure to harmful chemicals and microplastics from food packaging on our health is not known, precautionary measures should be taken. To protect future generations, **hazardous chemicals (substances of concern) need to be removed from consumer products**, in particular those that contribute to exposure of pregnant women, women of reproductive age, infants, children and other vulnerable groups. The current legislative framework for food packaging shows inconsistencies and gaps, and it is outdated considering actions promised under the more recent EU Chemicals Strategy for Sustainability. These actions notably include extending the generic approach to risk management to **eliminate the most harmful chemicals from products giving priority to those product categories that affect vulnerable populations as well as those with the highest potential for circularity, such as packaging, including food packaging**.[22]

Consumer safety cannot be overlooked any longer

Over the last years, consumers' relationship with products appears to have shifted, with beliefs that they should be safe taking an increasingly important role.

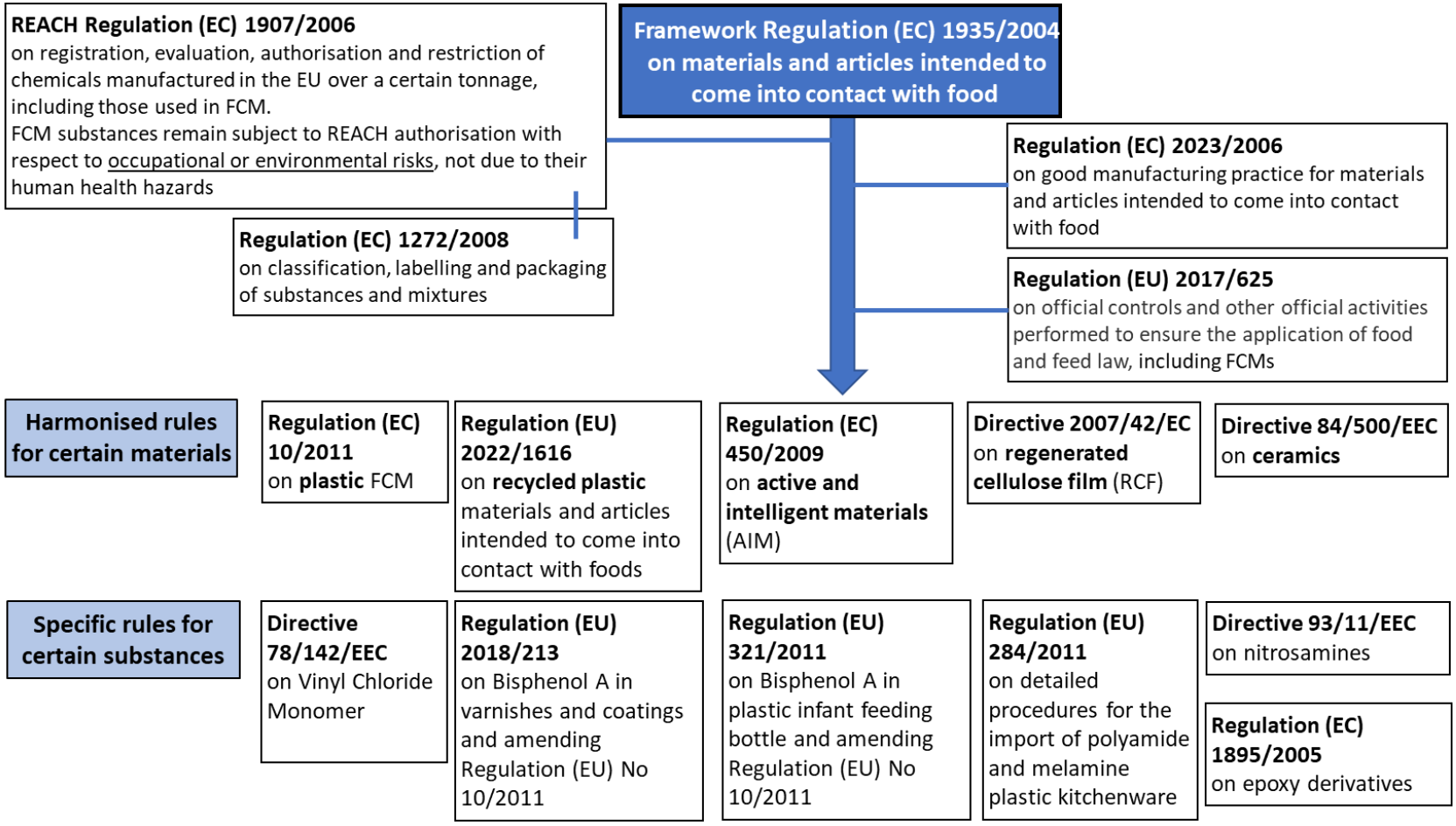
A Eurobarometer survey held in 2019 showed that consumers are increasingly concerned about the effect of chemicals on health. Consumer safety concerns are reflected in the willingness to accept higher prices in order to have safer food packaging or kitchenware (66%). For consumers and consumer representatives, safety remains one of the first priorities when it comes to food contact materials.

A very recent consumer survey by BEUC, the European Consumer Organisation, showed notable concerns about the negative impact food packaging could have on health (70%) and a significant support from consumers for more protective EU actions, on both reducing the use of hazardous chemicals in food packaging (90%), and on requirements to use only safely reusable and recyclable packaging materials (80%).[23]

[22] "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Chemicals Strategy for Sustainability". European Commission, 2020. eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0667

[23] *UNWRAPPED - What Consumers Say about Safe and Sustainable Food Pacakaging. Findings of an Eleven-Country Consumer Survey.* BEUC - the European Consumer Organisation, 2023. Brussels. Accessed 4 July, 2023. www.beuc.eu/sites/default/files/publications/BEUC-X-2023-041_What_consumers_say_about_safe_and_sustainable_food_packaging.pdf

Fig. 1: The most relevant current regulatory requirements applying to chemicals used in food packaging*



**The information contained herein is based on data correct at the time of writing.*

Shortcomings related to the current regulation of chemicals in food packaging

The EU started to legislate FCMs in 1976 with *Council Directive 76/893/EEC* in recognition of the potential risks to human health from FCMs and potential problems concerning the functioning of the internal market. Since then, the legislation has been revised twice; once in 1989 by way of *Directive 89/109/EEC10* and again in 2004 when the current *FCM Regulation* was adopted.

The very first systematic evaluation of this legislation was completed last year[24] and revealed a number of shortcomings which prevent it from effectively achieving its two main objectives: to secure a high level of protection of human health and consumer interests, and to ensure the optimal functioning of the internal market.

COMMON ASSUMPTION: Regulation (EC) No 1935/2004 (also called FCM Framework regulation) ensures a high level of protection for consumers of packaged food.

FACT: The evaluation of FCM law indicated that, often, it simply cannot be concluded if food packaging placed on the market is actually safe. Protection of human health is, therefore, not maximised.

[24] "European Commission - Have Your Say." Accessed 4 July, 2023. ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1212-Evaluation-of-Food-Contact-Materials-FCM-_en

The *Regulation (EC) No 1935/2004*[25] sets a principle legal requirement (Article 3a) which states that "Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health".

Article 3 alone is however insufficient to secure a high level of protection of human health, since it does not define the level of safety expected, how this should be achieved or how it can be demonstrated, while stakeholders differ in their views on how to define safety levels and demonstrate compliance.

Additionally, there is a growing concern about the specific risk assessments that aim to determine protective levels in the form of TDIs (Tolerable Daily Intake) and SMLs (Specific Migration Limits), notably for substances with serious and irreversible effects. It is important to acknowledge that the concept of a "safe level" often does not make sense for non-threshold substances i.e. substances that can still have adverse effects even at extremely low concentrations. Therefore, a 'generic approach to risk management' (also called the hazard-based approach) is a fundamental (and arguably very needed) departure from the current FCM rules. It targets chemicals for regulatory action based on intrinsic hazard properties – regardless of where and how they will be used. The goal is to remove most hazardous chemicals from consumer products (no exposure = no risk).

Under the current system, actors in the supply chain must often rely on the self-assessment done by their suppliers and secondly do their own self-assessment and decide what information is needed and what procedures must be in place. **Even for plastic FCMs, where detailed harmonised specific measures are in place, the provisions are inadequate as they require assessment on a substance-by-substance basis, while in real life we are potentially exposed to a complex cocktail of chemicals migrating from food contact articles and other sources, such as personal care products, textiles, cleaning products, furniture, to name a few.**

In addition to the chemicals that are deliberately used in a food contact material, impurities and substances from chemical reactions or degradation, known as non-intentionally added substances (NIAS), are also present in food packaging. Despite scientific improvements, identification and assessment of all possible NIAS are still very challenging, if not impossible in practice. A study from 2006 claimed that the level of migrating substances from packaging materials including the NIAS may well exceed other contaminants in the food by a factor of 100.[26] Whilst EU rules require NIAS to be considered, there is insufficient guidance agreed upon at the EU level.

Due to the lack of alignment between the *Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)* legislation and the legislation on FCMs, several substances of very high concern

[25] Regulation (Ec) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. Official Journal of the European Union, 2004. Accessed 4 July 2020. eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004R1935&from=EN

[26] Grob, Koni, Maurus Biedermann, Ellen Scherbaum, Maria Roth, and Karl Rieger. 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 (7): 529–35. doi.org/10.1080/10408390500295490

(SVHCs) under REACH are still permitted in food contact materials in Europe. This situation should not be accepted anymore (see Case Example 1).

COMMON ASSUMPTION: All types of materials used in food packaging are specifically dealt with at the EU level.

FACT: Specific, harmonised rules at the EU level exist only for 5 out of 17 categories of FCMs.

Specific harmonised EU rules exist for ceramics, regenerated cellulose, active and intelligent materials and for plastics, including recycled plastics. Importantly, **the majority of food contact materials (12 out of 17)**, including paper and cardboard, metal and glass, silicones and rubber, adhesives, coatings, inks and linings **are not controlled by harmonised EU-level laws**, and national legislation may apply if it exists. As highlighted by a JRC study, the result is a current patchwork of different national schemes for risk assessment, chemical safety, compliance documentation, and regulatory approaches.[27]

The distinction between harmonised (e.g. plastics) and non-harmonized sectors (e.g. paper and board) implies also that **European citizens are not guaranteed the same level of protection against hazardous chemicals depending on where they live**. For example, in France consumers will be protected from the hazardous substance Bisphenol A banned at the national level in all packaging, containers and utensils coming into contact with food. And in Denmark, they will be protected from per- and polyfluorinated alkyl substances (PFAS) banned in paper and cardboard food packaging. In Germany, consumers will soon be better protected from the number of metals and primary aromatic amines (PAA) migrating from food contact printed materials and articles. However, residents of other EU countries do not receive the same protections.

Where no specific EU rules exist, the mutual recognition principle should apply to ensure market access for products that are not subject to EU harmonisation. However, there is a widely shared view among FCM

[27] Simoneau Catherine; Barbara Raffael; Simone Garbin; Eddo Hoekstra; Anja Mieth; Lopes João Filipe Alberto; and Vittorio Reina. 2017. "Non-Harmonised Food Contact Materials in the EU: Regulatory and Market Situation: BASELINE STUDY: Final Report." JRC Publications Repository. January 17, 2017. publications.jrc.ec.europa.eu/repository/handle/JRC104198

industry representatives that the mutual recognition system is not working properly in the sector, which constitutes a significant barrier to the functioning of the internal market.

Also, a question emerges: **why is the current EU FCM legislation so focused on plastics when other non-plastic materials have been increasingly used in food packaging in recent years?** A very good example is paper and cardboard food packaging, which are unfortunately not controlled by harmonised EU-level laws, and they are not necessarily safer than single-use plastics. We are currently dealing with widespread use of and contamination by PFAS in disposable paper food packaging across Europe. Moreover, hazardous chemicals like bisphenols and phthalates can be found in recycled paper used for food packaging. Like plastics, paper and board FCMs are complex materials that can contain hundreds of different chemical substances (both intentionally and non-intentionally added).[28]

Examples of harmful chemicals found in paper and cardboard food packaging

- A 2015 Danish consumer test of pizza boxes made of recycled paper and board found high levels of fluorinated substances in all of the tested materials; along with mineral oils, phthalates, bisphenol A and nonylphenol also suspected to come from recycling material.[29]
- A 2016 EU JRC analysis of paper napkins found leaching carcinogenic primary aromatic amines from half of the tested items.[30]
- A 2019 Danish consumer tests on 20 different disposable food packaging products from the Danish market revealed that paper coffee cups and paper straws may contain suspected carcinogens.[31]
- A 2019 European Consumer Organisation (BEUC) survey highlighted the use of problematic chemicals in paper and board food packaging.[32]

[28] Groh, Ksenia J., Birgit Geueke, Olwenn Martin, Maricel Maffini, and Jane Muncke. 2021. "Overview of Intentionally Used Food Contact Chemicals and Their Hazards." *Environment International* 150 (May): 106225. doi.org/10.1016/j.envint.2020.106225

[29] "Chemicals of Concern in Pizza Boxes | Food Packaging Forum." 2015. www.foodpackagingforum.org/news/chemicals-of-concern-in-pizza-boxes#:~:text=Three%20different%2C%20randomly%20selected%20brands%20of%20pizza%20boxes.

[30] Yavuz, Oguzhan, Sandro Valzacchi, Eddo Hoekstra, and Catherine Simoneau. 2016. "Determination of Primary Aromatic Amines in Cold Water Extract of Coloured Paper Napkin Samples by Liquid Chromatography-Tandem Mass Spectrometry." *Food Additives & Contaminants: Part A* 33 (6): 1072–79. doi.org/10.1080/19440049.2016.1184493

[31] "Test: Unwanted Chemicals in Colorful Foodpackaging." n.d. Taenk.dk. Accessed 4 July, 2023. taenk.dk/kemi/english/test-unwanted-chemicals-colorful-foodpackaging

[32] More than a paper tiger - European consumer organisations call for action on paper and board food contact materials. BEUC - the European Consumer Organisation, 219. Brussels. Accessed 4 July 2023. www.beuc.eu/sites/default/files/publications/beuc-x-2019-042_more_than_a_paper_tiger_test_summary_food_contact_materials.pdf

Examples of harmful chemicals found in paper and cardboard food packaging

- A 2021 consumers report found PFAS widespread in disposable food packaging from popular fast-food chains across Europe.[33]
- Of the 2881 food contact chemicals that were extracted or detected to migrate from FCMs, 887 are associated with paper and board).[34]
- In 2021, the Swedish Chemicals Agency tested over 60 different paper and cardboard-based packaging materials (e.g. bags for French fries and popcorn, muffin wrappings, packaging for several cereal-based food items for kids, straws, plates, cookie wrappings and more). And the test results were quite astonishing: out of the 61 packaging materials that were tested, 49 (over 80 percent) contained the chemical DEHP, which is a SVHC and impairs human reproductive health.[35]
- Additionally, use of recycled materials potentially creates new pathways through which humans can be exposed to hazardous chemicals in contaminated material flows, as shown for example in the recent report from the human biomonitoring consortium (HBM4EU), where bisphenols and phthalates were found in recycled paper used for food packaging.[36]

Finally, there is clear evidence that the production of food packaging is evolving with new and **innovative types of material being used** and introduced onto the market, including those that are either bio-based, possess more biodegradable properties than traditional packaging materials, or use nanomaterials. Yet, **these trends are not well accommodated in the current *REACH and FCM legislations***, which favour risk assessment and risk management of well-established chemistries. These gaps should be filled in the context of the EU's *Packaging and Packaging Waste Regulation* in order to ensure that new products entering the market are safe for consumers to use as well as being more sustainable and better for the environment.

Overall, the situation created by a lack of EU-specific measures for the majority of materials and a multitude of national measures has created legal uncertainty, barriers to businesses, and confusion over required or acceptable levels of safety of food packaging present on the EU market. This situation should not be accepted any longer (see Case Example 2).

[33] "'Forever Chemicals' Widespread in Disposable Food Packaging from Popular Fast-Food Chains across Europe, New Study Shows." Arnika. Accessed 4 July, 2023. arnika.org/EN/news/forever-chemicals-widespread-in-disposable-food-packaging-from-popular-fast-food-chains

[34] Geueke, Birgit, Ksenia J. Groh, Maricel V. Maffini, Olwenn V. Martin, Justin M. Boucher, Yu-Ting Chiang, Frank Gwosdz, et al. 2022. "Systematic Evidence on Migrating and Extractable Food Contact Chemicals: Most Chemicals Detected in Food Contact Materials Are Not Listed for Use." *Critical Reviews in Food Science and Nutrition*, May, 1–11. doi.org/10.1080/10408398.2022.2067828

[35] "Testing Finds That 8 out of 10 Packaging Materials for Food Contain Highly Toxic Chemicals." CHEMSEC. Accessed 4 July, 2023. chemsec.org/testing-finds-that-8-out-of-10-packaging-materials-for-food-contain-highly-toxic-chemicals

[36] "Chemicals in a Circular Economy Using Human Biomonitoring to Understand Potential New Exposures." HBM4EU, 2022. Accessed 4 July 2023. www.hbm4eu.eu/wp-content/uploads/2022/07/ChemicalsCircularEconomy.pdf

COMMON ASSUMPTION: The system of declaration of compliance and market control is a pillar of food packaging safety.

FACT: Information is lost in the supply chain. The current systems of official controls cannot adequately enforce the requirements of the legislation.

The risk assessment of the chemicals in the final food packaging article is often hampered by the lack of transfer of safety-related information along the supply chain. Declarations of compliance (DoC, a written declaration from a supplier stating that FCMs comply with the specific rules) are often incorrectly filled-in and incomplete. Obtaining adequate information through the whole of the supply chain is very difficult; downstream users do not currently have access to necessary information that is contained in confidential documentation supporting DoCs provided by the chemical industry. A study by enforcement authorities has also underlined that following a request by Member States, the **chemical industry could not provide adequate supporting documentation showing that they comply with the *FCM Regulation***.[37]

Another important issue is that the main focus of the DoC and the supporting compliance work is still on the substances used in the manufacturing of the starting material. It is much less on the substances actually present in or migrating from the final food packaging, which include both the intentionally added substances and the non-intentionally added substances.

National requirements for the DoC vary between Member States, and many of them do not require DoCs for non-harmonised materials. Recent evaluation revealed that Member States are able to carry out inspections and controls only in a very limited capacity, and the current systems of official controls as implemented cannot adequately enforce the requirements of the legislation.

Overall, it can be concluded that gaps exist in the flow of information along the supply chain which, together with insufficient enforcement by control authorities, undermine the effectiveness of ensuring compliance and safety of FCMs.

A general overview of the identified basic inconsistencies and gaps related to the current legislative framework for chemicals in food packaging in the EU is shown on **Figure 2**.

[37] McCombie, Gregor, Karsten Hötzer, Jürg Daniel, Maurus Biedermann, Angela Eicher, and Koni Grob. 2016. "Compliance Work for Polyolefins in Food Contact: Results of an Official Control Campaign." Food Control 59 (January): 793–800. doi.org/10.1016/j.foodcont.2015.06.058

Fig. 2: An overview of inconsistencies and gaps related to the current legislative framework for chemicals applying for food packaging*

Safeguarding the health and interests of consumers is not adequately achieved today

REACH Regulation (EC) 1907/2006

- FCM substances are not a subject to REACH authorisation due to their human health hazards
- **At least 11 chemicals recognised as "Substances of Very High Concern" (SVHCs) are permitted in food contact materials**
- A slow legislative process: the redrawing of SVHCs from the market could take up to 10 years
- A targeted revision of REACH delayed

Framework Regulation (EC) 1935/2004

- **Art.3 does not define the level of safety expected, how this should be achieved or how it can be demonstrated**
- **Safety of migrating substances and their mixtures is not transparent** – is a food packaging actually safe?
- **Safety is insufficiently defined at EU level for most food contact materials**
- **More focus is needed on the finished materials and articles**
- **New materials and products are entering the market that challenge present categories**

- Declaration of compliance (DoC) is often incorrectly filled-in and incomplete
- Downstream users do not currently have access to necessary information related to chemicals due to confidentiality
- So far, plastic and regenerated cellulose film are the only materials for which authorised lists of substances exist at EU level
- **A CRUCIAL ISSUE**: A further delay of a targeted **revision of FCM regulation – already overdue** (it's difficult to say when factual legislative proposal will be ready and what will contain)

Harmonised EU rules for materials

Lacking for:

- Adhesives
- Cork
- Rubbers
- Glass
- Ion-exchange resins
- Metals and alloys
- Paper and board
- Printing inks
- Silicones
- Textiles
- Varnishes and coatings
- Waxes
- Wood

Regulation (EC) 450/2009

The authorised list for active and intelligent materials has not been established. Although in force – this law has not been fully implemented

Regulation (EU) 2022/1616

Recycled plastic materials and articles must comply with Article 3 of Regulation (EC) No 1935/2004

Novel recycling technologies to be placed on the market and then revoked later if collected safety data shows critical consumer exposures

Other recycled materials (including paper & cardboard) not covered in EU level regulation !

Regulation (EU) 2017/625

Public authorities have insufficient capacity to

- risk assess all substances
- harmonise and manage specific FCM rules under the present system
- comprehensively enforce compliance and safety

Regulation (EC) 10/2011

- The effectiveness of the approach - general restrictions such as an overall migration limit (OML) and specific restrictions such as SMLs - is limited in several ways
- Currently, over 900 substances are authorised for use in the manufacture of plastic FCMs. This represents no more than around 10% of the overall number of substances used in FCM manufacture
- New scientific knowledge is not reflected in a timely manner in the authorisations
- According to a 2016 opinion by EFSA, a more refined risk assessment of substances is necessary but is not feasible with the current risk management approach due to the consequential demand on resources and practical complexities, such as multiple SMLs for the same FCM
- **The approach used in the Regulation would require fundamental changes**

Directive 84/500/EEC

Measures needed to significantly lower the limits of lead, cadmium and introduce limits for aluminium, arsenic, barium, cobalt, chromium and nickel

**The information contained herein is based on data correct at the time of writing.*

Case examples

These examples illustrate why, without taking extra actions now – preferably in the PPWR –, problematic situations related to food packaging safety will only perpetuate in the future, and may even become more frequent when we start to witness more and more "innovative" food packaging.

1 - BPA as an example of chemical that is regulated "too little and too late", despite existing procedures under *REACH* and *FCM* laws

What happened?

- Bisphenol A (BPA) is used to produce epoxy resins found in protective coatings and linings for food and drink cans and vats. The use of substance in food and beverage cans is particularly significant, as approximately 80% of them utilise the BPA based epoxy-resin technology as a coating. With a staggering production of 50 billion beverage cans and 20 billion food cans annually in the EU, the widespread use of this substance raises questions about its impact on consumer safety.
- Evidence pointing to the hazardous properties of BPA emerged years ago. Recognising its potential reproductive toxicity and endocrine-disrupting effects on human health, the EU designated BPA as a Substance of Very High Concern (SVHC). However, the EU's current food contact materials regulations only restrict BPA in infant bottles and, more recently, in varnishes and coatings.
- In 2015, France took the lead in implementing protective measures by banning BPA in all food contact materials. Several other Member States also imposed restrictions, primarily focusing on its use in tableware for small children.
- The European Food Safety Authority (EFSA) recently conducted a comprehensive scientific assessment of BPA, leading to a startling conclusion. The EFSA's latest opinion recommends a drastic 20,000-fold reduction in the current safe limit for human ingestion of BPA. Additionally, the EFSA highlights the alarming fact that dietary exposure to BPA poses a health concern for EU consumers of all ages (!).

What can we learn?

The findings from human biomonitoring studies further fuel concerns about the widespread exposure to BPA, as well as other related bisphenols - that act similarly - and are used as substitutes.

This raises important questions about the effectiveness of current regulations and risk assessments. Despite being classified as a highly harmful substance under the EU's *Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)* framework years ago, the timely translation of this classification into actionable measures within the *Food Contact Materials (FCM) regulation* is lacking. Instead, a separate and often time-consuming process is required to issue opinions and establish "safe limits," which may not adequately protect consumers over time, especially considering emerging evidence.

It became therefore increasingly apparent that addressing the issue of hazardous chemicals in food and beverage packaging requires urgent action that prioritises consumer safety above all else. This situation calls for a pressing need to follow up the actions promised under the *Chemical Strategy for Sustainability* and revamp the chemical risk management approach, i.e. adopt a generic approach to risk management (GRA) to the most harmful chemicals and a group assessment of chemicals with similar hazards.

2 -"Eco-friendly" "natural" "organic" bamboo as an example that safeguarding consumer safety against the growing trend to replace plastic with "new" materials is not well accommodated in the current REACH and FCM legislations

What happened?

- In a span of just two years (2019-2021), the European Union market witnessed a significant influx of supposedly eco-friendly and child-safe alternatives to traditional plastics, prominently featuring "bamboo" reusable food contact articles. Advertised as a sustainable choice, these products contained however unauthorised additives and toxic chemicals, namely melamine and formaldehyde. Alarming evidence suggests that these substances react excessively to heat and fat, posing a potential health risk as they migrate beyond specific safety limits.
- What compounds the issue further is the regulatory ambiguity surrounding bamboo as a material. Many perceived it as a "fuzzy" material with no clear guidelines governing its usage. Preliminarily, only some Member Countries of the European Union, such as Austria, took a precautionary stance and banned the sale of bamboo tableware.
- However, it was eventually determined that these products violated EU FCM law, necessitating a wide enforcement action to curb their sales, with 21 countries joining the one-year lasting coordinated action.
- The pressing question that arises from this disconcerting situation is how numerous cups, marketed as "compostable" and "bamboo," managed to be legally sold by numerous 'green' business operators and organisations. Such a development has not only eroded trust among consumer groups but also raised concerns about the efficacy of public health protection measures.

What can we learn?

This troubling example assumes great significance of how we regulate chemicals when considering the evolving landscape of food packaging production. New and innovative materials are increasingly being introduced to the EU market, "revolutionising" the sector. However, it remains unclear which substances are permitted in these novel packaging solutions and how business operators ensure the chemical safety of such products.

So it became evident that the current EU rules, or in some cases the lack thereof, fail to prevent the marketing of "new" materials that have not undergone rigorous testing or may contain harmful chemicals. This loophole poses a critical risk to consumer health, as hazardous substances can migrate from food packaging to the food they hold. To address this alarming situation, it is imperative to harmonise and develop adequate EU rules on chemicals under sectoral legislation, that apply universally to all materials used in food packaging.

It also seems much more straightforward to set such general harmonised rules for all packaging under the PPWR, which would eliminate the need for separate legislation for each material used in food packaging - which currently amounts to a complex network of 17 material types under the *FCM* regulatory framework.

Ultimately, every sector-specific legislation should prioritise transparency and declaration regarding the chemical content of consumer products, and incentivise the timely incorporation of scientific research and risk assessment into risk management practices. By doing so, the focus can be shifted towards avoiding the use of the most harmful chemicals altogether.

The way forward: the need for more effective regulation on chemicals of concern in food packaging

There is a clear urgency to act on hazardous chemicals. Current chemical pollution levels are still far too high: over 10% of annual premature deaths in the EU each year are related to environmental pollution. This is mainly due to air pollution, but also to exposure to chemicals in products, of which impacts on health are likely to be underestimated.[38] Scientists recently declared that chemical pollution has passed the safe limit for humanity.[39]

The amount of chemicals coming from food packaging on EU citizens– such as PFAS, bisphenols and plasticisers, just to mention the most recognisable - are a health concern and call for additional regulatory action.[40] By reducing consumers' exposure to hazardous chemicals, the EU will not only protect society's vulnerable groups over the long term, but also improve quality of life for all.

Action is long overdue.[41] The European Ombudsman opened recently their own-initiative inquiry **to look into the risk management role of the European Commission regarding dangerous chemical substances in the EU** and, notably, the time taken to place substances on the authorisation list and introduce restrictions to mitigate risks.[42]

Since the publication of the PPWR proposal, we witness a continuous exchange of arguments and counter-arguments about best ways to improve the sustainability of the packaging value chain. When it comes to reusable packaging safety, many misconceptions about its relation to compromised food hygiene

[38] *European Environment Agency.* "Health Introduction." Accessed 4 July, 2023. www.eea.europa.eu/publications/zero-pollution/health/health-introduction

[39] Carrington, Damian. 2022. "Chemical Pollution Has Passed Safe Limit for Humanity, Say Scientists." The Guardian. January 18, 2022. www.theguardian.com/environment/2022/jan/18/chemical-pollution-has-passed-safe-limit-for-humanity-say-scientists

[40] "April 2022 HBM4EU Newspaper European Human Biomonitoring Initiative. Accessed 4 July, 2023. www.hbm4eu.eu/wp-content/uploads/2022/05/HBM4EU-Newspaper.pdf

[41] "The need for speed: why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections". European Environmental Bureau (EEB), 2022. Accessed 4 July, 2023. eeb.org/wp-content/uploads/2022/07/Need-for-speed_Online_Final.pdf

[42] "The risk management of dangerous chemical substances by the European Commission". European Ombudsman, 2023. Accessed 4 July 2023. www.ombudsman.europa.eu/en/opening-summary/en/170893

and health concerns have been spread.[43] Much less attention has, however, been paid to the fact that the current rules on chemicals in packaging are deficient and provide insufficient protection of consumers.[44]

At present, the regulatory framework defines food packaging (and the food contact materials they are made from) as "safe" if they comply with the regulatory setting of "safe levels" for a small set of well-studied chemicals. But legislation, so far, fails to ensure the real safety of products, namely the absence of hazardous and untested chemicals in consumer products. A reformed legislative EU regime should respect **the principle of 'no data, no market'**, requiring manufacturers to declare and demonstrate use of safe chemicals through a chemical safety report.

The European Union policies should be based on **the principle that preventive action should be taken at source**, and any revised / new EU legislation should therefore implement a generic approach to managing risks of the most harmful chemicals. The goal is to remove the most hazardous chemicals from consumer products (no exposure = no risk).[45]

The *PPWR* proposal is an excellent opportunity for sectoral legislation to close existing gaps. Therefore, rather than a vague goal of "*minimising use of substances of concern*", clear measures effectively addressing their presence and targeting their elimination from food packaging, as well as ensuring transparent monitoring and reporting, should be introduced. This is even more crucial now than ever, given the focus in the proposal to reuse, recycle, and achieve mandatory recycled content targets.

The *PPWR* provides the opportunity to regulate not only sustainability aspects of food packaging, but also to harmonise at the EU level the rules applied to materials and articles from a chemical safety perspective. Clearer EU rules and delegation of responsibilities on chemicals in the supply chain are needed to improve effectiveness and ensure the safety of the final food packaging articles entering the market. In fact, it also will support functioning of the single market through common principles and a regulatory approach with harmonised rules for all materials.

"In line with the objectives of the Circular Economy Action Plan and the Chemicals Strategy for Sustainability, and to ensure the sound management of chemicals throughout their life cycle and the transition to a toxic-free and circular economy, and considering the relevance of packaging in everyday life, ***it is necessary that this Regulation addresses impacts on human health and on the environment*** *and on broader sustainability performance, including circularity,* ***resulting from impacts of substances of concern on the whole life cycle of packaging,*** *from manufacture to use and end-of life, including, waste management."*

Packaging and Packaging Waste Regulation proposal (Recital 14)

[43] "Debunking Common Myths about Food Hygiene, Food Waste, and Health Concerns Related to Reusable Packaging". Zero Waste Europe, 2023. Accessed 4 July, 2023. zerowasteeurope.eu/wp-content/uploads/2023/05/Debunking-recycling-myths-ZWE-factsheet-May2023.pdf

[44] "Feedback on the EU Packaging Regulation Revision Recommendations for an Ambitious Revision of the Packaging and Packaging Waste Regulation (PPWR)." Zero Waste Europe, 2023. Accessed 4 July, 2023. zerowasteeurope.eu/wp-content/uploads/2023/04/Position-Paper-PPWR-2.pdf

[45] Napierska, Dorota. "How the EU Chemicals Strategy Can Help to Make Our Food Packaging Toxic-Free." Zero Waste Europe. March 30, 2022. zerowasteeurope.eu/2022/03/how-the-eu-chemicals-strategy-can-help-to-make-our-food-packaging-toxic-free

Our recommendations

- As more sustainable circular economy solutions are developed, the critical aspect of chemical safety cannot be left behind. Significant improvements in food packaging design to enable reuse and recycling must go hand in hand with well-proven safety from the chemicals perspective.

- Avoiding the upstream introduction of hazardous substances to food packaging is a preferable approach to ensuring its safety. EU legislation should urgently phase out the most hazardous chemicals and ensure that food packaging and other food contact articles are safe for use, reuse and recycling. As a principle, products that cannot be safely used, reused and recycled should not be produced or placed on the market in the first place. This will require specifically testing the safety of the final packaging product.

- The *Packaging and Packaging Waste Regulation* should introduce harmonised EU rules on substances of concern applied to all materials and packaging articles, i.e. incentivise avoidance of the most harmful chemicals and require reporting on the use and tracking of such chemicals along the supply chain.

- Coherence and synergy between chemicals legislation and all EU regulations have to be ensured. 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 or endocrine disruptors, should be automatically prohibited in all consumer products, including food packaging, without delay.

- As a matter of priority, to truly ensure a high level of protection of human health, the F*ood Contact Material Framework Regulation (EU 1935/2004)* needs a comprehensive revision. A reformed *FCM* regime should respect the principle of 'no data, no market' already required within the *REACH regulation*.

Zero Waste Europe (ZWE) is the European network of communities, local leaders, experts, and change agents working towards the prevention and elimination of waste in our society. We advocate for sustainable systems; for the redesign of our relationship with resources; and for a global shift towards environmental justice, accelerating a just transition towards zero waste for the benefit of people and the planet. www.zerowasteeurope.eu

Rethink Plastic is an alliance of leading European NGOs, representing thousands of active groups, supporters and citizens in every EU Member State. We are part of the global Break Free From Plastic movement, consisting of over 11,000 organisations and individuals worldwide demanding an end to plastic pollution.

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ZERO WASTE EUROPE

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