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ARTICLE

Dangerous Legacy of Food Contact Materials on the EU Market: Recall of Products Containing PFAS

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Abstract

Toxic substances and endocrine disruptors are present in consumer goods on the European Union (EU) market, such as in food contact materials like cookware. This article investigates whether a legal recall obligation of such products exists in EU law, and in the absence of such an obligation, how the EU legislature has ensured that such products are disposed of in a manner that does not compromise human health and the environment when they become waste. For this purpose, this Article analyses recall obligations for food contact materials containing persistent organic pollutants, as well as their waste regulations. It focuses on a class of substances with non-stick properties, some of them formerly used in cookware, such as pentadecafluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). We show that there is no single legal recall obligation; rather, many legal obligations are scattered among different provisions of EU law. When read together, they form a complex web of obligations, which may lead to recall measures for most of these products. However, doubts over the feasibility and effectiveness of such recalls remain.

Keywords: disposal; endocrine disruptors; food contact materials; hazardous waste; liability; per- and polyfluoroalkyl substances (PFAS); persistent organic pollutants; recall; traceability

I. Introduction

Per- and polyfluoroalkyl substances (PFAS) are in the regulatory spotlight.[1] Once heralded for their useful properties, they have been widely used in consumer goods. However, exposure to PFAS has adverse effects on consumers' health such as an increased risk of infertility in women.[2] It has been linked to the suppression of the immune system, different

[1] See, for example, the US EPA's proposed regulation to remove PFAS from drinking water, see "Per- and Polyfluoroalkyl Substances (PFAS); Final PFAS National Primary Drinking Water Regulation" (United States Environmental Protection Agency, n.a.) <https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas> (accessed 9 January 2023); J Tollefson, "How the US will remove 'forever chemicals' from its drinking water," (2023) Nature News, <https://doi.org/10.1038/d41586-023-00822-7> (accessed 18 March 2023). As for regulatory efforts aimed at regulating these substances in the EU, see V Obolevich "One Step Closer to Zero Chemical Pollution: The Legal Adoption and Implications of the Per- and Polyfluoroalkyl Substances Restriction Proposal," (2023)14(4) European Journal of Risk Regulation 793-799 <https://doi.org/10.1017/err.2023.64> (accessed 12 December 2023).

[2] N J Cohen, M Yao, V Midya, S India-Aldana, T Mouzica, S S Andra, SNarasimhan, A K Meher, M Arora, J K Y Chan, Shiao-Yng Chan, S L Loy, L Minguez-Alarcon, Y Oulhote, J Huang and D Valvi, "Exposure to perfluoroalkyl substances and women's fertility outcomes in a Singaporean population-based preconception cohort," (2023) 873 Science of The Total Environment 162267 <doi: 10.1016/j.scitotenv.2023.162267> (accessed 24 July 2023).

types of cancer, thyroid diseases, and reproductive and developmental impairments.[3] For this reason, governments have been reducing exposure to these chemicals. Authorities in Denmark, Germany, Netherlands, Norway, and Sweden submitted a proposal to the European Chemicals Agency (ECHA) to impose restrictions concerning around 10,000 substances of the PFAS family.[4] If adopted, this would be the broadest restriction of substances in history.[5]

Despite the regulatory efforts to limit exposure to toxic chemicals, certain products historically present in European households contain PFAS, such as perfluorooctanoic acid (PFOA), associated with endocrine disruption.[6] PFOA had been used in particular in cookware, such as frying pans, thanks to its resistance to fat and water and non-stick properties.[7] PFOA has a complicated regulatory history in the EU and worldwide.[8] Approximately two decades

[3] S Mededovic Thagard "Focusing water treatment efforts on the destruction of poly- and perfluoroalkyl substances (PFAS): the United States perspective," (2022) 24 Clean Technologies and Environmental Policy 1619 <https://doi.org/10.1007/s10098-022-02362-6> (accessed 24 July 2023).

[4] "ECHA publishes PFAS restriction proposal" ECHA/NR/23/04 (European Chemicals Agency official website, n.a.) <https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal> (accessed 11 July 2023).

[5] "The PFAS Restriction Proposal" (European Chemicals Agency official website, n.a.) <https://echa.europa.eu/documents/10162/2082415/2023-02-07_pfas+media+briefing_en.pdf/1661579d-353a-2fb0-1062-38fc3eb4bd78?t=1675849038730> (accessed 11 July 2023).

[6] Endocrine disruptors are defined as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations." See Commission, "Communication from the Commission to the Council and the European Parliament - Community strategy for endocrine disrupters - A range of substances suspected of interfering with the hormone systems of humans and wildlife" (Community Strategy for Endocrine Disruptors) COM/99/0706 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:51999DC0706>, (accessed 24 June 2023); A Chaparro-Ortega, M Betancourt, P Rosas, F G Vázquez-Cuevas, R Chavira, E Bonilla, E Casas and Y Ducolomb, "Endocrine disruptor effect of perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) on porcine ovarian cell steroidogenesis," (2018) 46 Toxicology In Vitro 86, 93 <https://doi.org/10.1016/j.tiv.2017.09.030>. However, PFOAs are not included in Annex XIV REACH as endocrine disruptors already identified and subjected to authorisation because of their intrinsic properties as endocrine-disrupting chemicals. Provisions in POP Regulation are more restrictive than the provisions applying to authorisations under REACH Regulation. In the opposite case "[i]f a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants (26), the Commission shall withdraw the authorisation for that use" (Art 61(6) REACH Regulation).

[7] A Ramírez Carnero, A Lestido-Cardama, P Vázquez Loureiro, L Barbosa-Pereira, A Rodríguez Bernaldo de Quirós and R Sendón, "Presence of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in Food Contact Materials (FCM) and Its Migration to Food" (2021) 10(7) Foods, 1443 <https://doi.org/10.3390/foods10071443>.

[8] According to "Commission Recommendation (EU) 2022/1431 of 24 August 2022 on the monitoring of perfluoroalkyl substances in food" C/2022/5001 OJ L 221, 26.8.2022, p. 105–109 ELI: http://data.europa.eu/eli/reco/2022/1431/oj (accessed 9 July 2023), the Member States should test for the presence in food of the following PFASs, e.g. (a) Perfluorooctane sulfonic acid (PFOS); (b) Perfluorooctanoic acid (PFOA); (c) Perfluorononanoic acid (PFNA); (d) Perfluorohexane sulfonic acid (PFHxS). This was preceded by another 'Commission Recommendation of 17 March 2010 on the monitoring of perfluoroalkylated substances in food' OJ L 68, 18.3.2010, p. 22–23 (EN) ELI: <http://data.europa.eu/eli/reco/2010/161/oj > (accessed 9 July 2023). According to Commission Recommendation (EU) 2019/794 of 15 May 2019 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food C/2019/3519 OJ L 129, 17.5.2019, p. 37–42 (EN) ELI: http://data.europa.eu/eli/reco/2019/794/oj (accessed 9 July 2023), Member States should adopt a coordinated control plan to test fluorinated compounds in paper and board based materials and articles, including those used to wrap fast-food, takeaway and bakery products and microwave popcorn bags. EFSA adopted a scientific opinion in May 2022 entitled "Identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food," (EFSA's Panel on Food Contact Materials, Enzymes and Processing Aids), EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), C Lambré, J M Barat Baviera, C Bolognesi, A Chesson, P S Cocconcelli, R Crebelli, D M Gott, K Grob, E Lampi, M Mengelers, A Mortensen, G Rivière, IL Steffensen, C Tlustos, H Van Loveren, L Vernis, H Zorn, B Ahrens, E Fabjan, R Nicolas, L Polci, K Baert, K Volk and L Castle, "Identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in

ago, PFOA started being replaced by other chemicals from the PFAS family.[9] However, some cookware and other products that contained PFOA remained with consumers: for example, the lifespan of a non-stick frying pan is on average 5 years[10] but some pans containing PFOA can still be found on second-hand markets, inherited or in use in European households. Such cookware may not be labelled to indicate whether they were coated with PFOA. Moreover, it is difficult to find consumer-friendly information on PFOA or other PFAS, such as, when manufacturers ceased using PFOA in cookware, or when the last frying pan containing PFOA was placed on the market in the EU. When shopping for new cookware today, some packaging contains labels such as "PFOA-free," "NO-PFOA" or "Safe Non-Stick." (as illustrated in Figure 1, see below). Some labels indicate that cookware does not contain perfluorochemicals (PFCS), perfluorooctanesulfonic acid (PFOS), or other PFAS. Others include voluntary producers' information that they contain GenX coatings, such as ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (FRD-902)[11] or PTFE,[12] both belonging to PFAS.[13] Shopping around for everyday domestic essentials, it seems as if one chemical of questionable safety is replaced by another.[14]

Employing cookware as a case study, this article examines how European Union (EU) law tackles the issue of toxic legacies in food contact materials. Specifically, it investigates whether EU law provides a basis for the organisation of recalls of cookware by competent authorities. The article examines whether such a basis exists in three regimes regulating the enforcement of obligations relating to food contact materials: EU chemical law, food law, and product safety law. The article identifies overlaps of these regimes that render their systemic interpretation difficult. As a result, a clear legal basis for recall of toxic cookware historically present in European households does not exist. The lack of clear legal basis impacts upon the level of protection afforded by EU legislature concerning

materials and articles intended to come into contact with food" (2022) 20(5) EFSA Journal, 7231 <https://doi.org/10.2903/j.efsa.2022.7231>.

[9] See K S. Betts, "Perflouroalkyl Acids: What Is the Evidence Telling Us?" (2007) 115(5) Environmental Health Perspectives A250 <https://doi.org/10.1289/ehp.115-a250>.

[10] A Palermo "How Long Do Non-Stick Pans Last? (When to Replace Your Pan)" (Prudent Reviews, 20 September 2023) <https://prudentreviews.com/how-long-do-non-stick-pans-last/>, (accessed 9 July 2023).

[11] FRD-902 was recently subject to a dispute brought by Chemours Netherlands (previously DuPont and the largest manufacturer of PFOA in Europe) against the ECHA. In 2019, ECHA classified FRD-902 as a substance of very high concern, and Chemours contested this decision. The action of Chemours was dismissed by the GC in 2022 and its appeal was again dismissed by the CJEU in 2023. Respectively, Case T-636/19 *Chemours Netherlands BV v ECHA* (2022) ECLI:EU:T:2022:86, before the GC, and Case C-293/22 P *Chemours Netherlands v ECHA* (2023) ECLI:EU:C:2023:847, before the CJEU.

[12] PTFE is produced using ammonium salt of PFOA. The use of the ammonium salt of PFOA was authorised in 2007 by an amendment to Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. The authorisation was based on the scientific opinion of the European Food Safety Authority (EFSA) issued in June 2005. EFSA concluded that based on the available toxicological information, ammonium salt of PFOA could be used only in conditions associated with negligible consumer exposure. Its use in repeated-use articles sintered at high temperatures was considered to result in negligible consumer exposure and as such was authorised at EU level. In 2008, the EFSA concluded in another risk assessment that it is unlikely that adverse effects of PFOS or PFOA are occurring in the general population. It also stated that further data on PFASs levels in food and in humans would be recommended, particularly with respect to monitoring trends in human exposure.

[13] Other PFAS were also authorised for anti-stick coatings in food applications and the authorisations remain in place per Annex I of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 012 15.1.2011, p. 1, inter alia, perfluoromethyl perfluorovinyl ether to be used in anti-stick coatings and in fluoro- and perfluoropolymers intended for repeated use applications where the contact ratio is 1 dm2 surface in contact with at least 150 kg food.

[14] "PFAS explained" (EPA US Environmental Protection Agency, n.a.) <https://www.epa.gov/pfas/basic-information-pfas#difference>, (accessed 9 July 2023). In case of BPA, see also M Thoene, E Dzika, S Gonkowski and J Wojtkiewicz, "Bisphenol S in Food Causes Hormonal and Obesogenic Effects Comparable to or Worse than Bisphenol A: A Literature Review" (2020) 12(2) Nutrients 532 <https://doi.org/10.3390/nu12020532>.

Figure 1. Images of labels claiming the absence of PFOA in several advertised frying pans.[15]

health and the environment that emerge after the purchase of products newly identified as toxic based on recent scientific evidence.[16] Such a level of protection is determined, for example, by responding to consumers' willingness to know whether PFOA is still used in food contact materials, including cookware, and if so, when it stopped being produced. Establishing a clear legal basis mandating recalls for cookware manufacturers, distributors, or retailers would increase such level of protection.[17] Conversely, a selective reading of certain provisions governing control and enforcement of health protection may seem to warrant the organisation of recalls. Such reading, although well-intentioned, would however encounter practical hurdles, such as feasibility challenges given the sheer number of affected consumers and products and effectiveness challenges in safeguarding human health. Consequently, the article explores the potential implications and obligations related to waste management that could arise in the absence of a recall obligation. By doing so, this article contributes to the ongoing debate surrounding consumer protection and regulatory governance in the EU as regards PFAS.

II. Recalls in chemical law

Chemicals used in cookware are subject to three regulatory regimes: REACH,[18] the Persistent Organic Pollutants (POP) Regulation,[19] and the Food Contact Materials (FCM) Regulation.[20] These regulations provide for specific pre-market authorisation regimes of substances and materials coming into contact with food. Although they provide for differing regulatory regimes, these may intersect in the case of PFAS. This is because PFAS are specific substances used in food contact materials whose regulation per the POP

[15] Pictures taken by the authors of frying pans offered for sale in a nearby supermarket.

[16] See S Gold and W Wagner, "Filling gaps in science exposes gaps in chemical regulation" (2020) 368(6495) Science, 1066, 1068. See also M Herzler, P Marx-Stoelting, R Pirow, C Riebeling, A Luch, T Tralau, T Schwerdtle and A Hensel, "The 'EU chemicals strategy for sustainability' questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?" (2021) 95 Archives of Toxicology, 2589-2601 <https://doi.org/10.1007/s00204-021-03091-3>.

[17] See for the US account on this K Cronin, "FDA-Approved: How PFAS-laden Food Contact Materials are Poisoning Consumers and What to do About it" (2022) 6(1) The Business, Entrepreneurship & Tax Law Review 117, 152, available at <https://ssrn.com/abstract=4301327>.

[18] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1–849.

[19] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast), OJ L 169, 25.6.2019, p. 45–77.

[20] 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. OJ L 338, 13.11.2004, p. 4–17.

Regulation follows international harmonisation of the Stockholm Convention.[21] Those PFAS, which are not regulated by the POP Regulation fall under the general chemical law, i.e. REACH Regulation. If a substance's authorised use under REACH is subsequently prohibited or otherwise restricted in the POP Regulation, the Commission must withdraw the authorisation for that use under REACH.[22] Moreover, under the FCM Regulation,[23] the Commission may draw a list of substances used in cookware authorised for use in manufacturing materials and articles.[24] Thus, in certain cases, the material scope of these three EU regulations overlaps.

The POP Regulation stipulated that an article containing a prohibited substance could be allowed on the market only when notified by Member States and subsequently by the Commission to the Stockholm's Convention Secretariat. The Commission made such a notification in February 2024 including the continued use of PFOA in non-stick cookware, pans, and kitchen utensils.[25] The Stockholm Convention does not require state parties to legislate for recalls of PFOA or other PFAS articles. However, it refers to the polluter pays principle and the precautionary principle, which call for measures to reduce possible releases of regulated substances and eliminate their sources. From these principles, one cannot infer an explicit obligation to recall affected products.[26] However, state parties can establish recall obligations in relation to old PFOA-coated cookware if these are identified as a source of exposure. For such an obligation to be established, it would need to be mentioned explicitly in the respective annex, for example as *ex tunc* elimination of uses without exemption unless remaining uses are notified.[27] An obligation to legislate for recalls of existing products could be in line with the spirit of the convention, which leaves a margin for its implementation.[28] The existing obligation to eliminate or restrict the use of certain substances concerns only future use; it does not follow from states' practice that recalls are contained in that obligation. A state practice that did not involve legislating for recalls of PFAS articles or the absence of notification of continuous uses has not been disputed.[29]

The POP Regulation, notably its annexes, is revised by the EU legislature to reflect new amendments agreed in the Stockholm Convention, such as new concentration limits of

[21] The Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention) (adopted on 22 May 2001), available at <https://www.pops.int/TheConvention/Overview/tabid/3351/Default.aspx> (accessed 9 July 2023).

[22] Art 61(6) REACH Regulation.

[23] Art 5 of Food Contact Materials Regulation.

[24] The EU has only established a positive list of food contact substances for plastics, while national legislation applies to other contact materials based on migration or compositional limits. Regulation (EU) No 10/2011 (supra, note 13) could be potentially changed to prohibit use of PFASs in plastic food contact materials (above a certain limit).

[25] "Notification of Articles in use" (Stockholm Convention's official website, n.a.) <https://chm.pops.int/Implementation/Exemptions/NotificationsofArticlesinuse/tabid/452/Default.aspx>, (accessed 9 July 2023).

[26] Art 3 of the Stockholm Convention.

[27] Annex I, Part A and B, note (ii) of the Stockholm Convention. Related to recall could also appear the obligations regarding public information, awareness and education in Art 10 of the Stockholm Convention.

[28] For example, under Art 5(b) of the Stockholm Convention, states must "promote the application of available, feasible and practicable measures that can expeditiously achieve a realistic and meaningful level of release reduction or source elimination."

[29] Other international legal instruments, such as the Montreal Protocol to the Vienna Convention for the Protection do not include an obligation on the part of states to impose recall obligations (Montreal Protocol on Substances that Deplete the Ozone Layer Montreal (16 September 1987) to the Vienna Convention for the Protection of the Ozone Layer Vienna (22 March 1985), both documents available at <https://legal.un.org/avl/ha/vcpol/vcpol.html>). See e.g. for the Netherlands: M Stoop and A Lambert, "Processing of discarded refrigerators in The Netherlands" (1998) 18(2) Technovation, 101, 110 <https://doi.org/10.1016/S0166-4972(97)00070-9>; West Germany: J Granat and J Weig, "Present Efforts Will Not Make the Holes Disappear: International Efforts to Protect the Ozone Layer" (1998) 5(1) Florida Journal of International Law 135, 148, available at <https://scholarship.law.ufl.edu/fjil/vol5/iss1/7>

certain substances.[30] If a substance is listed in Annex I, it must not be manufactured, placed on the market, and used,[31] whether on its own, in mixtures, or in articles, unless specific exemptions, such as unintentional trace contaminants, in manufacturing, placing on the market or use apply.[32] Article 4(2) (first sentence) establishes that for substances added to Annex I after 15 July 2019, prohibitions do not apply for a 6-month transitional period if the concrete substance is present in articles produced before or on the date that substance becomes regulated per the POP Regulation.[33] Similarly, Article 4(2)(second sentence) establishes that for substances present in articles already in use before the date the POP Regulation came into effect for those substances, prohibitions do not apply (with no temporal limit).[34] Hence, the marketing and use of articles already produced or in circulation in the Union before or on 4 July 2020 containing PFOA, its salts and/or PFOA-related compounds, is allowed.[35]

The FCM Regulation also provides for a pre-market authorisation procedure for new substances that may be used in the manufacture of materials and articles intended to come into contact with food.[36] As part of this authorisation procedure,[37] a safety assessment must be carried out[38] proving that substances must not release their constituents into food in quantities that could endanger human health under typical or foreseeable conditions of use.[39] The application of a specific pre-authorisation regime of food contact materials per the FCM Regulation the FCM does not exclude the application of Annex XVII of REACH

[30] Art 15(1) of the Persistent Organic Polluntants Regulation empowers the Commission to adopt delegated acts to modify existing entries of Annex I to adapt them to scientific and technical progress. Both Commission Delegated Regulation (EU) 2020/784 and Commission Delegated Regulation (EU) 2021/115 amended Annex I to the POP Regulation as regards the listing of PFOA, its salts and PFOA-related compound. Respectively, Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, C/2020/1973, OJ L 188I, 15.6.2020, p. 1–3 <http://data.europa.eu/eli/reg_del/2020/784/oj>, and Commission Delegated Regulation (EU) 2021/115 of 27 November 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds C/2020/7980, OJ L 36, 2.2.2021, p. 7–9 <http://data.europa.eu/eli/reg_del/2021/115/oj>.

[31] Art 3(1) Persistent Organic Pollutants Regulation.

[32] Art 4 Persistent Organic Pollutants Regulation in connection with Annex I of Persistent Organic Pollutants Regulation.

[33] Art 4(2) Persistent Organic Pollutants Regulation. For example, for PFOA and any of its salts present as unintentional trace contaminants, the upper limit has been set to concentrations equal to or below 0,025 mg/kg. For PFOA-related compounds present in substances, mixtures or articles, the upper limit has been set to concentration of 1 mg/kg. If PFOA and its salts are present in PTFE micropowders, which can be applied to pans' coatings, the same concentration limit applies. Yet PFOA, its salts and PFOA-related compounds are allowed in, for example, textiles for oil- and water-repellency for the protection of workers from dangerous liquids, until 4 July 2023.

[34] The exemption aligns with the proposal for a regulation on persistent organic pollutants, which had envisaged the use of substances present in articles already manufactured or in use upon notification of their remaining use, where appropriate. Proposal for a Regulation of the European Parliament and of the Council on persistent organic pollutants (recast), COM/2018/0144 final - 2018/070 (COD). In Annex I, Part A and B, note (ii) of the Stockholm Convention, the wording of "where appropriate" does not appear, however. In the adopted version of the regulation, Art. 4(2), a Member State must inform the Commission and the ECHA immediately upon becoming aware of the existence of such an article.

[35] Regarding the substances included in Annex I part A, fourth column, par. 8, row Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds.

[36] This procedure is related to new substances to be authorised for use in the manufacturing of materials and articles; or otherwise authorised to be incorporated in active or intelligent food contact materials and articles (as per in points (a) and (b) of the second subparagraph of Article 5(1) Food Contact Materials Regulation).

[37] Art 8 (2) Food Contact Materials Regulation.

[38] Art 9(1)(a)(ii) Food Contact Materials Regulation.

[39] Art 3 (2) Food Contact Materials Regulation.

Regulation.[40] This Annex sets out restrictions of certain hazardous substances, mixtures and articles for their marketing and use on the EU market, including substances found in food contact materials.[41] However, unlike authorisations under the FCM Regulation, REACH establishes that the chemical safety report of such substances does not need to take into account risks to human health arising from end uses.[42] This effectively bifurcates the protection against hazardous substances in food contact materials such as PFAS into two regulatory regimes.

Unlike recalls or withdrawals in product safety and food law, which must be perfected immediately, operators and competent authorities are given time to implement restrictions under EU chemical law. The Stockholm Convention, and the POP Regulation as a matter of the Convention's implementation, as well as REACH require a socio-economic analysis, which, *inter alia*, determines the time limit in which a restriction needs to be implemented.[43] Furthermore, derogations from restrictions for the continuous use of a dangerous substance can be adopted.[44] These are justified by proving certain economic and technological conditions, such as an essential use, a lack of technically and economically feasible alternatives, and minimisation of emissions. Such derogations as well as any possible future restrictions are subject to continuous risk assessment and data gathering. Importantly, REACH does not contain any provision similar to Article 4(2) POP Regulation which would exclude the application of restrictions from the products already on the market.[45] On the contrary, alternative solutions are proposed for certain substances, and REACH leaves a certain leeway for the EU as well as Member States to regulate "creatively."[46] Member States may, for reasons of protection of human health, restrict, prohibit or create subject-specific conditions for the use of such articles before they are disposed of or reach the end of their service life.

As for a first preliminary conclusion, the POP Regulation is the baseline norm for PFAS regulation in case of implementing the Stockholm Convention amendments, and REACH for all other cases of PFAS regulation, unless the FCM Regulation is not applicable by virtue of the Commission's implementing regulations. However, these different pieces of legislation may include diverging approaches to products already marketed. If PFAS are

[40] According to Art 67(1) REACH Regulation, a substance for which Annex XVII contains a restriction shall not be manufactured, placed on the market, or used unless it complies with the condition of that restriction.

[41] Such as Bis(2-ethylhexyl) phthalate (DEHP), a substance that has been classified both in Annex XIV (num. 4) and in Annex XVII (num. 51), see C Ribes Ortega "The Law Is Elastic but Does Not Bend: A Literal Interpretation of European Union Chemical Legislation Could Leave Health and the Environment Unprotected" (2023) 14(3) European Journal of Risk Regulation 612, 625 <https://doi.org/10.1017/err.2023.41>.

[42] Art 14(5)(a) REACH Regulation.

[43] See European Commission, REACH Regulation and the Stockholm Convention as well as the UNECE POP Protocol: A Common Understanding: "In principle, any risks related to the exempted uses of that substance should be addressed through adaptation to technical progress under the POP Regulation and, therefore, the REACH authorisation requirement should only be superimposed on the provisions of the POP Regulation if there are good reasons for doing so." (p. 4) <https://ec.europa.eu/docsroom/documents/5805/attachments/1/translations/en/renditions/native&usg=AOvVaw2dX0L90VePry3HGqyAVX_Y&opi=89978449>, (accessed 20 September 2023).

[44] See, for example, ECHA, "Analysis of derogations included in the restrictions on the manufacture, placing on the market and use of perfluorocarboxylic acids (PFCAs), their salts and related substances and perfluorocarboxylic acid (PFOA), its salts and related substances," 30 August 2020. See in this regard, K Garnett and GVan Calster, "The Concept of Essential Use: A Novel Approach to Regulating Chemicals in the European Union" (2021) 10(1) Transnational Environmental Law, 159, 187 <https://doi.org/10.1017/S2047102521000042>.

[45] Art 4(2) POP Regulation establishes exemptions from control measures. It states that substances added to Annex I or II after July 15, 2019, Art 3 is not applicable for six months if present in articles produced before this regulation applies. It also does not apply to substances in use before the regulation date.

[46] For certain other substances, labelling requirements have been adopted. For example, the use of articles containing asbestos fibres which were already installed before 1 January 2005 may continue to be permitted until those articles are disposed of or reach the end of their service life (Annex XVII, number 6(1) Asbestos, of REACH Regulation).

considered under REACH, measures can be adopted to prohibit the use of products containing PFAS, not only the use of the substances in products *ex nunc*.[47] Regarding enforcement, REACH prescribes that Member States must maintain a system of official controls and other activities as appropriate to the circumstances.[48] Restrictions should not be conflated with recalls; nevertheless, specific restrictions under REACH may indeed necessitate recalls. This approach is precluded, however, under the POP Regulation which supersedes in cases where a substance is regulated under the Stockholm Convention.

III. Recalls in food law

Within the EU, the General Food Law (GFL)[49] is the cornerstone of food safety legislation.[50] To ensure an integrated approach to food safety, there is a broad definition of food law, covering a wide range of provisions with a direct or indirect impact on the safety of food and feed, including provisions on food contact materials, as stated in Recital 11 of the GFL. Its Articles 5 to 10 are the only ones that are horizontally applicable beyond the GFL to all measures taken within the ambit of food law.[51] None of them, however, refer explicitly to food contact materials.[52]

Despite this limitation, the GFL contains provisions to address responses to food hazards through withdrawals or recalls. These measures, underpinned by Articles 19, 17 and 14 of the GFL,[53] serve as critical mechanisms for rapidly addressing potential risks posed by food on the market. Whether triggered by contamination concerns or other safety non-compliances, these provisions mandate food business operators (FBO) as well as public authorities to take action in order to ensure a high level of protection of human health and consumers' interests in relation to food, which is the main aim of the GFL.[54]

If, then, EU food law comprises food contact materials, but corrective measures of Articles 19, 17 and 14 GFL do not apply horizontally, it is questionable to consider recall mechanisms of the GFL as applicable to food contact materials. Certain applicability is evidenced by Articles 50 to 52 GFL as well as IMSOC Regulation[55] which serve as the basis of the EU Rapid Alert System on Food and Feed (RASFF), a system for notification of health

[47] E.g. Annex XVII, number 6(2) Asbestos, of REACH Regulation.

[48] Art 125 REACH Regulation.

[49] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, (OJ L 031 1.2.2002, p. 1) <http://data.europa.eu/eli/reg/2002/178/oj> (accessed 12 July 2023).

[50] K Purnhagen, "Food Safety" *Elgar Concise Encyclopedia of Consumer Law* (2024).

[51] See Art 4(2) of the General Food Law.

[52] These articles either refer to general objectives, risk analysis, precautionary principle, protection of consumer interests, public consultation and information.

[53] Art 14(8) of the General Food Law states that despite a food's conformity with specific provisions applicable to that food, the authorities must not be prevented from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal where reasons exist to suspect the food is unsafe. Art 17 (2) GFL prescribes for Member States to maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food safety and risk, food safety surveillance and other monitoring activities.

[54] Art 1(1) of the General Food Law.

[55] Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation), (OJ L 261 14.10.2019, p. 37) <http://data.europa.eu/eli/reg_impl/2019/1715/oj> (accessed 12 July 2023). The IMSOC Regulation provides for specific procedures for transmitting notifications and supplementary information for the Rapid Alert System for Food and Feed (RASFF), as required by the General Food Law.

and nutritional risks of foods.[56] In RASFF, incidents related to food contact materials are also reported, where those which relate to plastic materials and articles in contact with food per Commission Regulation (EU) No 10/2011 count among the most numerous.[57,58] A migration of a food contact material may present a food hazard (e.g. physical, chemical, biological) which triggers an obligation to adopt a measure, such as to withdraw or recall a food. The decision whether to recall or withdraw a food affected by a food contact material depends on whether the food has reached consumers and whether there are no other sufficient measures "to achieve a high level of health protection," that is, a necessity test.[59] However, it is evident from RASFF that some notifications concern exclusively food contact materials and not food per se. Also, cases of recalls can be noted.[60] It is, however, not possible to establish from the system's interface on which basis the authorities acted in specific cases concerning food contact materials.

This situation of unclear application of the GFL as regards food contact materials is also due to the fact that the FCM Regulation[61] does not make any reference to the GFL as regards withdrawal or recall obligations. The regulation also does not contain any specific provisions that would require competent authorities or operators to adopt measures in case materials or articles transfer their constituents to food in quantities that could endanger human health. The FCM Regulation, however, imposes specific obligations with respect to the traceability of materials and articles, which are intended to facilitate control, the recall of defective products, consumer information, and the attribution of responsibility.[62] Article 24 of the FCM Regulation prescribes Member States to carry out official controls in accordance with the relevant Union law. Currently, this is embodied in the Official Controls Regulation.[63] Article 138 of the Official Controls Regulation lists possible actions in a non-exhaustive fashion that competent authorities are authorised to take in the event of established non-compliance. The competent authorities take measures to ensure that the concerned operator rectifies the non-compliance and prevents further occurrences of such non-compliance. Such measures may include ordering the operator the recall, withdrawal, removal, and destruction of goods.[64]

This is similarly stated in Article 17 GFL concerning the responsibilities of Member States. However, in the GFL, recalls ordered by the authorities are subsidiary to those

[56] Frequently, the competent authorities respond to incidents reported in the RASFF involving food contact hazards, such as specific migration of an authorised substance above the limit specified in Annex I to Commission Regulation (EU) No 10/2011 by destroying non-compliant products or withdrawing them from the market. Notification 2022.3124 Migration of BFDGE in loaf pan from China via Greece, (RASFF Window, 31 August 2022) available at: <https://webgate.ec.europa.eu/rasff-window/screen/notification/548115>, (accessed 9 July 2023).

[57] For instance, in 2022, RASFF notified 70 incidents classified as "serious" risk concerning food contact material with causes often referring to the migration of chemicals (e.g. nickel, cadmium, lead, cobalt, phthalates) from cookware. RASFF Window, <https://webgate.ec.europa.eu/rasff-window/screen/search>, (accessed 31 December 2022).

[58] Commission Regulation (EU) No 10/2011 (supra, note 13).

[59] Art 19 of the General Food Law imposes an obligation on food business operators to recall products from consumers, if necessary and if other measures are not sufficient to achieve a high level of health protection.

[60] For example, from France <https://webgate.ec.europa.eu/rasff-window/screen/notification/651167 and https://rappel.conso.gouv.fr/fiche-rappel/2023-05-0081> (accessed 9 April 2024).

[61] Supra, note 23.

[62] Art 17(1) of the Food Contact Materials Regulation.

[63] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1–142, <http://data.europa.eu/eli/reg/2017/625/oj> (accessed 9 April 2024). The Official Controls Regulation applies to food contact materials by virtue of Art 1(2)(a).

[64] Official Controls Regulation, Art 138(2)(g).

carried out by FBOs[65,66] (i.e., when the FBOs do not start taking action by themselves or their action is not appropriate to the circumstances). The GFL does not contain an explicit provision that empowers the authorities to "impose" obligations or to "order" a recall, although they have this faculty, indirectly mentioned in Article 50(3)(a) GFL.[67] In the GFL, enforcement is a broad term that encompasses a "system of official controls and other activities," as well as measures and penalties that are "effective, proportionate and dissuasive."[68] Under this wording the GFL frames national and EU enforcement laws, providing a wide umbrella for competent authorities to organise or order recalls in case operators fail to take action to achieve a high level of protection. In fact, Articles 19, 17 and 14 GFL prioritise withdrawals or recalls initiated by food business operators over those mandated by competent authorities.[69] This is a different approach than the one explicitly permitted by the Official Controls Regulation.

In addition to the GFL provisions on recall, the Official Controls Regulation also contains provisions in this regard. Indeed, it is also noteworthy that the Official Controls Regulation prescribes a different test for measures, including recalls, which is based on the notions of "appropriateness," "nature of non-compliance" and operator's history with regard to compliance, compared to the one laid down in the GFL.[70] Although the nature of non-compliance may be a factor in the necessity test under the GFL, the nature of non-compliance alone does not imply that various measures need to be analysed and ranked according to their effectiveness. In other words, while the nature of the non-compliance may include hazard and risk characterisation, it does not imply that a recourse to recall is only possible where other means cannot achieve the same level of protection. Secondly, the history of the operator's actions in a situation of non-compliance is not mentioned in the GFL and the FCM Regulation. Furthermore, some measures that the competent authorities may take, such as the destruction of goods,[71] may be more severe than recalls from the perspective of operators. This consideration could also overhaul the necessity test in the GFL. It is, therefore, questionable whether Article 19(1) GFL should be or could be applied cumulatively to Article 138(1) of the Official Controls Regulation as regards food contact materials or whether the Official Controls Regulation functions as a *lex specialis* to Article 17(2) GFL as regards food contact materials but not as regards food in contact with hazardous food contact materials.

As for the second preliminary conclusion, despite EU food law comprising food contact materials, the necessity test applicable to recalls under the GFL would likely not be used for

[65] K Purnhagen and A Molitorisová, "Public and Private Enforcement in European Union Food Law" (2022) 13(3) European Journal of Risk Regulation 464, 476 <https://doi.org/10.1017/err.2021.59> (accessed 9 April 2024).

[66] Handling of the recalls under the GFL is supported by competent authorities who have an obligation to inform about a food's health risk, depending on the nature, seriousness and extent of that risk, including identifying to the fullest extent possible the measures taken or about to be taken per GFL, Art 10.

[67] Additionally, see Art 14(8) of the General food Law: "Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe."

[68] Art 17(2) of the General Food Law.

[69] Art 14(8) of the General Food Law states that despite a food's conformity with specific provisions applicable to that food, the authorities must not be prevented from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal where reasons exist to suspect the food is unsafe. Art 17 (2) of the General Food Law prescribes for Member States to maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food safety and risk, food safety surveillance and other monitoring activities.

[70] Art 138 of the Official Controls Regulation, establishes that, when deciding which measures to take, the competent authorities must take into account the nature of that non-compliance and the operator's past record with regard to compliance.

[71] However, destruction is not explicitly mentioned in the GFL as a remedial measure.

recalls of food contact materials. It would only be applicable where the food's safety is directly affected by the material in contact with that food. Such food can be withdrawn or recalled because of migration of a food contact material containing substances above the limits set by the Commission's implementing regulation. Instead of the GFL, the test under the Official Controls Regulation would likely apply as *lex specialis*, as a legal instrument to enforce provisions of the FCM Regulation. However, the Official Controls Regulation may be only applicable to enforce general requirements for the manufacture (and not use or placing on the market) of food contact materials[72] or specific measures adopted by the Commission for the groups of materials and articles listed in Annex I FCM Regulation.[73] This would also suggest that a recall of hazardous food contact material would not be considered *ultima ratio* but a more permissive test based on appropriateness, nature of non-compliance and operator's history. In the case of PFAS, this is tentatively supported also by the specific nature of the risk exerted by persistent pollutants, such as PFAS, which may typically materialise after the recall. If recalls are conceived as a last resort, the high level of health protection may not be guaranteed in light of the nature of the risk present in PFAS food contact materials. With a more permissive test, a recall may be justified upon the assumption of a continuous risk, increased by the passage of time and the use of food contact material. This may require the application of the precautionary principle to establish proper justification of the recall decision. Nonetheless, it is difficult to establish that the reference to the Official Control Regulation in the FCM Regulation is the vehicle for the enforcement of POP Regulation or REACH Regulation-based limits of substances used in food contact materials.

IV. Recalls in product safety and liability

1. Defective products

The FCM Regulation imposes traceability obligations on operators with respect to the "recall of defective products."[74] Nonetheless, this provision is the only place where the term "defective products" is used in that regulation, which leaves room for interpretation as to what constitutes a "defective" food contact material.[75] The GFL stipulates that the provisions of Chapter II "General Food Law" are without prejudice to Product Liability Directive.[76,77] This creates additional ambiguity in determining whether the legal framework for addressing non-compliant food contact material should be qualified as a food law (bearing in mind Recital 11 GFL and horizontal applicability of certain provisions) or as being part of the product safety regime. This lack of clarity is apparent in the reporting of incidents related to food contact materials in RASFF as well as the Rapid Alert System for Dangerous Non-Food Products (RAPEX).[78] RAPEX is a European database[79] that

[72] Art 3(1) of the Food Contact Materials Regulation.

[73] Ibid., Art 5(1).

[74] Art 17 of the Food Contact Materials Regulation.

[75] See the definition of a defective product under Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985, p. 29–33, <http://data.europa.eu/eli/dir/1985/374/oj>.

[76] See, supra, note 74.

[77] Art 21 of the General Food Law.

[78] For the definition and distinction between the two, see: "RAPEX/RASFF" (Università Cattolica del Sacro Cuore, ModaCult, Centro per lo studio della moda e della produzione culturale, n.a.) <https://centridiricerca.unicatt.it/modacult-r-s-t-rapex-rasff> (accessed 24 January 2024).

[79] Currently, RAPEX' abbreviated name has been changed into Safety Gate, which consists of three components: firstly, there's a swift alert system concerning hazardous non-food items allowing national authorities and the Commission to share information about these products (Safety Gate Rapid Alert System). Secondly, there's a web platform designed to inform the public and facilitate the submission of complaints

reports dangerous products, which come into contact with food and do not comply with the current General Product Safety Directive or any other sector specific regulation, notably with both REACH and POP Regulations.[80]

By virtue of Article 21 GFL, and the notion of "defective products" used by the FCM Regulation, the Product Liability Directive is applicable to the food law regime as well as to the general product safety regime. Article 6 of the Product Liability Directive considers a product as defective when it does not provide the safety a person is entitled to expect, taking into account, *inter alia*, the time when the product was put into circulation.[81] This invites multiple interpretations, one of which is hinted at in Article 7 of the Product Liability Directive.[82] Accordingly, producers may avoid liability by proving, for example, that the state of scientific and technical knowledge at the time could not have detected the defect, [83] including hazard and risk identification and characterisation. Notably, the Product Liability Directive applies solely to products that caused damage, rather than to products that exert risk.[84] Thus Article 6 of the Product Liability Directive, *ratione temporis*, provides for a limited scope of the notion of "defective product"; for this reason, neither the Product Liability Directive nor the FCM Regulation may be applicable in most cases, such as the present example of PFAS-containing cookware. Such a reading would however render the application of the Official Controls Regulation ineffective.

2. *Presumption of safety*

The scope of the notion of "defective product" under the Product Liability Directive can be contrasted with the presumption of safety of products under the General Product Safety Directive,[85] where a product is deemed to be safe if it complies with safety requirements set out by specific EU law.[86] The General Product Safety Directive introduced a broad

(Safety Gate Portal). Lastly, there's a web portal provided for businesses to fulfil their duty of informing authorities and consumers about unsafe products and incidents (Safety Business Gateway). See Recital 68 of the GPSR, infra note 108. See the official website of Safety Gate, 'Safety Gate: The EU Rapid Alert System for Dangerous Non-Food Products' <https://ec.europa.eu/safety-gate-alerts/screen/webReport> (accessed 02 February 2024).

[80] For example, muffin forms or cupcake paper that come in direct contact with food were recently reported to contain excessive amounts of PFOA, in violation of the POP Regulation. See "Safety Gate: The EU Rapid Alert System for Dangerous Non-Food Products," "Alert number: A12/01518/21, published on 12/11/2021 - Report-2021-45", accessible at: <https://ec.europa.eu/safety-gate-alerts/screen/webReport/alertDetail/10004572?lang=en> as well as "Alert number: A12/01289/22 Published on 16/09/2022 - Report-2022-37" <https://ec.europa.eu/safety-gate-alerts/screen/webReport/alertDetail/10006439?lang=en> (accessed 9 August 2023).

[81] The CJEU held that, for certain products, the safety level that the consumer is entitled to expect is to be considered particularly high due to the inherent function of the product, the vulnerability of the typical user and its abnormal potential for damage that the product presents (Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse* (C-503/13), *Betriebskrankenkasse RWE* (C-504/13), ECLI:EU:C:2015:148. (accessed 9 August 2023).

[82] However, the Product Liability Directive applies solely in the context of damage caused by a defective product that requires to be proven, together with the causal relationship between the defect and damage, by the injured party.

[83] Art 7(e) of the Product Liability Directive.

[84] Art 1 of the Product Liability Directive.

[85] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, (OJ L 011, 15.1.2002, p.4-17). This Directive's date of end of validity is 12 December 2024; since it has been repealed by Regulation (EU) 2023/988 (known as the General Product Safety Regulation), see infra, note 88.

[86] See on the distinct regime of the Product Liability Directive and the General Product Safety Directive H.-W. Micklitz, "Soft law, technical standards and European private law" in Mariolina Eliantonio, Emilia Korkea-aho and Ulrika Mörth (eds.), *Research Handbook on Soft Law* (Edward Elgar 2023), ch, 152 <https://doi.org/10.4337/9781839101939.00019>.

definition of a safe product[87] as a product which does not present any risk or only the minimum risk compatible with the product's use, considered to be acceptable with a high level of protection for the safety and health of persons (not the environment).[88] Both the presumption of safety of products as well as the concept of safe product remain the same under the recent General Product Safety Regulation (GPSR),[89] which will replace the General Product Safety Directive from 13 December 2024 onwards. Food has been explicitly excluded from the scope of the GPSR,[90] whereas food contact materials are explicitly covered by the regulation, insofar as risks concerned are not covered by the FCM Regulation or "by other food-specific legislation which only covers chemical and biological food-related risks."[91] If the FCM Regulation nor the GFL are applicable, as explained above, the GPSR applies to food contact materials. The new GPSR provides for some important changes to the product recall regime, including its applicability to products covered by EU harmonisation legislation "to the extent that there are no specific provisions with the same objective in such Union harmonisation legislation" (as a general clause).[92] One of the noteworthy features of the newly enacted GPSR in this sense is that it has empowered competent authorities to employ all appropriate measures in instances where evidence suggests that, despite the initial presumption, the product is dangerous.[93,94]

3. *Discretion of national competent authorities under the GPSR*

The GPSR therefore provides wide discretion to competent authorities to determine whether products are dangerous despite their conformity with the law in cases where products are suspected to be dangerous. The authorities may, for example, be considering evidence of hazards resulting from long-term exposure that goes directly against the standard to which a product conforms, as well as to consider a time dimension in the appreciation of "normal or reasonably foreseeable use" in the risk analysis. Under such considerations, a food contact material with long lifespan may change its characteristics over time;[95] for example, the propensity for migration of dangerous substances from the pan into the cooked food may increase. Such factors could pose an augmented risk

[87] Arts 2(b) and 3 of the General Product Safety Directive.

[88] One may recall here the bifurcation of the protection of health under the Food Contact Materials Regulation and the environment under REACH Regulation against hazardous food contact materials as explained above.

[89] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, (General Product Safety Regulation) OJ L 135, 23.5.2023, p. 1–51.

[90] Art 2(2)(b) of the General Product Safety Regulation.

[91] Recital 11 of the General Product Safety Regulation.

[92] Recital 8 of the General Product Safety Regulation.

[93] Art 7(3) of the General Product Safety Regulation.

[94] Under the old regime of the General Product Safety Directive, it had been the discretion of the respective competent national authorities to determine whether this safeguard mechanism was being triggered or not. As it had been made clear by the CJEU in *A.G.M. -COS.MET*, without the authorities' discretion to initiate the safeguard procedure, the presumption of safety prevails and no action for the protection of consumers can be justified. Extrapolating to recall obligations, there can be no recall obligations as long as authorities did not exercise their discretion in such a way as to initiate the safeguard procedure. The new GPSR empowers market surveillance authorities to go further than the initial safeguard procedure. Whether these new formulations will now also translate into an obligation of the market surveillance authorities to interfere, an action that had been rejected by the CJEU in A.G.M. -COS.MET, remains to be seen. The clearer, more unconditional wording and the fact that the instrument has turned from a directive into a regulation may lead the Court to be more willing to hear such arguments. Case C-470/03 *A.G.M.-COS.MET Srl v Suomen valtio and Tarmo Lehtinen*, ECLI:EU:C:2007:213. See also N Reich, "AGM-COS.MET or: who is protected by EC safety regulation?" (2008) 33(1) European Law Review 85, 100.

[95] Art 3(2) of the General Product Safety Regulation.

rendering the product "unsafe."[96] Statements such as "do not scratch" are often attached onto cookware packaging because scratching a frying pan is likely to increase exposure to PFAS substances.[97] Under the GPSR, any warnings and instructions for safe use of a product and disposal must be taken into account when assessing whether a product is safe.[98] Additionally, the GPSR contains a specific provision on the obligation to cooperate with market surveillance authorities, including to provide upon request a description of the risk presented by the product and any corrective measures taken to address that risk.[99] These considerations could have an important bearing on the assessment of safety of PFAS-containing food contact materials but it is difficult to predict in which way they would struck: whether, in a particular risk analysis, a warning on a food contact material is sufficient to lower a risk or, on the contrary, whether a particular warning is not susceptible to lower the risk.

4. *Market Surveillance Regulation as lex specialis?*

Currently, alongside the General Product Safety Directive, Regulation (EU) 2019/1020 on market surveillance and compliance of products[100] (Market Surveillance Regulation) also applies to the POP and REACH Regulations. Recital 5 suggests that Market Surveillance Regulation is *lex specialis* to the General Product Safety Directive as regards different measures authorities may take in relation to dangerous products. This could change with Recital 60 of the new GPSR, which brings the two instruments into line and strives to create a coherent legal framework for market surveillance of products, both covered and not covered by Union harmonisation legislation. That recital prescribes application of certain articles of the Market Surveillance Regulation to products covered by the GPSR.

These include various provisions concerning enforcement measures taken by the authorities or operators. For example, as for the authorities, they must take appropriate and proportionate measures where the operator fails to take a corrective action:[101] (a) they have the power to require operators to take appropriate action to bring an instance of non-compliance to an end or eliminate the risk presented by the product[102]; (b) they have the power to take appropriate action when an operator fails to take adequate corrective action or when non-compliance or risk persists[103], including the power to prohibit or restrict the marketing of a product or to order its withdrawal or recall.[104] Furthermore, a corrective action may include alerting the public to the risk presented, destroying the product or otherwise rendering it inoperable.[105] If a product presents a serious risk,[106] it must be withdrawn or recalled, where there are no other effective means available to

[96] Art 6 General Product Safety Directive or Art 3(2) of the General Product Safety Regulation.

[97] This may be a result of the requirement set in Art 15(1)(b) of the Food Contact Materials Regulation.

[98] Art 6 of the General Product Safety Regulation.

[99] Art 10 of the General Product Safety Regulation.

[100] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products, OJ L 169, 25.6.2019, p. 1–44.

[101] Art 11 of the Market Surveillance Regulation.

[102] See Art 3(19) of the Market Surveillance Regulation.

[103] "Non-compliance" and "risk" are understood as defined in Arts 3(7, 18) of the Market Surveillance Regulation.

[104] Art 14(4)(g) and (h) of the Market Surveillance Regulation.

[105] See also European Commission, Directorate-General for Justice and Consumers, "CASP 2020: Coordinated Activities on the Safety of Products: Recall Effectiveness", (European Union official website, Publications Office of the European Union, 2021), available at: <https://op.europa.eu/en/publication-detail/-/publication/e25e9f2d-4e68-11ec-91ac-01aa75ed71a1/language-en>

[106] Understanding "product posing a serious risk" as defined in Art 3(20) of Market Surveillance Regulation, considering "the combination of the probability of occurrence of a hazard causing harm and the degree of severity

eliminate the serious risk, or its marketisation must be prohibited.[107] Therefore, under the Market Surveillance Regulation, the recall obligation is subject to the interpretation of "seriousness" of a risk, that may entail such factors as health effects, the probability of effects materialising, the number of affected people and products, the estimated average product life, doses and the possibility of mix of substances to create "toxic cocktails."[108] Here, according to the new GPSR, serious risk is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate.[109] This phrasing may be read to render market surveillance authorities' discretion more favourably in support of an obligation to interfere.[110] Depending on the particular risk assessment, competent authorities may perceive PFAS-coated food contact material as highly risky and order its recall. Furthermore, the products that have been deemed to be dangerous on the basis of a decision of a market surveillance authority in one Member State shall be presumed dangerous by market surveillance authorities in other Member States. In case different Member States may reach divergent conclusions, divergent risk assessment may be now referred to the Commission by any Member State, requesting its opinion on the matter.[111] Under the GPSR, products presenting serious risks may also warrant a Union action implemented via implementing regulations of the Commission. Such an action may include any appropriate measure "adapted to the gravity and urgency of the situation" if the risk cannot be dealt with by other procedures laid down by the specific Union law applicable to the products concerned and can only be eliminated effectively by the adoption of such measures.[112]

As a third preliminary conclusion, a PFAS-coated food contact material would not become defective by virtue of setting concentration limits per the POP Regulation or REACH. It would be presumed to be safe per the General Product Safety Directive (soon Regulation). However, in the absence of the concentration limits or above such concentration limits, the product would not enjoy such presumption of safety. A PFAS-coated food contact material present, for example, in cookware could be considered not safe given new scientific evidence not yet incorporated in sector-specific legislation just as the POP Regulation or REACH. In that case, producers and distributors may organise recalls or be ordered to do so by competent authorities. As for the more specific measures available to competent authorities under the Market Surveillance Regulation, a recall of a product is linked to the assessment of seriousness of a risk exerted by the product. If competent authorities regard PFAS-coated food contact material as highly risky, they must consider its recall. Similarly, under the new GPSR, where a manufacturer considers or has reason to believe, on the basis of the information in their possession that a product which is placed on the market is a dangerous product, the manufacturer must immediately take a corrective action including recall, as appropriate.[113] This obligation is reinforced by the requirement placed on competent authorities to focus on the scrutiny of internal conformity procedures of the operators, in addition to traditional market surveillance

of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate."

[107] Art 19(1) of the Market Surveillance Regulation.

[108] See for example V Mustieles, JP Arrebola, and M Porta, "From old pollutants to the regulation of bisphenol A: Lessons learned for health promotion and disease prevention" (2023) 169 Preventive Medicine, ff107460 <https://doi.org/10.1016/j.ypmed.2023.107460>.

[109] GPSR, Art 3(5) of the General Product Safety Regulation.

[110] Supra, note 119.

[111] Art 29(1) and (2) of the General Product Safety Regulation. The Commission can also act upon its own initiative.

[112] Art 28(1) of the General Product Safety Regulation.

[113] Art 9(8)(a) of the General Product Safety Regulation.

activities,[114] as well as to take appropriate measures where the operator fails to take a corrective action.[115] There is no obvious hierarchy of action of an operator versus a competent authority similar to the GFL.[116]

V. Disposal of non-recalled cookware containing PFOA

Given that operators carry out a risk analysis internally and assess the level of "seriousness" and "necessity,"[117] the question arises as to what happens if the operators do not order the recall of the products and neither do the competent authorities. There is no immediate link between risk and action, but whatever action is taken, it must be with a view towards proportionality and effectiveness. In the event a product (e.g., a frying pan) is not recalled, only some of the consumers will eventually become aware of the health risks that may be associated with cooking in it.[118] As pointed out above: most of the obligations of both the actors in the supply chain (*ex* Articles 32, 33, and 34 REACH) and downstream users (*ex* Article 38 REACH) to provide information on substances and mixtures or substances in articles (e.g., frying pan containing a substance) cease to exist as soon as the product is made available to consumers. In addition, there is no obligation to inform consumers of all the chemicals present in the product often because of confidential industry information. However, the frying pan could contain a substance for which (1) the potential adverse effects are not yet known; or (2) the risks are known but the substance is present *below* the maximum concentration limits; or (3) the risks are known and the substance is present *above* the maximum concentration limits because the concentration limit was higher or did not exist at the time when the article was first placed on the market. That said, there is little chance that the consumer could reasonably know that the frying pan in their possession contains these substances and that using it could endanger their health. If the consumer comes to know of the frying pan's characteristics,[119] he or she can decide to dispose of the frying pan. As soon as the frying pan is discarded, it is considered waste and not a product, with corresponding changes in the applicable legal regime.

In the EU, Directive 2008/98/EC on waste[120] and POP Regulation,[121] among other legislation[122] regulate the disposal of food contact materials containing POPs. Directive 2008/98/EC, the Waste Framework Directive (WFD), is the main EU legislation regulating waste management. It aims to reduce waste, promote reuse, and recycle, with a view to

[114] Recital 64 of the General Product Safety Regulation.

[115] Infra, note 129.

[116] Art 4(3)(d) of the Market Surveillance Regulation.

[117] However, the operators' power of discretion is limited. For instance, there are some legal guidelines for considering risks in accordance with Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System "RAPEX" established in Directive 2001/95/EC on general product safety and its notification system (C(2018) 7334) DO L 73,15.3.2019, p. 121/187 (EN), Art 12. For example, see Section 2.3 for cumulative risks or Section 3.3 for consumer characterisation, par. 15–16 on "Frequency and duration of use," which seem of significant importance in relation to risk associated with the use of products like cookware.

[118] Although the consumer may not know the exact composition of the pan, there could be a hypothetical case where the consumer remembers buying the pan containing material "x", which was advertised as safe at the time of purchase, and which is banned after some time precisely because of the dangers of cooking in it.

[119] This could happen, for example, by exercising the consumer's right to request information on substances in articles under Art 33(2) REACH Regulation (Supra, note 37).

[120] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3–30.

[121] Supra, note 21.

[122] Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, OJ L 190, 12.7.2006, p. 1–98.

protect human health and environment, as well as to contribute to a circular economy,[123] and to the environmentally sound disposal of hazardous waste that is not to be reused.[124]

The WFD defines "waste" in Article 3(1) and distinguishes between "waste" and "hazardous waste." "Waste" is "any substance or object which the holder discards or intends or is required to discard." This concept has been widely interpreted by the CJEU, establishing criteria to determine whether a substance or object, including materials, is to be considered as waste.[125] The holder's behaviour is a key factor, leading to a distinction between *subjective* waste (voluntary disposal) and *objective* waste (compulsory disposal). Bearing this in mind, the concept of "intentionality" is crucial, as an item may be (still) considered a product or (already) waste, based on the holder's intention. However, intention depends on each individual case and its interpretation may differ from one Member State to another.

Imagine three houses next to each other on the same street, in each of which a frying pan is left in the garage. However, in house A, a family living there does so with the intention to throw it away as waste; in house B, a family intends to sell it later as a second-hand item; in house C, a family intends to keep using it again, however it does not fit in their small kitchen. This example illustrates that, given the same factual situation (leaving a frying pan in a garage), the intention of each of the families living in these three imaginary houses differs. In the light of such interpretative difficulties and factual conundrums, the CJEU emphasised that, in assessing whether a substance or object is waste, all the circumstances of the individual case must be considered, taking into account the objective of the WFD and being careful not to undermine its effectiveness.[126] Therefore, it will fall to the national judge to determine the real intention, for which a number of *indicia* exist,[127] but a unified definition lacks.[128] Similar factual situations may render different legal status for the same product. Returning to the imaginary case, the frying pan would still be considered a product of use in houses B and C, and as such would be subject to recall obligation. On the other hand, the frying pan would be considered as waste in house A, so the recall obligation would be extinguished and other obligations under waste legislation would arise.

[123] According to Art 1 Waste Framework Directive. For more information on the EU Circular Economy Action Plan, please see: Commission, Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A new Circular Economy Action Plan for a Cleaner and more Competitive Europe COM/2020/98 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN>, (accessed 24 June 2023).

[124] Although, according to G Van Calster, the "Union law does not, as a matter of principle, exclude the possibility that hazardous waste may cease to be waste within the meaning of Directive 2008/98 if '*a recovery operation enables it to be made usable without endangering human health or harming the environment and, also, if it is not found that the holder of the object at issue discards it or intends or intends or is required to discard it*'" (Case C-358/11, *Lapin elinkeino,* ECLI:EU:C:2013:142). In Van Calster *EU Waste Law* (2nd edn., Oxford 2015), p. 88. Therefore, hazardous waste could be recovered and returned as products. This is in line with Art 7 of the POPs Regulation. Infra, p. 19.

[125] Case C-629/19, *Sappi Austria Produktions-GmbH & Co KG and Wasserverband, Region Gratkorn-Gratwein' v Landeshauptmann von Steiermark.* ECLI:EU:C:2020:824, par. 42–53; Case C-624/17, *Criminal proceedings against Tronex BV*. ECLI:EU:C:2019:564, par. 17–25; Case C-188/07, *Commune de Mesquer v Total France SA and Total International Ltd.* ECLI:EU:C:2008:359, par. 41; Case C-113/12, *Donal Brady v Environmental Protection Agency.* ECLI:EU:C:2013:627, par. 40–41.

[126] Case C-624/17, *Tronex Case*, par. 20 (see ibid).

[127] For example, it will be taken into account whether it is a production or consumption residue and whether it has lost its utility, so that it could represent a burden which the holder might reasonably wish to discard (*Sappi*, paras 46 and 49; *Tronex*, para 22; *Commune de Mesquer*, para 41; *Brady*, para 40). See supra, note 124.

[128] Art 3(1) of the Waste Framework Directive.

Once the frying pan is considered as waste, its subsequent treatment depends on its classification. If the frying pan contains PFOS it could be considered as hazardous waste.[129] This includes waste that contains one or more substances toxic to reproduction at or above one of the concentration limits listed in Table 7 of Annex III of the WFD. Since PFOS, a class of PFAS is classified as Repr. 1B in Annex VI of the CLP Regulation,[130] a frying pan containing PFOS could be legally considered as hazardous waste, but not necessarily.

It follows from the above that in the case of a food contact material such as a frying pan containing in particular PFOS, the general waste rules apply if the limit values in Table 7 are not equalled nor exceeded. In case such limit values are equalled or exceeded, Article 2(4) of the WFD allows for specific rules on the management of particular waste categories. This leads to the application of Article 1 of the POP Regulation, which stipulates specific provisions for waste consisting of, containing, or contaminated by POPs. On the other hand, two specific rules may concurrently apply, as illustrated by the recent Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with food which applies exclusively to recycled plastic.[131] A collision between regulations could occur if packaging made from recycled plastic contains or is contaminated with a substance identified as a POP.[132] To make things more entangled, a proposal for a regulation on packaging and packaging waste as currently debated in the legislative process proposes to prohibit any food contact packaging containing intentionally added PFAS from being placed on the market 18 months from the date of entry into force of the regulation, as a matter of a *lex specialis*.[133] Considering that a frying pan is usually made of aluminium, steel, iron or copper, it may be also considered "municipal waste,"[134] which definition includes mixed waste and separately collected waste from households, including paper and cardboard, glass, *metals*, plastics, bio-waste, wood, textiles, packaging, etc.[135] Thus, PFOS-containing frying pans could be considered at the same time both "municipal waste," as well as "hazardous waste." As a result, the way in which this waste is disposed of, collected, and further treated will be determined by these classifications.

[129] Art 3(1) of the Waste Framework Directive defines "hazardous waste" as the "waste which displays one or more of the hazardous properties listed in Annex III" of this Directive, including the category of "toxic for reproduction." The category of "toxic for reproduction" is defined as "waste which has adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring," according to the wording of Annex III of the Waste Framework Directive.

[130] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJ L 353, 31.12.2008, p. 1–1355 (EN).

[131] Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, OJ L 243, 20.9.2022, p. 3–46 (EN). This recent regulation is one of the measures promoted within the framework of the New Circular Economy Action Plan (CEAP), European Parliament resolution of 10 February 2021, (2020/2077(INI)) OJ C 465, 17.11.2021, p. 11–29 (EN).

[132] H D. Whitehead and G F. Peaslee, "Directly Fluorinated Containers as a Source of Perfluoroalkyl Carboxylic Acids" (2023) 10 (4) Environmental Science & Technology Letters 350–355 <https://doi.org/10.1021/acs.estlett.3c00083>, (accessed 21 July 2023) pointed to the presence of PFAS in food contact materials and concluded that "[b]ased on the large number of applications where directly fluorinated containers find use, the observation of PFAS migration suggests use regulations are warranted, and future studies should explore their fate when disposed or recycled."

[133] Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, COM(2022) 677 final. See <https://www.europarl.europa.eu/doceo/document/TA-9-2023-0425_EN.html> (accessed 10 March 2023).

[134] Art 3(2) of the Waste Framework Directive.

[135] For more information, see Commission, Separate Collection of Household Hazardous Waste (Notice) 2020/C 375/01 C/2020/7473, OJ C 375, 6.11.2020, p. 1–24 (EN): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC1106(01)> (accessed 10 March 2023).

In terms of how and where to dispose of a frying pan, consumers need to locate the nearest waste facilities. These are places where appropriate procedures should be in place to manage incoming hazardous waste. In relation to how the frying pan is collected and treated is in the hands of the various waste management operators, their task also seems to be challenging, because the difficulty of traceability remains at this stage. However, it is important for them to know whether the waste in question is hazardous, because depending on this classification, the waste must be treated in a special way.[136] On this point, the POP Regulation lays down specific requirements for the management and disposal of POPs. Notably, Article 7 outlines the conditions for waste management in connection with Annexes I, IV and V, all of which include PFOS. The Article lists several requirements for the disposal of waste containing or contaminated with POPs, with an emphasis on disposal or recovery operations that ensure the destruction or irreversibly transformation so that the remaining waste and releases do not exhibit the characteristics of POPs.[137]

Under Article 20(1) of the WFD, EU Member States are required to set up a separate collection scheme for household hazardous waste fractions by 2025. This provision aims to ensure proper treatment in accordance with the waste hierarchy (Article 4) and to protect human health and the environment (Article 13) while preventing contamination of other municipal waste streams. Irrespective of whether this new scheme is established, its practical feasibility will probably be hindered by the persisting problem of traceability, which is likely to continue to challenge the performance of waste management.

As a fourth preliminary conclusion, non-recalled products that become waste and are considered hazardous waste due to their reprotoxic properties, as well as products of household origin, need to be managed and disposed of in an environmentally sound manner. For this purpose, the Member States must take measures to encourage the options that deliver the best[138] overall environmental outcome.[139] However, the current labelling and identification regime for these products represents an impediment in terms of traceability, which could hinder both corrective actions, in the event of an effective consumer recall when the item was still a product, and waste management once the item has already become waste. This ultimately puts the environment and consumers at risk, calling into question the regulatory effectiveness of these various EU regulations, which have as their primary self-proclaimed objective the protection of the environment and human health.[140]

[136] On this regard, please visit Commission Notice on Separate Collection of Household Hazardous Waste (ibid) (accessed 7 August 2023). This Commission note is addressed to Member States' authorities at all levels, with the purpose of facilitating their task of implementing the separate collection system in accordance with the obligation set out in Art 20(1) of the Waste Framework Directive.

[137] Art 7 of the Persistent Organic Pollutants Regulation also prohibits operations that may result in the recovery, recycling, reclamation, or re-use of POPs. In exceptional cases, however, waste containing or contaminated by POPs may be dealt with in a different manner if certain conditions are met, such as demonstrating that decontamination or destruction of the POP content is not feasible and obtaining authorisation from the competent authority. Art 7 also allows for the adoption of implementing acts by the Commission to specify the format of information to be submitted by Member States in relation to such exceptional cases.

[138] Achieving the "best overall environmental outcome" will depend on an array of circumstances. Art 12 of the Waste Framework Directive establishes that Member States shall ensure that, where recovery is not undertaken, waste undergoes safe disposal operations, meeting the provisions of the following article. Art 13 WFD establishes provisions with the aim of protecting human health and the environment.

[139] See Art 4(2) of the Waste Framework Directive.

[140] See Art 1 of the Waste Framework Directive; Art 1(1) of the CLP Regulation; and Art 1(1) of the REACH Regulation.

VI. Economics and effectiveness of recalls and waste collection

One of the key questions in the context of recalls is whether a recall is effective, i.e. whether recalls successfully remove potentially harmful or defective products from the consumer's use. Once having eventually overcome the difficulty in establishing the obligation to recall, the next obstacle is to enforce it. The crucial question to be asked by competent authorities revolves around the feasibility of recalling potentially millions of food contact articles, such as cookware, from the EU market.[141] In case of a theoretical recall obligation of historical articles containing food contact materials surpassing current PFOA (or other PFAS) limits, effectiveness could be measured by the current level of consumer awareness and participation in a recall (through actual return rates); risk perceptions of the recalled product (e.g. from the number of customer complaints); level of awareness about the recall among other businesses in the supply chain, including online platforms; or levels of safe reworking/destruction.[142]

However, effectively conveying information to consumers can be challenging, especially in the case of PFAS-coated cookware. Challenges include ensuring that consumers know that the information provided relates to the products they own. This is exacerbated by difficulties in identifying and tracing the product in violation of Article 17 FCM Regulation.[143] Such difficulties are linked to the practice of businesses to frame the information provided on cookware's labelling in negative (e.g., "PFOA-free") rather than positive terms (e.g., "This product contains PFAS"). Furthermore, the traceability information is usually included on the packaging, as the FCM Regulation provides a choice as to where to attach the mandatory information,[144] and it is reasonable to assume that consumers discard the packaging shortly after the purchase. To avoid this difficulty, warning labels or improved instructions of safe use can be added to the product.[145] It may be also remembered that REACH gives consumers certain rights, such as to ask the operator about the information concerning the safe use of the product.[146] Moreover, per Article 11 POP Regulation, the Commission, ECHA[147] and Member States are mandated to

[141] Historically, this has been often juxtaposed with the issue of standard setting. In the history of automobile safety regulation, for example, rules and recalls were seen not as complementary but as exclusive, and the regulator's shift from rules to recalls represented a new safety strategy. Today those rules and recalls are employed side by side, including in the case of food contact materials. See J Mashaw and D Harfst, *The Struggle for Auto Safety*. (Harvard University Press, 1990).

[142] European Commission, "Coordinated Activities on the Safety of Products. Recall Effectiveness: protecting European consumers together" (CASP 2020) <https://op.europa.eu/en/publication-detail/-/publication/e25e9f2d-4e68-11ec-91ac-01aa75ed71a1> (accessed 7 August 2023).

[143] Art 17(1) of the Food Contact Materials Regulation.

[144] Art 15(7) of the Food Contact Materials Regulation. Under the new General Product Safety Regulation, manufacturers must ensure that their products bear a type, batch or serial number or other element enabling the identification of the product and which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

[145] Section 4 of the Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System "RAPEX" established under Art 12 of Directive 2001/95/EC on general product safety and its notification system, (C(2018) 7334) OJ L 73, 15.3.2019, p. 121–187 (EN) (accessed 7 August 2023).

[146] See Art 33(2) of REACH Regulation. As Pape puts it: "[T]he explanation of having a 'right to know' relates to the explanation of autonomy and informed choice and subsequently to the main rationale, because just such a right allows people to make choices about self-protection." S.B. Pape; *Warnings and product liability Lessons learned from cognitive psychology and ergonomics* (Eleven International Publishing 2011), p. 289. See also smart solutions supporting consumers in exercising their rights, J Schenten et al. "Breathing life into consumer rights: smartphone tools facilitating the 'right to know' on substances of very high concern in REACH articles." (2020) 32 Environmental Science Europe 114 <https://doi.org/10.1186/s12302-020-00387-6>, (accessed 9 August 2023).

[147] European Chemicals Agency's official website, <https://echa.europa.eu/es/home> (accessed 9 August 2023).

promote awareness programmes for regulated substances, such as PFOA, targeting policy- and decision-makers and particularly vulnerable groups. Notably, although there is an emphasis on promoting the provision of information to the public,[148] the POPs Regulation does not explicitly mention the "right to information"[149] as the REACH Regulation. Another possibility is to provide consumers with information that certain products exceed newly established PFAS levels, although, as a matter of law, the set levels apply only to the products not yet marketed. But even with this information, it may be nearly impossible for consumers to determine whether their product is part of the batch affected by the risk in question. In this regard, it may be noteworthy that the GPSR states in its recitals that "the information about the identification of the product and of the economic operators, as well as instructions and safety information, could in addition be provided by the economic operators in a digital form by means of electronic solutions, such as a QR or data matrix code."[150] Such requirements "could be made stricter" in the case of products likely to present a serious risk "by [implementing] a system of collection and storage of data enabling the identification of the product's components,[151] although it is hardly conceivable how this could be perfected without the a priori knowledge of such risk at the time of the production. With that information, it would also be possible to carry out "targeted recalls."[152] However, the problem of product information vis-à-vis emerging new risks and risks in certain grey zones, i.e. awaiting regulatory action due to the emerging body of evidence as to their gravity, remains. In order to improve recall effectiveness even further, "consumers should be encouraged to register products" in order to be directly notified about recalls, and the Commission is supposed to adopt implementing acts to that purpose; however, given their lifecycle, it is likely that food contact materials will constitute a category of products for which such a requirement is installed.[153]

A recall involves considerable economic costs. The cost distribution will affect the risk aversion of producers or other supply chain actors putting products into circulation. In this respect, the GPSR highlights that operators have differentiated responsibilities depending on the role they play in the supply chain.[154] Economic operators initiating a product recall are expected to offer consumers at least two options between repair, replacement, or adequate refund of the value of the recalled product, except where impossible or disproportionate.'[155] Remedies offered must be effective, cost-free and timely, without a time limitation to activate the remedy.[156] In the case of food contact materials, replacement or adequate refund could be only two options realistically considered. These could be coupled with additional incentives to motivate consumers to participate in a recall, such as vouchers, discounts, or complementary products. While the regulation reasons that, "offering consumers a choice between remedies can improve the effectiveness of a recall,"[157] it could be subject to interesting behavioural research whether consumers would opt for PFAS-free cookware from the same producer or a refund.[158] Recalls could benefit the food business

[148] This is not only derived from Art 11 of the Persistent Organic Pollutants Regulation, but also its Recital 22 mentions that "[t]he Union should ensure access to information."

[149] In any case, as far as business information to consumers is concerned, in the absence of provisions on specific acts, the General Product Safety Directive (Art 2 Directive 2001/95/EC) applies, which recognises the obligation of producers to inform consumers. The Directive was repealed by Regulation 2023/988, cf. Art 9(2)(b) of the GDPR.

[150] Recital 32 of the General Product Safety Regulation.

[151] Recital 42 of the General Product Safety Regulation.

[152] Ibid.

[153] Recital 86 of the General Product Safety Regulation.

[154] See for example Recitals 32 and 38 of the General Product Safety Regulation.

[155] Recital 91 of the General Product Safety Regulation.

[156] Art 37 of the General Product Safety Regulation.

[157] According to the Recital 91 of the General Product Safety Regulation.

[158] For example, market dynamics surrounding the "risky" product can make it easier for consumers equipped with the information to replace the product with another from another operator.

operator's reputation by demonstrating their responsibility to consumers.[159] If consumers largely stick with the operator's brand, a recall could be beneficial to the operator's reputation. Marketing measures may therefore complement the recall obligations and soothe its economic (reputational) impacts. Also, recalls could be incentivised by economic subventions if replacements can be shown to be free of risks.[160] Such subventions could align the precautionary principle with the support for innovation, offering precautionary consumer protection while providing a means of introducing new (higher quality) products to the market.[161]Also, customers are affected due to trust issues and economic considerations potentially resulting in participation as well as non-participation in the recall.[162] Therefore, remedies offered in case of recalls cannot place an excessive burden on consumers.[163] According to the new GPSR, it is best to contact the affected consumers directly, and operators must, "use any customer data already at their disposal to inform consumers of recalls and safety warnings."[164] However, consumers must agree to such contact before, either at the time of the purchase or entering into a loyalty programme. Therefore, despite targeted recalls, operators should make all their customers aware of the recall notice.[165] Moreover, the effectiveness of a recall may depend on the share of the cost of the recalled product in the average household income. If the recalled product costs only a small fraction of a consumer's monthly income, it could make it difficult for the consumer to cooperate in the recall of the product, as substituting the product with a new purchase would be the preferred option. Also, if a consumer needs to invest a significant time and resources to participate in the recall (i.e., finding out how, where and when, placing the recalled product, collecting the replacement, etc.), he or she may tend to just purchase a new product and dispose of the old one. On the other hand, if the recalled product costs a significant fraction of a consumer's monthly income, this could make it difficult for the consumer to cooperate in the recall of the product, if a replacement product is not provided. This could presumably be exacerbated by the fact that, according to behavioural economics, consumers appear to have an emotional attachment to products they already own.[166]

However, the question is also one of who is responsible for acting in the event of risk present in a food contact material. If authorities are mandated to intervene, initially by ensuring compliance from operators and subsequently by implementing their own measures, it prompts further questions on whom (which operators) they impose

[159] N Smith "Food Labelling Issues and Trends in Europe: Lessons for US and European Practitioners from Recent Allergen Recalls" (2018) 33(1) Natural Resources & Environment 40, 44.

[160] The current proposal to regulate PFAS, particularly the one concerning consumer cookware, notices that "there is sufficiently strong evidence that technically and economically feasible alternatives are widely available on the market. These include 'ceramic' coatings, anodised aluminium and stainless steel." ECHA, Annex XV Restriction Report; Proposal for a Restriction [on Per- and polyfluoroalkyl substances (PFASs)] (2023, p. 87) <https://www.seaj.or.jp/activity/kankyo/file/8d57c56ca0703f1985caf61361ae685dfc8efb96.pdf> (accessed 9 July 2023).

[161] For more information on the innovation principle, visit European Commission's official websavailable atte, Research and innovation, "Ensuring EU legislation supports innovation": <https://research-and-innovation.ec.europa.eu/law-and-regulations/ensuring-eu-legislation-supports-innovation_en> (accessed 9 July 2023).

[162] Recital 87 of the General Product Safety Regulation notes: "One-third of consumers continue to use dangerous products despite seeing a recall notice, particularly because recall notices are drafted in a complex way or minimise the risk at stake. The recall notice should therefore be clear, transparent and clearly describe the risk at stake, avoiding any terms, expressions or other elements that may decrease consumers' perception of the risk. Consumers should also be able to get more information, if needed, through a toll-free telephone number or other interactive instrument."

[163] Recital 92 of the General Product Safety Regulation.

[164] Recital 85 of the General Product Safety Regulation.

[165] Ibid.

[166] More information can be found under the concept "endowment effect." See, e.g., Kahneman, Knetsch, and R. H. Thaler "Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias." (1991) 5(1) Journal of Economic Perspectives193, 206. <https://doi.org/10.1257/jep.5.1.193> (accessed December 2022).

corrective measures. An obvious answer would be on operators who violated a general requirement not to place on the market a dangerous product, i.e. persons who brought the product into circulation. If however such persons are no longer existing, such obligations remain unenforceable. Consequently, competent authorities may take charge by orchestrating recalls, running information campaigns, ordering retailers to retrieve recalled products for compensation and even providing compensation directly to consumers themselves. However, one may query whether these actions resemble more policy interventions rather than corrective measures outlined in the Market Surveillance Regulation or the GPSR. The challenges related to traceability and the considerable costs with organising recalls, particularly of cookware tainted with toxic PFAS raise significant doubts about the feasibility of such recalls in that context.

Therefore, where recall serves as a last resort, there may be alternative corrective actions available.[167] One must be also mindful of the opportunity costs of using resources for a recall rather than other activities that may yield better health or environmental outcomes, e.g. consumer information campaigns, pricing, and subvention strategies that incentivise consumers to buy new products without health risks, such as PFAS-free pans, or swap old cookware for new one. In order to fully assess the effectiveness of recalls, the costs and benefits of recalls coupled with a disposal of the recalled product as a remedy should be weighed against any costs and benefits associated with a system of waste collection of hazardous products that would normally be recalled, yet, are now subject to special waste treatment. In the case of PFAS, an inspiration for analysis can be found in the EU rules on treating waste electrical and electronic equipment.[168] Furthermore, it must be acknowledged that generic risk assessment opens way to imposing restrictions on many thousands of substances, potentially affecting millions of products simultaneously.[169] If such a restriction would not exclude its applicability to the products already marketed, it is important to revisit the question of the feasibility of potential recall of dangerous food contact materials. A potential answer could be found in prioritising Union action concerning seriously dangerous products per Article 28 of the GPSR.

VII. Conclusion

The POP Regulation serves as the fundamental standard for regulating PFAS. Concerning food contact materials, EU food law can only trigger recalls under the GFL if the safety of the food is directly impacted by the material in contact with it. Instead of relying on the GFL, the Official Controls Regulation would likely apply as the *lex specialis*, functioning as a legal instrument for enforcing provisions outlined in the POP Regulation or REACH. Consequently, a recall of PFAS-containing food contact materials would not be viewed as a last resort, but rather as a more permissive measure based on appropriateness, the nature of non-compliance, and the operator's track record.

However, if recalls are perceived as a last resort, the level of health protection may not be adequately guaranteed, especially considering the inherent risks associated with food contact materials, such as those posed by PFAS. Specifically, these risks often manifest after the recall, assuming a continuous and increasing risk over time with the

[167] See A Newstead, European Overview, ch in: J Harmon, A Newstead, D Ross (eds.), "Product Recall" (9th ed., Law Business Research Ltd 2017) pp. 7–11.

[168] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE), OJ L 197, 24.7.2012, p. 38–71.

[169] L Zimmermann et al. "Implementing the EU Chemicals Strategy for Sustainability: The case of food contact chemicals of concern." (2022) 437 Journal of Hazardous Materials 129167 <https://doi.org/10.1016/j.jhazmat.2022.129167>.

continued use of the food contact material. In such cases, the precautionary principle may need to be invoked under the necessity test to justify the recall decision properly.

Setting concentration limits per the POP Regulation or REACH would not render a PFAS-coated food contact material defective. It would still be presumed safe under the General Product Safety Directive. However, in the absence of concentration limits, this presumption of safety would not apply. For instance, a PFAS-coated food contact material, like that found in cookware, might be deemed unsafe due to new scientific evidence not yet incorporated into sector-specific legislation like the POP Regulation or REACH. In such instances, under the Market Surveillance Regulation, producers and distributors may initiate recalls or be mandated to do so by competent authorities, but only as resorted to the risk is serious enough.

It is worth noting that the POP Regulation restricts the application of PFOA limits to articles already on the market, creating a presumption of the safety based on temporal limitations. Nevertheless, this presumption of safety can pose problems, as exemplified by PFOA frying pans. It fails to adapt to evolving scientific knowledge and can jeopardise public health and the environment. Moreover, it is crucial to underscore that different pieces of legislation, such as the POP Regulation and REACH, may adopt distinct approaches to articles already in circulation. If PFAS are addressed under REACH, measures can be implemented to prohibit the use of articles containing PFAS, not just the use of the substances in articles going forward. As for the current state of the FCM Regulation, it lacks meaningful provisions for regulating recalls or PFAS used in food contact materials.

Although setting concentration limits per the POP Regulation or REACH would not render a PFAS-coated food contact material defective, it may render it hazardous once a product becomes waste. Consequently, the applicable legislation changes as well. Several pieces of EU legislation ensure that products classified as hazardous waste, due to their reprotoxic properties or originating from households, are managed and disposed of in an environmentally responsible manner. Article 4(2) of the WFD mandates Member States to promote options that yield the best overall environmental outcome. This results in the paradoxical situation that millions of products containing PFAS enter a grey zone, whereas they are left to free circulation due to the temporal limitations of newly established maximum concentration limits, yet with the mere intention of a consumer to dispose of such products, they would be considered hazardous. However, Member States cannot recall anything considered waste, even hazardous. This situation ultimately jeopardises the environment and consumer safety, casting doubt on the regulatory effectiveness of these various EU regulations, which profess to prioritise environmental and human health protection.

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