Breast Cancer UK comments on the European Commission's public consultation on Food Contact Materials

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1. About Breast Cancer UK

Breast Cancer UK's mission is to prevent breast cancer through scientific research, collaboration, education and policy change. We are dedicated to the prevention of breast cancer by reducing public exposure to the carcinogenic, hazardous and endocrine disrupting chemicals routinely found in the environment and everyday products.

2. Overview

Breast Cancer UK welcomes the opportunity to comment on the European Commission's evaluation of EU Legislation on Food Contact Materials (FCMs). We believe that the EU's legislative framework for FCMs is not fit for purpose and requires a radical overhaul to fulfil its objective of providing "a basis for securing a high level of protection of human health in the interests of consumers"[1]. We are disappointed that the Commission has failed to regularly review and take action to improve the effectiveness of FCM legislation, given its public health implications, particularly with regards to Breast Cancer risk.

The EU must develop a harmonised set of rules and regulations for the chemicals within FCMs and prohibit Substances of Very High Concern (SVHC) and Endocrine Disrupting Chemicals (EDCs). We continue to work with our EU partners to press for a more robust regulatory environment for FCMs, promoting the phasing out of carcinogenic or otherwise hazardous chemicals and their replacement with safer alternatives.

The remainder of this paper first focuses on identifying the gaps within the current regulatory framework which make it unfit for purpose, then provides specific proposals for the prohibition or reduction in the use of certain chemicals in FCMs, and finally proposes a set of 5 principles which we believe the next EU Commission should adopt through its evaluation of FCM legislation.

3. Gaps within The EU's Regulatory Framework

The EU's REACH Regulation currently exempts the consideration of the impact on human health of chemicals in FCMs from chemical safety reports and authorisation. Instead, the legislative framework for FCMs is governed by specific food contact regulations:

- The EU Framework Regulation EC 1935/2004 "on materials and articles intended to come in contact with food"[2].
- The EU Regulation on Good Manufacturing Practices for materials and articles intended to come in contact with food (EC) 2023/2006[3].

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[1] European Commission (2004) '*Regulation (EC) No 1935/2003 of the European Parliament and of the Council*' available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02004R1935-20090807&from=EN (Accessed 1st May 2019)

[2] European Parliament (2016) '*Food Contact Materials- Regulation (EC) 1935/2004*' available at: http://www.europarl.europa.eu/RegData/etudes/STUD/2016/581411/EPRS_STU(2016)581411_EN.pdf (Accessed 1st May 2019)

[3] European Commission (2016) '*Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food*' available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R2023 (Accessed: 1st May 2019)

These regulations cover materials and articles intended to come into contact with foods, and which are used within food processing, storage and packaging. These also include materials and articles in contact with liquids for human consumption. The purpose of these regulations is to secure a high level of protection of human health and ensure that migrating chemicals do not enter food in quantities which pose substantial risks to public health. In practice however, this legislative framework fails to fulfil these objectives due to the regulatory gaps noted below.

3.1 The Majority of FCMs are not covered

Whilst these measures provide a foundation for comprehensive EU action on FCMs, there are no EU-wide rules covering all the various chemicals contained within FCMs. Specifically, only 5 of the 17 different types of FCMs are regulated, including plastics and ceramics, which means that other FCMs such as ink, coatings & adhesives are not regulated. As a consequence, countries such as France and Denmark have adopted their own approaches to address these shortfalls, leaving the majority of member states and their consumers without specific legislation in place for FCMs containing hazardous chemicals[4].

These regulatory gaps in EU and national law mean that industry must conform to the general safety requirements in the framework regulation and determine for themselves which methods to use for conducting safety assessments and setting migration levels. Breast Cancer UK calls on the EU to introduce specific legislation covering all types of FCMs and not to rely on a system of mutual recognition to uphold a high level of human protection, including the mitigation of Breast Cancer risk.

3.2 Non-Intentionally added substances are not assessed

Non-Intentionally added substances (NIAS) are chemicals that are present within FCMs but not added, for technical reasons, during the food production process. Current legislation requires that NIAS are put through a risk assessment, however many are unidentified and detailed guidance on how companies should conduct such assessments is not defined[5]. As a result, many chemicals with potential implications for human health are not assessed by public authorities. Breast Cancer UK calls on the EU to legislate to initiate risk assessments of mixtures, revise established safe migration levels and require testing of finished food contact articles.

3.3 Harmful Chemicals are overlooked

Chemicals, whose harmful impact has already led to their usage being phased out under REACH, remain permitted within FCMs. An estimated 58 chemicals, recognised as SVHC, are authorised within FCMs[6]. This includes chemicals with links to cancer and those with other harmful properties such as hormone disruption. As the number of SVHCs grows so does the number of harmful chemicals within FCMs. This enhances consumers' exposure and contradicts the overarching principles of REACH to protect public health. Breast Cancer UK calls for improved safety measures within REACH and assurances that all SVHCs will be phased out from FCMs as part of a new EU regulatory framework.

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[4] European Commission (2016) '*Non-harmonised food contact materials in the EU: regulatory and market situation: Baseline Study: Final report' available at:* https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study (Accessed 1st May 2019)

[5] ChemTrust (2016) '*Chemicals in food contact materials: A gap in the internal market, a failure in public protection'* available at: https://www.chemtrust.org/wp-content/uploads/chemtrust-foodcontactchemicals.pdf (Accessed 1st May 2019)

[6] HEAL (2016) '*Food Contact Materials and Chemical Contamination'* available at: https://www.env-health.org/food-contact-materials-and-chemical-contamination/ (Accessed 1st May 2019)

3.4 Endocrine Disrupting Chemicals are not addressed

The presence of EDCs within FCMs is a cause for great concern. Numerous scientific studies have associated these chemicals with hormonal cancers, including breast, prostate and testicular cancer[7]. Despite this, the majority of chemicals in FCMs have not been tested for their endocrine disrupting properties. Furthermore, few of these chemicals are subject to the REACH authorisation procedure. Present testing methods are inconsistent and the associated requirements for timings, doses, extrapolations are completely inadequate as they only touch upon the broad range of hormone disrupting effects. Breast Cancer UK calls for EDCs to be prohibited across FCMs, with associated dates and targets defined for all material types. For more information please see our background briefing on EDCs.

4. Health Concerns associated with specific chemicals

To date, chemicals, hazardous to human health, are present in plastics and other materials that come in contact with food. These chemicals include substances which may cause cancer, disrupt the endocrine system, affect DNA, harm reproduction, do not break down in the environment, and are capable of building up in humans and animals[8]. These chemicals can be absorbed or migrate into food from FCMs and accordingly into the human body. Below we highlight our specific concerns with regards to certain chemicals which are known to be present within FCMs[9] and may be associated with breast cancer risk [10].

4.1 Bisphenol A and bisphenol substitutes

Bisphenol A (BPA) is an EDC which mimics the female hormone, oestrogen. As well as being linked to breast cancer it may also be linked to obesity, heart disease and cardiovascular problems. BPA is used in polycarbonate plastic food and drink packaging – microwave ovenware, storage containers, water and milk bottles and cutlery. It is also used in epoxy resins that line certain metal cans of food and drink. There is sufficient evidence to suggest that dietary exposure is the main route of human exposure to BPA[11].

In March 2011, the EU banned the use of BPA in baby bottles due to its adverse effect on human health[12]. In 2015, France took unilateral action to ban the use of BPA in all food and drinks packaging and utensils intended to come in contact with food[13]. In 2016, the Commission agreed to classify BPA as an SVHC due to its classification as a category 1b presumed reproductive toxicant, which can adversely affect the human

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[7] IPCS (2002*) 'Global assessment of the state-of-the-science of endocrine disruptors*' Geneva, Switzerland, World Health Organization, International Programme on Chemical Safety, available at: http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/ [Accessed 1st May 2019)

[8] EEA (2012) '*Technical Report No 2/2012: The impacts of endocrine disrupters on wildlife, people and their environments The Weybridge+15 (1996–2011) report'* available at: https://www.eea.europa.eu/publications/the-impacts-of-endocrine-disrupters (Assessed 2nd May 2019)

[9] Danish Consumer Council (2015) '*Paper and board food packaging contains endocrine active chemicals'* available at: http://www.food.dtu.dk/english/News/Nyhed?id=FABD19E8-B58C-4ED8-A212-98779F7AE8B (Accessed 2nd May 2019).

[10] Danish Consumer Council (2015) '*Test: Unwanted chemicals found in pizza boxes'*, available at: https://kemi.taenk.dk/bliv-groennere/test-unwanted-chemicals-found-pizza-boxes (Accessed 2nd May 2019)

[11] European Food Safety Authority (2013) '*DRAFT Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs –Part: exposure assessment 1:*' available at: http://www.efsa.europa.eu/sites/default/files/consultation/130725.pdf (Accessed 2nd May 2019)

[12] European Commission (2011) '*Bisphenol A: EU ban on baby bottles to enter into force tomorrow'* available at: http://europa.eu/rapid/press-release_IP-11-664_en.htm (Accessed 2nd May 2019)

[13] The French law can be read here

reproductive system[14]. In 2017, it was most welcome to see the Member State Committee of the European Chemicals Agency support the French proposal to classify bisphenol A as an SVHC based on its endocrine disrupting properties and the health effects on humans and the environment[15]. We submitted evidence to European Food Safety Authority expressing concerns that studies relating to low dose exposure had been dismissed[16]. For more information please see our background briefing on BPA.

Breast Cancer UK continues to call for BPA to be prohibited across all food and drink packaging and for any restrictions to be extended to other bisphenols which may be used as BPA substitutes. Increasing numbers of studies show that nearly all bisphenol substitutes including BPS, BPAF, BPB and BPF are similarly toxic and damaging to human health and the environment and are also likely to be linked to breast cancer risk[17] [18].

4.2 Phthalates

Phthalates are a group of chemicals which are used in a variety of consumer products including food packaging. The main source of human exposure to phthalates is diet, mainly through the consumption of food and drink wrapped in different plastic packaging[19]. Many phthalates are EDCs with anti-androgenic and oestrogenic properties; many *in vitro* studies suggest phthalates increase breast cancer risk[20]. They may also have numerous other detrimental health effects including male infertility, obesity and diabetes[21].

Phthalates have been shown to migrate from packaging into food. The EU has already taken measures to restrict the use of certain phthalates (DEHP, BBP, DBP and DIEP) in consumer products such as toys, due to their toxic effect on reproductive health and the endocrine system. However, these measures do not apply to FCMs and whilst the EU has limited the use of phthalates in FCMs made of plastic, these loopholes enable their continued use, despite being identified as hazardous to public health.

Breast Cancer UK calls on the EU to make current restrictions of phthalates to consumer products applicable to FCMs. For more information please see our response to the Committee for Risk Assessment and the Committee for Socio-Economic Analysis on an Annex XV dossier proposing restrictions on four phthalates.

4.3 Poly- and perfluoroalkyl substances (PFASs)

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[14] ENDs Europe (2016). *'BPA toxicity classification strengthened'* available at: http://www.endseurope.com/search?tag=112,41&type=1,3,4,5&start=31 (Accessed 2nd May 2019).

[15] Breast Cancer UK (2017) '*EU Member States Committee recognise BPA as Substance of Very High Concern*' available at: https://www.breastcanceruk.org.uk/news-and-blog/news-eu-member-states-committee-recognise-bpa-as-substance-of-very-high-con/ (Accessed 2nd May 2019)

[16] Breast Cancer UK (2018). '*Bisphenol A and other bisphenols*' available at: https://www.breastcanceruk.org.uk/policy-campaigns/our-policy-work/bisphenol-a/ (Accessed 2nd May 2019)

[17] Mesnage, R. et al. (2017) '*Editor's Highlight: Transcriptome Profiling Reveals Bisphenol A Alternatives Activate Estrogen Receptor Alpha in Human Breast Cancer Cells'*. Toxicological Sciences 158(2):431-443 available at: https://www.ncbi.nlm.nih.gov/pubmed/28591870 (Accessed 2nd May 2019)

[18] Lin, Z. et al. (2019) '*Bisphenol S promotes the cell cycle progression and cell proliferation through ERα-cyclin D-CDK4/6-pRb pathway in MCF-7 breast cancer cells'*. Toxicology and Applied Pharmacology 366: 75-82, available at: https://www.ncbi.nlm.nih.gov/pubmed/30684532 (Accessed 2nd May 2019)

[19] Zuccarello P. et al. (2018) 'Implication of dietary phthalates in breast cancer'. A systematic review. Food & Chemical Toxicology 118: 667-674, available at: https://www.ncbi.nlm.nih.gov/pubmed/29886235 (Accessed 2nd May 2019)

[20] Zuccarello P. et al. (2018) *ibid*

[21] Cao, Y. et al. (2019) '*Disease burden attributable to endocrine-disrupting chemicals exposure in China: A case study of phthalates'* Science of the Total Environment 662: 615-621, available at: https://www.ncbi.nlm.nih.gov/pubmed/?term=Disease+burden+attributable+to+endocrine-disrupting+chemicals+exposurein+China%3A+A+case+study+of+phthalates (Accessed 3rd May 2019)

Poly- and perfluoroalkyl substances (PFASs) include a broad range of synthetic substances such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). PFASs have many industrial applications including use in food contact materials; this is due to their oil-resistant and water-repellent properties. EFSA identified 16 PFASs that were present in non-plastic food contact material[22]. A number of studies, including some epidemiological studies, suggest certain PFASs may be linked to breast cancer risk[23].

PFOA and PFOS are EDC's which affect oestrogen and PFOA has been shown to promote cell proliferation, migration and invasion of breast cells *in vitro*[24]. PFASs are highly persistent in the environment, bioaccumulate and degrade slowly. Breast Cancer UK supports the phase out of all PFASs and believe strongly they should not be permitted in food contact materials.

5. A New Regulatory Framework for Chemicals within Food Contact Materials

We welcome the Commission's initiative to evaluate existing FCM legislation, including the consideration of future steps to improve effectiveness. The evaluation provides a good opportunity to discuss how these ineffective laws must be improved to ensure that consumers are properly protected from harmful chemicals migrating into our food.

In order to contribute productively to these discussions, a group of environmental NGOs, have analysed the gaps and flaws in the current EU legislative framework. Breast Cancer UK supports their call for the adoption of five key principles which should govern the future legislation on FCMs, which must ensure:

5.1 A high level of protection of human health

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

5.2 Thorough assessment of chemicals in materials and final articles

The presence in, and migration of, chemicals in food contact articles – including NIAS (for example nonylphenol which has been linked to breast cancer[25]) - should be measured, assessed and controlled. Absence of reliable migration data should imply presumption of full migration. Assessments of migration should include mixture effects and take a precautionary approach to exposures from non-FCM sources. Both

[22] EFSA (2012) '*Report of ESCO WG on non-plastic Food Contact Materials'* available at: http://www.efsa.europa.eu/en/supporting/pub/139e (Accessed 3rd May 2019)

[23] Mancini F. R. et al. (2019) '*Perfluorinated alkylated substances serum concentration and breast cancer risk: Evidence from a nested case-control study in the French E3N cohort'* International Journal of Cancer. 2019 Apr 22. doi: 10.1002/ijc.32357. [Epub ahead of print] available at: https://www.ncbi.nlm.nih.gov/pubmed/31008526 (Accessed 3rd May 2019)

[24] Pierozan, P. et al. (2018) '*Perfluorooctanoic acid (PFOA) exposure promotes proliferation, migration and invasion potential in human breast epithelial cells'* Archives of Toxicology 92(5): 1729-1739, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5962621/ (Accessed 3rd May 2019)

[25] Lee H. R., et al. (2014) '*Progression of breast cancer cells was enhanced by endocrine- disrupting chemicals, triclosan and octylphenol, via an estrogen receptor-dependent signaling pathway in cellular and mouse xenograft models'* Chemical Research in Toxicology, (27(5): 834−842, Available at: DOI: 10.1021/tx5000156. Epub 2014 Apr 8. (Accessed 3rd May 2019)

industry and regulators should ensure that any migration is understood and limited to ensure a high level of protection of public health.

5.3 Effective enforcement

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

5.4. A clean circular economy based on non-toxic material cycles

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

5.5 Transparency and participation

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

We urge the new Commission to deliver these needed reforms as a key priority.

May 2019