

Submission from Breast Cancer UK

to the Environmental Audit Select Committee Inquiry into The Future of Chemicals
Regulation after the EU Referendum

1. Summary

- 1.1 Breast Cancer UK is dedicated to the prevention of breast cancer by addressing all risk factors, including exposure to carcinogenic and hazardous chemicals.**
- 1.2 Ineffective chemical regulations and consequent exposure to hazardous chemicals can damage public health and the environment. There are numerous historical examples where regulations have failed to protect human health, and action has only been taken after significant harm has been done.**
- 1.3 Exposure to environmental carcinogens can cause breast cancer. There is also growing scientific evidence that exposure to certain endocrine disrupting chemicals (EDCs), which mimic, inhibit, or interfere with natural hormones such as oestrogen can increase the risk of developing breast cancers.**
- 1.4 An effective chemicals regulation system needs to be based on the precautionary principle and feature a hazard-based element in its approach to regulation.**
- 1.5 The UK leaving the EU does not mean that it needs to leave REACH. The UK should commit to staying within REACH, to protect regulations designed to protect the environment and public health; facilitate continued trade with the EU; and avoid the costs, bureaucracy and uncertainty necessitated by setting up a separate regulatory system.**

2. About Breast Cancer UK

- 2.1 Breast Cancer UK is dedicated to the prevention of breast cancer. It is a disease that we are increasingly vulnerable to. 55,200 new cases of breast cancer were diagnosed in the UK in 2014; that's 150 new cases every day.¹ 1 in 5 cases is diagnosed in women under the age of 50. Whilst improvements in diagnosis and treatment have led to a reduction in mortality rates for breast cancer, efforts to prevent the disease have stalled.**

¹ Cancer Research UK <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer#heading-Zero>

2.2 Breast Cancer UK believe it is time for a fresh approach to the prevention of breast cancer. Reductions in the incidence of the disease can be achieved by addressing lifestyle risk factors, such as alcohol consumption and obesity, and reducing exposure to carcinogenic and hazardous chemicals.

3. The link between chemicals and breast cancer

3.1 As well as lifestyle factors, environmental risk factors also affect breast cancer, including exposure to chemical pollutants. Exposure to environmental carcinogens such as some polychlorinated hydrocarbons (PCBs)², polycyclic aromatic hydrocarbons³ and ionizing radiation⁴ can cause breast cancer. There is also growing scientific evidence that exposure to certain endocrine disrupting chemicals (EDCs), which mimic, inhibit, or interfere with natural hormones such as oestrogen can increase the risk of developing breast cancers and other diseases.⁵ For example, Bisphenol A is a weak oestrogen mimic that has been linked to breast cancer even when exposure occurs at very low levels, hence the reason it was banned from baby bottles via EU legislation in March 2011.⁶

3.2 The links between chemical exposures and human health can sometimes be difficult to prove. Many of these chemicals have a widespread presence in the environment leading to difficulty in identifying unexposed control groups. The effect of chemical exposures, especially for diseases such as breast cancer, is often delayed^{7,8} and some chemicals, including certain EDCs, may cause adverse effects at very low concentrations, during specific developmental periods (especially *in utero*) and in combination with other chemicals.⁹ Furthermore, chemical exposures may especially affect the health of those with a particular genetic background, such as individuals with a mutated *BRCA1* gene (which affects their ability to repair DNA), increasing their risk of breast cancer and other diseases (e.g.¹⁰). Such associations are difficult to establish using standard epidemiological studies. Finally, it can take significant time and resources to build up enough high quality data to prove a link between a

² Leng, L. et al. (2016). Polychlorinated biphenyls and breast cancer: A congener-specific meta-analysis. *Environment International* 88, 133–141.

³ Korsh, J. et al. (2016). Polycyclic Aromatic Hydrocarbons and Breast Cancer: A Review of the Literature. *Breast Care* 10: 316–318.

⁴ Boice, J. D. et al. (1979). Risk of Breast Cancer following low-dose radiation exposure. *Radiology* 131(3): 589-597.

⁵ Giulivo, M. et al. (2016). Human exposure to endocrine disrupting compounds: Their role in reproductive systems, metabolic syndrome and breast cancer. A review.

⁶ European Commission (2011) 'Ban of Bisphenol A in baby bottle' Health & Consumer Voice - March - 2011

Edition. http://ec.europa.eu/dgs/health_consumer/dyna/consumervoices/create_cv.cfm?cv_id=716.

⁷ UNEP and WHO (2013) *ibid*

⁸ Bellingham M, et al. (2012) Effects of exposure to environmental chemicals during pregnancy on the development of the male and female reproductive axes. *Reproduction in Domestic Animals* 47: 15–22

⁹ Kortenkamp, A (2007) 'Ten Years of Mixing Cocktails: A Review of Combination Effects of Endocrine-Disrupting Chemicals. *Environmental Health Perspectives* 115(1): 98–105

¹⁰ Ghisari, M. et al. (2014). Polymorphisms in phase I and phase II genes and breast cancer risk and relations to persistent organic pollutant exposure: a case-control study in Inuit women. *Environmental Health* 13(1):19.

chemical and a health problem. Therefore, it is vital that the precautionary principle is applied to the assessment and regulation of chemicals.

- 3.3 The historical use of PCBs highlights the need for effective chemicals regulation based on the precautionary principle. They were once widely used, for example in electrical products, in paper, and in flame resistant coatings. It took several decades for enough evidence to be compiled that demonstrated they posed a serious threat to human health and the environment, before they were banned. During this time people were regularly exposed to these environmental carcinogens. PCBs are persistent pollutants in our environment, which bio-accumulate (build up inside cells, including breast tissue¹¹), and humans and animals are still being exposed today.
- 3.4 Effective regulations and evidence based environmental and public health policies are needed to reduce exposures to harmful chemicals, and help prevent diseases like breast cancer. In the EU, steady progress has been made in chemicals regulation, and towards more effective assessment and regulation of EDCs. Thanks to the development of REACH, UK citizens are exposed to fewer carcinogens and EDCs.

4. A note on the precautionary principle and hazard v risk based regulation

- 4.1 The precautionary principle, when applied to chemicals regulation, enables action to be taken to restrict a chemical which might cause harm to the public or the environment, even if there is no scientific consensus on the issue. Emerging scientific data can then be used to inform policy reviews.
- 4.2 A hazard-based approach to chemicals regulation assesses whether a chemical is harmful to health or the environment, how harmful it could be, and which people or parts of the environment could be harmed. A risk-based approach evaluates how often and through which pathways we are exposed to a chemical.
- 4.3 A risk-based approach requires estimates of possible exposures to a chemical throughout its lifecycle, and it can necessitate using very complex models to try to predict patterns of exposure. A lack of data, or low quality data, can make predictions of how much of a risk a hazardous chemical will pose unreliable and inaccurate. A hazard-based element in regulation is essential to overcome these limitations.

¹¹ Ellsworth, R. E. et al. (2015). Abundance and distribution of polychlorinated biphenyls (PCBs) in breast tissue. *Environmental Research* 138: 291–297.

- 4.4 REACH uses all three approaches in combination to ensure an effective chemicals regulatory system.
- 4.5 An alternative approach is used by the United States (U.S.). The U.S. follow a more risk based approach to chemicals regulation. As a result, several chemicals banned or restricted for use in the EU are still commonly used in the United States and consequently public exposure to certain harmful chemicals is greater:
- i. The EU has agreed to ban the use of the chemical Bisphenol A (BPA) in thermal paper till receipts using REACH. There is evidence that BPA is harmful even at low levels of exposure.^{12 13} There is no such restriction on BPA in the U.S.
 - ii. Other chemicals used in cosmetics and personal care products such as formaldehyde or formaldehyde-releasing ingredients are heavily restricted in the EU, but are under no such restrictions in the U.S. Formaldehyde is a known human carcinogen. Despite many years of research, it is unclear what level of exogenous exposure is likely to be associated with increased cancer risk.¹⁴
 - iii. The maximum residue levels of certain pesticides in food are considerably higher in the US than the EU, for example permethrin in cabbage (MRL, mg/kg: US: 6 and EU: <0.5)¹⁵. Increasing evidence suggests that permethrin¹⁶ might have a variety of toxic effects on animals and humans.

5. What is REACH?

- 5.1 REACH is the EU's main chemical law – it stands for the Regulation, Evaluation, and Authorisation of Chemicals. It has been in force since 2007. It applies to substances manufactured or imported into the EU in quantities of 1 tonne or more per year, with some exceptions. It aims to protect human health and the environment from the use of chemicals, allow the free movement of substances in the single market, and incentivise innovation in the EU chemicals industry.
- 5.2 REACH requires companies to provide and utilise safety information on chemicals, and provides mechanisms to ban or restrict the use of hazardous chemicals. It applies to both the trade in chemicals and chemical use within products.

¹² Vandenberg, L. N. et al. (2012). 'Hormones and endocrine-disrupting chemicals: low-dose effects and nonmonotonic dose responses.' *Endocrine Reviews* 33(3): 378-455.

¹³ Jenkins, S. et al. (2011). 'Chronic oral exposure to bisphenol A results in a nonmonotonic dose response in mammary carcinogenesis and metastasis in MMTV-erbB2 mice.' *Environmental Health Perspectives* 119(11): 1604-1609.

¹⁴ Swenberg, J. A. et al. (2013). Formaldehyde Carcinogenicity Research: 30 Years and Counting for Mode of Action, Epidemiology, and Cancer Risk Assessment. *Toxicology and Pathology* 41(2): 181-189.

¹⁵ CIEL report (2015) Erica Smith, David Azoulay, and Baskut Tuncak. Lowest Common Denominator: How the proposed EU-US trade deal threatens to lower standards of protection from toxic pesticides. http://ciel.org/Publications/LCD_TTIP_Jan2015.pdf

¹⁶ Wang, X. et al. (2016). Permethrin-induced oxidative stress and toxicity and metabolism. A review. *Environmental Research* 149: 86-10.

- 5.3 REACH is a world-leading regulatory system, that uses both risk and hazard-based approaches to regulation. In the first step, chemicals are identified as Substances of Very High Concern (SVHC) based purely on their hazardous properties, and subsequently placed on the Candidate List. The message is that these hazardous chemicals should be avoided as far as possible. However, in cases where it is not yet possible to replace them, and where the benefits of continuous use outweigh the risks, authorisation for continuous specific use can be granted.
- 5.4 REACH has led to the restriction of numerous chemicals linked to breast cancer including BPA and formaldehyde. Without this mechanism, it is possible that many of these chemicals may still be used in products across the UK (as they are in the US). Because of the EU's precautionary approach, the UK enjoys strong protection of public health and the environment, and safer consumer products. The EU is the global leader in chemicals regulation and several non-EU countries follow its lead.

6. The economic costs of having a UK-only chemicals regulatory policy

- 6.1 Leaving REACH and setting up a UK-only chemicals regulatory policy would entail significant short and long-term costs. This includes the loss of economies of scale from utilising the REACH database, developing the necessary I.T. system, designing and implementing data sharing systems, and hiring staff with specialist skills and knowledge.
- 6.2 A UK-only system would not be a quick-fix for reducing the regulatory burden on businesses. In fact, it would create another layer of bureaucracy as many businesses who export to the single market would still have to meet REACH requirements, as well as meeting the requirements of a UK-only system.
- 6.3 A UK-only regime could result in the UK becoming a dumping ground of products insufficient to meet REACH criteria but that meet weaker or out of date UK regulations. It would require significant resources just to copy changes in REACH regulations, and any divergence would provide companies with opportunities for offloading old stock into the UK market.
- 6.4 A more risk-based UK-only regime could lead to less innovation and hazardous chemicals staying on the market longer. REACH incorporates a hazard-based element to regulation that incentivises industries to innovate and change in a way that benefits public health and the environment. For example, when a chemical is added to the REACH SVHC candidate list, businesses will look to develop and purchase safer, greener alternatives.

- 6.5 A UK-only regime that abandoned the hazard-based elements of REACH, and developed a purely risk-based system would not only be detrimental to public health, it would create uncertainty for businesses and consumers. New research can rapidly change our understanding of the risk posed by an individual compound. Therefore, under a purely risk-based system any new compound introduced into a product could later be deemed to pose a risk to human health or the environment.
- 6.6 Setting up a UK-only regime is would be less cost effective and more bureaucratic than simply staying in REACH. Staying in REACH offers the UK all the benefits it could expect from a separate regime, but without the extra costs.

7. Conclusions

- 7.1 The EU's approach to chemicals regulation and the utilization of the precautionary principle has meant that the UK benefits from some of the most effective chemicals regulations in the world. This has helped to protect public health, provide healthier food and safer consumer products, and facilitate trade with the single market.
- 7.2 Leaving REACH would entail ongoing costs in setting up and running a separate regulatory system, and would subject businesses that export to the EU to two regulatory systems.
- 7.3 A system which sought to weaken chemicals regulation could lead to importers dumping products in the UK not fit for the EU; trade barriers for UK exporters; damage to public health; and risk contributing to the rising incidence of diseases such as breast cancer.

8. Recommendations

- The UK should remain in REACH, to protect public health while minimising regulatory costs and bureaucracy.
- The UK should not allow changes in its relationship with the EU to weaken chemicals regulation.
- Any new UK chemicals regime should be based on the precautionary principle, incorporate a hazard based approach to chemicals management, and mirror developments in REACH.