

BCUK response to EC Roadmap: Rules concerning use of Bisphenol A (BPA) in food contact materials

Submitted December 23 2015

Roadmap-title: Rules concerning use of Bisphenol A (BPA) in food contact materials

Breast Cancer UK is dedicated to the prevention of breast cancers by reducing public exposure to the carcinogenic, hazardous and hormone disrupting chemicals routinely found in the environment and everyday products. We believe there is a significant amount of scientific evidence to show that even low level exposure to the chemical Bisphenol A (BPA) has an adverse effect on the development of breast tissue, and that dietary exposure is the main route of human exposure to BPA. We have long campaigned for BPA to be banned, due to its potential role in increasing breast cancer risk. For further information on the potential role of BPA in breast cancer risk please see our publication "BCUK Fact Sheet: Bisphenol A"¹.

Breast Cancer UK welcomes DG-SANTE's re-consideration of the regulation of BPA in food contact materials, as described in the EC roadmap "Proposal for a new measure on bisphenol A (BPA) in food contact materials" and supports option 5, which calls for a ban on BPA in food contact materials at EU level. In addition; Breast Cancer UK believe the restriction should be extended to other bisphenols which may be used as BPA substitutes, as these are also suspected of being similarly toxic and damaging to human health and the environment.

As stated in the roadmap, some EU Member States have introduced national bans on the use of BPA in plastic and other food contact materials, based on safeguard measures under Article 18 of Regulation (EC) No 1935/2004. Furthermore, EFSA has introduced a temporary TDI of 4 µg/kg bw (from 50µg/kg bw), pending the outcome of further studies. However, EFSA's scientific opinion states that the level of BPA consumers are exposed to is well below the temporary TDI. Breast Cancer UK disagrees with EFSA's conclusion that this t-TDI represents a safe level, and would like to draw attention to a recent study (published after publication of EFSA's RAC and SEAC opinions on restriction of BPA in thermal paper) which provides further evidence that BPA is likely to be harmful at low, environmentally relevant levels (below the t-TDI proposed by EFSA). The study by Pfeifer et al. (2015)² found that low dose (nanomolar) exposure of BPA to human breast cells grown in 3D tissue culture generated higher levels of DNA-damaging reactive oxygen species; resulting in more DNA damage, an increased production of cell-cycle regulatory proteins, including the cancer promoting protein c-Myc, and induced proliferation of breast cells, irrespective of oestrogen receptor status. The study also suggests a possible mechanism of action for BPA to induce breast cancer. Previous cell culture studies have shown high concentrations of BPA are toxic to cells and cause DNA damage, but these effects have not been seen previously following exposure to low, environmentally relevant, concentrations. A likely explanation for this may be because earlier studies exposed breast cells to BPA for shorter time periods (up to 24hr, as

opposed to 72hr). Evidence of the carcinogenic effects of low dose BPA exposure is summarised in a review article by Seachrist et al. (2015)³.

In the section titled “Consultation Approach”, the roadmap states that “The Commission will continue to engage with and consult all relevant stakeholders including industry as well as with experts of the EU Member States via the Working Group meetings on food contact materials and the Standing Committee on Plants, Animals, Food and Feed”. We are disappointed that NGOs have not been invited to be part of this consultation process. Many environmental and health NGOs, including Breast Cancer UK, have expertise in this area and should be encouraged to actively participate in this process.

The roadmap’s two stated policy objectives are to secure a consistent and high level of protection for human health and the interest of consumers in the EU and to ensure the functioning of the internal market and the absence of unjustified barriers to trade. It would appear that the second policy objective has taken priority over the first.

The roadmap suggests that DG-SANTE does not support option 5 as it would have a significant administrative and practical burden on industry and be difficult to enforce. This argument could be used against banning most chemicals. It is true to say that it is consistent with EFSA’s current advice, however as stated previously, we believe there is sufficient (and growing) evidence to support the view that low level exposure to BPA is a health risk, including a risk to developing breast cancer risk.

¹ BCUK Fact Sheet: Bisphenol A. <http://www.breastcanceruk.org.uk/science/bcukfs-bpa/>

² Pfeifer D. et al. (2015). Effects of low-dose bisphenol A on DNA damage and proliferation of breast cells: the role of c-Myc. *Environmental Health Perspectives* **123**:1271–1279. <http://dx.doi.org/10.1289/ehp.1409199>.

³ Seachrist, D. D. et al. (2015). A review of the carcinogenic potential of bisphenol A. *Reproductive Toxicology*. <http://dx.doi.org/10.1016/j.reprotox.2015.09.006>