Breast Cancer UK response to the HSE's request for comments on the EU Commission's proposal setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009

Submitted to UK Chemicals Regulation Directorate Health and Safety Executive: 14/9/16

Breast Cancer UK would like to see significant changes in the proposed criteria for identifying endocrine disrupting chemicals (EDCs). The current proposal requires such a high burden of proof that it will only identify a very small proportion of EDCs. Currently, around 1000 chemicals are listed as putative EDCs by the non-profit group The Endocrine Disruption Exchange[1].

Over 1300 scientific studies link EDC exposures to increasing rates of hormone-related cancers, fertility problems, diabetes, obesity and behavioural problems in children[2]. Breast Cancer UK is especially concerned that routine exposures to combinations of EDCs (including certain pesticides) are leading to an increased risk of breast cancer. Breast Cancer rates in the UK[3] and elsewhere continue to increase and EDC exposures may be partly responsible. The World Health Organization has called EDCs a "global threat". The health costs of diseases associated with EDC exposures are estimated at €157 billion yearly in the EU[4].

In the 7th Environmental Action program[5], the EU made a commitment to minimise exposure to EDCs. The proposed criteria are inconsistent with this aim.

The Commission proposes to identify EDCs only if they are "known to cause an adverse effect" relevant to human health or non-target organisms. Demanding such high burden of proof weakens the current law, which includes regulation of substances that "may" cause harm. It also undermines expert opinion about the likelihood of a detrimental effect and is likely to result in damage to humans and the environment before action is taken.

This is inconsistent with the precautionary principle enshrined in the EU Treaty and part of the biocide and pesticides law. Furthermore, it is inconsistent with the identification of carcinogens, mutagens and reproductive toxicants, which is based on known or presumed adverse effects. Substances should be identified as EDCs on a similar basis to these harmful chemicals. Breast Cancer UK welcomes the use of the WHO/IPCS definition of EDCs, but believes the best option for EDC identification is to include 3 categories (known, suspected, potential) according to the level of evidence available (option 3 of the Commission's roadmap).

The Commission also proposes widening the current exemption for those pesticides identified as EDCs, introducing a major loophole. The proposal to change `negligible exposure' to 'negligible risk´ would mean continued exposure to these EDCs. The Commission has gone beyond their

identification task and weakened the law by reintroducing specific risk assessments for pesticides identified as EDCs.

The proposal is a revision of option 2 of the Commission's roadmap. It is disappointing this revised option was not presented in the roadmap, for consideration by the public. Furthermore, by proposing this option the Commission has ignored the majority of respondents to its 2015 public consultation.

Conclusion

We believe the proposed criteria should be changed to ensure a high level of protection for health and the environment, preventing endocrine-related diseases and averting damage to ecosystems. France, Sweden and Denmark have expressed their disagreement to the proposal[6]. The Endocrine Society[7] and other scientists[8] have strongly criticised the proposal, as has the construction company Skanska, who support stronger criteria in order to identify and phase out potentially harmful materials[9].

EDCs are a threat to our society's public health and prosperity. Europe should take a leading role in regulating EDCs; this will stimulate innovation so that industries can develop and use better and safer alternatives.

Breast Cancer UK would like the proposed criteria for identifying EDCs to change from "known" to cause an adverse health effect to "may" cause an adverse health effect, and to include three categories (known, suspected, potential) of EDCs, and specify a substance can only be approved if exposure (not risk) is negligible.

Dr Margaret Wexler
Science policy officer
Breast Cancer UK
margaret.wexler@breastcanceruk.org.uk
http://www.breastcanceruk.org.uk/
Reg. Charity No: 1138866 | Reg. Company No. 7348408

[1] http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/overview (accessed September 13, 2016)
[2] Gore et al. (2015) Endocrine Reviews 36 593–602
[3] Office of National Statistics (2016) Cancer Registration Statistics, England, 2014. http://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/cancerregistrationstatisticscancerregistrationstatisticsengland (accessed September 5, 2016)
[4] Trasande et al. (2015) Journal of Clinical Endocrinology and Metabolism 100: 1245–125
[5] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386 (accessed September 13, 2016)
[6] http://goo.gl/oU3QDS (accessed September 13, 2016)
[7] https://goo.gl/MNE4c7 (accessed September 13, 2016)
[8] http://goo.gl/u0LtIl (accessed September 13, 2016)
[9] http://goo.gl/pmYHkh (accessed September 13, 2016)