

Dr Thérèse Coffey MP
Defra
Nobel House
17 Smith Square
London
SW1P 3JR

29 November 2016

Dear Minister,

I understand that the Standing Committee on Plants, Animals, Food and Feed will meet in the new year to discuss a revised version of the EU Commission's proposed criteria for identifying endocrine disrupting chemicals (EDCs). Breast Cancer UK is concerned that the Commission is attempting to push through criteria that is seriously flawed, and which will fail to protect public health.

Over 1300 scientific studies link EDC exposures to increasing rates of hormone-related cancers, fertility problems, diabetes, obesity and behavioural problems in children.¹ 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 and elsewhere continue to increase and EDC exposures may be partly responsible.

I copy below text from the current revised criteria (as numbered in the Pesticide Regulation) that the Commission proposed in early November, and the changes that we would like to be made to the text.

- **3.6.5.2.2.(1) "it shows an adverse effect in an intact organism or its progeny"** should be changed to **"it is known or can be presumed to cause an effect in an intact organism or its progeny"**. This is to allow for data from in-vitro or in-silico methods to be used when these are deemed to be sufficiently predictive.
- **3.6.5.2.2.(2) "it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system"** should be changed to **"it alters the function(s) of the endocrine system"**. This is to bring it in line with the World Health Organisation (WHO) definition of an EDC, and make it clear that full details of the mode of action are not required.
- **3.6.5.2.2.(3) "the adverse effect is a consequence of the endocrine mode of action"** should be changed to **"the adverse effect is considered a likely consequence of the alteration in the function of the endocrine system"** or **"there is a plausible link between the adverse effects and the alteration in the function of the endocrine system."** This is because acquiring proof that the adverse effects are a consequence of an endocrine disrupting mode of action is very difficult. For example, researchers on chemicals such as polychlorinated biphenyls (PCBs) have found that that getting

proof of modes of action may take several decades. In addition, it needs to be recognised that these criteria will be used in other laws, such as cosmetics regulations, where the data requirements are much less than under the pesticides and biocides laws.

Furthermore, we do not support the change in the derogation for continued use of pesticides with endocrine disrupting properties, which effectively requires a move from hazard based controls, as specified in the original text of the Pesticides Regulation, to risk assessment. The original text requiring negligible exposure rather than negligible risk should be re-instated.

Pesticides are typically used in open field settings (which can be near houses or footpaths) where exposure is inevitable. Therefore, pesticides with endocrine disrupting properties should not be used, unless there is some form of closed system application that really does give rise to negligible exposure. Moving to a risk assessment process, which would be required to establish negligible risk, would entail trying to establish a threshold for the adverse effects. This would require exhaustive animal testing looking at various endpoints, including looking for adverse effects in subsequent generations. Given the aim to reduce animal testing in the EU, it needs to be recognised that this will not be reliably achieved.

On behalf of Breast Cancer UK, I ask that UK members of the Standing Committee call for significant changes to the proposed criteria, to protect the health of EU citizens.

Furthermore, could you clarify the Government's current position on the proposed EDC criteria? I would be happy to meet with officials in Defra to discuss our concerns.

I look forward to hearing from you.

Yours sincerely,



Lynn Ladbrook
Chief Executive

¹ Gore et al. (2015) *Executive Summary to EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals*. *Endocrine Reviews* 36 593–602