14 September 2016
Lancaster Environment Centre
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**Response to HSE consultation on proposed EU criteria for identification of EDCs (PPP)**

To whom it may concern,

Thank you for giving us the opportunity to respond to the HSE consultation on EU criteria for identification of EDCs. The responses below in part reiterate comments we have already made in responding to the EU Commission's public consultation on their proposed EDC criteria[i], and also a letter to the EU Health Commissioner[ii] which we co-authored.

We need to apologise as this has been written in something of a hurry, and as such there is likely to be need for additional clarification of the points raised, but we hope it is useful nonetheless. Below we present answers to your questions in order of asking.

Yours sincerely,

Paul Whaley and Crispin Halsall

Lancaster Environment Centre
13 September 2016

## A. The proposals published by the Commission

In our response to the Commission's public consultation, we expressed concern that the criteria place an under-defined, and potentially unprecedentedly high, burden of proof on identifying problem compounds as having endocrine disrupting properties. We believe this will result in an identification process which could be conducted very inconsistently, and may identify for regulatory restriction only a small proportion of the sum total of actual EDCs.

We also felt the criteria present a confused set of processes for identifying, evaluating and integrating scientific evidence which unnecessarily privilege certain types of study, and cannot be adequately operationalised for regulatory identification of EDCs. In your consultation document you state that "identifying substances as having endocrine disrupting properties would be based on: all available relevant scientific evidence; and weight of evidence; and expert judgment".

In fact, the proposed Criteria also describe a role for systematic review (SR) methods. This is encouraging, as we believe SR methods are a "gold standard" for evidence assessment and have the potential to bring much greater transparency, reproducibility and scientific robustness to the process of identifying EDCs than can be achieved with current weight-of-evidence methods.

However, the role of SR methods, when they should be used, and how they relate to weight-of-evidence methods is unclear. This is a problem, as it may lead to variation in the scientific standards by which evidence of endocrine disrupting potential is assessed, and lead to use of approaches of

lower validity being used rather than gold-standard evidence assessment methods. The standards required in the processes of assessing evidence need to be more carefully considered and articulated.

### B. Their likely impact for industry and agriculture

There is understandable concern about the impact of the regulations on industry and agriculture. However, there is also considerable concern that EDCs represent an under-estimated and under-regulated impact on human and environmental health. We would not want to see impact on industry and agriculture being excessively weighted when trying to determine how to identify EDCs. In fact, from a scientific perspective, economic impact of classification as an EDC seems irrelevant to determining what the criteria for qualification as an EDC should be; this is something which should be managed after potential hazards and risks posed by a chemical have been identified.

### C. Changes you would wish to see, why, and the likely impact of those changes

In our letter and response to the Commission's consultation, we identified six changes we would like to see:

***1. A clear, unambiguous definition of "known to cause adverse effects relevant for human health".*** We did not feel that this was in fact sufficiently clear, as it implies a standard of evidence without articulating sufficient criteria for when that standard has been met. In later exchanges, we have been made aware that these standards are defined in other legislative documents, but we are still not completely confident this is being satisfactorily addressed: so long as one person's knowledge is another's uncertainty, there is a risk of an uneven standard of evidence being applied by different evaluators to different chemical substances.

In particular, we have become concerned that the requirement that exposure be "known to cause adverse effects" is setting too high a burden of proof for a chemical substance to be identified as an EDC. For carcinogens, we understand the standard is only that exposure be "presumed" to cause an adverse effect, which seems more appropriate and ought also to be applied in the case of EDCs.

***2. Allowance for regulatory identification of a chemical substance as an EDC in the absence of "sufficient" evidence of harm from epidemiological studies.*** Whether this is satisfactorily allowed for seems to be a matter of ongoing debate. At the very least, any ambiguity needs to be thoroughly cleared up.

***3. The introduction of a hierarchy of categories for EDCs, with clear, unambiguous criteria distinguishing "known" from e.g. "probable", "possible" or "not classifiable".*** We feel it is essential that the criteria capture a range of levels of evidence for EDC potential, to distinguish chemicals for which we have strong evidence they are EDCs, from those for which there is only moderate or weak evidence. As for point #1 above, it should be as unambiguous as possible as to what the strength of evidence for each chemical is, and how that results in its final regulatory classification.

***4. The articulation of a systematic and coherent process for integrating evidence across the three components of the WHO/IPCS definition of EDC.*** In order to achieve #3 and #1, there needs to be guidance as to how evidence across the three components of the WHO/IPCS definition of EDC is to be found, appraised and integrated, to yield the final classifications of EDC potential. This process should ideally be systematic, as an advance on weight-of-evidence approaches, but where weight-of-

evidence approaches are thought necessary their relationship to systematic approaches needs defining.

***5. The definition of clear and unambiguous standards for strength of evidence within each of the three individual components of the EDC definition.*** To achieve #1, #3 and #4, there needs to be a process internal to evaluation of each evidence stream which is also unambiguous and systematic, and in need of definition. Again, this process should ideally be systematic, as an advance on weight-of-evidence approaches, but where weight-of-evidence approaches are thought necessary their relationship to systematic approaches needs defining.

***6. Ensuring all evidence is assessed on merit without prior privileging of certain study types.*** There is suggestion in the proposed criteria that some study types ought to be privileged, stating apparent preference for those which are "performed according to internationally agreed study protocols" as the evidence on which regulatory identification as an EDC is to be "primarily" based. While some studies are more reliable than others, it is not possible to determine *a priori* which type of study is going to produce the most useful, robust information for classification as an EDC; rather, each study has to be individually appraised on its own merits using a fair test of study quality. This needs to be made clear in the proposed criteria.

## D. The risks to humans and non-target organisms of a risk-based approach as compared to a hazard-based approach to controlling exposure to endocrine disrupting substances.

As we see it, the risk of a risk-based approach comes from systematically under-estimating and/or failing to manage health risks when a class of chemicals presents pose risks to health which either defy accurate quantification, or they end up being distributed in the environment in such a way that vulnerable populations cannot be protected. This risk is particularly acute when health risks are poorly-understood, such as when they are novel and/or when evidence allowing risks to be characterised or quantified is relatively sparse.

In these circumstances, special regulatory treatment of compounds presenting difficult-to-quantify health risks is justifiable, and selection of a hazard-based approach to restricting their use appears warranted. This is the case for carcinogens and POPs, and arguably ought to be the case for EDCs, because it is believed that EDCs pose health risks that are too difficult to anticipate at levels too small to effectively manage. So long as this is the case (as it seems to be) then a risk-based approach would be too risky, and a hazard-based approach would seem justified in its place.

[i] See https://ec.europa.eu/info/law/better-regulation/initiatives/ares20163071834/feedback/F2_en
[ii] See http://policyfromscience.com/open-letter-to-eu-commission-about-proposed-edc-criteria/