REQUIREMENTS FOR THE PROPER REGULATION OF CHEMICALS WITH ENDOCRINE DISRUPTING PROPERTIES

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There are well-founded concerns about the gender disrupting effects of hormone or endocrine disrupting chemicals (EDCs) in wildlife. Furthermore, EDCs are suspected of playing a role in disrupting human brain development, the deterioration of male reproductive health, the increased incidence of male and female hormone related cancers and in the increase in cardiovascular disease, obesity and diabetes. We therefore call upon the European Commission, Member States and the European Parliament to put in place the following pre-requisites for the robust regulation of chemicals with endocrine disrupting properties.

1. IMPLEMENT A STRATEGY TO IDENTIFY ENDOCRINE DISRUPTING CHEMICALS (EDCs), FACILITATE DATA EXCHANGE AND TO DETERMINE AGREED CRITERIA FOR EDCs

1.1. Update the 'EU EDC list' and create an EU EDC database

A comprehensive list of chemicals with endocrine disrupting properties should be drawn-up from both existing data and from the screening and testing of chemicals, including toxicity data provided under EU legislative instruments and data from screening and testing programmes in other countries. The EU's list of category 1 and 2 EDCs - for further evaluation - must be updated to include additional substances.
The EU list is mostly over a decade old and was based on the BKH study published in 2000.[1]

The European Commission's initiative to convert the EU list of category 1 and 2 EDCs into a data-base containing all endocrine disruption-relevant test data must ensure that all peer reviewed and published independent data (such as that generated in academic laboratories) is included on the data base. Furthermore, any data-base must be adequately resourced with ongoing funding in order to keep it up to date.

1.2. Give due weight to both OECD and non-OECD validated tests in hazard assessment

Hazard assessment must give due weight to non-OECD test results, particularly as OECD test methods are often less sophisticated and may not reflect current knowledge on sensitive end-points etc. All peer reviewed and published scientific literature should therefore be taken into account, and where available, information on all endocrine-related end-points should be scrutinised. Studies done under good laboratory practice (GLP) certification should not be considered to be of higher value compared to well-conducted and well-reported studies, which are not done in GLP certified laboratories.

1.3. Screen chemicals to identify those needing further attention

Given the large universe of chemicals a pragmatic approach is required to minimise the amount of animal testing. All relevant chemicals should be screened using *in-silico* and *in-vitro* test methods in order to identify those needing further attention. However, where significant human exposure is predicted, a robust strategy is required to avoid false negatives (that is, missing harmful chemicals).

[1] BKH 2000. Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting, BKH report M0355008/1786Q final with annexes 1 to15, Delft, 21 June 2000.

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1.4. Implement a testing strategy that addresses the complexity of the endocrine system.

For toxicity testing to protect human health there is a need to move beyond attempts to validate a handful of narrowly-focussed tests on rodents that detect only a very small component of endocrine disruption. There is therefore a need for a comprehensive review and strategy to get better screens and tests in use in the EU to identify chemicals with endocrine disrupting (ED) properties. A particular focus should be to identify chemicals that may play a part in the adverse trends in human health, for example, including obesity, diabetes, breast cancer and prostate cancer.

There is an urgent need to find robust non-animal methods to identify EDCs, but recognising these are currently not available we suggest that this strategy should include a comprehensive, multi-organ assay to detect the most sensitive alterations in embryonic and fetal development and function. Such an assay also needs to include looking for effects which may develop in old age, as these are currently not included in any of the guidelines for reproductive toxicity. A comprehensive assay, looking at all the tissues and organs, although daunting in its scope, would ultimately achieve a significant reduction in animal testing and make up for the time lost over the past decade. Scientists who understand the complexity of the endocrine system should design this proposed comprehensive assay. Therefore, independent academic scientists who have been involved in EU and government funded research projects on endocrine disruptors, should be given the opportunity to design a comprehensive assay looking at all tissues and organs. There is also a need for the tissues and organs from such studies to be sent 'blind' for examination by real experts trained in that particular field.

This initiative should then be taken forward in the OECD context, in order to get the best test methods harmonised at the global level.

1.5. Update REACH toxicity testing requirements

An impartial group made up of EDC experts from Member States and stakeholders should scrutinise the data requirements under REACH in relation to its ability to identify chemicals with endocrine disrupting properties. The REACH toxicity data requirements should be updated to include test methods able to identify chemicals with ED properties as far as is currently possible. The testing required under other legislative instruments should also be regularly reviewed and improved particularly with regard to its ability to identify EDCs.

1.6. Involve stakeholders in the development of the criteria for identifying chemicals with ED properties

The development of criteria to identify pesticides (and other chemicals) with ED properties should be the subject of international meetings involving stakeholders.

1.7. Implement a classification and labelling system for EDCs

Giving due regard to the criteria that will be developed to identify chemicals with ED properties, the EU should implement a classification and labelling system for such chemicals. With respect to pesticides, any substance with ED properties will be governed by cut-off rules.

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2. EXPEDITE CONTROLS ON EDCS AND REDUCE EXPOSURES

2.1. Expedite the use of REACH to control exposures to EDC

Under REACH, chemicals with ED properties should be subject to restrictions or authorisation as soon as possible, with priority based on their toxic properties and likely exposure levels. SIN List 2.0 can be taken as a starting point for this.

2.2. Flag chemicals with ED properties that are substances of very high concern (SVHCs) due to other properties

We call upon Member States and the European Chemicals Agency (ECHA) to ensure that the dossiers for chemicals which are nominated for inclusion on the REACH candidate list not only specify the CM or R (carcinogenic, mutagenic or reprotoxic) or PB(T) (persistent, bioaccumulative and toxic) properties, but also specify their endocrine disrupting properties, where relevant. Nominating a chemical for inclusion on the list of SVHC based on their PB(T) or C, M or R properties **and** their ED properties may have a bearing on the granting of the authorisation, particularly as there is a mandated review by June 2013 of the conditions for granting authorisations to chemicals with ED properties.

2.3. Given the likely mixture effects, the goal is the elimination of exposure to chemicals with ED properties

Given the possible additive effects of chemicals which act on the same end-point, we consider that the goal should be to eliminate exposure to chemicals with ED properties, whenever possible. For industrial chemicals, this would require a review (under Article 60.3 of REACH) to exclude authorisations under the "adequate control" route for EDCs. For pesticides, such substances are to be banned, as ED properties are included in the cut-off criteria.

2.4. Ensure all EU legislative instruments give due regard to the need to reduce environmental and human exposure to EDCs

EU legislative instruments dealing with chemicals need to be reviewed and improved so that they reduce overall exposure to chemicals with ED properties (eg. Directive 92/85/EEC (which addresses the health and safety of pregnant workers and women who are breastfeeding) and the Cosmetics Directive).

2.5. Implement a precautionary approach

Given the limitations of test methods, determination of whether a chemical possesses relevant ED properties should endeavour to err on the side of caution. For example, the default assumption should be that if a substance is shown to affect mammalian systems then the effects will be relevant to humans.

2.6. If testing chemicals on animals is to be limited the need to regulate chemicals on the basis of in-vitro tests must be recognised

We call upon the Member States and the Commission to agree that in the absence of data from animal studies, and given the drive to reduce toxicity testing on vertebrate animals, it is necessary to accept regulation on the basis of *in-vitro* test methods.

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