Identifying endocrine disruptors – thoughts and recommendations for implementation in the EU

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INTRODUCTION

The endocrine system is responsible for the regulation of growth, reproduction, metabolism, and weight in humans and other animals. Endocrine disruptors (EDs) are substances that are thought to disrupt these processes and can lead to cancer and reprotoxic effects. Endocrine disruptors can also impact the environment, potentially harming wildlife by causing reproductive abnormalities and population decline. Due to increasing concern over EDs, the European Commission's (EC) 'Chemicals Strategy for Sustainability' has proposed to identify and restrict the use of EDs. The EC proposes to amend the European Union's Classification, Labelling and Packaging (CLP) Regulation and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annexes to include ED-specific information requirements identified using in vivo tests which are fundamentally not fit-for-purpose - they demonstrate poor reproducibility and have a lack of relevance to human health.

METHODOLOGY

Responses to public EU consultations, open letters, and scientific analyses from a range of stakeholders have been compiled to accurately describe the current state of play in the EU with respect to the identification of endocrine disruptors (EDs). This poster will provide an overview of (1) why in-vivo tests for ED identification are not fit for purpose (2) why in-vitro assays are not sufficient as stand-alone flags for EDs (3) how the EC's proposals will result in an escalation of animal testing without providing sufficient information concerning EDs and (4) how the EU may be able to learn from other countries' approaches to the same issue.

RESULTS

Preliminary analysis from animal protection organisations indicates that millions of additional animals will be used in chemical safety assessments if the EC's proposal to include a separate classification for endocrine disruptors is successful. The proposed supplementary testing is unlikely to confer any greater protection of human health or the

environment over and above what is already provided for under the European Union's (EU) existing safety legislation, REACH. Evaluation of endocrine activity and identification of potential endocrine disruptors has been of deep interest for decades, and methods and approaches for this purpose have been developed and refined by other entities, including the Organisation for Economic Cooperation and Development (OECD) and the United States Environmental Protection Agency (US EPA). Here we draw from recommendations and lessons learned from these programmes to offer suggestions on how existing approaches could be expanded to create a more effective approach to identification of endocrine-disrupting substances in the EU.

DISCUSSION

The EC's current approach to EDs is to 1) develop CLP categories for EDs 2) implement changes to annexes to REACH that would allow CLP classification of all chemicals. There are several scientific and practical issues that prevent this approach from being effective. First, scientific justification for the proposed CLP categories is lacking. Second, the proposed testing schemes for implementation under REACH are a strained combination and involve inappropriate application of screening and assessment tools without a clear decision context. We propose instead that the EU build on the recent evolution of ED evaluation by others and implement a science-led approach based on a solid understanding of endocrine pathways and identification of potency thresholds for related adverse outcomes in order to develop an approach specifically designed for regulatory use to protect against potential ED-mediated effects. Such an approach may take more time to implement in the short term than the current proposals; however, it will result in a more effective and efficient programme for the regulation of endocrine disruptors in the long term, with the concomitant benefits to human health and the environment.