Code Number and Title:

LRI-EMSG58: Quality assessment of the epidemiological evidence of adverse effects to humans of endocrine active substances in the environment.

Background

The potential health impact of the exposure of humans and the natural habitat to endocrine active chemicals are of concern to industry and regulators worldwide. In the EU, criteria are put forward that foresee discrimination of endocrine active substances, i.e. a substance without adverse effects, and endocrine disruptors, i.e. a substance that potentially lead to adverse effects, on the basis of epidemiological evidence and stringent chemicals management is foreseen for the later.

A recent report commissioned by the EU Directorate General on the 'State of the Art Assessment of Endocrine Disruptors' [Kortenkamp et al. 2011] plays a pinnacle role in this discussion. The report bases relevant conclusion on epidemiology studies. Unfortunately, the report lacks the description of a systematic evaluation of the quality and reliability of the studies used in the assessment.

The intended project aims to provide a critical review of the quality of the epidemiology studies (human and environment) that contribute to the debate on ED. As a relevant subset of such studies the project can focus on those used in internationally relevant publications like the 'State of the Art Assessment of Endocrine Disruptors' [Kortenkamp et al. 2011] and the report on the 'State of the science of endocrine disrupting chemicals' by the WHO/UNEP [2013]. The review should define and apply a transparent scheme for assessing the reliability and significance of epidemiological studies, including factors such as appropriate research design, quality of exposure data, validity of health outcome parameters and adjustment for confounding factors. This scheme should be then applied on the studies used in the reports to derive a decision whether adverse effects are caused *inter alia* as a consequence of exposure to endocrine active substances. The assessment scheme should ideally build on already existing guidelines for assessing the quality of observational epidemiology studies are used, such as the STROBE guidelines [von Elm et al., 2007], or the criteria by Vlaanderen et al. [2008] or another available set of quality criteria for observational epidemiological research, but it must be specified in the project proposal.

Objectives

The project's objective is to develop a systematic evaluation scheme to assess the quality and reliability of the epidemiological evidence for endocrine active substances to exert adverse effects based on an endocrine mode of action. This scheme is then to be applied to studies and substances discussed in relevant international publications like 'State of the Art Assessment of Endocrine Disruptors' [Kortenkamp et al. 2011] and the 'State of the science of endocrine disrupting chemicals' [Bergman et al, 2013].

Based on this assessment the project should also make suggestions on how to use evidence from epidemiological studies in a weight of evidence assessment of endocrine mediated adverse effects from the exposure to chemicals.

Scope

Conduct a systematic review of the quality of epidemiology studies on adverse health effects from exposure to endocrine disruptors in the human environment.

Deliverables

The assessment scheme and the findings of the assessment and any recommendation for improvement of the use of epidemiological evidence should be summarised as manuscripts to be submitted to scientific journals preferably with a high impact factor and should be presented at scientific meetings. A final report shall contain an executive summary (2 pages max), a main part (max. 50 pages) and a detailed bibliography.

Cost and Timing

Start in January 2014, duration 2 years

Budget in the order of € 200.000

Partnering/Co-funding

Applicants should provide an indication of additional partners and funding opportunities that can be appropriately leveraged as part of their proposal. Partners can include, but are not limited to industry, government/ regulatory organisations, research institutes, etc. Statements from potential partners should be included in the proposal package.

Fit with LRI objectives/ Possible regulatory and policy impact involvements/ Dissemination

The systematic review of epidemiology studies is intended to assist regulators in the decision making process relating to these compounds. As a further support in this process the project may include the development of a minimum set of standards that the epidemiological evidence must meet in order to warrant regulatory action.

References

Kortenkamp, A., O. Martin, et al. (2011). "State of the Art Assessment of Endocrine Disruptors." from http://ec.europa.eu/environment/endocrine/documents/studies_en.htm.

von Elm, E., D. G. Altman, et al. (2007). "The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies." Epidemiology **18**(6): 800-804

Vlaanderen, J., R. Vermeulen, et al. (2008). "Research Guidelines to Evaluate Human Observational Studies for Quantitative Risk Assessment." Environ Health Perspect. **116**(12): 1700–1705.

Bergman, Å., J. J. Heindel, et al. (2013). State of the science of endocrine disrupting chemicals - 2012, WHO UNEP**:** 296.

DEADLINE FOR SUBMISSIONS: 1 September 2013

Please see www.cefic-lri.org for general LRI objectives information, project proposal form and further guidance for grant applications. For further assistance do not hesitate to contact lri@cefic.be.