New testing and screening methods to identify endocrine disrupting chemicals

New and improved approaches are needed to increase the quality, the efficiency and the effectiveness of existing methods to meet demanding and evolving regulatory requirements worldwide. In consultation with relevant regulatory bodies, research should improve and harmonise screening and testing protocols/strategies and hazard/risk assessments by developing better and faster tools, test methods or models, including in vitro and in vivo tests, high-throughput and in silico methods (e.g. QSAR), potentially combined with research on adverse outcomes pathways. For in vitro tests, appropriate coupling of their results to human health effects should be ensured. Information is also needed as regards how epidemiological and field monitoring data, which are also to be considered as data sources in a regulatory context, can be used to gain information about possible associations between levels of exposure to specific chemicals and ED-related effects. Focus should be on the most urgent regulatory needs, e.g. methods addressing the thyroid axis, developmental neurotoxicity, metabolic disorders, female reproduction and non-genotoxic carcinogenicity. Proposals should involve, in addition to academic researchers, regulatory agencies and other actors as appropriate. Proposers should consider sex and gender analysis when relevant. International cooperation is essential. Proposals are required to describe how they will contribute to ongoing international ED related activities (e.g. OECD work, EU level databases), including decision schemes under development. To speed up regulatory uptake of tests, validation is an essential step to be included in the proposals.

The Commission considers that a proposal requesting an EU contribution between EUR 4 to 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Collaboration between successful proposals will be encouraged.
Proposals could consider the involvement of the European Commission Joint Research Centre (JRC) as an added value in order to provide an effective interface between the research activities and regulatory aspects and/or to translate the research results into validated test methods and strategies fit for regulatory purpose. In that respect, the JRC will collaborate with any successful proposal.

There are a variety of natural and anthropogenic chemicals that can produce adverse effects via a disruption of the body’s endocrine (hormone) system, referred to as endocrine disruptors (EDs)\[WHO/UNEP-State of the science of endocrine disrupting chemicals – 2012: http://www.who.int/ceh/publications/endocrine/en\]. EDs are of increasing importance in chemical regulations in the European Union, and criteria to identify EDs have recently been presented for two pieces of EU legislation (Biocidal Product Regulation and Plant Protection Products Regulation)\[Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products: http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm\].

In the EU, the legislation regulating chemical substances often includes their screening and testing according to the EU test methods regulation\[eurl-ecvam.jrc.ec.europa.eu/alt-animal-testing-safety-assessment-chemicals/test_method_reg\], which predominantly contains test methods developed under the OECD\[OECD work on endocrine disrupters: http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm\]. The current testing tools, including regulatory in vivo tests and novel in vitro assays, do not appropriately identify effects related to certain less studied endocrine-mediated pathways or health outcomes, in which EDs may be implicated. Moreover, the new ED criteria require information about both the adverse effects and the endocrine mode of action.

- Improved hazard and risk assessment of EDs, including in the workplace.
- Novel ED assay candidates for regulatory use.
- Support for the OECD work on testing and assessing chemicals for ED identification.
- Enhanced international cooperation.
- Contribution to the development of an international strategy and guidelines for testing EDs and assessing associated hazard and risk.