Helsinki, 19. 10. 2017

Ex-ante publicity notice in negotiated procurement procedure

Subject: **ECHA/2017/384 Design of *in vivo* study suitable for transcriptomics and metabolomics measurements and analysis of how New Approach Methodologies (NAMs) can inform regulatory work**

Description of the contract:

The European Chemicals Agency (the Agency, http://echa.europa.eu) envisages awarding a service contract for developing a list of conditions in an experimental test set-up, which allow for the collection of meaningful metabolomics and transcriptomics data in *in vivo* tests (repeated dose toxicity 90-day), and an analysis of how NAMs can be utilised to inform regulatory work, with a focus on environmental hazard assessment of industrial chemicals under REACH.

Description of the services:

The project will be part of the preparatory work for a new, large international initiative aiming to assess industrial chemicals, using and developing new approach methodologies (NAMs). NAMs are understood in a broad context to include *in silico* approaches, *in chemico* and *in vitro* assays, as well as the inclusion of information from the exposure of chemicals in the context of hazard assessment. They also include a variety of new testing tools, such as "high-throughput screening" and "high-content methods" e.g. genomics, proteomics, metabolomics, as well as some "conventional" methods that aim to improve understanding of toxic effects, either through improving toxicokinetic or toxicodynamic knowledge for substances.

This project shall inform the set-up of the experimental design in order to check the concordance between NAMs and classical toxicological tests. The *in vivo* tests will follow the repeated dose toxicity 90-day test protocol modified to incorporate measurements of mechanistic parameters, which will allow for comparison between the outcomes from *in vitro* and *in vivo* tests. Transcriptomics and metabolomics are of key importance to seek to identify the toxicological mode of action of each chemical and to derive quantitative estimates of molecular no-effect and lowest-observable-effect levels. In this project, the contractor shall develop a list of conditions, which can be used to guide the design of experiments to collect meaningful metabolomics and transcriptomics data during repeated dose toxicity testing.

The project shall additionally include an analysis of how NAMs can be utilised to inform regulatory work, with a focus on environmental hazard assessment of industrial chemicals under REACH.

Description of the procedure:

This ex-ante publicity is the first stage of a negotiated procurement procedure below 60 000 Euros with a minimum of 3 candidates, through which the Agency may award the above-mentioned contract.

The purpose of this notice is to support the Agency in the selection of the list of candidates to be invited to submit an offer for the contract. Please note that offers submitted in the subsequent negotiated procedure with a value above 60 000 EUR will be rejected.

All economic operators interested in providing the services described above should send a declaration of interest before **3/11/2017, 17h00 Helsinki time**, by e-mail to procurement@echa.europa.eu with the same subject reference as indicated above.

In their declaration of interest (300 words maximum) interested economic operators should demonstrate their ability to provide the relevant services. This information will be assessed by the Agency in order to select suitable candidates. All interested economic operators will be informed of the decision of the Agency.

The Request for Offers and related documents will be provided by e-mail only to the selected candidates.

Please note that the Agency reserves the right not to launch the negotiated procedure. If that were the case, all interested economic operators would be informed of this decision.

We look forward to receiving your declaration of interest.

Yours faithfully,

Jukka Malm
Deputy Executive Director