

Helsinki, 17/11/2022

## **Preliminary Market Research – Questionnaire regarding development of NAM based tools and data for hazard identification and characterisation of industrial chemicals, including polymers and nanoforms**

### **Introduction**

The European Chemicals Agency in Helsinki (hereinafter "ECHA"<sup>1</sup>) is inviting you to reply to this questionnaire by **6/01/2023 by 18.00 Helsinki time (EET)**, via e-mail addressed to the functional mailbox [procurement@echa.europa.eu](mailto:procurement@echa.europa.eu).

**This questionnaire is meant for market consultation conducted by ECHA in order to better appreciate the current market offering on services related to New Approach Methodologies (NAM) based tools and data for hazard identification and characterisation.**

In accordance with the principles of non-discrimination, equal treatment and transparency, a Prior Information Notice for this contract has been published in the Official Journal of European Union ([Services - 636980-2022 - TED Tenders Electronic Daily \(europa.eu\)](#)) including the invitation to participate in this market consultation.

**Important:** Before answering the questions, please read carefully the background information provided below.

ECHA will preserve the confidentiality of the information provided in response to this questionnaire. Your data will be processed in accordance with [ECHA's privacy rules](#).

### **1. General Information**

- The information included in this questionnaire is only indicative; it is meant to give context for the respondents to provide their answers, but does not commit or bind ECHA, i.e., with regard to any procurement launched by the Agency in the future.
- The responses do not bind the respondents in any way. The information to be collected through this questionnaire will not be considered by ECHA in the evaluation of request to participate or tenders submitted during an eventual procurement procedure launched by the Agency.
- The identity of the companies that will respond to this questionnaire will not be disclosed to any third party, except to the European Court of Auditors, the European Anti-Fraud Office or, for the processing of personal data, the European Data Protection Supervisor if requested for the performance of audits and checks.
- The responses to be provided in the free text fields of this questionnaire should be clear and standalone, i.e., without web links to documents or websites.

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<sup>1</sup> <https://echa.europa.eu/>

- No further interviews are planned to take place with the respondents. Therefore, we kindly invite you to provide as much information as you feel relevant for ECHA to assess best the market situation.

## 2. Background Information

ECHA aims to take a more proactive role in promoting and introducing New Approach Methodologies (NAMs) into various regulatory applications under REACH<sup>2</sup> and CLP<sup>3</sup>.

However, based on multiple discussions and consultations with experts in the field, there seems to be an agreement that there are not yet solutions available allowing full transition into animal free hazard identification and assessment for horizontal regulatory systems like REACH and CLP. To allow the full replacement, substantial progress in methodological development is needed and, in parallel, there is a need for some intermediate solutions, which on one hand would allow significant reduction in the animal use, and at the same time would allow ECHA and EU member states experts to gain confidence in using NAMs for regulatory decisions with possibility to cover also nano forms and polymers.

Therefore, ECHA is considering launching procurement to establish a framework contract to inform the development of New Approach Methodologies (NAMs) based solutions applicable to the hazard identification and characterisation of industrial chemicals, including polymers and nanoforms. The contract would cover the development of methods, as well as their application for data generation as part of the REACH standard information requirements.

### 2.1. The following regulatory applications and priority areas have been identified:

- Definition and application of NAM-based criteria to support grouping and read across
- Development of in-vitro to in-vivo extrapolation (IVIVE) techniques applicable to wide spectrum of industrial chemicals.
- Development of approaches allowing the demonstration that:
  - NAMs can also be used to confirm safety (so that the substance can be considered as safe).
  - Toxicological effects can be reliably predicted by NAMs (so that the results can be used to directly inform risk management)
- Review of the state of the art and applicability of current NAMs for hazard identification and classification (within the current regulatory system, i.e. hazards as defined in REACH and CLP).
- Review and state of the art of NAMs used to characterise the hazard of nanomaterials
- Review and state of the art of NAMs used to characterise the hazard of polymers
- Review and analysis of the feasibility of nanomaterials and polymers testing using the test methods covering current standard information requirements.

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<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

<sup>3</sup> The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) is based on the United Nations' Globally Harmonised System (GHS) and its purpose is to ensure a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles.

- Recommendations on test material definition and preparation when testing polymers, including proposals for modification of current test protocols, using both traditional test methods and NAMs

## 2.2. NAMs data generation will cover the following areas:

- Generation of metabolomics data and analysis, including the integration with other sources of information (e.g., other omics) and development of dedicated bioinformatics approaches and workflows
- Generation of transcriptomics data and analysis, including the integration with other sources of information (e.g., other omics) and development of dedicated bioinformatics approaches and workflows
- Design and execution of NAM enhanced *in vitro* studies, e.g., combined *in vitro* Toxicokinetic assay complemented with metabolomics and/or transcriptomics measurements
- Design and execution of NAM enhanced *in vivo* studies, e.g., OECD TG407, 421, 422 complemented with metabolomics and/or transcriptomics measurements

## 3. Questions

1. Does your company offer services related to the NAM methodological developments listed in section 2.1 above, if yes please specify?
2. Does your company offer services related to NAM data generation, as listed in section 2.2 above, if yes please specify?
3. Do you have any experience in developing hazard assessment methodologies or in generating hazard data for nanoforms?
4. Do you have any experience in developing hazard assessment methodologies or in generating hazard data for polymers?
5. Regarding data generation tasks, would you prefer to provide services based on an established catalogue of services (with corresponding fixed prices) related to data generation, data processing and data analysis or every time submit the offer accounting for the specificity of each request?
6. What timeline should be considered for your organisation to be in a position to provide some or all of the products/services mentioned in section 2?; Are there any prerequisites before you can start providing products?
7. Having in mind the nature of the services that may be requested by ECHA, what, in your opinion, should be the duration of the contract: e.g., rather short as this field evolves rapidly and the scope might be outdated relatively soon, or rather long due to the complexity of the matter and multiple co-factors which shall be considered?
8. What is your level of interest in submitting an offer if ECHA decides to launch a call for tenders for a framework contract for the development of NAMs based solutions applicable to the hazard identification and characterisation and NAM data generation services?
9. We understand that it is not yet possible to provide an accurate answer, but how much time would you estimate necessary to prepare an offer addressing the topics

to be included in the contract?

10. Would you be in a position, and willing to disclose the estimated average price (e.g., price per person-day) for the expertise required to deliver the services in the contract?
11. Would you be in a position, and willing to disclose the estimated price for performing an OECD 407/422 study complemented with metabolomic measurement of blood plasma or full transcriptomic measurements from specified key organs (one time point).
12. Is there any IPR issue that could be relevant for the implementation of the contract that you would like to raise at this stage?
13. Any other feedback/remarks

**END OF QUESTIONNAIRE**