

# Partnership for the Assessment of Risks from Chemicals

Deliverable D2.8

1st Annual CL/ML reports' coordination and submission

WP2 – T2.2



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Responsible author(s)	Maria Rita Paiva Pessoa, INSA, <a href="mailto:rita.pessoa@insa.min-saude.pt">rita.pessoa@insa.min-saude.pt</a> Sónia Namorado, INSA, <a href="mailto:sonia.namorado@insa.min-saude.pt">sonia.namorado@insa.min-saude.pt</a> Isabella Apruzzese, BfR, <a href="mailto:isabella.apruzzese@bfr.bund.de">isabella.apruzzese@bfr.bund.de</a> Matthias Herzler, BfR, <a href="mailto:matthias.herzler@bfr.bund.de">matthias.herzler@bfr.bund.de</a>
Co-authors	
Internal Reviewers	Magnus Løfstedt, EEA, <a href="mailto:magnus.lofstedt@eea.europa.eu">magnus.lofstedt@eea.europa.eu</a> Maria Uhl, EAA, <a href="mailto:maria.uhl@umweltbundesamt.at">maria.uhl@umweltbundesamt.at</a>
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<sup>1</sup> PU = Public

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1	31/01/2024	INSA	First draft
2	13/03/2024	MB members	Draft reviewed by the Management Board
3	15/04/2024	INSA PARC CT	Final draft taking into accounts the comments from reviewers

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## Abstract

Under PARC, Chemical Leaders (CLs) and Methodology Leaders (MLs) are nominated to follow the work being developed related to the priority chemicals and methodologies. The CLs and MLs also help to connect PARC's activities with policy makers and regulators and to disseminate PARC results and activities.

Task 2.2 is responsible for the process of identifying potential candidates and of coordinating the nomination of the CLs and MLs. As such, Task 2.2 has disseminated an open call for applications by email to the whole PARC consortium.

For the initially selected chemicals and methodologies, eight successful candidates (three CLs and five MLs) were selected for the roles. Applicants were first screened by T2.2 co-leaders and subsequently nominated by the Management Board (MB). However, not all roles were filled, and CLs and MLs for the unfilled roles will be selected in the future.

The call for applications will continue to be open for the unfilled positions and if new candidates appear, the nomination process will be initiated. The call will be periodically disseminated and, if additional chemicals or methodologies are identified as priorities under PARC, it will be modified to include these.

This annual report summarises the application, selection and nomination process of current CLs and MLs, as well as activities carried out related to their role in this brief period since their nomination.

## Key Words

Chemical Leader, Methodology Leader, Human Health, Environmental Health, Definition of priorities, Knowledge translation, Dissemination activities.

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## Authors and Acknowledgements

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## Abbreviations and acronyms

CL(s)	Chemical Leader(s)
CRA	Chemical Risk Assessment
EDCs	Endocrine Disrupting Chemicals
ML(s)	Methodology Leader(s)
NAMs	New Approach Methodologies
PARC	Partnership for the Assessment of Risks from Chemicals
PBK	Physiologically based kinetic (modelling)
PFAS	Per- and Polyfluorinated Substances

## 1. Background

As stated in PARC's proposal, one of the objectives of Task 2.2 is to coordinate the nomination of the Chemical Leaders (CLs) and Methodology Leaders (MLs). As such, Task 2.2 developed a procedure for members of the PARC consortium who are experts in the relevant fields to apply to these roles on chemical substances (or groups of chemicals) and methodologies addressed in PARC, including criteria for the selection of the experts before nomination by the Management Board (MB). Task 2.2 is also responsible for the coordination of the work developed by the CLs and MLs throughout PARC.

## 2. Role of Chemical Leaders and Methodology Leaders

CLs and MLs have a crucial role in channelling the work related to priority chemicals and methodologies in PARC. They will have a helicopter view of these chemicals and methodologies, help connecting PARC's activities with policy makers and disseminate PARC results and activities (Figure 1).



Figure 1 Diagram presented to CLs and MLs at the 1<sup>st</sup> meeting (21/09/2023), to summarise their role and responsibilities in a broad view.

Responsibilities associated to the role of CL/ ML are the following:

- To be informed about and support collaboration on work developed on the chemical substance or method across the different WPs within PARC;
- To support WP2 in the evaluation of projects related to the specific chemical/method (as far as the CL/ML is not personally involved in the respective project), and contribute to the production of knowledge and content for PARCopedia and in the development of PARCroute;
- When necessary, to support WP3 in the development of targeted communication products and dissemination activities related to the respective chemical/methodology and in the establishment of synergies with external activities/projects;
- To elaborate and update, every two years, a scoping document on the chemical substance or methodology;
- To keep updated on and follow current and new EU regulations concerning the chemical substance or methodology;
- When necessary, to provide advice in relevant deliverables or documents produced by PARC related to the chemical substance or methodology;

- To contribute to the preparation of scientific publications on the chemical substance or methodology, if requested by the main authors or if significant work has been developed that contributed to the publication;
- To support the definition of the regulatory questions on priority substances and methods and the ranking procedures;
- When necessary, answer questions from policy makers at national and EU-level;
- To be available to present PARC results on the specific chemical/methodology at project meetings and at external scientific meetings;
- To report yearly on activities on the specific chemical/methodology by participating in a CL and ML online annual meeting and producing a short report with the updates with support of the task and project leaders involved in the work related to the chemical/methodology.

## 3. Current list of Chemicals and Methodologies

### 3.1. Chemicals

Phthalates and substitutes

EDCs

PFAS

Bisphenols and alternatives - no candidates

Metals – no candidates

Mixtures - no candidates

Pesticides and biocides - no candidates

Nanomaterials (approved on 8th January 2024 by MB, applications not yet advertised)

Microplastics (approved on 8th January 2024 by MB, applications not yet advertised)

### 3.2. Methodologies

Omics

Pre-validation of new methods

PBK modelling

Environmental Risk Assessment (approved on 8th January 2024 by MB, applications not yet advertised)

Biodiversity (approved on 8th January 2024 by MB, applications not yet advertised)

IATAs - no candidates

AOPs - no candidates

## 4. Resources for CLs and MLs

A total of 15 CLs and MLs is foreseen. For them, a budget of 30 PMs/year (1 PM per leader per year in a total of 210 PMs) and 1 386 000 € was estimated and temporarily allocated to ANSES. PMs for the roles of CLs and MLs will be reported under Task 2.2, clearly stating the activities (WPs, Tasks, projects) where they worked.

## 5. Nomination of Chemical and Methodology Leaders

An online survey was developed using the REDCap software<sup>1</sup> and sent to PARC consortium members on 24<sup>th</sup> February 2023. Candidates were able to fill information on their expertise and interest to fulfil this role. Selection criteria were previously defined, based on A. Scientific qualifications (up to 15 points); B. Expertise concerning the Chemical/ Methodology (up to 9 points); C. Social presence and engagement, including on PARCopedia (up to 3 points). For most chemical substances/ methodologies, whenever applicable and necessary, two co-leaders will be nominated: one with expertise in human health and one with expertise in the environmental area.

A total of five applications for Chemical leaders and seven applications for Methodology leaders were received and evaluated by Task 2.2 co-leaders and subsequently presented to the Management Board (MB). On 16<sup>th</sup> May 2023, the MB formally nominated the first CLs and MLs (Table 1), for a period of 3 years, after which there is a possibility of renewal until the end of PARC (April 2029).

A review of the work performed by the CLs and MLs will be carried out annually by T2.2 and presented to the MB. If their performance is considered inadequate by the MB, they can be replaced. Also, the CL or ML may ask to be replaced in case of specific circumstances to be duly justified (change in work position, change of employer, etc). In these cases, one of the applicants not initially selected can be nominated to take up this role, or, in case there are no applicants available or willing to take up this role, a new call will be sent out.

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<sup>1</sup> “REDCap is a secure web application for building and managing online surveys and databases.” More information on [www.project-redcap.com](http://www.project-redcap.com)

Table 1. Nominated CLs and MLs by the MB members on 16<sup>th</sup> May 2023

Chemical/ Methodology	Co-leader for human health	Co-leader for environment
<b>Phthalates and substitutes</b>	<i>Antje Gerofke*</i> (UBA, Germany)	
<b>EDCs</b>		Nikiforos Alygizakis (NKUA, Greece)
<b>PFAS</b>	Thorhallur Ingi Halldorsson (UI, Iceland)	
<b>Omics</b>		Josef Daniel Rasinger (IMR, Norway)**
<b>Pre-validation of new methods</b>		Miriam Jacobs (UKHSA, UK)
<b>PBK modelling</b>	Spyros Karakitsios (AUTH, Greece) Sylvia Escher (Fraunhofer ITEM, Germany)	Vikas Kumar (IISPV, Spain)

\* Antje Gerofke is no longer with UBA or any PARC institution (from January 2024); the CL role for Phthalates and substitutes will be advertised again

\*\*Josef Rasinger changed employer to EFSA, but will remain ML for Omics (Environment)

## 6. Future nominations

The [online survey](#) for application for the role remains open for candidates. Nevertheless, due to the low number of candidates, Task 2.2 co-leaders will directly invite potential candidates to apply to these roles, by identifying people within specific PARC projects relevant to selected Chemicals and Methodologies.

## 7. Activities

### 7.1 Meetings

A first online meeting with the CLs and MLs was organised on 21<sup>st</sup> September 2023. The meeting was attended by Josef Daniel Rasinger, Spyros Karakitsios, Nikiforos Alygizakis, Vikas Kumar, Miriam Jacobs and Thorhallur Ingi Halldorsson. Antje Gerofke and Sylvia Escher have excused themselves from the meeting.

In this meeting the roles and responsibilities of CLs and MLs were presented (overviewed in Figure 1) and there was an open discussion on their expectations and questions. The timeline for the foreseen activities was also presented and discussed (Figure 2). Additionally, PARCopedia was presented and their contributions (beta-test, knowledge base) were requested, namely, to participate on the beta-test, write WIKI articles as lead experts and create discussion groups and *fora* on the platform.

It was agreed upon to have a dedicated meeting to discuss and define the scoping document' structure and length, as well as the specific deadline. Additionally, it was proposed that a shorter document that could translate main highlights on the chemical or methodology could be prepared within the next few months, to be further discussed.

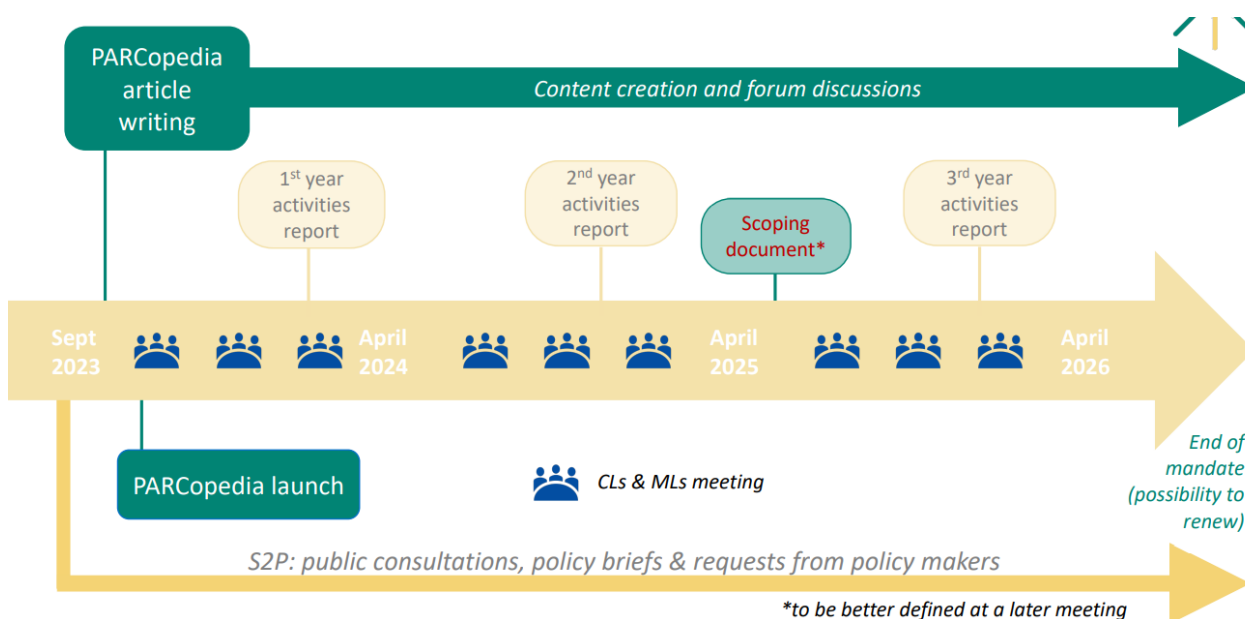


Figure 2: Timeline diagram presented at 1<sup>st</sup> meeting (21/09/2023)

### 7.2. Activities conducted by CLs and MLs (as of January 2024)

#### 7.2.1. Pre-validation of new methods

In her role as ML for the pre-validation of new methods for the human health area, Miriam Jacobs presented an online workshop on NAMs OECD validation process on 19<sup>th</sup> June 2023. This online workshop offered a presentation on the basics/foundations of *in vitro* 'NAMs' validation of test methods for regulatory purposes.

Mirjam Jacobs also participated on the workshop on OECD validation process for NAM's and PARC's contribution at the joint meeting of the Grant Signatory Board (GSB) and Management Board (MB). This workshop also had the participation of OECD representatives and WP5 and 6 co-leaders. In this workshop the PARC activities on the (pre)validation of NAMs were presented, discussions on how these contribute to the OECD validation process and on the definition of the role of PARC in the (pre)validation of NAMs took place.

## 7.2.2 Endocrine Disrupting Chemicals (EDCs)

Nikiforos Alygizakis has been developing his work on EDCs in PARC T4.2, but also in other European projects, such as [TerraChem](#) and [ONE-BLUE](#). He has also focused on preparing a list of potential EDCs (also under PARC T4.2), using the [NORMAN Substance Database](#). In addition, as a tool to help design monitoring campaigns, he and other collaborators have searched mass spectrometry samples to gather more evidence regarding EDCs' occurrence in the environment.

## 7.2.3 Physiologically based kinetic (PBK) modelling

Sylvia Escher leads the department *in silico* toxicology at Fraunhofer ITEM. In the last five years, her group developed a bottom up PBK model to simulate the absorption, distribution, metabolism and excretion (ADME) properties of mainly airborne compounds such as aerosols and gases. This model is currently further improved in different project such as [ZeroPM](#), [RISKHUNT3R](#), [ASPIS](#) and PARC. In PARC, Sylvia Escher leads the Task 5.3.4, which aims to close knowledge and data gaps in bottom up PBK modelling.

Spyros Karakitsios is involved in various activities related to PBK modelling (human health) in PARC, including co-leading Activity 6.2.2 on Human exposure through life, as well as co-leading Task 8.3 on Integrative Modelling. The PBK activities will be important for linking various activities in PARC, i.e. in translating *in vitro* test doses into equivalent exposure estimates and *vice versa* in WP5, or for providing the dose that triggers the MIE in AOPs. In addition, it will be used for exposure reconstruction (reverse dosimetry) of the human biomonitoring (HBM) data that will be collected in WP4. In WP6, internal dosimetry will be used for risk assessment. by delivering health-based guidance values based on HBM data, as well as for estimating toxicokinetic interactions of mixtures. Finally, PBK modelling is a vital part of Integrative Modelling in WP8, because it provides the mechanistic link between external exposure and early biological responses.

Vikas Kumar has been leading the PBK model developments and harmonisation activities linked to PARC WP5 (Kinetic data gap, and model development), WP6 (model development and case studies), WP7 (FAIR data and ontology development), and WP8 Integrated modelling platform). A case study paper of IVIVE-PBPK is published, which was a result of an external collaboration. For the PBK ontology development and harmonisation activities, collaboration with modelling communities outside PARC has also been started, and work is shared through a GitHub open code sharing platform. Many

of these works are also being developed in collaboration with other EU and national projects including a recent EU funded project on EDCs, "MERLON". Research activities were presented at EUROTOX 2023, delivered seminar at institutional workshop, multidisciplinary seminars. PBPK work will be also presented at Congress of Toxicology in Developing Countries (CTDC-12), Santiago, Chile, in April 2024. PBPK ontology and harmonisation work has also been submitted for SETAC 2024 and will be presented in May 2024.

### 7.2.4 Omics

In 2023, Josef Rasinger has been developing tools for his work on mycotoxins in PARC T5.1.1. In addition, he advanced work on the use of omics for applications in marine and food sciences, under different national projects. Integrating knowledge gained from PARC, he contributed with omics focused tasks to a successful project application (CONTRAST) for Horizon Europe; the overall aim of CONTRAST is to apply integrated approaches for assessing the impact of contaminants of emerging concern on the marine environment. In parallel to his research, J. Rasinger was involved with teaching and disseminating information on PARC when lecturing on the use of "omics for risk assessment" for students attending the NutriNOR summer school in Bergen Norway, and for EFSA EU-FORA fellows during their training in module 2. Towards the end of 2023, J. Rasinger took on a new position as Senior Scientific Officer for Toxicology at EFSA.

### 7.2.5 Per- and Polyfluorinated Substances (PFAS)

Since his nomination in summer 2023, Thorhallur Ingi Halldorsson has worked on an application for a new project on chemical hotspots. He has been developing his work on PFAS within PARC's Task 6.4.1

## 7.3 Conclusions and future plans

This annual work report summarises the application, selection and nomination process of the CL and ML, as well as reports newly selected priority chemical substances and methodologies by the MB for future leaders' nominations. The reporting period of the activities by the current CLs and MLs focuses on the last quarter of 2023 (October – December) and January 2024.

Due to the brief period of time in their role, CLs and MLs activities are yet to be fully developed. A more personalised approach by T2.2 Co-leaders, with 1-to-1 meetings and more consistent feedback and planning will be considered and discussed with the MLs and CLs, to ensure they are fully supported and informed in their role. Crucially, identification of potential candidates for the unfilled roles will be carried out by approaching researchers directly that are working in PARC projects.