

Partnership for the Assessment of Risks from Chemicals

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2nd Annual CL/ML reports' coordination and submission

WP2 – T2.2



Partnership
FOR THE
Assessment
OF
Risks
FROM
Chemicals



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Abstract

Under PARC, Chemical Leaders (CLs) and Methodology Leaders (MLs) are nominated to follow the work 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, their ongoing work as well as the collection and review of the scoping documents. As such, Task 2.2 has disseminated, in the beginning of 2023, 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).

As not all roles were filled, the call for applications has continued open for the unfilled positions, but no new candidates have been proposed. Since two new chemicals (nanomaterials and microplastics) and one new methodology (next generation environmental risk assessment) were selected, a new open call for applications was disseminated by email to the whole PARC consortium, not only for the new chemicals and methodology, but also for the roles not filled yet. Following this call six successful candidates (three new CLs and three new MLs) were selected for the roles and were nominated by the MB.

This annual report summarises the application, selection and nomination processes of current CLs and MLs, as well as activities carried out related to their role concerning the period being reported (year of 2024).

Key Words

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

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Abbreviations and acronyms

AOPs	Adverse Outcome Pathways
CL(s)	Chemical Leader(s)
CRA	Chemical Risk Assessment
EDCs	Endocrine Disrupting Chemicals
ML(s)	Methodology Leader(s)
NAMs	New Approach Methodologies
NG-ERA	Next Generation Environmental Risk Assessment
PARC	Partnership for the Assessment of Risks from Chemicals
PBK	Physiologically based kinetic (modelling)
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances

1. Background

As stated in PARC's proposal, one of the objectives of Task 2.2 is to coordinate the nomination and the work of the Chemical Leaders (CLs) and Methodology Leaders (MLs) on chemical substances (or groups of chemicals) and methodologies addressed in PARC. 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, 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, having a helicopter view of the work done related to these chemicals within and outside of PARC and methodologies, helping to connect PARC's activities with policy makers and to disseminate PARC results and activities (Figure 1).



Figure 1 - Diagram summarising the role and responsibilities of CLs and MLs.

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 methodology across the different WPs within PARC;
1. To support WP2 in the evaluation of projects related to the specific chemical/methodology (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;
 2. 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;
 3. To elaborate and update a scoping document on the chemical substance or methodology;
 4. To keep updated on and follow current and new EU regulations concerning the chemical substance or methodology;
 5. When necessary, to provide advice on relevant deliverables or documents produced by PARC related to the chemical substance or methodology;

6. 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;
7. To support the definition of the regulatory questions on priority substances and methods and the ranking procedures;
8. To answer questions from policy makers at national and EU-level;
9. To be available to present PARC results on the specific chemical/methodology at project meetings and at external scientific meetings;
10. 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

The chemicals addressed in PARC and selected now to have CLs are the following:

- Bisphenols and alternatives
- Endocrine Disrupting Chemicals (EDCs)
- Metals
- Microplastics
- Nanomaterials
- Perfluoroalkyl and Polyfluoroalkyl Substances (PFAs)
- Pesticides and biocides
- Phthalates and substitutes

3.2. Methodologies

The methodologies addressed in PARC and selected to have MLs are the following:

11. Adverse Outcome Pathways (AOPs)
12. Next Generation Environmental Risk Assessment (NG-ERA)
13. Omics
14. Physiologically Based Kinetic (PBK) modelling
15. Pre-validation of new methods

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 for the whole duration of PARC) 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. Nominated Chemical and Methodology Leaders

An online survey was developed using the REDCap software and sent to PARC consortium members on 24th 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 are 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 16th May 2023, the MB formally nominated the first CLs and MLs (Table 1), for a period of 3 years, after which will be decided by the MB if they continue their work until the end of PARC (April 2029). The first CLs were nominated for Phthalates and substitutes, EDCs and PFAS and the first MLs were nominated for Omics, PBK modelling and pre-validation of new methods.

During the MB of 8th January 2024, the decision memorandums on the nomination of CLs for nanomaterials and microplastics and on the nomination of MLs for Next Generation Environmental Risk Assessment (NG-ERA) were approved and similarly to what was done in 2023, a new call was sent to PARC consortium members, not only for the new chemicals and methodology but also for the chemicals and methodologies without leaders nominated.

A total of five applications for CLs and four applications to MLs were received and evaluated by Task 2.2 co-leaders and subsequently presented to the MB. On 8th April 2024, the MB formally nominated new CLs and MLs (Table 1). CLs were nominated for PFAS, nanomaterials and microplastics and MLs were nominated for Omics and NG-ERA.

A review of the work performed by the CLs and MLs is 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.

Table 1 - CLs and MLs nominated by the MB

Chemical/Methodology	Co-leader for human health	Co-leader for environment
Bisphenols and alternatives	No applicants	No applicants
EDCs	No applicants	Nikiforos Alygizakis* (NKUA, Greece)
PFAS	Thorhallur Ingi Halldorsson* (UI, Iceland)	Lutz Ahrens** (SLU, Sweden)
Metals	No applicants	No applicants
Microplastics	Dorte Herzke** (NILO, Norway)	No applicants
Nanomaterials	Iseult Lynch** (UOB, UK)	Susana Loureiro** (UAVR, Portugal)
Pesticides	No applicants	No applicants
Phthalates & substitutes	No applicants	No applicants
Methodology	Co-leader for human health	Co-leader for environment
Adverse Outcome Pathways (AOPs)	No applicants	No applicants
NG-ERA	Not foreseen	Johan Axelman** (KEMI, Sweden) Romana Hornek-Gausterer** (FHTW, Austria)
Omics	Martin von Bergen** (UFZ, Germany)	Josef Daniel Rasinger* (EFSA)
Pre-validation of new methods		Miriam Jacobs* (UKHSA, UK)
PBK modelling	Spyros Karakitsios* (AUTH, Greece) Sylvia Escher* (Fraunhofer ITEM, Germany)	Vikas Kumar* (IISPV, Spain)

*Nominated in May 2023. **Nominated in April 2024.

6. Future nominations

The online survey for application for the role remains open for candidates for the open positions. 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 meeting with the CLs was organized on 15th April 2024 to discuss the next steps as CLs and a meeting with the MLs was organized on 26th April 2024 with the same objective.

In these meetings each CL/ML has described the work/experience on the chemical/methodology they lead and their motivation to apply for this role. The roles and responsibilities of CLs and MLs were again 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, and the document created to support the CLs/MLs in the yearly planning of their activities was presented. Additionally, the knowledge management platform, developed by WP2 – Task 2.2, [PARCopedia](#), was presented and the CLs/MLs were asked to contribute by writing WIKI articles as lead experts and creating discussion groups and fora on the platform.

It was agreed upon to have dedicated meetings to discuss further the next activities for each CL/ML. Dedicated meetings with each CL and the NG-ERA MLs were organized (EDCs 30th April 2024, PFAS 30th April 2024, nanomaterials 3rd May 2024, microplastics 29th April 2024, NG-ERA, 4th June 2024).

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

7.2.1. Endocrine Disrupting Chemicals (EDCs)

Nikiforos Alygizakis has continued to develop his work on EDCs under 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.

He has created the PARCopedia group "EDCs in PARC" and has prepared a Wiki article for PARCopedia on EDCs that is currently under review to be published in May 2025.

Feedback on the factsheets "Next steps on Future Activities for 2024-2027" was provided (April/May 2024).

7.2.2. Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

Since his nomination, Thorhallur Ingi Halldorsson has been developing his work on PFAS within PARC's Task 6.4.1, while Lutz Ahrens has been involved in the development of the new early warning system tools (Task 8.2) to identify new hazardous substances such as PFAS, at an early stage to improve risk assessment and regulation of these substances.

They have provided feedback on the factsheets "Next steps on Future Activities for 2024-2027".

Following the request for more information on PFAS activities voiced during the PARC Governing Board (GB) meeting of November 2023, Thorhallur and Lutz have organized, in the context of the GB meeting of 13rd November 2024, the GB Workshop on PFAS that took place on 31st October 2024. The objective of this GB workshop was to present an overview of the work related to PFAS developed in PARC with a highlight on specific activities. This workshop had the participation of several PARC participants such as Katrin Vorkamp (Task 4.2), Jussi Reinikainen (Task 6.3), Robin Vestergren (Task 6.4.3) and Wieneke Bil (Task 6.2). The workshop also had external participants such as Anna Kärman/Leo Yeung that have addressed the assessment of PFAS total in humans and the environment and Ron Hoogenboom that has addressed the human risk assessment applying Relative Potency Factors (RPFs).

7.2.3. Nanomaterials

Following the second round of prioritisation of chemicals in PARC, in which nanomaterials (and their broader class of advanced materials) were identified as being of interest to both ECHA and EFSA, nanomaterials were selected as chemicals addressed in PARC that should have CLs and Iseult Lynch and Susana Loureiro were nominated as CLs for, respectively, human health and the environment.

Following their nomination they have provided feedback on the factsheets "Next steps on Future Activities for 2024-2027" and have created a PARCopedia group on Nanomaterials (and Advanced Materials) in PARC.

During the GB meeting organised on 16th May 2024, representatives from the member states expressed keen interest in the organisation of a discussion on nanomaterials. Consequently, an online workshop was organized on 29th October 2024 with the objective of presenting the main findings of the CLs on nanomaterials. This workshop also presented an opportunity for the CLs to showcase the main findings of the state-of-the-art which they were tasked to prepare and use it as a basis for discussion with GB and MB members on how PARC can or cannot contribute (within its mandate and resources). During this workshop an interactive activity using the online tools Mentimeter and Klaxoon has allowed to gather input from the GB.

The CLs have worked on the landscape mapping and recommendations for where and how PARC can support regulatory research on nanomaterials that will be finalised by the end of PARC's year 3. Furthermore, two other scoping activities are under way: the first assessing what adaptations will be needed to PARC to developed New Approach Methodologies (NAMs) to make them suitable for use with nanomaterials and the second assessing the availability of analytical methods for detection of nanomaterials in human biomonitoring studies.

Furthermore, they have presented the oral communication “PARC roadmap for nanomaterials – exploring how PARC can contribute most usefully” at MaterialsWeek 2024 that took place in Limassol, Cyprus, from June 18 to 20, 2024.

7.2.4. Microplastics

Also following the second round of prioritisation of chemicals in PARC, in which microplastics were identified as being of interest to both ECHA and EFSA, microplastics were selected as chemicals addressed in PARC that should have CLs and Dorte Herzke was nominated as CL for human health.

Following her nomination she has provided feedback on the factsheets “Next steps on Future Activities for 2024-2027”.

Similarly to nanomaterials, representatives from the member states expressed interest in the organisation of a discussion on microplastics during the GB meeting organised on 16th May 2024. As such, an online workshop was organized on 6th November 2024 with the objective of presenting the work already developed. Besides Dorte Herzke, Iseult Lynch was involved in the organization and chairing of this workshop. In this workshop the landscape assessment performed was presented and it was discussed whether PARC should plan dedicated microplastics projects in subsequent years.

The CL has worked on the landscape mapping and recommendations that will be finalised by the end of PARC’s year 3.

7.2.5. Physiologically based kinetic (PBK) modelling

In PARC, Sylvia Escher leads the Task 5.3.4, which aims to close knowledge and data gaps in bottom up PBK modelling. She has developed a bottom up PBK model to simulate the absorption, distribution, metabolism and excretion properties of mainly airborne compounds such as aerosols and gases, that is being further improved in different project such as ZeroPM, RISKHUNT3R, ASPIS and PARC.

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

was also presented at the Congress of Toxicology in Developing Countries (CTDC-12), Santiago, Chile, in April 2024. PBPK ontology and harmonisation work has also presented at the SETAC 2024, Seville, Spain, in May 2024.

7.2.6. Omics

Josef Rasinger has been developing tools for his work on mycotoxins in PARC A5.1.1. 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.

7.2.7. 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 19th June 2023 as well as several webinars to inform the PARC community. The online workshop offered a presentation on the basics/foundations of in vitro 'NAMs' validation of test methods for regulatory purposes. It is worth mentioning that she plays a pivotal role within the OECD (Organisation for Economic Co-operation and Development) as the UK National Coordinator to the OECD Test Guideline Programme. She is actively involved in several expert groups, including those focused on Adverse Outcome Pathways (AOP) development and the Validation Management Group for Non-Animal methods (VMG-NA). She has significantly contributed to the development and validation of OECD Test Guidelines, particularly in the areas of endocrine disruptors and non-genotoxic carcinogens.

Mirjam Jacobs also participated in 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.

During 2024, Miriam Jacobs has continued to work on NAMs validation being involved in several WP6 activities, having contributed to the publication "A 2024 inventory of test methods relevant to thyroid hormone system disruption for human health and environmental regulatory hazard assessment" at the journal Open Research Europe (doi: 10.12688/openreseurope.18739.1).

7.2.8. Next Generation Environmental Risk Assessment

As MLs for NG-ERA and biodiversity Johan Axelman and Romana Hornek-Gausterer have had the chance to get an overview of all initiatives in PARC of relevance for ERA. They have mapped an impressive amount work ongoing in PARC and external projects, all addressing many relevant regulatory needs, from NAMs to improving the ecological relevance of ERA. They also found significant

opportunities to improve the integration of data, knowledge and insights across these projects to more efficiently address the systemic nature of drivers for biodiversity loss. Bringing together scientific excellence and all key regulatory actors in the EU, PARC constitute a unique opportunity to co-shape and drive such a transition to NG-ERA. As MLs they are currently organising high-level initiatives and platforms for transdisciplinary dialogue in concert with proof-of-concept research providing innovative solutions as well as new insights from cross-disciplinary integration of data.

Romana Hornek-Gausterer is one of the organizers of the session “Biodiversity and Chemical Hazard/Risk Assessment: Regulatory Frameworks, Integrative Approaches and Research for a Sustainable Future” that will take place at the SETAC Europe 35th Annual Meeting that will take place between 11 and 15 May 2025 in Vienna, Austria. She has also proposed a special issue to the journal *Environment International* (Impact Factor 10.3) on “Bridging Science and Risk Assessment to Protect Biodiversity from Chemical Pollution”, for which she is guest editor and the call for papers will be open until 28th August 2025.

7.3. Conclusions, challenges and future plans

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 well as their work. Following the two open calls for applications fourteen successful candidates (six CLs and eight MLs) were selected for the roles and were nominated by the MB. However, not all roles have been filled. During PARC’s year 4 efforts will be made to enhance the visibility and appeal of these roles, by showcasing the work done by the nominated CLs and MLs in PARC’s website and social media. Efforts to identify suitable candidates through targeted outreach will also be done.

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 concerning the period being reported (year of 2024).

Regarding CLs and MLs future plans, it is foreseen that they prepare a scoping document based on factsheets which have already been produced by task 2.1 (Prioritisation). Following PARC’s D1.10 Annual Workplan Y4, regular meetings with the CLs and MLs will be organised to keep track of the work being developed. Furthermore, annual work plans for their activities will be prepared, to support their work across PARC (M40, September 2025). A report on the work done will be submitted at the end of Y4 (D2.15, January 2026). Assessment of further needs concerning CLs and MLs will be conducted and, if deemed necessary, nomination of CLs and/or MLs for additional chemicals and/or methodologies will be performed. The MB will be regularly updated on the work performed in the respective areas.