# Draft proposal for a European Partnership under Horizon Europe

# Partnership for the Assessment of Risk from Chemicals (PARC)

Version 03/06/2020

**About this draft**

In autumn 2019 the Commission services asked potential partners to further elaborate proposals for the candidate European Partnerships identified during the strategic planning of Horizon Europe. These proposals have been developed by potential partners based on common guidance and template, taking into account the initial concepts developed by the Commission and feedback received from Member States during early consultation[1]. The Commission Services have guided revisions during drafting to facilitate alignment with the overall EU political ambition and compliance with the criteria for Partnerships.

This document is a stable draft of the partnership proposal, released for the purpose of ensuring transparency of information on the current status of preparation (including on the process for developing the Strategic Research and Innovation Agenda). As such, it aims to contribute to further collaboration, synergies and alignment between partnership candidates, as well as more broadly with related R&I stakeholders in the EU, and beyond where relevant.

This informal document does not reflect the final views of the Commission, nor pre-empt the formal decision-making (comitology or legislative procedure) on the establishment of European Partnerships.

In the next steps of preparations, the Commission Services will further assess these proposals against the selection criteria for European Partnerships. The final decision on launching a Partnership will depend on progress in their preparation (incl. compliance with selection criteria) and the formal decisions on European Partnerships (linked with the adoption of Strategic Plan, work programmes, and legislative procedures, depending on the form). Key precondition is the existence of an agreed Strategic Research and Innovation Agenda / Roadmap. The launch of a Partnership is also conditional to partners signing up to final, commonly agreed objectives and committing the resources and investments needed from their side to achieve them.

The remaining issues will be addressed in the context of the development of the Strategic Research and Innovation Agendas/ Roadmaps, and as part of the overall policy (notably in the respective legal frameworks). In particular, it is important that all Partnerships further develop their framework of objectives. All Partnerships need to have a well-developed logical framework with concrete objectives and targets and with a set of Key Performance Indicators to monitor achievement of objectives and the resources that are invested.

Aspects related to implementation, programme design, monitoring and evaluation system will be streamlined and harmonised at a later stage across initiatives to ensure compliance with the implementation criteria, comparability across initiatives and to simplify the overall landscape.

[1] https://www.era-learn.eu/documents/final_report_ms_partnerships.pdf

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For information on the SRIA development process and next steps in the preparation of this Partnership please see section 2.2.8 below.
Information about the Partnership will also be made available by end of June on https://www.anses.fr/en/content/networks-and-projects-which-anses-participates

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# Abbreviations and definitions

## Abbreviations

| | |
|---|---|
| 3R | Reduce, Refine, Replace animal testing |
| AI | Artificial Intelligence |
| ANSES | French Agency for Food, Environmental and Occupational Health & Safety |
| AO | Adverse Outcome |
| AOP | Adverse Outcome Pathway |
| ATR | Annual Technical Report |
| AWP | Annual Work Plan |
| CAS | Chemical Abstracts Service |
| CLP | Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures |
| CLRTAP | Convention on Long-Range Transboundary Air Pollution |
| CP | Concept Paper |
| EAP | Environmental Action Programme |
| ECHA | European Chemicals Agency |
| EDPB | Ethics and Data Protection Board |
| EEA | European Environment Agency |
| EFSA | European Food Safety Authority |
| EUB | EU Board |
| FAIR data | Findable, Accessible, Interoperable and Reusable data |
| GDPR | General Data Protection Regulation. Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data |
| GSB | Grant Signatories Board |
| HBM4EU | European Joint Programme on Human Biomonitoring |
| IATA | Integrated Approaches to Testing and Assessment |
| IB | International Board |
| ILO | International Labour Organization |
| IPCHEM | Information Platform for Chemical Monitoring |
| KE | Key Events (in toxicology) |
| KER | Key Events Relationships |
| LTP | Linked Third Party |
| MB | Management Board |
| MIE | Molecular Initiating Event |
| MoA | Mode of Action |

| | |
|---|---|
| MS | Member State |
| NAM | New Approach Methodology |
| NGO | Non-Governmental Organisation |
| NH | National Hubs |
| OECD | Organisation for Economic Co-operation and Development |
| PARC | Partnership for the Assessment of Risk from Chemicals |
| PBK | Physiologically Based Kinetics |
| PIC | Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals. |
| PoD | Point of Departures |
| POP | Persistent Organic Pollutant |
| PRTR | Protocol on Pollutant Release and Transfer |
| QA/QC | Quality Assurance (QA) and Quality Control (QC) |
| qAOP | Quantitative Adverse Outcome Pathway |
| QIVIVE | Quantitative In Vitro In Vivo Extrapolation |
| QSAR | Qualitative, Quantitative Structure Activity Relationship |
| REACH | Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| R&I | Research and innovation |
| SDG | United Nations Sustainable Development Goals |
| SG | Steering Group |
| SMART | Specific, Measurable, Attainable, Realistic, Timely |
| SOP | Standard operating procedures |
| SRIA | Strategic Research and Innovation Agenda |
| SSbD | Safe-and Sustainable-by-Design |
| TTC | Threshold of toxicological concern and ecoTTC: Ecological Threshold of toxicological concern |
| WEEE | Waste electrical and electronic equipment |
| WFD | Water framework directive |

# 1. General information

## 1.1. Draft title of the European Partnership

Working title and acronym: Partnership for the Assessment of Risk from Chemicals "PARC"

## 1.2. Lead entity (main contact)

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## 1.4. Summary

PARC is an EU-wide research and innovation programme to support EU and national chemical risk assessment and risk management bodies with new data, knowledge, methods, networks and skills to address current, emerging and novel chemical safety challenges. It will facilitate the transition to next generation risk assessment to better protect human health and the environment, in line with the Green Deal's zero-pollution ambition for a toxic free environment and will be an enabler for the EU Chemicals Strategy for sustainability.

# 2. Context, objectives, expected impacts

## 2.1. Context and problem definition

### *2.1.1. Policy Context*

The purpose of the Partnership is to drive innovation in chemical risk assessment and thereby enable the sustainable use and management of chemicals whilst protecting human health and the environment and contributing to a non-toxic environment by:

a) strengthening the scientific basis for chemical risk assessment in the EU, by bringing risk assessors and managers together with scientists to accelerate method development, the generation of necessary data and knowledge, and
b) facilitating the transition to next generation evidence-based risk assessment.

Political agendas around the world are committed to address the **UN Sustainable Development Goals** (SDGs). Given that chemicals and waste affect all aspects of sustainable development, the sound management of chemicals and waste is essential and supports the implementation of many, if not all, SDGs[2].

[2] SDG1 on No poverty, SDG2 on Zero hunger, SDG3 on Good health and well-being, SDG4 on Quality education, SDG5 on Gender equality, SDG6 on Clean water and sanitation, SDG7 on Affordable and clean energy, SDG8 on Decent work and economic growth, SDG9 on Industry, innovation and infrastructure, SDG10 on Reduced inequalities, SDG11 on Sustainable cities and communities, SDG12 on Responsible consumption and production, SDG13 on Climate action, SDG14 on Life below water, SDG15 on Life on land, SDG17 on Partnerships for the goals (https://sustainabledevelopment.un.org/).

Chemicals of anthropogenic origin can be organised in a cause - effect perspective. Chemicals being handled, manufactured and applied are in principle known chemicals and mixtures of chemicals. This knowledge relates to SDGs 6 (water), 7 (energy), 9 (industry, innovation and infrastructure), 11 (cities and communities) and 12 (consumption and production). Environmental as well as workplace release of chemicals and subsequent adverse effects on ecosystems and humans unintentionally affect the achievement of the SDG addressing food (2) and drinking water (6), health (3), protection of the planet (13), aquatic environment (14) and soils (15). Moreover, adverse effects of chemicals indirectly relate to the goals on poverty (1), work and economy (8), climate change (13), and, though less pronounced, implicitly contributes to areas such as education (4), societal (10) and gender (5) equalities[3]. Handling the complexity of chemical pollution requires intensified competence building for all professionals involved in the assessments of hazards and risk of chemicals in general, but in particular with regards to the mixtures of chemicals which humans and the environment are subjected to. This ambition is in line with SDG 4 on education and SDG 17 on global partnerships.

In the **Global Environment Outlook** 6[4], the UN calls for immediate action to address pressing environmental issues and, including human health risks of chemical pollution, to achieve the SDGs. The UN states that regulations, assessment and monitoring, and industry and consumer responsibility in informing and substituting the use of chemicals of global concern with safer alternatives when technically and economically feasible, are needed.

Policies have, for decades, had a vision to protect human and environmental health, as well as ecosystem services such as clean air, water, soil and food, but are lagging behind on delivering (SOER2020)[5]. Minimising the negative impacts of the use of chemicals has been set as a goal in the **7th Environment Action Programme**[6], but downstream mitigation and adaptation tools on single chemicals, legislated as single substances incoherently across policy silos have been ineffective in reaching these goals. Upstream prevention is broadly agreed to be a more effective tool to avoid pollution[7], i.e. to achieve 'Zero Pollution'[8]. Meanwhile Europe and countries struggle to achieve a circular economy[9], in part due to the difficulty in tracking, separating and removing toxic chemicals from material cycles.

As announced in the political guidelines[10] for the 2019-2024 von der Leyen Commission, the **Green Deal**[11] Communication was issued in December 2019. The Green Deal resets the Commission's commitment to tackle climate change and environmental-related challenges. Amongst other ambitious goals the Green Deal includes a zero-pollution ambition for a toxic free environment. In this context, the Commission announces a 'Zero Pollution Plan for Air, Water and Soil' in 2021, cross-linked with the recently adopted Communication on the 'Farm

[3] http://www.euro.who.int/__data/assets/pdf_file/0007/352249/3.9-Fact-sheet-SDG-Hazardous-chemicals-26-10-2017.pdf?ua=1

[4] United Nations Environment Programme (2019) Global Environment Outlook 6; https://www.unenvironment.org/resources/global-environment-outlook-6

[5] The European environment — state and outlook 2020: knowledge for transition to a sustainable Europe https://www.eea.europa.eu/soer

[6] https://ec.europa.eu/environment/action-programme/

[7] EEA 2020. Europe's state of the environment 2020: change of direction urgently needed to face climate change challenges, reverse degradation and ensure future prosperity

[8] European Commission, 2019. The European Green Deal

[9] European Commission, 2015. Closing the loop – An EU action plan for the circular economy

[10] https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

[11] https://ec.europa.eu/info/publications/communication-european-green-deal_en

to Fork strategy'[12] and with the 'Chemicals Strategy for Sustainability'[13] planned for fall 2020. This Partnership will be a direct contribution to the new Chemicals Strategy and to cross-linked actions.

The Green Deal also aims at mobilising industry for a clean, healthy and circular economy. In March 2020 a new 'Industrial Strategy'[14] was presented, together with a 'New Circular Economy Action Plan[15]'. The latter includes a sustainable product policy framework to support the circular design of all products and prevent harmful products from being placed on the EU market. Further, the Green Deal announced the Biodiversity Strategy for 2030[16], which Communication has recently been published. All these strategies developed in parallel will benefit from innovation in chemical risk assessment. Main challenge lies at the interface between different strategies and the balance between benefits and risks of (new and existing) chemicals.

The Council Conclusions[17] of June 2019 **'Towards a Sustainable Chemicals Policy Strategy of the Union'** underline the need to protect human health and the environment through the sound management of chemicals. The Council urged the Commission to develop a Union strategy for a non-toxic environment, which proposes clear objectives for a comprehensive long-term sustainable EU chemicals policy. The conclusions acknowledge the importance of continuously improving our knowledge about the human and eco-toxicity of chemicals and of adequately addressing the uncertainties regarding exposure to chemicals. The Council recognise the significance of environmental monitoring and human biomonitoring for recording the combined exposure of the environment and humans to chemicals and the unique role of these instruments in identifying hitherto unknown exposure to problematic chemical substances. Environmental monitoring not only helps to identify potential chemical pathways to humans but also protects "ecosystem services" such as clean and safe water, which are integral to human health. The Council further underlined the need for a sustainably funded structure for research encompassing inter alia a continuation of existing initiatives in the areas of human biomonitoring, the development and adaptation of test methods in toxicology and the scientific basis for risk assessment and risk management of chemicals. Moreover, the Council stresses the importance to prevent and minimise the exposure to chemical substances of very high concern and embed the principles of green and sustainable chemistry in EU policy.

The **Council Conclusions**[18] **for the 8th Environmental Action Programme** (EAP) 'Turning the Trends Together' recall that the Union is committed to a high level of protection of the environment and of human health, to the improvement of the quality of the environment, and to combating climate change. It again urges the Commission to present without any further delay a Union strategy for a non-toxic environment, in close collaboration with the Member States and the Union institutions, in line with the 7th EAP and the June 2019 Council Conclusions on chemicals.

Meeting the new European policy goals towards a non-toxic environment, sustainable development and the Green Deal will demand a critical eye to the applicability of the EU regulatory framework for chemicals. Today's **EU regulatory framework for chemicals** is well advanced. Chemical substances may be covered by many different legislations such as those for chemicals control, for the environment and specific media such as air, water, waste, and industrial emissions, those specifically covering exposure to chemical agents and chemical

[12] https://ec.europa.eu/food/farm2fork_en
[13] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12264-Chemicals-strategy-for-sustainability-
[14] https://ec.europa.eu/info/sites/info/files/communication-eu-industrial-strategy-march-2020_en.pdf
[15] Reflection paper: Towards a sustainable Europe by 2030. European Commission, January 2019
[16] https://ec.europa.eu/environment/nature/biodiversity/strategy/index_en.htm
[17] http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf
[18] https://www.consilium.europa.eu/media/40927/st12795-2019.pdf, Council conclusions October 2019

safety, but also for food safety and food contact materials, health and safety at work and products control. Within these, many core pieces of legislation related to chemicals and their market introduction and approved use, emissions to the environment and impacts on human and environmental health (e.g. REACH, CLP, PIC Regulation, Protocol on Pollutant Release and Transfer (PRTR), Stockholm Convention on Persistent Organic Pollutants (POP) and Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (CLRTAP), General Food Law and sectorial legislation for specific sectors of the food chain, Plant Protection Products and Biocidal Product Regulations, Regulation on (Veterinary) Medicinal Products, Cosmetic Regulation, Restriction of the use of certain Hazardous Chemical substances in electric and electronic equipment, Toy Safety Directive, Air Quality Directive, Marine Strategy Framework Directive, Water Framework Directive, Groundwater Directive, Drinking Water Directive, Waste Framework Directive, Industrial Emissions Directive, Sewage Sludge Directive, Occupational Safety and Health Directives) have been implemented during the past two decades. They have introduced strict rules for health protection, be it for workers, consumers or the environment (including animals and plants), considerably improved human and environmental safety testing and monitoring requirements for chemicals, and increased access to information on the occurrence and inherent toxicological properties of chemicals and their conditions of use. These pieces of legislation are supported by additional strategies when specific challenges are identified, e.g.; the EU Framework for Endocrine Disruptors[19] or the Strategy for Pharmaceuticals in the Environment[20]. However, in contrast to monitoring obligations for environmental compartments, a monitoring system for human exposures including through human biomonitoring, as a valuable tool to assess actual exposure to specific chemicals integrating all sources and exposure routes, is not yet mandatory.

This Partnership will also contribute with data generation, analysis and management approaches to support the European Strategy for Data[21], in particular through its contribution to the Common European Green Deal data space that aims to use the major potential of data in support of the Green Deal priority actions such as the zero-pollution strategy.

In the EU, the process for assessing risks of most chemicals on the market is based on the responsibility of the producers or importers to perform health and environmental risk assessments with guidance from different regulatory frameworks, depending on their intended use. As shown in Figure 1 the risk assessment and management process is cyclic, involving different actors in different steps. This Partnership targets those parts under the responsibility of public authorities to strengthen the public knowledge base and thereby support their activities.

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1553617067256&uri=CELEX:52018DC0734
[20] https://ec.europa.eu/commission/news/pharmaceuticals-environment-2019-mar-11_en
[21] https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en

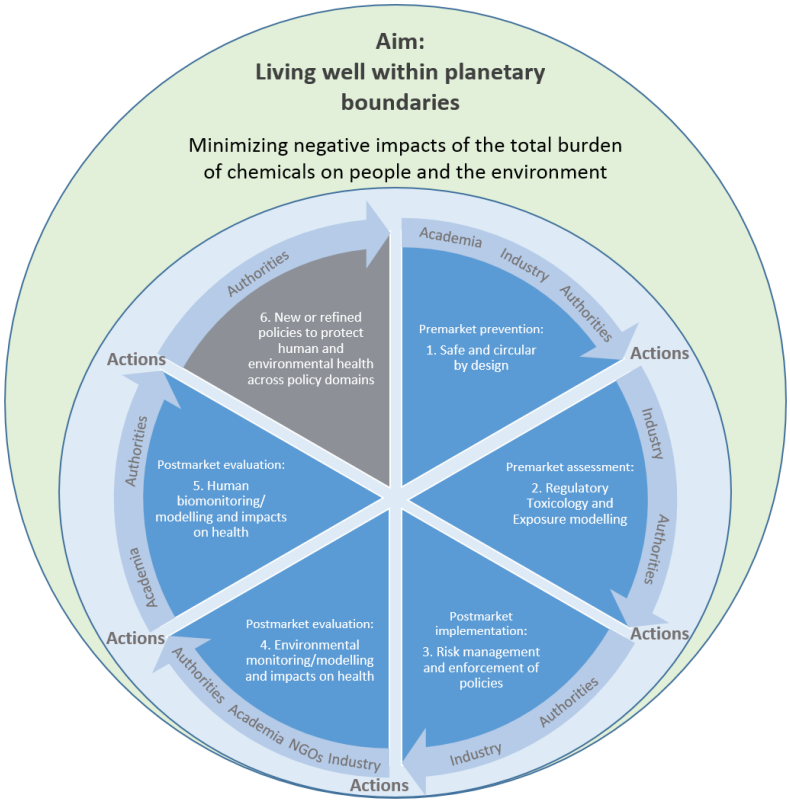


*Figure 1: The different parts of the risk assessment and management cycle.*

### 2.1.2. Scale of the problem and bottlenecks and associated research and innovation needs

The present Partnership is not meant to propose solutions for all the problems and bottlenecks listed below, as some go well beyond research and innovation needs and others may reflect political or societal concerns. However, due to the interlinkages of problems and solutions, the Partnership can aim at providing new scientific evidence in some areas and thereby encourage changes in other areas.

**The Partnership will focus on addressing priority knowledge gaps for evidence-based chemical risk assessment, as identified by risk assessors and risk managers, and where research and innovation (R&I) activities bring added value.**

Activities carried out through the Partnership shall **not** substitute for testing and information requirements under existing regulatory frameworks (e.g., as part of marketing authorisation applications for chemicals or products), or to replace routine monitoring obligations (e.g. such as those under the water and air legislation). The Partnership focuses on issues of regulatory concern that cannot be clarified within these frameworks and which **require independent and additional research and innovation activities**. A more detailed description of the portfolio of activities can be found in chapter 3.

Number and diversity of chemicals

One of the complexities and challenges for chemicals policy is the dynamics of new knowledge and developments in technology and innovation. The CAS registry[22] currently contains over 159 million organic and inorganic chemicals. In 2018, the total number of industrial chemicals in commerce globally was conservatively, excluding small volumes, estimated at 40.000 to 60.000, with 6.000 of these chemicals accounting for more than 99% of the total volume. The

[22] https://www.cas.org/support/documentation/chemical-substances

number of chemicals on the market is increasing as a result of a larger and growing number of composites as well as industrial and consumer products such as computers, mobile phones, furniture, and personal care products, all of which contain various mixtures of chemicals[23].

More than 60% of the volume of chemicals produced and used in the EU are classified as hazardous to human health, while around 35% are hazardous to the environment[24]. Global chemical sales (excluding pharmaceuticals) are projected to grow from EUR 3.47 trillion in 2017 to EUR 6.6 trillion by 2030, which equals almost a doubling of the sales. During the same period, EU production is estimated to increase by around 30%[25].

Due to the large and growing number of chemical substances on the market, challenges for risk assessment and management are expected to increase significantly. Only a small fraction of the chemicals on the market have been sufficiently characterised in terms of their toxicological properties or exposure scenarios, or are regularly monitored, while limited or no data are available for the overwhelming majority chemicals[26]. While we are exposed to tens of thousands of chemicals, most of our knowledge is focused on only a fragment of these, being counted in the range of hundreds.

The Partnership will contribute to closing the knowledge gaps by addressing R&I needs more specifically identified in the following sections.

### Incomplete occurrence and exposure data

Significant gaps remain in our knowledge of which chemicals, single or in combination, and what concentrations, humans and the environment are being exposed to[27]. Early identification of environmental fate and exposure pathways of hazardous chemicals is of great importance to enable timely measures to reduce or to eliminate exposure. A drawback of many chemical regulations is that they tend to target a limited subset of chemicals considered to be of relevance for human or environmental health at the time the legislation is established, while being inherently limited with regard to emerging and future chemicals of concern, or with mixtures of chemicals.

For chemicals in the environment, the regulatory framework is based on the precautionary principle of source control, with limited mechanisms to measure its efficacy. The numbers of chemicals monitored and reported at EU level mount to 91 under the European Pollution Release and Transfer Mechanism; 45 under the Water Framework Directive (WFD) and 26 under the Convention on Long-Range Transboundary Air Pollutants (CLRTAP)[28]. These numbers show that we do not have the complete insight into chemicals in the environment and their impacts; neither on the environment nor how they affect human health through direct exposure or in terms of impacts on ecosystem services. Moreover, in some cases, analytical methods sufficiently sensitive for monitoring chemical substances in the environment at the lowest levels that could cause effects are non-existent, too expensive or not documented.

With regards to chemical contaminants in food and feed, many are naturally occurring e.g. aflatoxins or heavy metals. Maximum levels are set for the contaminants of greatest concern to EU consumers, due to either their toxicity or their potential prevalence in the food chain.

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[23] UNEP (2019), Global Chemicals Outlook, From Legacies to Innovative Solutions. Synthesis Report, p. 4.
[24] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics
[25] UNEP 2019, Global Chemicals Outlook https://wedocs.unep.org/bitstream/handle/20.500.11822/27651/GCOII_synth.pdf?sequence=1&isAllowed=y
[26] EEA (2019) The European environment — state and outlook 2020: knowledge for transition to a sustainable Europe. Chapter 10, Chemical pollution. https://www.eea.europa.eu/soer-2020/intro
[27] European Commission (2019), Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries Fitness check chemicals legislation. Staff Working Document. p. 42-46.
[28] EEA (2019) The European environment — state and outlook 2020: knowledge for transition to a sustainable Europe. Chapter 10, Chemical pollution. https://www.eea.europa.eu/soer-2020/intro

The levels are set on the basis of scientific advice provided by the European Food Safety Authority (EFSA) and Member State authorities are responsible for sampling food products, to ensure that they comply with the legislation.

Monitoring programmes only include a relatively limited selection of chemicals, while new chemicals are continuously introduced to the market, regulated or banned chemical substances are replaced by alternatives, production and use patterns may shift, waste electrical and electronic equipment (WEEE) is rapidly increasing, products (including food and feed) are imported from outside the EU and chemicals arrive by long-range atmospheric transport. For some chemicals, human exposure estimates could be improved if monitoring could be better targeted by making use of spatially detailed information on production, sales, use, consumption, chemical composition and insights into exposure to chemicals from specific products and articles. The new SCIP[29] database developed by ECHA is a first step in this direction. In addition, due to globalisation and social changes (e.g. more frequent changing in jobs, immigration), cumulative chemical exposures over time may even become more complex, which even further warrants exposure monitoring programmes.

Workers are often highly exposed and represent a category of people at higher risk and in this context is important to identify the contribution of occupational exposure sources to the general population exposure. New technologies, production of advanced new materials, combined exposure scenarios bring new risks to workers. New EU goals on green energy and circular economy should absolutely include safe working conditions.

*R&I needs*

The Partnership will sustain the endeavour of further developing a European **human biomonitoring** platform started by the European Joint Programme Co-fund HBM4EU[30]. No legal mandates are yet in place for human biomonitoring and therefore this activity still depends on research funding to deliver exposure information. The Partnership is also an opportunity to further improve and reinforce the specific European collaboration on **occupational monitoring** and risk assessment established under HBM4EU.

Moreover, research and innovation to develop tools, methods and models to **track the source of chemical exposure,** the **route of exposures** as well as **combined and aggregated exposures** are needed and will be undertaken by the Partnership. To identity emerging and new exposures **non-targeted and suspect screening** methods for environmental and human matrices will be developed, to support also the monitoring of real-world **mixtures**.

In certain cases, the Partnership will also investigate how different parameters (e.g. the move to a circular economy, occupation, lifestyle and the physical environment) act as **determinants of exposure** and identify subgroups of the population that are particularly at risk.

To assess health impacts of exposures, models establishing the **link between external exposure and internal exposure** will be developed and the causal relations between exposure biomarkers measured in human biomonitoring studies and effect biomarkers and health outcomes studied. Occupational cohorts represent an added value in this context.

Last but not least the analysis and interpretation of exposure data also requires research on how to define **limit values** to be used in regulatory contexts.

[29] Database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts): https://echa.europa.eu/scip-database
[30] www.hbm4eu.eu, Horizon 2020 Grant 733032

## Gaps in toxicological information

In May 2020, the REACH database contained 25,405 unique substances and the EU Pesticides database[31] contained 1,429 entries (authorised and non-authorised). Only a small fraction of the chemicals on the market have been sufficiently characterised in terms of their hazardous toxicological properties or exposure scenarios, or are regularly monitored, while limited or no data are available for the overwhelming majority of chemicals[32]. There are situations where data are lacking (for example on "orphan" chemical substances or on natural toxins) and others where controversies arise from (inherent) scientific uncertainties as well as political and societal debate. In such cases, agreeing on an assessment that is mutually accepted by science and by society has proven challenging, at least on the basis of the data available.

Safety assessments carried out by companies only concern chemicals specifically included in regulations (e.g. those produced in large tonnages) and are limited to the mandatory data requirements. Often, they do not provide complete insight into hazard and risks of all chemical components of products and their metabolites and all chemical substances (including precursors or by-products). This may result in the presence of emerging contaminants of concern for which no or very limited toxicity data, for human health and the environment, are available. Moreover, the capacity and resources of the EU and/or Member State authorities to check the quality of self-assessments are constrained[33].

The limited or not readily available toxicological information for many chemical substances means that risk assessors can be confronted with knowledge gaps that may present strong public health concerns. The needs for generation of toxicological data can be described as:

- "proactive", in a situation where a lack of data is observed or anticipated;
- "in response" to a situation of scientific controversy and uncertainty

Regulatory hazard assessment, feeding into risk assessment schemes, mainly use traditional toxicity test methods which may not be the best suited to respond to the current challenges risk assessment face (mixtures, cocktail effects, endocrine disrupters, new materials like nano-materials, emerging hazards, etc.). A paradigm shift is needed, notably in order to deal with the large amount of untested chemicals, with an emphasis on 3R strategies and novel methods in toxicity testing such as *in silico* and *in vitro* models of relevance to humans, or uncertainty assessments. Often toxicity assays, guidelines for those assays and international recommendations are still missing. New technologies such as Artificial Intelligence (AI) will enable assessment of mechanism of action and the design of new chemicals and predictions of related hazard[34]. However, criteria for reliable and robust algorithms to make them applicable in regulatory settings have not yet been developed and required high-quality databases are sparse. There is also an inherent problem with complex computational methods (including AI, deep learning etc.) related to transparency, traceability and quality management systems like Good Laboratory Practices (GLP) that urgently needs to be addressed.

### *R&I needs*

The Partnership will address the need for more **high quality and validated toxicological data** to be generated and openly shared. The Partnership will engage in overcoming barriers to the usability of **alternative (non-animal) assessment methods** for regulatory purposes by providing test guidelines for certain endpoints and proof of the biological or toxicological

[31] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
[32] EEA (2019) The European environment — state and outlook 2020: knowledge for transition to a sustainable Europe. Chapter 10, Chemical pollution. https://www.eea.europa.eu/soer-2020/intro
[33] European Commission (2019), Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries Fitness check chemicals legislation. Staff Working Document. p. 46.
[34] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6688471/

relevance of the endpoints assessed for human health. The **functionality, applicability and relevance** and, when possible, **validation** of new and existing *in vivo, in vitro* and *in silico* models will be addressed and their take-up by the regulatory system supported.

Furthermore the Partnership will work on improving **test methods and guidelines** regarding aspects of neurotoxicity, immunotoxicity, transgenerational effects, epigenetics and endocrine disruption and on new methods to capture peculiarities of emerging chemicals e.g. nanomaterials or micro/nano-plastics. **Effect-based methods** and the development of **trigger values** for mixtures of chemical substances to be used as early warning tools or to identify drivers of toxicity are needed. **New technologies** such as artificial intelligence (AI) and machine learning to bring forward algorithms to predict toxic effects will be explored.

Access to information and data

Although access to information on chemicals and their toxicological properties has improved considerably, e.g. through REACH or EFSA's new open access platform[35], risk assessment agencies and regulatory bodies, at the EU and Member State level, find themselves confronted with gaps in knowledge [36,37,38].

Most knowledge on chemicals (tonnages, tons/use, uses in general, use categories, purity of substances, impurities, emissions and reference material of substances) is often very difficult to obtain from the producers. Information is often incomplete, not publicly available and even unavailable for risk managers. It is important to assess the risk of chemicals in different media and materials, including waste and recycled products, but this is challenging due to the lack of shared information on use and occurrence of chemicals and the overall chemical flows, and on the exposure of humans and the environment during the entire life cycle of the products. This is also true in the case of occupational data: authorities working in the occupational health field need data related to the use, exposure sources and possible routes of exposure at the workplaces, exposure levels and most common risk management measures in place. The lack of this data also hampers the shift to more comprehensive risk assessment strategies addressing aggregate (same chemical via multiple sources and pathways) and combined (multiple chemicals simultaneously) exposures scenarios.

Today, in Europe, the two main sources of toxicological data are: 1) studies from national or EU publicly-funded academic research aimed at the advancement of knowledge, whose accessibility often depends on their publication in international scientific journals, and 2) industry-funded studies to support applications for marketing authorisations, carried out in a regulatory framework with limited public access to the raw data (though some changes are being implemented as part of the new Regulation on the transparency and sustainability of the EU risk assessment in the food chain –Regulation (EU) 2019/1381).

Shared information about the common toxicological properties of chemical substance groups and risk assessment relevant for such groups is also required to avoid 'regrettable'

[35] http://www.efsa.europa.eu/en/press/news/190117

[36] European Commission (2019), Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries Fitness check chemicals legislation. Staff Working Document. p. 42-46.

[37] European Commission (2017) Study on the cumulative health and environmental benefits of chemical legislation. https://op.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en / https://ec.europa.eu/environment/chemicals/reach/pdf/study_final_report.pdf

[38] OECD workshop on Managing Contaminants of Emerging Concern in Surface Waters: Scientific developments and cost-effective policy responses, 5 February 2018. https://www.oecd.org/water/Summary%20Note%20-%20OECD%20Workshop%20on%20CECs.pdf

substitutions, for instance, structural analogues that may turn out to be unsafe or lack sufficient safety data[39].

*R&I needs*

The Partnership will **promote harmonisation of data and exchange** between different actors (scientific community, health agencies, regulators, policymakers etc.) and disciplines (exposure science, toxicology) to promote transparency, support risk assessment, and allow for reuse. To achieve this, it will build on existing data platforms included in or collaborating with the Partnership and contribute to extend their usability for risk assessors and managers. It will ensure data and associated information is **FAIR** (findable, accessible, interoperable, and reusable) and addresses the **GDPR** related challenges for data exchange. The Partnership will follow-up on the EC commissioned study on a Data Platform for Chemicals[40] and, provide opportunities for further developing the initial pilot.

Public concerns and health costs

Despite a well-developed system for chemical risk assessment and management, knowledge gaps remain leading to concerns among citizens, civil society organisations, scientists, regulatory authorities and other stakeholders about the safety of chemicals and their combined presence in the environment, in food and drinking water, in consumer products and in workplaces. One in four EU citizens are 'very concerned' about exposure to chemicals in their daily lives[41].

Health costs caused by chemical exposure are mostly not included in the calculation of the Global Burden of Disease due to lack of data. A 2011 estimate attributed 5.7% of the total disease burden and 8.3% of total deaths to chemicals globally, with the scope of this estimation confined to a small number of chemicals for which causality is well described[42]. Considering the workers, according to International Labour Organization (ILO) over 2,780,000 workers globally die from unsafe or unhealthy conditions of work each year[43]. It is estimated that one worker dies at least every 30 seconds from exposure to toxic industrial chemicals, pesticides, dust, radiation and other hazardous substances. Given that incidents of exposure are underreported in some contexts and countries, this figure is an underestimation. Approximately 160 million cases of occupational disease are reported annually.

*R&I needs*

Through the activities on exposure monitoring and toxicology the Partnership will foster a better understanding the **health impacts** of exposures and thereby indirectly contribute with evidence for health cost estimations.

**Communication and dissemination** of the Partnerships activities and results will contribute to increased mutual awareness and understanding of scientific evidence and chemical risk assessment procedures amongst citizens, policy makers, scientist and other stakeholders. This should also help to encourage the uptake of new scientific knowledge in **chemical legislation** and accelerate the pace of innovation.

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[39] Milieu Ltd, Ökopol, RPA and RIVM (August 2017), Study for the strategy for a non-toxic environment of the 7th Environment Action Programme. Tickner and Jacobs (2016). Needs and opportunities to enhance substitution efforts within the context of REACH.
[40] Feasibility Study on a Common Open Platform on Chemical Safety Data. https://etendering.ted.europa.eu/cft/cft-display.html?cftId=5516
[41] EC, 2017b, *Special Eurobarometer 456, chemical safety: summary*, European Commission.
[42] Prüss-Ustün, A., et al., 2011, 'Knowns and unknowns on burden of disease due to chemicals: a systematic review', *Environmental Health* 10, 9.
[43] ILO (2019), Safety and health at the heart of the future of work: building on 100 years of experience.

Separate policy frameworks

Policies in different sectors have developed separately and at different times, and are implemented by different institutions, leading to inconsistencies between pieces of legislation and potential policy gaps. Chemical risk assessment is performed in the context of specific life stages, types of use, environmental compartments, or protection targets and, as such, is fragmented. The use of a specific chemical may be restricted according to one regulation while being at the same time approved in another. Limit values given under different regulatory schemes may substantially differ resulting in confusion. Enhanced cooperation between existing regulatory frameworks, exchange of information, and 'one chemical substance, one assessment' paradigm could facilitate more coherent, harmonised, and efficient evaluation of environmental and human exposure, hazard and health risk as well as prioritisation and regulation. This need to simplify and strengthen the legal framework is acknowledged in the EC Roadmap for the Chemicals strategy for sustainability[44]. "*The Commission will review how to use better the EU's agencies and scientific bodies to move towards a process of* ***'one substance – one assessment'*** *and to provide* ***greater transparency*** *when prioritising action to deal with chemicals*."

The protection of human health and the environment are the overall objectives of many pieces of chemicals legislation. These two aspects are also closely interrelated: chemicals with adverse impact on the environment in many cases are also toxic to human health and humans are in many cases exposed via the environment (e.g. through the food chain, air, water, and soil). In an overall perspective, human health and wellbeing relies on healthy ecosystems, e.g. through their ability to provide ecosystem services, and on the preservation of natural resources such as drinking water and agricultural soils. Hence, the protection of these from contamination and degradation caused by chemicals exposure is crucial for society.

Adverse effects of chemicals can, in many cases, be detected in the environment before they are spotted in humans; well-known examples includes endocrine disruptors, persistent organic pollutants and heavy metals. Screening and monitoring for harmful effects in the environment, for rising levels of known chemicals and the occurrence of new ones in biota and environmental media can serve as early warnings for chemical threats. Important knowledge and data gaps remain to be filled for both human and environmental health aspects. Addressing these gaps involves the use of traditional methods and tools, as well as the development of e.g. grouping and high-throughput modelling approaches, effect based monitoring and analysis the fate of chemicals and will contribute to improving the protection of both human health and the environment.

*R&I needs*

This challenge cannot necessarily be solved by research and innovation activities. Still the Partnership will encourage, **cooperation and collaboration between sectors** to improve more coherent science-based risk assessment, knowledge sharing, consensus on obtained evidence and policymaking. The Partnership will cover **human and environmental health** aspects of chemicals risk assessment, screening and monitoring, with a particular focus on the **synergies** between these areas, **across regulatory silos** and with efforts on the reduction of the impact and burden of disease caused by chemicals. The Partnership will follow-up on the EC

[44] Ref. Ares (2020)2460806 - 09/05/2020

commissioned study on an **Early Warning System**[45,46]and provide opportunities for further developing the initial concept.

Need for new risk assessment paradigms

With increased knowledge about chemicals acquired over the years and development of new technologies and new categories of chemicals, new policy and research questions have arisen and will continue to emerge, e.g. the management of hazardous chemicals in the circular economy. Chemicals occasionally have new and different properties, e.g. nanomaterials, perfluoroalkylated substances, micro- and nanoplastics, and hence cannot necessarily be dealt with by straightforward application of current risk assessment paradigms.

Methods and standards for testing and risk assessment must undergo further development not only to enable early and more precise identification of toxicological risks, fate of chemicals in the environment and relevant exposure pathways but also to enable regulation to keep pace with innovation. The ultimate aim is to support timely measures to reduce or eliminate exposure to hazardous toxic compounds.

The current 'chemical-by-chemical' risk assessment and management approach may be adequate to efficiently prevent risk to the environment and human health from single chemical substances but may not be sufficient to address mixtures of chemicals[47,48]. Mixture risk assessment is particularly complicated because of the required multiple routes of exposure and the frequent lack of mechanistic data. Most exposure scenarios imply the simultaneous exposure to several chemicals, a specific example being workers who are exposed both in occupational settings and as consumers.

To deal with the ever-increasing number of chemicals, it is necessary to move towards the use of grouping approaches and non-targeted monitoring strategies for risk assessment and management. Group-wise risk assessment based on classes of chemical structures will better inform on health risks of combined exposures and contribute to preventing 'regrettable', 'not necessarily safer' substitutions[49] of chemicals which are being phased out.

Many non-commercial chemical substances fall outside the regulatory scope or not all the contexts where exposure can happen are regulated for instance when chemicals are present in natural products either as constituents or contaminants. The pattern of contamination can be modified due to climate change, leading to a change of exposure scenario with potentially different health effects.

The reduction of the net negative impact on ecosystems and people without burden shifting between different policy objectives[50,51] requires a more holistic approach to the design of chemicals, products and processes that considers safety as well as their life-cycles and long-term sustainability. The Safe-and Sustainable-by-Design (SSbD) concept aims to identify the

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[45] Feasibility Study on a Common Open Platform on Chemical Safety Data, ENV/2019/OP/0014, https://etendering.ted.europa.eu/cft/cft-display.html?cftId=5516

[46] Study for the strategy for a non-toxic environment of the 7th EAP, Sub-study: Early Warning Systems for emerging chemical risk, https://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20g%20early%20warning%20syst.%20NTE%20final.pdf

[47] Swedish Governmental Inquiry, 2019, Future chemical risk management Accounting for combination effects and assessing chemicals in groups

[48] Drakvik et al 2019 and Kortenkamp & Faust 2018

[49] Milieu Ltd, Ökopol, RPA and RIVM (August 2017), Study for the strategy for a non-toxic environment of the 7th Environment Action Programme. Tickner and Jacobs (2016). Needs and opportunities to enhance substitution efforts within the context of REACH.

[50] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[51] The European environment — state and outlook 2020: knowledge for transition to a sustainable Europehttps://www.eea.europa.eu/soer

risks and uncertainties concerning human and environmental safety from the earliest possible phase of the innovation process through the whole life cycle. So far, this concept has mainly been developed with regards to nanomaterials[52], how to make use of it for the wider chemical landscape is under discussion. In view of the amount of chemicals that will need assessment, it is in the public interest that both regulatory authorities and companies have powerful tools and transparent processes ensuring the safety of chemical products entering the marketplace.

*R&I needs*

**New risk assessment approaches** and more **holistic risk assessment frameworks,** which enables to assess **combined risks** caused by exposures from different sources under different regulatory frameworks, **will be further developed and validated.** The Partnership will follow up and contribute to the development of the **Safe and Sustainable-By-Design concept**[53,54,55,56]. The Partnership acknowledges the fact that artificial intelligence (AI) and digitalisation are shaping the future and will contribute to improve the evaluation process through the development and use of **new decision support tools** for risk assessors and managers based on AI[57].

The right skills

To tackle all these challenges, there is a need for new **experts** with experience in (regulatory) risk assessment tools and approaches, and for training current experts to be able to apply new tools and methodologies.

Furthermore, in the current complex communication environment with a multitude of platforms, it is a challenge to **communicate risk** in a targeted yet coordinated way. It is of great importance that sensitive information is communicated by professionals using credible sources of information, and clear and understandable communication products. Effective communication increases transparency and credibility, generating trust in science.

*R&I needs*

The Partnership will develop **training programmes** to enhance the skills of scientists contributing to risk assessment, risk assessors and managers to deal with new tools and understand scientific methods. It will also operate to make the risk assessment profession attractive to young students and communicate on required skills to higher education institutions.

### *2.1.3. Links to previous R&I Partnerships and other large scale EU-funded activities*

The new Partnership will build on lessons learned and knowledge acquired not only in the previous European Joint Programme Co-fund on human biomonitoring (HBM4EU), but also in other large scale projects or project clusters funded or co-funded under Horizon 2020 or previous research framework programmes.

HBM4EU was the first European Join Programme Co-fund under Horizon 2020 and is as such a key frontrunner for the current Partnership. HBM4EU investigates the internal exposure of

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[52] e.g. of some large scale projects under NMBP programme of H2020 (NanoReg2, ProSafe (https://www.nanosafetycluster.eu/)

[53] Tickner et al. 2019. Advancing alternatives assessment for safer chemical substitution: A research and practice agenda. Integr Environ Assess Manage 15:855-866. http://doi.org/10.1002/ieam.4094

[54] Fantke & Illner 2019. Goods that are good enough: Introducing an absolute sustainability perspective for managing chemicals in consumer products. Curr Opin Green Sustain Chem 15:91-97. http://doi.org/10.1016/j.cogsc.2018.12.001

[55] Warner & Ludwig 2016. Rethink how chemical hazards are tested. Nature 536:269-270. http://doi.org/10.1038/536269a

[56] van der Waals et al. 2019. Safe-by-design for materials and chemicals. http://doi.org/10.5281/zenodo.3254382

[57] Wittwehr et al, Comp Tox 2020, https://www.sciencedirect.com/science/article/pii/S2468111319300349

people to prioritised chemicals, identifies the impact of exposure on health and facilitates the transfer of scientific results into policy. HBM4EU has shown that cooperation between national agencies, research organisations and the EC services and EU Agencies can work well and foster mutual understanding and joint knowledge. Key experiences and results from HBM4EU which this Partnership will build on and further develop are:

- the notion of National Hubs for increased national coordination;
- the prioritisation process involving EC services, EU agencies, Member-states (MS) institutions and stakeholders to decide on which substances to monitor;
- the alignment of national HBM surveys, the laboratory network for harmonised analysis and the resulting harmonised data;
- the build-up of scientific knowledge on the prioritised chemicals and mixtures of these, e.g. AOPs and models, and the development of tools to monitor emerging substances.
- the collaboration with the European Commission's Information Platform for Chemical Monitoring (IPCHEM) database and experiences with heterogeneous data management and analysis;
- communication and dissemination activities in particular towards citizens, stakeholders and policy makers.

In addition, this Partnership will also build on the experience and link to other EU-funded projects and partnerships, which address(ed) research, innovation, deployment bottlenecks in the areas of new testing and assessment methods for adverse effects, chemical mixtures and exposure. Annex II (Background document) provides an extensive list of all these projects; a shorter summary is presented here:

- EU-ToxRisk, the integrated European 'flagship' programme driving mechanism-based toxicity testing and risk assessment for the 21st century.
- The EURION cluster of eight H2020 projects developing new testing and screening tools for endocrine disruptors. These projects were designed to put emphasis on ensuring new tools and methods can be taken forward to existing validation processes.
- The collaboration on mixtures between the EU funded projects SOLUTION, EDCMIXRISK, EUROMIX, HBM4EU and EUTOXRISK resulting in a good overview of EU level research on mixtures and a position paper[58] with a statement on policy and research measures needed for mixture risk assessment.
- SOLUTIONS, an FP7 project dedicated to providing innovative approaches for assessing effects of emerging pollutants on the status of water resources.
- The NORMAN Association, a European monitoring network spawned by an EU-funded project. The NORMAN Association analysed challenges that the European Union Water Framework Directive faces with regard to chemical assessment and management in European surface water resources and recommended more holistic chemical assessments[59].
- The European Exposome Cluster, a collaboration of three FP7 projects EXPOSOMICS, HELIX and HEALS set out to understand better the link between life-course exposure and potential health outcomes. This initial cluster is followed-up by the European Human Exposome Network, an overarching network of nine new H2020 projects, which will provide integrated toolboxes to support the applicability of the exposome concept in policymaking.

[58] https://edcmixrisk.ki.se/wp-content/uploads/sites/34/2018/05/Position-paper-180417-for-the-EC.pdf
[59] http://www.oecd.org/chemicalsafety/risk-assessment/considerations-for-assessing-the-risks-of-combined-exposure-to-multiple-chemicals.pdf

- HERA, a research/policy coordination group identifying knowledge gaps and developing a European Health and Environment Research Agenda 2020-2030, as well as developing guidelines for health impact and risk assessment.
- The EU NanoSafety Cluster and the ERANET EuroNanoBio are initiatives to enhance the synergies between European-level projects addressing the safety assessment of nanomaterials.
- The Malta Initiative, a collaboration of EU member states, EC, ECHA, industry and other institutions aims to amend OECD Test Guidelines and Guidance Documents to address nano-specific issues for fulfilling regulatory requirements.
- The European Partnership for Alternative Approaches to Animal Testing (EPAA) is a collaboration between the European Commission, European trade associations, and companies from 8 industry sectors in which partners are pooling knowledge and resources to accelerate the development, validation and acceptance of alternative approaches to animal testing.

## 2.2. Common vision, objectives and expected impacts

### *2.2.1. Vision*

The Partnership will establish an EU-wide research and innovation risk assessment hub of excellence to support EU and national chemical risk assessment/management authorities and processes with new data, knowledge, innovative methods and skills to address current, emerging and novel chemical safety challenges and **enable the transition to the next generation risk assessment**.

This Partnership builds on the experiences acquired when implementing the European Joint Programme on Human Biomonitoring, HBM4EU, but goes well beyond it. The objective to maintain and further develop the acquired harmonised capacities for human biomonitoring in Europe will be met through the new Partnership's aim to integrate human biomonitoring as one part of the larger toolbox needed to drive innovation in chemical risk assessment.

The Partnership will bring together the European and Member State chemical risk assessment bodies and regulators/risk managers to identify and prioritise joint challenges and to develop strategic research and innovation agendas to tackle them in cooperation with the scientific community and ensure the use of the results in a regulatory context.

The production of data and knowledge will enable risk assessment institutions to give better advice to risk managers and decision-makers. This will contribute to a higher level of public health protection of Europe's citizens and the environment and help to maintain and reinforce the trust that Europe's citizens have in their risk assessment and risk management institutions.

This Partnership brings the opportunity for a combined, cross-sectoral chemical risk assessment and an opportunity to obtain a more holistic picture of chemical exposures, hazards and associated risks. Looking forward to the next generation of risk assessment paradigms, the Partnership will aim to develop and deliver new methods, strategies, approaches, tools, data and information for risk assessment, so to improve the efficiency and effectiveness of risk assessment of chemicals in the EU, drive innovation in risk assessment and address emerging or new risks.

An expected co-benefit of a durable programme would be to reinvigorate the human and environmental exposure, toxicology and ecotoxicology research community in Europe and contribute to alleviating the shortage of experts in those domains.

### *2.2.2. Duration*

Given the breadth and ambitious goals of this Partnership and the impacts it aims to achieve, a seven years duration is a minimum. The diversity of partners (risk assessment bodies, research

institutes, universities ...), and the scientific fields they cover is an asset yet there will be challenges for the collaborations to be developed. Harmonising procedures, defining references, implementing monitoring activities, promoting data sharing, answering regulatory questions, validating new tools and methods and promoting their uptake in regulatory processes require planning on a multi-annual time scale. The political dialogue needed at high-level to discuss and find solutions for the long-term sustainability of the programme also requires a longer timeframe.

The seven years of the Partnership is considered sufficient to allow partners to establish the required cooperation schemes, deliver on concrete identified priorities and set up the basis for the sustainability of the programme. The governance, specifically involving national and EU bodies responsible for the risk assessment and management of chemicals in the EU, will foster the regulatory relevance of the programme and its results and will allow for the long-term political commitment and strategic framing of the Partnership.

#### *2.2.3. General, specific and operational objectives and draft associated indicators*

The Partnership aims at innovating chemical risk assessment in the EU and has the following objectives to achieve the long-term impacts:

**General objective: Consolidate and strengthen the EU's research and innovation capacity for chemical risk assessment to protect human health and the environment and contribute to a non-toxic environment and a circular economy.**

Section 2.1.1 describes the wider policy context in which this Partnership is developed. To establish the objective of the Partnership, the focus has been on the most recent policy documents and the new requirements they define. The objectives therefore respond to the research and innovation needs identified in the following policy documents:

- Council Conclusions June 2019 (Towards a Sustainable Chemical Policy Strategy of the Union)[60]
- European Green Deal[61] (in particular the Zero Pollution Ambition for a toxic free environment, including the Chemicals Strategy for Sustainability and the Zero pollution Action Plan, the Farm to Fork Strategy, the European Industry Strategy and the Circular Economy Action Plan).
- The 7th Environment Action Programme[62] (still valid although the 8th EAP is expected later in 2020)
- EU Strategic Framework on Health and Safety at Work 2014-2020[63]
- Findings of the Fitness Check[64] of the most relevant Chemicals Legislation (excluding REACH) and identified challenges, gaps and weaknesses
- Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions [65]
- Towards a comprehensive European Union framework on endocrine disruptors[66]
- Communication on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation[67]

[60] http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf
[61] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[62] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386
[63] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332
[64] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN
[65] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN
[66] https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF
[67] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52018DC0032

- Conference conclusions: EU Chemicals Policy 2030, building on the past, moving to the future[68]
- European Non-Toxic Environment Strategy, endorsed by 9 EPA Network members[69]
- Commission Staff Working Document: Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council on the Quality of Water intended for Human Consumption (recast)[70]
- Commission Staff Working Document on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation[71]
- Communication A European strategy for data[72]

**Specific objective 1: Set up an EU-wide cross-disciplinary network to identify and agree on research and innovation needs and support research uptake into regulatory chemical risk assessment.**

Operational objective 1.1: Set up and operate a high-level group of EU and national representatives engaged in regulatory risk assessment and risk management, to strategically steer the Partnership.

**Provisional indicators:**

- No. of European Member States represented in the Country Board (annually, end target 27)
- No. of EU entities represented in the EU Board established (annually, end target 8)
- No. of needs and activities identified by the Country Board and the EU Board for consideration in the 3-year common strategies[73] (annually starting Y1, increasing, no target)

**Exit strategies**

- Expression of interest between MS representatives to continue the collaboration on identifying needs and research challenges
- Established EU-level Coordination Group to guide EU research and innovation activities for chemical risk assessment across programmes

Operational objective 1.2: Create a long-term sustainable network of National Hubs that interact with stakeholders to exchange and feed expertise, knowledge and needs into the Partnership and promote uptake of results.

**Provisional indicators**

- No. countries with an active national hub (annually, target 27)
- No. of coordinated activities between the national hubs (annually, increasing, no target)
- No. of National Hubs responding to requests for input (annually, target all)

[68] https://euchemicalspolicy2030.teamwork.fr/docs/report.pdf
[69] https://epanet.eea.europa.eu/reports-letters/reports-and-letters/non-toxic-environment-paper-epa-network.pdf/view
[70] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017SC0449
[71] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52018SC0020
[72] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:66:FIN
[73] 3-year common strategies are 3-year research and innovation strategic agendas defined jointly in the Partnership to achieve the objectives set out, they will include the Partnership's research and innovation goals and agenda for the 3 years and will be used to define the more specific annual work plans

- No. of actions/needs identified by National Hubs (annually, increasing)

**Exit Strategy**

- National decisions for the long-term sustainability of their hubs
- Agreements between National Hubs for continued collaboration and continued interactions with Commission DGs and EU agencies

### Operational objective 1.3: Define common research and innovation strategies with transparent criteria and prioritisation process to address the regulatory knowledge needs for chemical risk assessment and management

**Provisional indicators**

- No. of consultations launched per group of stakeholders (including e.g. National Hubs, stakeholder forum) (periodically, increasing, no target)
- No. of replies per stakeholder group to each round of prioritisation (periodically, increasing)
- No. of foresight activities, tracking of innovations to feed into the prioritisation process (periodically, no target)
- No. of 'scoping' documents setting out the priority R&I activities identified in the consultation (periodically, no target, timely submission)
- Timely provision of draft 3-year common strategies to address the priorities to the high-level network accompanied by scoping documents (periodically, no delay, decreasing)

**Exit Strategy**

- Established process for joint priority setting
- Conclusions on remaining knowledge gaps and research and innovation needs for future prioritisation processes.

### Operational objective 1.4: Actively foster the regulatory uptake of knowledge produced under the Partnership in chemical risk assessment and regulatory processes.

**Provisional indicators**

- No. references to the Partnership related results in policy documents (periodically, no target, increasing)
- No. new methodologies (particularly alternative (non-animal) methods) considered for use in regulatory frameworks and/or applied in risk assessment in addition to standard toxicology (periodically, no target, increasing)
- No. of regulatory and policy gaps addressed by the Partnership in the 3-year common strategies (annually starting Y1, increasing, no target)

**Exit strategy**

- Declaration of interest from risk managers, risk assessors and the scientific community to continue a sustained, continuous dialogue to accelerate awareness and uptake of new scientific evidence and tools in risk assessment.

### Operational objective 1.5: Promote cooperation with other research & innovation partnerships, programmes and activities across Europe and foster European leadership at the international level for research and innovation in chemical risk assessment

**Provisional indicators**

- No. of other relevant initiatives identified and contacted (every 2 years, no target)

    - No. identified synergies/collaborations with other EU initiatives
    - No. identified synergies/collaborations with non-EU initiatives
- No. of collaborations established with other R&I partnerships, programmes and activities (periodically, increasing)
- No. of members in the International Board (IB), their geographical coverage and linkage to important activities for synergies
    - No. of synergies facilitated by the IB

**Exist strategy**

- NA

Operational objective 1.6: Effectively and transparently communicate and disseminate knowledge produced by the Partnership, ensure public accessibility to results and increase citizens' understanding and awareness of the principles of European chemical risk assessment.

**Provisional indicators**

- No. of scientific communications (including publications and bibliometric analysis; oral/poster presentations) (annually, increasing)
- No. of other communications (including reports in non-scientific media; published policy briefs) (annually, increasing)
- No. of Partnership events (annually, target 1 main event per year)
- No. of users or followers of PARC (including website and social media) (annually, increasing)

**Exist strategy**

- NA

**Specific objective 2: Carry out joint EU research and innovation activities responding to the priorities identified in the 3-year common strategies supporting the current regulatory risk assessment processes and responding to emerging challenges.**

Operational objective 2.1: Develop and implement annual research and innovation work programmes on the basis of the 3-year common strategies

The strategic indicators will have to be developed and specified during the development of the 3-year common strategies and annual work programmes but examples include:

- Percentage of the activities set out in the 3-year common strategy covered by AWPs (annually, increasing)
- No. of demands from the 3-year common strategies on which the AWPs have delivered results (annually, increasing, target 100%)
- No. of activities of the Partnership generating new open data (annually, increasing)
- No. of data gaps closed (annually, end target ratio 1 for a 3-year plan).
- No. of new methods, tools or models developed and consolidated (periodically, increasing)
- No. of activities of the Partnership integrating data from different sources (annually, increasing)
- No. of human health effects associated to exposure identified and evaluated (periodically, increasing)
- No. of risk assessment agencies /organisations involved in the research programme (annually, end target > 27)

- No. of research organisations involved in the research programme (annually, increasing and stabilising)

**Exit strategy**

- Memorandum of Understanding on long-term cooperation signed by risk assessment bodies involved the Partnership

Operational objective 2.2: Consolidate, maintain and further develop the human biomonitoring platform and further develop the network of qualified laboratories for biomarker analysis created in HBM4EU.

**Provisional indicators**

- No. of aligned human biomonitoring studies within the Partnership, generating exposure and effect data (every 2 years, increasing number of countries/substance)
- No. of harmonized SOPs applied for study design, fieldwork, sample collection, questionnaires (periodically, target all substances)
- No. of candidate labs for chemical analysis, QA/QC support and new method development (annually, increasing)
- No. of qualified labs for chemical analysis (annually, increasing)
- No. of exposure biomarkers covered in the QA/QC process (every 2 years, increasing)
- No. of effect biomarkers covered in the QA/QC process (every 2 years, increasing)
- No. of soft policy actions based on results of the human biomonitoring platform (e.g. sensitisation activities) (periodically, target 1 per substance group)

**Exit strategy**

- Collaboration agreement between laboratories implementing the QA/QC process and between certified laboratories
- Network of interdisciplinary HBM experts established
- National and/or EU level decisions to keep and extend capacities for human biomonitoring (HBM laboratory network and HBM studies).

Operational objective 2.3: Develop tools to facilitate the acceptance and use of the Partnership's results in regulatory risk assessment processes and support (existing) standardisation and validation processes for innovative approaches to risk assessment.

**Provisional indicators**

- No. of new methods (toxicological, analytical, IATAs…) developed and discussed (periodically, increasing)
- No. SOPs/guidance documents prepared (periodically, increasing)
- No. of meetings between Partnership partners and National, EU or international standardisation bodies (annually, target 1 per year)
- No. of proficiency tests and round robin tests carried out (annually, increasing)

**Exit strategy**

- Guidance on how to integrate the R&I methods developed by the Partnership in chemical risk assessment with demonstration of the added-value (use scenario and non-use scenario)

**Specific objective 3: Strengthen existing capacities and build new EU-wide, transdisciplinary research and innovation platforms to support chemical risk assessment**

Operational objective 3.1: Create a FAIR[74] data culture enabling open science and enhance effective exchange of data and information between different stakeholders and policy domains.

**Provisional indicators**

- No. of guidelines and templates developed for data collection, generation, reporting, harmonisation and sharing (periodically, target all data types in Partnership)
- No. of collaborations with external data platforms for the storage of data from the Partnership (periodically, target all data of Partnership)
- No. of datasets developed in the Partnership stored in an interoperable mode (annually, target all)
- No. of quality control schemes developed or promoted in the Partnership and/or taken up by other initiatives (periodically, increasing)
- No. of partners engaged in quality control/no. of data sets produced and quality controlled (annually, increasing)
- No. of approvals for data sharing between partners/with external users (annually, increasing)

**Exit strategy**

- Signed agreements between partners to keep established quality control schemes operational
- Contribution to a EU-level common data portal

Operational objective 3.2: Consolidate existing and develop new analytical, toxicological and fit-for-purpose networks of laboratories and research centres

**Provisional indicators**

The indicators will have to be developed and specified during the development of the 3-year common strategies and annual work programmes but examples include:

- Timely delivery of criteria and procedures for developing laboratory networks (2022, timely delivery, no delay)
- No. of new laboratories identified to be networked according to the gap analysis in the 3-year common strategy (annually, increasing geographical coverage)
- No. of new laboratories participating in the networks (annually, increasing geographical coverage)

**Exit strategy**

- Collaboration agreements signed between involved laboratories

Operational objective 3.3: Develop models and innovative concepts for risk assessment and deliver toolboxes to promote their acceptability and uptake by different stakeholder communities.

**Provisional indicators**

- No. of innovative concepts actively supported with scientific evidence by the Partnership in the wider scientific or regulatory debate (annually, increasing)

[74] FAIR: findability, accessibility, interoperability, and reusability.

- No. of ‘toolboxes’ made available through the Partnership for the wider stakeholder community (annually, increasing)

**Exit strategy**

- Toolboxes (integrative risk assessment models, early warning system, Safe-and Sustainable-by-Design) are sustainable/have a governance and exploitation plans.

Operational objective 3.4: Build capacities by developing and carrying out training and exchange programmes in chemical risk assessment related to the activities of the Partnership and in collaboration with other existing programmes.

**Provisional indicators**

- No. training activities done by the Partnership (annually, target: 2 per year)
- No. attendees per country in the Partnership training activities (annually, increasing)
- No. of PhD and post-doc positions available in the partner organisations of PARC in the area of chemical risk assessment (every 2 years, increasing)

**Exit strategy**

- Contribution to academic and competent authority training programmes in areas relevant to regulatory risk assessment

**Intervention logic**

Figure 2 shows the intervention logic leading from challenges and R&I needs to the objectives and actions (operational objectives) planned in the Partnership. Figure 7 (see section 3) defines the link between the objectives and the implementation structure of the Partnership.

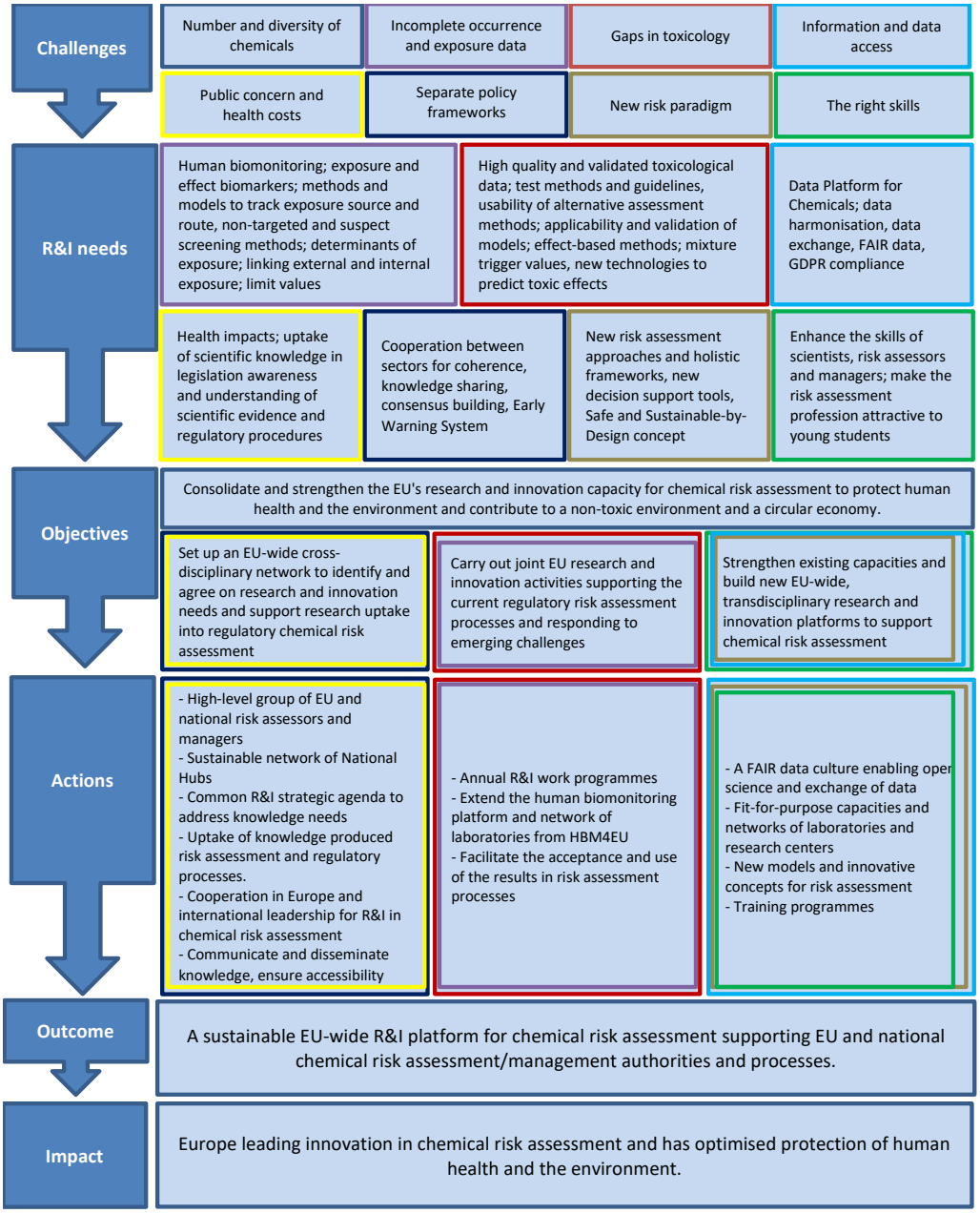


*Figure 2: Intervention logic*

### 2.2.4. Monitoring of progress

The Partnership aims to answer policy questions on chemical safety and will include many European countries, European agencies and Commission DGs. In order to achieve the ambitious objectives set by the Partnership and contribute to the EU policy goals, the Partnership has suggested a logical flow of interconnected activities to enable the whole Partnership to progress together and ensure the sustainability of the processes and dialogues implemented (Figures 2 and 7).

The objectives are organised around three essential levels required to address current, emerging and novel chemical safety challenges and achieve the transition to next generation risk assessment:

- A high-level and interagency coordination network
- An operational level implementing the jointly-designed R&I work programmes
- Laboratory/research/expertise capacities supporting the operational level with analytical and data management competences

A first set of numerical indicators are proposed here to support the objectives. More detailed indicators will be developed during the Partnership's conception phase and finalised in the first 6 months of its implementation. The experience from HBM4EU and other relevant European networks will be built on. Specific operational objectives and indicators linked to the 3-year common strategies[75] will be proposed there, refined in the Annual Work Plans and reported on each year in the Annual Technical Reports together with the overall indicators. Clear targets for indicators should be set and approved by the governance structures of the Partnership in an early phase to ensure their relevance for evaluating the progress of the Partnership and their follow up by all partners. Part of the task on sustainability (see Figure 7) is dedicated to defining, monitoring and reporting on indicators.

The yearly joint meetings of the Country Board and EU Board will contribute to monitoring the advancement, success and the usability of the Partnership for risk assessment and evaluate whether it continues to respond to the policy needs.

In the same way as what has been developed for HBM4EU[76], indicator leaflets can be designed with an illustrative character, linking project indicators to the overarching objectives and specific goals of the Partnership. Combining all this information will enable the Partnership to draw conclusions on its achieved impacts and sustainability.

#### *2.2.5. Collaboration with other partnerships and Union programmes*

This Partnership should act as a reference point for research questions related to chemical risk assessment (complementing the available regulatory information). Building the knowledge base on chemical hazards, toxicity and on chemical exposure can increase public and environmental health protection and inform other partnerships about the safer and sustainable use, production, safety assessment and management of chemicals as well as stimulate the promotion of green and sustainable chemistry or the use of alternative technologies. Information on risks posed by chemicals is important for many of the other Horizon Europe candidate partnerships proposed in the different clusters, especially in the "Cluster Food, Bioeconomy, Natural Resources, Agriculture and Environment" (Rescuing Biodiversity to Safeguard Life on Earth; Safe and Sustainable Food Systems), as well as for the Missions (on Soil Health and Food; Cancer; Healthy Oceans, Seas, Coastal and Inland Waters).

Likewise, information on novel technologies and processes explored in other proposed candidate partnerships should also contribute to the identification and management of new and emerging chemical risks and new exposure scenarios to be considered in this Partnership.

Contacts with the other partnerships will be established when possible directly via Partnership members involved in more than one partnership or more formally via bilateral contacts of the coordinators. Experiences and contacts gained from previous projects will be capitalised on.

A specific work package will be implemented to foster and create synergies, collaborations and raise awareness. This is linked to the specific objective which has been developed in order to ensure the Partnership has access to the work going on in areas of relevance and to boost the impact of the results of the partnerships, ensure their diffusion and ensure additionality. The concept paper for the Partnership will be published on the link below, as for all partnerships: https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/european-partnerships-horizon-europe/candidates-european-partnerships-health_en

[75] 3-year common strategies are 3-year research and innovation strategic agendas defined jointly in the Partnership to achieve the objectives set out, they will include the Partnership's research and innovation goals and agenda for the 3 years and will be used to define the more specific annual work plans

[76] https://www.hbm4eu.eu/result/indicators_of_success/

*Table 1: Relevant areas, candidate partnerships and missions identified for establishing synergies*

| Areas | Candidate Partnerships | Details (e.g. purpose, form) |
|---|---|---|
| **Health** | Innovative Health<br><br>One Health/Antimicrobial Resistance<br><br>ERA for Health Research | Information about health impacts of chemicals, the occurrence of specific substances in the environment or in humans and associated risks will be communicated to the different Health Partnerships as relevant. |
| **Digital, Industry and Space** | European metrology | Accurate data is essential for monitoring and managing the environment and health. One of the aims of PARC is to define the relevant analytical methods for exposure assessment and source monitoring and to support them in the different stages of validation. Some of these methods will be used for regulatory monitoring of the environment or for biomonitoring in occupational environments. Collaboration will be important to assess the performance of new methods and ensure the effective transfer and standardisation of new approaches and methods in the regulatory framework. |
| | | Next generation chemical risk assessment will increasingly rely on the analytical and interpretative capacity of data from devices with high information content (genomics, transcriptomics, proteomics, high-resolution mass spectrometry, 2D microscopic imaging, dynamic 3D, etc.) used at different scales (from molecule to population in different environments) obtained at different temporal and spatial resolutions. Collaboration with digital sciences and imaging techniques at different scales will be sought to benefit from innovations in these fields in terms of data acquisition, modelling and analysis. |
| **Climate, energy and mobility** | | Many new technologies will be based on new chemical products. Therefore, an open and transparent dialogue with partnerships in this area will be needed to ensure new understandings of chemical risks will be shared and the safe-and-sustainable by design concept promoted based on a joint understanding and joint efforts. |
| **Food, Bioeconomy, Natural Resources, Agriculture and Environment** | Rescuing Biodiversity<br><br>Safe and Sustainable Food System<br><br>Water4All<br><br>Blue economy partnership | Collaborations with partnerships in charge of food, water, environment and bio-economy will be developed and strengthened within the framework resulting from the prioritisation of specific activities for the chemical risk assessment Partnership. A specific task will be dedicated to establish links and share knowledge with other partnerships: both to identify possible challenges for chemical risk assessment and management, e.g. most likely related to chemical pollution as well as to share tools, methods and data from the chemical risk assessment |

| | | |
|---|---|---|
| | | partnership for uptake in other partnerships as relevant. |
| **Industrial partnerships** | | As above, priorities involving new substances or the development of the safe-and-sustainable-by-design concept will require shared reflection with the industrial partnerships concerned, particularly to better understand new uses or new recycling processes in order to analyse them and co-develop exposure scenarios. |
| **Other Pillars** | European Open Science Cloud | The EOSC Partnership will design and support the deployment of the Web of FAIR (Findable, Accessible, Interoperable, Reusable) Data. This will be important for PARC as setting up the Partnership presupposes the rapid establishment of conditions for access and sharing of data and software, and a good exchange with the partnership on European Open Science Cloud (EOSC) will promote common concepts. |
| **Mission Areas** | ▪ Soil Health and Food Mission<br>▪ Cancer Mission<br>▪ Healthy Oceans, Seas, Coastal and Inland Waters | Like for collaboration with other Partnerships the focus would be needs identified in the missions related to chemical pollution, risk assessment and management as well as sharing of results and data to from the chemical risk assessment Partnership for uptake in the missions. |

In addition to the coordination with other partnerships, linkages and collaboration with projects funded under H2020 will also be established – see section 2.1.3. Collaborations will also be sought with new projects arising from the last H2020 calls such as SC1-BHC-11 on safety assessment of chemicals without animal testing, SC1-BHC-36 on the health impacts of micro- and nano-plastics and the Green Deal call topics focusing on mitigating the effects of persistent and mobile chemicals and chemical and pharmaceutical mixtures.

In addition, the European Chapter of the International Society for Exposure Science (ISES Europe) is currently establishing an overarching European Exposure Science Strategy[77], which should be closely monitored and synergies created with the Partnership.

Opportunities arising from other Union programmes will also be explored.

*Table 2: Overview of EU programmes offering opportunities for this Partnership*

| Programmes at EU, national or regional level | Purpose | Details (form etc.) |
|---|---|---|
| **Structural Funds (ERDF/Cohesion)** | ▪ Development of national/regional capacities | MS to explore national opportunities offered and benefit from peer-to-peer learning in the partnership to develop capacities. Possibilities to use structural funds for co-funding to be explored. |

[77] Fantke, P., von Goetz, N., Schlüter, U., Bessems, J., et al., 2020. Building a European exposure science strategy. J Expos Sci Environ Epidemiol. http://10.1038/s41370-019-0193-7

| | | |
|---|---|---|
| **European Social Fund Plus (ESF+)** | ▪ Working environment, Public Health and chemical exposures | More targeted funding opportunities for implementing results from the Partnership or collaborating on key challenges. |
| **LIFE** | ▪ Environmental pollution | More targeted funding opportunities for implementing results from the Partnership or collaborating on key challenges for projects dedicated to technologies for the environment and climate. |
| **ERASMUS+** | ▪ Promote actions in the field of education, training and skills development in the area of chemical risk assessment | The different organisations in the Partnership will have to explore funding opportunities to foster innovative skills.<br><br>Input to programme development with identified needs and to promote actions in the field of education, training and skills development in the area of chemical risk assessment |
| **Research Infrastructures** | ▪ Research Infrastructures | Collaboration on the development of infrastructures, e.g. for human biomonitoring, for the development of technological platforms for physico-chemical analysis, for high throughput or high information content analysis and to establish conditions of sustainability of network of laboratories in exposure and toxicology science. |
| **Marie Sklodowska-Curie Actions** | ▪ Marie Sklodowska-Curie Actions | To reach its goals for training, the Partnership will develop synergies to support training through doctoral and fellowship programmes and rely on opportunities for training schemes to promote the initial (doctoral) and professional training of scientists in risk assessment in collaboration with academic partners. |

### *2.2.6. Investment targets & monitoring*

Two kind of investments can be considered for the Partnership: on one hand the required R&I funding for the proposed activities within the Partnership; on the other hand investments beyond the Partnership related to the long-term sustainability of the research capacities for innovation in chemical risk assessment or triggered by synergies and collaborations with other initiatives.

With regards to an estimate of the required research funding for the Partnership, the following information has been used:

- HBM4EU is a 50M€ investment from Horizon 2020 with 25M€ co-funding from participating countries → 75M€
- Horizon 2020 also invested in a topic on new testing and screening methods for Endocrine disruptors → 50M€

- Horizon 2020 also funded the project EU-ToxRisk[78] for animal-free, mechanism-based integrated approach to chemical safety assessment with 27.8M€ out of a total budget of 30.1M€, and another topic for 60M€ is currently open → 90.1 M€
- Two projects related to mixtures EuroMix[79] and EDC-MixRisk[80] also represented 8.8M€ (8M€ from the EU) and 6.2M€ total budgets respectively → 15M€

Altogether, basing ourselves only on the most directly related Horizon 2020 projects financed already amounts to a budget of 202M€ funding from Horizon 2020, and 288M€ co-funding (from Member States or industry). The average length of projects supported is 5 years.

The proposed investment of 200M€ from Horizon Europe, is therefore in line with the current investments under Horizon 2020 and can even be considered too limited. The gain is to be seen in the leverage of MS funding. There is currently no overall estimation of MS total investments in R&I for chemical risk assessment. However a 200M€ budget from Horizon Europe with a 50% co-funding rate would require a ~1M€ to be invested by each of the 27 MS per year over 7 years.

Investments beyond the Partnership are hard to estimate as there are often little information available to serve as baseline. An effort should be made to monitor these better in the Partnership so as to be able to evaluate these at the end. Examples of additional resources include:

- The resources for required national networking (see National Hubs) to ensure a good representation in the Partnership. These activities will not be funded by the Partnership, only the work of a liaison person, and do not represent large budgets, but bring a lot of benefit to the European Research Area and Chemical Risk Assessment landscape.
- Additional resources invested nationally to facilitate Partnership related activities but for which no costs are claimed in the official reporting and they therefore remain unaccounted for: e.g. workshops or conferences organised.
- Leverages of investments by industry or other stakeholders resulting from collaborations and triggered by activities or results of the Partnership.
- Re-direction of national funds according to the Partnerships objectives and research priorities, aiming to better align national research funding capacities with those defined in a comprehensive European perspective.

Investments will be monitored in different ways – some of these proposed below still need to be consolidated into practical and feasible applications:

- Direct investments are tracked via the official cost reporting where total costs need to be reported to receive the 50% EU co-funding.
- In addition partners will be encouraged in the Annual Technical Report to include any major additional investments made related to the Partnership – e.g. costs for National Hubs, workshops or conferences, national promotional materials produced etc. This will allow to estimate of a baseline for additional investments.
- Stakeholders or collaboration partners will be surveyed periodically on investments made based on results or activities of the Partnership.
- EC services and EU agencies will also be encouraged to report on resources invested in the Partnership; e.g. person-months spent to follow and interact with the Partnership

Along these lines, specific indicators for investments will be developed and monitored in the sustainability task.

[78] https://www.eu-toxrisk.eu/
[79] https://www.euromixproject.eu/
[80] https://edcmixrisk.ki.se/

### 2.2.7. Exit strategy

A crosscutting and holistic long-term approach for research and innovation in chemical risk assessment is needed 1) to support the ambitions of the Green Deal, 2) to improve for the sound management of chemicals and waste, 3) to help meet the Sustainable Development Goals.

The Partnership responds to the June 2019 Council of the EU conclusions 'Towards a Sustainable Chemicals Policy Strategy of the Union'[81] that states:

> *ACKNOWLEDGING the importance to continuously deepen the knowledge about the hazards of chemicals and (eco)toxicological effects and to adequately address the uncertainties regarding the exposure to chemicals, RECALLING the significance of environmental monitoring and human biomonitoring for recording the combined exposure of the environment and humans to chemicals and the unique role of these instruments to identify hitherto unknown exposure to substances problematic for human health and the environment and to control the efficacy of rules and regulations aiming to reduce such exposure; UNDERLINING the urgent need for a sustainably funded structure for applied research in this area. This should embrace inter alia a continuation of existing initiatives in the areas of human biomonitoring, the development and adaptation of test methods in toxicology and the scientific basis for risk assessment and risk management of chemicals;*

The new Chemical Strategy announced in the Green Deal offers an opportunity to address this request by the Council. The seven years of the Partnership will allow for proof of feasibility, while in parallel EU and MS institutions engage in the political discussion on long-term sustainability to be triggered based on the Council conclusions. A long-term sustainable Partnership in Europe should not be reliant on research funds only but achieving this sustainability requires wider political endorsement and investments.

During the development phase of the Partnership, when seeking the political commitment at national level for participation, the long-term vision for sustainability shall be discussed and the national interests confirmed. The Country Board and EU Board of the Partnership will be tasked upfront with manoeuvring for sustainability. They will be accompanied by a dedicated task on sustainability in the Partnership, which will develop and implement strategies to achieve the exist goals identified for each of the Partnerships' objectives and define new goals as the Partnership develops.

Initial activities already identified as part of the exit strategy have been reported as part of the objectives identified in section 2.2.3.

The Partnership will count on coordination between Commission services and EU Agencies to provide input into its work and ensure synergies with relevant activities at EU level. At the national level, the sustainability of the national hubs shall be promoted and agreements sought for continued collaboration between national hubs. The Partnership will identify and support necessary policy actions in order to support the anchoring of the high-level group created and its working modalities in the EU-level chemical framework including a processes to continue the dialogue and awareness raising between risk managers, risk assessors and the scientific community.

This will allow for contributing to the sustainability of the joint priority setting process for research and innovation developed and continue its application to define future priorities. Furthermore, decisions to keep and extend capacities at national and EU level for research and innovation in chemical risk assessment and for human biomonitoring will be sought. The

[81] http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf

Partnership will strive to support the implementation of an EU-level common data portal and to ensure the toolboxes developed in the Partnership are sustainable.

### 2.2.8. Strategic Research and Innovation Agenda (SRIA) development

After nomination by the Horizon Europe Shadow Programme Committee of country representatives to be involved in the Partnership development, a first meeting was organised by DG R&I in September 2019 to present the idea of the Partnership. At this meeting the development of the Concept Paper for the Partnership was launched and a Steering Group[82] for the Partnership development was created as well as a smaller drafting group. The drafting group was composed of volunteers actively involved in the four major topics of the Partnership: data management, exposure aspects, toxicology aspects and safe-by-design aspects. Topical drafting groups were responsible for framing the areas and proposing activities to be included. A smaller group of country representatives and DG R&I was in charge of drafting the other parts of the paper. A first consultation round with the relevant institutions, both nationally, under the responsibility of the members of the Steering Group, and within the Steering Group, took place on the draft Concept Paper. A second meeting took place in November 2019 in Brussels hosted by Flanders and third meeting in December 2019 in Helsinki hosted by Finland. The meetings have alternated with rounds of comments and revisions by the Steering Group and the drafting teams. Further to the virtual Steering Group meeting on 13 March 2020, a smaller group of volunteers worked on clarifying the impacts, objectives and structure of activities to be carried out in the Partnership. A revised version of the Concept Paper was submitted for approval for publication by the Steering Group in its virtual meeting on 27 May 2020.

An interim Partnership management board will be established during summer 2020 to bring forward the proposal preparation and further develop and focus the activities to be carried out in the Partnership. In parallel, a survey on challenges risk assessors and managers currently encounter and related research and innovation needs will be launched in synergy with HBM4EU. The EU Green Deal actions may play a pivotal role when informing priority setting activities, in particular the forthcoming Chemicals Strategy for Sustainability and the Zero Pollution Ambition for a toxic-free environment. An "evidence-based, both relying on scientific and policy considerations" priority setting process will be developed to draw up the first 3-year common strategy for the Partnership (see section 2.2.9) based on the outcome of the consultation.

The present concept paper will be disseminated though EU and national networks to ensure awareness and transparency. Other possibilities to inform and engage stakeholders (e.g. R&I days 2020) will be explored in view of timely feasibility. Once the Partnership is launched several activities are dedicated to communication, dissemination and consultation.

### 2.2.9. Priority setting process

In the preparation phase, the Partnership will benefit from the collaboration with HBM4EU to run a survey amongst national and EU risk assessors and managers to identify the needs for research and innovation activities to support chemical risk assessment/management. A prioritisation process will be developed with the current pre-Partnership Steering Group, to allow the Country Board (CB) and EU Board (EUB) (see section 3.3 on Governance) together with the interim Partnership Management Board (MB), once constituted, to draw up the first 3-year common strategy for the Partnership. This process will be further refined once the Partnership is operational.

[82] Steering Group (SG): The Group of country representatives' nominated by the Shadow Horizon Europe Programme Committee and the nominated representatives of EC DGs and EU Agencies involved in the development of the Partnership

The MB of the Partnership will consult with the Grant Signatories Board and the Consortium about the feasibility of the activities, e.g. scientific challenge, available resources, expertise and timeframe. The MB will then inform the EUB/CB about the feasibility and eventual need for new expertise to be added in form of new Linked Third Parties (LTPs). The CB and EUB will thereafter, based on the input and discussion with the MB, validate a list of research priorities for the following three years. Each year the MB will, in collaboration with the Grant Signatories Board and the Consortium translate these plans into Annual Work Plans (AWPs). The AWPs will be submitted annually for comments and approval to the CB and EUB. The MB will yearly report to the CB and EUB about the process of the agreed activities.

As soon as they will be constituted, the MB will consult the Stakeholder Forum &/or International Forum on the priorities and the foreseen activities.

This priority setting process will take place during the proposal preparation and then at least every two years. Each round (except for the first one) will also include an assessment of the ongoing activities and their successful implementation, including the possibility to stop activities should they not deliver according to the objectives set out, or to propose new ones linked to potential **urgent** needs from EU chemical safety policies and related chemical safety policies.


*Figure 3: Priority setting process*

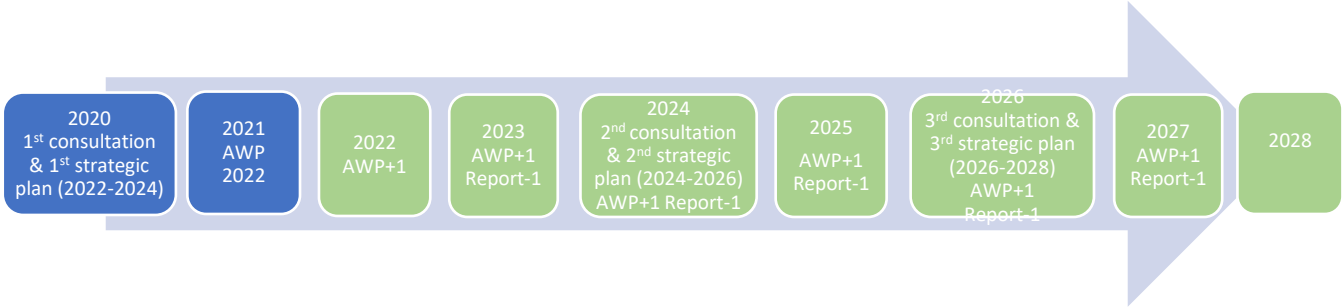


*Figure 4: Timeline for priority setting, reporting and AWP development*

## 2.3. Necessity for a European Partnership

### *2.3.1. Addressing the objectives of Horizon Europe*

The general objective of Horizon Europe is to deliver scientific, technological, economic and societal impact from the Union's investments in research and innovation so as to strengthen the scientific and technological bases of the Union and foster its competitiveness in all Member States including in its industry. Horizon Europe will thereby deliver on the Union strategic priorities and contribute to the accomplishment of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals, and to strengthen the European Research Area. The Programme shall thus maximise Union added value and deliver additionality by focusing on objectives and activities that cannot be effectively achieved by Member States acting alone, but in cooperation.

The European Partnership on Assessment of Risk of Chemicals will respond directly to the identified need for a 'sustainably funded structure for applied research in this area' in the 2019 Council Conclusions. The Conclusions also highlight *'the importance of sustainable research and innovation funding towards improving the scientific understanding of the impacts of hazardous chemicals on the environment, health, biodiversity and eco-system resilience, as well as promoting research on improving methods for the identification of hazards related to chemicals'* and acknowledges *'the research programme on human biomonitoring HBM4EU at the interface of science and European chemicals policy, as well as the IPCheM initiative and encourages a similar research programme on environmental monitoring as well as the improved sharing and use of local, regional, national and EU-level monitoring data both between countries but also between policy areas (e.g. water, chemicals, air, biomonitoring, health, etc.) and relevant institutions;'*.

Horizon Europe encourages the collaborative links in Europe to contribute in reducing the R&I divide. This type of partnership aims to close the gap between R&I and regulatory processes by creating a large network of partners and stakeholders. This network will also liaise with representatives of health, environment and research ministries at national level and EU level to ensure the R& I impact in different policy areas. The cooperation among countries will help to build a pan-European network that will facilitate the sharing of experiences, knowledge and regulatory science needs as well as providing a stimulating environment to foster the excellence-based participations from all Member States (and countries associated to Horizon Europe), independent of their R&I performance level. These ambitions go well beyond what can be achieved with normal HE calls.

In terms of directionality, this Partnership will contribute to generate knowledge and build capacities in the area of chemical risk assessment and exposure and support the development of a sustainable EU chemicals policy strategy. The knowledge, new technologies, tools and approaches derived from this collaboration will support other policy needs and strategies, including the implementation of the circular economy action plan and address challenges, such as zero-pollution and toxic-free environment and the future 'farm to fork' strategy on sustainable food.

### 2.3.2. Supporting a meaningful collaboration with countries

A co-funded Partnership is the best instrument to support collaboration between national public organisations which conduct risk assessment and/or regulatory activities, the corresponding EU agencies and European Commission, and the contributing research community. The EU added value of aligning such activities lies in a more efficient use of existing (human, infrastructures, financial) resources as well as knowledge, data and best-practice transfer between countries and with the EU organisations.

The European Joint Programme HBM4EU has shown that a Partnership at EU level is apt to promote national networking and capacity building. Frontrunners can share their acquired experience and develop a joint way forward, while newcomers benefit from access to knowledge and experience and can therefore catch up faster whilst, with a developing system, offer possibilities to test new ideas.

This Partnership will continue building on the networks of National Hubs developed under HBM4EU, enlarging them to include the additional expertise required to cover the whole remit of the Partnership and ensure the ability of the Partnership to tap into all available national expertise and stakeholders in the field. Two specific objectives will contribute to ensuring meaningful collaboration with and between countries: the high-level group of EU and national representatives engaged in regulatory risk assessment and risk management, which will strategically govern the Partnership, and the long-term network of National Hubs that act as intermediates between the Partnership and national and regional stakeholders in the field.

## 2.4. Partner composition and target group

### *2.4.1. Type and composition of partners*

All EU Member States as well as countries associated to Horizon Europe will be invited to participate. This section focuses exclusively on the grant signatories and linked third parties of the Partnership. The strategic governance and the collaboration with EU Agencies and EC services is described in section 3.3.

The grant signatories shall be:

- the national/regional institutions in charge of chemical risk assessment and carrying out research and innovation activities either in-house or through collaboration with research organisations or academic groups
- the research programme owners/funding agencies if required to manage the network of national partners, e.g. if the national risk assessors do not have the required capacities, and
- eventually, and based on their individual legal and operational frameworks, the EU Agencies involved in chemical risk assessment and/or producing knowledge on chemical impacts on the environment and health[83]

Additional partners joining as linked third parties are:

- academia and research organisations part of the national networks on research for chemical risk assessment and with established links to the risk assessing institutions

To avoid an excess of grant signatories (ideally limited to 1 or 2 per MS), national coordination and the use of linked third parties to structure participations from countries is mandatory.

National/regional programme owners, such as authorities or ministries in charge of chemical safety policies shall mandate the grant signatories to engage the national programmes in the Partnership.

*Table 3: Schematic overview of partners*

| **Grant Signatories** | **Linked third parties** |
|---|---|
| *Programme manager mandated by a Programme Owner* | *Legal link to GS* |
| • Risk Assessors (RA) engaged in research and innovation activities<br>• Research funding agencies if needed because for coordination capacity<br>• EU Agencies on a case by case basis, depending on the individual Agency's legal and operational frameworks | • Research institutions<br>• Academia |

**Composition of the entities in the steering group preparing the Partnership and geographical representation**

The current organisations involved in the preparation of the Partnership, as part of the Steering Group, come from 25 countries[84] and include Ministries (for research, health, environment …), national chemical risk assessment agencies and research organisations as well as academia.

[83] In eventual cases where certain EU Agency(ies) could not be grant signatories, collaboration modalities will be established to ensure that the EU Agency(ies) will duly contribute to and access relevant PARC activities and outputs.

[84] Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland.

In addition to these national bodies involved in chemical risk assessment and risk management, EU agencies (ECHA, EEA, and EFSA) are involved as well as European Commission Directorates General (DG ENV, DG GROW, DG R&I, DG SANTE and JRC).

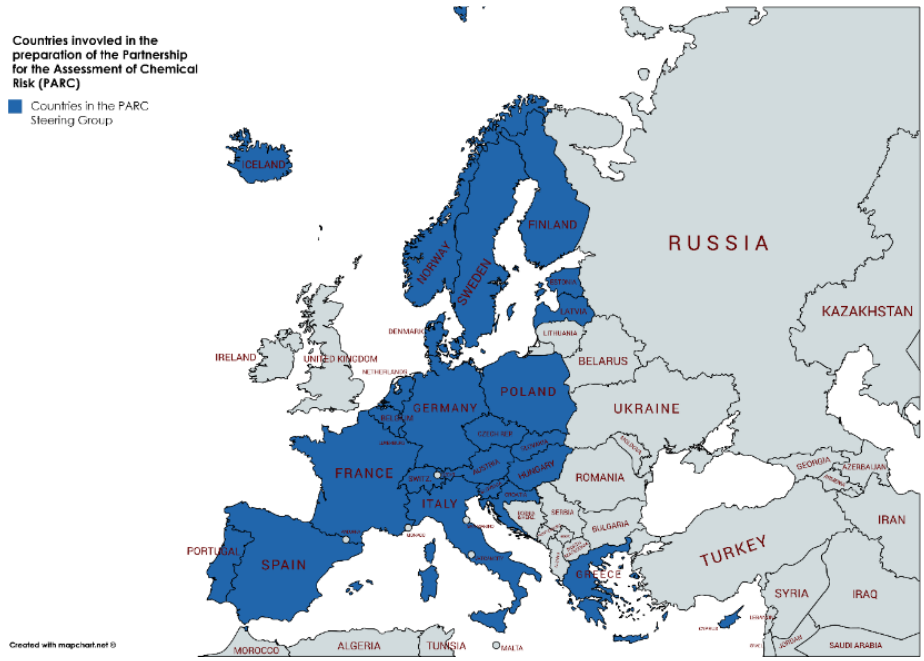


*Figure 5: Geographical representation of the countries represented in the Steering group involved in the preparation of the Partnership*

## Skills and expertise in the Partnership

The partners involved in the Partnership preparation have extensive skills and expertise in all aspects to be covered by the activities (see figure 6 below). Several partners have participated in and coordinated various EU projects on the topic of chemical risk assessment.

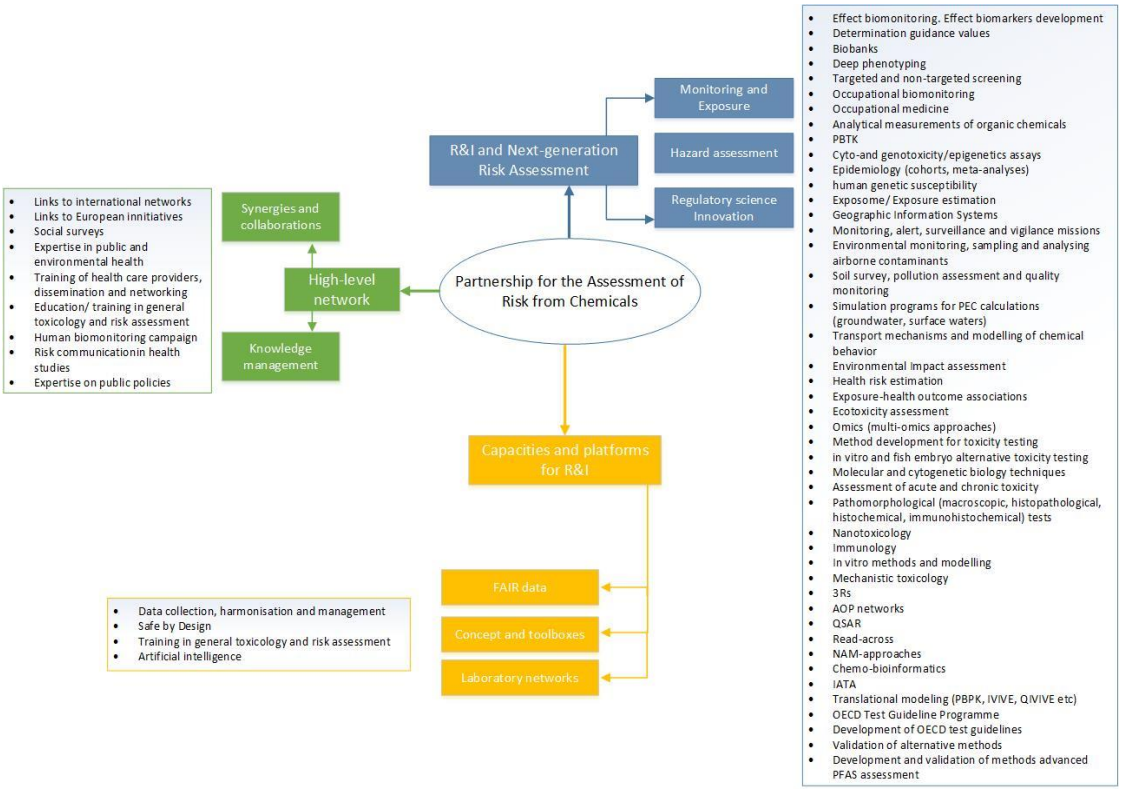


*Figure 6: Skills mapping of partners in the Partnership*

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) is the coordinator of the Partnership. ANSES was created on 1 July 2010. It is an administrative public establishment accountable to the French Ministries of Health, Agriculture, the Environment, Labour and Consumer Affairs. ANSES undertakes monitoring, expert assessment, research and reference activities in a broad range of topics that encompass human health, animal health and well-being, and plant health. ANSES fully addresses all types of risks (chemical, biological, physical, etc.) to which a person may be subjected, intentionally or otherwise, at all ages and stages of life, including through exposure at work, while travelling, while engaging in leisure activities, or via their diet. ANSES's duties include risk assessment in the fields of food, animal health & welfare, plant health & protection, the environment (air, water, consumer products) and the workplace, for the purpose of assisting the authorities with their policies on health and safety. ANSES's strategy on the European and international scene is underpinned by an integrative approach to its various activities and areas of competence. ANSES is a major player in national and European research through conducting research activities in its laboratories and in its risk assessment department, identifying priorities for research and funding research to bring research and risk assessment closer together. It conducts risk assessment of chemicals (and in some cases issuing of marketing authorisations) in the context of several European chemicals regulations (REACH, CLP, biocides, plant protection products, veterinary medicinal products). ANSES is committed to promoting openness to society and organises regular discussion meetings with stakeholders.

ANSES has proven experience in implementing and coordinating large-scale European projects. The coordination skills have been developed over the past years and experience acquired in coordinating several European projects co-funded by the Research and Innovation Programme or by the EU Health Programme. Currently ANSES is coordinating two projects co-funded by the EU's Horizon 2020 Research and Innovation Programme notably the large-scale European Joint Programme (EJP) on One Health.

### *2.4.2. New partners or actors*

The consortium remains open to the integration of additional European countries or entities that want to join and contribute with their knowledge and resources. To achieve this, organisations from countries with the intention to join the Partnership have the opportunity to take part in a Management Board (MB) meeting as a guest. They will have the chance to introduce themselves and any activities related to the Partnership. In follow up, the MB will consider how the country's organisations might be integrated into the workflow and will inform the applicant regarding possible task allocations within the next Annual Work Plan (see section 3.4.4). If the applicant and the MB come to an agreement, the Country Board will vote on the country's integration into the project.

The National Hubs, as national networks of decision makers, research funders, risk assessors, stakeholders and the research community will play a crucial role in identifying potential new partners and expertise that could benefit from participating and being included in the Partnership.

### *2.4.3. Enforcing existing networks*

The Partnership builds on existing knowledge, expertise, and infrastructure and will enforce these. Due to the broad scope of this action and the diversity of fields of expertise needed in this Partnership, it will seek the engagement of a number of expert communities. Annex II (background document) provides an overview of the relevant identified networks and will continue to evolve during the Partnership's lifetime. The current list of networks holds a range of expertise and competences and includes laboratories in the field of internal and external exposure monitoring (including EU Reference Laboratories) and laboratories experienced on in vivo and in vitro test methods, expertise to assess the potential regulatory relevance and

suitability of proposed test methods and testing strategies or identification of experts to participate in specific areas.

Examples of key networks to be enforced are:

- The HBM platform developed by HBM4EU, e.g. the network of reference laboratories and the QA/QC system including guidance on harmonised sampling and sample handling.
- Network of laboratories for non-targeted screening of chemicals in human samples.
- IPCheM the EC managed information platform for chemical monitoring data.

Examples of key networks for cooperation are:

- The European Union Reference Laboratories and their network of National Reference Laboratory network for food and feed safety for residues of pesticides in plant products, residues of veterinary medicines and contaminants in food of animal origin[85]
- The Network of reference laboratories (NORMAN)[86], research centres and related organisations for monitoring of emerging environmental substances
- The EU Reference Laboratory for alternatives to animal testing[87].

Specific objectives of the Partnership cover the identification and evaluation of capacities and the consolidation of existing networks and encourage the development of new networks as required to support the common strategies and research and innovation activities of the Partnership to promote the transition to the next generation of chemical risk assessment.

#### *2.4.4. Stakeholder community, citizen engagement and international dimension*

There are solid foundations and experiences on which to build a new Partnership. The Partnership will respond not only to regulators' needs but also to citizen's expectations for a safer chemical environment. The new Partnership should allow all actors to interact and bring into play the best expertise around Europe. The Partnership will provide a forum to discuss stakeholder's interests, needs and priorities, as well as the strategic and technical aspects to ensure the progress of chemical risk assessment. Annex II (background document) provides an initial overview of the relevant identified stakeholders.

A major challenge is transparent and effective communication with all relevant stakeholders and to engage with them, in particular with non-governmental stakeholders. This includes parties from industry, academia, non-governmental organisations (NGOs), trade unions and civil society organisations. The Partnership will ensure public accessibility to results and foster citizens' understanding and awareness of the principles of European chemical risk assessment and risk management. A stakeholder forum consisting of NGOs; industry/business associations; employers and worker representative bodies and consumer organisations will be implemented. The Partnership will promote open knowledge and communication to citizens and policymakers and will use the expertise of stakeholders to enhance the uptake of results and translate research on and knowledge about chemical safety into policy in an effective way. To enhance the outreach to and communication with citizens dedicated focus groups with citizens will be organised.

The Partnership will strive towards fostering European leadership at the international level for research and innovation in chemical risk assessment and will promote cooperation and collaboration across Europe and internationally. The Partnership will contribute to international fora, dealing with chemicals, pollution and the SDGs, such as the World Health Organisation (WHO) (e.g. International Programme on Chemical Safety IPCS Chemical Risk

[85] https://ec.europa.eu/food/ref-labs_en
[86] https://www.norman-network.net/
[87] https://ec.europa.eu/jrc/en/research-facility/european-union-reference-laboratory-alternatives-animal-testing-eurl-ecvam-laboratory

Assessment Network) and Strategic Approach to International Chemicals Management (SAICM), UN Environment Programme (UNEP) and OECD, dealing with chemicals, pollution and the SDGs. Bilateral relations with major international risk assessment agencies (e.g. U.S. Environmental Protection Agency) and research institutions (e.g. U.S. National Toxicology Program) will also be envisaged. MS are already contributing as single entity to many of these networks. Collaboration of MS in the Partnership will strengthen the influence of the EU in addressing global challenges associated with chemical risk assessment and place the EU as the front runner of the international community in this area.

Dialogue and collaboration with the international community is essential for mutual support and for the identification of needs and opportunities for harmonisation actions and development of tools that support the collaboration. Connecting this Partnership with the international community will foster the dissemination of results and will promote the importance of data and knowledge sharing among international networks. An international board consisting of experts from other international chemical risk assessment platforms, scientific advisory boards or scientific societies, or experts in related EU or international activities will contribute to ensuring the Partnership establishes links and dialogue with relevant international activities.

# 3. Planned Implementation

## 3.1. Portfolio of Activities

In order to respond to the research and innovation needs set out in section 2.1.2 and meet the objectives identified above, the following implementation structure is proposed for the Partnership. Detailed scientific activities are described in the Strategic Research and Innovation Agenda (SRIA, see Annex I) and the actual targeted priorities the Partnership will work on will be established through the prioritisation process defined in section 2.2.9.

The suggested implementation structure developed to follow the intervention logic used for the three levels of objectives will consist of 8 key work packages, each of them subdivided in a limited number of tasks (Figure 7), plus the overall Partnership management and coordination work package.

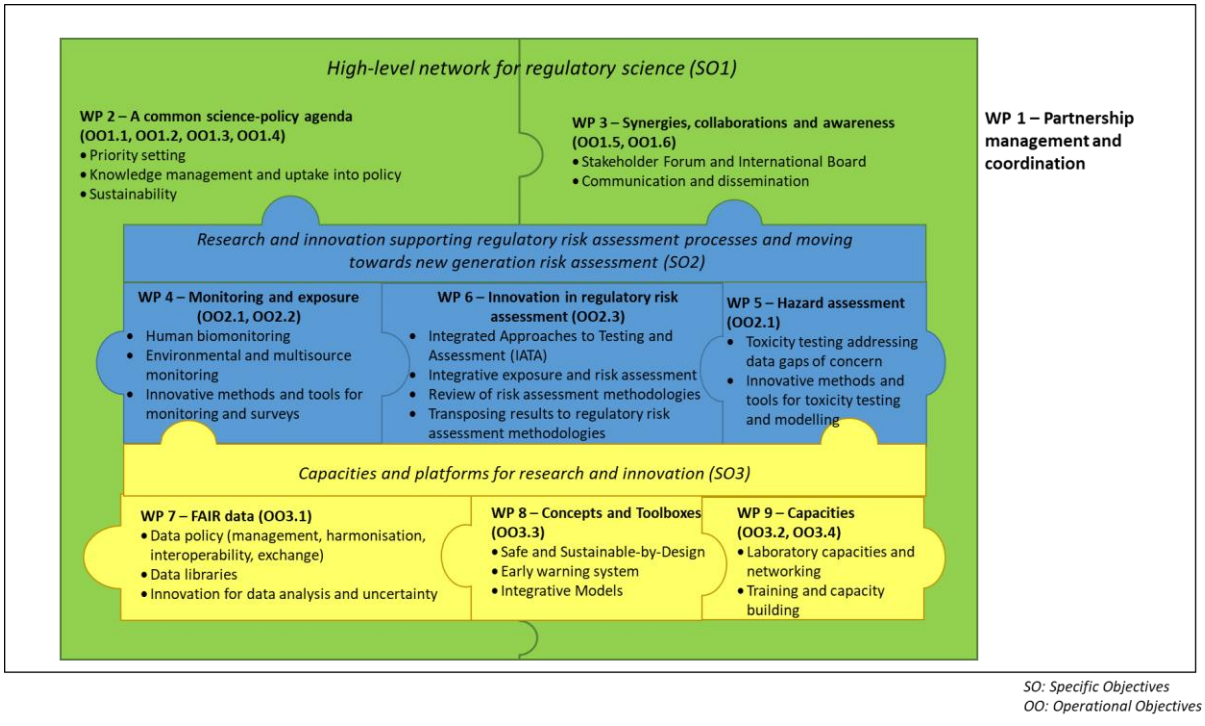


*Figure 7: Suggested structure of the Partnership with 9 work packages*

A strong interlinkage of all areas will be ensured in order to deliver as best as possibly on the priorities and the objectives (Figure 8).

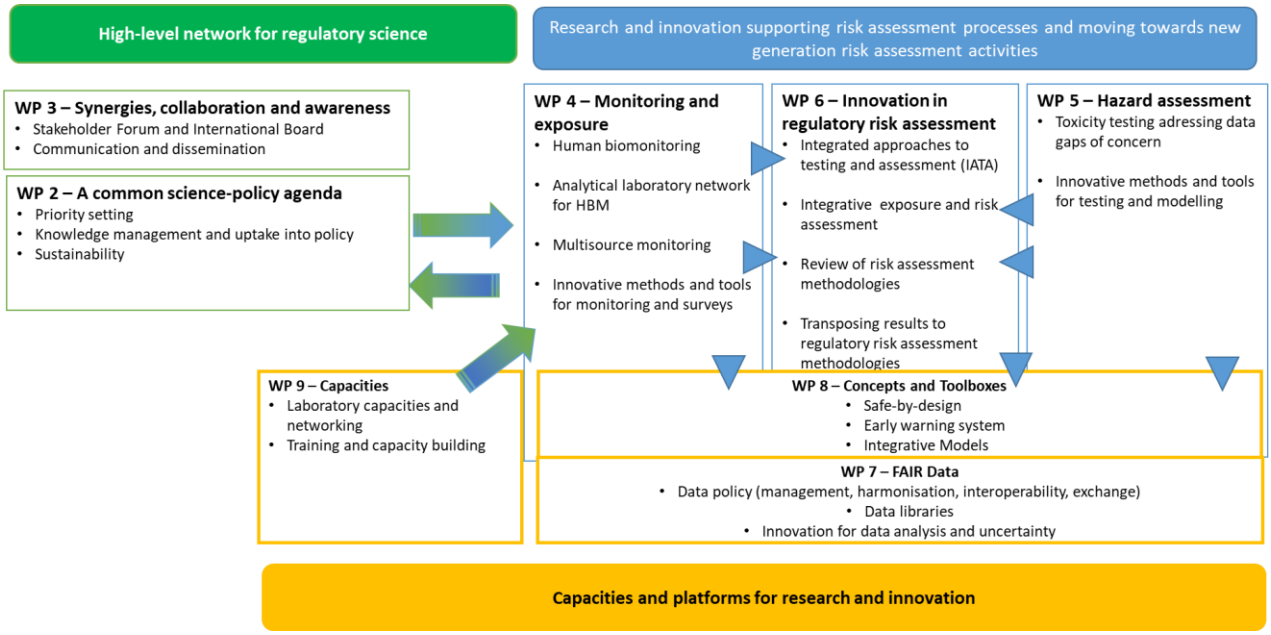


*Figure 8: Interlinkages between WPs and tasks in the suggested structure of the Partnership*

### *3.1.1. High-level network for regulatory science*

#### WP 2 – A common science-policy agenda

The aim of the Partnership is to bring together the European risk assessment agencies and regulatory entities to identify joint challenges and research priorities and develop a strategic research and innovation agenda to tackle these in collaboration with the scientific community. The joint priority setting and upfront steering by risk assessors and managers will frame the research activities to the challenges they encounter and ensure the use and uptake of the results in a regulatory context.

*i) Priority setting*

The main objective of this task will be to support the Country and EU Boards to agree on the 3-year common strategies for 2022-2024 and 2025-2027 as well as for the last year of the Partnership 2028 and beyond. The work will consist in establishing a process for prioritisation (see also section 2.2.9 on the priority setting process), running surveys and consultations, organising workshops, processing the collected information, preparing and supporting the joint discussions in the Country and EU Boards and finally drafting the 3-year common strategy to be adopted by the Boards.

*ii) Knowledge Management and uptake into policy*

A core activity of this task will be to harvest and manage existing and new scientific knowledge in the areas of chemical safety assessment that can contribute to EU regulatory science and policy-making. This task will:

- serve as the general 'knowledge keeper' of PARC's activities and its results and will facilitate the immediate access of risk assessors/managers to these data
- use the knowledge to facilitate an ongoing dialogue between the Partnership and regulatory scientists in the EU institutions
- identify relevant new/recent knowledge in the areas of chemical safety and biology that can potentially contribute to regulatory science and policy making
- identify knowledge gaps to contribute to priority setting for PARC

- ensure the exchange of information between different work packages and tasks in which common methodologies are used (Adverse Outcome Pathways, Physiologically-Based PharmacoKinetic modelling, Uncertainty analyses…)
- support the Management Team in translating the 3-year common strategies into Annual Work Programmes and establish a transparent process to distributing the work in the different activities

*iii) Sustainability*

This task will focus on pursuing the sustainability of the Partnership, e.g. the network and its joint activities by:

- further developing the first set of indicators
- monitoring the indicators and reporting on them in the Annual Technical Reports
- developing and implementing workflows to achieve the objectives identified in the exit strategy
- proposing new ideas for the exit strategy to the Country Board and EU Board

### WP 3 – Synergies, collaborations and awareness

To achieve the objectives of the Partnership, synergies, collaborations and awareness raising activities are required with all stakeholders. These activities aim to boost the impact of the outcomes of PARC and the diffusion of knowledge in this area at national, EU and international level. It will enable risk assessment institutions to give better advice to risk managers and decision-makers and to reinforce the trust in risk assessment and risk management institutions.

*i) International Board and Stakeholder Forum*

This task will manage the setting-up and running of the International Board (IB) and Stakeholder Forum (SF).

The IB will consist of international and EU experts in risk assessment, experts from international chemical risk assessment platforms, representatives of scientific advisory boards or scientific societies, representatives of related EU or international activities (e.g. WHO, OECD, UNEP). The role of the IB is to establish links and coordination or cooperation with major related and relevant EU and international activities and contribute to facilitating the uptake of results into chemical safety regulatory science and policies.

The SF will consist of non-governmental organisations (NGOs), industry/business associations, employers and worker representative bodies and consumer organisations. The SF shall be involved in the prioritisation process and act as a sounding board to enhance the accountability and credibility of the activities and results of the Partnership.

*ii) Communication and dissemination*

Communication and dissemination of information is a key success factor in achieving the goals of the Partnership. Target groups for communication include the national risk assessment communities, EU authorities/regulators in the field of chemical risk assessment, different stakeholders including researchers and the general public. Each of these target groups need specific, targeted communication strategies and materials. To enhance the outreach to citizens dedicated focus groups with citizens will be organised.

This task will also be in charge of fostering synergies with other relevant initiatives at national, EU or international level by identifying these and promoting open communication to increase mutual awareness and recognition of work planned and results obtained. When collaborations can be envisaged these will be supported by the knowledge management task.

### 3.1.2. Research and Innovation activities supporting the current regulatory assessment processes and moving towards next generation risk assessment

#### WP 4 – Monitoring and exposure

The aim is to gather information on the exposure of humans to chemicals from new and existing monitoring schemes considering multisource distal (e.g. outdoor air, soil, water) and proximal (e.g. indoor air, food) environmental exposures. New tools and methods will be developed and promoted for exposure monitoring.

*i) Human biomonitoring*

This task will be built on the human biomonitoring platform established in the context of HBM4EU[88], to advance the capacities for a Europe-wide high quality, harmonised human biomonitoring programme. Study designs, questionnaires, fieldwork and sampling protocols will continue to be harmonised and their use will be encouraged in ongoing studies and will be set as standards for new studies. The re-use of existing samples and already planned studies, as well as the launch of new studies will be encouraged. Exposures of the general population, workers and vulnerable population or specifically exposed groups will be measured depending on the prioritised chemicals. Linkages to Health Examination Surveys and cohort studies and possible integration of Human Biomonitoring studies in these will be pursued.

Analytical activities (development and assays) will be performed by the laboratory network established by HBM4EU. The quality assurance/control system developed in HBM4EU will be further developed as required. Analytical methods will be developed according to the needs of the surveys in close collaboration with the promoter of them and harmonised across laboratories. Samples will be analysed respectively for targeted, suspect or non-targeted exposures and effect biomarkers.

Data management and data analysis of individual HBM study data sets (exposure levels, accompanying data, questionnaire data) will be taken care of and after quality assurance and data analyses be fed into the data pool in WP 6. Statistical plans and standards will be further developed and applied in close cooperation with the "FAIR data" work package.

Causal associations between (combined) exposures to chemicals and health outcomes in the general population and sub-populations thereof will be explored though linkage of Human Biomonitoring data with information on external exposure and the use of epidemiological and of toxicological information. Human biomonitoring guidance values, reference values and exposure indicators will be elaborated in response to specific regulatory questions. This transversal activity will be performed in collaboration with the "Innovation in regulatory risk assessment" work package.

*ii) Environmental and multisource monitoring*

This work aims to better understand the presence of chemicals in the environment via multiple sources and the resulting exposure of humans when chemical substances come from multiple sources and move along different pathways, fostering a "one health" chemical risk assessment strategy.

To better allow the assessment of aggregated, combined and cumulative exposures, efforts will be directed at monitoring, in different matrices, the co-occurrence of chemical substances, their metabolites and degradation products. It will include efforts to catalyse the ongoing development of effect-based monitoring (e.g. within the EU Water Framework Directive). It will include the design of sampling protocols and will utilise existing sampling programmes,

[88] www.hbm4eu.eu

whenever possible. This will be performed in collaboration with existing laboratory networks and trigger the implementation of new laboratory networks as necessary.

Another focus will be on producing data (related to chemical risks for the environment and to human health) for the development of an early warning system in the "Concept and Toolboxes" work package.

*iii) Innovative methods and tools for monitoring and surveys*

For harmonised and standardised monitoring of the exposure of humans to chemicals (including nanomaterials) from various sources, actions will aim to develop robust, reliable and fit-for-purpose tools and methods to improve or renew existing human and environmental monitoring schemes.

Particular attention will be paid to improvement of methods to identify exposures to emerging chemicals and mixtures such as non-targeted/suspect screening approaches and also effect-based monitoring in the environment.

This task will also aim to develop new tools (surveys, participative science, big data analysis, etc.) to gather data on consumption behaviours (dietary habits, life habits, etc.) and occupational conditions (occupational scenarii) that will lately be used to estimate aggregate exposures. New methodologies will be developed for new scenarios of exposure associated with development of circular economy.

All these developments will be performed in close collaboration with existing laboratory networks be they within the Partnership or not.

### WP 5 – Hazard assessment

The primary aim of this work package is to fill data gaps identified by risk assessors, managers or scientists, and to match innovative methods, tools and approaches for toxicological hazard assessment with regulatory needs. Toxicological or ecotoxicological studies generating new data (mechanistic, *in silico*, *in vitro* and *in vivo* data) for chemical substances/materials (including nanomaterials) and for mixtures relevant to public health will be designed and performed. New tools and methods will be developed according to the needs.

*i) Toxicity testing addressing data gaps of concern*

This task aims at filling data gaps identified by a transparent decision process based on regulatory needs. Depending on these needs, testing will be substance or group of substances specific and address endpoints of concern by applying regulatory accepted Test Guidelines (TG) studies. Endpoints of concern may differ and range from e.g. sensitization over genotoxicity to carcinogenicity or developmental (neuro) toxicity. The testing programme will take into consideration the 3Rs principle (Reduce, Refine and Replace animal testing), and if available, regulatory accepted tests (OECD guidelines). All relevant knowledge and data (physico-chemical, biological, toxicological, etc.) available will be taken into account to define the necessary studies to fill the data gaps. Integrating new approach methodologies (e.g. Adverse Outcome Pathway (AOPs), identification of biomarkers) within classical experimental designs would contribute to improving the hazard characterization through better understanding of the mechanism of action. This would ultimately facilitate the acceptance of New Approach Methodologies (NAMs) by risk assessors and managers and eventually enrich existing databases (e.g. AOPs, QSAR…).

*ii) Innovative methods and tools for toxicity testing and modelling*

Another aim is to develop and promote the regulatory acceptance of novel mechanism-based NAMs (including AOP and quantitative AOP (qAOP), *in silico*, *in vitro* methods as well as *in vivo* methods enhanced with mechanistic information) through (pre)validation or applicability studies thereby taking into account the relevant AOPs.

Examples of the different types of activities in the (regulatory) chemical risk assessment context that will be implemented include:

- evaluation of the relevance of the new innovative methodologies based on new technologies (e.g., genomic, transcriptomic, high-content analysis microscopy, mass spectrometry) to assess (eco)toxicological endpoints not yet covered by standardised regulatory method
- development and use of Physiologically-Based Kinetic (PBK) models to perform *in vitro - in vivo* extrapolation (IVIVE), taking into account, inter-species and intra-human variability of toxicokinetic parameters and linking external to internal exposures.
- development and use of (eco)systems toxicology, through the integration of classical (eco)toxicology with quantitative analysis of the molecular and functional changes occurring as a result of chemical exposure will allow the development and use of quantitative AOPs networks.

All these activities will be planned to support the progressive shift from classical chemical hazard assessment to Integrated Approaches to Testing and Assessment (IATA) to address human health and environmental risks.

### WP 6 – Innovation in regulatory risk assessment

This work package will integrate the results generated and knowledge acquired within the other work packages. The aim is to drive innovation to develop and foster science supporting regulatory risk assessment. This will be accomplished by testing and validating integrative approaches for chemical risk assessment combining existing models and tools, as well as newly developed and validated methods, models and tools so as to promote their wider regulatory acceptance.

*i) Integrated Approaches to Testing and Assessment (IATA)*

This task will strive to support the progressive shift from classical chemical hazard assessments to testing and assessment strategies that, for specific prediction goals, integrate data from traditional and novel methods and from diverse lines of evidence (*in silico*, *in vitro*, *in vivo* and human) into IATA programmes. The use of innovative data mining, machine learning, non-animal approaches and artificial intelligence will be encouraged. Data on indirect toxicity related to eco-toxicological effects (non-mammalian toxicity) might also be integrated in the approach (e.g. endocrine disruptors). Shared experience on the approach will be developed in the context of case studies to answer priority regulatory issues. The work under this task will be established in close collaboration with the OECD and other international parties.

*ii) Integrative exposure and risk assessment*

With respect to exposure, integrative models are needed to determine and quantify the internal exposure of humans to chemicals from different routes and sources of exposure and to combine several routes and sources of exposure and/or exposures obtained from different methodologies. Leading European models for (combined) exposure via food, air, consumer products, water and at the workplace should be integrated. The models should be in line with relevant EU legislation, such as legislation related to the food chain (e.g. EuroMix/MCRA models), the Air Quality Act and REACH (e.g. for consumer products ConsExpo/PACEM[89]).

Models to adequately describe and predict the behaviour of chemicals in the distal-field environment (air, water, soil) and the proximal-field environment (object, food and beverages, indoor air, etc.) during personal and occupational activities have been developed. These models should be integrated and connected to the task environmental monitoring. The applicability of

[89] Probabilistic Aggregate Consumer Exposure Model (PACEM)

these models will be tested in different risk assessment case studies to foster their acceptance and contribution to the integrative toolboxes.

For many chemical classes and routes of exposure, data might be lacking. Background exposure levels might be derived from appropriate biomonitoring studies. Kinetic models are also needed for combining different routes of exposure and for extrapolation of results from animal-free tests using cell systems (*in vitro*) to data needed for risk assessment and will be developed in cooperation with the hazard assessment WP described above.

The risk related to combined exposure to multiple chemicals is one of the challenge risk assessors currently face despite being the focus of many research programmes previously established. Therefore, initiatives to pursue research in this field towards practical approaches that can be implemented in a regulatory risk assessment will be supported.

*iii) Review of risk assessment methodologies*

This task should evaluate and map the performance, efficiency, and effectiveness of current methodologies employed in regulatory risk assessment. It should thereby identify methodological knowledge gaps/needs to inform overall "Priority setting" in the Partnership. The task should be performed in close collaboration between researchers, risk assessors and risk managers.

*iv) Transposing results to regulatory risk assessment methodologies*

This task will serve to foster innovative regulatory risk assessment methodologies and thus contribute to strengthening the science basis of risk management. There are several areas related to the risk assessment of chemicals (e.g. to chemical mixtures, endocrine disruptors, sensitive subpopulations of consumers (infants, pregnant/lactating women, persons with underlying diseases), exposure to chemicals from articles), that require development of regulatory risk assessment methodologies.

This task should foster the testing, validation, and standardisation of the relevant outputs of the Partnership or from collaborating projects that would ultimately lead to their use in regulatory risk assessment.

Furthermore, the knowledge generated in the Partnership can contribute to developing and adapting methodologies of EU and OECD regulatory risk assessment contexts for various activities (e.g. sampling, statistical analysis, risk assessment guidance documents).

### 3.1.3. Capacities and platforms for innovation

#### WP 7 – FAIR Data

The added value of an overarching work package on data is to develop and implement some general rules for all parts of the Partnership related to data collection, harmonisation, quality control, reporting, sharing, and processing, in consultation with the Ethics and Data Protection Board (EDPB). A central module for facilitating analysis of the data generated within the Partnership and their interpretation will be defined in close collaboration with all the work packages.

*i) Data policy (management, harmonisation, interoperability, exchange)*

Data storage, curation, use, treatment, and exchange within and outside the Partnership needs to be organised prudently, and practical and regulatory hurdles related to e.g. sharing of personal data will need to be overcome[90].

[90] OECD (2019), *Enhancing Access to and Sharing of Data: Reconciling Risks and Benefits for Data Re-use across Societies*, OECD Publishing, Paris, https://doi.org/10.1787/276aaca8-en

A data policy will be developed as the backbone of the data management. It defines the principles and conditions that govern provision, management, access, use and re-use of metadata in data repositories and the data themselves. As a first step, a framework of guiding principles will be developed, in close collaboration with existing data collections and by making best use of ongoing efforts for data standardisation and exchange and for joint data platforms and hubs, in order to establish common data management and harmonization guidelines. These guidelines will be developed according to the principles of FAIR data management, and take legal, ethical, privacy, security, etc. aspects into account. While the Partnership can build on ongoing efforts for standardization and harmonization for physicochemical and toxicity data, data generated by new approach methods and exposure data need specific attention. For personal data, solutions to GDPR related challenges, in particular the use of federated data systems, will be elaborated.

Standardised templates for collection and reporting of different types of data produced within the Partnership and associated information will be developed building on existing formats. In order to allow (re)use of data in different contexts, an adequate amount of related metadata needs to be provided and sufficient information to judge if the data is of sufficient quality for the envisaged use. A methodology for data harmonisation will be established for newly generated data under the Partnership and covering existing data where feasible. Ontologies (to be developed in consultation with OECD) and the use of standards at source and throughout the information lifecycle are needed; ISO-Standards for metadata must be implemented. A methodology for scrutinizing available data will need to be developed to guarantee the use of high-quality data. For actual data exchange, the use of a central portal redirecting to different data collections, application of Database Services and WebServices, and/or interagency linking to accomplish international standardised data collection should be explored.

*ii) Data libraries*

For storage of data generated within PARC, the Partnership should avoid building new databases and make better use and better interconnections between existing ones. Specialised data centres will be identified and the content and accessibility explored, and if feasible be considered as potential partners to store, update and exchange different types of data as appropriate. Interoperability of data platforms, hubs, and databases, application of the FAIR principles, and implementation of open data principles and disclosure of data collections hosted by different institutions are key requirements. The work to be undertaken will build on the results of the tender launched in 2019 by DG ENV for the 'Feasibility Study on a Common Open Platform on Chemical Safety Data'[91].

Currently, disciplinary data collections are stored in 'silos' focused at specific chemical substance groups, chemical life stages, types of use, environmental compartments, or protection targets. At the European level, existing data collections and platforms to be considered in the Partnership include e.g. the Information Platform for Chemical Monitoring (IPCheM), the European Commission's access point for searching, accessing and retrieving chemical occurrence data and eChemPortal[92]. Many databases for toxicological data exist as well, including e.g. the ECHA and EFSA data management efforts. Additionally, multiple institutes, projects and databases are also already dealing with storing and sharing of specific data (monitoring, hazard, population, etc.) e.g. the Global Monitoring Plan Data Warehouse established to support the supporting the implementation of the Stockholm Convention on Persistent Organic Pollutants, the European Bioinformatics Institute that specialises in storing and sharing variety of biological data, the ELIXIR distributed infrastructure for life-science information, the interoperable model and data platform integrating exposure and hazard data developed in the context of EuroMix, and the NORMAN Association's efforts to exchange

[91] https://ted.europa.eu/udl?uri=TED:NOTICE:215925-2020:TEXT:EN:HTML
[92] https://www.echemportal.org/echemportal/

data on emerging chemical substances between various research projects in support of European environmental policies.

Connections to international data platforms such as developed by the Center for Disease Control, Health Canada, Japanese and Chinese actors will be explored.

In addition, implementation of systems (such as tags) to allow extracting relevant combinations of chemicals will be pursued to be able to assess occurrence, exposure and toxicity of mixtures.

*iii) Innovation for data analysis and uncertainty*

In the overarching data analysis task, best practices in data analysis and case studies will be shared and new and improved methodologies will be developed, such as to support derivation of reference values and trigger values, evaluation of combined external exposure, internal exposure, and effects relationships as well as development of indicators for chemical exposure and health outcomes. Possibilities to apply innovative techniques, tools, and methods (such as data mining and machine learning) for developing complex algorithms for data processing, and computational analyses will be explored. Methodologies to collect, process, combine, and integrate varying types of data (e.g. (environmental) monitoring and modelling data, human biomonitoring and health status data, and different types of *in vivo*/*in vitro*/*in silico* toxicity data) will be developed, aiming at identifying correlations and attributions. A procedure for computerised analysis of different types of data will be developed.

Uncertainty analysis at each step of data analysis is fundamental to, *in fine*, perform reliable risk assessment. At many steps, uncertainty is only qualitatively described as over or underestimation of the considered parameter. The Partnership will promote the use of these methodologies and explore new methodologies to quantitatively estimate uncertainties to strengthen risk assessments.

The methods will be transparently communicated and their application in the different tasks supported.

### WP 8 – Concepts and toolboxes

The aim is to further develop and consolidate new concepts and approaches in chemical risk assessment, which still require an agreement of a joint understanding in the stakeholder community and the identification of tools and methods to support their practical use.

*i) Safe and sustainable by design*

This task will provide support to the EC's work on defining the Safe-and-Sustainable-by-Design (SSBD) concept[93] and implementation criteria and propose a toolbox to support the application of these criteria aimed at human and environmental health protection.

A transdisciplinary process, involving scientists, risk assessors, policy makers, stakeholders, and the public, will be initiated to develop conventions for "safe" and "sustainable", which determine the key protection goals and implementation criteria for a safe and sustainable design of chemicals, products, materials, packaging and application processes.

Secondly, a SSBD assessment toolbox will be proposed, based on existing and new tools developed in the Partnership, in support of the application of such evaluation criteria. This toolbox will be used to describe methods with which critical properties (such as toxicity, exposure, reparability, reusability, recyclability) of chemicals, products, materials, packaging and application processes can be identified at an early stage of innovation. Guidelines for implementing the toolbox will be formulated. Development at the international level (in particular within OECD) will be followed and taken into account along the process.

[93] http://doi.org/10.5281/zenodo.3254382

*ii) Early warning system*

The Partnership will study the outcome of the tender on developing an EU Early Warning System launched by DG ENV in 2019[94] to see how the initial pilot study can be further developed. Results from the tender are expected end of 2020.

Data analysis from multiple sources to identify emerging chemical threats is a key feature of the system. The system should allow for connection and exchange of information between existing systems and databases of authorities and institutions at EU-level and in Member States, automatically convert diverging data on chemical substances into early warning signals, and feed the generated information into regulatory systems.

The major aim is to support the development of tools and approaches that inform risk assessors and risk managers at an early stage of some future challenges or emerging issues. The activities will involve methodological development and data collection as well as assist in the identification and dissemination of information on emerging issues and identified emerging risks.

*iii) Integrative models*

This task will support the task integrative exposure modelling and risk but focusses more on the technical part. The modelling approaches carried out in the Partnership needs to be openly accessible and the underlying models needs to comply with FAIR principles, which implies that each model should be available on an open source repository.

Accessibility to the integrative models requires Cloud computing. New Information and communications technology (ICT) techniques, such as containerisation of models, will be explored. This will enable downloadable versions of the integrative model on the local ICT server of the user of the Partnership integrative models including the Partnership stakeholders. Technical user requirements will be explored and user guidance will be provided.

The link between environmental models needs integration with Geographical Information Systems. This will support spatial modelling requirements. Automated links in the form of Application Programming Interfaces (API) are foreseen for the PARC data collection and for data collection elsewhere (e.g. EFSA, IPCheM, EEA and ECHA).

### WP 9 – Capacities

*i) Laboratory capacities and networking*

There is a need to continue maintaining existing networks and to develop new laboratory networks in key areas providing sufficient laboratory capacities to support next generation risk assessment. The aim is to cooperate with existing networks established through EU regulations, and identify the needs for new laboratory networks and support their development. Each of these laboratory networks will be involved in the research activities described above.

Laboratory networks could be developed in function of the needs included in 3.1.2 (e.g. consumer products, nanomaterials, soil). The structuring of laboratory networks is important to contribute to the standardisation of methods, to ensure the quality of measurements and tests by making available internal and external QA/QC and to promote the implementation of new methods through training and exchange of knowledge and experience. By collaborating with existing networks and identifying areas requiring new analytical or toxicological testing capabilities, method standardisation, the supply of "reference" materials and QA/QC, the Partnership will provide support for the development of new networks, the strengthening of existing ones and the interconnection between all in favour of an integrative approach.

[94] https://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20g%20early%20warning%20syst.%20NTE%20final.pdf

ii) *Training and capacity building*

This task is in charge of developing the required skills amongst partners, but also in the general risk assessment and management community to ensure data, methods, tools and models promoted by the Partnership can be used at a wider scale. Training needs in the Partnership will be identified and transposed into training programmes to:

- meet the needs of professionals from EU and MS regulatory agencies and competent authorities and other stakeholders, to foster the understanding/uptake of new data and methods
- promote best practices for harmonised procedures
- build communication skills of scientists or risk assessors when interacting with e.g. media, non-specialised citizens or when having to communicate results to policy makers
- foster better understanding of the regulatory context by scientists and other relevant stakeholders

Training materials such as manuals, handbooks and method description will be developed and made publicly available. In addition, dialogues with national education systems will be established to promote the innovation of transdisciplinary curricula for the next generation of researchers, engineers and risk assessors.

## 3.2. Resources

The present Partnership will not involve open (external) calls for research projects, but base it activities on in-house research carried out by the partners. Therefore, no direct cash flow into the Partnership is required and partners will report active costs for which Horizon Europe will provide the expected (50%) co-funding. At the overall Partnership level there is no differentiation of co-funding rates for different cost categories, but such arrangements can be decided upon in the consortium agreement, e.g. certain activities such as administrative and management costs may be covered 100% which will automatically require that other categories of activities will receive a smaller than the expected 50% EC contribution.

Resources required should cover the foreseen research and innovation activities, administrative and financial management of the Partnership, communication and dissemination activities as well as engagement in activities related to policy uptake of results and validation and standardisation activities.

Therefore, it is expected that different co-funding sources by country will be envisaged. Partner countries should explore the possibilities to use other EU funding programmes, beyond Horizon Europe, such as structural funds for the co-funding and the development of their structural or human capacities. The Partnership as such will look at possibilities to use Marie-Sklodowska-Curie funds or the ERASMUS programme to facilitate the training of next generation scientists and risk assessors.

For the uptake of results from the Partnership into national research or regulatory activities, possibilities for funding under the LIFE and ESF+ programmes could also be explored.

At national level, it is also expected that resources will come from different policy domains. Many risk assessment bodies have their own allocated budgets from public governmental budgets, a part of which is often already dedicated to research activities – the ambition of the Partnership being to join forces on these and thereby optimise the use of resources. Depending on the specific national organisation in charge of the risk assessment, these funds will originate from different Ministries, e.g. Environment, Health, Agriculture, Industry etc., and each case will be country specific.

In addition, national research budgets will be solicited. Specific solutions to allow the use of such funds are under investigation for those countries where the access to such funds requires open calls.

## 3.3. Governance

### *3.3.1. Provisional governance*

The Partnership will bring together national and EU authorities and agencies dealing with chemical risk assessment and management, and the related scientific community. It thus requires an overarching structure that will identify and prioritise the research and innovation needs of risk assessors and risk managers and transpose them into a set of research and innovation activities to be undertaken in the Partnership. Likewise, it has to ensure an efficient uptake of the results of the Partnership.

**This proposed provisional governance will be further refined in the proposal and in subsequent documents such as the Consortium Agreement.**

Strategic Governance

The bodies involved in the strategic governance and the high level network for regulatory science (including priority setting), bringing together high level representatives in the chemicals risk assessment process in Europe are: the Country Board (CB) and its EU counterpart, the EU Board (EUB), the Management Board (MB), which includes the Partnership coordinator and the work package leaders, and the Bureau of the CB/EUB composed of a core set of representatives from the CB and EUB. These boards will be supported by the Grant Signatories Board (GSB), the National Hubs (NH) and their EU counterpart the EU Hub, on an operational level to ensure the strategic decisions are implemented throughout the Partnership.

Their envisaged role and functions area as follows:

- **Country Board (CB):** composed of representatives of national authorities in charge of risk assessment and/or risk management and responsible for the national political and financial commitment to the Partnership (national programme owners; e.g. Ministries). Each national CB members will be closely liaising with their National Hub (NH), including the country's grant signatories. The coordination with research funders will be managed at national level by the CB representative(s). The CB together with the EU Board (EUB – see below) will frame and guide the Partnership, facilitate uptake of results and ensure sustainability. The CB will be set-up during the proposal preparation and operate as an interim Board until grant signature, following which the CB will confirmed. The CB will elect a chair and vice chair and set down its rules for procedures. The CB will be supported by a secretariat provided by the Partnership or by DG R&I while in the interim period. The CB Chair will convene joint CB-EUB meetings in coordination with the Chair of the EUB and in collaboration with the secretariat. The CB Chair can also convene separate CB meetings if necessary. The CB will:
  - Endorse the future proposal
  - Validate priorities and related activities for the Partnership together with the EUB and in consultation with the MB and National Hubs (3-year common strategies)
  - Assess and approve the Annual Work Plans (AWPs) together with the EUB
  - Assess and approve the Annual Technical Reports (ATRs) together with the EUB
  - Approve the ethical and legal framework and the Data Management Plan
  - Facilitate the uptake of the results of the Partnership
  - Interact with the National Hubs (NH) when new expertise and new Linked Third Parties (LTPs) are needed.
  - Foster the political commitment for the long-term sustainability of the Partnership, supported by the sustainability task.

- **EU Board (EUB)**: The EUB will involve representatives of the relevant institutions, in particular Directorate Generals (DGs) of the European Commission, to equal the national Ministries in the CB. At this stage the following DGs, have committed to the EUB:
    - Directorate-General for Research and Innovation (DG R&I)
    - Directorate-General for Health and Food Safety (DG SANTE)
    - Directorate-General for Environment (DG ENV)
    - Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)
    - The Joint Research Centre (JRC)

The EUB together with the CB will frame and guide the Partnership, facilitate uptake of results and foster the sustainability of the Partnership. The EUB members will interact with their committees and other networks as appropriate for the Partnership. The EUB will:

- Validate priorities and related activities for the Partnership together with the CB and in consultation with the MB and the EU Hub (3-year common strategies)
- Assess and approve the Annual Work Plans together with the CB
- Assess and approve the Annual Technical Reports together with the CB
- Facilitate the uptake of the results of the Partnership
- Liaise with the individual work packages and tasks when in-house activities of the EUB institutions are complementary to activities of the Partnership – these cases will be identified during the prioritisation process.
- Interact with the CB for developing and implementing a long-term sustainability strategy

- **EU Hub (EUH):** In equivalence to the National Hubs in the countries, the inter-service group supporting the EUB will be composed of a wider network of Commission services and EU Agencies to ensure the EU-level coordination. The EU Hub will be supported by a secretariat delivered by DG R&I. This EU Hub is expected to include representatives of the following bodies, in addition to the EUB members:
    - Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL)
    - The European Chemicals Agency (ECHA)
    - The European Environment Agency (EEA)
    - The European Food Safety Authority (EFSA)
    - The European Agency for Safety and Health at Work (EU-OSHA)
    - The European Medicines Agency (EMA)

- **Bureau of the CB/EUB**: This Bureau is in charge of the maintaining the link between the CB and EUB and the MB of the Partnership. It will be composed of a core set of representatives (number and mode of selection to be decided by the joint CB/EUB) and elects its own chair. The Bureau will be supported by a secretariat provided by the Partnership (or by DG R&I in the interim period until the Partnership starts).

- **Management Board** (**MB**): is involved in the strategic governance of the Partnership to ensure the strategic decisions are implemented throughout the activities of the Partnership and is also in charge of the day-to-day management. It is composed of the **work package leaders** and the Partnership **coordinator**. For the more detailed description of the MB duties see section on operational management. The CB/EUB will consult the MB to define the feasibility for the Partnership to address the R&I-related risk assessment and risk management needs. The MB will further consult with the **Grant Signatories Board** and when needed the full Consortium (grant signatories and linked third parties). The role of the MB is to ensure coherence and the integration of all the work packages and tasks of the Partnership through the establishment of links, synergies, avoiding overlaps and promoting

efficient internal communication channels. The MB will be supported by a secretariat provided by the coordinating institution.

- **National Hubs (NH):** Network of decision makers, research funders, grant signatories, stakeholders and the research community at the national level providing input and support to the CB representative and ensuring synergies and collaboration with other initiatives be they at national or EU level. The National Hubs will also provide input to the Consortium when consultations are run or new expertise sought. Each country can decide on the organisation of its National Hub and its participants. Each National Hub forms a long-term network at country level for the exchange of information, expertise and best practice, bringing together experts and activities from participating countries and ensuring that they are coordinated, feed their national needs into the Partnership, contribute to the objectives, and learn from the work performed within the Partnership.

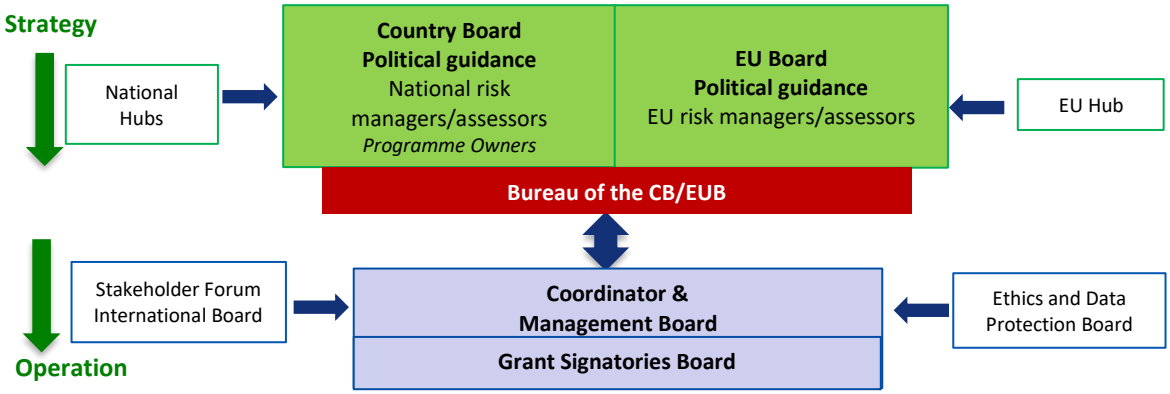


*Figure 9: Strategic Governance (green) and its interface with the Partnership management (blue)*

Operational implementation

- The tasks of the **MB** are to:
  - Ensure the implementation of the overall Partnership
  - Interact with the CB/EUB during the prioritisation process and provide the input from the Partnership
  - Translate the 3-year common strategies agreed by the CB/EUB into AWPs with support from the different internal boards and leaders
  - Report yearly to the CB/EUB on progress achieved and results obtained
  - Monitor the achievements of milestones and deliverables and ensure the overall quality control before submission to the EC or CB/EUB
  - Manage the budget and the use of resources in line with the agreed AWPs
  - Update and maintain the Consortium Agreement
  - Prepare and submit requests to amend the Grant Agreement
  - Cross-coordinate between work packages and tasks
  - Ensure a good and transparent communication to the GSB and the consortium
  - Organise Consortium Meetings
  - Convene the Ethics and Data Protection Board
  - Oversee the communication and dissemination strategy of the Partnership
  - Liaise with the GSB to find solutions to problems encountered during the implementation

In the operational implementation and on the translation of the 3-year common strategies to AWPs, the MB will be supported by 'internal' boards and bodies with specific roles:

- **Grant Signatories Board (GSB):** The Grant Signatories will be national programme owners or mandated programme managers, e.g. national agencies in charge of risk assessment. EU Agencies, if joining as partners will also be in this Board. Within each country, the GSB member liaises closely with their CB/EUB representatives and the NH/EUH. The GSB supports the MB in the priority setting process, in identifying new LTPs when new expertise is required and in solving day-to-day managerial problems. The GSB will be supported by the same secretariat as the MB.
- **Ethics and Data Protection Board (EDPB)**: Specialists in ethics, legal matters and data protection from the partner organisations, supporting the MB in these matters and reviewing all related documents as well as established processes for the management of contractual requirements in these areas. At least one member of the EDPB should be an accredited Data Protection Officer and one member should be a Legal Officer in their institutions. The EDPB will decide on its own secretarial support to be provided by one of the EDPB member organisations.
- **Coordinator:** This role is defined in the Grant agreement as being overall responsible leader and contact point for the EC for the Partnership with regards to technical and financial aspects.
- **Work Package Leaders (WPLs):** together with the Coordinator, they form the MB, and are in charge of managing and leading their work package (WP). This includes drafting the contributions to the AWPs and ATRs, ensuring the work as agreed is carried out, overseeing deadlines, quality controlling deliverables and supervising the financial management and reporting for the WP. They will also ensure the ethical and legal framework compliance of their WP. They will be supported by the task leaders and collectively they will set-up an adequate collaboration scheme for this. Institutions endorsing the role of WP leaders will provide secretariats for the WP, as required. WP leaders should have an integrative vision of the work of their WP within the project, ensure that optimal links and interactions are established within their WP and with other WPs and activities and are in charge of managing and leading their WP (which includes, in relation with Task leaders, ensuring that the work as agreed is carried out, overseeing deadlines, quality controlling deliverables and supervising the management of the resources and the reporting for the WP).
- **Task Leaders (TLs)**: they are responsible for managing their tasks and contributing to the development of AWPs, implementing the AWPs and contributing to the financial and technical reporting. They will interact closely with the WP leaders and benefit from any secretarial support created by the WP leaders. They are responsible for ensuring that the work is conducted in accordance with the appropriate deadlines and resources, and delivered with high scientific quality. They will interact closely with the WP leader and alert the WP leader of any difficulties and propose solutions for these difficulties.
- **The Chemical Leaders (CLs):** experts in charge of following the work on a specific chemical substance/group of chemical substances, reporting on the results and challenges encountered and closely monitoring and identifying communication and dissemination of the results. The CLs will be managed via a dedicated task in the Common Science Policy Agenda work package.
- **The New Approach Methodologies Leaders (NAMLs):** experts in charge of following the work on a specific new approach methodology(ies), reporting on the results and challenges encountered and closely monitoring and identifying communication and dissemination possibilities of the results. The NAMLs will be managed via a dedicated task in the Common Science Policy Agenda work package.

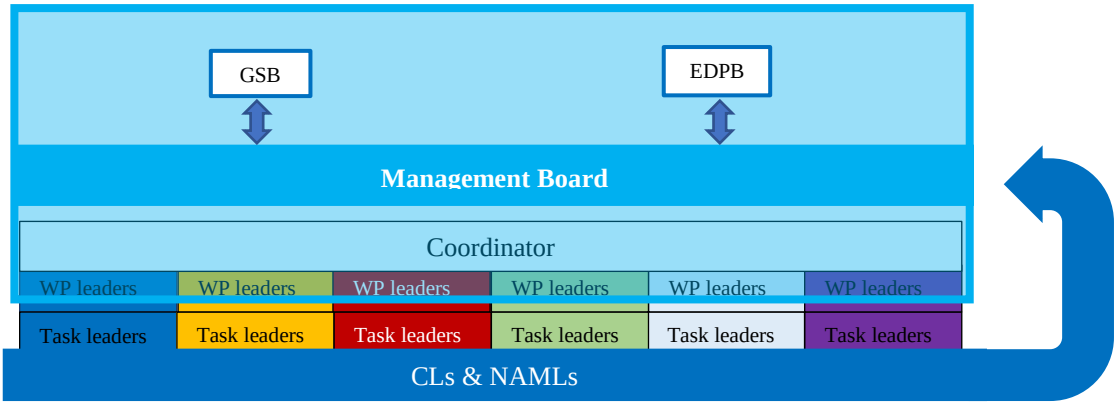


*Figure 10: Internal Management Structure*

#### 3.3.2. Involvement of EU institutions

The different EU institutions listed above in the description of the EUB and EU Hub have been involved in the development of the Partnership since the beginning.

They are either directly part of the Steering Group created to prepare the Partnership, or are following the development through the extended inter-service group accompanying the HBM4EU project.

Given the purpose of the Partnership, the active involvement of the EU institutions in charge of different chemical safety regulatory frameworks is necessary to ensure that the Partnership meets its objectives. This active involvement in the strategic governance is described above. In addition, some EU Agencies may be directly involved in implementing the Partnership. Currently the plan is for EEA to join as a partner, whilst ECHA and EFSA would engage in a dedicated collaboration agreement with the Partnership. The exact form of this collaboration agreement is under discussion. The Joint Research Centre of the Commission owns different databases whose use by the Partnership is of mutual interest and will therefore also establish collaboration agreements as required.

In addition EU institutions can also liaise directly with the Partnership on specific issues should there be need for specific collaborations. These cases will be identified in the prioritisation process.

### 3.4. Openness and transparency

#### 3.4.1. Establishment of the Partnership

The Partnership is developed together with a wider Steering Group composed of mandated representatives of those EU countries or countries associated to Horizon 2020 (expected to be associated to Horizon Europe) and EU institutions, which are involved in chemical risk assessment or management. Countries are welcome to join the work as the Partnership develops. By engaging with policymakers of different policy domains early in the development of the Partnership, different policy needs will be reflected in the Partnership structure and the Strategic Research and Innovation Agenda. The National Hubs to be developed shall ensure the wider outreach and coordination between different chemical related policy areas in the countries. The final proposal shall be validated by the Country Board and EU Board as described in the strategic governance section (see 3.3).

#### 3.4.2. Access to results

Communication and information sharing are key success factors in achieving the goals of the Partnership. Communication with policymakers, stakeholders, the scientific community and the general public will be two-way, with partners both providing and requesting information. A Stakeholder Forum and an International Forum will accompany the Partnership to maintain

a steady dialogue with EU stakeholders and related international activities. All information about the Partnership and results will be made available via the Partnerships web site. Open access publications will be the norm for scientific publications. Data generated by the Partnership will be FAIR and findable via a centralised data library and made available for risk assessment and research teams for analysis. An ethical and legal framework will be developed to enable the use and re-use of data for different purposes and by different users, while respecting data privacy legislation.

#### 3.4.3. Addressing public concern and engagement with citizens

There is a growing unease amongst citizens that the existing legislation is not enough to protect them. To address public concern, citizens involvement is considered important to capture not just scientific but also societal and policy considerations in assessing the extent of certain topics.

As part of a participatory strategy in the HBM4EU project, focus groups[95] were organised to better understand the public's concern of chemicals and their understanding of human biomonitoring and the risk of health effects related to chemical exposure. A similar approach will be established in this Partnership, with specific focus groups to understand the citizens' concerns, awareness, beliefs, attitudes and behaviours on the risk assessment of chemicals and chemical exposure, as well as specific communication to make them aware of national and EU projects and existing legislation (see also section 2.4.4).

Citizens have also understood the need for more proactive representatives i.e. citizens that take the initiative to directly influence the political decision-making process in order to make political actions meet peoples' interests. According to participants in focus groups performed in HBM4EU, this pro-activism should be based on reliable information; however, for this to happen science should be effectively communicated to and understood by the citizens.

#### 3.4.4. Consultations on the Annual Work Plan

The Annual Work Plan (AWP) will result from the prioritisation process described above under section 2.2.9. During the prioritisation process the Country Board and the EU Board can ask the consortium to carry out consultations via the Stakeholder Forum or the International Forum. The consortium can choose to do so also for the AWP development.

[95] https://www.hbm4eu.eu/outreach-to-the-european-public/

# 4. Annex I: Strategic Research and Innovation Roadmap

The final Strategic Research and Innovation Agenda (SRIA) will be developed by the Partnership consortium and validated by the Country Board (CB) and EU Board (EUB) of the Partnership to ensure its EU-added value. The SRIA describes the kind of activities the Partnership can engage in depending on the priorities identified in the prioritisation process (3-year common strategies) and validated by the CB/EUB. The SRIA and the 3-year common strategies will together be the basis for defining the Annual Work Plans (AWPs).

All work packages and tasks will have to interact together and collaborate to ensure the relevance of the outputs, in particular between exposure and monitoring, hazard assessment, and innovation in regulatory risk assessment and the supporting capacities work packages.

## 4.1. High Level network for regulatory science

### *4.1.1. A common science-policy agenda*

Priority setting

- Develop and run surveys and consultations on research and innovation challenges for chemical risk assessment and evaluate their outcomes.
- Develop and implement a prioritisation strategy to decide on joint prioritise, based on experience acquired in the Partnership preparatory phase.
- Support development and drafting of the 3-year strategic agendas (2022-2024 and 2025-2027 as well as for the last year of the partnership 2028 and beyond.

Knowledge management and uptake into policy

- Facilitate the immediate access of risk assessors/managers to the results of the Partnership.
- Facilitate an ongoing dialogue between the Partnership and regulatory scientists in the EU institutions based on the acquired knowledge to encourage uptake of results in risk assessment methodologies
- Harvest and integrate existing and new scientific knowledge in the areas of chemical exposure, hazard, safety and risk analysis (including identification of data gaps) that can contribute to EU regulatory science and policymaking.
- Ensure accessibility of the overview of relevant data sets, platforms and hubs established under 'FAIR data' and identify constraints in terms of open access.
- Establish an appointment process for the 'Chemical Leaders (CLs)' and 'New Approach Methodologies Leaders (NAMLs)' and implement it; supervise the work of the CLs and NAMLs across work packages and compile their yearly reports.
- Ensure the exchange of information between different work packages and tasks in which common or related methodologies are used.

Sustainability

- Support the development of national hubs through peer-to-peer learning activities.

- Provide assistance for capacity building – peer reviews, information about funding, inter-country dialogues.
- Develop and monitor performance and impact indicators and report on them in the Annual Technical Reports and monitor funding decisions and national investments.
- Develop and implement workflows to achieve the objectives identified in the exit strategy.
- Monitor the work of the Partnership to identify new exit strategies and develop and implement workflows for these when approved by the CB/EUB.

#### *4.1.2. Synergies, collaborations and awareness*

International Board and Stakeholder Forum

- Establish selection criteria for the membership of the International Board (IB) and Stakeholder Forum (SF), a list of corresponding candidates and mandates.
- Seek approval of criteria, mandate and candidates by the MB and CB/EUB.
- Set-up the IB and SF and provide a secretariat for both.

Communication and dissemination

- Maintain a flow of open information (using a website and social media) about the Partnership's work plans, protocols, data, results and other outcomes.
- Develop an open access publication strategy for the Partnership.
- Develop and implement a communication and dissemination strategy for the Partnership making use of innovative, interactive approaches in communication and taking into account the special needs of the following target groups: the National Hubs and the national risk assessment communities, the Country and EU Boards, EU and national authorities/regulators in the field of chemical risk assessment, stakeholders including researchers and citizens.
- Establish and maintain links to ongoing research projects, EU partnerships and/or national activities, to avoid overlaps, build on experience and promote results.

### 4.2. Research and Innovation activities supporting the current regulatory assessment processes and moving towards next generation risk assessment

#### *4.2.1. Monitoring and exposure*

Human biomonitoring

Continue to implement the EU human biomonitoring platform developed by HBM4EU[96] by:

- Establishing appropriate and harmonised survey designs, questionnaires, fieldwork and sampling protocols for prioritised substances.
- Carrying out EU-wide aligned human biomonitoring surveys, based on existing or new national studies, in general population or targeted surveys in sensitive/highly exposed populations based on the common guidelines and harmonised standard operating procedures.

[96] www.hbm4eu.eu

- Enable the re-use of existing samples to avoid duplication of efforts.
- Link human biomonitoring to health examination surveys, when possible include HBM in these, or administrative registers and to data on socioeconomic factors.
- Expand and implement quality assurance / control systems for analysis of prioritised substances to strengthen existing laboratory network with QA/QC compliant laboratories.
- Harmonise analytical methods across laboratories, in particular new methods developed in the partnership and develop SOPs for analytical methods.
- Identify and develop required reference materials.
- Identify and implement exposure biomarkers (including real life mixtures) and effect biomarkers for the general population as well as vulnerable groups and specific populations (e.g. occupational exposure) in collaboration with the laboratory network.
- Decide on analytical methods according to the needs of the specific survey in close collaboration with the promoter of the surveys and the analytical laboratory network.
- Analyse the samples emerging from human biomonitoring task.
- Use harmonised methodologies and terminology (e.g. catalogues) to link human biomonitoring to information used to estimate external exposure (e.g. lifestyle, food consumption patterns) in order to identify exposure sources and routes.
- Propose HBM-based guidance values, reference values and exposure indicators responding to specific regulatory questions and making use of toxicological and epidemiological data from the scientific literature and/or generated in the Partnership.
- Based on exposure data, identify real-life mixtures that should be studied for hazards.

Environmental and multisource monitoring

- Collaborate with existing networks in charge of monitoring air, water, food, soil, consumer products to promote sharing of data and knowledge as well as to identify gaps in data, tools and methods.
- Establish harmonised methods to identify sources of exposure.
- Design sampling protocols for monitoring co-occurrence of substances, their metabolites and degradation products and implement these when possible in collaboration with existing sampling programmes.
- Identify environmental and human exposure sources by integrating data on different sources (products, emissions, ...), fate, and routes of exposure, including air, water, soil, food, consumer products, food contact materials, cosmetics, pharmaceuticals, pesticides, biocides and waste.
- In collaboration with laboratory networks, promote the use of non-targeted analysis in available samples.
- Ensure that data produced can be used for the development of an early warning system in the concepts and toolboxes work package.

Innovative methods and tools for monitoring and surveys

- Develop and implement new monitoring methods and tools for multiple exposures (environmental, food, and others) and for emerging chemicals: e.g. non-targeted/suspect screening approaches and effect-based monitoring. f
- Develop analytical methods capable of monitoring concentrations below the regulatory threshold levels.
- Develop and implement new methodologies for data processing for non-targeted analysis.

- Improve the cost-effectiveness, efficiency and speed of analytical tools and methods.

- Encourage the testing of new tools in pilot studies within existing monitoring programmes to assess their usefulness and scope.

- Foster the collaboration between environmental monitoring and biomonitoring programs in the development and implementation of non-targeted screening methods and annotation libraries.
- Develop methodologies and surveys to address exposure from particular life cycle stages and vulnerable life phases (in utero, during puberty).
- Develop monitoring tools and methods linked to article service life and the circular economy: reuse stage, refurnish stage, end-of-life and waste stage and finally end-of-waste stage).
- Provide complete lifestyle surveys to assess exposure from various sources (air, water, soil, food, consumer products, food contact materials, cosmetics, pharmaceuticals, pesticides, biocides and waste)

#### *4.2.2. Hazard assessment*

Toxicity testing addressing data gaps of concern

- Design new studies to meet regulatory needs and improve toxicity testing in specific areas (i.e.: immunotoxicity, mitochondrial toxicity, etc...).
- Include in the studies design regulatory relevant parameters/endpoints supporting the development of AOPs, qAOP and quantitative models to identify toxicity tests that are needed to address data gaps of concern and with the perspective of developing models in systems toxicology. The study programme will take into account all relevant existing data.
- Facilitate collaboration between research groups by sharing biological materials for innovative and specialised measurements.
- Identify effect biomarkers to be used in chemical risk assessment (e.g. in HBM studies under the task ‘Human biomonitoring’ or in environmental monitoring).

Innovative methods and tools for toxicity testing and modelling

- Develop and/or evaluate the relevance of new technologies (e.g., genomic, transcriptomic, high-content analysis microscopy, mass spectrometry) to assess (eco)toxicological endpoints not yet covered by standardised regulatory methods thereby taking into account the AOP framework.

- Develop tests and methodologies to identify drivers of toxicity in mixtures and to support the grouping of chemicals, including the application of read across.
- Promote the development and application of predictive *in vitro* and *in silico* tools to identify specific hazard or to derive a toxicological point of departure.
- Combine different *in silico* methods for hazard assessment.
- Collaborate on the development of new in vitro models addressing new challenges (*in vitro* repeated exposures, *in vitro* models for specific human population) and for new models for testing environmental health.
- Develop further the burden of disease models in order to prioritise chemicals for hazard and exposure assessments.
- Collaborate with research programmes and other partnerships to support the research and innovation in implementing system biology models.
- Collaborate with the European Partnership for Alternative Approaches to Animal Testing (EPAA)[97] to promote New Approach Methodologies (NAMs) and with EURL ECVAM[98] from JRC.
- Collaborate with research groups in the field of human biomonitoring on the development of analytical methods and computational approaches to study the metabolism of chemical substances in different biological systems (cells, organoids, organs, blood…) for comparison between species.
- Contribute to the development of artificial intelligence and computer learning software that can be used in hazard and risk assessment and increase automatisation of the performance of systematic literature reviews.

#### 4.2.3. Innovation in regulatory risk assessment

Integrated Approaches to Testing and Assessment (IATA)

- Develop IATA for regulatory purpose according to the problem formulation developed during the priority setting steps in the "common science policy agenda" work package.
- Contribute to the development of state of the art AOPs and AOP networks to be used for regulatory purposes. The availability of more (networks of) AOPs will significantly benefit a transition towards a more mechanism-based and animal-free hazard assessment of chemicals and more specifically reduce scientific uncertainties in areas such as endocrine disruptors and mixtures.
- Contribute to identifying and verifying the plausibility of biomarkers of effects, in collaboration with the exposure work package and tasks to improve toxicological risk assessment.

[97] https://ec.europa.eu/growth/sectors/chemicals/epaa_en
[98] https://ec.europa.eu/jrc/en/eurl/ecvam

- Identify innovative tests and new approaches able to fill some gaps or be integrated in new IATA through open communication of regulatory needs and collaboration with research programmes outside the partnership.
- Communicate the gaps identified in the process to promote new research and innovation projects within or outside the partnership.
- Support innovation in weight of evidence and read across approaches through mechanistic hazard data, when appropriate.
- Contribute to the pre-validation of tests in an IATA, in collaboration with JRC.
- Communicate about innovation, level of validation in testing and data integration in risk assessment.
- Establish an appropriate framework for risk assessment of human relevance using non-animal data, analogous to the WHO/IPCS Mode of Action Framework (for cancer and non-cancer risk assessment)[99] framework in collaboration with WHO/IPCS and other international partners.

Integrative exposure modelling and risk assessment

- Develop tools and methodologies for combining and integrating heterogeneous data (e.g. environmental exposure, human biomonitoring, and different types of (eco)toxicity data) from available databases (including ECHA and national databases on use of chemicals).
- Define the routes and sources of environmental and human exposure by integrating data on the various sources (products (pharmaceuticals, pesticides, etc.), emissions, etc.), their fate and the transmission routes of chemical substances, in particular via the air, water, soil and food, taking into account waste management.
- Develop tools to establish mixture assessment groups with respect to combined external and/or internal exposures, chemical structure, MoA or other properties.
- Further develop models to assess cumulative, aggregate, and combined exposures of human and environment (for specific categories of chemical substances or not).
- Develop and integrate models to adequately describe and predict the behaviour of chemicals in the distal field environment (air, water, soil) and the proximal environment (products, food and beverages, indoor air, etc.).
- Use exposure modelling and PBK to estimate internal exposure (from one single or multiple routes) or to perform reverse dosimetry evaluation.

Review of risk assessment methodologies

- Evaluate and map the performance and efficiency of current regulatory methodologies for assessing risks to establish best practices and identify knowledge gaps/needs to inform "Priority setting".

[99] https://www.who.int/ipcs/methods/harmonization/areas/cancer/en/

Transposing results to regulatory risk assessment methodologies

- Promote systematic and transparent approaches for integrating and evaluating evidence from different sources, including the evaluation of the relevance and reliability of data.
- Develop and test tools for assessment of relevance and reliability of *in vitro*, *in vivo* and *in silico* models.
- Analyse the different types of evidences that can be included in the risk assessment process. Clarify additional data needs compared to OECD guidelines.
- Engage in validation of novel tools and methods developed in the Partnership or from collaborating projects.
- Compile and evaluate the data and new knowledge generated within the partnership with the aim of generating recommendations for improving regulatory frameworks, testing strategies and decision-making processes.
- Contribute to developing and adapting methods and guidance documents under EU and OECD contexts for various activities (e.g. sampling, statistical analysis, risk assessment guidance documents).
- Propose health based guidance values within the scope of the regulatory challenge identified.
- Explore the opportunities triggered by artificial intelligence, text mining tools and machine learning in risk assessment.
- Develop guidelines for mixture risk assessment supporting and complementing existing EU guidance, including for aggregate exposure to mixtures of chemicals from multiple sources.
- Develop methodology for risk ranking to support risk management in coordination with ongoing national or European activities.

## 4.3. Capacities and platforms for innovation

### *4.3.1. FAIR Data*

Data policy (management, harmonisation, interoperability, exchange)

- Develop a data policy for the partnership defining the principles and conditions that govern provision, management, access, use and re-use of metadata in data repositories and the data themselves.
- Establish a framework of guiding principles, in adherence with the principles of FAIR data management and including legal, ethical, privacy, and security aspects, for development of data management and harmonization guidelines for the partnership.
- Develop common data management and data harmonisation guidelines.
- Develop standardised templates for collection and reporting of different types of data, metadata, and associated information produced within the Partnership.
- Establish a methodology for data harmonisation for newly generated data.
- Develop a methodology for scrutinizing available data and to guarantee the use of high-quality data.

- Identify most relevant information to see how access can be improved, identifying barriers and facilitators to data sharing, including data from industry.
- Develop Ontologies (in consultation with OECD) and the use of standards at source and throughout the information lifecycle.

Data libraries

- Build on the results of the tender launched in 2019 by DG ENV for the 'Feasibility Study on a Common Open Platform on Chemical Safety Data'[100].
- Identify specialised data centres (e.g. IPCHEM[101], eChemPortal[102], OECD[103], NORMAN[104], databases at ECHA[105] and EFSA[106], Global Monitoring Plan Data Warehouse[107], ELIXIR[108], the European Bioinformatics Institute[109]) and explore their content and accessibility, to identify potential partners to store, update and exchange different types of data.
- Organise and manage storage of data developed within the partnership, making them accessible and connectable while guaranteeing ethically correct, scientifically sound and GDPR-compliant use of the data.
- Connect data generated within the partnership to databases and platforms from different the identified programmes that acquire and host related data collections.
- Identify gaps and develop missing standards and solutions for interoperability between platforms and databases and interagency linking e.g. by Database As A Service and WebServices (REST, API) and ensure collaboration with similar ongoing activities.
- Implement systems (such as tags) to allow extracting relevant combinations of chemicals to assess occurrence, exposure and toxicity of mixtures.

Innovation for data analysis and uncertainty

- Facilitate analysis and interpretation of data generated within the Partnership.
- Explore possibilities to apply innovative techniques, tools, and methods (such as data mining and machine learning) for data analysis and computational analyses.
- Develop a procedure for computerised analysis of different types of data.
- Develop new methodologies to quantitatively estimate uncertainties for different type of data.



[100] https://ted.europa.eu/udl?uri=TED:NOTICE:215925-2020:TEXT:EN:HTML
[101] https://ipchem.jrc.ec.europa.eu/
[102] https://www.echemportal.org/echemportal/
[103] https://data.oecd.org/home/
[104] https://www.norman-network.net/?q=node/24
[105] https://echa.europa.eu/information-on-chemicals
[106] https://www.efsa.europa.eu/en/science/data
[107] https://www.pops-gmp.org/index.php?pg=gmp-data-warehouse
[108] https://elixir-europe.org/about-us
[109] https://www.ebi.ac.uk/

### 4.3.2. Concepts and toolboxes

Safe and sustainable by design

Ssupport to the EC's work on defining the Safe-and-Sustainable-by-Design (SSBD) concept[110] and implementation criteria

- Develop and implement a transdiciplinary process to derive conventions for "safe" and "sustainable" protection targets and acceptance criteria.
- Developan assessment methodology to combine criteria and methodological elements so that overall safety and sustainability can be comparatively assessed considering alternatives of chemicals, processes and products.
- Identify tools and methods relevant to the above identified criteria and the design of chemicals and materials stemming from integrated testing, computational modelling of exposure, physical-chemical properties, and hazard and toxicity screening developed within or outside of the Partnership.

Early warning system

- Analyse the outcome of the tender for an EU Early warning system[111] and further develop the system based on the experience gained in the initial study.
- Together with the "FAIR Data" work package, facilitate the connection and exchange of information between existing system and databases of authorities and institutions at EU-level and in Member States.
- Develop tools and methodologies for data analysis to assist in the identification and dissemination of information on emerging issues.

Integrative models

- Integrate leading European models for (combined) exposure via food, air, consumer products, water and at the workplace in line with EU legislation.
- Provide access and information on models used to combine several routes and sources of exposures.
- Provide access and information on kinetic behaviour of chemicals in human body and associated kinetic models developed In PARC.
- Implement Cloud computing process for use of models.

### 4.3.3. Capacities

Laboratory *capacities and networking*

- Identify and develop collaboration with relevant existing laboratory networks.

[110] http://doi.org/10.5281/zenodo.3254382
[111] https://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20g%20early%20warning%20syst.%20NTE%20final.pdf

- Support the structuring of new needed laboratory networks identified across the partnership e.g. to support the standardisation of methods, to make available internal and external QA/QC or to promote the implementation of new methods through training and exchange of knowledge and experience.
- Support the implementation of quality assurance and quality control systems by laboratories and maintain a network of quality controlled analytical laboratories.

Training and capacity building

- Establish and implement an inclusive training programme open beyond the Partnership to support capacity building.
- Develop and disseminate guidance on training programmes for university students, continued education of professionals or for risk assessment specialists and overall academia.
- Promote best practices and SOPs for harmonised procedures.
- Develop and adapt guidance under EU regulations and at OECD for various activities (recruitment, sampling, chemical and statistical analysis, risk assessment).
- Foster better understanding of the regulatory context by scientists and other relevant stakeholders.
- Initiate dialogues with national education systems to promote the innovation of transdisciplinary curricula for the next generation of researchers, engineers and risk assessors.

# 5. Annex II: Background document

## 5.1. Related EU activities

### *5.1.1. EU regulations and Commission Communications*

- The European Green Deal
- The General Food Law : Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain
- The implementation of REACH, CLP and the 2018 REACH REFIT
    - Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
    - Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures (CLP)
- Plant Protection Products Regulation (EC) No 1107/2009 and the legislation on residues of plant protection products
    - The fitness check of the Plant Protection Products regulation
- Framework directive on occupational safety and health (Council Directive 89/391/EEC of 12 June 1989)
    - The Fitness Check of the Framework Directive on Occupational Safety (OSH)
- Biocidal Products Regulation (EU)528/2012
- Directive 2004/37/EC (Carcinogens and Mutagens Directive) and Directive 98/24/EC (on risks related to chemical agents at work)
- Evaluation and fitness check of the food contact materials legislation
- The Fitness Check of the Water Framework Directive
- Regulation (EC) no 1223/2009 of 30 November 2009 on cosmetic products
- Regulation (EC) no 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- The announced Fitness Check of all chemical legislation with regards to endocrine disruptors (see Commission Communication on endocrine disruptors listed below)
- Commission Communication 'Towards a comprehensive European Union framework on endocrine disruptors' (2018)
- Commission Communication on a European Union Strategic Approach to Pharmaceuticals in the Environment (2019)
- Commission Communication on options to address the interface between chemical, product and waste legislation (2018)
- Commission Communication on a European plastics strategy for a circular economy (2018)
- The 7th Environment Action Programme (2014-2020) and its possible follow-up.

- The Commission Communication on Combination Effects of Chemicals (2012)
- The Circular Economy Package and the impact on chemicals in material flows
- The European Environment Agency (EEA)'s State of the Environment (SoE)
- EU roadmap on carcinogens
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)

### 5.1.2. Council conclusions

- 26 June 2019 Council Conclusions 'Towards a Sustainable Chemicals Policy Strategy of the Union'

### 5.1.3. EU Committees and networks

| Name | Mandate | Website |
|---|---|---|
| EFSA Scientific Network on Chemical Monitoring Data collection | Established end 2018. It brings together the different EU agencies and MS counterpart and is a consolidation of three previous EFSA Scientific Networks: chemical occurrence data, veterinary medicinal products residues data collection, and pesticide monitoring. | http://www.efsa.europa.eu/en/data/networks |
| PARERE | PARERE is a network of national regulators that provides EURL ECVAM with upstream input and preliminary views on potential regulatory relevance of methods or approaches submitted to EURL ECVAM for validation and/or peer review. | https://ec.europa.eu/jrc/en/eurl/ecvam/alternative-methods-toxicity-testing/advisory-bodies/parere |
| EURL ECVAM Scientific Advisory Committee (ESAC) | Scientific Advisory Committee that advises EURL ECVAM on scientific issues. ESAC's main role is to conduct independent peer reviews of validation studies of alternative test methods, assessing their scientific validity for a given purpose. | https://ec.europa.eu/jrc/en/eurl/ecvam/alternative-methods-toxicity-testing/advisory-bodies/esac |
| European Union Network of Laboratories for the Validation of Alternative Methods (EU-NETVAL) | EU-NETVAL is a EURL ECVAM network of specialised laboratories located in the EU member states. EU-NETVAL's mission is to provide support for EURL ECVAM validation studies to assess the reliability and relevance of alternative methods that have a potential to replace, reduce or refine the use of animals for scientific purposes. It has 26 members, including 25 test facilities from EU Member States plus EURL ECVAM, approved by the National Contact Points. NETVAL was set up by EURL ECVAM in response to the provision of the Directive on the protection of animals used for scientific purposes which requests that EU Member States assist the European Commission in the validation of alternative methods. | https://ec.europa.eu/jrc/en/eurl/ecvam/alternative-methods-toxicity-testing/eu-netval |

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| NORMAN | The NORMAN network enhances the exchange of information on emerging environmental substances, and encourages the validation and harmonisation of common measurement methods and monitoring tools so that the requirements of risk assessors and risk managers can be better met. It specifically seeks both to promote and to benefit from the synergies between research teams from different countries in the field of emerging substances. | https://www.norman-network.net/ |

### 5.1.4. Monitoring schemes

| Scheme | Mandate | Document |
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| EEA's State of the Environment | Since December 2015, EU Member States have been publishing the second river basin management plans (RBMPs) for achieving the environmental objectives of the Water Framework Directive (WFD_. The Commission has started the process of evaluating the WFD, with the publication of the evaluation roadmap Fitness check on the Water Framework Directive and the Floods Directive (EC, 2017a). To accompany and inform this process and to fulfil the requirement of WFD Article 18 (5), the EEA has produced this report on the state of Europe's water and presented more detailed WFD results in the Water Information System for Europe (WISE). The report presents results on the status of surface waters and groundwater in Europe, providing overviews at EU, Member State and river basin districts (RBDs) levels. | https://www.eea.europa.eu/highlights/soer2020-europes-environment-state-and-outlook-report<br>EEA Report No 7/2018<br>https://www.eea.europa.eu/publications/state-of-water<br>https://www.eea.europa.eu/ds_resolveuid/5BUVOP1X6Y |
| EEA/ EIONET National Reference Centres | NRC on Biodiversity<br>NRC on Environment and Agriculture<br>NRC on Environment and Health<br>NRC on Forests<br>NRC on Industrial pollution | https://www.eea.europa.eu/about-us/countries-and-eionet |

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| | NRC on Marine, coastal and maritime water<br>NRC of Resource efficiency and circular economy | |
| Non-target and other screening and monitoring under the Water Framework Directive | The development in water status should be monitored by Member States on a systematic and comparable basis throughout the Community. Adaptation of certain technical elements to technical development and the standardisation of monitoring, sampling and analysis methods should be adopted by committee procedure.<br>Monitoring of surface water status, groundwater status and protected areas . For groundwaters such programmes shall cover monitoring of the chemical and quantitative status (Article 8).<br>The Commission shall submit a proposal setting out a list of priority substances selected amongst those, which present a significant risk to or via the aquatic environment. Substances shall be prioritised for action on the basis of risk to or via the aquatic environment (Article 15).<br>Member States shall use the information collected above, and any other relevant information including existing environmental monitoring data, to carry out an assessment of the likelihood that surface waters bodies within the river basin district will fail to meet the environmental quality objectives set for the bodies under Article 4. Member States may utilise modelling techniques to assist in such an assessment. | EUR-Lex - 32000L0060 - EN |
| River Basins | Identification of River Basin Specific Pollutants under the Water Framework Directive. Monitoring of ecological status and chemical status for surface waters. The surface water monitoring network shall be established in accordance with the requirements of Article 8. | https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32000L0060<br>https://op.europa.eu/en/publication-detail/-/publication/00ee76f2-dd65-45ba-bc8d-762155206858 |

### 5.1.5. Research FP/H2020 projects

| Acronym/ project title | Project objective | Duration | Coordinator | Project website |
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| Projects arising from the last H2020 calls<br><br>European Green Deal call<br><br>Societal Challenge 1 | The Green Deal call will mobilise research and innovation to foster a just and sustainable societal transition aiming at 'leaving nobody behind'.<br><br>Projects are expected to deliver tangible and visible results relatively quickly and show how research and innovation can provide concrete solutions for the Green Deal main priorities. Projects arising from call topics focusing on mitigating the effects of persistent and mobile chemicals and chemical and pharmaceutical mixtures will be especially relevant.<br><br>Proposals to be funded under calls such as SC1-BHC-11 on safety assessment of chemicals without animal testing and SC1-BHC-36 on the health impacts of micro- and nano-plastics | Expected start dates 2021 | | https://ec.europa.eu/info/research-and-innovation/strategy/european-green-deal/call_en&pk_campaign=rtd_news<br><br>https://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf |
| HBM4EU - European human biomonitoring initiative | Generate knowledge to inform the safe management of chemicals and so protect human health. We will use human biomonitoring to understand human exposure to chemicals and resulting health impacts and will communicate with policy makers to ensure that our results are exploited in the design of new chemicals policies and the evaluation of existing measures. | 01/01/2017-31/12/2021 | UBA (German Environment Agency), Germany | https://www.hbm4eu.eu/ |
| EuroMix - A tiered strategy for risk assessment of mixtures of multiple chemicals | Develop an experimentally verified, tiered strategy for the risk assessment of mixtures of multiple chemicals derived from multiple sources across different life stages. | 15/05/2015-14/05/2019 | RIVM, Netherlands | https://www.euromixproiect.eu/ |

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| EDC-MixRisk - Safe chemicals for future generations | Integrating Epidemiology and Experimental Biology to Improve Risk Assessment of Exposure to Mixtures of Endocrine Disruptive Compounds | 01/05/2015-30/04/2019 | Karolinska Institutet, Sweden | http://edcmixrisk.ki.se/ |
| EU-ToxRisk - An Integrated European 'Flagship' Programme Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st century | The vision of EU-ToxRisk is to drive a paradigm shift in toxicology towards an animal-free, mechanism-based integrated approach to chemical safety assessment. | 01/01/2016-31/12/2021 | Universiteit Leiden, Netherlands | http://www.eu-toxrisk.eu/ |
| Solutions - for present and future emerging pollutants in land and water resources management | To produce consistent solutions for the large number of legacy, present and future emerging chemicals posing a risk to European water bodies with respect to ecosystems and human health. | 01/10/2013-30/09/2018 | Helmholtz Centre for Environmental Research, Germany | https://www.solutions-project.eu/ |
| OpenRiskNet - Open e-Infrastructure to Support Data Sharing, Knowledge Integration and *in silico* Analysis and Modelling in Risk Assessment | The main objective to develop an open e-Infrastructure providing resources and services to a variety of communities requiring risk assessment, including chemicals, cosmetic ingredients, therapeutic agents and nanomaterials. OpenRiskNet is working with a network of partners, organized within an Associated Partners Programme. | 01/12/2016-30/11/2019 | Douglas Connect GMBH, Germany | https://openrisknet.org |
| PROTECTED - PROTECTion against Endocrine Disruptors; Detection, mixtures, health effects, risk assessment and communication. | PROTECTED aims to develop expertise and protective capabilities against Endocrine Disruptors (EDs). The PROTECTED Innovative Training Network [ITN] proposes a holistic approach by providing 15 individual, personalised research projects with exposure to scientific, innovative and entrepreneurial training mobility across the ITN. The intersectorial network is comprised of 12 training sites at academia, research centres, a bioassay technology SME, a QSAR | 01/01/2017-31/12/2020 | Queen's University of Belfast, UK | www.protected.eu.com |

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| | technology SME, water provider, and animal feed supplier. Together they cover multiple disciplines including analytical science of food, feed, and environment, epidemiology, risk assessment, social science and toxicology. | | | |
| In3 «Integrated *in vitro* and *in silico* tool - An integrated interdisciplinary approach to animal-free chemical and nanomaterial safety assessment | Innovative Training Network (MSCA-ITN for short) that aims to drive the synergistic development and utilisation of *in vitro* and *in silico* tools for human chemical and nanomaterial (NM) safety assessment. Here are our dedicated, motivated, dynamic, early stage researchers (Marie Curie Action). | 01/01/2017-31/12/2020 | Stichting VU, Netherlands | www.estiv.org/in3/ |
| SmartNanoTox Smart Tools for Gauging Nano Hazards | In this project, using a comprehensive self-consistent study, which includes in-vivo, in-vitro and in-silico research, we address main respiratory toxicity pathways for representative set of nanomaterials, identify the mechanistic key events of the pathways, and relate them to interactions at bionano interface via careful post-uptake nanoparticle characterisation and molecular modelling. | 01/03/2016-29/02/2020 | University College Dublin, National University of Ireland, Ireland | www.smartnanotox.eu |
| HERA - Integrating Environment and Health Research: a Vision for the EU | HERA will set the priorities for an environment and health research agenda in the EU by adopting a holistic and systemic approach in the face of global environmental changes. | 01/01/2019-31/12/2021 | Inserm, France | https://www.hareresearcheu.eu |
| EURION Cluster - European Cluster to Improve Identification of Endocrine Disruptors) | Cluster of 8 Horizon 2020 projects working on new testing and screening methods for endocrine disruptors (OBERON, GOLIATH, ATHENA, FREIA, ERGO, SCREENED, EDCMET, ENDPOINTS) | 01/01/2019-31/12/2023 | | http://eurion-cluster.eu/home/ |

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| OBERON - An integrative strategy of testing systems for identification of Endocrine Disruptors related to metabolic disorders | Will build an integrated testing strategy (ITS) to detect endocrine disruptors (EDs)-related metabolic disorders by developing, improving and validating a battery of test systems. | 01/01/2019-31/12/2023 | Inserm, France | https://oberon-4eu.com/ |
| GOLIATH - Generation Of NoveL, Integrated and Internationally Harmonised Approaches for Testing | Will generate the world's first integrated approach to testing and assessment (IATA) specifically tailored to metabolism disrupting chemicals (MDCs). | 01/01/2019-31/12/2023 | Universiteit Utrecht, Netherlands | https://goliath.wp.hum.uu.nl/ |
| ATHENA - Assays for the identification of thyroid hormone axis-disrupting chemicals: elaborating novel assessment strategies | Project objective: to develop new test methods and a testing strategy for the protection of the developing and adult brain from harm through chemicals that disrupt the thyroid hormone axis. | 01/01/2019-31/12/2023 | Brunel University London, UK | http://athenaedctestmethods.net/ |
| FREIA - Female Reprotoxicity of Endocrine disrupting chemicals (EDCs): a human evidence-based screening and Identification Approach | Project objective: to provide dedicated, human-relevant test methods to identify EDCs that affect female reproductive health. | 01/01/2019-31/12/2023 | Vrije University Amsterdam, Netherlands | http://freiaproject.eu/wp/ |
| ERGO - EndocRine Guideline Optimisation | ERGO aims to improve hazard assessment of EDCs by breaking down the wall that currently exists between the different research fields that investigate adverse effects of EDCs in different vertebrate classes, from fish and amphibians (non-mammalian vertebrates) to humans (mammalian vertebrates) by demonstrating that it is feasible to extrapolate effects of EDCs across the vertebrate classes. | 01/01/2019-31/12/2023 | Syddansk Universitet, Denmark | https://ergo-project.eu/ |

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| SCREENED - Screening for the influence of endocrine disruptors on the male and female thyroid gland | SCREENED aims to develop three-dimensional (3D) cellbased in vitro tests to better characterize the effects of endocrine disruptors on thyroid gland function. | 01/01/2019-31/12/2023 | Maastricht University, Netherlands | https://www.screened-project.eu/ |
| EDCMET- Metabolic effects of endocrine disrupting chemicals: novel testing methods and adverse outcome pathways | Together we aim to develop novel validated test methods and models to assess the metabolic effects of endocrine disruptors and to identify molecular initiating events linked to adverse outcomes. | 01/01/2019-31/12/2023 | University of Eastern Finland, Finland | https://www.uef.fi//en/web/edcmet |
| ENDPOINTS - Novel testing methods for endocrine disruption linked to developmental neurotoxicity | To develop an integrated platform of *in vivo, in vitro* and *in silico* methods for testing chemicals for ED properties impacting on neurodevelopment. | 01/01/2019-31/12/2023 | Uppsala University, Sweden | https://endpoints.eu/ |
| Water JPI Knowledge Hub on Contaminants of Emerging Concern | The Knowledge Hub seeks to address knowledge gaps as well as to consolidate knowledge regarding their behaviour in the environment (water, soil, air, living organisms) and their long-term impact on the health and lives of ecosystems and citizens. | | National Research Agency, France | http://www.waterjpi.eu/implementation/thematic-activities/water-jpi-knowledge-hub-1/water-jpi-knowledge-hub-on-contaminants-of-emerging-concern |
| NanoSafety Cluster | The EU NanoSafety Cluster maximises the synergies between European-level projects addressing the safety of materials and technologies enabled by the use of nanoforms. The studied aspects include toxicology, | Ongoing | University of Birmingham, UK | https://www.nanosafetycluster.eu/ |

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| | ecotoxicology, exposure assessment, mechanisms of interaction, risk assessment and standardisation. | | | |
| ACROPOLIS - Aggregate and Cumulative Risk Of Pesticides: an On-Line Integrated Strategy | To develop a framework for cumulative and aggregate risk assessment of pesticides in an understandable way, accessible for all actors involved in European risk assessment and management. | 01/06/2010-30/11/2013 | Rijksinstituut voor volksgezondheid en Milieu-RIVM, Netherlands | https://cordis.europa.eu/project/rcn/94836/factsheet/en |
| RECIPES - REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders | The RECIPES project aims to reconcile innovation and precaution by developing tools and guidelines to ensure the precautionary principle is applied while still encouraging innovation. | 01/01/2019 - 31/12/2021 | Universiteit Maastricht, Netherlands | https://recipes-project.eu/about/project-description |
| EuroNanoBio -EUROpean scale infrastructure in NANOBIOtechnology | EuroNanoBio aims at defining the key features of the future EU capacity in nanobiotechnology and the roadmap to reach this goal. It will establish the features of the infrastructure, the role of the various stakeholders and the way to establish it. | 01/02/2009-31/01/2010 | Commissariata l'Energie Atomique et aux energies Alternatives, FR | https://cordis.europa.eu/project/id/231654 |
| BALTHEALTH - Baltic Sea multilevel health impacts on key species of anthropogenic hazardous substances | BALTHEALTH is a BONUS funded project to assess the impact of multiple stressors on the ecological functioning and overall health of the Baltic ecosystem. The project has a strong focus on the impact of anthropogenic hazardous substances (AHSs) on all levels of the Baltic ecosystem, and therefore requires a holistic approach to assess environmental health.<br>The overall objective of the project is to investigate how multiple natural and anthropogenic stressors have been impacting key ecological and commercial species | 2017-2020 | Aarhus University, Denmark | https://projects.au.dk/bonusbalthealth/ |

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| | within the Baltic food web, from the individual to the population and ecosystem level | | | |
| PROMOTE - Protecting Water Resources from Mobile Trace Chemicals. | European Union Joint Programming Initiative "Water Challenges for a Changing World" (Water JPI).<br><br>PROMOTE focuses on persistent and mobile organic chemicals (PMOC) and aims at closing the significant knowledge gaps with respect to: (a) trace analytical methods for screening and quantitative determination of PMOC in groundwater and surface water, (b) occurrence and levels of PMOC in source water used for drinking water production, (c) environmental emissions, (d) clean-up strategies in the drinking water production. Based on the expected results, PROMOTE strives to develop recommendations with respect to chemical regulation ( REACH) and water quality monitoring ( WFD watch list). | 01/01/2015<br>31/12/2017 | Seven partners and seven associated partners from five European countries form the consortium. | https://www.ufz.de/promote/ |
| AquaticPollutants Joint Transnational Call 2020 | The three Joint Programming Initiatives (JPIs) on Water, Oceans and Antimicrobial Resistance (AMR) have announced a joint transnational call for research and innovation projects on risks posed to human health and the environment by pollutants and pathogens present in the water resources.<br><br>The call will support research and innovation projects that establish integrated and cross-sectoral approaches for risk-management combining the research areas of contaminants of emerging concerns (CECs), pathogens and antimicrobial resistance. The whole water cycle, from the source through the river basins and eventually to the estuaries and oceans, has to be considered. 26 countries are pooling resources of about 22 M€ to | 12/2020<br>06/2024 | | http://www.waterjpi.eu/joint-calls/joint-call-2020-aquaticpollutants/joint-call-2020-aquaticpollutants |

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| | implement the joint transnational call for research and innovation projects. | | | |
| PERFOOD - PERFluorinated Organics in Our Diet | PERFOOD brings together the institutes most renowned in Europe and the Globe for their chemical analytical work on PFCs with experts in food consumption and drinking water quality as well as food processing and packaging. The aims of the present project are to develop robust and reliable analytical tools including reference materials for the determination of PFCs in food items | 01/08/2009 30/09/2012 | Universiteit van Amsterdamm Netherlands | https://ibed.fnwi.uva.nl/perfood/ |
| European Human Exposome Network | The European Human Exposome Network is the world's largest network of projects studying the impact of environmental exposure on human health. It brings together 9 research projects, receiving €106 million from Horizon 2020 over 5 years, the EU's framework programme for research and innovation. These projects address issues such as exposures to air quality, noise, chemicals, urbanisation etc. and health impacts, the projects' results and will contribute to advancing the European Green Deal's ambition to protect citizens' health and well-being from pollution and environmental deterioration by providing new evidence for better preventive policies.<br>The projects are:<br>• EXPANSE: Exposome powered tools for healthy living in urban settings<br>• EQUAL LIFE: Early Environmental quality and life-course mental health effects<br>• LongITools: Dynamic longitudinal exposome trajectories in cardiovascular and metabolic non-communicable diseases | 01/01/2020 31/12/2024 | Projects co-coordination | https://www.humanexposome.eu/ |

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| | • ATHLETE: Advancing tools for human early lifecourse exposome research and translation<br>• EXIMIOUS: Mapping exposure-induced immune effects: connecting the exposome and the immunome<br>• HEDIMED: Human exposomic determinants of immune mediated diseases<br>• HEAP: Human Exposome Assessment Platform<br>• REMEDIA: Impact of exposome on the course of lung diseases<br>• EPHOR: Exposome project for health and occupational research | | | |

### *5.1.6. Projects from other programmes*

| Acronyme/ project title | Project objective | Duration | Coordinator | Project website |
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| TRISK - European Toxicology Risk Assessment Training Programme | Project objective: To provide comprehensive training in toxicological risk assessment that serves as a model for future European training in risk assessment and for the certification of European risk assessors.<br>Co-financed by the 2nd EC Programme of Action in the field of health (EU-Health Programme). | 01/02/2009-31/01/2012 | University of Milan, Italy | www.eurotox.com/trisk/ |
| LIFE APEX - Systematic use of contaminant data from apex predators and their prey in chemicals management | Demonstrate four novel, regulatory applications of chemical monitoring data from apex predators and prey, support and sustain regulatory take-up of these applications, replicate and transfer LIFE APEX approaches and methods with partners across Europe, disseminate and communicate the LIFE APEX approaches and methods and in particular optimize uptake by regulators and industry (LIFE Programme). | 30/09/2018-01/08/2022 | Environmental Institute, s.r.o., Slovak Republic | https://lifeapex.eu/ |

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| LIFE NanoEXPLORE | Integrated approach for exposure and health effects monitoring of engineered nanomaterials in workplaces and urban areas. | 01/09/2018-28/02/2022 | ALCON Consultant Engineers Ltd Athens, Greece | https://www.lifenanoexplore.eu/ |
| PRORISK - Best chemical risk assessment professionals for maximum Ecosystem Services benefit | This H2020 MSCA ITN project aims to train new generation of risks assessors and develop a holistic risk assessment framework that will integrate (1) the knowledge on chemical-biological interactions and exposure, (2) the AOPs linking the toxicity to ecosystem service-providing units - populations and communities, (3) the trait-based analyses for ecological impacts, with the (4) socio-economic valuation. | 01/04/2020-31/03/2024 | Masaryk University, Czech Republic | www.prorisk-itn.eu |
| The European Partnership for Alternative Approaches to Animal Testing (EPAA) | The European partnership for alternative approaches to animal testing (EPAA) is a unique voluntary collaboration between the European Commission, European trade associations, and companies from 8 industry sectors.<br>The work of the project teams contributes to the development, validation, acceptance and implementation of 3R alternatives, in regulatory testing and decision making, in Europe and beyond. | Ongoing | EU Commission and industry partners | https://ec.europa.eu/growth/sectors/chemicals/epaa_en |

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| SUBSPORT Project - Moving Towards Safer Alternatives | From 2010 to 2013, the "SUBSPORT" Portal was developed within the framework of the LIFE+ Program of the European Union. As result of the project, since 2013, this Portal offered in various languages a wide range of information related to substitution, which allows to plan substitution in a systematic way and to inform about the possibilities to substitute substances and how to approach assessment of alternatives.<br>To ensure that after the project stage the Portal remains up to date and will be developed further, in 2018 the German Federal Institute for Occupational Safety and Health (BAUA), has taken responsibility for the Portal. From now on, SUBSPORT is available under the new name SUBSPORTplus. | Ongoing | Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Germany | https://www.subsportplus.eu/ |

### 5.1.7. *In-house activities (databases and expert networks)*

| Name | description | Duration | Owner | Website |
|---|---|---|---|---|
| IPCHEM - Information Platform for Chemical Monitoring | IPCHEM is the European Commission's reference access point for searching, accessing and retrieving chemical occurrence data collected and managed in Europe. The platform has been developed to fill the knowledge gap on chemical exposure and its burden on health and the environment. IPCHEM is structured into four modules, according to the chemical monitoring data categorisation: Environmental monitoring, Human Bio-Monitoring, Food and Feed, Products and Indoor Air. | Ongoing | DG JRC | https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html |

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| LUCAS - Land Use and Coverage Area frame Survey | The LUCAS survey, carried out by EUROSTAT on a three-yearly basis since 2006. The survey is carried out *in-situ;* a large number of observations are made and registered throughout the EU. In 2012, all 27 EU countries have been covered and over 270,000 points have been analysed on different land cover types (*cropland, grassland, forest, built-up areas, transport network, etc.*). On these points, the surveyors have examined the land cover and land use, irrigation management and structural elements in the landscape. The results are used to assess environmental factors, update European soil maps, validate soil models, and measure the quantity of organic carbon in the soil which is an important factor influencing the climate change. | Ongoing | DG JRC | https://esdac.jrc.ec.europa.eu/projects/lucas |
| DG JRC Certified Reference Materials | The JRC is one of the major developers and producers of reference materials in the world. Reference materials are reliable quality assurance tools that improve confidence in test results obtained by laboratories. The JRC currently provides about 660 different reference materials in the fields of food and feed analysis, environmental analysis, engineering and health applications. EU policy needs drive the development of reference materials at the JRC and new requests are prioritised against these needs. | Ongoing | DG JRC, EC | https://crm.jrc.ec.europa.eu/ |

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| European Union Observatory for Nanomaterials (EUON) | The EUON is a webpage developed by the European Chemicals Agency. This webpage contains a searching database listing nanomaterials that are currently on the EU market. The data is collected from publicly available information from REACH registrations, the Cosmetics Regulation as well as French and Belgian national inventories. The results are linked to ECHA's chemicals database. | Ongoing | ECHA, EC | https://euon.echa.europa.eu/search-for-nanomaterials |
| ECHA- Information on Chemicals | The agency has built a substance databases with data from registration dossiers submitted to ECHA by the date indicated as last update. Registration dossiers include information on uses of the substance and release to the environment through a use descriptor system based on five separate descriptor lists, which in combination with each other form a brief description of the use and exposure for a certain lifecycle stage. | Ongoing | ECHA, EC | https://echa.europa.eu/ |
| European Food Safety Authority - Data collection, standardisation and analysis | EFSA carries out two types of data collection activities: Ongoing collection of harmonised EU-wide data to assess and monitor trends over time and support risk management measures, and specific collections to support risk assessments and other tasks. EFSA's Data Warehouse gives access to summary statistics. | Ongoing | EFSA, EC | http://www.efsa.europa.eu/en/science/data |

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| EFSA Chemical hazards data – OpenFoodTox | OpenFoodTox provides open source data for the substance characterisation, the links to EFSA's related output, background European legislation, and a summary of the critical toxicological endpoints and reference values. OpenFoodTox is a tool and source of information for scientific advisory bodies and stakeholders with an interest in chemical risk assessment. | Ongoing | EFSA, EC | http://www.efsa.europa.eu/en/microstrategy/openfoodtox |
| EMODnet Chemistry portal | The European Marine Observation and Data Network (EMODnet) is part of the Blue Growth strategy, Marine Knowledge 2020, and its main task is to ensure that European marine data will become easily accessible, interoperable, and free of restrictions on use. EMODnet Chemistry first goal is to provide interoperable, high quality and publicly available data and products on marine water quality issues. Its activity is firstly to collect, validate, and guarantee access to marine pollution data streams, and secondly generate and publish corresponding data products. EMODnet Chemistry is focused on eutrophication, ocean acidification, contamination, and marine litter issues, which are relevant to the Marine Strategy Framework Directive and to global climate change. Currently six major European sea regions are covered by EMODnet Chemistry: Arctic Ocean (Norwegian Sea including Barents Sea), Baltic Sea, Northeast Atlantic Ocean (Celtic Sea, Iberian coast and Bay of Biscay, Macaronesia), North Sea, Black Sea, Mediterranean Sea. | Ongoing | DG MARE, EC | https://www.emodnet-chemistry.eu |

## 5.2. National activities

| Name | Description | Duration | Owner | Website/Documents |
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| EU Toxicology Programme (EU-TP) initiative | The EU-TP is proposed to fill the knowledge gaps identified by bodies conducting and/or using risk assessment and to anticipate emerging risks. The production of independent, impartial and transparent toxicological data and knowledge on agents of interest for public health will enable risk assessors to provide better advice to risk managers and decision-makers thereby ensuring an even higher level of public health protection of Europe's citizens. Through an independent and transparent process of consultation of national and European risk assessment bodies, a publicly funded programme will generate data for a number of questions identified and nominated for independent and impartial studies. The raw data from the studies will be publicly available through a unique database or portal. The EU-TP is not intended as a substitute for studies required under existing regulatory frameworks. The general objective is to act at the interface between public health and research by contributing to a better knowledge of the potential impact on health of chemical agents that already exist or for new substances issued from new products and innovation. The programme will contribute to reinforcing the trust that Europe's citizens have in their risk assessment and risk management institutions. | Letter of intent | ANSES and Inserm (FR)<br>FPS and AFSCA (BE)<br>BfR (DE)<br>DTU-Food (DK)<br>FSAI (Ireland)<br>RIVM (NL) | Available upon request:<br>euchemrisk@anses.fr |
| Mistra SafeChem | Developing new chemicals through green chemistry and a safe-by-design concept. The project will develop | 01/01/2020-31/12/2023 | IVL Swedish Environmental Research | https://www.mistra.org/forsknings |

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| | new synthesis methods and new tools for risk assessments. | | Institute, Sweden | program/mistra-safechem/ |
| SELMA-studien – Swedish Environmental Longitudinal, Mother and child, Asthma and allergy study | Exposure for endocrine disruptors and their effect in developing chronic illnesses. New tools for risk assessment of chemical mixtures. | 2007 – 2010; phase II 2019- | Karlstad University, Sweden | https://selma.hotell.kau.se/selmastudien/ |
| Combination effects of toxic chemical compounds and elements on child/adolescent health - an integrated epidemiological and bioactivity testing approach (Swedish Research Council for Environment Agricultural Sciences and Spatial Planning (FORMAS) Grant number: 2018-02251) | The aim is to characterize chemical mixture exposure of children/adolescents in Sweden, to identify the most toxic combinations of chemicals threatening health development, and to determine possible sex differences in combination effects. | 01/12/2018-30/11/2022 | Swedish University of Agricultural Sciences, Sweden | https://app.dimensions.ai/details/grant/grant.8447263 |
| RiskMix - Risk modeling of mixtures of endocrine disrupting chemicals relevant to human exposure, using zebrafish (*Danio rerio*) embryo as model organism. (FORMAS: Grant number: 2018-02264) | This project will develop a generic risk assessment approach for the evaluation of chemical mixtures (the RiskMix strategy), to support the Swedish environmental quality objectives to reach a non-toxic environment. Advanced exposure profiles will be established in a selection of populations e.g. developing children, and mixtures created for experimental evaluation in zebrafish studies. | 01/12/2018-20/11/2022 | Swedish University of Agricultural Sciences, Sweden | https://app.dimensions.ai/details/grant/grant.8448669 |
| DANTE - Effect-directed analysis as a tool towards a non-toxic environment - identification of mixture | This project will use the strategy of effect-directed analysis, by combining bioassays, fractionation and state-of-the art chemical analysis (including non-target screening), aiming to identify the chemicals that are | 01/12/2018-30/11/2022 | Swedish University of Agricultural | https://app.dimensions.ai/details/gr |

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| effects and toxicity drivers in water (FORMAS: Grant number: 2018-02256) | driving toxicity in the aquatic environment and to perform an assessment of mixture effects in the very complex mixtures that can be found in the environment. | | Sciences, Sweden | ant/grant.8448668 |
| Phthalates in female reproduction –impact of mixture composition on hazard characterization (FORMAS: Grant number: 2018-02280) | This project will utilize different methods for defining mixtures and experimentally study the impact on hazard characterization. The focus will be on phthalates and female reproduction, a poorly studied system in the field of risk assessment. This project will ultimately provide a systematic comparison of how three analogous phthalate mixtures affect central reproductive processes in women, identify the importance of mixture composition on hazard characterization, and suggest novel biomarkers of human-relevance for reproductive toxicity in women that could be incorporated into regulatory guideline tests. | 01/12/2018-30/11/2022 | Karolinska Institute, Sweden | https://app.dimensions.ai/details/grant/grant.8444310 |
| A systems toxicology-based approach to reveal early-life dysregulation of body functions by combined exposures to toxic metals (FORMAS: Grant number: 2018-02275) | This project will characterize combined exposures in pregnancy (completed) and in the children from birth to 4 years of age, using both questionnaires and measurement of multiple metal biomarkers. Also, it will analyse epigenetics, transcriptomics and metabolomics in placenta and/or blood (repeatedly), and evaluate the links of complex metal exposure with changed patterns in the molecular pathways, and the further links to health effects (sensitization, allergy, cognition/behaviour, and growth), using novel biostatistics. | 01/12/2018-30/11/2022 | Karolinska Institute, Sweden | https://app.dimensions.ai/details/grant/grant.8447219 |

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| The chemical exposome and male reproduction: sperm alterations and effects on child health (FORMAS: Grant number: 2018-02282) | This project aims to increase the understanding of if, and how, adult male exposure to mixtures of environmental contaminants may affect sperm count, sperm epigenome and children via paternal epigenetic inheritance. The project will accomplish this by initiating the unique Swedish POHaD (Paternal Origins of Health and Disease) birth cohort, measure the chemical exposome by novel non-target mass spectrometry approaches, determine sperm counts, analysing sperm noncoding RNA and DNA methylation by sequencing to conduct detailed studies of cocktail effects and paternal impact on child health. | 01/12/2018-30/11/2022 | Stockholm University, Sweden | https://app.dimensions.ai/details/grant/grant.8444695 |
| Toxicity of Personalized Contaminant Mixtures in Human Blood by NonTarget Exposomics and High-Throughput in vitro Screening (FORMAS: Grant number: 2018-02268) | Sweden has the objective of a Non-Toxic Environment by 2020, but Naturvardsverket admits this will not be met because environmental levels of many substances remain too high, including endocrine disruptors suspected of contributing to common disease. To address this problem, this project will make new use of national infrastructure by integrating mass-spectrometry exposomic workflows with strategic high-throughput toxicity screening (HTS) and reconstruct the analysis of 'personalized contaminant mixtures' in cohorts by robotic liquid handling and testing their endocrine disruption and epigenetic activity by HTS. This project will also estimate margins of exposure and validate a new approach to risk assessment of real-world mixtures. | 01/12/2018-30/11/2022 | Stockholm University, Sweden | https://app.dimensions.ai/details/grant/grant.8444309 |
| Smart, benign and synergistic antifouling cocktails for achieving a non-toxic environment: formulation | This project will study biocide combinations, which show promising high efficacy at target sites and low environmental impacts. In recent times, concern has been raised about the risks of combination effects of | 01/12/2018-30/11/2022 | RISE Research Institutes of | https://app.dimensions.ai/details/grant/grant.844722 |

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| and ecotoxicological evaluation (FORMAS, Grant number: 2018-02284) | chemical mixtures. Therefore, both the industry as well as the public and regulatory authorities will benefit from increased ecotoxicological knowledge of synergistic mixtures. Further, the project will also directly contribute to the non-toxic environment by providing a sustainable and implementable antifouling/antimicrobial technology to industrial stakeholders and end-users. | | Sweden, Sweden | |
| NOVANA - National Monitoring and Assessment Programme for the Aquatic and Terrestrial Environment | The national surveillance program for the aquatic environment and natures (NOVANA), which surveys the aquatic environment and the state of the nature of areas that are prioritised, within the politically set economic boundaries. NOVANA particularly contributes to fulfil the obligations defined by Danish has cf. national. EU and international legislations and conventions on surveillance of the aquatic environment, nature and air. NOVANA consists of 8 sub-programmes. Data collected on the aquatic environment and nature collected by NOVANA is the main basis for the national water-plans and Natura2000 plans. | Ongoing | The Danish Environmental Protection Agency | https://mst.dk/natur-vand/overvaagning-af-vand-og-natur/ |
| VANDALF - Linking of Chemical and Toxicological Fingerprints: A new method to prioritize monitoring and regulation of pollutants in water.<br>Grand Solutions, Innovation Fund Denmark. Grant number: 9067-00032B | The overall vision of VANDALF is to develop and implement flexible and dynamic effect-based tools to identify the chemicals causing the remaining 95-99% of toxicity in effluent water. VANDALF will develop and implement an innovative toxicology-driven risk assessment platform to identify CECs in wastewater. VANDALF will provide information on CECs which are not removed by the current wastewater treatment technologies (or are created in the process), and therefore require the development of new technologies | 01/10/2019 31/09/2023 | University of Copenhagen, Denmark | https://plen.ku.dk/english/research/env_chem_phys/ac/research-projects/vandalf/ |

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| | or the enforcing of regulatory measures on their use and emission.<br>In VANDALF, the approach is to link technology-specific, but otherwise unbiased and non-targeted chemical detections ('chemical fingerprints') with sets of relevant toxicological endpoints ('toxicological fingerprints') to identify which chemicals or groups of chemicals that can explain the toxicity. | | | |
| GANDALF - Untargeted Fingerprinting Analysis and GIS Visualization of Contaminants – A New Paradigm for Chemical Impact Assessment in Urban Development.<br>Grand Solutions, Innovation Fund Denmark. Grant number: 5150-00008A | The chemical impact assessment of soil and sediment contamination is today restricted to measuring concentrations of target organic and element contaminants covered by national quality criteria. GANDALF vision is to support sustainable economic growth of urban areas by providing a data-driven analysis tool that can be used to prioritize treatment of contaminated soil and sediment. This project aims to move to a paradigm where fingerprinting of entire contaminant profiles allows accurate chemical impact assessments, and where appropriate visualization tools for larger areas makes this information easily accessible. | 01/03/2016<br>31/09/2020 | University of Copenhagen, Denmark | https://plen.ku.dk/english/research/env_chem_phys/ac/research-projects/gandalf/ |

## 5.3. International activities

| Name | Description | Owner | Website |
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| NORMAN - Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances | The NORMAN network enhances the exchange of information on emerging environmental substances, and encourages the validation and harmonisation of common measurement methods and monitoring tools so that the requirements of risk assessors and risk managers can be better met. It specifically seeks both to promote and to benefit from the synergies between research teams from different countries in the field of emerging substances. This network has attracted the participation of more than 70 leading laboratories and authorities across Europe and North America. | INERIS, France | https://www.norman-network.net/ |
| U.S. National Toxicology Program (NTP) | The National Toxicology Program is an inter-agency program run by the United States Department of Health and Human Services to coordinate, evaluate, and report on toxicology within public agencies. | National Institute of Environmental Health Sciences, US | https://ntp.niehs.nih.gov/ |
| WHO Chemical Risk Assessment Network, IPCS | Established in 2013, the WHO Chemical Risk Assessment Network is a voluntary collaborative initiative whose overall goal is to improve chemical risk assessment globally through facilitating sustainable interaction between institutions on chemical risk assessment issues and activities. The Network has been established to enhance global efforts to assess risks to human health from exposure to chemicals. The activities of the Network promote the objectives of the Strategic Approach to International Chemicals Management (SAICM). | WHO | https://www.who.int/ipcs/network/en/ |
| OECD's Environment, Health and Safety Programme - | The programme aims to assist OECD Member countries' efforts to protect human health and the environment through improving chemical safety and biosafety, make chemical control policies more transparent and efficient and save resources for government | OCED | https://www.oecd.org/env/ehs/aboutchemicalsafetyandbiosafety.htm |

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| Chemical safety and biosafety | and industry; and prevent unnecessary distortions in the trade of chemicals, chemical products and products of modern biotechnology. | | |
| OECD Alternative Assessment Group | This group provides guidelines for substitution to safer alternatives to hazardous chemicals | OECD | https://www.oecd.org/chemicalsafety/substitution-of-hazardous-chemicals.htm |
| AOP wiki | Collaborative Adverse Outcome Pathway Wiki (AOP-Wiki). This wiki is hosted by the Society for the Advancement of Adverse Outcome Pathways (SAAOP) and serves as one component of a larger OECD-sponsored AOP Knowledgebase (AOP-KB) effort. The AOP-KB represents the central repository for all AOPs developed as part of the OECD AOP Development Effort by the Extended Advisory Group on Molecular Screening and Toxicogenomics. | OECD | https://aopwiki.org/ |
| WHO Environment and health process (EHP) | Process to eliminate the most significant environmental threats to human health. Progress towards this goal is driven by a series of ministerial conferences held every five years and coordinated by WHO/Europe. | WHO Europe | http://www.euro.who.int/en/health-topics/environment-and-health/pages/european-environment-and-health-process-ehp |
| Tool for assessment of cumulative risks from indoor air pollutants in public settings for children | Development of a tool to facilitate assessments of the risk to human health from combined exposures to hazardous chemicals in indoor air, especially in public settings for children. | WHO Europe | http://www.euro.who.int/en/health-topics/environment-and-health/air-quality/publications/2019/towards-a-tool-for-assessment-of-cumulative-risks- |

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| | | | from-indoor-air-pollutants-in-public-settings-for-children.-meeting-report-bonn,-germany,-3-4-december-2018 |
| GLAM - Guidance on Environmental Life Cycle Impact Assessment Indicators | The GLAM project combines environmental and consumer and worker exposure into a consistent method that is also applicable to Sustainable and Safe by Design | UN Environment | https://www.lifecycleinitiative.org/category/glam/ |
| OSPAR Commission | OSPAR is the mechanism by which 15 Governments & the EU cooperate to protect the marine environment of the North-East Atlantic. OSPAR started in 1972 with the Oslo Convention against dumping and was broadened to cover land-based sources of marine pollution and the offshore industry by the Paris Convention of 1974. These two conventions were unified, up-dated and extended by the 1992 OSPAR Convention. The new annex on biodiversity and ecosystems was adopted in 1998 to cover non-polluting human activities that can adversely affect the sea. The fifteen Governments are Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom. | OSPAR secretariat, United Kingdom | www.OSPAR.org |
| Baltic Marine Environment Protection Commission | The Baltic Marine Environment Protection Commission – also known as the Helsinki Commission (HELCOM) – is an intergovernmental organization (IGO) and a regional sea convention in the Baltic Sea area, consisting of ten Contracting Parties, namely Denmark, Estonia, the European Union, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. | HELCOM secretariat, Finland | www.HELCOM.fi |

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| | A platform for environmental policy making at the regional level, HELCOM was established about four decades ago to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental cooperation. | | |
| International Society of Exposure Science, European Chapter (ISES Europe) | The 'Exposure Models' Working Group, established under the auspices of the International Society of Exposure Science, European Chapter (ISES Europe), has the overarching aim to establish within the exposure science scientific and regulatory community a common understanding of use, documentation, validity and limitations of the models and tools for exposure assessment. This working group addresses the need to have guidance to enhance transparency of choices made in the selection of models, tools and exposure-related input data, and to better understanding the quality aspects of model results<br><br>The 'Data Repositories & Data Analytics' Working Group, established under the auspices of the International Society of Exposure Science, European Chapter (ISES Europe), aims to: (a) provide an overview of the existing exposure data landscape and related requirements for data analytics and repositories across European regulations. (b) To map available exposure data to data requirements in order to identify needs and ways forward for improved data analytics and repositories with the objective to identify what additional data need to be produced and where regulations could more efficiently take up existing data. (c) To translate the identified exposure data needs into an operational action plan to advance data production and management, increase regulatory uptake of evidence-based exposure data in Europe, and prioritize actions and translate them into specific tasks with clear timelines. The resulting action plan for exposure data analytics and repositories is considered an important part of defining and implementing a 'European Exposure Science Strategy' 2020-2030. | ISES Europe Working Group 'Exposure Models' Chair: Federal Institute for Occupational Safety and Health (BAuA), Germany<br><br>ISES Europe Working Group 'Data Repositories & Analytics' Chair:<br><br>DG JRC, EC | https://ises-europe.org/group/data-repositories-and-analytics |

## 5.4. EEA Ad Hoc Expert Group on chemicals

| Organisation | Website | Country |
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| Environment Agency Austria | https://www.umweltbundesamt.at/ | Austria |
| Executive Environment Agency (ExEA) of Bulgaria | http://eea.government.bg/en | Bulgaria |
| Federal Public Service of Public Health, Food Chain Safety and Environment | https://www.health.belgium.be/en | Belgium |
| Czech Environmental Information Agency - CENIA | www.cenia.cz | Czech Republic |
| The Danish Environmental Protection Agency (EPA) | www.mst.dk | Denmark |
| Estonian Ministry of Environment, Environment Agency | https://www.envir.ee/en | Estonia |
| Finnish Environment Institute | www.environment.fi/syke | Finland |
| German Environment Agency (UBA) - Umweltbundesamt | https://www.umweltbundesamt.de/ | Germany |
| Environment Agency of Iceland | www.ust.is | Iceland |
| Irish Environmental Protection Agency | https://www.epa.ie/irelandsenvironment/ | Ireland |
| Italian Institute for Environmental Protection and Research, ISPRA | http://www.isprambiente.gov.it/en | Italy |
| Latvian Environment, Geology and Meteorology Centre | https://www.meteo.lv/en/lapas/environment/environment-introduction?id=1450&nid=405 | Latvia |
| Norwegian Institute for Air Research (NILU) | https://www.nilu.no/en/ | Norway |
| National School of Public Health of the Nova University Lisbon | https://www.ensp.unl.pt/ | Portugal |
| Portuguese Environment Agency | https://apambiente.pt/index.php?ref=x178 | Portugal |
| Slovak Environment Agency | https://www.sazp.sk/en/slovak-environment-agency-sea.html | Slovakia |
| S.G. de Calidad del Aire y Medio Ambiente Industrial Ministerio para la Transición Ecológica | https://www.ine.es/dyngs/IOE/es/listadoIoeActual.htm?def=orga&id=1259945947614<br>https://www.miteco.gob.es/en/ | Spain |
| Swedish Chemicals Agency (KEMI)<br>Swedish Environmental Protection Agency | https://www.kemi.se/en<br>http://www.swedishepa.se/ | Sweden |

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| RIVM, Environmental and Safety Centres | https://www.rivm.nl/<br>https://www.rivm.nl/en/about-rivm/organisation/centre-for-environmental-safety-and-security | Netherlands |

## 5.5. Stakeholder groups

- Chem Trust
- Downstream Users of Chemicals Co-ordination Group (DUCC)
- Eurometaux
- European Chemical Industry Council (CEFIC)
- European Consumer Organisation (BEUC)
- European Environment Bureau (EEB)
- European Federation of Allergy and Airways Diseases Patients' Associations (EFA)
- European Trade Union Confederation (ETUC)
- Food Packaging Forum
- Health and Environment Alliance (HEAL)
- Pesticide Action Network Europe (PAN-Europe)
- Plastics Europe
- Small and Medium Enterprises United (SMEunited)
- Women Engage for a Common Future (WECF)
- International Chemical Secretariat (ChemSec)