European Partnership for the Assessment of Risks from Chemicals

PARC

Horizon Europe candidate Partnership

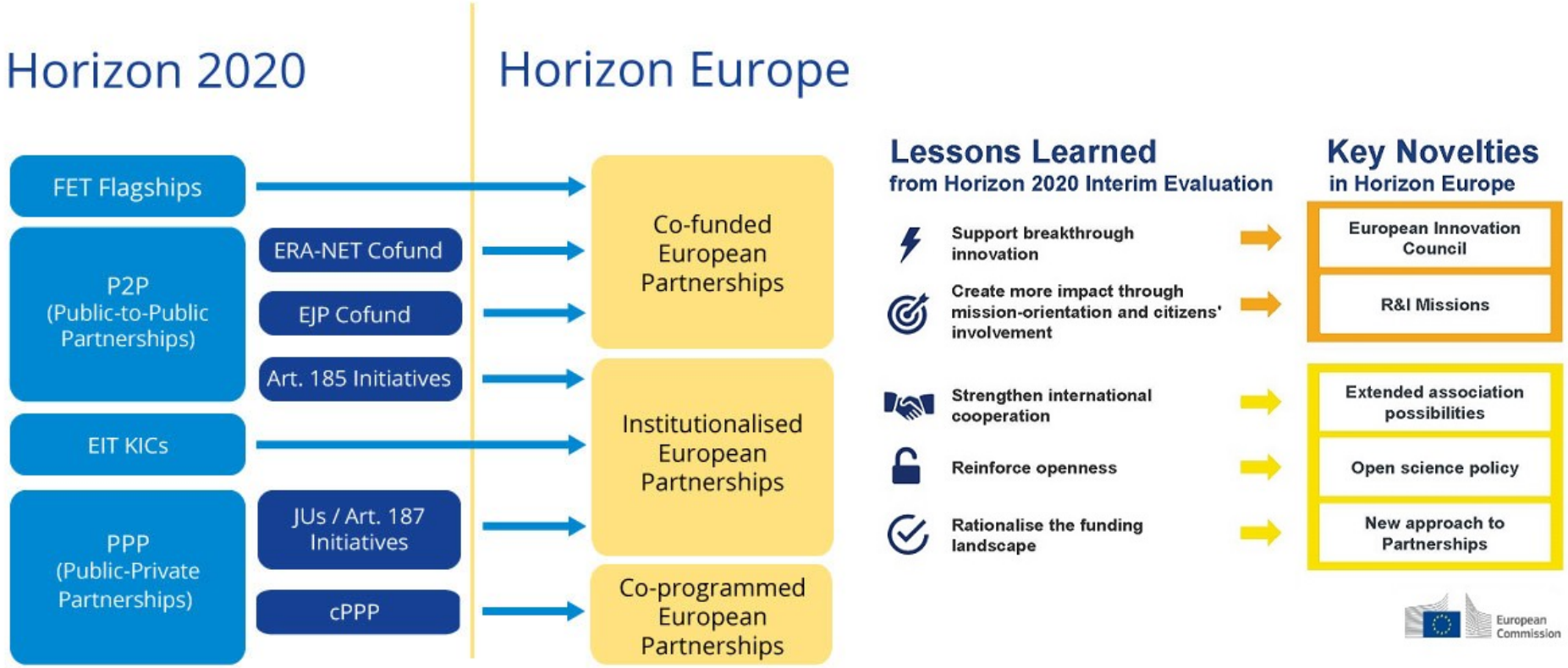
NORMAN

12th General Assemby

02/12/2020

ANSES

What is a Horizon Europe Partnership



Co-Construction European Commission/Member State

Context for the PARC proposal

Challenges: Risk assessment agencies and regulatory bodies and associated research community in the EU are confronted with

- persistent science-regulatory gap
- gaps in knowledge of and information on hazards,
- occurrence and exposures to chemicals and mixtures
- scattered and non-accessible evidence
- screening, testing and assessment methods to be developed, validated and taken-up
- duplication of efforts and inefficient use of resources
- insufficient risk communication

Opportunity: Horizon Europe

A partnership to boost research and innovation in support of chemical risk assessment

Responding to policy priorities:

SDGs, 2019 Council Conclusions, Green Deal, Towards a Sustainable Chemicals Policy Strategy …

Requirement:

A joint research and innovation roadmap set by risk assessors & managers in consultation with academia, association, industry and other stakeholders

Worked on it with a Steering Group (Sept 2019-Nov 2020):
25 countries: AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, IS, IT, LV, LU, NL, NO, PL, PT, SE, SI, SK

And ECHA, EEA, EFSA, JRC,
DG R&I, DG SANTE, DG ENV, DG GROW & others

Concept paper published early June 2020:
Provides an overview of the context, objectives and expected impacts and the planned implementation with the suggested structure, activities and governance

Setting the scene

Concept paper

Challenges


Number & diversity of chemicals

Gaps in toxicology



Incomplete occurrence and exposure data

Separate policy frameworks



Need for new risk paradigms

Restricted data access



Lack of skills

High public concern



Environmental and public health costs

R&I needs

Science - Policy dialogue to drive regulatory innovation

Innovating toxicology: new methods and approaches

Monitoring and impact assessment

Cooperation across sectors

New risk assessment approaches and decisions support tools

FAIR data and open and connected platforms

Training for new skills

Improved communication

Objectives

Consolidate and strengthen the R&I capacity for chemical risk assessment

An EU-wide cross-disciplinary network to identify and agree on R&I needs and support uptake of results into regulatory chemical risk assessment

Joint EU R&I activities supporting the current regulatory risk assessment processes and responding to emerging challenges

Strengthen capacities and build new EU-wide, transdisciplinary R&I platforms to support chemical risk assessment

Actions

Support a common science policy agenda

Evolve hazard assessment

Advance monitoring and exposure assessment

Create and strengthen synergies & collaborations

Drive Innovation in regulatory risk assessment

Define new concepts and toolboxes

Support and contribute to FAIR data

Enhance capacities: infrastructure and skills

Foster communication across stakeholder groups

Outcomes

A sustainable Europe-wide R&I platform for chemical risk assessment

Support **the European Green Deal** activities with new evidence, tools and methodologies.

Zero Pollution


Empower the **Common European Green Deal Data Space** by providing FAIR data on chemicals.

Minimise the negative **impacts of chemicals on human health** and the environment.



Enhance the **protection of workers** from chemical risks.

Support the mobilisation of industry for a **circular economy**



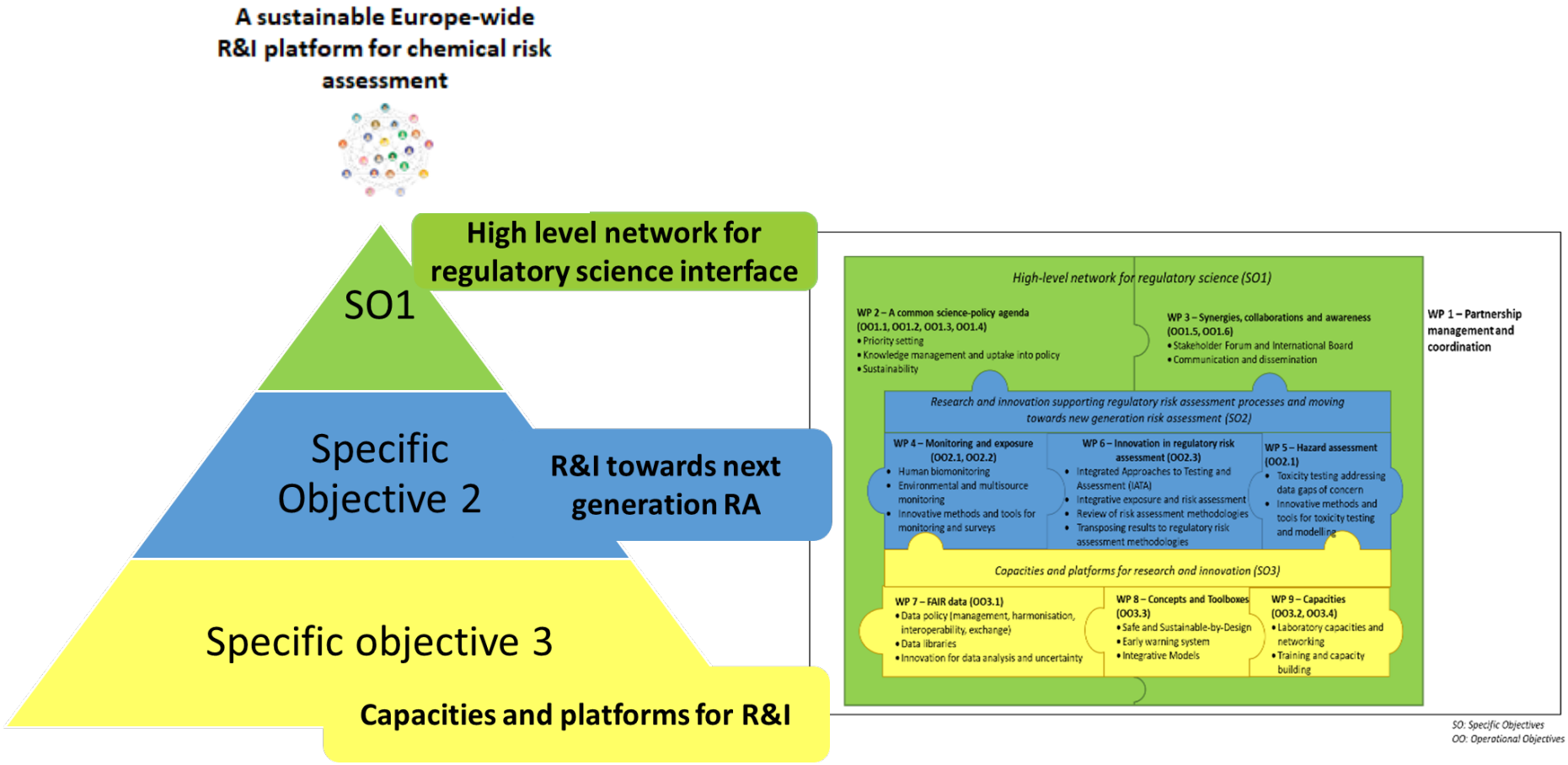
Reinforce the **sound management** of chemicals and waste.

IMPACT

Establish the EU as an internationally recognised **driver of innovative chemical risk assessment** with an optimal protection of human health and the environment

Free images from Pixabay: OpenIcons, Colin Behrens, Marek Studzinski, PublicDomainPictures, Gordon Johnson, John Hain, 200 Degrees, Mystic Art Design

Description of the objectives-oriented organisation



Key Performance Indicators

KPI

GENERAL PARC OBJECTIVE

Consolidate and strengthen the **EU's R&I capacity for chemical risk assessment** to **protect human health and the environment** and contribute to a **non-toxic environment** and a **circular economy**

IMPACT PARC

The EU as an internationally recognised **driver of innovative chemical risk assessment** with an **optimal protection of human health and the environment**

Outcomes: Contributions to EU Policy Goals

- Create a **sustainable** Europe-wide **R&I network** for **chemical RA** in support of **EU Chemicals Policy 2030 and chemicals strategy for sustainability**
- Enhance the **protection of workers** from chemical risks in line with **EU Strategic Framework on Health and Safety at Work**
- **Minimise** the negative **impacts of chemicals on human health** and the **environment through the zero pollution strategy**
- Support the **European Green Deal** activities with **new evidence, tools and methodologies**
- Reinforce the **sound management** of **chemicals** and waste and thereby contribute to the achievement of many of the **UN Development Goals**
- Empower the **Common European Green Deal Data Space** by providing **FAIR data on chemicals**
- Support the mobilisation of industry for a **circular economy by innovating chemical RA** in line with the Commission's **Industrial Strategy** and the **New Circular Economy Action Plan**

PARC SPECIFIC OBJECTIVES

- Set up an EU-wide cross-disciplinary network to **identify R&I needs** and **support** research uptake
- **R&I programme** to support current regulatory RA processes and emerging challenges
- **Strengthen** existing **capacity** in EU and build a **transdisciplinary R&I infrastructure** in support of chemical RA

PARC IMPACT INDICATORS

Policy impact
- Recognition of the partnership's results in international fora and regulatory processes
- Memorandum of Understanding on long-term cooperation signed by risk assessment bodies

Scientific impact
- Number of scientific publications from the partnership considered core contributions to science
- Interdisciplinary scientific network for risk assessment across the EU

Societal impact
- EU Chemical Open Data Space
- Recognition of the partnership's results by key stakeholder associations and NGOs
- **Citizen awareness** about chemical risk and human and environmental protection and trust in regulators

PARC OUTCOME INDICATORS	PARC OPERATIONAL OBJECTIVES	PARC OUTPUT INDICATORS
No. of countries and EU institutions interested in identifying R&I challenges in risk assessment together.	Set up and operate a high-level group of EU and national representatives to strategically steer the Partnership.	• No. of countries and EU entities participating in governance structures and activities and type of entities • No. countries with an active national hub • No. of coordinated activities between the national hubs • No. of R&I activities identified by the country and EU Board • Timely provision of 3-year strategies • No. of consultations launched per group of stakeholders and % of replies obtained. • No. of meetings between partners and National, EU or international standardization bodies
No. of active National Hubs involving a broad network of stakeholders and engaged in collaboration.	Sustainable network of National Hubs that interact with stakeholders.	
Established and widely recognised joint prioritisation processes.	Define common R&I strategies to address regulatory knowledge needs for chemical RA and RM.	
No. of regulatory gaps addressed by the Partnership.	Foster the regulatory uptake of knowledge produced risk assessment and regulatory processes .	
No. of the partnership's results recognised by different EU and national agencies.		
No. of synergies established with other partnerships, initiatives and programmes.	Promote cooperation and foster European leadership for R&I in chemical RA.	• No. of synergies or collaborations with other initiatives explored • No. of members in the International Board; geographical coverage, interdisciplinarity • Timely delivery of the AWPs • Timely delivery of deliverables and milestones • % of activities in the 3-year strategy covered by AWPs • No. of aligned human biomonitoring surveys • No. of candidate labs and qualified labs • No. of exposure/effect biomarkers quality approved and/or measured • No. of new methods developed • No. SOPs/guidance documents prepared • No. of proficiency tests & round robin tests done
No. of scientific communications.	Develop and implement strategic annual R&I work programmes.	
No. substances for which PARC has delivered new exposure, hazard or health data.	Consolidate, maintain and further develop the human biomonitoring platform created in HBM4EU.	
No. of new methods, tools or models developed, consolidated and reliable for risk assessment.	Facilitate the uptake of results in regulatory RA and support standardisation & validation of new approaches.	
No. of burden of disease and disease costs assessments for humans and the environment.		
No. of approvals for data sharing between institutions and collaborations with data platforms.	Create a FAIR data culture between stakeholders and policy domains.	• No. and % of activities generating new open data • No. of datasets developed, quality controlled and stored in an interoperable mode • No. guidelines, templates for data generation, collection, harmonization, reporting and sharing • Timely delivery of criteria and procedures for consolidating and developing laboratory networks • No. of networks of laboratories identified or established and No. of laboratories participating in networks • No. of 'toolboxes' developed and made available • No. of new models in open access • No. training activities done and no. of attendees • No. of junior scientists (PhD) involved • No. of non-scientific communications • No. of Partnership events • No. of users or followers of PARC social media • No. of open documents on website and downloads
No. of collaboration agreements signed between laboratories.	Consolidate existing and develop new networks of laboratories and research centres.	
No. of new concepts and toolboxes applied by stakeholders.	Develop innovative models and concepts for RA and toolboxes to promote their acceptability and uptake.	
No. of academic and competent authority training programmes delivered in areas relevant to regulatory risk assessment.	Build capacities by developing and carrying out training and exchange programmes .	
Opinions of stakeholders and citizens on the added value of the partnership.	Communicate and disseminate knowledge produced by the Partnership to stakeholders and citizens.	

Prioritisation process

2 Surveys: PARC / HBM4EU

HBM4EU

science and policy
for a healthy future

22 June-18 Sept
- Online survey on priorities for work on chemical risk assessment

21 Sept 2020
- 21 Sept – present proposed process to the interim WP leaders

Oct/Nov 2020
- Analysis by interim WP leaders

Nov/Dec 2020
- Consult interim Country Board, EU Board, Grant Signatory Board

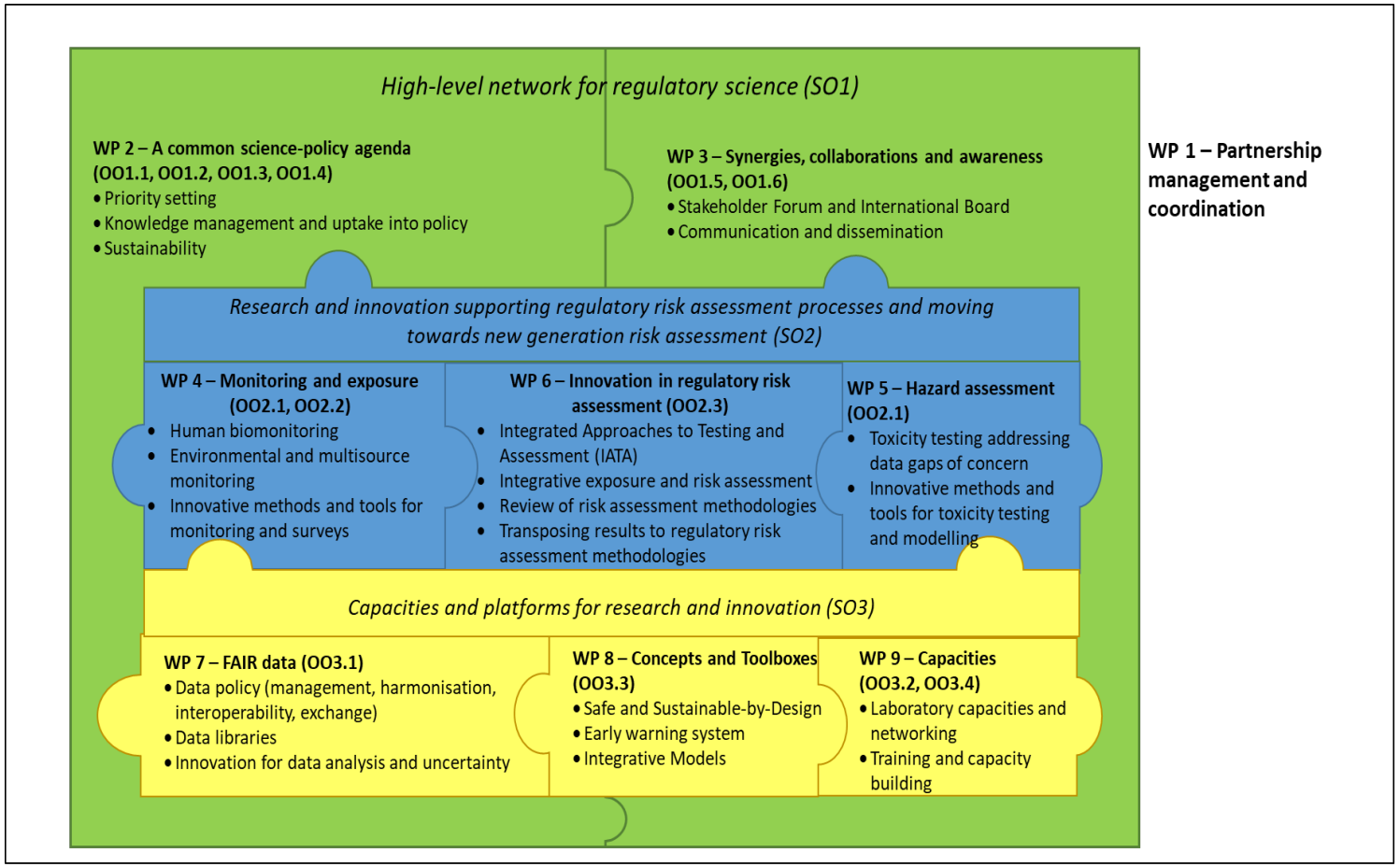
Survey on PARC priorities
- 156 entries

Survey on substances for human biomonitoring
- 36 entries

Supporting WPs	•Q1. Overall knowledge needs
WP4 Monitoring and exposure	•Q2. Priorities for monitoring & exposure
WP5 Hazard assessment	•Q3. Priorities for hazard assessment
WP6 Innovation in regulatory RA	•Q4. Priorities for innovation in chemical risk assessment
WP8 Concepts & toolboxes	•Q5. Priorities for new concepts and tools
Supporting WPs	•Q6. Additional priorities and references

Implications for WP7 on data and WP9 on capacity building

Objectives-oriented structure



SO: Specific Objectives
OO: Operational Objectives

WP4: Monitoring and exposure

Interim WPL: UBA (DE), SpF(FR)
Interim Team: VITO (BE), ISCIII (ES), AU (DK), INERIS(FR), EEA (EU), INRAE (FR), VU-EH (NL), MUI (AT), EFSA (EU)

4.1 Human Biomonitoring	• **Alignment and harmonisation of HBM programmes**
4.2 Environmental and multisource monitoring	• **Multiple sources, chemical fates and environmental exposure pathways of chemicals** • **Long term and life cycle stages associated exposure** • **Environmental monitoring in support of the regulatory framework**
4.3 Innovative methods and tools for monitoring and surveys	• **Non-targeted screening and emerging chemicals** • **Characterise mixtures for exposure assessment** • **Link exposure and health related information**

- Relevance
- Needs
- Activity planning
- Costs

WP5: Hazard assessment

Interim WPL: ANSES (FR), BfR (DE)
Interim Team: NIPH (NO), VUB (BE), DTU (DK), INSERM (FR), INSA (PT)

	Degradation products	PFAS & precursors
5.1 Toxicity testing addressing data gaps of concern	Conduct of 90-d GL studies with single substances and, real life‘ mixture; simultan analysis of classical parameters and omics techniques; simulatn. analysis of kinetics	Conduct of **90-d GL** studies with **toxins**; (relevant mixtures) simultan analysis of **classical parameters** and **omics** analysis; simulation. analysis of **kinetics**
5.2 Innovative methods and tools for toxicity testing and modelling	In vitro screening of DBP, co-formulants; cell painting; cytotox; HCS, reporter genes, enzyme interactions	In vitro screening of toxins, cell painting; cytotox; HCS, reporter genes, enzyme interactions; AOP development
5.3 Regulatory use of hazard data (in collaboration with 6.1)	In vitro kinetic interactions E.g.CYP inhibition+induction	In vitro kinetic interactions E.g. CYP nhibition+induction

Substances
BPA alternatives
Toxins

Materials
Nano, µ plastics
nanomaterials

Adverse outcomes
(non-genotoxic)
Carcinogenicity
Genotoxicity
Endocrine disruption
Neurotoxity
DNT
Immunotoxicity
Reproductive & Developmental toxicity
Specific organ toxicity

Ecological risks

Overarching topics
Combinatorial effects/mixtures
Grouping
QSAR/Read across
Systems biology
TK/PBPK

- Relevance
- Needs
- Activity planning
- Costs

WP6: Innovation in regulatory risk assessment

Interim WPL: RVM (NL), KEMI(SE)
Interim Team: UL-LACDR (NL), Sciensano (BE), VITO (BE), ANSES (FR), EFSA (EU), BPI (EL), ACES (SE), UNIBAS (CH)

WP6.1 Integrative approaches to testing and assessment (IATA)	• Development and testing of IATAs for regulatory purposes • Development and/or expansion of (quantitative) Adverse Outcome Pathways • Identification and validation of effect biomarkers • Development of a workflow for assessing the human relevance of AOPs, as well as the relevance of associated test methods and tools • Pre-validation of test methods used in IATA • Development of computational modelling approaches for integrating outputs from non-animal methods and tools towards quantitative hazard assessment • Evaluation of IATAs, using weight of evidence approaches for integrating human data and data from traditional and novel (test) methods and including characterisation of uncertainty	
WP6.2 Integrative exposure and risk assessment	• Mixture risk assessment • Aggregate exposure from different Sources of exposure Routes	• Linking internal exposure to external aggregate exposure and vice versa • Ecological risk assessment
WP6.3 Review of risk assessment methodology	• Tools to help enforcement of legislation with focus on articles • Develop a decision support system	
WP6.4 Transposing results to regulatory risk assessment methodologies	• Efficient risk assessment processes • Develop regulatory and legally accepted risk assessment and management methods for for chemical mixtures, • for articles in circular material flow, complex situations with severe knowledge gaps • Facilitate the regulatory acceptance and use of new methods • Research to support the inclusion of new endpoints in chemical regulation to increase the protection of biodiversity, including the integrity and resilience of ecosystems	

WP2: A common science policy agenda

Interim WPL: EEA(EU), EAA (AT)
Interim Team: ANSES (FR), ECHA (EU), EFSA (EU), INSA (PT), BfR (DE), NPHC (HU), Inserm (FR)

2.1 Priority setting	• Evaluation and uptake of first survey • Drafting the first research and innovation agenda	• Developement and implementation of a prioritisation strategy	• Support drafting of the 3 year strategic agendas • 2022-2024
2.2 Knowledge management and uptake into policies	• Develop a process to ensure the immediate access of risk assessors / Managers [Early Warning System]	• Develop a format for dialogue between partnership/regulatory scientists and EU Institutions	
	• Compile existing knowledge and define data gaps to addressed • Map list of ongoing activities by regulatory bodies, OECD work	• Develop an appointment process for Chemical Leaders (CLs) and New Approach Methodologies' Leaders (NAMLs)	• Develop workflows to achieve the objectives identified in the exit strategy
	• Guarantee open access and fair data	• Develop a proposal for consistent and coherent information flow	
2.3 Sustainalibilty	• Mapping of needs of national hubs & establish a peer to peer learning activity process together with WP9	• Concept for capacity building	• Exit Strategy

Collaboration with all WPs

Regular consultations
- Governing Board
- Scientific communities
- Stakeholders

Close collaboration
National Hubs, EUHUb

WP3: Synergies, collaborations and awareness

Interim WPL: INSA (PT), GSCL (EL)
Interim Team: EAA (AT), ECHA (EU), EFSA (EU)

3.1 Stakeholders forum and international board	Set-up of the International Board, Stakeholder Forum and nomination of the PARC Ambassador	Running of the International Board and Stakeholder Forum
3.2 Communication and dissemination	Development of a graphical identity for PARC Website and channels in social media Development of a communication and dissemination strategy	Establishment of synergies and collaborations with national, EU-level and international activities Outreach activities and awareness raising

WP8: Concepts and tools

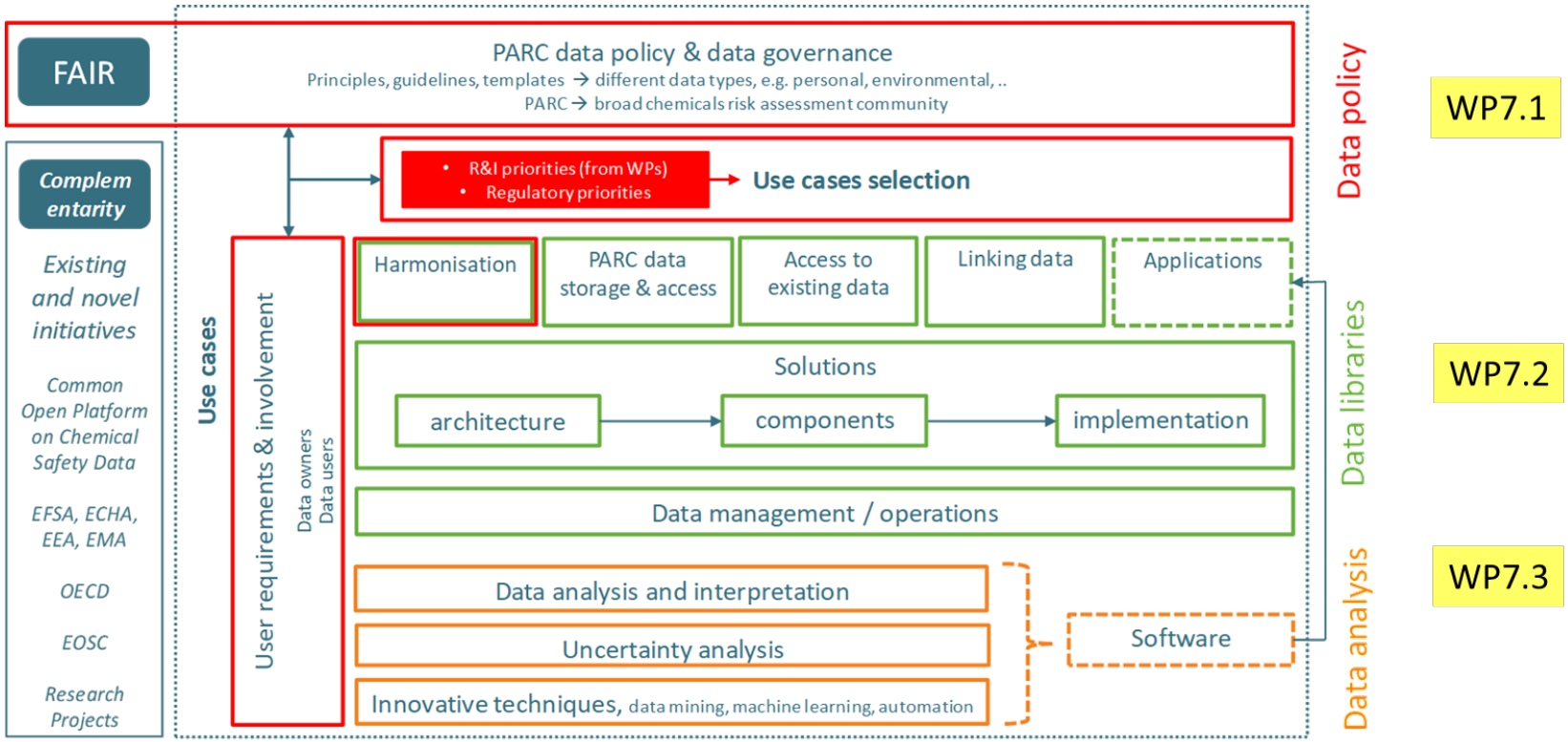
Interim WPL: AUTh (EL)
Interim Team: EMPA (CH), UF2N (IT), RIVM (NL), WR-Bio (NL), KEMI (SE)

8.1 Safe and sustainable by design	• Key protection goals and implementation criteria • Develop conventions for the terms 'safe' and 'sustainable' in relation with the key protection goals	Development of a SSBD assessment toolbox ▪ Describe methods with which critical properties (such as toxicity, exposure) of chemicals in function of usage (reparability, reusability, recyclability) ▪ Develop guidelines for the toolbox implementation, following OECD recommendations
8.2 Early warning system	• Identification of the needs and user requirements for an early warning system • Enable searches in chemical inventories on their potential of being new emerging risk chemicals (NERC), • link with development in Non Targeted Screening analysis	• Development of the computational framework to support the early warning system). • Develop guidelines for the toobox implementation (OECD recommendations)
8.3 Integrative models	Development of the toolbox for integrative modeling of exposure and risk assessment • Mobility in the environment, accounting for their overall environmental fate • Exposure pathways and routes • Toxicity potency, using QSARs and other computational methods developed in WP5 • Identify whether they will be potential NERCs	Toolbox implementation based on cloud computing and application programming interfaces (APIs) Case studies using the integrative modeling toolbox

- Relevance
- Needs
- Activity planning
- Costs

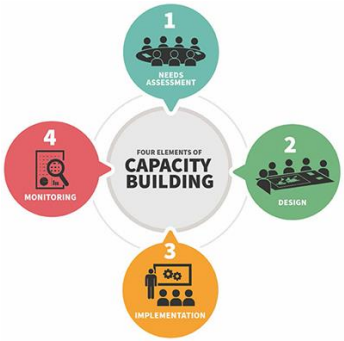
WP7: FAIR Data

Interim WPL: VITO (BE), TNO (NL)
Interim Team: MU (CZ), EFSA (EU) UU-IRAS (NL), support by JRC, DG ENV



WP9: Capacities and networks

Interim WPL: MU (CZ), ISCIII (ES)
Interim Team:



Capacities	Capacity Mapping and Strengthening Laboratory Networks Cooperation Standardisation of approaches ¨.
Training	Development of templates and questionnaires to identify the training needs and relevant groups of stakeholders beyond the Partnership Collection and management of needs identified in other WPs within expert working groups comprising experts from WP 4-8 representatives Implementation of the needs *via* • Organisation of (on-line) training activities • preparation of annual (on-line) training programmes within and beyond Partnership • development of online materials • development or adaptation of guidance on training programmes and harmonisation procedures • organisation of periodical seminars Collaboration with education sector and national hubs Dissemination of training materials and training programmes (in cooperation with WP3)

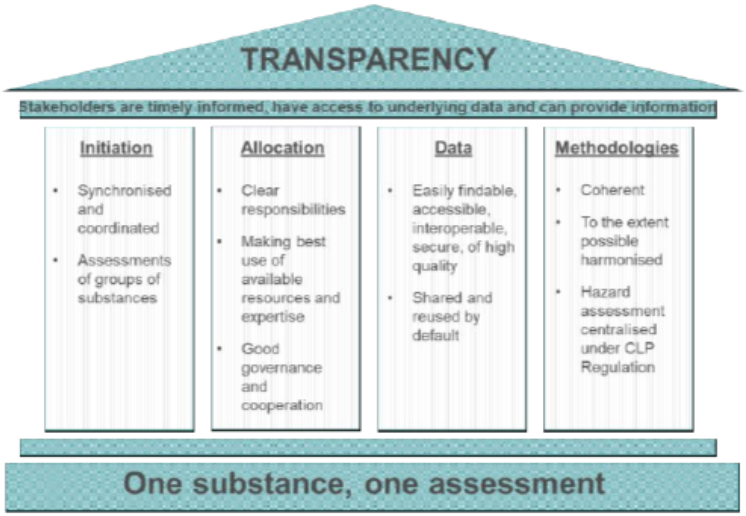
Several examples of training topics
analyses of exposures (target and NTS),
analyses of related environmental and health effects,
assessment of risks,
management and analysis of data,
modelling, use of models etc

- Needs by activity
- Design Training programme
- Implementation
- Monitoring

Link to EU Chemicals Strategy for Sustainability – published 14/10/2020

Encourage innovation

Promote the development of **safe and sustainable chemicals and materials**, clean production processes and technologies, **innovative tools for testing and risk assessments.**



- **Contribute to the development of EU criteria**
  - Safe and sustainable chemicals (WP8)
  - Early Warning System (WP8, WP4)
  - Mixtures assessment factors (WP6, WP8)
  - Environmental risk assesments (WP6)
- **Development of**
  - innovative tools (WP4,5,6, 8)
  - methodologies that take into account the whole life cycle of substances, materials
- Development and uptake of methods to generate information on endocrine disruptors through screening and testing of substances (WP5, 6)
- Contribute on the methodologies and data (WP5, 7)

Partnership implementation strategies

Construction process of the Partnership

Description of actions

By WP

Challenges

Targets/Objectives

Expected outputs

Task and deliverable description

(similar to the concept paper)

- Concept paper
- National commitments
- Steering Group

SRIA

Identification of challenges to be addressed

Near future (1-3Y) - Precise

Long term (4-7Y) - General

- Priorities questionnaire
- Interim MB
- GSB/LTP
- GB

Planning of activities

3Y common Strategy

List **of detailed activities**

Precise work based on WP/T related to DoA

1st **annual work** plan

- Interim MB
- GSB/LTP
- GB

Proposal

- Consultation GB
- EU Call

SRIA: Strategic Research and Innovation Agenda
WP/T: Worpackage and Tasks
DoA: Description of Action

Roadmap for the next steps – 2021

1 Dec 2020	• **First meeting of the GB/GSB to discuss priorities**
Dec - March 2021	• Interim WP co-leaders translate the priorities into the 3-year common strategy and first annual work plan for the Partnership
March-April 2021	• **Second meeting of the GB/GSB to** adopt the final 3-year common strategy, the 1st annual work plan
April 2021 TBC	• **Publication of the Work Programme 2021-2022 by the EC**
April-June	• **Preparation of the proposal submission**: *administrative, technical and budgetary data and CA preparation*
June-Aug TBC	• **Submission of the complete proposal to the Commission**
Aug-Nov TBC	• **Evaluation by the European Commission**
Nov-Dec 2021	• **Contractual process**: *Verification, signature of the administrative forms, preparation of the Kick-off meeting*

Jan 2022 (TBC) : Launch of the Partnership and kick off meeting in France (under French presidency of the Council of the EU)

Conclusion

Objectives of NORMAN are in line with PARC objectives.

Joint data space and cutting-edge research tools for Risk assessment of contaminants of emerging concern

Advanced data analysis tools: towards a European Early Warning system

- Prioritisation of substances and priority setting

Support to national and European chemical risk asessment: harnessing, combining and sharing evidence and expertise on CECs

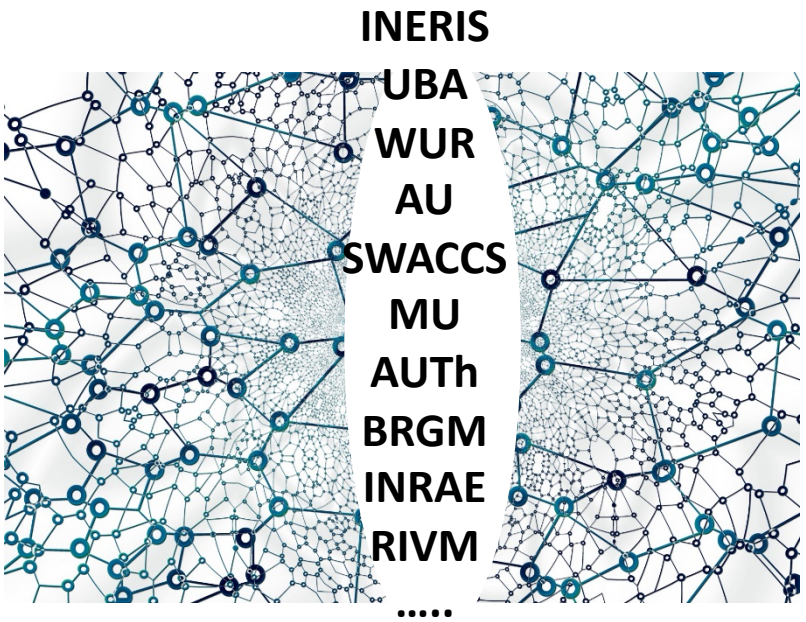
Dulio *et al. Environ Sci Eur (2020) 32:100*
https://doi.org/10.1186/s12302-020-00375-w

Environmental Sciences Europe

COMMENTARY Open Access

The NORMAN Association and the European Partnership for Chemicals Risk Assessment (PARC): let's cooperate!

NORMAN & PARC networks are connected



Project contact details

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