



**CHEMTrust**

Protecting humans and wildlife  
from harmful chemicals

**Submission**

## **10 Points for PARC**

### **Considerations for a Partnership for the Assessment of Risk from Chemicals**

September 2020

This submission is made in response to this survey: [https://www.hbm4eu.eu/parc\\_survey/](https://www.hbm4eu.eu/parc_survey/)

CHEM Trust welcomes the opportunity to comment on the plans for a new Partnership for the Assessment of Risk from Chemicals (PARC).

As the goal is to *Consolidate and strengthen the EU's research and innovation capacity for chemical risk assessment protect human health and the environment and contribute to a non-toxic environment and a circular economy* the research strategy needs to be closely coordinated with the societal needs and expectations from the health and environmental community.

In our view the 3 biggest needs to enhance current protection for human health and the environment from harmful chemicals and thus relevant for PARC are:

- a) *Filling data gaps for faster regulatory action on harmful chemicals*
- b) *Developing approaches for grouping of substances which can be used in regulation*
- c) *Addressing the combination effects of chemicals*

Over the last years many important EU research projects have been carried out and the list of outstanding policy actions is long. An implementation of existing methods and risk management requirements according to existing EU laws would already result in a better protection in the short term. This means PARC should focus on future-oriented challenges rather than on current or retrospective questions which can be addressed without additional basic research. One element PARC should include is an analysis of the reasons for the delay in science-policy uptake and why risk management has so far often failed to act in an early and precautionary way.<sup>1</sup>

Moreover, PARC should be set up with the understanding that it is the companies' responsibility to carry out risk assessments and ensure safe use of their chemicals and products. This burden of proof will remain on industry. Any new approach should be developed with a focus on how protection can be efficiently and effectively increased through better identification of priority risks from chemicals.

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<sup>1</sup> See e.g. conclusion in the REACH REFIT evaluation from 2018 that the precautionary principle has not been explicitly applied.

CHEM Trust would like to make the following 10 points for a future PARC:

- 1) As priorities for monitoring and exposure: a strong priority should remain on generating new (bio)monitoring data which can be used to inform regulatory decisions for future prevention. This should be done by consolidating and further developing the human biomonitoring platform and network of qualified laboratories for biomarker analysis created in HBM4EU. Only by addressing some of these knowledge gaps on priority chemicals can the protection goals be met. However, it should be kept in mind that HBM data should never become a prerequisite for regulation but that the aim is rather to prevent the exposure of people and the environment to harmful chemicals in the first place.
- 2) As priorities for the hazard assessment it will be crucial to generate reliable and independent toxicity data, and develop tests and guidelines for neurotoxicity, immunotoxicity, transgenerational effects, epigenetics and endocrine disruption, but also emerging chemicals including impacts from micro/nano-plastics. Any work should complement ongoing research activities in the EURION cluster.<sup>2</sup>
- 3) As priorities for innovation in regulatory risk assessment there should be an emphasis on a) integrating mixture assessment methods for cumulative exposures,<sup>3</sup> b) developing interfaces with regulatory risk management decision making (e.g. cut-off criteria when a property indicates a need for precautionary action and further risk assessment is not needed) and c) better (long-term) hazard prediction models in case of missing data.
- 4) The uptake of scientific knowledge to policy development and legislation should be improved. However, caution should be taken to avoid establishing parallel structures to existing committees, e.g. subgroups of CARACAL or ECHA expert groups. In any case transparency and balanced stakeholder access would need to be guaranteed.
- 5) New concepts and methods are needed for developing predictive methods and use of new technologies as early warning tools. Human biomonitoring has to be regarded as a 'late warning tool': the exposure cannot be turned back and impacts cannot be prevented once the chemicals are found in people and wildlife.
- 6) Priority chemicals should be those substances or groups of substances that have known or suspected properties of concern (i.e. CMR, PBT, vPvB, PMT, vPvM properties, as well as EDCs, neurotoxicants and immunotoxicants) and that are still in widespread use. Many of the priority chemicals and groups from HBM4EU should be taken forward to PARC, based on the results and remaining knowledge gaps identified. A strong emphasis for new analyses should be laid on the 'replacement chemicals' which are used as substitutes but are suspected as being equally harmful than known regulated ones. This is one of the largest challenges in current chemical's management, see e.g. CHEM Trust's report on bisphenols.<sup>4</sup>
- 7) Other priorities: For the planning of PARC a critical evaluation of HBM4EU will be crucial to decide which data and tools contributed to advancing health and environment protection. In recent years there has been a tendency to develop a plethora of new methods and tools, some of them generating complex background information without actually accelerating

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<sup>2</sup> <https://eurion-cluster.eu/>

<sup>3</sup> [https://chemtrust.org/wp-content/uploads/Final-NGO-comments-combination-effects-CARACAL-CA\\_MS\\_47\\_2020.pdf](https://chemtrust.org/wp-content/uploads/Final-NGO-comments-combination-effects-CARACAL-CA_MS_47_2020.pdf)

<sup>4</sup> <https://chemtrust.org/toxicsoup/>

decision making. What is needed are concrete answers to support the current regulatory risk assessment processes or responding to emerging challenges. The HBM4EU evaluation should include aspects like: which data gaps were closed and which policy needs fulfilled? Which policy decisions were taken based on the new data (or are in the pipeline)? Which new methods/tools were not as suitable to be used in regulation as originally hoped.

- 8) Any future work on guidance values linking internal exposures and health impacts should have the purpose of targeting specific policy interventions for protection, and need to be carefully communicated. They should not be misused as an indicator for an assumed 'safe level' in humans, because of the enormous uncertainties involved in the assumptions and as it would ignore the cumulative effects of the total body burden.<sup>5</sup>
- 9) PARC's involvement of stakeholders should be based on experience gained in HBM4EU: stakeholder involvement should be turned into a true participation rather than mainly for enhancing the credibility of the project. The same applies to addressing public concern and engagement with citizens which has not been very visible in HBM4EU (yet).
- 10) As a final remark: we are sceptical about the size and complexity of the envisaged initiative and are worried it might be unsuitable for achieving tangible outcomes which can help overcome current obstacles in risk management. If the EU is really interested in added value from its research projects it will be important to keep them focussed on specific questions and tasks which will deliver on increased health and environment protection.

**Additional information:**

CHEM Trust comments on the EU Commission's roadmap for a Chemicals Strategy for Sustainability

<https://chemtrust.org/wp-content/uploads/CHEM-Trust-chemical-strategy-roadmap-consultation-response-FINAL.pdf>

CHEM Trust policy paper: A new path for EU control of Endocrine Disruptors

<https://chemtrust.org/wp-content/uploads/CHEMTrust-newEDPolicy-July2020.pdf>

CHEM Trust response to EU Fitness Check on Endocrine Disruptors

<https://chemtrust.org/wp-content/uploads/CHEM-Trust-Submission-ED-Fitness-Check-Jan-2020.pdf>

Joint NGO paper submitted on combination effects from chemical mixtures, CARACAL August 2020

[https://chemtrust.org/wp-content/uploads/Final-NGO-comments-combination-effects-CARACAL-CA\\_MS\\_47\\_2020.pdf](https://chemtrust.org/wp-content/uploads/Final-NGO-comments-combination-effects-CARACAL-CA_MS_47_2020.pdf)

**Contact details:**

Ninja Reineke, Head of Science, CHEM Trust

[ninja.reineke@chemtrust.org](mailto:ninja.reineke@chemtrust.org)

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<sup>5</sup> <https://chemtrust.org/synthetic-chemicals-body/>