

## Report

**Event:** **2<sup>nd</sup> German PARC Stakeholder Dialogue:**

**Risk assessment of chemical mixtures**

PARC and stakeholders in dialog –

It's the mix that matters!

November 27, 2024 (1-5.30 p.m.)

Hybrid event

**Venue:** **Konferenzzentrum (KOM27) Mauerstraße 27, 10117 Berlin**

**Further information:** The program and presentations (in German) are available for viewing and downloading in the event [archive](#).

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### I. Background and objectives of the 2nd German PARC Stakeholder Dialogue

Tewes Tralau (Federal Institute for Risk Assessment, BfR) and Claudia Röhl (Federal Environment Agency, UBA) opened the 2<sup>nd</sup> German PARC Stakeholder Dialogue at the Konferenzzentrum in Berlin. In their role as representatives of the German signatory institutions in the Grant Signatory Board of the European Partnership for the Assessment of Risks from Chemicals (PARC), they warmly welcomed the participants on-site and online. Within PARC, BfR and UBA have co-leadership functions in the work packages “Monitoring and exposure” and “Hazard assessment” as well as in the task “Knowledge management and uptake into policy” and thus provide important impulses for the future risk assessment of chemicals in Europe. With the implementation of this dialog, BfR and UBA aimed at facilitating an exchange with stakeholders that addressed a topic of high relevance for both human and environmental toxicology within the field of risk assessment of chemical mixtures. In addition to the exchange, the discussion intended to enable stakeholders to present their own perspectives and provide important impetus for PARC. The speakers' keynote speeches and the program are available in German in the event [archive](#) (German).

### II. Final discussion with stakeholders

Due to the wide range of participating stakeholders, numerous aspects from various areas were addressed in the discussion. One of these aspects concerned the lengthy processes in the risk assessment of chemicals and the question of how these could be shortened, using the example of

aspartame<sup>1</sup>. Longer risk assessment processes are indeed a problem, which is mainly due to capacity factors. Regulatory procedures are also always integrated into legal procedures, which must follow legally defined processes and comply with defined minimum requirements. These processes take time, which also affects regulatory authorities. In these complicated procedures, however, companies must also be given appropriate time and deadlines in order to be able to react adequately. It was also discussed that regulatory procedures, despite their necessary legal framework, should be made more efficient, for example by the industry providing relevant data at an earlier stage.



Source: Sara Graetz/ BfR

BfR and UBA hosted the 2<sup>nd</sup> German PARC Stakeholder Dialogue in Berlin on November 27, 2024, which was attended by a broad spectrum of representatives from science, regulatory authorities, NGOs and industry.

It was also discussed how results from PARC can be incorporated into the regulatory system and what efforts have been made to date within the partnership. The work package “Innovation in regulatory risk assessment” is working on driving innovation in regulatory risk assessment, in particular by strengthening the scientific basis for this. This work package is primarily dedicated to the implementation of PARC results in regulatory risk assessment methods and their review.

During the final discussion, the Mixture Assessment Factor (MAF) was one of the most prominent discussion points, which was addressed several times by stakeholders. Aspects of the controversial discussion on the application of a “silo-dependent MAF” or a “generic MAF” were addressed, which may not have received sufficient attention. While some stakeholders were in favour of the MAF as a sensible precautionary instrument, others pointed out possible unintended consequences, e.g., the loss of important biocides. One proposal from the plenary session was to initially introduce the MAF

<sup>1</sup> Information about the risk assessment of sweeteners in food - Selected questions and answers (BfR FAQ, 14 July 2023): <https://www.bfr.bund.de/cm/349/sweeteners-in-food-selected-questions-and-answers.pdf>

as an indicator or alarm signal in order to make risks visible without directly enforcing regulatory consequences. Some stakeholders critically questioned whether the existing individual substance assessments offer sufficient protection if co-exposures from different legal areas occur in reality and are well documented by human biomonitoring (HBM). The challenge of “silo structures” in regulation was pointed out several times and the need to promote cross-sectoral approaches was emphasized. Another point of discussion was the lack of availability of reliable exposure data, particularly for air, indoor spaces and persistent substances. Stakeholders called for more transparency and early publication of exposure data by the industry as well as a strengthening of monitoring - also with regard to sensitive groups such as children or workers with increased exposure. In addition, some stakeholders criticized the risk assessment of mixtures under the European REACH regulation (REACH: Registration, Evaluation, Authorization and Restriction of Chemicals) as inadequate. This criticism was not supported by some of the regulators present. However, there was agreement that REACH processes do indeed take a lot of time. As a European partnership, PARC is neither a legislative body nor is it able to make regulatory or political decisions. PARC is intended to support regulation by providing scientific data and filling knowledge gaps required for regulation.



Source: Sara Graetz/ BfR

The 2<sup>nd</sup> German PARC Stakeholder Dialogue highlighted the current scientific status of risk assessment of chemical mixtures and the regulatory context from both the human and the environmental toxicology perspective.

PARC can only make recommendations that could be implemented through regulation. The aspect of sustainability is therefore of particular importance in PARC and is specifically addressed in the task area “Sustainability and exit strategy”, as part of the work package “A common science-policy agenda”. This task area is responsible for developing a strategy for measures that extend beyond the term of PARC.

The discussion showed that PARC plays a central role as a mediator between science and regulation. However, it was also emphasized that the translation of scientific findings into practicable policy measures still needs to be improved. In particular, greater cooperation between authorities, science, industry and civil society was called for in order to develop realistic, accepted solutions.

Furthermore, the distinction between scientific results and political aspects is important. The latter concern management and are therefore outside the scope and tasks of PARC. However, it is certainly one of PARC's tasks to initiate dialogs between the scientific and the management or political level. In their work on the European Commission's "Roadmap to phasing out animal testing in chemical safety assessment", BfR and UBA are involved in the development of concrete strategies for the introduction of Next Generation Risk Assessment (NGRA) into European chemicals regulation and are also actively involving stakeholders.



Source: Sara Graetz/ BfR

Representatives of human and environmental toxicology as well as consumer and environmental protection discussed the basics, challenges and possibilities of risk assessment of chemical mixtures with project participants from BfR and UBA.

In their closing remarks, Tewes Tralau and Marike Kolossa-Gehring thanked all participants for their valuable contributions during the lively and constructive discussion. PARC reveals gaps and which key challenges exist for the risk assessment of chemical mixtures. PARC is well on its way to significantly shaping the future of risk assessment in the 21st century and is making important contributions to scientific policy advice.



An overview of PARC and the German activities can be found on the [BfR](#) and [UBA](#) websites as well as in the flyer and in the [overview article](#) (German).

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