Design of the impact study

The impact study is intended to investigate ultrafine particles' potential impacts on health. In advance of the tender to conduct the impact study, a study design was commissioned which would translate the questions formulated by the FFR into scientific methods and approaches.
The following work packages are planned in the design study:

WP 1 Literature search: evaluation and classification of current epidemiological, toxicological and other environmental medical studies

- **Question:** "Does exposure to ultrafine particles increase the risk of health problems and specific diseases in the general public, and among the workforce?"
- **Objective:** to compile and evaluate the current knowledge concerning epidemiological, toxicological and other environment medical studies of UFP, so that a causal model of the effects of UFP can be devised.
- **Hypothesis formulation and development of a causal model**
- Developing a **model** of the effects of UFP on human health based on own hypotheses →which population groups, which specific exposures (e.g. cumulative UFP exposure, UFP peaks) and which specific outcomes (e.g. respiratory, immunological, cardiovascular and metabolic diseases, cognitive health) can be investigated?

WP 2 Preparation of brief profiles for different possible study modules

Based on the results from WP 1, at least five brief profiles will be prepared in the areas of epidemiology and toxicology.
Core information to be included in the profiles:

- Elements of the causal model (end points and mechanisms of action) and of the design (method, population investigated, number of participants, etc., power estimate, procedure)
- Possible statements about methodological risks

- Transferability of the results to the overall population or to certain groups
- Options for attributing impacts to specific sources / necessary UFP exposure data and possibly additional data
- Estimated costs and time needed to complete the module.

WP 3 Requirements for measuring and modelling UFP exposure

Descriptions of the suitable exposure models relating to the study models presented for consideration

- Important metrics in connection with UFP are the number size distribution, the specific surface area, the concentrations of volatile and non-volatile UFP, the oxidation potential and certain components of dust.

WP 4 Prioritising elements of the study design using the module profiles

Selection of two to four study modules at a workshop

- **Interim stop:** involvement of the FFR, SQA (scientific quality assurance), the exposure study consortium, (regional) experts / stakeholders
- The **Konvent** will be involved at the preparatory stage: presentation of the status reached in March

WP 5 Elaborating details of the design and reflection

- Addition of more detail and depth to the design description
- Continuation of the iterative process and finalisation at another expert workshop

WP 6 Proposals for scientific study management and synthesis of results

Preparation of a proposal for the overall study management that has to assume various tasks in organisation and coordination of the subject matter (also with the FFR).

WP 7 Proposals for data management

The conceptual design will include the following points:

- Data protection and obligation to inform
- Central data storage and linking
- Quality control
- Data storage and archiving
- Data access management and documentation.

WP 8 Reporting

The final design developed for the impact study with the modules “exposure” and “impact” will be presented in the FFR’s bodies following approval from the SQA.

The design of the UFP impact study will be prepared in close cooperation with the consortium commissioned to carry out the UFP exposure study.