

ERA-NET SIINN
Safe Implementation of Innovative
Nanoscience and Nanotechnology



Deliverable D3.3

Health Data Selection

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Introduction

Part of ERA-Net SIINNs WP3 is to perform “Validation of evidence-based risk assessment for human health” (Task 3.2).

According to the projects Description of Work,

“The objective of this task is to critically evaluate the available safety and toxicological data for NMs with respect to their suitability for performing an assessment of NM risks to human health and to thus identify areas requiring further research (to be used as input for Task 3.4).”

Furthermore, “Consideration will be paid to information regarding exposures and exposure pathways, hazard identifications and mode of action studies. This task will thus focus on:

- The selection and evaluation of individual pieces of information,
- Risk assessment overviews based on all available information,
 - Exposure assessment (exposure of general public as well as occupational exposure),
 - Hazard assessment (animal studies, in vitro studies, human studies),
 - Mode of action assessment.”

“The acceptability of data for the purpose of risk assessment will rely on the data’s:

- i) Relevance,
- ii) Validity, quality and reliability. This includes the evaluation of data in terms of inherent quality, to what degree the experimental procedures have been validated, and whether or not the findings are reproducible between experiments (deliverable D3.3).”

In other words, in order to be able to evaluate if the publicly available data body is appropriate for the different facets of risk assessment, as well as for identifying data gaps that are the foundation for the Call Topics in the SIINN Calls, an appropriate collection of data has to be built up. This data collection is the backbone for all the work performed in Tasks 3.2 and 3.4.

The process of building up and maintaining the data collection, the considerations in selection of individual pieces of data, and an index of part of the data collection (Annex; references obtained from PubMed using specific search criteria) are presented in this deliverable.

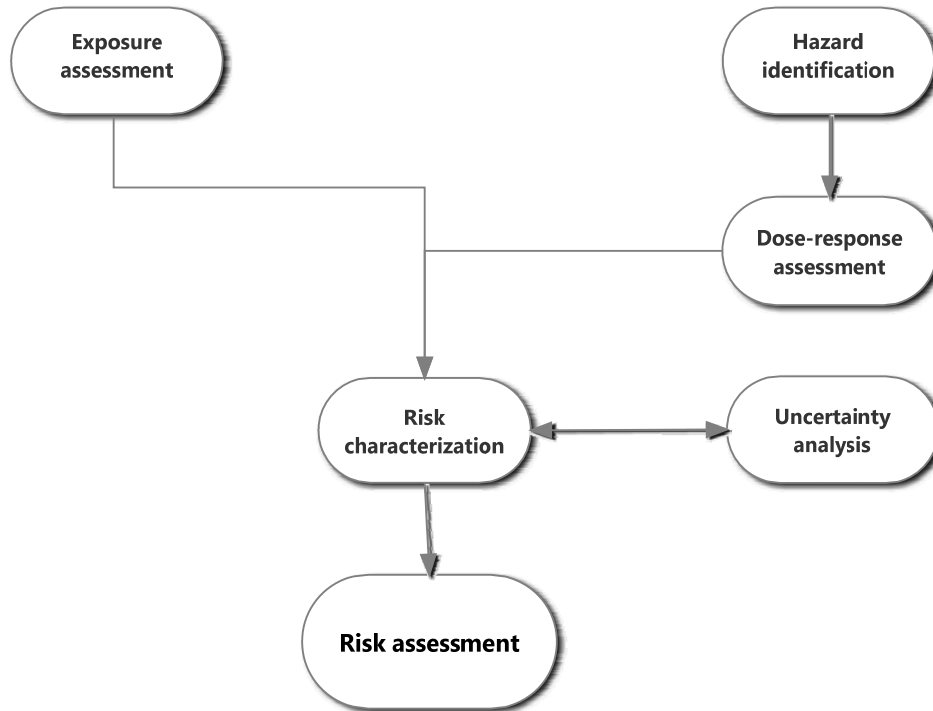
Risk assessment requirements

The key driver for the health data selection and subsequent data collection is the usefulness of the data for risk assessment. The purpose of risk assessment is to provide risk managers (authorities, health and safety personnel etc.) with a science-based foundation for decision making in management of agents possibly affecting health and environment.

The principal stages of risk assessment are depicted in the flow chart below and can be summarized as follows:

- Hazard identification
- Examination of dose-response relationships (hazard characterization)

- Exposure assessment
- To highlight uncertainties in the determination of hazards and dose-response relationships
- To evaluate possible modes (mechanisms) of actions for the hazard of concern.



Accordingly, the data that has been searched for is selected on the basis of suitability for the different aspects of risk assessment.

Data sources for risk assessment

The data used for the task has been searched for and collected continuously during the entire period of the project. Typically, publicly available data bases (PubMed, Chemical Abstracts, Biological Abstracts) have been searched on a regular basis. A number of different keywords have been regularly used during the period 2010-2015. Appropriate data pieces have then been collected and evaluated for the usefulness for the task at hand.

Information has been obtained primarily from original research papers published in international peer-reviewed scientific journals in the English language (with some exceptions of papers published in German or Swedish). This includes meta-analyses and reviews when deemed appropriate. Additional sources of information have also been considered, including web-based information retrieval, and documents from Governmental bodies and authorities.

Quality criteria for health data selection

Not all pieces of data were found to be appropriate for the purpose of the task. In contrast, a large amount of the initially identified studies are either lacking in quality or not useful because of other reasons, such as a focus of the study that did not correspond to the different aspects of risk assessment.

The table below summarizes the different criteria that need to be fulfilled for a study to be useful. Note that there are different types of studies that may have a bearing on the overall purpose.

- "Epidem." stands for epidemiological studies, which can be of different types, such as ecological, case-control, or cohort studies.
- Clinical studies are studies performed on individual subjects (healthy or diseased) under strictly controlled conditions.
- *In vivo* studies refer in this case mainly to experiments done on rodents. There are also occasional studies employing non-mammalian species.
- *In vitro* studies are performed on animal cells in culture, most commonly from mammalian tissues (normal or neoplastic).
- *In silico* studies are modelling and simulation studies using appropriate computer software. Also certain statistical studies belong in this category.

Regarding the different parameters listed in the table, the "devil is in the details". The usefulness of an article is mostly not possible to estimate unless the noted categories are investigated in detail.

- Exposure refers to the identification of the ENM and its amount and duration.
- Dosimetry partially overlaps exposure (amount, such as mass or concentration) may be a dose metric as well, but the dosimetry also includes other physical-chemical parameters and also tissue distribution, kinetics etc.
- The biological model should be appropriate for the study objective, and/or the hypothesis.
- The endpoint should be relevant for the study objective and furthermore investigated with the most appropriate experimental approach
- The statistical approach should be adequately chosen, taking into account parameters such as power and sample size. Also replication number, independent experiments, and replicability belong in this category.
- Blinding procedures are necessary for avoiding subject and/or experimenter bias. For clinical studies, anything less than a "double blind" study is inadequate.

- Necessary controls, both positive and negative, are needed to be included to validate the approach the obtained results. Also historical data can be useful to put data into perspective, but cannot replace controls.

Study type	Exposure	Dosimetry	Biol. model	End-point	Statistics	Blinding	Controls
Epidem.	X			X	X		
Clinical	X	X		X	X	X	X
<i>In vivo</i>	X	X	X	X	X	X	X
<i>In vitro</i>	X	X	X	X	X	X	X
<i>In silico</i>	X	X	X	X	X		

Annex 1. Sample data collection for the period 1985-2015.

This particular collection is based on monthly searches on PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) using the search terms

nanomaterial OR nanoparticle AND inflammation OR inflammatory marker.

The collection is not edited or adjusted according to quality criteria, but represent the collection in its "raw" form.

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