T1.6 Verification of mutually accepted tools to ensure availability of high quality data

Questionnaire on verification of tools (i.e., methods) for high quality, mutually accepted data

This questionnaire refers to two concepts which are relevant for those using data for regulatory/risk assessment purposes (whether scientific/(nano) ecotoxicological data or other types of relevant data):

- **Data quality:** this may be understood as the extent to which any type of data (e.g., toxicological, exposure, trade, employment) are "fit-for-purpose," i.e., suitable for a specific aim/purpose. Data quality may be considered to encompass:
  - completeness: the extent to which data comply with regulatory requirements, e.g., the availability of complete and relevant physicochemical characterization data of test nanomaterial(s) and extent to which the experimental set-up and methods are described and validated,
  - relevance: suitability/appropriateness of data for a given purpose, and
  - reliability: inherent quality of the data independent of the context, e.g., the quality and consistency of the design, performance, and analysis of the experimental work.
- **Mutual acceptance of data (MAD):** the MAD is a system developed by the OECD for harmonizing national approaches to *chemical (including nanomaterial) testing and regulation* to reduce conflicting and duplicative requirements and decrease barriers to trade.
  - What this signifies: studies which are 'MAD-compliant' are conducted according to OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP).
  - For whom it is important and why: For those involved in government/regulatory risk assessment and decision-making, MAD-compliant data are considered the gold standard for data and therefore of high quality. Consequently, all scientific (e.g., toxicological, exposure) data used for these purposes, ideally, are MAD-compliant or fulfill similar standards of quality.

Intended audience for the questionnaire: all actors involved, whether directly or indirectly, in nanomaterial regulatory risk assessment.

Purpose of the questionnaire: To understand the varied viewpoints of different stakeholders (spanning from scientists and regulators to members of civil society) on data quality and its role in regulatory risk assessment and decision-making. This issue is relevant since the quality of data used for risk assessment considerably affects risk management and risk governance. In other words, poor data quality may mean that risk management practices have to be altered in order to account for more unknowns in the risk of a given material (e.g., this could translate into the introduction of more protective measures during the production process). If data quality is unaccounted for and necessary precautions are not taken, the use of a given nanomaterial may then present an unnecessarily high risk to public health. The results of this questionnaire are ultimately intended to assist in the creation of a new nanorisk governance framework (NRGF) which will be based on the understanding that a multi-stakeholder approach is needed to provide new data, tools, and guidance to adequately

match the complexity associated with nanotechnology and particular stakeholder needs, interests, and perceptions.

Data Quality and EU regulation

Within the existing EU regulatory framework, (nanomaterial) data quality is considered in terms of adequacy (i.e., the general suitability of data for risk assessment purposes), relevance (i.e., suitability of data for a specific hazard identification or risk characterization), and reliability (i.e., the innate quality of the data). In existing regulatory practice, Klimisch scoring[1] is used to assess data reliability, and an overall weight of evidence (WoE) approach[2] or scoring system is used to rank overall study quality according to the best judgment of the assessor.

This questionnaire is unique from other recent project questionnaires in that the main focus is on data quality within the context of nanomaterial risk assessment, regulation, and governance that takes into account multi-stakeholder participation.

1) What is the name of your organization?

Women Engage for a Common Future / Wecf France

2) What sector are you involved in?
   a. Academia/research
   b. Consulting
   c. Industry
   d. Government/regulatory
   e. Civil society organization (CSO)
   f. End user/civilian

3) What is your involvement in risk assessment?

   a. I am a regulator and perform risk assessments
   b. I work for a government agency and am involved in the risk assessment process, even if I do not directly perform them
   c. I work for the insurance or consultant industries and perform risk assessments
   d. I work for the insurance or consultant industries and am familiar with risk assessments
   e. I am a scientist/technologist and I believe my results (generated knowledge) could support risk assessment

[1] Klimisch scoring is used to assess the quality (reliability) of toxicological studies, serving as a foundation for most other data quality assessment methods. Studies are scored on a scale from 1 (reliable without restriction) to 4 (not assignable), with emphasis placed on whether experimental guidelines (e.g., OECD) and internationally-accepted test procedures are followed.

[2] Data quality may be weighted, for example, by expressing data quality as a percentage of total points obtained, which may then be compared against a scoring categorization scheme to assign a quality grade/ranking.

f. I work in industry and am responsible for workplace risk assessment and evaluation
g. I am a worker's representative responsible for a safe workplace
h. I work in a civil society organization (CSO) critically following emerging materials in society
i. I understand what risk assessments are but do not perform them
j. I have only a slight knowledge of the risk assessment process and do not perform them
k. Other

4) How do you obtain information about risk?
   a. Scientific literature
   b. Purchased company reports/assessments
   c. In-house experts
   d. Other (please explain below)

Reports/publications from official bodies: national (Anses, DGCCRF, etc.) / EU (ECHA, EFSA, EEA, etc.) / International bodies (UNEP, WHO, etc.) and other reports released by stakeholders including other CSOs on risks

5) How do you or others at your organization make judgements about risk for a particular material/substance?

Very hard question to answer, we are not ourselves "judges".

We consider the existing literature, its robustness, its relevance, etc. and as well follow a "precautionary approach" in our statements/positions. We work in network with other CSOs and exchange information.

For instance, if only 1 study reflects on critical risks for pregnant women/unborn child/newborns, this is for us a warning, and we would ask urgently for more investigation and for a phasing-out of the said substance/product which safety is questioned, to ensure protection of the most vulnerable, and prevent consequences on human health.

6) Would you consider/accept data that were not produced under MAD conditions (not strictly following GLP or OECD Test Guidelines, but other scientific standards), but which are determined to be of high quality by a rigorous test and data quality assessment method?
   a. Yes because if the quality + rigor + robustness is there, why should it be ignored? Science/tests methods/etc. have to evolve, to evaluate effects of pollutants on certain endpoints, as illustrated by the debate on endocrine disruptors. Nanomaterials are part of this approach.
   b. No
   c. No opinion

7) **In your opinion, is the use of a comprehensive data quality assessment scheme (i.e., a tool or scheme designed to assess a study or data in detail) a necessary component for overall transparency in the risk assessment process?**
   a. Yes
   b. No
   c. No opinion

8) **Do you believe that more guidance or other changes are needed within the current EU nanomaterial regulatory framework to account for data incompleteness and uncertainties? If yes, what would you recommend, and how do you currently deal with data incompleteness/uncertainty?**
   a. Yes
   b. No
   c. No opinion

Improvements are always possible, and in the case of nanomaterials, several issues have to be addressed, including that of the definition. Refer to other NGOs working especially on the "nano" issues to get more precise insights on this point.

9) **Please add any additional comments you feel may be relevant.**

3 points :

1) **the funding issue**: **public research funding?** Many public research bodies reflect poor funding/uncertainties issues. Continuity of research. Private funding can mean that the research is oriented and biases may exist. As well, the FAIR principle for data is not always respected, preventing risk assessors to get information and use it.
2) **The amount of money spent in research projects vs investment in actions to prevent/protect health of populations/ecosystems** – how much is the Commission spending in primary prevention actions?
3) The gender dimension : how women's health/pregnancy is considered or not in research on adverse effects of chemicals/nanomaterials + generally impacts on women's health poorly addressed in research programmes.