DELIVERABLE No.	**D1.3**
DELIVERABLE TITLE	**Defining criteria to assess data quality and completeness based on MAD**
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Executive Summary

The aim of D1.3 is to address and elaborate criteria for data quality and completeness that can be used for regulatory risk assessment and decision-making based on MAD. Assessing and assuring data quality and completeness is an essential component of regulatory risk assessment and decision-making based on the mutual acceptance of data (MAD) as well as for the successful creation of an effective nanorisk governance framework within the context of NANORIGO and the other NMBP-13 projects. Evaluating toxicological data for quality (which is generally defined to encompass multiple dimensions such as reliability, relevance [fit-for-purpose], and completeness) is a fundamental component of nanomaterial risk assessment that presents a massive and on-going challenge for regulatory decision-makers (The ProSafe Project Office, 2017). The term 'data quality' is also problematic because no standard definition (i.e., denotation) currently exists. Within a nanomaterial risk governance framework, data quality is a critical component for the **mutual acceptance of data (MAD)** principle. The MAD is a system developed by the Organization for Economic Co-operation and Development (OECD) for harmonizing national approaches to chemical testing and regulation to reduce conflicting and duplicative requirements and decrease barriers to trade. However, MAD-compliant studies must adhere to OECD Test Guidelines for the Testing of Chemicals and OECD Principles of Good Laboratory Practice (GLP), both of which present large costs to the producers of data (OECD, 2019a). Frameworks and guidelines are therefore needed to accurately assess data quality and fitness for purpose so that appropriate data from non-guideline, non-GLP studies can still be used.

Given the importance of data quality for regulatory risk assessment and for the professionals involved in these activities (i.e., data producers, such as scientists or material manufacturers, and data users, such as risk assessors, modellers, and decision-makers), an overview and comparative evaluation of existing data quality assessment methods which are relevant to (nano)ecotoxicity studies (as an example) and of tools and approaches for the inclusion of no-effect data was completed along with recommendations for the assessment of data quality and completeness based on the needs and aims of the NANORIGO project and its users, as summarized in Table 1.

Table 1: Summary of evaluated quality assessment methods and their suitability for NANORIGO along with additional criteria which have been recommened for use with the SciRAP checklists.

Quality assessment methods highly recommended for NANORIGO	Quality assessment methods recommended for NANORIGO (some updates needed)	Quality assessment methods not recommended for NANORIGO
• SciRAP • GUIDEnano • caLIBRAte • NANOcred • DaNa	• Klimisch • ToxRTool • Card and Magnuson • ECHA for REACH	• Durda and Preziosi • Langdon et al. • CRED • Lubinski et al. • NANoREG • CaNanoLab • MOD-ENP-TOX (not yet publicly available • MIAN • NKI • Simkó et al. • Hristozov et al. • U.S. EPA (methods for environmental data and ECOTOX literature)
Additional recommended criteria with the use of SciRAP checklists		
• Inclusion of all metadata associated with the measurement of physicochemical parameters (i.e., techniques and sample preparation methods used) • Have relevant potential nanomaterial transformations been investigated and accounted for (as elaborated in the OECD report: *Physical-Chemical Decision Framework to Inform Decisions for Risk Assessment of Manufactured Nanomaterials (2019b)*)? • Has the dispersion of the nanomaterials in the stock test solution been investigated prior to testing? • Have the methods used for acquiring physicochemical data been validated in any way so as to be repeatable, reproducible, etc.? • Has the nanomaterial exposure/spiking procedure been described (to be distinguished from preparation of a nanomaterial dispersion or other sample preparation)?		

The results of D1.3 emphasize that 'data quality' remains an open concept that is highly defined by context or 'fitness for purpose.' For this reason, we recommend that 'fitness for purpose' should be used in place of the term 'data quality,' since data may still be usable for regulatory risk assessment without adherence to MAD criteria. For NANORIGO, we specifically recommend the use of the SciRAP checklists with some minor adjustments that reflect the most recent available guidance. After a critical evaluation of the gathered data quality assessment methods, we also recommend the use of the GUIDEnano, caLIBRAte, NANOcred, and DaNa methods due to their focus on (nano)ecotoxicity data, while the Klimisch, ToxRTool,

Card and Magnuson, and ECHA methods might also be used, although they are not as up-to-date as needed (especifically in the case of REACH, the use of Klimisch scoring to assess reliability is not as up-to-date as it could be).

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