Inception report with recommendations for a network of FAIR nanoEHS databases

Introduction

In support of the establishment of a **Nano Risk Governance Council (NRGC),** an **Inception Report** has been prepared (**D1.1**), outlining the steps required to successfully launch and develop a **GO FAIR**-compliant **Implementation Network (IN)** called the **AdvancedNano IN**, which will assist the science-based risk governance of manufactured nanomaterials (MNMs) and other advanced material formulations, including the elucidation of the mode of action, grouping, read-across, development of quantitative structure-activity relationships, and Safe-by-Design aspects of nano and advanced material production and use. Incorporating the nanosafety data generated over a decade of research, as well as data to be generated in the future, into a FAIR-compliant network of participating stakeholders, related experts, and NanoEHS data resources will help to enhance access to quality, curated, and validated data. Our starting point **is eNanoMapper**, a FAIR-compliant data repository, incorporating standardised data templates and open metadata standards, which contains an inventory of established NanoEHS databases sourced from several EU-funded projects (NanoReg2, caLIBRATe, NanoCommons, and GRACIOUS).and a few select, internationally-established databases (CEINT NIKC, NECID). The FAIR data principles: **Findable, Accessible, Interoperable and Re-usable (FAIR),** are the foundation-stone of the **European Open Science Cloud (EOSC),** a virtual environment for open and seamless services for the storage, management, analysis and re-use of research data, which allows for the maximum in data usability across multiple domains in science and the public interest. At the same time, the AdvancedNano IN will provide for the accessibility of such data to be controlled as per the desires of the generator and/or owner of the data. FAIR-compliant datasets will support science-based data evaluation, which in turn will greatly enhance the ability of the NRGC to evaluate, make assessments, and manage the risks of nano and advanced material formulations as they play an increasingly important role in many domains. The aim of the **Inception Report** (**D1.1**) is to: 1) present the FAIR principles and their landscape, 2) describe the initiation of the **AdvancedNano IN**, and 3) to explain how the implementation of the FAIR principles for NanoEHS data will be advanced in WP 1 of Gov4Nano.

Description of Work

An Inception Report and accompanying manifesto has been developed for the launch, and further development of the **AdvancedNano IN**, the first GO FAIR-compliant network of FAIR nanoEHS databases, for the co-ordination, dissemination, evaluation, and analysis of data related to the potential risks posed by nano and advanced materials and nano-enabled products. A complete synopsis of the IN and the basis upon which it is developed can be found within the **D1.1. Inception report**, which focuses on the main organisational aspects of the IN. Briefly, resources will be co-ordinated through a series of interactions between data producers, scientists, regulators, industry specialists, and citizen participation in nano and advanced materials, with an interest in the potential risks of nano and advanced materials to human health and the environment. Our starting point for the IN, with respect to datasets and infrastructure, will be the eNanoMapper database as a first example of a FAIR data-compliant data warehousing and retrieval database with an extensible and robust set of ontologies. Through the **AdvancedNano IN**, the Gov4Nano consortium aims to help with data integration; in conjunction with other EU Horizon 2020 projects such as **NanoCommons, NANORIGO, RiskGONE, NanoinformaTIX, NanoSolveIT** and others (see **Table 2 and Annex II of D 1.1** for details). Early efforts in the development of the IN will be focussed on the goal of an interoperable database infrastructure with reference to the **Joint Milestone 2** of the projects **NANORIGO**, **RiskGONE**, and **Gov4Nano**, wherein we will make a priority list of which databases to make interoperable.

Main Results

In order to move towards an open, comprehensive, and scientifically based risk governance of nano and advanced materials, a framework for the creation of an interoperable network of FAIR-compliant NanoEHS databases, which contain validated and curated data, has been developed. The key outcome of this Inception Report is the launch of the **AdvancedNano IN**, a collection of NanoEHS databases, experts and stakeholders who wish to provide, collate, curate, validate, and further evaluate and analyse all available data pertaining to the risk assessment of nano and advanced materials to human and environmental health. The basic structure of the IN, including it's relationship to the NRGC, is illustrated in Figure 1, including, eNanoMapper, data warehouses such as NanoCommons, NanoSolveIT, and NanoInformaTIX, the FDOF and the EOSC. Lessons learned and future directions in the

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development of the **AdvancedNano GO FAIR IN** for **Gov4Nano** are available in the full public version of **Deliverable 1.1**. They include:

- **The need for stakeholder engagement in the development of an open GOFAIR-compliant data environment.**
- **An outline of the steps required for the development of a FAIR data community within the domain of nano and advanced material safety research.**
- **A framework for stakeholder (research, regulation, governance and civil society) participation in the dissemination, evaluation, and analysis of NanoEHS data. This framework integrates the process of the use of NanoEHS data, from its generation, dissemination, curation, and evaluation by an NRGC.**

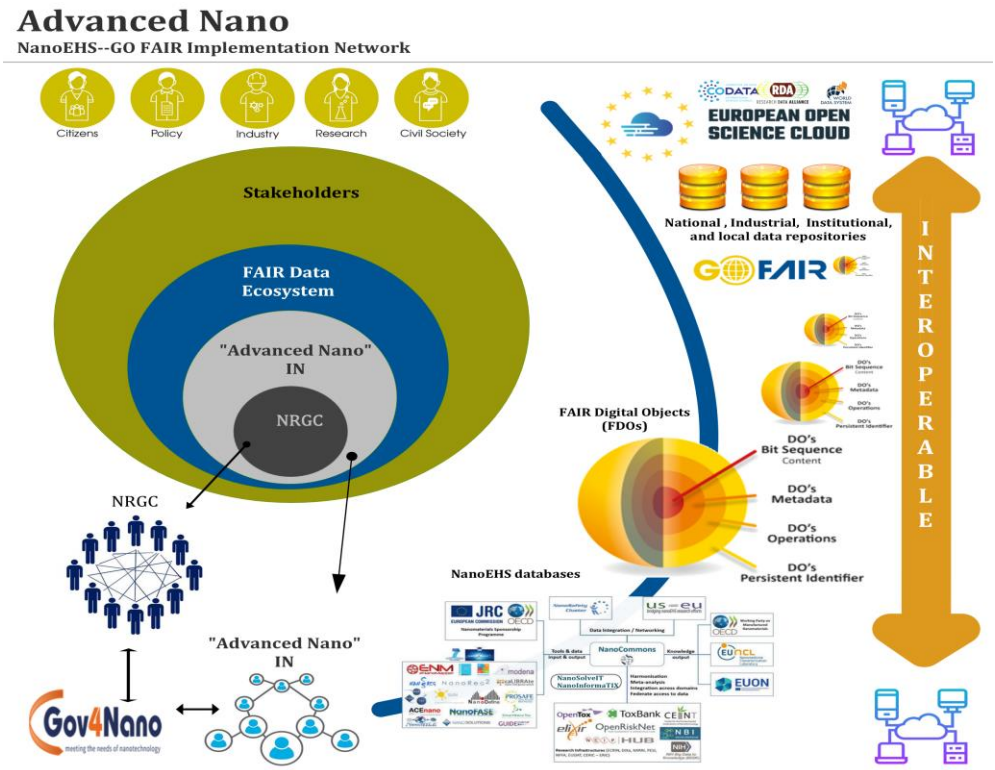

Figure 1: **Key players/institutions in the domain of FAIR nanoEHS and their relationships.**

Conclusions

We have prepared an **Inception Report, D 1.1 (WP1),** outlining the necessary steps for the development of the **AdvancedNano IN**. Further work on the IN within Gov4Nano: Task 1.1 stakeholder network development; Task 1.2 Persistent identifiers; Task 1.3 Electronic Laboratory Notebooks (ELNs); Task 1.4 Re-use of: 'omics data, ecotoxicological data, NanoReg2 genotoxicity data, and NECID exposure data. The Implementation Network is a central pillar in the development of a Nano Risk Governance Council (**NRGC**) for nanotechnologies and advanced material formulations (**WP5**), ensuring effective stakeholder engagements (**WP3**) and developing future monitoring schemes for the Risk Governance Council (**WP7**). These aspects were compared with the mandates of key European institutions, to evaluate the positioning of the **NRGC** in the context of EU policy development.

*EHS: Environmental, Health and Safety
•IN: Implementation Network
*FAIR: Findable, Accessible, Interoperable and Re-usable
*NRGC: Nano Risk Governance Council.
*NanoEHS: Nano Health and Safety Data
* FDOF: FAIR Digital Object Framework

For more details about the Gov4Nano project please visit the Gov4Nano website. Public deliverables will be made available in due time via this website.