	Executive summary D2.2
DELIVERABLE TITLE	**Options for the harmonisation of existing international standards**
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D2.2 Options for the harmonisation of existing international standards

This deliverable aims to analyse options for the harmonisation of the NANORIGO Risk Governance Framework (NRGF) with existing regulatory frameworks and international standards and guidelines for risk assessment. The deliverable reviews terminology and definitions of risk, specifically in the context of chemical safety regulation in the EU. Moreover, key parameters of regulatory risk assessment in chemical safety and nanotechnologies are identified based on an overview of regulatory guidance for risk assessment of chemicals and MNMs in different countries. The deliverable also examines approaches for risk evaluation and management under the circumstances of uncertainty regarding the influencing aspects of risk, in particular the hazard potential of certain nanomaterials.

The intended use of a new nano-materials is generally considered beneficial in exploiting their superior technical, economic, and functional performance. However, there is reason to assume that the nanoform of solid-state materials (so-called nano-objects) may pose hazards that are not present in the bulk form of the same substance. Thus far, there is scientific uncertainty regarding the nature and the extent of the hazards of nano-materials as well as regarding possible pathways of exposure. Therefore, the risk governance of nanotechnologies is challenged by deficits in available hazard relevant data as well as difficult interpretation of existing data.

In contrast, the risks-factors are usually tangible, as for normal chemicals or materials, that is: the hazards can principally be identified (tested) and described by a dose-response model. The established regulatory approaches for chemical risk assessment and occupational / environmental health protection are designed to cope with such tangible risk aspects but it is inadequate to cope with nano-specific uncertainty. The REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) is the cornerstone of EU chemicals legislation. It regulates the use of certain chemicals that may be harmful to human health or the environment. Therefore, in order to ensure a high level of safety, there is a need to complement the chemical risk assessment approaches based on REACH with a risk governance framework that addresses the specific risk aspects of nanotechnologies and takes into account the prevailing uncertainties. This deliverable 2.2 reviews options for the harmonisation of the NanoRigo RGF to be developed with existing European regulatory frameworks and international standards for the risk assessment of chemicals and materials.

D2.2 focuses on the following aspects of risk governance that are most relevant for harmonisation with pre-existing regulatory frameworks and standards:

- Terminology and definitions of risk, specifically in the context of chemical safety

- Identification of key parameters of regulatory risk assessment in the field of chemical safety and nanotechnologies.

- Approaches for risk evaluation and management under the circumstances of uncertainty regarding the influencing aspects of risk, in particular, hazard potential of certain nanomaterials.

- Overview of regulatory guidance for risk assessment of chemicals and MNMs in different countries.

A review of terminology. Definitions and concepts of the term risk is provided as a contribution to the adequate use of terminologies used by the RGF. Since there are several disciplinary approaches to determine the meaning of risk, which are somewhat ambiguous when discussed in a bigger interdisciplinary setting, the deliverable reviews the disciplinary definitions of risk and recommends a definition that can be useful for the risk governance of nanotechnologies. The following concepts of risks are taken into account:

- In technical and chemical risk assessments, risk values are calculated by the formula probability (of occurrence of a negative event) * expected loss (or impact) by this event or a triple function: f (event, probability, consequence).

- Other approaches use the terms hazard potential and exposure for calculating risk.

- Uncertainty refers to not knowing exactly the (adverse or positive) outcome of certain events or interventions. However, uncertainty can exist due to a lack of knowledge or if knowledge is too fragmented. Uncertainty is usually expressed by probabilities. However, a probability-based approach yields problems in new or emerging risks, for instance, due to new technologies, when no past events or experience can be derived to base probabilities on and knowledge about long-term behaviour of substances is too scarce.

- Regarding risk perception - 'measuring risk' yields results different from what lay people (i.e. potential consumers of nano-products) perceive.

- A Socio-economic definition of risk as "the effect of uncertainty on objectives" considers the uncertainty of a risk aspect in relation to the expected outcome of an activity (i.e. the use of nano-technologies). The intended goal of actions is described by its objectives and refers to the desired outcome of innovations in the area of nanotechnologies. Objectives are actor-specific and can differ widely among actors, stakeholders, bystanders, regulators, and society. In the context of regulatory risk governance, the overarching objective should be to protect safeguarded subjects, namely human health and the environment, from harm. Hence, the **risks can be regarded as a possible deviation from the objective to keep harmful impacts away from humans and natural organisms.**

- The precautionary principle is recommended in order to avoid both extremes of decision-making results, A) lock-in effect in a trajectory of action that produces undesired effects and B) paralysis-by-analysis, which hampers the progress of innovation as well as the implementation of safeguard measures.

The D2.2 also reviews several frameworks for governing the risks of nanotechnologies, that have been developed and proposed by various scholars. A participatory and deliberative procedure is

recommended, starting a wider societal debate on nanomaterials, objectives, and governance modes. In the EU context, the RGF must be consistent with and, at best, embedded in existing regulatory risk assessment frameworks and should be aligned with the legislative implementation assigned to the competent authorities. The central pieces of EU regulation of risk assessment are the REACH regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) together with the Classification, Labelling and Packaging (CLP) Regulation (1272/2008/EC).

Other guidelines and standards, which the NanoRigo RGF should be aligned with are the guidelines developed by the OECD`s Working Party on Manufactured Nanomaterials (WPMN), which aim to “promote international co-operation in human health and environment safety related aspects of manufactured nanomaterials in order to assist their safe development.” Additionally, D2.2 provides an overview of the current status of WPMN guidelines, as well as standards, technical specifications and technical reports on various aspects of nanomaterial risk assessment published by the international and European standardization bodies ISO and CEN.

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