NANORIGO

D2.2

Options for the harmonisation of existing international standards

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Introduction

- D2.2 provides information support regarding the current status of regulatory risk assessment and risk management approaches.
- D2.2 gives recommendations for harmonising risk governance for nanotechnologies with existing European and international standards and guidelines in the broader context of chemical safety policies.
- Relevant aspects of risk governance in regard to harmonisation with pre-existing regulatory frameworks and standards:
  - Terminology and definitions of risk
  - Key parameters of regulatory risk assessment in the field of chemical safety and nano.
  - Approaches for risk evaluation and management under circumstances of uncertainty.
  - Overview of regulatory approaches for risk assessment of chemicals and MNMs in different countries.

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Terminology and definitions of risk

- Risk is defined as the impact of uncertainty on objectives

  Uncertainty = not knowing exactly the (adverse or positive) outcome of certain events (i.e. using manufactures nanomaterials in applications) due to insufficient scientific knowlede

  Regulatory **Objectives =** Safeguarding human and environmental health from harmful effects

- Risk as a Function of probability (of occurrence of a negative event) and expected loss (or impact) by this event.
- Risk as a Function of hazard potential and exposure.
- Risk as an expression of perceived threats or expected losses -> Uncertainty related to the inability of non-experts to fully understand the meaning of scientific knowledge. (not even experts claim to be able to make sense of existing risk assessment data)

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Regulatory risk governance concepts

- In regulatory toxicology, a risk is expressed as the ratio between the hazard (the severity of impacts) and exposure (a safeguard subject being subjected to a hazard).
  1) The intrinsic hazard potential of a chemical = the property of a substance to cause health or environmental damage
  2) The likelihood and extent to which organisms (including humans) are exposed to a substance
- Regulatory Risk mitigation strategies:
  1) Assessing, classifying and labeling the intrinsic hazard potential of chemicals -> REACH
  2) Reducing the likelihood of exposure of humans and the environment to a hazardous substance, by:
    - Restricting the application of a hazardous substance (i.e. REACH annex XVII)
    - Authorisation of particular uses of a hazardous substance (i.e. REACH annex XIV)
    - Substitution of less hazardous substances for hazardous ones in applications
    - Containment of hazardous substances (avoiding its release from an application)

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The risk assessment approach under REACH

1. **Human health hazard assess.** → **.. Derivation of DNEL - values**
2. **Physico-chemical properties**
3. **Environmental hazard assess.** → **.. Derivation of PNEC - values**
4. **PBT and vPvB assessment**
5. **Exposure assessment** → **Step 1: Development of exposure scenarios**
   Step 2: Exposure Estimation
   ➔PECs
   ➔Models
6. **Risk characterisation**

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- **Comparison** exposure human population – DNEL
- **Comparison** PEC – PNEC
- Assessment of other endpoints

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How to deal with uncertainties regarding the risk of Nano

- Despite a wealth of scientific risk assessment results (such as the OECD-WPNM`s extensive sponsorship programme) on manufactured nanomaterials (MNM), knowledge about their intrinsic hazard potential remains inconclusive.
- Lack of unambiguous definitions, harmonised hazard / exposure testing procedures and interpretation rules for test results.
- Nanomaterials exhibit properties, which make them different from classical chemicals and are difficult to assess by means of established risk assessment methods for chemicals -> This is one reason, why MNM are not specifically addressed under REACH and why a special risk governance structure for nano is needed.
- Hence, risk governance in nanotechnologies calls for the precautionary principle: “If future risks are highly uncertain and potential remedial measures unclear, precaution should prevail” (Treaty on the Functioning of the EU).
- Precautionary principle: Implementing measures to mitigate a risk while not waiting until full scientific evidence about the hazard and the exposure emerges

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