Horizon 2020 Work Programme for Research & Innovation 2018-2020

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NMBP Programme
Governance, Science-based Risk Assessment and Regulatory Aspects

Luca Polizzi – Industrial Technologies

DG Research & Innovation

Research and Innovation

Governance, Science-based Risk Assessment and Regulatory Aspects

Calls:

Topic: NMBP-13-2018
Risk Governance of nanotechnology (RIA)

Topic: NMBP-14-2018
Nanoinformatics: from materials models to predictive toxicology and ecotoxicology (RIA)

Topic: NMBP-15-2019
Safe by design, from science to regulation: metrics and main sectors (RIA)

European Commission

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NMBP Programme
Topic NMBP-13-2018
Risk Governance of nanotechnology (RIA)

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NMBP-13-2018: Risk Governance of nanotechnology (RIA)

Specific Objective:

- **To establish transdisciplinary risk governance based on:**
  - a clear understanding of risk,
  - its management practices and
  - the societal risk perception by all stakeholders.

- **It should propose and apply clear criteria for:**
  - risk evaluation and acceptance and
  - transfer of acceptable risk.

- **It should develop:**
  - reinforced decision making tools incorporating those aspects and
  - facilitate risk communication to relevant stakeholders, including industry, regulators, insurance companies and the general public.

NMBP-13-2018: Risk Governance of nanotechnology (RIA)

Scope:

- **Data and information management** and framework tools with regard to:
  - the safety of nanomaterials for risk assessment,
  - hazard and exposure,
  - human health,
  - environment,
  - and risk mitigation including regulatory aspects of safe-by-design;

TRL 4-6

- **Responsible communication** with:
  - stakeholders and
  - the civil society based on good quality information and valuable feedback;

RIA 100%

- **Plans for future** scientific and regulatory research paying attention to social, ethical and environmental aspects, to achieve:
  - completeness,
  - consistency,
  - maximum synergy of actions and international cooperation;

- **Mechanisms to monitor progress** in several industrial sectors and to revise plans.

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NMBP-13-2018: Risk Governance of nanotechnology (RIA)

Expected impact:

- A transparent, self-sustained and science-based **risk governance council**;

- **Governance framework tools** for managing possible nanotechnologies risks in regard to social, environmental and economic benefits;

- **Availability of high quality data** for industry and regulators decision making;

- **Sustainable solutions** demonstrated at a level that will allow both consistent integration of scientific results and regulatory application of scientifically sound concepts;

- **Consistency of science based risk management approaches** in all EU Member States and synergy with similar actions internationally**.**

International Cooperation

Integration of additional funding

Launch of specific calls

EUR around 5 million(s)

European Commission

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NMBP Programme
Topic NMBP-14-2018: Nanoinformatics: from materials models to predictive toxicology and ecotoxicology (RIA)

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NMBP-14-2018: Nanoinformatics: from materials models to predictive **toxicology** and ecotoxicology (RIA)

Specific Objective:

Despite the significant amounts of data on physico-chemical and toxicological and ecotoxicological properties of nanomaterials generated over the last decades, **detailed knowledge** on how these properties are linked to specific physico-chemical characteristics **is only beginning to emerge.**

The challenge:

to **develop and implement modern methods**, more cost effective and less reliant on animal testing, for toxicity investigations in each stage of product innovation, through making best use of joining existing and emerging data **with the help of progress in nanoinformatics**.

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NMBP-14-2018: Nanoinformatics: from materials models to predictive toxicology and ecotoxicology (RIA)

Scope:

- Development of models that support the prediction of both specific functionalities and hazard and are crucial to establish **safe-by-design principles at early stages** of material development;

- Development of a **sustainable multi-scale modelling framework**, based on the integration/linking of different types of nanoinformatics models in order to advance towards predictively linking of physico-chemical NM property models to NM functionality and hazard;

- Uptake and valid use of these tools and nanoinformatics models, **user-friendly interfaces** to enhance accessibility and usability of the nanoinformatics models, and clear explanations of their applicability domains, especially regulatory compliance, should be provided **for different stakeholders** (industry, regulators, and civil society).

TRL 4-6

RIA 100%

NMBP-14-2018: Nanoinformatics: from materials models to predictive toxicology and ecotoxicology (RIA)

Expected impact:

- **Reliable nanomaterials safety data systems**, models and strategies to allow material characteristics to be linked to adverse outcomes;

- A **validated accessible framework**, designed to predict human and environmental toxicological hazards;

- **Increased confidence** in nanosafety nanoinformatics predictive models through agreed standards, harmonised standard operating procedures, considering OECD validation principles.

EUR around 6 million(s)

International Cooperation
Integration of additional funding
Launch of specific calls

European Commission

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NMBP Programme
Topic NMBP-15-2019:
Safe by design, from science to regulation: metrics and main sectors (RIA)

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NMBP-15-2019: Safe by design, from science to regulation: metrics and main sectors (RIA)

Specific Objective:

- **Risk management involves**
  - quantifying hazard (toxicity) and exposure,
  - taking the necessary steps to reduce both to acceptable levels,
    ideally at an early stage of the nanomaterial development process (Safe-by-Design).

- **Various industrial sectors**
  - in particular structural or functional materials,
  - coatings and cosmetics,
  - as well as pharma and health technology
    are currently searching for ways to mitigate possible risks from nanomaterials and
    nano-containing products.

The challenge now
  - to distil existing methods into
    – simple,
    – robust,
    – cost-effective methods
  - for monitoring and modelling of physical-chemical properties and biological effect
    assessment of nanomaterials in relevant use conditions
    including in product-relevant matrices.

NMBP-15-2019: Safe by design, from science to regulation: metrics and main sectors (RIA)

Scope:

- **Degradation** of nano-enabled products and ageing of nanomaterials, and mixture toxicity;

- **New Safe by Design** methods that enable reduction of hazard and exposure through design to an acceptable risk level without affecting the material performance and guide development of safer products at different stages;

- Implementation of **control measures and mitigation strategies** for nanomaterials specific scenarios in various industrial sectors to reach acceptable regulatory risk level on the effectiveness of such measures, and develop computational approaches to model them;

- For this topic the **parallel calls scheme** is envisaged with the USA-NNI. Resulting projects should establish **close cooperation** mechanisms. Legal, policy making and Responsible Research and Innovation aspects should be integrated in the proposal.

TRL 4-6

RIA 100%

NMBP-15-2019: Safe by design, from science to regulation: metrics and main sectors (RIA)

Expected impact:

- **Safe by design approaches** and tools at an early stage of the nanomaterial development process;

- **Quality workplaces** that ensure maximum technical and economic performance in line with acceptable risk levels;

- **Control and mitigate exposure** to acceptable risk level in case after release of nanomaterials from products;

- Develop and validate **low-cost techniques** for delivering an integrated exposure driven risk assessment and the associated design of the required post-use monitoring.

International Cooperation

Integration of additional funding

Launch of specific calls

EUR 5-6 million(s)

European Commission

Thank you!

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