EU-US Bridging NanoEHS Research Efforts

EU Funding Opportunities

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Overview

ProSafe Call (planning process started)

Actual Call ideas:

- Implementation of Safe-by-Design concept(s) in industries innovation process for (specific) products
- Common data base supporting the Safe-by-Design concept(s)
- Risk Assessment along the value chain of a product
- Exposure assessment along the value chain of a product
- …
Linking of existing initiatives and approaches as well as promoting the acceptance/uptake of **Safe-by-Design** within the EU-COM its Member and Associated states and international efforts (OECD, CoR EU-US on regulatory aspects of nano).
NANoREG’s Safe-by-Design concept

A common European approach to the regulatory testing of nanomaterials

Uncertainty

FROM POTENTIAL RISKS TO MANAGED RISKS

ProSafe:
Implementation of safe-by-design concept in industrial innovation processes
Safe-by-Design, Concept vs. (nano-)related scientific data

There must be a strict differentiation between the Safe-by-Design innovation concept and the nano-related data the concept is using even though both are part of the NANoREG projects.
NANoREG Safe-by-Design concept for nanomaterials, etc.

A common European approach to the regulatory testing of nanomaterials

**Idea**
- Gate 1

**Stage 1**
- Reduction of nano related uncertainties
- List of potential nano related risks
- Analysis of alternatives

**Stage 2**
- Theoretical nano related risk analysis
- Nano related risk mitigation
- Grouping principles
- Read across

**Stage 3**
- Experimental nano related risk analysis

**Stage 4**
- Nano related risk assessment before launch

**Stage 5**
- Update nano related risk assessment after launch

**Post Implement. Review**
- Occupational health management during production

**Pre-commercialisation Business Analysis**
- Occupational and product safety
- Consumer safety
- Environmental safety

**Post Development Review**
- Organized Dossier shared by stakeholders (Robust nano safety data)
- Reach Dossier

**Decision on Business Concept**
- Role of regulators along the GATES

**Decision on Business Case**
ProSafe

Action: Preparation of the first call

ProSafe is offering two main opportunities for the implementation of the Safe-by-Design concept in industrial innovation processes:

✓ **Common Calls:** Definition and funding of joint innovation projects addressing the development of nano material or nano products with the respective processes integrating the Safe-by-Design concept along the entire value chain.

✓ **Twinning of projects:** Collaboration with the innovation funding agencies on a national scale participating in calls for nanomaterials and products containing nanomaterials by supporting the Safe-by-Design concept with methods, training and other activities.
The adaptable Safe-by-Design concept covers:

a. the entire value chain or
b. a defined part with input and output parameters
Action: Preparation of the first call

ProSafe will be a supporting partner e.g. with training, implementation support, etc. in joint innovation projects on a national scale. ProSafe will support the twinning and triggering of common projects between innovation funding and regulatory agencies supporting safe innovations of nanomaterials and of products containing nanomaterials.
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NANoREG Safe-by-Design Benefits
for
Regulatory Authorities and Funding Agencies

- SbD delivers transparent data for all stages of the innovation process
- The SbD process delivers pre-regulatory organized dossiers and data formats shared by all stakeholders
- SbD uses ISO and OECD Standards as well as their Guidance Manuals and the NANoREG’s Guidance Document
- Identification of uncertainties and risks at the earliest possible time
- Reduction of uncertainties and risks at the earliest possible time
- The strict separation of data allows an easy check and up-date of the data and thus a new risk analysis
- Be prepared to meet todays and future regulatory requirements
- SbD delivers a good balance between safety, functionality and costs

Summary: higher transparency, better process understanding
Thank you for your attention.