Identifying criteria for environmental risk assessment models at different stagegates of nano-material/product innovation considering requirements of various stakeholders

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are flexible enough to deal with a rapidly diversifying market, and secondly to provide industry with a system which could be rapidly implemented in a cost effective manner.

To put to the test this approach, the NanoReg[2] project has designed seven case studies where SbD is being implemented. An initial step was the identification of hot spots for SbD and gaps in knowledge through the application of risk assessment tools to the selected case studies. The work presented here introduces 1) the description of the case studies in terms of production processes and materials and the formulation of the potential exposure and hazard profiles for workers, professional users, consumers, and the environment, 2) the comparison of the different tools for the risk assessment, 3) the strategy behind selection of risk assessment tools adapted to the particular cases 4) the results of the exercise and lessons learnt and 5) the plan to cover knowledge gaps prior to the implementation of SbD. In general, not all the data required by the tools were available and, in these instances, data derived from the literature or the bulk material were used to feed the tools. Knowledge gaps identified in all case studies included biopersistance, exposure assessment information, dustiness and toxicological reactions (generation of ROS species and inflammation). The main hotspots identified were, in general, the use/handling of nanomaterials in powder form, and 2) chemical composition including toxic substances (eg. Cadmium, Silver). Environmental release was also a potential issue during disposal of wastes and, in some cases, due to accidental dispersion inside the working environment. Hot spots during the innovation chain susceptible for SbD implementation have been identified.

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The EU H2020 project "calibrate" overall aims to establish a state-of-the-art versatile risk governance framework for assessment and management of human and environmental risks of manufactured nanoparticles (MN) and MN-enabled products applicable throughout the innovation process (stage-gates) for these materials and products.

Initial efforts have focused on identifying criteria for environmental risk assessment (ERA) models and tools for such governance framework. It was recognized that some criteria are applicable to both environmental and human risk assessment (HRA), and these so-called "overall" criteria were identified through joint efforts of the ERA and HRA working group experts in caLIBRAte. The identified "overall" criteria relate to RA model features and resources needed to use the tools, whereas the criteria specific to ERA models relate to model outcome on hazard, exposure and risks

The identified criteria were listed against the Cooper stage-gates®, thus forming a table in which the importance or relevance of each criterion could be assessed for each of the stage-gates. This was formed into questionnaires with defined response options for each criterion and stage-gate combination, such as picklists and ratings of importance of the criterion. These questionnaires were sent to stakeholders representing regulators, consultants, researchers and industries, who provided