

Guidance for establishment of the nano-risk innovation governance board

Human and environmental risk assessment data are still rarely available on specific manufactured nanomaterials (or in REACH substances on nanoform). Several regulations (e.g., chemicals, biocides, food additives, food contact materials, cosmetics, medical devices) have made specific requirements for manufactured nanomaterials, which needs to be taken into account. Immediate societal acceptance also vary application. Down-stream users and consumers may have concerns about the use of manufactured nanomaterials in specific product groups, which affect their purchase willingness. Hence, an extra effort may be required in product documentation, risk assessment, risk management, regulatory registration, and stakeholder interaction for successful commercialization.

Consequently, it is recommended that nanomaterials and nanomaterial-based product innovation and implementation in existing productions is governed by a dedicated manager, board or steering group, which we generally refer to as nano-risk innovation-project governance entity. The entity may consist of several participants or just a single manager depending on the size of the organization and needs for the specific project. However, the board should consist of staff required to govern the technical aspects and scale of the project in the specific organization appropriately. *If needed, external participants (e.g., academic researchers, consultants, sponsors, authorities and public stakeholders depending on specific project requirements) may be part of the board or invited for case-by-case participation as experts.*

The nano-risk innovation-project governance entity ensures that potential challenges are considered at organizational level and with accountability at management level to enable overall decision making for the project. The board must therefore have the capacity and mandate to make “go”, “re-work” and “stop” decisions based on the available information, including risk assessment data. The board is accountable for the decisions with the company managers being legally accountable.

The management and board may consult ISO21505:2017 *Project, programme and portfolio management – Guidance on governance*, ISO31000:2009 Risk Management – Principles and



guidelines; CEN/TS16937:2016 *Nanotechnologies – Guidance for the responsible development of nanotechnologies*; ISO/TR13121:2011 *Nanotechnologies – Nanomaterial risk evaluation*; and ISO/TS12901-1:2012: *Nanotechnologies – Occupational risk management applied to engineered nanomaterials – Part 1: Principles and approaches* to define the board and criteria for the work.

It may also be relevant to get familiar with specific regulatory requirements and developments in the specific production and application domains of the invention. [\[LINK TO OUR REGULATORY LIST\]](#).