Nanomaterials: Regulation and Risk Assessment - DTU Orbit (14/12/2018)

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The topics of regulation and risk assessment of nanomaterials have never been more relevant and controversial in Europe than they are at this point in time. In this entry, we present and discuss a number of major pieces of legislation relevant for the regulation of nanomaterials, including REACH, the Water Framework Directive, pharmaceuticals regulation, and the Novel Foods Regulation. Current regulation of nanomaterials entail three overall challenges: 1) limitations in regard to terminology and definitions of key terms such as a “substance,” “novel food,” etc.; 2) safety assessment requirements triggered by thresholds values not tailored to the nanoscale but based on bulk material; and 3) limitations related to lack of metrological tools, (eco)toxicological data, and environmental exposure limits as required by, e.g., REACH, the pharmaceuticals regulation, and the recast of the Novel Foods Regulation. Chemical risk assessment provides a fundamental element in support of existing legislation. Risk assessment is normally said to consist of four elements, i.e., hazard identification, dose–response assessment, exposure assessment, and risk characterization. Each of these four elements hold a number of limitations specific to nanomaterials, i.e., the fact that mass might not be the proper metric to describe the dose in dose–response assessment. These limitations are not easily overcome despite the fact that a lot of effort is being put into investigating the applicability of each of these four elements.