A common European approach to the regulatory testing of nanomaterials

Flow chart for risk assessment of nanomaterials

(Towards a nanospecific approach for risk assessment)

Deliverable 5.8

Introduction

An efficient strategy to assess the impact of nanomaterials on environment and human health is crucial to fully exploit the innovative and economical potential of these materials. Such a strategy should provide sufficient comfort for society regarding the safety of nanomaterials and the products they are incorporated in. At the same time it should be cost-effective and be applicable for industry and small and medium sized enterprises involved in the production and application of nanomaterials.

The flow chart for risk assessment of nanomaterials developed within the NANoREG project presents a proposal for such a strategy for human health. It is an important building block of one of the main outcomes of the NANoREG project: the Regulatory Framework (Deliverable D1.11) .The implementation of the strategy is supported by the NANoREG toolbox (Deliverable D1.12) This tool box provides available testing methods, models and data sets that can be used to apply the strategy.

Description of Work

The development of the strategy builds upon the results of a great number of related nanosafety projects like Marina, GUIDEnano, ITSnano, SUN, ECETOX, and the knowledge developed by ECHA, OECD, SCENHIR and RIVM. The outcome of a great number of other activities within the NANoREG project also has been used.

Main Results

In the flow chart, six overlapping elements have been identified as most important nanospecific determinants within the risk assessment of nanomaterials: exposure potential, dissolution, nanomaterial transformation, accumulation, genotoxicity, and immunotoxicity. In the deliverable, the six elements are shortly explained and a short argumentation for the selection of the different elements is given.

The main objectives of the proposed strategy are:

a. to prioritise those applications of nanomaterials that have the highest potential to cause human health effects;
b. to identify the most important information needed to address the nanospecific issues within the risk assessment.

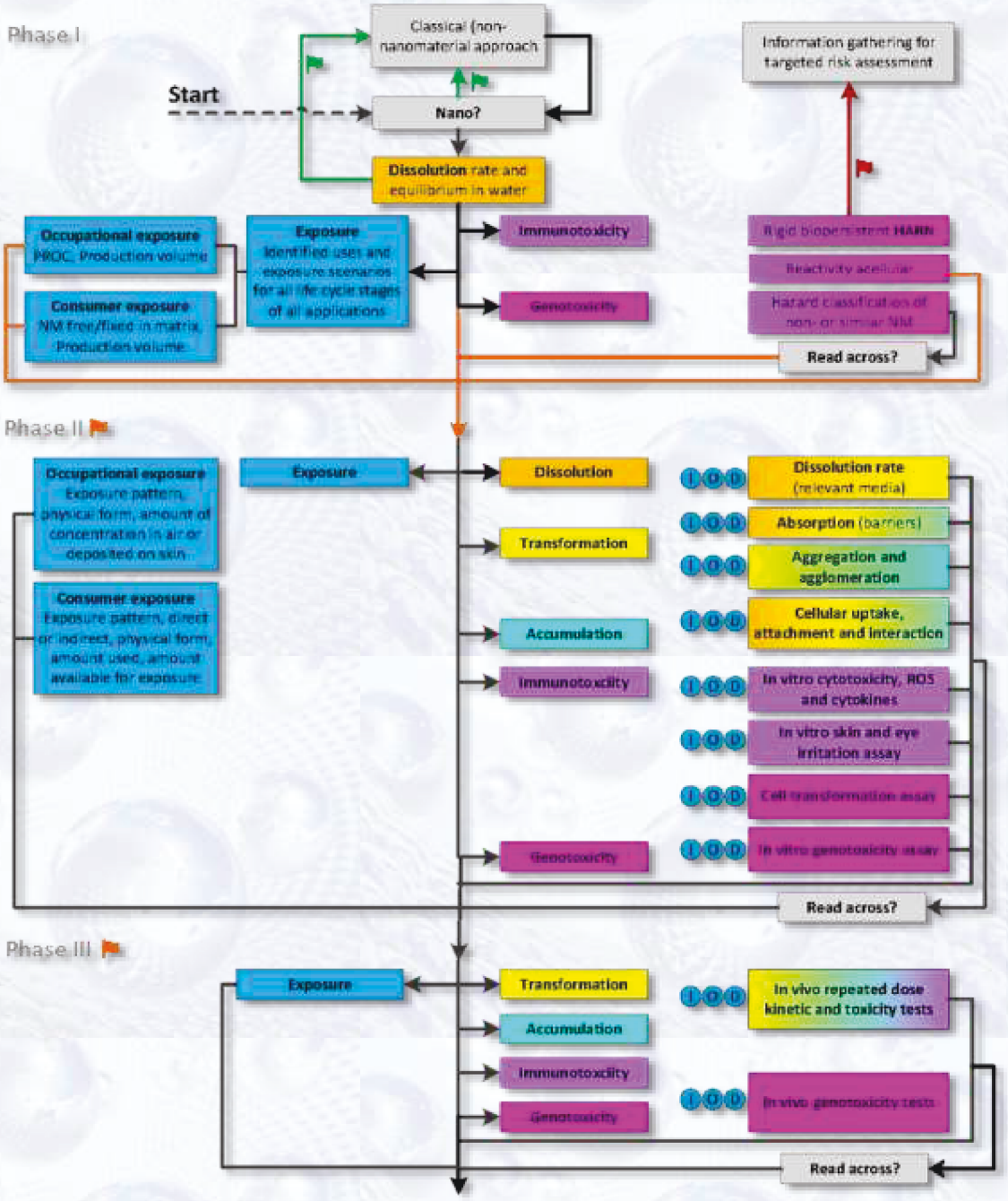
The first objective (prioritisation of applications) is addressed in the first phase of the strategy, while the second objective (identification of information) is mainly addressed in the second and further phases (see figure on page 2).

The strategy gives direction to the most important information needed depending on the specific application, life cycle stage and exposure situation. Furthermore, the strategy identifies possibilities for grouping and read-across primarily based on physicochemical properties and in vitro data.

The proposed strategy is suitable for different uses by policy makers, regulators and industry. Policy makers and regulators can predominantly benefit from using the first phase of the strategy to prioritise those applications that need to be addressed most urgently. Industry can use the first phase to get an

initial impression on the suitability of the application of the nanomaterial in a specific product based on the potential of a specific nanomaterial to cause hazardous health effects during the different life stages of that product. The second and further phases can be used by regulators and industry to identify the most important information needs to address the nanospecific issues. With the current strategy it is possible to identify those situations where the use of nanospecific grouping, read across and (Q)SAR tools is likely to become feasible in the future. In addition, these phases can be used to point towards the generation of the type of data that is needed for scientific justification, which may lead to regulatory acceptance of nanospecific applications of these tools.

Figure: different phases with the various relevant elements depicted for each phase.



Details on the various phases of the flow chart and elements within that phase are elaborated and –as far as possible- made operational in the deliverable and publication, which are publicly available at: www.nanoreg.eu and www.sciencedirect.com/science/article/pii/S0273230016301581.

For more details about NANoREG please visit the official website **www.nanoreg.eu.**

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