A Portuguese Contribution to the Nanomaterials Regulation

Gouveia, **H**[1]., Vital. N[1]., Alberto, R[1]., Silva, M.J[2]., Louro, H[2]., Saraiva, F[3]., Borges, T[4]., Lavinha, J[2].

[1]Institute of Welding and Quality (ISQ), Taguspark – Oeiras, Av. Prof. Dr. Cavaco Silva, nº 33 2740-120 Porto Salvo, Portugal [2]The National Institute of Health Dr. Ricardo Jorge I.P (INSA), Avenida Padre Cruz, 1649-016 Lisboa, Portugal. [3]The Portuguese Institute of Quality (IPQ), Rua António Gião, nº 2 2829-513 Caparica, Portugal [4]The General Directorate of Health (DGS), Alameda D. Afonso Henriques, nº 45 - 1049-005 Lisboa, Portugal

hngouveia@isq.pt; m.joao.silva@insa.min-saude.pt

Abstract

Nanotechnologies and the use of manufactured nanomaterials (MNMs) are widespread and bring improvements to nearly every aspect of modern living, particularly when incorporated in products of everyday use. The rapid development of nanotechnology is evident with new MNMs, as well as new applications, continuously emerging in the market, highlighting the unquestionable innovative and economic potential of MNMs to today's society. However, the full exploitation of nanotechnology and use of nanomaterials is threatened by limited understanding of MNM safety aspects along the value chain. Therefore, urgent actions by multi-stakeholder are critical on understanding environmental, health and safety (EHS) issues. While a wide range of toxicity data is becoming available and is giving insights into the potential hazard from exposure to MNMs, its relevance to legislators and regulators is often unclear or unproven. The development of a complete toxicity data set together with human exposure characterization is crucial to deliver accessible and robust risk assessments for nanoproducts and to respond the answers from regulators and legislators.

In this context, an international multi-stakeholder collaboration project, within the FP7, is ongoing - NANoREG "A common European approach to the regulatory testing of nanomaterials" - that started on March 1st, 2013 and runs until August 31st, 2016 (42 months). This project aims at: (i) providing legislators with a set of tools for risk assessment and decision making instruments for the short to medium term, by gathering data and performing pilot risk assessment, including exposure monitoring and control, for a selected number of nanomaterials used in products, (ii) developing for the long term, new testing strategies adapted to a high number of nanomaterials where many factors can affect their environmental and health impact and (iii) establishing a close collaboration among authorities, industry and science leading to efficient and practically applicable risk management approaches for MNMs and products containing MNMs.

Portugal participates in the NANoREG project through a consortium - PToNANO - established by four different entities: Institute of Welding and Quality (ISQ), the National Institute of Health Dr. Ricardo Jorge I.P (INSA), the Portuguese Institute of Quality (IPQ) and the General Directorate of Health (DGS), a multidisciplinary group representative of different areas of interest, in the field of nanotechnology, including science, industry and regulation. The main contributions of PToNANO for the

NANoReg project will be presented, as well as the preliminary data that have been obtained on the safety evaluation of selected MNMs through the characterization of their toxic effects.

PToNANo has been developing its strategic work in the following domains: i) identification of the key needs and gaps in knowledge about MNMs safety and potential impacts on human health and environment within the production and/or use of nanomaterials in Portugal; ii) identification and involvement of the various national entities with an interest in nanotechnology; iii) safety assessment of nanomaterials through *in vitro* genotoxicy characterization; iv) integration of all information towards the development of a toolbox for assessing the risk associated with exposure to nanomaterials.

Firstly, emphasis has been given to the characterization of the national stakeholders, through the elaboration and application of an inquiry aimed at identifying the institutions or industries that are involved in nanotechnology. In a more advance phase, PToNANO will disseminate the knowledge generated by the NANoREG project to all stakeholders, including industry, legislators and the public authorities, towards a responsible development of nanotechnology in Portugal and in the EU. Furthermore, questions related to legislation and regulation issues, defined in NANoREG will also be assessed by national entities and discussed in open forums.

It is expect that the results generated during the project can strengthen, expand and share knowledge required for a comprehensive risk assessment of nanoparticles, enabling established strategies that can deliver relevant and reliable data on the safety of nanomaterials, to provide the right answers to society, legislators, regulators, industry and public health authorities at a European level. As final outcomes it is expected that PToNANO work, at national level, will be able to contribute to the establishment of national priorities in nanotechnology and to the national regulatory systems.