



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

Directorate D – Industrial Technologies
D.3 – Advanced Materials and Nanotechnologies

Malta Initiative Workshop

Brussels – COV2 Auditorium ERCEA (SDR2), 11 December 2018 10.00-13.00

Draft agenda

Scene Setter

Nanosafety is becoming one of the main areas of concern among the civil society and the industry sector. It virtually affects all areas where nanomaterials are applied, including food, cosmetics, medical products, buildings and batteries, to name a few. Over the last decades, large amount of data has been collected on nanomaterials and many studies have been performed on risk assessment and their safety. However, the data generated and collected is not coherent and comparable for regulatory purposes. Therefore it is crucial to provide legally binding guidelines and standards for testing the safety of nanomaterials, and hence, the safety of the European citizens.

Preparatory work has been completed by the projects NANOREG and PROSAFE jointly funded by EU and Member States. These projects have been supported with significant international input from Brazil and South Korea and in close cooperation with similar work in the USA.

The "Malta Initiative" is a joint RTD – Member States initiative to increase EU presence and contribution on adapting and developing new nano-specific OECD testing guidelines and guidance documents. The European Commission was initially approached by Germany and the Netherlands to spearhead this initiative, together with other Member States, industry stakeholders and the Nanosafety Cluster.

Objective

The goal is to bring together relevant knowledge, testing methods and harmonised standards gathered and developed in several research projects. At the heart of this initiative is the international collaboration needed to bridge the current gap in nanosafety and nanomaterials regulation. Besides being an integral part of the OECD work on chemicals management, the "Malta Initiative" is also extremely important for implementation of REACH annexes.

Involved speakers

The opening statement will be provided by Director General Jean-Eric Paquet followed by Director of Directorate D, Peter Dróll, who will underline the importance the Commission attaches to nano-safety. He will also provide the dynamics for starting the next steps in our cooperation with Member States, notably to develop safe-by-design technologies for nanomaterials and for safe chemicals innovation, including the regulatory research phase and the technologies necessary for regulation deployment and implementation.

The workshop will gather about 50 participants from academia and Member States, notably members of the High Level Group on Nanosciences, Nanotechnologies and Advanced Materials, members of the Working Party for Manufactured Nanomaterials of OECD, members from the Nanosafety Clusters, official governmental representatives and stakeholders from industry and academia.

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| 09:30-10:00 | Registration and welcome coffee |
| 10:00-10:10 | Opening – <i>Jean-Eric Paquet</i> TBC |
| 10:10-10:20 | Scene Setter – Peter Dróll |
| 10:20-10:30 | <i>George Katalagarianakis</i> , EC, DG RTD: DG RTD initiatives towards regulation and standardization of NMs |
| 10:30-10:55 | <u>Co-presentation</u> of <i>Peter Kearns</i> , Principal administrator at OECD and EC, DG <i>JRC</i> , Italy (Juan M. Riego Sintes or Kirsten Rasmussen): The OECD WPMN/WNT/TGP actions for support to regulatory nanosafety. Working procedures, MAD, relations with EU regulatory needs, prioritisation. Creating synergies between research and regulation |
| 10:55-11:20 | <u>Co-presentation</u> of <i>Anke Jesse</i> , Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Germany and <i>Thomas Kuhlbusch</i> , Federal Institute of Occupational Safety and Health (BAuA), Germany: The Malta Initiative - a joint action for adopting OECD test guidelines |
| 11:20-11:30 | <i>Emeric Frejafon</i> , INERIS, Chair of CEN/TC 352, France: Standardisation and harmonisation, two faces of a coin. |
| 11:30-11:45 | Coffee break |
| 11:45-11:55 | <i>Jenny Holmqvist</i> , ECHA, Finland: Regulatory Relevance of test guidelines, standards and guidance documents |
| 11:55-12:05 | <i>Flemming Cassee</i> , Dutch National Institute for Public Health and Environment, Netherlands: Relations between Research and regulatory needs |
| 12:05-12:15 | <i>Iseult Lynch</i> , Nanosafety Cluster, UK: Enabling FAIRness and Openness of EU Nanosafety cluster data – the NanoCommons approach |
| 12:15-12:25 | <i>Andrew Nelson</i> , coordinator of project HISENTS, UK: How the HISENTS technology informs on surface properties and toxicokinetics of nanomaterial dispersions |
| 12:25-12:35 | <i>Monique Groenewold</i> , head of the Dutch delegation at the WPMN; coordinator of project Gov4Nano |
| 12:35-12:45 | <i>Claire Skentelbery</i> , Nanotechnology Industries Association, Belgium: Promoting safe and sustainable innovation in nano |
| 12:45-13:00 | <i>Helene Chraye</i> : Closing remarks |