July 2024

MALTA INITIATIVE

This document summarises the concept of the Malta Initiative.
It is a self-organised group without any legally binding status.

Innovation is one of the key factors in securing the wealth of current and future generations. To ensure the trust of citizens in innovation, legislation has to keep pace with innovative developments. Appropriate and clear legislation is a key factor for long-term investments. International collaboration at OECD level is one element in addressing the global challenges associated with innovation. The OECD Council Decision on Mutual Acceptance of Data (MAD) is a legally binding instrument in OECD member countries and non-OECD countries which have adhered to them (there are currently six). MAD is an important instrument in facing these global challenges of testing nanomaterials. In essence, MAD means that data collected as part of a regulatory risk assessment of a chemical in one country must be accepted (in a legal sense) in all countries, provided that (an) agreed OECD Test Guideline(s) has/have been used and the OECD Principles of Good Laboratory Practice have been applied during the collection of the data. MAD avoids the double testing of substances, reduces the amount of animal testing and saves on resources.

Generally, Test Guidelines (TG) and Guidance Documents (GD) for the testing of 'traditional' chemical substances are also applicable to nanomaterials. For a number of endpoints, however, TGs/GDs do not address specific information requirements when dealing with nanomaterials, or are considered not applicable for the testing of nanomaterials.

The "Malta Initiative" (MI) arose during the Maltese EU Council Presidency in 2017, when Germany initially approached the EU Directorate-General for Research and Innovation (DG RTD) to request political and financial support to develop and amend TGs and GDs to ensure that nano-specific issues for fulfilling regulatory requirements are addressed. The Malta Initiative brings together a group of EU member states, the European Commission (notably the DG RTD, DG ENV, DG GROW and JRC), ECHA, industry and other institutions committed to this aim and welcomes additional international collaborators.

In line also with existing procedures at the OECD, any country or organisation with expertise interested in working on adapting existing OECD TGs or developing new OECD TGs and/or GDs is welcome to become an active contributor to the "Malta Initiative".

The activities of the MI are supported through national, international and EU resources by means of direct funding, in-kind contributions, or providing expertise.

Austria, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland, United Kingdom, ECHA, European Commission and BIAC currently support the Malta Initiative.

Advanced materials must also undergo regulatory accepted safety and sustainability testing, using harmonized test methods and guidelines. Therefore, the scope of the Malta Initiative will be in the future enlarged to Advanced Materials.

The Malta Initiative Board

An advisory body, the "Malta Initiative Board" has been formed to facilitate and steer the activities of the MI. The MI Board members have been selected in order to represent EU member states, European Commission Directorates-General and agencies, the EU Nano Safety Cluster (NSC), and industry (notably through BIAC). Furthermore, members have been selected in order to include renowned experts from three relevant fields of expertise, namely: physical-chemical characterization; environmental and biotic effects; and human health effects. The board members also have strong links to various OECD working parties and other groups (e.g. ISO/CEN) and are familiar with OECD working practices and procedures.

The Board ensures that the MI focuses with emphasis on regulatory needs. The members are expected to act as "ambassadors" for the MI and its spirit.

Members:

Member Malta Initiative Board	Representing
Flemming Cassee, RIVM, The Netherlands Eugenia Valsami-Jones, University of Birmingham, United Kingdom	NanoSafety Cluster (NSC), EU
Monique Groenewold and Eric Bleeker	National Institute for Public Health and the Environment (RIVM), The Netherlands
Elisabeth Heunisch and Thomas Kuhlbusch (Vice Chairs)	Federal Institute for Occupational Safety and Health (BAuA), Germany
N.N.	European Chemicals Agency (ECHA), EU
Anke Jesse (Chair) and Laura Gross	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), Germany
Elisabeth Blaton and Elmire Chauvière François Xavier Ouf, George Favre	Ministère de la Transition écologique, France Laboratoire National de métrologie et d'essais (LNE), France
Philippe Hallegot	NanoMesureFrance, France
Alexander Pogány	Austrian Ministry for Transport, Innovation and Technology
Kirsten Rasmussen	European Commission (JRC-Ispra), EU
Kathrin Schwirn and Doris Völker	German Environment Agency (UBA), Germany
Jacques-Aurélien Sergent, Solvay, Belgium Karin Wiench, BASF, Germany Blanca Suarez Merino and Sean Kelly, Nanotechnology Industries Association (NIA), Belgium	The Business and Industry Advisory Committee (BIAC)

Lars Montelius	AMI2030, University Lund, Sweden
Tommaso Serchi	Luxembourg Institute of Science and Technology (LIST), Luxembourg
Gregory Moore	Swedish Chemicals Agency (KEMI), Sweden