

Tools for ENM safety assessment

OECD Test Guidelines and Guidance Documents and how to develop them

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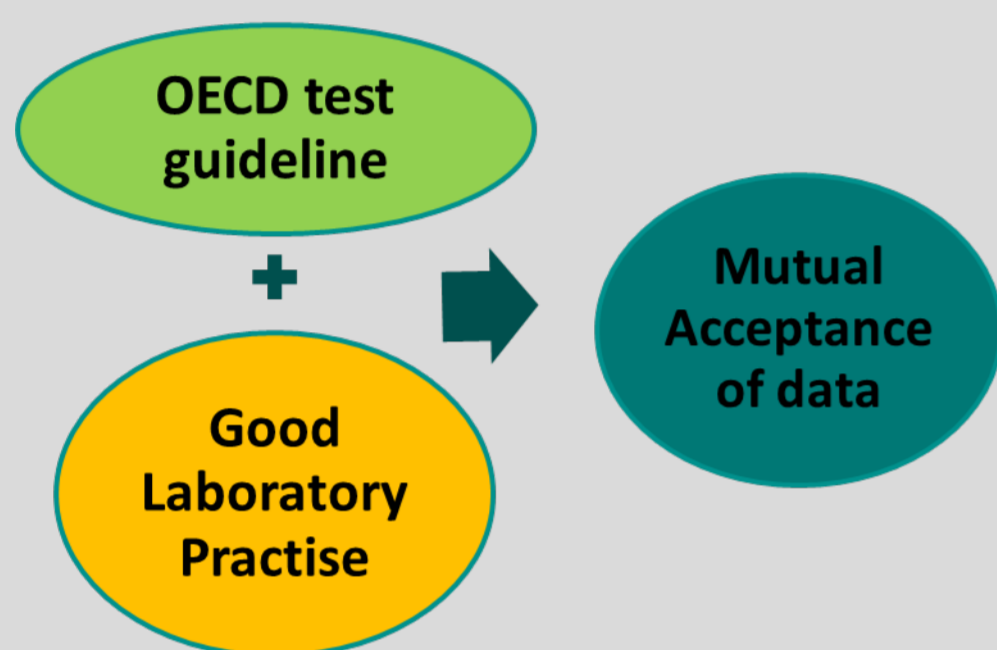
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1. Abstract

The OECD test guidelines (TGs) for testing chemicals have been widely used for regulatory purposes all over the world since the establishment of the Mutual Acceptance of Data (MAD) principle in 1984. This MAD principle ensures that, if a chemical is tested under the Good Laboratory Practice (GLP) conditions accordingly to an OECD TG, the data should be accepted in all OECD member countries (MC). The TGs have been developed, harmonized, internationally validated (ring-tests) and adopted by OECD countries to be used for the hazard identification and risk assessment of various chemicals. OECD also publishes Guidance Documents (GDs), which usually give guidance how to use TGs and how to interpret the results. These GDs do not have to be fully experimentally validated, and hence they are not under MAD, but they are based on the latest published scientific research. But are the TGs with the GDs applicable and adequate for the regulatory testing of nanomaterials? In principle, most of the "endpoints" or more precisely measurement variables are applicable. However, for some endpoints new TGs are needed. In addition, more precise advice on the test performance, e.g. including sample preparation and dosage of the test material, the characterization of the exposure and understanding the results need specific guidance, in order to gain regulatory relevant data.

2. Introduction

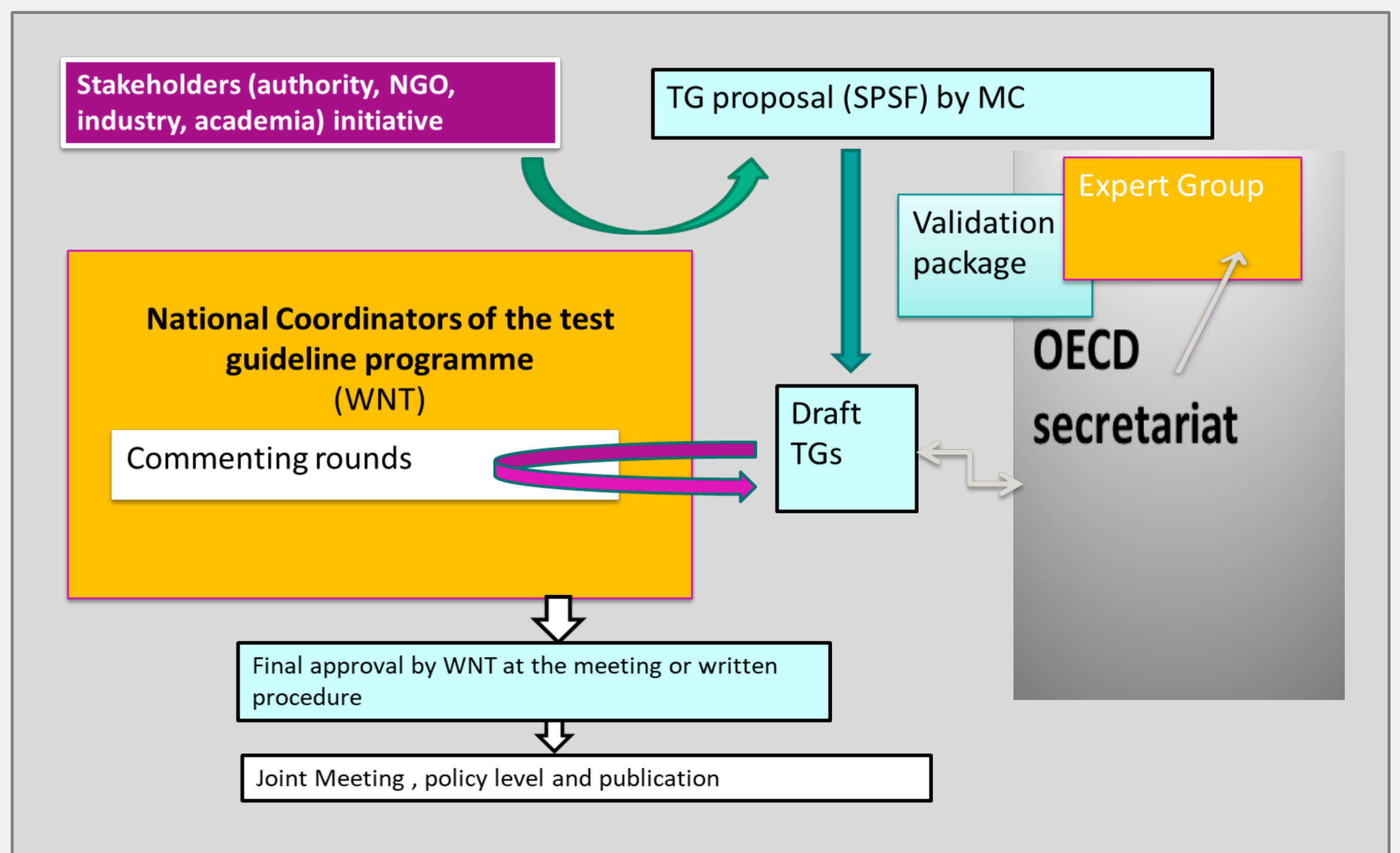
Why to have OECD TGs and EU methods (also) for NM testing?



- For testing intrinsic properties of chemicals (substances)
- Binding OECD countries and selected non-members

- ▶ Avoids duplication of testing
- ▶ Reduces use of animals
- ▶ 160 million euros saved each year (2010)
- ▶ "easily" adopted to EU regulation (440/2008) for EU regulatory needs

3. Procedure for TG or GD development



4. Difference between OECD TGs and GDs

Test Guideline

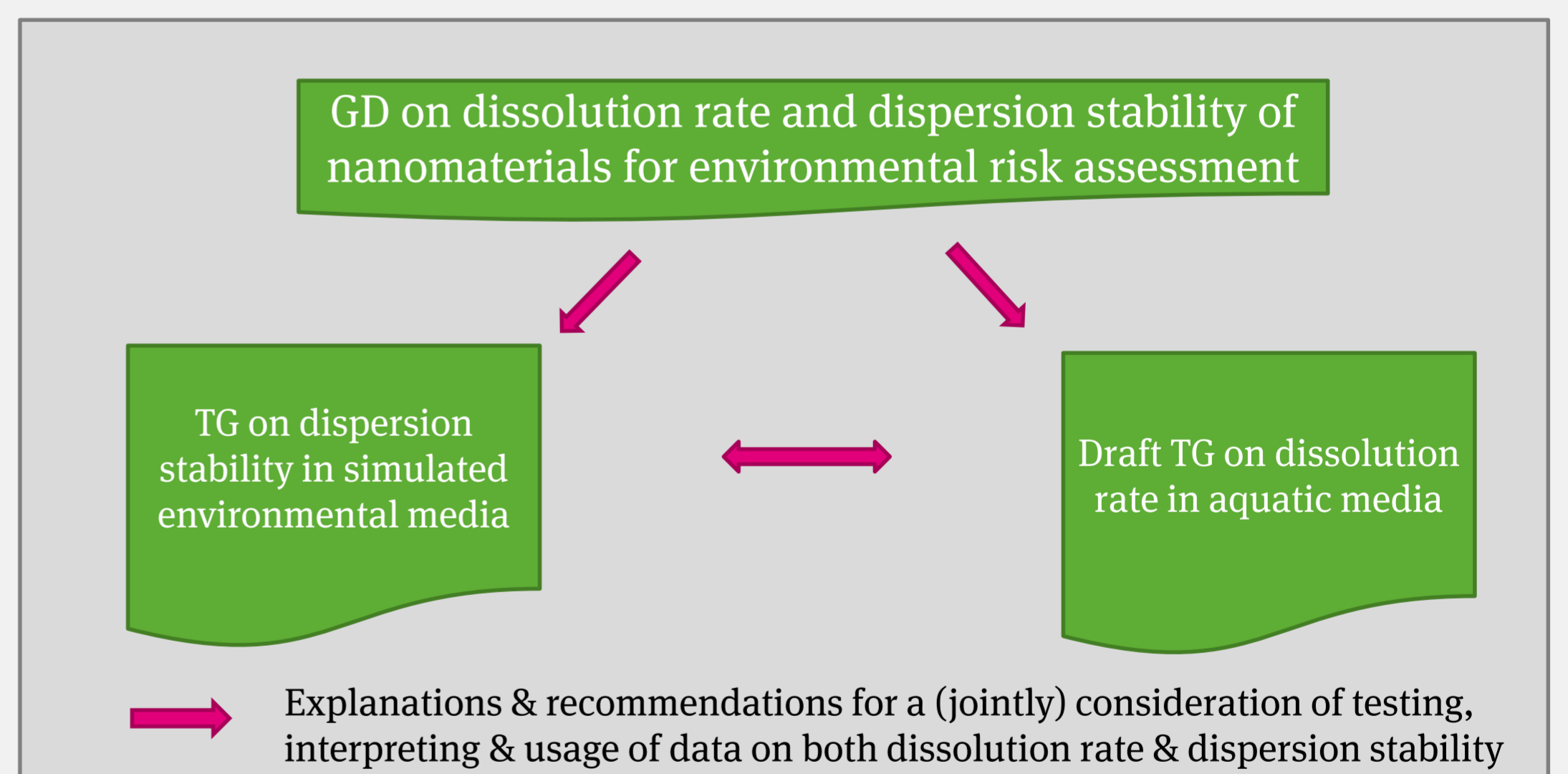
- Regulatory need explained by the SPSF*
- **Covered by MAD**
- Fixed test protocol with **validity criteria**
- Thorough experimental validation needed with fixed protocol
- Takes time and resources and more cumbersome to update

Guidance Document

- Regulatory need
- Not covered by MAD
- Can be a test method, or it provides technical guidance for the use of test guidelines
- Scientific validation could be limited and based on published literature
- Faster to develop and revise

*SPSF = Standard Project Submission Form

5. An Example: Relationship of the TGs on dispersion stability and dissolution rate of ENMs in aquatic media



6. List of current projects on ENM TG and GD development included in the program of work of WNT

- (New) TG on Dispersion Stability of Nanomaterials in Simulated Environmental Media
- (New) TG on Dissolution Rate in Aquatic Media
- (New) TG for Removal from Wastewater
- (New) GD to Assess the Apparent Accumulation Potential for Nanomaterials
- (New) GD Aquatic (and Sediment) Toxicity Testing
- (New) GD (Decision Tree) on Dispersion Stability and Dissolution Rate in Aquatic Media
- Amendments to Inhalation TGs and GD
 - TG 412 (Subacute Inhalation Toxicity)
 - TG 413 (Subchronic Inhalation Toxicity).
 - TG 403 (Acute Inhalation)
 - TG 436 (Acute Inhalation – Acute Toxic Class)
 - GD 39 (Inhalation Toxicity Testing)
- (New) GD for TG 312 - Leaching in Soil Columns

References:

OECD, 2009: GD 1 Guidance Document for the Development of OECD Guidelines for Testing of Chemicals (as revised in 2009).
 OECD, 1998: OECD Series on principles of Good Laboratory Practice and compliance monitoring number 1.
 OECD, 2005: GD 34 Guidance Document on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment.

Research and activities of UBA at: <https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology>