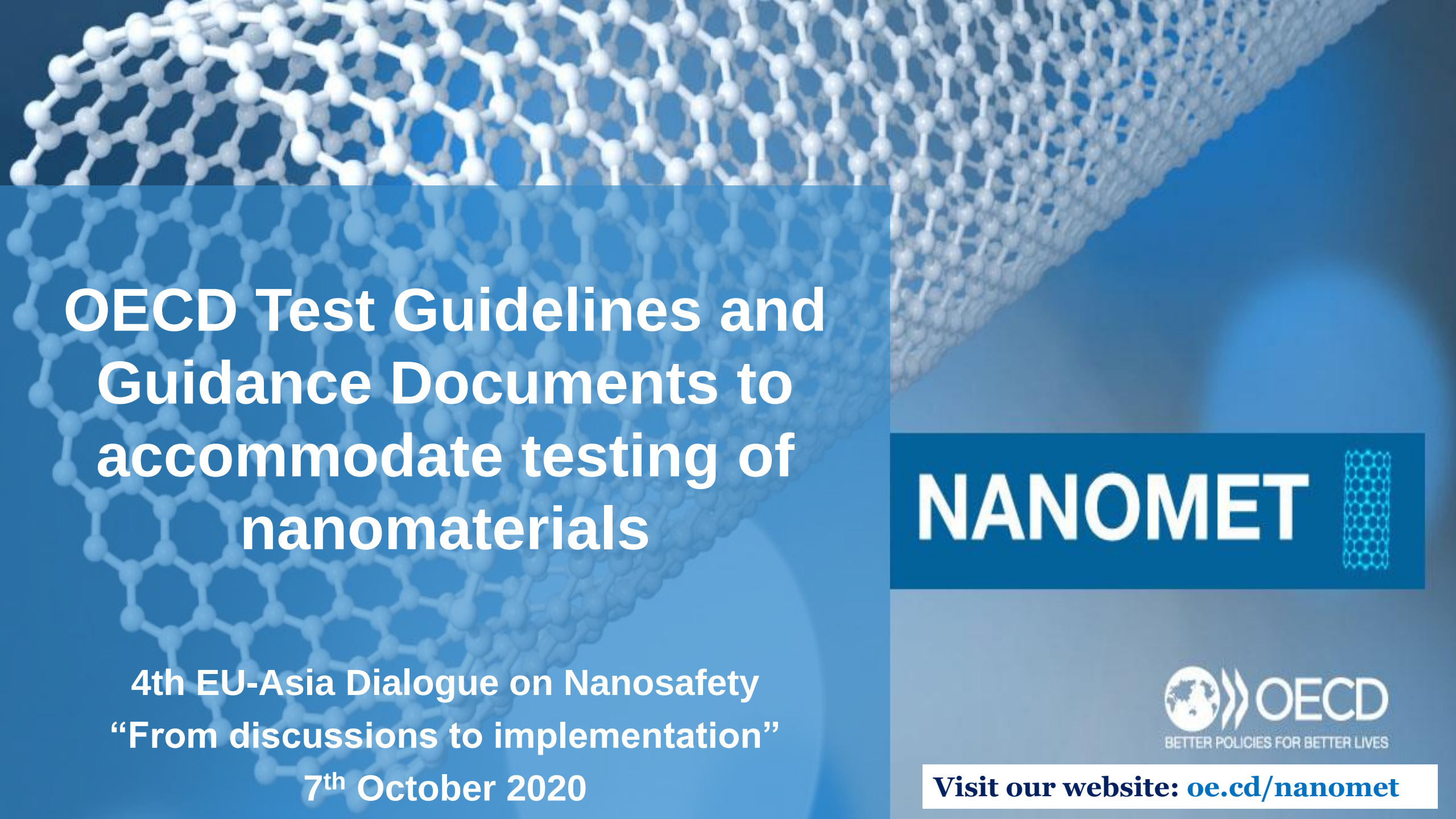




OECD Test Guidelines and Guidance Documents to accommodate testing of nanomaterials

4th EU-Asia Dialogue on Nanosafety
“From discussions to implementation”

7th October 2020

NANOMET



Visit our website: oe.cd/nanomet



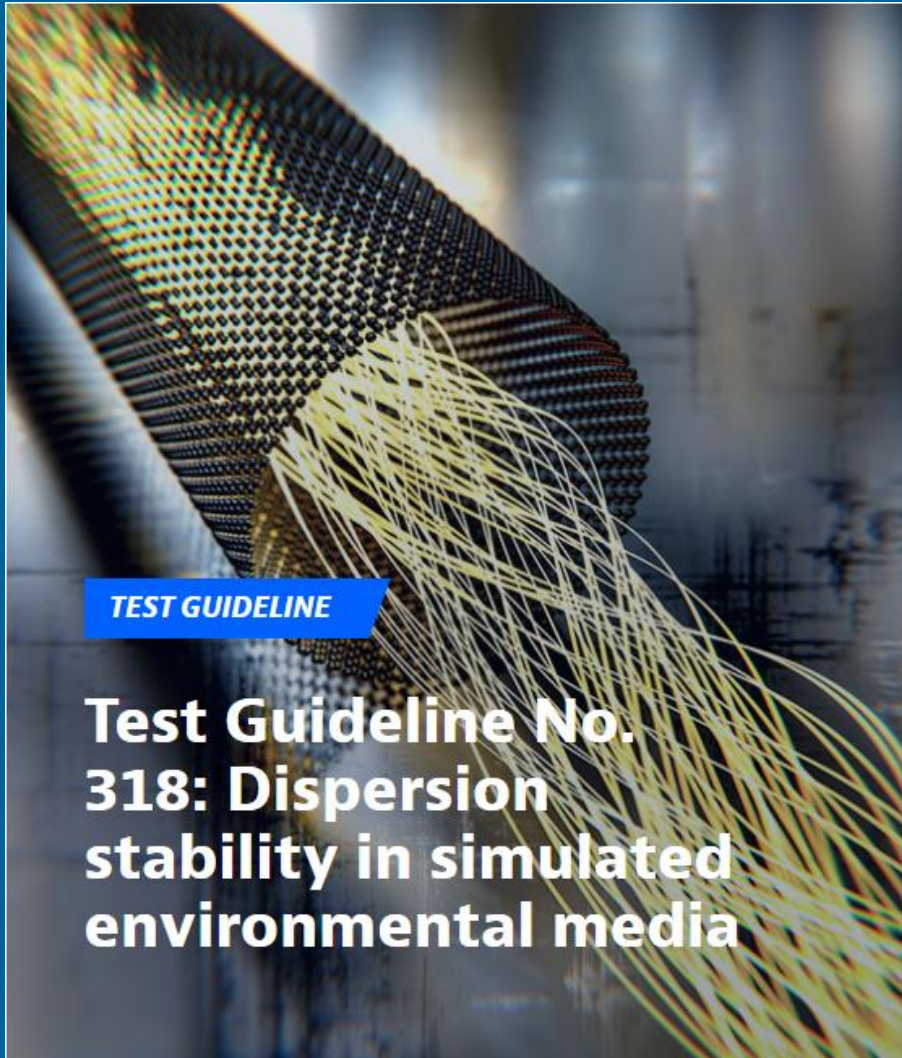
Overview



- What is a Test Guideline and Guidance Document
- Test Guidelines features
- Process



OECD TEST GUIDELINES



TEST GUIDELINE

**Test Guideline No.
318: Dispersion
stability in simulated
environmental media**

- ✓ Physical-chemical properties
- ✓ Ecotoxicity (aquatic, terrestrial)
- ✓ Environmental fate
- ✓ Human health effects
- ✓ Pesticides residues chemistry





Guidance Documents



GUIDANCE DOCUMENT

**Guidance document
No. 318: Solubility
and dissolution rate**

EXCEL TOOL

**Tool accompanying
guidance document
No. 318**

VALIDATION REPORT

**Validation report
supporting Test
Guideline 318**

GUIDANCE DOCUMENT

**Guidance document
No. 317: Aquatic and
sediment ecotoxicity
testing**



Test Guidelines $\neq$ Guidance Documents



Test Guideline

- ✓ Regulatory need
- ✓ **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



**Applied
Research
&
Development**



**Harmonisation
of
Testing Methods**



TEST GUIDELINE

**Single Quality
Standard for the
Safety
Assessment of
Chemicals**



**Lead Country/
Consortium**

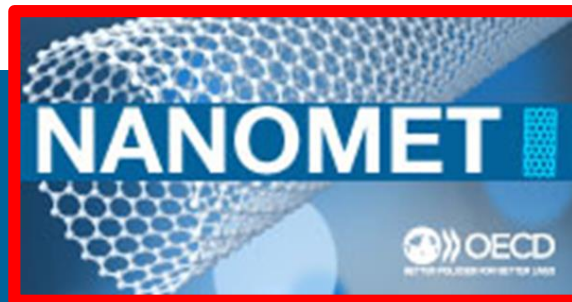
Malta Initiative



=

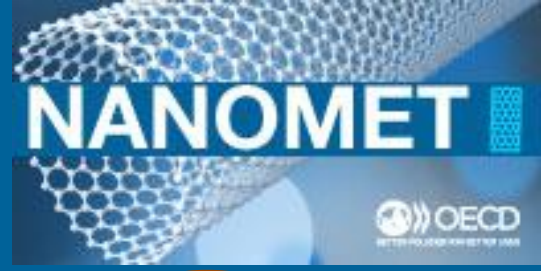
TEST GUIDELINE

**Single Quality
Standard for the
Safety
Assessment of
Chemicals**





OECD check list for an OECD TG



- Harmonised testing methodologies that are:
 - Robust and reliable for governments to base their decisions
 - Mindful of animal welfare considerations, “3Rs principles”
 - Mindful of economic implications of testing
 - As broadly accessible as possible
- Support the uptake of new and/or complex methods by relevant and sufficient guidance on testing and interpretation of data, and the reporting via templates
- Stay at the forefront of the state-of-the art science and techniques
 - Encourage review papers in novel areas of testing (*in vitro*, toxicogenomics, nanomaterials...)

Validation



THE MUTUAL ACCEPTANCE OF DATA SYSTEM IN THE ASSESMENT OF CHEMICALS

Nanomaterials



**Test
Guidelines**

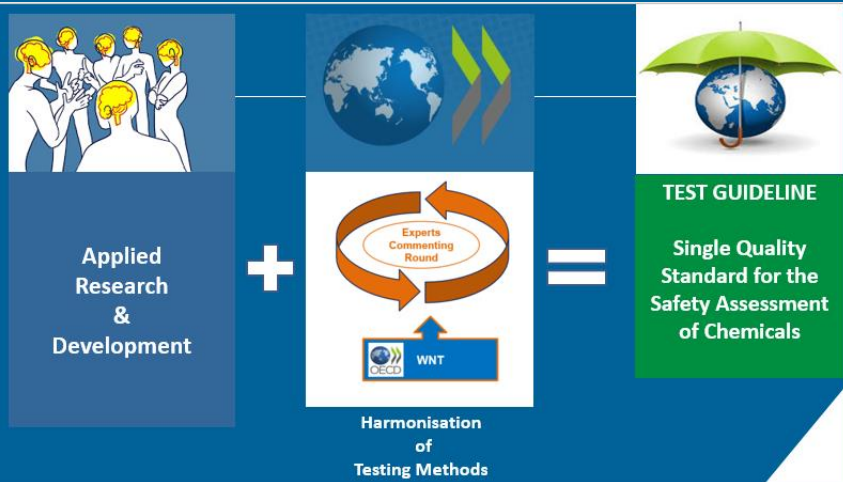
A **single quality standard**
should be applied for
testing of all chemical
substances

**Good Laboratory
Practice**

A **single quality** standard
for test facilities
throughout OECD

Mutual Acceptance of Data
Legally binding on OECD Member countries
and other MAD Adherents

“tested once, accepted everywhere.”



Mutual Acceptance Of Data
(MAD)



Used National
Legislation



- OECD facilitates but not a regulatory body!
- Test Guidelines and Guidance Documents respond to a regulatory need
- OECD Member countries are the one that decide by consensus the methods
- They are used by professionals in industry, academia and government involved in the testing and assessment of chemicals.
- MAD is a legally binding agreement
- OECD development of TG depends on research and on the efforts countries do



For more information



Website: oe.cd/nanomet

Contacts: Anne.Gourmelon@oecd.org; Mar.gonzalez@oecd.org

Newsletter sign up: <http://bit.ly/newsletter-chemical-safety>

Follow us on social media:



[@OECD ENV](https://twitter.com/OECD_ENV)



<http://bit.ly/youtube-chemical-safety>

