

OUTCOMES OECD WNT-38

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Overview of the OECD

- ▶ **Organization for Economic Cooperation and Development (OECD)**
 - ▶ Founded in 1961 as a multilateral organization, the OECD is a consensus-based forum where its 38 member countries and other key partners collaborate to promote economic growth, prosperity, and sustainable development and address the challenges of a global economy.
 - ▶ Through its 300+ committees, working parties, expert groups, ad hoc groups, etc., the OECD covers a wide range of key policy areas, including tax, digital transformation, environment, energy, trade, education, and finance, among others.
 - ▶ The Chemicals and Biotechnology Committee oversees OECD work on chemical safety and biosafety through eleven working parties, which collectively conduct research and develop guidelines on how to test chemicals for hazards to human health and the environment. The Working Party of the National Coordinators of Test Guidelines Program (WNT) is one of these eleven.

Overview of the OECD WNT

- ▶ **Working Party of the National Coordinators of Test Guidelines Program (WNT)**
 - ▶ The WNT, through its National Coordinator structure consisting of member governments, mutual acceptance of data (MAD) adhering countries, and the European Commission, works to harmonize and approve test guidelines, guidance, and related documents through consensus.
- ▶ **Mutual Acceptance of Data (MAD)**
 - ▶ MAD requires OECD governments to accept non-clinical environment and health safety data developed for regulatory purposes in another country if these data were generated in accordance with the OECD Test Guidelines Program and Good Laboratory Practice (GLP) principles.
 - ▶ This “test once, accept everywhere” approach is also accepted in non-OECD member countries that adhere to MAD.
 - ▶ MAD increases the efficiency and effectiveness of chemical notification and registration procedures by ensuring high-quality test data and a common basis of information for assessing risks to human health and the environment.
 - ▶ <https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/test-guidelines.html>

April 2026 OECD WNT-38 Summary

- ▶ Approved seven new test guidelines.
- ▶ Updated or revised five existing test guidelines.
- ▶ Approved corrections for ten test guidelines.
- ▶ Approved two new guidance documents, one U.S.-led detailed review paper on respiratory sensitization, and a number of other documents, including 14 validation and peer review reports.
- ▶ Reviewed twelve new project proposals based on the WNT's Standard Proposal Submission Form (SPSF) and approved ten for placement on the WNT Workplan, including the U.S./ICAPO proposal to develop a new test guideline on *in vitro* reconstructed human respiratory epithelium (RHRE) test method for identifying respiratory tissue irritation.
- ▶ The United States, through the technical, scientific, and financial contributions of many federal agencies and departments, actively participates in a number of the working groups, expert groups, and ad hoc groups that support the work of the WNT.

WNT-38 New Test Guidelines Approved

- ▶ Test guideline on the dustiness determination of materials containing nano-objects and their aggregates and agglomerates
- ▶ Test guideline for the determination of effects on earthworms (*Oligochaeta*, *Annelida*) in field studies
- ▶ Test guideline on bumble bee (*Bombus* spp.) chronic oral toxicity test (10-day feeding)
- ▶ Test guideline on determination of the solubility and dissolution rate of nanomaterials for environmental fate assessment
- ▶ Test guideline on the determination of Cytochrome P450 (CYP) induction using differentiated human hepatic cells
- ▶ Test guideline on the ToxTracker assay for genotoxic hazard and genotoxic/non-genotoxic mechanisms of action
- ▶ Test guideline on the Glucocorticoid Receptor Transactivation Assay

WNT-38 Test Guidelines Updated

- ▶ Updated Test Guideline 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test
- ▶ Updated Test Guideline 442D with 2 new methods:
 - ▶ Epi2SensA (Appendix 1C)
 - ▶ α -Sens (Appendix 1D)
- ▶ Updated Test Guideline 429 on the local lymph node assay (LNCC inclusion)
- ▶ Updated Test Guideline 497 for inclusion of a regression model for derivation of a quantitative point of departure
- ▶ Updated Test Guideline 498- Keraskin™ Phototoxicity assay

WNT-38 Other Documents Approved

- ▶ Corrections for ten test guidelines
- ▶ New guidance document on toxicokinetics to accommodate testing of nanoparticles
- ▶ New guidance document for *in vitro* testing of the intestinal fate of orally ingested nanomaterials
- ▶ New detailed review paper on respiratory sensitization
- ▶ Updated Guidance Document 151 Supporting the Implementation of Test Guideline 443 and Guidance Document 43
- ▶ +14 validation reports and peer review reports

New Project Proposals Accepted for WNT Workplan

No.	SPSF title and files attached	Country(ies)	Decision for the work plan
1	New TG on Semi-Field Study Design to Investigate Potential Impacts of Crop Protection Products on cavity-nesting solitary bees (<i>Megachilidae</i>)	GER/CH	Included
3	New GD on biodegradation testing of <u>difficult-to-test substances</u>	EC	Included
4	New TG Bioaccumulation of Nanomaterials in <i>Hyalella azteca</i> : Aqueous and dietary exposure (nanoHYBIT)	GER	Included
5	Revision of OECD GD 280 (2018): 'Guidance Document on the Determination of in vitro intrinsic clearance using cryopreserved hepatocytes (RT-HEP) or liver S9 subcellular fractions (RT-S9) from rainbow trout and extrapolation to in vivo intrinsic clearance'	UK	Included
6	Revised TG 492B: EpiOcular time-to-toxicity test method for hazard identification and labelling of eye irritating chemicals	SK	Included
7	Reporting Guidance for Biotransformation Systems: Addition to GIVIMP	UK/CZ/SE	Included
10	New TG on <i>In vitro</i> reconstructed human respiratory epithelium (RHRE) test method for identifying respiratory tissue irritation	US/ICAPO	Included
12	DRP on <i>in vitro</i> renal cytotoxicity assays for future creation of new TG	JP	Included
13	New TG Zebrafish Embryo Developmental Neurotoxicity Screening Test (ZEDNT)	KO	Included
14	New TG on a Human Mineralocorticoid Receptor Transactivation Assay: MRTA	FR/GER	Included

WNT Programmatic Updates

- ▶ There is continued progress on **Guidance Document 34**, which the WNT formally approved revising in 2023 to modernize the processes to validate and develop test guidelines to keep pace with emerging science and technologies that provide alternatives to animal testing for chemical safety. Led by the EU-JRC, NL, and USA.
- ▶ **The SPSF template** will be revised by adding a new section 9 on biological materials.
- ▶ In order to more easily update and reference SOPs in test guidelines, the WNT indicated its preference for having **detailed SOPs in a separate document** from test guidelines.
- ▶ The WNT's **Work Plan** was reviewed, projects coming to fruition in 2026-27 were identified, and agreement was reached to **support efforts to increase the visibility of test guidelines** and supporting information.
- ▶ **Supported engagement with Biological Resource Centers (BRCs)** to have a dialogue on the needs of the OECD Test Guidelines Program, needs, including to update the Material Transfer Agreement and provide clear guidance for method developers and users in their interactions with BRCs.

WNT Approved New Approach Methods Relevant Documents

- ▶ Revised Test Guideline 492B: EpiOcular time-to-toxicity test method for hazard identification and labelling of eye irritating chemicals
- ▶ Reporting Guidance for Biotransformation Systems: Addition to GIVIMP
- ▶ New test guideline on *In vitro* reconstructed human respiratory epithelium (RHRE) test method for identifying respiratory tissue irritation
- ▶ Detailed review paper on *in vitro* renal cytotoxicity assays for future creation of a new test guideline
- ▶ New test guideline for the Zebrafish Embryo Developmental Neurotoxicity Screening Test (ZEDNT)
- ▶ New test guideline on a Human Mineralcorticoid Receptor Transactivation Assay: MRTA

Approved for Publication

- ▶ New test guideline on the determination of Cytochrome P450 (CYP) induction using differentiated human hepatic cells
- ▶ New test guideline on the ToxTracker assay for genotoxic hazard and genotoxic/non-genotoxic mechanisms of action
- ▶ New test guideline on the Glucocorticoid Receptor Transactivation assay
- ▶ New guidance document for in vitro testing of the intestinal fate of orally ingested nanomaterials
- ▶ New detailed review paper on respiratory sensitization

Upcoming Relevant Dates

- ▶ Formation of new expert groups and ad hoc groups to support the new projects (SPSFs) added to the workplan is currently underway.
- ▶ Publication of all WNT-38 approved documents is expected by late August; several of the new test guidelines were posted earlier this month.
- ▶ New U.S. project proposals will be due to the OECD via the U.S. National Coordinator in mid-November.
- ▶ WNT-39: April 20-23, 2027

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