

# Recap of OECD WNT - 35

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# Overview the OECD WNT

- ▶ Organization for Economic Cooperation and Development (OECD)
  - ▶ Since 1961, the OECD has worked to advise international governments through policy analysis, recommendations, standards, and collaboration that foster prosperity, equality, opportunity and well-being for all.
  - ▶ OECD brings together 38 member countries and other Key Partners to collaborate on global economic, social, and scientific issues including: tax policy, digital transformation, climate change, energy, trade, education, finance, and other.
- ▶ Chemicals and Biotechnology Committee (CBC)
  - ▶ CBC oversees OECD work on chemical safety and biosafety through the activities on eleven Working Parties, which collectively conduct research and develop guidelines on how to test chemicals for hazards to human health and the environment.
  - ▶ Mutual Acceptance of Data (MAD) is built on the OECD Test Guidelines (TG) and Principles of Good Laboratory Practice (GLP). It 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 TGs and GLP Principles. These tests are also accepted in non-member countries that adhere to MAD.
- ▶ Working Party of the National Coordinators of Test Guidelines Program (WNT)
  - ▶ National Coordinator from each member and MAD adhering country and the European Commission
  - ▶ Harmonize and approve Test Guidelines and related documents through consensus
  - ▶ <https://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm>

# Summary of the OECD WNT-35 Meeting

- ▶ Organization for Economic Cooperation and Development (OECD)
  - ▶ Working Party for the Test Guideline Program (WNT) Meeting was held hybrid April 25-28, 2023.
- ▶ Meeting highlights
  - ▶ Added 12 new Standard Proposal Submission Form (SPSF) for placement on WNT Workplan
  - ▶ Approved 10 Items: Test Guidelines, Guidance Documents, Detailed Review Reports
  - ▶ US Led/co-Led activities on 2 SPSFs proposals and 2 approved Test Guidelines
    - ▶ US participated on other projects and presented 2 Any Other Business items
  - ▶ Other updates and upcoming activities

# Approved SPSF Project Proposals

No.	Title	Lead
1	New Avian in ovo screening assay for sex steroid hormone disrupting properties	JP/FR
2	Revise water- sediment <i>Myriophyllum spicatum</i> toxicity test (OECD TG 239)	DE
3	Revise GD 122 on the Determination of the Toxicity of a Test Chemical to Dung Beetles ( <i>Scarabaeidae</i> ): Inclusion of a test protocol for <i>Onthophagus taurus</i> as Annex into the Guidance Document	DE
4	New Defined Approach for Eye hazard identification for Solids	FR
6	Revise TG 442D for $\alpha$ -Sens® as FBS-free test system for detecting Key Event 2 (ARE-Nrf2 activation) of skin sensitization	JP
7	Detailed Review Paper to facilitate the Development of Test Methods to Predict the Respiratory Sensitization Potential of Substances	US/AT LU/NL ICAPO
8	New TG: Stably transfected human retinoic acid receptors hRARs transcriptional activation assay	FR
9	New TG: Development of a new Test Guideline for the <i>in vitro</i> $\gamma$ H2AX/phospho-Histone H3 assay, a multiplexed biomarker approach that provides genotoxic mode of action information	FR/DE
10	Revise TG 493 ((Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) <i>In Vitro</i> Assays to Detect Chemicals with ER Binding Affinity) performance and acceptability criteria	JP/UK
11	Revise Guidance Document 34 on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment	EC/US/ DK
12	New Guidance Document on “Efficacy of pressurized aerosols for control of flying and crawling insects”	DE
13	Corrections to existing Test Guidelines	SEC
14	Proposal to revise TG 455 LUMI-cell protocol	UK

# Approved Test Guidelines - Phys/Chem & Biotic

- ▶ TG on Determination of hydrophobicity index for nanomaterials
- ▶ Revision of TG 240 Medaka Extended One-Generation Reproduction Test\*
- ▶ Revision of TG 218-219 sediment-water *Chironomus* test using spiked-sediment or spiked-water
- ▶ Guidance Document on a Juvenile Medaka anti-androgen screening assay (JMASA)
- ▶ Detailed Review Paper on Inclusion of thyroid endpoints in OECD fish tests
- ▶ TG on IL-2 Luc assay for *in vitro* immunotoxicity

\* = US led/co-led project

# Approved Test Guidelines - Health and Fate

- ▶ Initial Guidance Document on Evaluation of Data from the Developmental Neurotoxicity (DNT) *In-Vitro* Testing Battery\*
- ▶ Study Report on applicability of the key event-based TG 442D for *in vitro* skin sensitization testing of nano-materials.
- ▶ Updated Performance Standards for Assessment for proposed Similar or Modified *In Vitro* Reconstructed Human Cornea-like Epithelium (RHCE) Test Methods for Eye Hazard
- ▶ Validation report and Peer review report of the Epidermal Sensitization Assay (EpiSensA)

\* = US led/co-led project

# Other Test Guideline Program Activities

- ▶ OECD Omics Reporting Framework (OORF)
  - ▶ Announced for review <https://www.oecd.org/chemicalsafety/testing/omics.htm> ✓
  - ▶ Ready to launch new version in May/June 2023
- ▶ Thyroid Disruption Methods Expert Group
  - ▶ Established 2022 and held initial meeting in May 2023 ✓
- ▶ Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST)
  - ▶ Reformed to Emerging Science in Chemicals Assessment (ESCA) ✓
  - ▶ Initial meeting in June 2023
- ▶ WNT to discuss any adaptations needed to the Test Guideline Program for the uptake on emerging technologies
  - ▶ Held 6 webinars <https://www.oecd.org/chemicalsafety/testing/webinars-on-emerging-science.htm> ✓
  - ▶ Held Workshop in December 2022 ✓
  - ▶ Initiate revision to GD 34 on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment
  - ▶ Hold Stakeholder Workshop on Organizational and Financial aspects of Technical Validation in December 2023

# Other Test Guideline Program Activities

- ▶ Good Laboratory Practice
  - ▶ Advisory Document on GLP & Cloud Computing Supplement 1 to Document No. 17
  - ▶ Potential future guidance on Emerging Technologies and Application to GLP
- ▶ Any Other Business
  - ▶ Update on workshop on Implementing Virtual Control Groups for Preclinical Safety Studies
  - ▶ Assessing the quality and making appropriate use of Historical Negative Control Data for *in vivo* genetic toxicology TGs
- ▶ Deadline to submit SPSF proposals to the OECD November 15, 2023
  - ▶ <https://www.oecd.org/chemicalsafety/testing/standard-project-submission-form.pdf>



Questions?