

Update on OECD WNT Activities

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Overview

- ▶ Summary of OECD WNT Meeting 2023
- ▶ Other Test Guidelines Program Updates
 - ▶ Emerging Science in Chemical Assessment
 - ▶ OECD Omics Reporting Framework
 - ▶ Emerging Technologies Workshop December 2022
 - ▶ Stakeholder Workshop on Technical Validation December 2023
- ▶ Upcoming Activities


Making informed decisions on chemical safety



How do I decide whether a chemical is safe for human health and the environment?



What methods or protocols are available to test a chemical?
How do I interpret a new technology?



What data/information is behind the test and how can that data/information be trusted?

Overview the OECD and 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 through the activities on twelve 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 country and MAD adhering country
 - ▶ WNT harmonizes and approves Test Guidelines and related documents through consensus annually, in accordance with the 3Rs principle to Reduce, Refine, and Replace animal testing
 - ▶ Test Guideline Program: <https://www.oecd.org/env/ehs/oecd-guidelines-testing-chemicals-related-documents.htm>

Over-simplified Test Guideline Development Process

Propose

- Develop a SPSF proposal for a new (or existing) method and identify context of use
- Submit SPSF project proposal for WNT approval

Validate

- Standardize the procedure
- Develop validation report to demonstrate reproducibility and present data analyses
- Develop draft Text Guideline

Review

- Conduct expert review

Approve

- Conduct WNT commenting and approval process

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) projects for placement on WNT Workplan
 - ▶ Approved 10 Items: Test Guidelines, Guidance Documents, Detailed Review Reports
 - ▶ <https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>
 - ▶ US Led/co-Led activities on 2 SPSF proposals and 2 approved Test Guidelines
 - ▶ US participated on other projects
 - ▶ 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 α -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> γ 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)

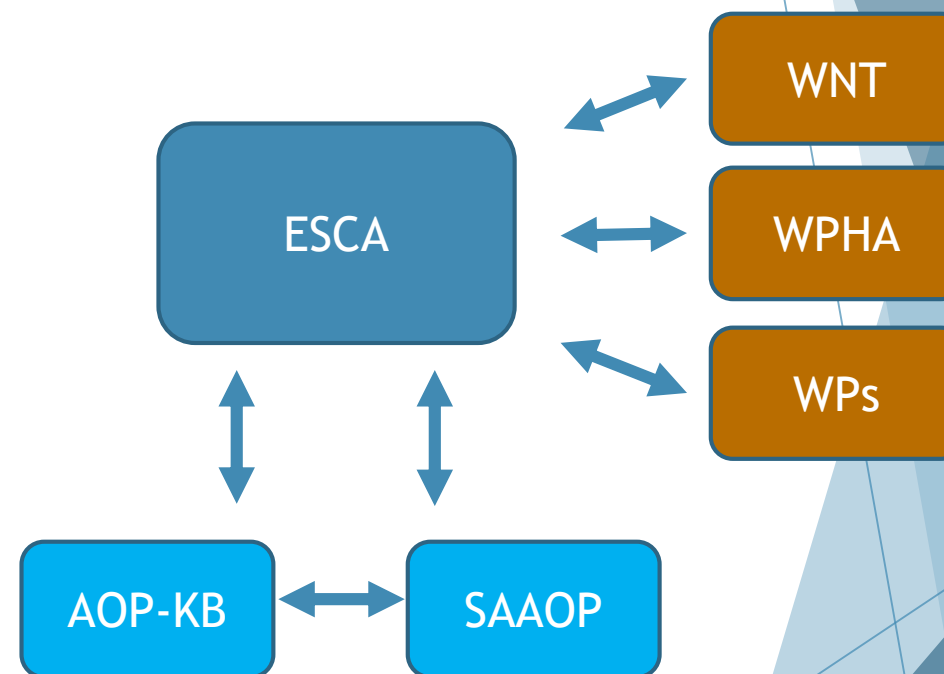
* = US led/co-led project

Other WNT Program Updates

- ▶ Emerging Science in Chemical Assessment
- ▶ OECD Omics Reporting Framework
- ▶ Emerging Technologies Workshop December 2022
- ▶ Stakeholder Workshop on Technical Validation December 2023

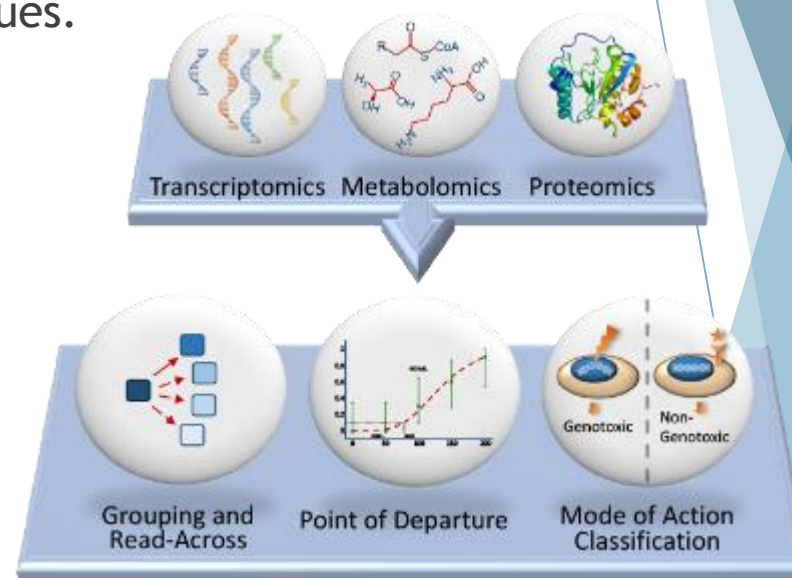
Emerging Science in Chemical Assessment (ESCA)

- ▶ New group to advise on emerging scientific approaches to support next generation chemical assessment to support application of NAMs
- ▶ Develop guidance or recommendations on emerging science and technologies for the benefit of regulatory applications
- ▶ Review and approve joint projects between ESCA and other WPs
- ▶ Oversee the essential elements of the Adverse Outcome Pathway Program Knowledge Base (AOP-KB)
 - ▶ <https://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>



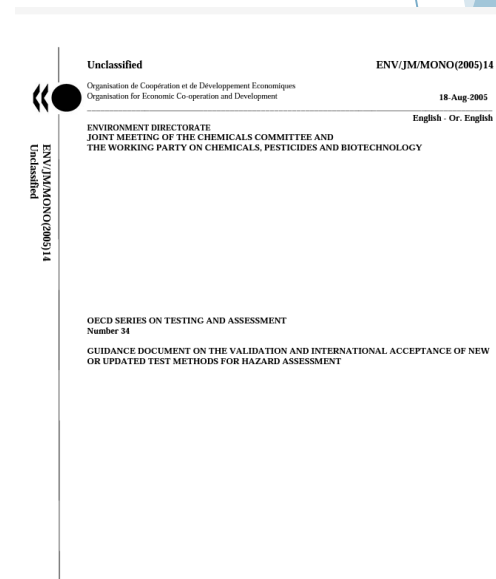
OECD Omics Reporting Framework (OORF)

- ▶ Omics describe approaches used to comprehensively measure the profiles of genes (transcriptomics), proteins (proteomics), or small molecule metabolites (metabolomics) within cells or tissues.
- ▶ OORF responds to a need to increase transparency in the reporting of Omics data:
 - ▶ Reporting framework and guidance for generating and analyzing Omics data
 - ▶ Merges a Transcriptomics RF and Metabolomics RF
 - ▶ Measure effects across a range of biological pathways simultaneously
 - ▶ Can be used to investigate a chemical's mode of action, predict toxicological effects, characterize dose response relationships, and understand species relevance
- ▶ OORF is still conducting trials of the framework to confirm utility and improve the guidance document
 - ▶ <https://www.oecd.org/chemicalsafety/testing/omics.htm>



Update Test Guideline Program Guidance

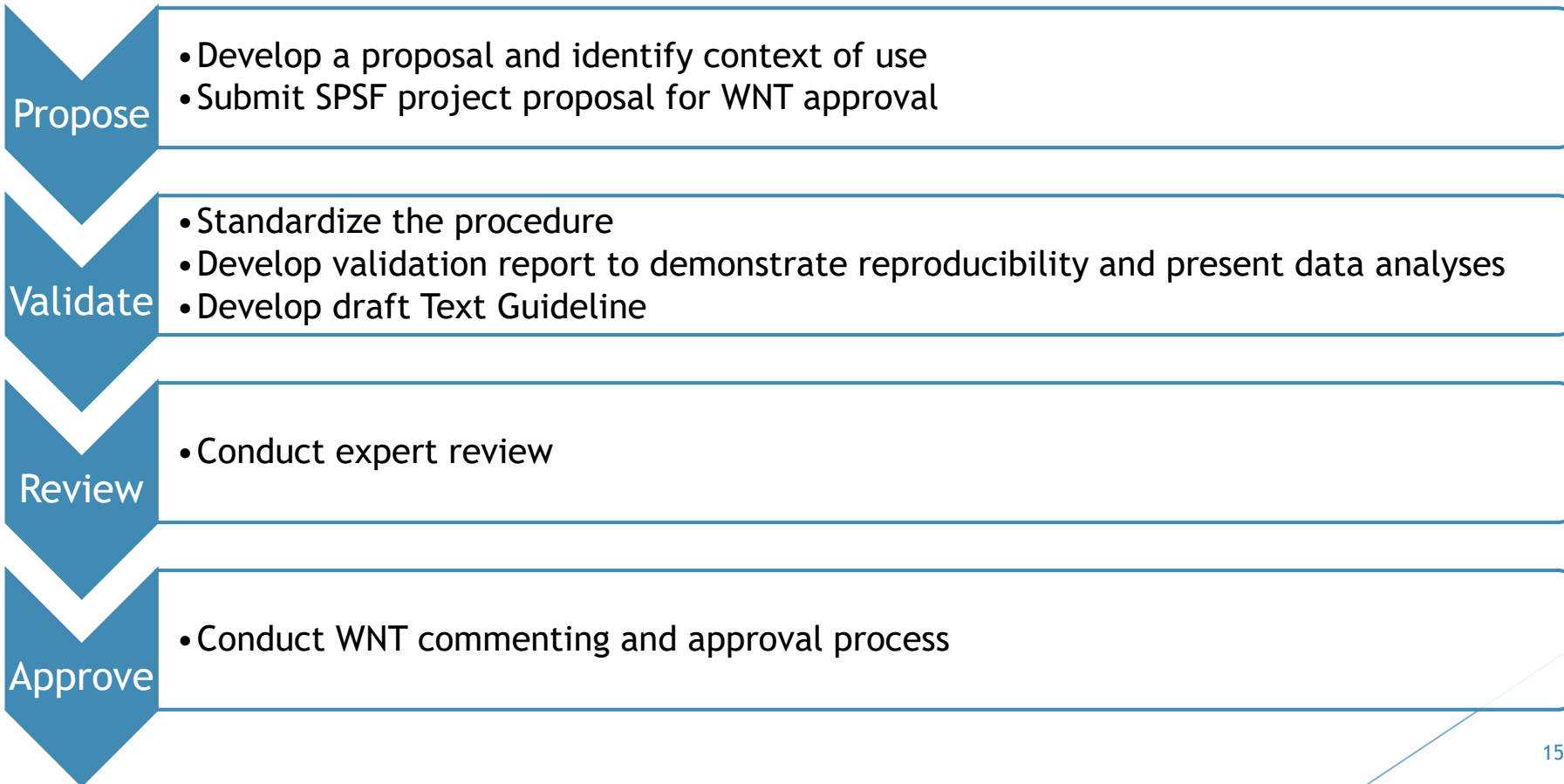
- ▶ WNT to discuss any adaptations needed to the Test Guideline Program for the uptake on emerging technologies
- ▶ Activities 2022
 - ▶ Held webinars series on Emerging Science to Improve Chemical Safety to discuss topics including validation, ecotoxicology, method readiness, and reproducibility
 - ▶ <https://www.oecd.org/chemicalsafety/testing/webinars-on-emerging-science.htm>
 - ▶ Held a workshop in December on how to prepare the Test Guidelines Program for Emerging Technologies
 - ▶ [https://one.oecd.org/document/ENV/CBC/MONO\(2023\)14/en/pdf](https://one.oecd.org/document/ENV/CBC/MONO(2023)14/en/pdf)
- ▶ Activities 2023
 - ▶ WNT approved project to revise Guidance Document 34 on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment
 - ▶ [https://one.oecd.org/document/ENV/JM/MONO\(2005\)14/en/pdf](https://one.oecd.org/document/ENV/JM/MONO(2005)14/en/pdf)
 - ▶ Next steps to update GD34



Technical Validation Workshop

- ▶ Call for funding for validation activities released in January 2023
 - ▶ Request for grant making institutions in member countries to prioritize the evaluation and validation of emerging science and technologies
 - ▶ <https://www.oecd.org/chemicalsafety/testing/urgent-mobilisation-national-regional-resources-to-support-the-validation-of-new-methods-safety-testing-of-chemicals.pdf>
- ▶ Host a workshop in December 2023 to:
 - ▶ Develop understanding of validation stakeholder community to clarify who is involved and how they work together
 - ▶ Understand the needs, drivers, and difficulties of validation for regulatory purposes and how the community is responding to those needs - hear what works well/does not
 - ▶ Discuss and determine acceptable and good practices to promote for inclusion in GD34
 - ▶ Discuss how to increase trust in processes, practices and results
- ▶ Disseminate a survey in advance of the workshop to expert groups, validation bodies, and other recommended target groups
- ▶ Outcome
 - ▶ Gain an overview of various validation initiatives and the stakeholders involved
 - ▶ Identify future drivers/needs and pragmatic approaches/practices to promote

Over-simplified Test Guideline Development Process



Upcoming WNT Activities

- ▶ SPSF proposals due to OECD by November 15, 2023
- ▶ Stakeholder Workshop on Technical Validation December 2023
- ▶ 36th WNT meeting April 15-18, 2024

Questions?

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