Work plan for the OECD Test Guidelines Programme (TGP)

-July 2024-

The work plan includes 5 sections for specific projects:

Section 1 (Projects related to Test Guidelines on physical-chemical properties)

Section 2 (Projects related to Test Guidelines on effects on biotic systems)

Section 3 (Projects related to Test Guidelines on environmental fate)

Section 4 (Projects related to Test Guidelines on health effects)

Section 5 (Projects related to other Test Guidelines)

Projects remain in the work plan until the publication of the Test Guideline or other Test Guideline-related document. Each project keeps the same identification number until it is completed.

Abbreviations used:

TG: Test Guideline

GD: quidance document DRP: detailed review paper

CBC: Chemicals and Biotechnology Committee

EDTA AG: Endocrine Disrupters Testing and Assessment Advisory Group

EG: Expert Group NC: National Coordinator

SPSF: standard project submission form

VMG-eco: Validation Management Group for Ecotoxicity Testing

WNT: Working Party of the National Coordinators for the Test Guidelines Programme

WPP: Working Party on Pesticides

WPMN: Working Party on Manufactured Nanomaterial

WPB: Working party on Biocides

SECTION 1 PROJECTS RELATED TO TEST GUIDELINES ON PHYSICAL-CHEMICAL PROPERTIES

Project 1.5: Guidance Document on Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media

Lead: Denmark/Germany

Inclusion in work plan: 2EG019

Project Status and milestones: Project Status and milestones:

- March 15 2024: One date for Follow-up meeting with project 1.5 laboratory partners
 - March 31 2024: Circulation of revised draft to the JEG for 2nd round of comments
 - April 2024: Input and contributions from Project 1.5 partners
 - May, 2024: JEG Teleconference to review comments addressed during 2nd round of comments and review of outstanding issues.
 - May 21 2024. Revised draft to JEG (revision based on comments from first circulation and further elaboration)
 - June 30 September, 2024: WNT Commenting round
 - Other commenting rounds if needed.
 - Expected to be submitted for approval to the WNT in 2025

Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of
	nanomaterials

Project 1.6: Guidance Document on Identification and quantification of the surface chemistry and coatings on nano- and microscale materials

Lead: Denmark/Germany
Inclusion in work plan: 2019
Project Status and milestones:

- ILC and evaluation of results is now completed.
- 1draft to be circulated to the JEG end March 2024
- JEG call early April to present the draft and address preliminary comments.
- Review of comments and preparation of a revised draft for the 2nd JEG commenting round of the (June-September)
- Additional commenting rounds to the JEG, if appropriate, otherwise initiate WNT review in October 2024
- Expected to be submitted for approval to the WNT in 2025

Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of
	nanomaterials

Project 1.8: TG on Determination of the Dustiness of Manufactured Nanomaterials	
Lead:	Denmark/Germany (previously France)
Inclusion in work plan:	2019
Project Status and milestones:	
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Project Status and milestones:	

- Discussion on how to harmonize data collection for various dustiness methods.
- Preparation of a template for data, and discussion on the models to be used for data treatment Q3-Q4 2020.
- Distribution of the materials (non-HARN) required for the ILC to all partners.

2021-2022

- Intra-lab Non-HARN testing (Q3-Q4 2021)
- Inter-lab Non-HARN testing (Q4 2021)
- Reporting preliminary Non-HARN results (Q4 2021).
- Storage of all transient & raw data (BSCW server, Q4 2021)
- Preparation of First draft TG (with treatment on Non-HARN materials tests) (Q4 2021- Q1 2022)
- Evaluation and further Non-HARN testing (Q1-Q2 2022)
- Distribution of HARN materials (Q3-Q4 2021)
- Intra-lab tests on HARN materials (Q4 2021-Q1 2022)
- Inter-lab tests on HARN materials (Q2 2022)

2023-2025

Participation of France in this project was discontinued.

- Draft version of the TG (including both HARN and non-HARN materials) ready for expert group commenting (Q1-Q2 2024)
- Draft version of the validation report available (Q1-Q2 2024)
- Test Guideline and Validation Report submitted to WNT for public commenting (Q3 2024)
- Approval of the TG and Validation Report by WNT: April 2025

HARN: high aspect ratio nanoparticles

Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of
	nanomaterials

•	ent of a new Guidance Document on the determination of
concentrations of nanoparticles in biological samples for (eco)toxicity studies	
Lead:	United Kingdom
Inclusion in work plan:	2021
Project Status and milestones:	

Project Status and milestones:

April 2021 – Nov 2022

- Expert Group established. 1st Meeting held 22 Sept 2021.
- Development of conceptual plan for guidance document; progress being made but initial draft GD not expected until late 2022 to fit in with relevant outputs from EU NanoHarmony project.
- Discussion with the OECD EG on the progress and the initial draft GD (Nov)
- Potential workshop on draft GD (organised in collaboration with the OECD secretariat and potentially supported by the NanoHarmony project) with anticipated involvement to include project Ad Hoc Expert Group and relevant WPMN and WNT Expert Groups (Nov)

Q4 2024 - 2026

- Virtual Meeting of the EG (Q4 2024 (Nov))
- EG Review on the draft GD (Q1/Q2 2025)
- 1st WNT commenting round on draft GD (Q3 2025)
- 2nd WNT commenting round on revised draft GD (Q4 2025 Q1 2026)

Submission to WNT for approval (2026)	
Subsidiary body of the JM	WNT
Expert group	Joint WNT-WPMN Expert Group on nanoconcentration in biological samples

SECTION 2 PROJECTS RELATED TO TEST GUIDELINES ON EFFECTS ON BIOTIC SYSTEMS

Project 2.47: New TG on D	Determination of Effects on Earthworms in Field Studies
Lead:	Germany

Inclusion in work plan: 2013

Project status and milestones:

Project Status and milestones:

Establishment of an ad hoc Expert Group nominated by WNT in April 2013;

2017-2018: validation of test design in pilot study;

March 2019: Meeting of extended project group;

Mid-2022: first draft TG and draft validation report for EG commenting;

Q1/Q2 2023 finalisation of EG review and start WNT commenting;

Earliest adoption of TG by OECD WNT (2025).

Subsidiary body of the JM	WNT
Expert group	Expert Group on earthworm toxicity testing

Project 2.54: Guidance Document on IATA for Fish Acute Toxicity Testing Lead: Inclusion in work plan: Project status and milestones: Austria/ICAPO 2015

Project Status and milestones:

Development of a first draft Guidance Document including the FET in the threshold approach for acute fish toxicity testing (GD 126) in mid-2016, discussed by the VMG-eco in October 2016; New scientific data were published in 2018 and 2019, however, further data to support the IATA development were generated during 2020-2022.

2023: these new data were integrated into the draft acute fish toxicity IATA guidance document for circulation and discussion by VMG-Eco experts; The new data and TG 249 were integrated into the draft acute fish toxicity IATA guidance document for circulation and discussion by VMG-Eco experts in October 2023.

• Finalisation of the project at WNT level is envisaged by the WNT meeting not before April 2025.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.55: Use and analysis of control fish in toxicity studies

Lead: United States/ICAPO Inclusion in work plan: 2015

Project status and milestones:

Part 1: Update of OECD Guidance Document 23 is completed. (This part was co-lead by the United States)

Part 2: Detailed Review Paper of use of controls in aquatic ecotoxicity tests

- June 2015: Project Group established and preliminary discussions during kick-off TC in July 2015
- May 2015 February 2016: Discussion of templates for data analysis with statistician.
- October 2015: Presentation of data analysis to VMG-Eco/Fish Drafting Group (OECD TG 203 and TG 212)

- Since January 2016: Data collection (OECD TG 210).
- January 2017 April 2018: On hold whilst completing update of GD 23.
- May 2019: Communication with statistician regarding publication of TG 203 and TG 212 data simulations and statistical simulations of available TG 210 data.
- April 2020– December 2021: Statisticial analyses and simulations of the effect of control choice on statistical power and the calculated treatment effects in TG 210 studies.
- October 2020: Discussion with the VMG-Eco
- November 2020: transfer of leadership from European Commission to United States
- 2022-2023: Drafting of a Detailed Review Paper and, if necessary, development of a proof-of-concept describing what is required before a single control can be used in aquatic ecotoxicity tests; consideration of whether it is necessary for all laboratories to maintain their own historical databases to support the use of a single control.
- 2023-2024: WNT commenting rounds of DRP;
- 2025: WNT approval.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.58: New Test Guideline on a Short-term Juvenile Hormone Activity Screening Assay using Daphnia magna	
Lead:	Japan
Inclusion in work plan:	2016
Project status and milestones:	
Project completed.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco/Invertebrate testing EG

Project 2.59: New Test Guideline on Zebrafish Extended One Generation Reproduction Test (ZEOGRT) Lead: Inclusion in work plan: Germany 2016

- Validation study is taking place 2017-2023: The aim is to test two substances according to the protocol by at least two to three laboratories;
- Draft protocol for the ZEOGRT assay was submitted and discussed at the October 2018 VMG-Eco meeting;
- Draft validation report part 1 was distributed to VMG-eco in 2020 for commenting (results or 4 studies in one lab);
- WNT call in April 2021 for additional laboratories to take part in the validation; Next steps
 will be proposed by the VMG-Eco after further validation results and submission of a first
 draft of the TG and validation report part 2 in Q2/Q3 2024;
- Finalisation of DE validation project for ZEOGRT study Q1/Q2 2024;
- Draft VR Phase 2 and draft TG to be submitted for VMGeco 2024 in Q2/Q3 2024;
- Proposal of next steps by VMG-Eco 2024.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.62: New TG on Growth Inhibition Test for the Rooted, Emergent Aquatic Macrophyte, Glyceria maxima

Lead: Netherlands/United Kingdom
Inclusion in work plan: 2019

Project status and milestones:

- First ring-test already completed, second ring-test with Imazapyr during Q3 2018 to Q4 2018;
- OECD Expert group established in July 2019; with first EG discussion in April 2020.
- Ring-test 3 was rescheduled for Q3 2021;
- July 2023: the project leads submitted the ring-test report, the draft TG and responses to experts comments dating from April 2020;
- Next step is to circulate the documentation to the OECD Expert Group for a commenting round; depending on the extent of feedback, the draft TG may require further work or a virtual meeting with the leads/experts or may go for a WNT commenting round later in Q2 2024 (Secretariat was fully booked in Q2-Q3 2024).

Subsidiary body of the JM	WNT
Expert group	To be determined

Project 2.64: Inclusion of thyroid endpoints in OECD fish Test Guidelines	
Lead: Inclusion in work plan: Project status and milestones:	Denmark/Germany/Belgium 2019

Project status and milestones:

2023-2024

- Detailed Review Paper approved in April 2023 (WNT).
- Four endpoints/biomarkers selected for validation: Swim bladder inflation, eye development (size and histopathology), thyroid hormone concentrations and thyroid follicle morphology (transgenic line or histopathology). SOPs prepared for TG 236 and TG 210.
- Conduction of validation ring test(s) involving experts and laboratories supported by the VMG-Eco (expenses have to be paid by the involved laboratories/institutions). Invitation letter prepared summer 2023.
- Evaluation of the ring test results and completion of a draft guidance for evaluation of THSD endpoints.
- Inclusion of suitable THSD endpoints in relevant fish TGs including OECD TGs 210, 234 and 236 and completion of a consolidated draft TG for submission to the OECD Secretariat

2025

- WNT commenting rounds.
- Acceptance of updated TG/TGs by OECD WNT.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.65: New TG on Acute Contact Toxicity Test for the solitary living Mason Bee (Osmia spp.) Lead: Inclusion in work plan: Switzerland 2019

Project status and milestones:

- First drafts of the guideline and the validation report were reviewed by the Honey Bee Expert Group in Q3 2023.
- Expert group meeting/Teleconference to discuss the validation reports and draft TG in Q1-Q2 2024.
- Revised validation reports and TG (based on comments) for a 1st commenting by the WNT in Q1-Q2 2024.

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Subsidiary body of the JM	WNT
Expert group	Expert Group on Honey bee and other bees testing

Project 2.66: REACTIV (Rapid Estrogen Activity In Vitro) Assay	
Lead:	France/ United Kingdom/ Japan
Inclusion in work plan:	2020
Project completed.	
Subsidiary body of the JM	WNT
Expert group	Validation Management Group for Ecotoxicity Testing

Project 2.67: Revision of OECD TG201 relating to the scientific name of algal strains and adding new algal strain	
Lead: Inclusion in work plan:	Japan 2021

- Basic data (characteristics of these strains, sensitivities to chemical substances, culturing and handling techniques and recommended medium for these strains, and so on.) was provided at VMGeco in 2021 and 2022.
- An inter-laboratory validation is conducted in 2023-24.
- A final report of the inter-laboratory and draft of revised test guideline including the update of the scientific name will be prepared in 2024.

Subsidiary body of the CBC	WNT
Expert group	Validation Management Group for Ecotoxicity Testing

Project 2.68: New Test Guideline on Sediment-Water Amphipod Toxicity Test	
Lead:	Japan/France
Inclusion in work plan:	2022

- Development of draft TG, Expert group and WNT commenting rounds (Oct 2022)
- An inter-laboratory ring trial using at least two chemicals with different physico-chemical properties; A call for additional testing laboratories if necessary (2022-25).
- Readjustment of the protocol as a function of comments from testing laboratories (2024-25).
- A final report of the inter-laboratory validation and draft revised TG will be prepared in 2025;
- Adoption of TG by OECD WNT (Apr 2026).

Subsidiary body of the CBC	WNT
Expert group	Expert Group Sediment-Water Toxicity Tests

Project 2.70: Revision of Guidance Document 75 on Honeybee Brood Test under semi-Field Conditions	
Lead: Inclusion in work plan:	Germany/Switzerland 2022
Project completed.	
Subsidiary body of the CBC	WNT
Expert group	Honeybee Testing Expert Group

Project 2.71: Revision of Guidance Document 317 on Aquatic Toxicity Testing of Nanomaterials	
Lead:	France/Spain
Inclusion in work plan:	2022

- 2023: Experimental work completed
- Drafting of technical annexes to Guidance Document on Aquatic Toxicity Testing of Nanomaterials.
- Submission to the expert group of the technical annexes: Q2 2024.
- Expected approval of updated Guidance Document in 2025.

Subsidiary body of the CBC	WNT
Expert group	Joint WPMN/WNT Expert Group on ecotoxicity and environmental fate testing

Project 2.73: New TG on Avian in ovo screening assay for sex steroid hormone disrupting properties Lead: Inclusion in work plan: Japan/ France 2023

Project status and milestones:

For the Japanese quail:

- The finalization of procedure and preparation of the draft protocol for validation studies will be completed in 2024.
- Validation test by multiple institutions will begin in 2024.

For the white Leghorn:

- Technical work, phase 1 (transferability): November 2022-Spring 2023 in 3 labs (Sweden, France, Spain).
- Technical work phase 2: end 2023-Summer 2025.

Draft test guideline and report(s) of validation studies will be prepared and submitted to the Ad Hoc Expert Groups in fall 2025.

Revised draft test guideline and validation reports will be submitted in 2026 for WNT commenting.

Final draft test guideline will be discussed for approval at the WNT in 2027.

Subsidiary body of the CBC	WNT
Expert group	Validation Management Group for Ecotoxicity Testing

Project 2.74: Revision of TG 239 on Water-Sediment Myriophyllum Spicatum Toxicity Test	
Lead:	Germany
Inclusion in work plan:	2023

Project status and milestones:

- Nomination of experts to participate in the ad hoc Expert Group (July 2023)
- Ad hoc Expert Group to review draft revised TG 239 (Oct. 2023)
- Circulation of draft revised TG 239 version #1 for 1st WNT commenting round (Q2 2024)
- Circulation of draft revised TG 239 version #2 for 2nd WNT commenting round (Q4 2024)
- Earliest WNT adoption of revised TG 239 (April 2025).

Subsidiary body of the CBC	WNT
Expert group	Myriophyllum EG

Project 2.75: Revision of the Guidance Document 122 on the Determination of the Toxicity of a Test Chemical to the Dung Beetle Aphodius Constans

Lead:	Germany
Inclusion in work plan:	2023
moldsion in work plan.	2023

- Nomination of experts to participate in the ad hoc Expert Group (July 2023);
- Ad hoc Expert Group to review draft revised GD 122 (Q1/Q2 2024)
- Circulation of draft revised GD 122 version #1 for 1st WNT commenting round (Q2/Q3 2024)
- Circulation of draft revised GD 122 version #2 for 2nd WNT commenting round if needed (Q4 2024)
- Earliest WNT adoption of revised GD 122 if possible (April 2025).

Subsidiary body of the CBC	WNT
Expert group	Dung beetle EG

Project 2.76: Mason bees (Osmia sp.), Acute Oral Toxicity Test	
Lead: Inclusion in work plan:	Finland/Switzerland 2024
Project status and milestone	S:

- First drafts of the guideline and the validation report will be ready for the Expert group commenting until June 2024.
- If necessary, expert group Teleconference or meeting to discuss the validation reports and draft TG in autumn 2024
- Revised validation reports and TG (based on comments) for the 1st commenting by the WNT in winter months 2024/2025
- 2nd WNT-commenting round in Autumn 2025. 5. Proposal of final validation report and draft TG for approval by the WNT in April 2026.

Subsidiary body of the CBC	WNT
Expert group	Honeybee testing Expert group

Project 2.77: Chronic Oral Toxicity Test for Solitary Bees (Osmia spp.)	
Lead:	Spain/Italy
Inclusion in work plan:	2024

- Q2 2024: repeat the ring test involving additional laboratories (even not decided yet by the WNT and/or the bee expert group if additional testing is needed, in such case, the test needs to be performed in spring).
- Q4 2024: the first drafts of the guideline and the validation report will be ready.
- Q1 2025: first round commenting and expert group meeting to discuss the validation reports and draft TG.
- Q2 2025: the revised validation reports and TG (based on comments) for a 2nd commenting of the WNT.
- Q3 2025: proposal of final validation reports and draft TG for approval by written consultation.
- Approval and finalization of the guideline thereafter.

Subsidiary body of the CBC	WNT
Expert group	Honeybee testing Expert group

Project 2.78: Bumblebee (Bombus supp. L.), Chronic Oral Toxicity Test(10-Day Feeding)	
Lead:	Spain
Inclusion in work plan:	2024

- First drafts of the guideline and the validation report will be ready for WNT commenting at end Q2 2024 so the WNT may comment during Q3 2024.
- Expert group meetings to discuss the validation reports and draft TG in Q3 2024.
- Revised validation reports and TG (based on comments) for a 2nd commenting by the WNT in Q4 2024 or Q1 2025.
- Proposal of final validation reports and draft TG for approval by the WNT in Q2 2025 (in WNT meeting April 2025) or later by written consultation.
- Approval and finalization of the guideline thereafter.

Subsidiary body of the CBC	WNT
Expert group	Honeybee testing Expert group

SECTION 3 PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE

Project 3.10: New TG on dissolution rate of nanomaterials in aquatic environment	
Lead:	Germany (since 2020)
Inclusion in work plan:	2014

Project status and milestones:

- Conceptional development (coordination with related TG and GD developments, exchange with project associated expert group): autumn/winter 2020
- Update of SPSF Nov 2020;
- Update of existing protocol to determine solubility and dissolution rate using batch test: end of 2022 (building upon previous project draft "Dissolution of metal nanomaterials in environmental media");
- Development of protocol to determine dissolution rate using dynamic testing flow through method): mid-2023;
- Frequent exchange with WNT projects 1.5 and 3.16;
- Validation study (both on batch and dynamic testing): Spring 2024;
- EG commenting: Q2/Q3 2024.

Subsidiary body of the CBC	WNT
Expert group	Joint WPMN/WNT Expert Group on ecotoxicity and environmental fate testing

Project 3.12: New GD on assessing the apparent accumulation potential for nanomaterials	
Lead:	Spain
Inclusion in work plan:	2014

Scope of the project. The aim of the project is to develop a GD for the study of the bioaccumulation of NMs in fish via water and via diet. The GD will focus on the assay and will not address how to waive it. Limitations of the project: Although the GD will address how to perform bioaccumulation studies with all NMs in fish, it will mainly focus on metal nanomaterials due to the limitations in the determination of non-metallic nanomaterials in feed and fish tissues.

Project status and milestones:

- Scientifical data was performed under the framework of the H2020 project Gov4Nano.
- Scientifi papers were published and Spain initiated the drafting of the GD
- The Draft GD will be circulated to the JEG Q2 2024 and it is expected to complete the commenting rounds on time for its submission to the WNT in 2025.

Note: the project was included in the PoW in 2014. In moving forward, the WNT agreed (2018) to split the project in two parts. The WNT project 3.12 is focused on TG305 and is led by Spain.

In parallel, the UK developed the A Tiered Approach for Reliable Bioaccumulation Assessment of Manufactured Nanomaterials in the Environment Whilst Minimising the Use of Vertebrate Testing - Scoping Review (ENV/CBC/MONO(2024)2, under the WPMN).

Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on Ecotoxicity and Environmental Fate
	Testing

Project 3.15: New Test Guideline to determine the uptake of chemicals by plant roots Lead: Inclusion in work plan: Germany 2018

- An ad hoc expert group has been established in order to give further advice on the test design before final validation.
- Pre-testing in 2019/2020;
- Validation study the aim is to test the uptake of substances according to the protocol in different crops by about 8-10 laboratories August 2021 to March 2022;
- Experimental results not as clear as expected; Germany will start new validation work.
- June/July 2024: Optimization of test protocol
- Q3 2024: Validation of optimized protocol by additional round robin test
- Q4 2024: Evaluation round robin test results
- Q1 2025: Decision on next steps in the OECD project.

Subsidiary body of the CBC	WNT
Expert group	Ad hoc Expert Group on plant uptake of chemicals

Project 3.16: Guidance Document Environmental abiotic transformation of nanomaterials	
Lead:	Austria
Inclusion in work plan:	2019
Project status and milestones:	
Oct. 2019 - March 2020:	
	, building of a scientific library for nanoscale and bulk related
transformation processes u environmental monitoring da	nder environmentally relevant conditions, data collection of tax with focus on transformation-relevant species. Framing the
	pathways in the environment.
species and conditions dri	ronmental media composition(s) representing both, the aquatic ving transformation and their concentrations and conditions
representative for the aquatic	environment.
Sept. 2020 – Dec. 2022:	as of a pat of quitable NIMa (quifidation formation of law polybla
solids other than sulphic	ng of a set of suitable NMs (sulfidation, formation of low soluble de, loss of coating). Development of protocols for nanomaterial (experimental and analysis) which are suitable for later
Q2 2023-Q1 2025:	
Submission of first dra reviews:	aft GD to the OECD Expert Group for review, followed by WNT
,	WNT for approval in April 2025.
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on Ecotoxicity and Environmental Fate
	Testing

Project 3.17: New TG on Hyalella azteca Bioconcentration Test (HYBIT)	
Lead: Inclusion in work plan: Project status and milestones:	France/Germany 2019
Completed.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Hyalella azteca bioconcentration test

Project 3.19: new Test Guideline for a marine biodegradation screening test for chemical persistence assessment (MaP test) Lead: Inclusion in work plan: United Kingdom 2021

Project status and milestones:

- Revision of project plan and proposal for additional testing (March 2024);
- Consult with Ad Hoc Expert Group to enact recommendations coming out of the independent report and to support/manage the subsequent validation work (April 2024).
- Draft new Test Guideline for peer review based on existing SOP and additional validation work, and carry out a stakeholder workshop towards the end of this work (April 2026).
- OECD WNT meeting for acceptance of new Test Guideline (April 2027).

Subsidiary body of the JM	WNT
Expert group	Expert Group on marine biodegradation screening test

Project 3.20: Revision of OECD Test Guideline 309	
Lead:	United Kingdom
Inclusion in work plan:	2024

- Literature analysis (Q1 2024)
- Chemical/inoculum selection and OECD expert group approval (Q1 2024)
- Ring trial completion (Summer 2024)
- Peer review by the relevant OECD EG (Q3 2024)
- Further discussion within the EG as required (e.g., of further data generation requirements, if needed) (Q4 2024)
- Submission of the draft revised TG 309 to the WNT for commenting rounds should all aspects above proceed in a timely and smooth fashion (Q4 2024), but should further data generation be needed, submission to the WNT will then be conducted in good time for the 2025 WNT meeting.

Subsidiary body of the CBC	WNT
Expert group	TBD

SECTION 4 PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS

Project 4.94: IATA on Non-Genotoxic Carcinogens Lead: United Kingdom 2015

Project status and milestones:

- Uncertainty analysis and collection of relevant assays conducted in 2016-2017;
- 3rd face to face meeting took place on 25-27 June 2018;
- Expert Group working on the evaluation of all relevant assays being identified 2019-2021;
- 1st draft IATA published 2020;
- Work progressing on the lead side, including (i) preparation of a NGTxC IATA draft Regulatory framework and (ii) work on publications to support the future IATA;
- Expert group meeting possibly organised in Q3-Q4 2024 (tbc);
- Integration of assays into an IATA and 1st draft IATA workshop reportexpected to be available for commenting in 2024.

Subsidiary body of the JM	WNT
Expert group	Expert Group on Non-Genotoxic Carcinogenicity

Project 4.97: EDTA Activity: Detailed Review Paper on Retinoid System	
Lead:	United States/OECD Secr. (starting 2021)2015
Inclusion in work plan:	
Project status and milestones:	
 Project completed; additi US author. 	onal chapter on cardiovascular system will be drafted in 2024 by the
Subsidiary body of the JM	WNT
Expert group	Expert Group on Retinoid Pathway/ EDTA AG

Project 4.106: New TG: Genomic Allergen Rapid Detection test for skin (GARDskin) test: An in vitro method for identification of skin sensitizers based on a genomic interpretation of the impact of chemicals on human dendritic cell-like cells (AOP key event 3).

Lead: Sweden 2016

Project status and milestones:

- GARDskin approved and was published in TG 442E on 30 June 2022;
- Additional data has been generated on GARDpotency, according to ESAC recommendations. The data will not be peer-reviewed at this time. Instead, the possibility to achieve quantitative assessment of sensitizing potency using the supplementary method GARDskin Dose-Response is being explored and will be further discussed with the EG on Skin sensitisation.

Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

Project 4.107: New TG: Toxicogenomic analysis on 3D reconstituted epidermis for measuring

skin sensitization potency – the SENS-IS assay.	
Lead: Inclusion in work plan: Project status and milestones:	France 2016

- Q2-Q3 2016: first full submission of the SENS-IS method to ECVAM for evaluation
- 2018: revised full submission to ECVAM;
- Since 2019: Addressing questions from ECVAM evaluation;
- In order to proceed with the project, predictive capacity of the SENS-IS method needs to be recalculated based on the LLNA/human database and the updated reference chemicals list, which are awaited from project 4.116 (Defined Approach(es) for Skin Sensitization);
- Peer review organised in Q2 2023; no outcome was communicated to the OECD yet.

The status of this project will be clarified at the WNT meeting in April 2024.

Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

Project 4.124: New Guidance Document on Developmental neurotoxicity (DNT) in vitro assays	
Lead: Inclusion in work plan: Project status and milestones:	EC (EFSA, JRC)/US/DK 2017

Project status and milestones:

Initial recommendations document approved in April 2023, project continues in 2024-2025 with the transfer of the assays to third parties laboratories, the development of testing strategy(ies), the guidance on quantitative in vitro to in vivo extrapolation and the chapter on zebrafish light-dark transition assay.

 November 2024: within the remit of both the WNT and WPHA: OECD Workshop on Critical Innovations in pesticides safety testing and chemical risk assessment for developmental neurotoxicity (DNT).

Subsidiary body of the JM	WNT (and also WPHA for some of the proposed activities)
Expert group	Expert Group on DNT

Project 4.125: New TG on the ToxTracker assay: a stem cell-based reporter assay for mechanistic carcinogenicity hazard assessment Lead: Inclusion in work plan: Netherlands 2017

Project status and milestones:

In line with OECD GD 34 a internal and external validation has been conducted; Validation Management Team has been installed;

Several laboratories were involved in blind testing (7 labs);

A set of 64 compounds has been tested (blind) in 3 labs;

2022: Data evaluated and report prepared;

2023: Draft documents (including the validation report) were submitted to the OECD; the peer-review was organised in Q4 2023; the next steps need to be discussed with the test developer and lead country in Q1 2024.

Subsidiary body of the JM	WNT
Expert group	Expert Group on non-genotoxic carcinogenicity

Project 4.130: Amendment to OECD Test Guideline 437 BCOP that includes a histopathological examination to revise the Decision Criteria for classification of chemicals requiring classification for eye hazard

Lead: Japan Inclusion in work plan: 2018 Project status and milestones:

- Spring 2018: Since the data supported inclusion in TG 437, Japan and IIVS submitted all the available results;
- Japan shared some of the BCOP histopathological slides to IVIS and VITO, Belgium for between laboratory reproducibility and peer review; an update on progress was made in Nov. 2018 at the EG meeting;
- Q2 2020: submission of the additional report on between laboratory reproducibility of this proposal to EG;
- Discussion on possible updates to TG 437 at the EG meeting in Q4 2020; harmonization of terminology and identification of decision criteria in Q4 2021;
- 2020-21: development of a common lexicon on eye histopathology evaluation to increase consistency of findings across pathologists and discussion on the next steps at virtual meetings in 2023.
- Discussion on BCOP histopathological examination and draft updated TG 437 and GD 160 will be shared with the EG by mid-July 2023.
- 2023: The leads have proposed some revised text for TG 437 and the revised TG will be presented for approval at the next WNT in April 2024.

Subsidiary body of the JM	WNT
Expert group	Expert Group on eye irritation

Project 4.139: In vitro genotoxicity testing for dermal exposure using 3D skin models: reconstructed skin micronucleus test and reconstructed skin Comet assay	
Lead: Inclusion in work plan:	Germany/France 2019
more plant	

- Q1 2020: submission of validation datasets for the reconstructed skin Comet assay (RS Comet), for ECVAM review.
- Q2 2020: submission of validation datasets for the reconstructed skin micronucleus test (RSMN), for ECVAM review.
- Q2 2021: full submission of RS Comet to ECVAM for peer-review
- Q3 2021: full submission of RSMN to ECVAM for peer-review
- Q1 2023-ongoing: ESAC peer-review.

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Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

Expert group

Project 4.145: Guidance document on an integrated approach on testing and assessment (IATA) for phototoxicity	
Lead:	Japan
Inclusion in work plan:	2020
Project status and milestones:	
 Project completed. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on phototoxicity testing

Expert group	Expert Group on phototoxicity testing	
Project 4.146: New Guida particles	Project 4.146: New Guidance Document on toxicokinetics to accommodate testing of nanoparticles	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands/ United Kingdom 2020	
Determine minimum requirereparation of a first draft Second half of 2020: Interest organised in collaboration Progress slower than expect hanges in the project lea December 2021: Virtual means of the project lea November 2022: Nanohal progress Q3/Q4 2023: Developmer June/September 2024 (TE) September 2024 – Janual comments (2 commenting April 2025 (TBC): Approver	rnational workshop on the toxicokinetics of (nano)particles (probably with the EU project NanoHarmony); ected due to impact of COVID on planned experimental studies and the d team. neeting of the joint Expert Group rmony workshop with the joint Expert Group to discuss experimental of the first draft GD Virtual meeting of the joint Expert Group (SC): Draft GD submitted for comments to WNT (second milestone); ry 2025 (TBC): WNT commenting rounds, revision of drafts based on grounds are envisaged);	
Subsidiary body of the JM	WNT	
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Project 4.147: EDTA: DRP on the State of the Art of Metabolic Disruption by Chemicals	
Lead: Inclusion in work plan: Project status and milestones:	UK/NL/SE/GER/FR 2020
A first draft DRP will be sent for review in late 2024. Several relevant papers have been published and more are underway through 2024.	
Subsidiary body of the JM	WNT
Expert group	Advisory Group on Endocrine Disrupters Testing and Assessment

Joint WPMN-WNT Expert Group on Toxicokinetics of NM

Project 4.150: New TG on the CYP induction (former project 4.76) Lead: Inclusion in work plan: Project status and milestones: UK 2021

On the basis of previous work and draft TG developed and validated under the leadership of the European Commission Joint Research Centre, the next steps are being taken by the new lead:

- Spring/summer 2021: Testing in lead (INRAE) and naïve laboratory (Utrecht) initiation of the 6 chemicals. In delay due to Covid and broken mass spec in one lab.
- Chemical selection and guidance for use manuscript published February 2022.
- Additional funding obtained to support the instigation of work in supplementary 3rd laboratory, starting May 2022; assay established February 2024 with current proficiency chemicals, additional augmentation chemical testing should be completed by May 2024.
- Q1 2024: Draft Chemical Augmentation report for the CYP induction Test Method, (ultimately
 intended to be a supplement to the validation report of the CYP induction test method).
 Manuscript in preparation also.
- Q3/Q4 2024: Submission of the chemical augmentation report by 2 laboratories minimum and revised draft TG, to the relevant OECD expert groups for peer review.
- April 2025: Potential approval of TG plus guidance document at WNT.
- Indications of use is included in a chemical selection manuscript for the ED CF, and nongenotoxic carcinogenicity IATA and will also be included in respective DRP and IATA projects (metabolic disruption and non-genotoxic carcinogenicity respectively) that can be cross referenced in the draft TG as deemed necessary.

Subsidiary body of the JM	WNT
Expert group	EG on Toxicokinetics

Project 4.151: OptiSafe as a me-too in TG 496 Macromolecular Test Method for Eye Hazard Potential	
Lead: Inclusion in work plan:	United States 2022
Project status and milestones: • Project completed.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on eye irritation

Project 4.152: Defined Approach for surfactants for Eye Irritation Hazard Potential	
Lead: Inclusion in work plan: Project status and milestones:	France 2022

- Gain EG consensus on application of evaluation framework (e.g. reference chemicals, documentation, applicability domain) Q2/Q3 2022
- Preparation and circulation of an issue paper on the proposed resolution for the issue discussed (i.e., limited number of Cat.2 surfactants) – Q1 2023
- Expert Group discussion (GO adopted)— Q2 2023;
- Continuing the development of the DA by exploring the mechanism and categories spectrum of surfactants – O3 2023;
- Preparation and circulation of a position paper for the issue discussed (full surfactants spectrum represented within the current surfactants set) Q3 2023
- Expert Group discussion Q4 2023; currently under discussion within the Expert Group. Not enough reference in vivo data available to benchmark DA performance.

Subsidiary body of the JM	WNT
Expert group	Expert Group on eye irritation

Project 4.153: Defined Approach on Skin Sensitisation for similar methods in TG 442C TG442D and TG 442E Lead: Inclusion in work plan: Project status and milestones: United States 2022

- Identify DAs and "me-too" information sources for assessment Q1 2022
- Gain EG DASS consensus on application of assessment framework (e.g. reference chemicals, documentation, applicability domain) – Q2 2023
- Generate additional in chemico/in vitro data (as needed) Q3 2023
- Adapt data interpretation procedure (as needed) Q4 2023
- Apply assessment framework to DAs with "me-too" information sources Q1 2024
- Draft additions to GL 497 Q2 2024.

Subsidiary body of the JM	WNT
Expert group	EG Defined Approaches on Skin Sensitisation

Project 4.154: Feasibility Study on Inclusion of the Skin Allergy Risk Assessment (SARA) Model into TG 497 on DASS Lead: Inclusion in work plan: United States/United Kingdom 2022

- Publish case study results for cosmetics (in preparation) Q1 2024
- Publish chemical case studies that cover a range of regulatory sectors (ongoing) Q4 2024
- Specific examples on-going with the fragrance industry in line with the U.S. EPA recommendation

- Apply general assessment framework for DAs for skin sensitisation quantitative risk assessment as proposed by EG DASS for SARA-ICE Model – Q2 2024
- Compare model results to assessments based on reference data to determine acceptance criteria. – Q2 2023
- Incorporate DASS EG feedback on model output Q2-Q3 2023
- Develop a publicly available and user-friendly version of the model (to be housed in the Integrated Chemical Environment) – 2024
- Draft addition to GL 497 for review by the WNT Q3 2024.

Subsidiary body of the JM	WNT
Expert group	EG Defined Approaches on Skin Sensitisation

Project 4.155: Feasibility study to develop a TG of Epidermal Sensitization Assay (EpiSensA): An In Vitro Method for Identifying the Skin Sensitisation Potential of Chemicals	
Lead: Inclusion in work plan:	Japan 2022
Project completed.	
Subsidiary body of the JM	WNT
Expert group	EG on Skin Sensitisation

Project 4.156: Update of TG 489 Comet Assay for gonadal cells to study germ cell specific genotoxic effects	
Lead: Inclusion in work plan: Project status and milestones:	Norway/Denmark 2022

2022:

- The project is included at the workplan of OECD at WNT in April 2022.
- Establish an *Ad Hoc* Expert Group following project approval by WNT (MI1; Q2/Q3, 2022). Throughout the project, the *Ad Hoc* Expert Group will initiate teleconferences as considered useful Conduct protocol control studies to develop appropriate protocols for tissue collection and the collection of germ cell data (MI2; Q2-Q3 2022).
- Conduct feasibility studies with carefully selected positive and negative control substances in rats (executed by lead countries (NO/DK)). The preparations for these follow-up experiments are ongoing and will be presented for the ad hoc Expert Group when established (MI3: Q2-Q4 2022).

2023:

- Expand the work and initiate validation of the method using tissue and/or historical data collected from an inter-laboratory call in consultation with the genotoxicity expert group (MI4; Q1-Q4 2023).
- Develop the first draft of the revised TG, with iterative discussions on the draft TG in the Ad Hoc Expert Group (MI5; Q1-Q4 2023).
- Plan and conduct follow-up in vivo experiments as deemed necessary to validate the proposed revision of TG 489 (MI6; Q1-Q4 2023). This could also be expanded into 2024 (Q1-Q2) depending on the ad hoc Expert Group's decisions.

2024:

- Finalise the follow-up *in vivo* experiments and the proposed revision of TG 489 (including feasibility study report) (MI7; Q1-2 2024).
- Discuss the draft feasibility study report and subsequent revision(s) of TG 489 with the appointed ad hoc Expert Group via teleconferences, physical meetings and electronic information exchange (MI8; Q3/4 2024).
- First WNT commenting round of feasibility study report and draft revised TG (MI9; Q4).

2025:

• Conduct a second round of WNT comment of the feasibility study report and the draft TG and revise the draft TG as necessary (MI10; Q 2-4 2025).

2026:

- Submit revised TG final feasibility study report and response to comments to WNT in Q1 minimum 6 weeks before April 2026 (MI11).
- Revised TG accepted by WNT in April 2026 (MI12).

Subsidiary body of the JM	WNT
Expert group	Expert Group on the in vivo Comet assay

- Workstream 1 (a) Terminology (b) Update the chapter according to current state of science as described in (c). (c) Non-testing methods, read-across and consulting with the informal working group on NATM.
- Workstream 2: Review criteria (a) Review and revise, as needed, the criteria for category 1B
 (b) Review and revise, as needed, the criteria for category 2 (c) Review and revise, as needed, the criteria for category 1A
- Workstream 3: Explore the relevant sections in Chapter 3.5 with reference to the results of workstream 1 and 2 and propose additional or modifying text, if deemed necessary (a) Ensure that any revised criteria for the different categories are consistent with each other.
 (b) Decision logic and guidance. (c) Consult with the PCI informal working group on technical errors and/or editorial improvements.
- The initial objective of the informal working group was to finalise a draft revised text of Chapter 3.5 and present to the sub-committee prior to December 2023 but the work has been delayed until at least December 2024.

Subsidiary body of the JM	WNT
Expert group	EG genotoxicity

Project 4.158: New Guidance Document on IATA for intestinal fate of orally ingested nanomaterials	
Lead: Inclusion in work plan:	Italy 2022
Project status and milestones: April 2022 – March 2023	

- Redefinition of the International Expert Group with entry of WNT experts
- Establishing of teleconferences calendar and meeting planning
- Potential workshop on GD dissemination (organised in collaboration with EU project NanoHarmony)
- Elaboration of the current state-of-the-art document
- Gathering of the experimental data obtained in the RR activities
- Development of the GD draft

May 2023 - December 2023

- First round of comments by WNT on the GD draft
- GD revision on the basis of comments received
- Second round of comments on the revised GD

February 2024

Development of the GD draft and Expert Group Commenting;

2025

Earliest possible approval of the draft Guidance Document by the WNT.

Subsidiary body of the JM	WNT
Expert group	

Project 4.159: Updated TG 456 for LC-MS based steroidogenesis assay	
Lead:	France
Inclusion in work plan:	2022

- Technical work, phase 1: August 2021-June 2022, testing 3 substances in full dose-response and 2 concentrations of positive controls in QC plates, measured after 48h of exposure. The data analysis will be done according to the revised DIP (as proposed by UK), focusing on estradiol and testosterone. Two laboratories successful, third laboratory failed to culture the cells and make them produce estradiol in sufficient quantity; WNT was consulted in April 2023 and agreed that if despite all efforts, a third laboratory cannot join the validation study, it is acceptable to continue the project with two labs.
- Work will be assessed by PEPPER's internal VMG before being discussed with a dedicated OECD expert Group.
- Technical work phase 2: September 2022, comparison of 2 timepoints (48h and 72h) for the secretion of the 19 hormones, for Forskolin and Prochloraz (full-dose responses) in two labs. Some literature shows a general increase of hormone production with time, which may ease hormone measurements (in particular for those with a lower concentration).
- Work will be assessed by PEPPER's internal VMG before being discussed in the dedicated OECD expert Group (Q3 2023), to decide on subsequent work.
- Technical work phase 3: Q3 2023 Q4 2023, all (6) proficiency chemicals will be tested in all labs (full dose-responses), for one or two timepoints (depending on expert group conclusions of phase 2 and subsequent agreement of WNT).
- Work will be assessed by PEPPER's internal VMG before being discussed in the dedicated OECD expert Group (Q4 2023).
- Technical work phase 4: starting Q1 2024, duration 2 months/3 substances. Testing in full dose
 response mode, one or two timepoints of a few substances specifically targeting progestogens
 and corticosteroids. Prior to selecting these few substances, review of the previous studies
 including Saito et al and Miyuki Breen which describes the needs for multiple time points and

Haggard et al which describes the 654 chemicals in multi-concentration. Chemical selection /review will be conducted in the 4th phase to focus on progestogens and corticosteroids, in consultation with the OECD Expert Group.

- Peer-review by internal VMG PEPPER' scientific council and dedicated OECD expert Group Q2 2024.
- Q3 2024: 1st round of comment from WNT on validation report, and draft augmented TG 456 (to address progestogens and corticosteroids).
- Q1 2025: 2nd round of comment from WNT on validation report, and draft augmented TG 456
- Submission draft TG to WNT, 2025, with some considerations of how the assay might be used in the EDTA context.

Subsidiary body of the JM	WNT
Expert group	Expert Group on in vitro ED methods

Project 4.160: New TG on hPlacentox			
Lead: Inclusion in work plan:	France 2022		

Project status and milestones:

- Technical work, phase 1 (transferability): August 2021-February 2022
- Technical work phase 2: August 2022- October 2022 originally but delayed due to the shortage of commercial ELISA kits;
- Timelines on the next steps will be updated once the experimental work can resume:
 - o Peer-review by internal VMG and PEPPER' scientific council December Q4 2024;
 - o 1st round of comments from expert group on validation report and draft TG (discussions by teleconferences, and written exchanges) Q2 2025.
 - o 1st round of comment from WNT on validation report, and draft TG: Q3 2025
 - o 2nd round of comment from WNT on validation report, and draft TG: Q4 2025
- Submission of the draft TG and validation report to WNT: 2026.

Subsidiary body of the JM	WNT
Expert group	Expert Group on in vitro ED methods

Project 4.161: New TG on Glucocorticoid receptor STTA assay	
Lead:	France/Canada
Inclusion in work plan:	2022

- Technical work, phase 1 (transferability): November 2021-March 2022. The technical work is finalised for 3 (out of 4) labs.
- Technical work phase 2: July 2022 September 2022
- Peer-review by internal VMG and PEPPER' scientific council: Q2 2023concluding to the need for complementary testing
- Technical work supplementary phase (2 laboratories): Q3 2023
- Peer-review by internal VMG and PEPPER' scientific council: Q4 2023
- 1st round of comments within expert group on validation report and draft TG (discussions by teleconferences, and written exchanges: Q1 2024
- 1st round of comment from WNT on validation report and draft TG: 2024
- 2nd round of comment from WNT on validation report and draft TG: 2024

Submission of the draft TG and validation report to WNT: 2025.

Subsidiary body of the JM WNT

Expert group Expert Group on in vitro ED methods

Project 4.162: Detailed review paper on methods and feasibility assessment for inclusion of mammary gland whole mount collection and evaluations

Lead:
Inclusion in work plan:
Project status and milestones:

Denmark
2022

Project status and milestones:

2022:

- January: Received feedback and comments from all countries.
- February: Amended the SPSF based on comments, responses to comments. Submitted Best Practices paper for publication at scientific journal.
- March before WNT: Direct feedback (e-mail) with critical countries
- April: WNT inclusion on the workplan as Project 4.162
- Summer: EG nominations
- First part of September: Convene the EG at a kick-off meeting (OECD Secretariate invite).
 Presented the project and the background. EG members presented themselves and how they could contribute. Scientific papers on public health importance, technical guidance, and Best Practice methods (published in Q1-3 of 2022), are shared in the EG.
- Mid-October: The outline of the DRP and feasibility report is shared in the EG. Remains
 two separate documents. The Round robin exercise is presented. The data reviews of WM
 vs pathology outcomes 5 and epithelial counts of longitudinal vs x-sectional sections will
 be used in the feasibility assessment report.

Teleconferences with EG when needed. Feedback on logistics of MG collection and evaluation from rats.

2023:

• Q1-Q2: Draft the DRP internally in part of EG

Q3-4: Create draft version of DRP WNT NCs and EG comment on and DRP (e.g., Teleconference with EG when needed)

Q4: second commenting round DRP and finalize DRP.

2024:

- Q1-Q3: draft feasibility report with EG, send for commenting end Q3
- Q2: DRP for discussion at WNT in April
- Q3-Q4: begin development of new SPSF for WM integration if suggested in feasibility report. That SPSF would then be submitted in Nov 2024

2025:

- Final DRP and feasibility report for discussion at WNT
- New SPSF under workplan of OECD.

Subsidiary body of the JM	WNT
Expert group	Expert Group on reproductive toxicity studies

Project 4.163: New TG on IL2-LTT assay for in vitro immunotoxicity assay	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2022

Phase 1 (feasibility study):

- The validation study report will be finalized by the end of Sep. 2022.
- Designation of an international ad hoc expert group (by Japan) for the peer review will be in Sep. 2022.
- An international peer review will start in Oct. 2022 and will end in Sept. 2023.
 - WNT check point: update and consultation of the WNT in April 2024.

Phase 2 (TG development)

- The draft TG will be made in Q2 2024.
- The validation report, peer review report, and draft TG will be submitted to the OECD by Q2 2024
- To define the individual performances and potential roles in the battery system with IL-2 Luc assay, it is anticipated that the OECD Expert Group on in vitro immunotoxicity assays will start discussion in Q2 2024.

Subsidiary body of the JM	WNT
Expert group	Expert Group on reproductive toxicity studies

Project 4.164: New Defined Approach on the Eye Hazard Identification for Solids	
Lead: Inclusion in work plan: Project status and milestones:	France 2023
Project completed.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitisation

Project 4.165: Revision of TG 442D: Proposal for α-Sens® as FBS-free test system for detecting Key Event 2 (ARE-Nrf2 activation) of skin sensitization		
Lead:	Japan	
Inclusion in work plan:	2023	

Project status and milestones:

Step-1:

- The validation study report will be finalized in Summer 2024.
- Designation of an international ad hoc expert group (by Japan) for the peer review, and a report will be completed by the Early 2025.
- The validation report and peer review report will be submitted to the OECD
- WNT check point: written update/consultation to the WNT and request for agreement to move forward with TG development

Step-2:

- The draft TG will be made.
- The draft TG will be submitted to the OECD

 To define the individual performances and potential roles in an ITS, it is anticipated that the OECD Expert Group on skin sensitisation will start discussion after the adoption of draft TG.

Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitisation

Project 4.166: DRP to facilitate the Development of Test Methods to Predict the Respiratory Sensitisation Potential of Substances

Lead: NL/AT/US/LUX/ICAPO Inclusion in work plan: 2023

Project status and milestones:

- Establish expert group: April 2023-August 2023
- Convene EG to develop outline and draft document August 2023-August 2024
- First draft of DRP circulated within EG-September 2024
- Revised draft of DRP prepared, circulated for WNT review November 2024
- Additional revisions, circulation of document to WNT Q4 2024- Q1 2025
- Submitted to WNT for approval April 2026.

Subsidiary body of the JM	WNT
Expert group	Expert group on skin sensitisation

Project 4.167: New TG on a Stably transfected human retinoic acid receptors hRARs transcriptional activation assay for detection of agonistic and antagonist activity of chemicals towards hRARs

Lead: France/Sweden
Inclusion in work plan: 2023

Project status and milestones:

- Technical work, phase 1 (transferability): October 2022-January 2023.
- Technical work phase 2 (further assessment of relevance and accuracy): March 2023-May 2023
- Peer-review by internal PEPPER VMG and PEPPER' scientific council: Summer 2023
- Q1-Q2 2024: 1st round of comments within OECD retinoid expert group on validation report and draft TG prepared by PEPPER and internal VMG (discussions by teleconferences, and written exchanges), pending no major issue during phase 2
- Q4 2024: 1st round of comments from WNT on validation report, and draft TG
- Q1 2025: 2nd round of comments from WNT on validation report, and draft TG Submission draft TG to WNT, 2025.

Subsidiary body of the JM	WNT
Expert group	Expert Group on retinoic acid pathway.

Project 4.168: DRP and a Retrospective Performance Analysis for the in vitro gH2AX/pH3 method: a multiplexed biomarker approach that provides information on genotoxic mode of action

Lead: France/Germany Inclusion in work plan: 2023

Project status and milestones:

 Establishment of Expert Working Group (EWG): immediately after project approval by WNT (Spring 2023);

Preparation of draft DRP and RPA document: Spring 2023-February 2024

- EWG commenting on draft DRP and RPA document, revision as necessary including additional experimental data if request by EWG: September 2024-November 2024
- Peer review of the validation status of the assay for the detection of aneugens/clastogens based on the DRP and validation of report/RPA. (Spring 2025)
- Public commenting on draft DRP and RPA document, revision as necessary: September 2025-November 2025
- Submit revised DRP and validation/RPA document to WNT: Nov 2025
- Upon WNT approval of DRP/validation/RPA (Spring 2026), submit a new SPSF for a TG to WNT: November 2026.

Subsidiary body of the JM	WNT
Expert group	Expert Group on genotoxicity testing

Project 4.169: Revision of OECD TG 498 – KeraSkin™ Phototoxicity Assay	
Lead: Inclusion in work plan:	Korea 2024

- July 2024: Submission of the draft validation study report to the OECD to EG.
- August 2024: Completion of scientific peer-review coordinated by KoCVAM.
- September 2024: Preparation and submission of draft peer-review report.
- October 2024~ February 2025: Preparation of the updated OECD TG 498 followed by EG and WNT Commenting Round.
- April 2025: WNT approval of the updated OECD TG 498 with KeraSkinTM Phototoxicity Assay.
- June 2025: Inclusion of KeraSkinTM Phototoxicity Assay in OECD TG 498.

Subsidiary body of the CBC	WNT
Expert group	Phototoxicity EG

Project 4.170: Revision of OECD TG 431 to include a new me-too reconstructed human epidermis test method – KeraSkin™ skin corrosion test Lead: Inclusion in work plan: Korea 2024

- 2024 The main validation study with 30 PS chemicals
- 2025 The evluataion study on prediction capacity using 49 chemicals from LabCyte validation
- Spring 2025 Preparation of Validation report, Draft TG.
- October 2025 International Peer-Review

Subsidiary body of the CBC	WNT
Expert group	Skin and eye irritation EG

Project 4.171: EASA as a me-too method in TG 442C In Chemico Skin Sensitisation	
Lead: Inclusion in work plan:	United States 2024

- Conduct Independent Peer Review of Validation Study, outside OECD (Q1 2024)
- SPSF Review at WNT (Q2 2024)
- Finalize Independent Peer Review Report (Q3 2024)
- SSEG begins review of method (Q3 2024)
- Incorporate SSEG feedback into Validation and Peer-Review Reports and test method (Q4 2024)
- Draft addition to TG 442C for SSEG review (Q4 2024)
- Submit update of TG 442C to WNT for Review (Q4 2024)
- Review and acceptance of addition to TG 442 at WNT (Q2 2025)

Subsidiary body of the CBC	WNT
Expert group	Expert Group Skin sensitisation

Project 4.172: Me-Too validation of the reconstructed human epidermis Epiderm model for the EpiSensA method	
Lead:	France/Japan
Inclusion in work plan:	2024

- November 2023 April 2024: Finalization of the protocol confirmation of the preliminary results on a set of 10 chemicals (6 skin sensitizers, 4 non sensitizers). Writing of the SOP – publication of the pre-validation study expected in March 2024
- April 2024: First meeting of the validation management team (VMT)
- April 2024 May 2024:
 - Training by the Italian lead laboratory of the 2 laboratories that will participate in the validation (1 laboratory in Germany and 1 laboratory in Japan) and evaluation of the transferability of a limited number of chemicals (4-6)
 - o Chemical acquisition and coding of the 20 chemicals from the PF chemical list.
- May 2024: second meeting of the VMT * April 2024: formal endorsement of the project by the WNT provided that the performance standards (PS) for the VRM are adopted during the WNT meeting. If the PS are not adopted the schedule of the project will be updated after consultation of the WNT.
- June 2024 November 2024: o Distribution of the coded chemicals
 - Starting of the multicentric study with the 3 laboratories
 - o 3rd meeting of the VMT during this phase
- Decembre 2024 January 2024:
 - Statistical analysis by independent statistician Evaluation of the BLR, WLR and reliability (repeatability/reproducibility) and accuracy of the similar method with the EpiDerm model.
 - Report of the validation study
 - Two meetings of the VMT are expected to be held during this phase
- January 2025: Establishment of the Peer Review Panel and Peer Review initiated
- May 2025: Submission to the OECD of the Peer Review Report on the similar EpiSensA method using the MaTek EpiDerm model
- Possible adoption in 2026.

Subsidiary body of the CBC	WNT
Expert group	Expert Group Skin sensitisation

Project 4.173: DA for skin sensitizer potency assessment based on quantitative regression models	
Lead:	Switzerland/Germany
Inclusion in work plan:	2024

- Publication of the quantitative regression models and evaluation against the DASS reference database (Done, Q2 2022, Q1 2023)
- Detailed instruction and publicly available Excel spreadsheet, deployment to interested CRO's (Done, Q2 – Q4 2022)
- Discuss the assessment framework for a PoD-based DA in the DASS expert group
- Discuss acceptance criteria and application domain
- Above two points are being addressed by the expert group in the scope of the SARA feasibility study, the progress of this discussion will affect the final timeline of the current proposal
- Apply the assessment framework and acceptance criteria for the proposed DA for skin sensitisation potency assessment (Q2 2024 – Q4 2024)
- Incorporate DASS EG feedback on framing and evaluation of the DA (Q1 2025)
- Draft DA as an addition to Part II of GL 497 (Q1 Q2 2025).

Subsidiary body of the CBC	WNT
Expert group	DASS EG

Project 4.174: Validation of the In Vitro Micronucleus assay for Engineered Nanomaterials	
Lead: Inclusion in work plan:	UK/DE/FR/NO and partners: US/LU 2024

- Q2-Q4 2024: selection of test materials;
- Q1-Q2 2025: proficiency testing at the laboratories;
- Q3 2025: staggered and blinded validation study;
- Q3 2026: statistical analysis of results;
- Q1 2027: report completion;
- Q2 2027: independent peer-review
- 2028: submission of revised TG 487 for approval.

Subsidiary body of the CBC	WNT
Expert group	EG genotoxicity (with input from nanomaterials experts)

Project 4.175: DRP on the application of error-corrected next generation DNA sequencing (ecNGS) for gene mutation evaluation	
Lead: Inclusion in work plan:	United States 2024
Project status and milestone	98:

- Establish an OECD EWG immediately after project approval by WNT in Spring 2024.
- Begin preparation of draft DRP, Spring 2024
- EWG participation as necessary including recommendations for additional experimental data and periodic review, Spring 2024 November 2026
- Submit completed DRP and RPA to WNT for comment November 2026
- Upon WNT approval of DRP (Spring 2027), submit a new SPSF to WNT to support the amendment
 of relevant gene mutation Test Guidelines (TG) for which ecNGS has been sufficiently validated
 (e.g., the Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (TG 488), the in vitro
 Mammalian Cell Gene Mutation Test Using Thymidine Kinase Gene (TG 490), and the Bacterial
 Reverse Mutation Test (TG 471), November 2027

Subsidiary body of the CBC	WNT
Expert group	EG genotoxicity testing

Project 4.176: Detailed review paper on specific target organ toxicity (liver) test method using liver organoid	
Lead:	Korea/OECD Secr.
Inclusion in work plan:	2024

- Commencement of OECD DRP development (May 2024
- Establishment of an international expert group (June 2024)
- Periodic teleconferences between expert groups every 2 months (June-Nov 2024)
- Submission of the draft DRP reflecting expert group feedback (November 2024)
- Approval of the draft DRP at OECD WNT meeting (April 2025).

Subsidiary body of the CBC	WNT
Expert group	ESCA

Project 4.177: Revision of in vivo genotoxicity test guidelines' "Evaluation and Interpretation of Results" and "Test Report" language	
Lead:	United States/Canada
Inclusion in work plan:	2024

- Convene the Genetic Toxicology EG to further develop the proposal and associated draft Annex that has been prepared by the ad hoc group. Note that while the proposed updates and draft Annex will be adaptable to a number of in vivo TGs (e.g., 470, 474, 488, and 489), initial efforts will focus on TGs 470 and 488. These two TGs already have Annexes that are similarly structured to our proposed version and can be most readily updated with new content. We envision moving on to TGs 474 and 489 after revisions to TGs 470 and 488 are adopted (see below).
- Submit the statistical analysis and data interpretation-centric Annexes (and associated minor main TG revisions) for TGs 470 and 488 to the WNT for consideration at the 37th WNT meeting in April 2025.
- Upon adoption of TG 470 and 488 revisions, begin work on analogous changes to TGs' 474 and 489 "Evaluation and Interpretation of Results" and "Test Report" sections, and incorporation of an Annex for consideration at the 38th WNT meeting in April 2026.

Subsidiary body of the CBC	WNT
Expert group	EG on genotoxicity testing

Project 4.178: Revision of OECD TG 443 (EOGRTS) and GD 151	
Lead:	European Commission (ECHA)/Denmark/Netherlands
Inclusion in work plan:	2024

- Nomination of ad hoc expert group / call for additional members in the existing EG, if needed (May 2024);
- First virtual meeting to discuss the proposed revisions of GD 151 and TG 443 (June 2024);
- Draft revised OECD TG 443 submitted for revision to the EG (August 2024);
- Draft revised GD151 submitted for revision to the EG (Autumn 2024);
- Circulation of the draft revised TG 443 version for 1st WNT commenting round (November 2024), second commenting February 2024;
- CRO WNT NC consultation to discuss unexpected/challenging findings in the EOGRTS (Q3/Q4 2024)1
- Circulation of revised draft GD 151 for 1st WNT commenting round Q1/Q2 2025 and 2nd WNT commenting round Q3/Q4 2025.
- If feasible, revised TG 443 submitted for adoption for WNT-37 (April 2025)
- If feasible, revised GD 151 submitted for adoption for WNT-38 (April 2026).

Subsidiary body of the CBC	WNT
Expert group	EG TG 443/GD 151

Project 4.179: Colorimetric assessment of deiodinases 1 activity based on Sandell-Kolthoff reaction with human microsomes: DIO1-SK assay

Lead:	France/Germany
Inclusion in work plan:	2024

Project status and milestones:

- Technical work, phase 1 (transferability): January 2024-May 2024
- Technical work phase 2: September 2024- December 2024
- Peer-review by internal VMG and PEPPER' scientific council Q1 2025. The outcome of the peer-review as well as the validation report and draft TG will be submitted to the expert group in Q1-Q2 2025 for a 1st round of comments (discussions by teleconferences, and written exchanges), pending acceptance of the project by WNT in April 2024, and no technical issue during phase 2
- Q3 2025: 1st round of comment from WNT on validation report, and draft TG
- Q4 2025: 2nd round of comment from WNT on validation report, and draft TG
- Submission draft TG to WNT, for possible adoption in 2027

Subsidiary body of the CBC	WNT
Expert group	Thyroid Disruption Methods EG

Project 4.180: Fluorometric assessment of transthyretin-binding activity based on the displacement of thyroxine labelled with fluorescein isothiocyanate: FITC-T4 TTR-binding assay

Lead:	Netherlands/France
Inclusion in work plan:	2024

- Further validation in two naïve labs, to be organised by the PEPPER, who have selected the FITC-T4 TTR-binding assay for their working program (supported by training of the naïve labs at WFSR (with input from VUA)):
 - Technical work, synthesis and characterisation of FITC-T4 label: May 2024 o Technical work, phase 1 (transferability): June-August 2024
 - o Technical work phase 2 (blinded compounds): October 2024-February 2025
- Peer-review by internal VMG and PEPPER' scientific council Spring 2025 before submission in
- Summer 2025: to the expert group for a 1st round of comments on validation report and draft TG (discussions by teleconferences, and written exchanges), pending acceptance of the project by WNT in April 2024, and no technical issue during phase 2
- Q3-Q4 2025: 1st round of comment from WNT on validation report, and draft TG
- Q1-Q2 2026: 2nd round of comment from WNT on validation report, and draft TG
- Submission draft TG to WNT, for possible adoption in 2027

WNT
Thyroid Disruption Methods EG

Project 4.181:New guideline for testing oral, dermal, inhalation and injection toxicity, pathogenicity, and infectivity of microbial pesticide	
Lead:	United States/Canada
Inclusion in work plan:	2024

Project status and milestones:

- OECD WNT meeting to decide if project will be added to the work programme (April 2024);
- Collect, review and summarize available information on the reliability and relevance of the methods to be referenced in the Introduction and/or Annex of the draft guideline, allowing tracing the information to the available data. Explore routes for further data collection and analysis on reliability and relevance.
- Draft guideline submitted to EGBP subgroup for discussion and comment via email; virtual discussion held if necessary (30 November 2024);
- Subgroup reviews and agrees on final draft and submits to EGBP for review and comment via email (31 January 2025);
- EGBP comments completed and sent to the subgroup via email (31 March 2025);
- Subgroup makes revisions and submits to WNT and WPP for commenting (15 May 2025);
- Earliest WNT and WPP adaption of guideline (April 2026).

Subsidiary body of the CBC	WNT/WPP
Expert group	EG Microbial pesticides

Project 4.182: Adverse Outcome Pathway (AOP) network leading to genotoxicity	
Lead:	Belgium/France
Inclusion in work plan:	2024

Project status and milestones:

• The first step in this project is to design an AOP for permanent DNA damage. The PARC project on the AOP-based IATA for genotoxicity officially started in May 2022 and will last until April 2025.

Subsidiary body of the CBC	WNT
Expert group	ESCA

SECTION 5 PROJECTS RELATED TO OTHER TEST GUIDELINES/ OTHER AREAS OF TESTING/ PROJECTS OF GENERAL NATURE

Project 5.6: Development of efficacy Test Guidelines and Guidance Document for public health antimicrobial biocides used on hard surfaces

Lead: United States through the WP Biocides

Inclusion in work plan: 2007, revised in 2010

Project status and milestones:

Four new Test Guidelines based on the protocols in the current Guidance Document on quantitative methods for evaluating the activity of microbicides used on hard non-porous surfaces, which was approved in 2013.

Protocols are quantitative methods for evaluating bactericidal, mycobactericidal, fungicidal and virucidal activity of microbicides used on hard non-porous surfaces.

- Expert meeting (teleconference) of Expert Group on Efficacy of Microbicides on Hard Surfaces held in March and October 2016, discussing the draft TGs dealing with the bactericidal and mycobactericidal protocols.
- Aim is to finalise these two draft TGs in the Expert Group in 2017/2018, followed by commenting by WGB and WNT; however additional analytical verification was initiated in 2019 and still ongoing.
- Draft TGs for fungicidal and virucidal activity of microbicides were planned for development after finalisation of the bactericidal and mycobactericidal protocols;
- However, recent discussions of the lead country with stakeholders raised concerns about the applicability of the proposed methods which will be discussed in the Expert Group on Efficacy of Microbicides on Hard Surfaces (date to be determined).

Subsidiary body of the JM	WNT & WGB
Expert group	Expert Group on Efficacy of Microbicides on Hard Surfaces

Project 5.7: Revision of Guidance Document 34 on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment

Lead: EC (JRC), United States, Netherlands
Inclusion in work plan: 2023
Project status and milestones:

- Establishment of new project group to discuss the revision of GD 34 (May/June 2023)
- Project Group meeting on 5 December 2023 (beginning Q4 2023). All communication will be done in writing and via videoconferences at this stage.
- Project group to establish a framework for the simplification of GD34 and define the specifications
 of the final GD in terms of content, length, and user-friendliness in consultation with the WNT
 (Q1 2024).
- Update on progress at OECD WNT meeting (April 2024), followed by PG meeting on 22-23 April 2024.
- Draft revised GD 34 circulated to WNT for commenting (Q3 2024).
- Discussion of revised GD 34 by the WNT in April 2025 and tentative adoption during the meeting or by written procedure.

Subsidiary body of the JM	WNT
Expert group	WNT itself (+nominated experts).

Project 5.8: New Guidance Document on "Efficacy of pressurized aerosols for control of flying and crawling insects"	
Lead:	Germany
Inclusion in work plan:	2023
Project status and milestones:	
Finalization of draft guidance Aug. 2024;	
 Discussion of draft guidance in WPB September 2024; 	
Submit draft GD to WNT beginning 2025.	
Subsidiary body of the CBC	WNT & WPB
Expert group	WPB

ANNEX 1

PROJECTS THAT ARE NO LONGER SUPPORTED

Project 1.2: Guidance Document on Bridging and Waiving of Physical/Chemistry studies of Plant Protection and Biocidal Products	
Lead:	WP Biocides
Inclusion in work plan:	2018
Project Status and milestones:	
 An Expert Group has been formed under the Working Group on Biocides; the proposed draft Guidance Document will be discussed via conference calls. Calls will be held as needed. A draft Guidance Document is under development under auspices of the WPB but currently on hold until sufficient resources are available from the Secretariat to resume the project. 	
Subsidiary bodies of the JM	WGP – WGB – WNT- WPHA
Expert group	Expert group on p-chem properties under the WGB

Project 1.9: TG on Determination of relative metal/metalloid release using a simple simulated gastric fluid	
Lead:	European Commission
Inclusion in work plan:	2020
Project Status and milestones:	

Project Status and milestones:

2020

- Establishment of an Ad-Hoc Expert Group. Meetings mostly via teleconference and electronic information exchange.
- Development of the first draft TG; iterative discussion
- Comments on the draft TG by the Ad-Hoc Expert Group.

2021

- Feb 2021: First draft TG for review by the WNT; next TC of the EG in May and June 2021;
- Second commenting round in December 2021 until Feb 2022.

2022

 Issues identified in the 2nd commenting round required bilateral discussions with some countries; expectation is that additional work to select reference and proficiency materials can resume when bilateral discussions have resulted in agreement to move forward; project on hold until issues are resolved.

2023

- New data on particle size were presented and discussed first with the Netherlands and later with the wider expert group during a TC in October.
- Multiple bilateral meetings with Canada to address their questions and concerns. Revisions to the TG were proposed by the leads in an attempt to reach a consensus. These revisions were considered insufficient by Canada. More extensive changes were put forward by Canada, which the leads found unacceptable. The positions of the leads and of Canada were presented to the EG during the TC in October.

- Despite discussions within the entire EG, no path forward could be found. During the TC in October, the UK offered to discuss with Canada in an attempt to find a solution to the current stalemate.
- At the WNT-36 meeting in April 2024; Canada and the UK prepared a document with their perspective and the EC prepared responses describing their perspective as well. The leads decided a discontinuation of the project at the OECD level, given the differences of opinion across countries/regions.

Subsidiary body of the JM	WNT
Expert group	Expert Group on Metal Release