

Work plan for the OECD Test Guidelines Programme (TGP)

-SEPTEMBER 2023-

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: guidance 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 1.2: Guidance Document on Bridging and Waiving of Physical/Chemistry studies of Plant Protection and Biocidal Products	
Lead: Inclusion in work plan: Project Status and milestones:	WP Biocides 2018
<ul style="list-style-type: none"> • An Expert Group has been formed under the Working Group on Biocides; the proposed draft Guidance Document will be discussed via conference calls.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 • A draft Guidance Document is under development under auspices of the WPB but currently on hold until sufficient resources are available from the Secretariat to resume the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 1.5: Guidance Document on Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media	
Lead: Inclusion in work plan: Project Status and milestones:	Denmark/Germany 2019
<ul style="list-style-type: none"> • Laboratory work delayed from 2020 to 2022; new timelines for development of Guidance will be presented to the EG meeting in January 2022. • A call for laboratories was launched in February 2022 to complete the ILC accompanying the GD; experimental work on-going in Q1 2023; • Drafting of a Guidance Document will take place in parallel in Q2 2023, while inter-lab data is reported and analysed. 	
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: Inclusion in work plan: Project Status and milestones:	Denmark/Germany 2019
<ul style="list-style-type: none"> • September 2019: Kick-off web-meeting to discuss and agree on the work plan, contributors and distribution of work towards development of the draft consensus report on specific analytical methods selection by December 2019. • December 2019: a face to face meeting was organised back-to-back with the WPMN to discuss: i) Draft protocols and preliminary test results; ii) SOPs and preliminary results; and iii) test parameters and criteria for the GD. • 1 st Quarter 2020 draft report to be submitted to the Expert Group for commenting. • 2 nd Quarter 2020: Test materials for intra- and inter-laboratory testing distributed to the methods laboratories; 	

<ul style="list-style-type: none"> • Laboratory work delayed from 2020 to mid-2021; data are being compiled and new timelines for development of Guidance will be presented to the EG meeting in January 2022. • A call for laboratories will be launched in February 2022 to complete the ILC accompanying the GD. • The intention is to have a draft GD 2nd Quarter of 2023. 	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials

Project 1.7: New TG on Determination of Surface Hydrophobicity of Manufactured nanomaterials	
Lead: Inclusion in work plan: Project Status and milestones:	European Commission 2019
<ul style="list-style-type: none"> • TG approved in April 2023, project completed. 	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials (JEG-PC)

Project 1.8: TG on Determination of the Dustiness of Manufactured Nanomaterials	
Lead: Inclusion in work plan: Project Status and milestones:	Denmark/France 2019
<p>Project Status and milestones:</p> <p>2020</p> <ul style="list-style-type: none"> • 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. <p>2021-2022</p> <ul style="list-style-type: none"> • 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) <p>2023-2025</p> <ul style="list-style-type: none"> • Draft version of the TG (including both HARN and non-HARN materials) ready for expert group commenting (Q1 2023) • Draft version of the validation report available (Q1 2023) 	

<ul style="list-style-type: none"> • Test Guideline and Validation Report submitted to WNT for public commenting (Q3 2023) • Preparation of a global Draft GD to support worker exposure assessment and ATEX safety (Q1- Q2 2023) • Draft GD delivered to Expert group for commenting (Q3 2023) • Draft GD submitted to WNT for public commenting (Q2 2024) • Approval of the TG and Validation Report by WNT: April 2024 • Approval of the GD by WNT: April 2025. 	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials

Project 1.9: TG on Determination of relative metal/metalloid release using a simple simulated gastric fluid	
Lead: Inclusion in work plan: Project Status and milestones:	European Commission 2020
<p>2020</p> <ul style="list-style-type: none"> • Establishment of an Ad-Hoc Expert Group. Meetings mostly via teleconference and electronic information exchange; development of the first draft TG; iterative discussions on the draft TG by the Ad-Hoc Expert Group. <p>2021</p> <ul style="list-style-type: none"> • Feb 2021: First draft TG for review by the WNT; TC of the EG in May; feedback on additional data, testing and/or considerations were asked to the EG; revised draft TG; • Second commenting round in December 2021 until Feb 2022. <p>2022</p> <ul style="list-style-type: none"> • Discussion on the establishment of a repository of reference materials was initiated; • Teleconference of the EG in February 2022. • February 2022-June 2022: discussion on the influence of particle size on the outcome of the metal release test and testing proposal; discussion on selection of reference materials and proficiency materials; • 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. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Metal Release

Project 1.10: Development of a new Guidance Document on the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies	
Lead: Inclusion in work plan: Project Status and milestones:	United Kingdom 2021
<p>April 2021 – Nov 2022</p> <ul style="list-style-type: none"> • 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. 2022)

2023

- Expert Group review on draft GD Q2 2023
- Virtual meeting of the expert group Q2/Q3 2023
- 1st WNT commenting round Q3 2023
- 2nd WNT commenting round Q4 2023/Q1 2024

2024

- Submission of GD to WNT for approval (mid Feb).

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 Determination of Effects on Earthworms in Field Studies	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2013
<ul style="list-style-type: none"> • 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 at Umweltbundesamt (Dessau, Germany) • Aug. – Sep. 2022: EG commenting on draft TG and draft validation report (VR); • Q4 2023: Revised draft TG and draft VR + RCOM based on EG comments (delayed due to organizational problems) for final review of EG; • 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
<ul style="list-style-type: none"> • 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 are being generated between 2020 and 2022, i.a. in the context of the SWIFT project (http://cefic-iri.org/projects/eco51-swift-strengthening-weight-of-evidence-for-fet-data-to-replace-acute-fish-toxicity/), all in order to answer the questions raised in 2016 by VMG-Eco. Moreover, the OECD TG 249 for fish cell line acute toxicity has been approved in 2021. • The new data and TG 249 will be integrated into the draft acute fish toxicity IATA guidance document for circulation and discussion by VMG-Eco experts. • Finalization of the project at WNT level is envisaged by the WNT meeting in April 2024. 	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.55: Use and analysis of control fish in toxicity studies	
Lead: Inclusion in work plan: Project status and milestones:	United States/ICAPO 2015
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: Statistical 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 2.57: Guidance Document on Juvenile Medaka Anti-androgen Screening Assay

Lead: Inclusion in work plan: Project status and milestones:	Japan 2016
<ul style="list-style-type: none"> • Guidance document approved in April 2023, project completed. 	
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: Inclusion in work plan: Project status and milestones:	Japan 2016
<ul style="list-style-type: none"> • Inter-laboratory validation was conducted in 2018-2019. • Japan presented a report of the validation studies including a further investigation into possible non-chemical stressors at the 15th VMG-Eco meeting in October 2020; • In the subsequent 2021 VMG-Eco meeting Japan provided additional results related to non-chemical stressors; next steps for the development of a TG are to be determined by 	

Japan; in April 2023, Japan indicated that additional experimental work is almost finished: a validation report and a draft TG will be prepared in the course of 2023.	
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: Project status and milestones:	Germany 2016
<ul style="list-style-type: none"> • 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 2023. 	
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, <i>Glyceria maxima</i>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands/United Kingdom 2019
<ul style="list-style-type: none"> • 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 2023. 	
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
2023-2024	

<ul style="list-style-type: none"> • 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 <p>2025</p> <ul style="list-style-type: none"> • 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 (<i>Osmia spp.</i>)	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland 2019
<p>Milestones</p> <ol style="list-style-type: none"> 1. First drafts of the guideline and the validation report will be ready for Honey Bee Expert Group commenting in summer 2023. 2. Expert group meeting/Teleconference to discuss the validation reports and draft TG in Autumn 2023. 3. Revised validation reports and TG (based on comments) for a 1st commenting by the WNT in winter 2023. 4. 2nd WNT commenting round of the final validation report and draft TG winter 2023. 5. Final validation report and draft TG for approval at the WNT in April 2024. 	
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: Inclusion in work plan: Project status and milestones:	France/ United Kingdom/ Japan 2020
<ol style="list-style-type: none"> 1. Completion of a comprehensive study plan (Autumn 2020). 2. An inter-laboratory trial testing of a minimum of 7 active and 3 inactive chemicals in 3 or more different laboratories, the active chemicals will be chosen to have a range of modes of action resulting in inhibition or activation of the estrogen axis via receptor interaction or interaction with steroidogenic enzymes. At least one laboratory will test more than 10 chemicals including 	

lipophilic chemical(s) which may partition to the vitellus and limit exposure (late 2020 – early 2021).	
3. Readjustment of the protocol as a function of comments received from testing laboratories.	
4. Completion of an integrated summary report that synthesises the data from all supporting studies (late 2021).	
5. Independent peer review of the assay by the VMG-Eco group (late 2021).	
6.	6. OECD VMG-Eco (late 2022).
7.	7. Revision of the draft TG in progress; improvement of statistical aspects.
8.	8. First WNT commenting round in early Q3 2023; submission for approval expected in 2024..
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: Project status and milestones:	Japan 2021
<ul style="list-style-type: none"> Basic data (characteristics of these strains, sensitivities to chemical substances, culturing and handling techniques and recommended medium for these strains, and so on.) will be provided at VMG-eco in 2021. An inter-laboratory validation might be conducted in 2023. 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: Inclusion in work plan: Project status and milestones:	Japan/France 2022
<ul style="list-style-type: none"> Development of draft TG, Expert group and WNT commenting rounds (Oct 2022) An inter-laboratory ring trial using at least two chemicals with different physicochemical properties; A call for additional testing laboratories if necessary (2022-2024). Readjustment of the protocol as a function of comments from testing laboratories (2024) Adoption of TG by OECD WNT (April 2025). 	
Subsidiary body of the CBC	WNT
Expert group	Expert Group Sediment-Water Toxicity Tests

Project 2.69: Revision of TG 218-219 sediment–water Chironomus test using spiked-sediment or spiked-water

Lead: Inclusion in work plan: Project status and	Germany/Switzerland 2022
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milestones:	
	<ul style="list-style-type: none"> Updated TGs 218-219 approved in April 2023, project completed.
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: Project status and milestones:	Germany/Switzerland 2022
	<ul style="list-style-type: none"> Honey bee ad hoc Expert Group to review draft revised GD 75 (July/Aug. 2022), all communication carried out in written and via virtual conferences July 2023: revised draft GD + RCOM based on EG comments for final review of EG; Draft revised GD 75 for WNT commenting (second half of 2023) Earliest WNT adoption of revised GD 75 April 2024.
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: Inclusion in work plan: Project status and milestones:	France/Spain 2022
	<ul style="list-style-type: none"> 2023: Experimental work in progress; results available end 2023; September 2023 –: Drafting of technical annexes to Guidance Document on Aquatic Toxicity Testing of Nanomaterials. Submission to the expert group of the technical annexes: Q1 2024. Expected approval of updated Guidance Document in 2025.
Subsidiary body of the CBC	WNT
Expert group	Validation Management Group for Ecotoxicity Testing

Project 2.72: Revision of TG 240 Medaka Extended One-Generation Reproductive Toxicity test

Lead: Inclusion in work plan: Project status and milestones:	Japan/United States 2022
	<ul style="list-style-type: none"> Updated TG 240 approved in April 2023, project completed.
Subsidiary body of the CBC	WNT

Expert group	Validation Management Group for Ecotoxicity Testing
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Project 2.73: New TG on Avian in ovo screening assay for sex steroid hormone disrupting properties

Lead: Inclusion in work plan: Project status and milestones:	Japan/ France 2023
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For the Japanese quail:

- The finalization of procedure and preparation of the draft protocol for validation studies have begun and will be completed in late 2023 or early 2024.
- Ring-test will be conducted in 2024-2025.

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
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Expert group	Validation Management Group for Ecotoxicity Testing
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Project 2.74: Revision of TG 239 on Water-Sediment Myriophyllum Spicatum Toxicity Test

Lead: Inclusion in work plan: Project status and milestones:	Germany 2023
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- Nomination of experts to participate in the ad hoc Expert Group (July 2023)
- Ad hoc Expert Group to review draft revised TG 239 (Sept. 2023)
- Circulation of draft revised TG 239 version #1 for 1st WNT commenting round (Q4 2023)
- Circulation of draft revised TG 239 version #2 for 2nd WNT commenting round (Q1 2024)
- Earliest WNT adoption of revised TG 239 (April 2024).

Subsidiary body of the CBC	WNT
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Expert group	TBD
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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: Inclusion in work plan: Project status and milestones:	Germany 2023
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- Nomination of experts to participate in the ad hoc Expert Group (July 2023)

<ul style="list-style-type: none"> • Ad hoc Expert Group to review draft revised GD 122 (Oct./Nov. 2023) • Circulation of draft revised GD 122 version #1 for 1st WNT commenting round (Dec. 2023) • Circulation of draft revised GD 122 version #2 for 2nd WNT commenting round if needed (Jan. 2023) • Earliest WNT adoption of revised GD 122 if possible (April 2024) 	
Subsidiary body of the CBC	WNT
Expert group	TBD

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:	<ul style="list-style-type: none"> • 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): autumn 2023; • WNT commenting: winter 2023/summer 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:	United Kingdom and Spain
Inclusion in work plan:	2014
Project status and milestones:	<p><i>Scope of the project:</i> 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.</p> <p><i>Limitations of the project:</i> 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.</p> <ul style="list-style-type: none"> • A first draft GD was completed in October 2015 with contributions of WPMN representatives of various delegations. Feedback provided indicated that additional experimental work was needed.

- At the WNT in April 2018, it was agreed to focus on the applicability of TG305 to nanomaterials considering mainly dietary exposure without developing further the tier approach, which will need additional new TGs for its validation.
- Work is being developed with Spanish resources and within the framework of the H2020 project Gov4Nano.
- A teleconference took place on 28th January 2020 with an ad hoc-expert group to discuss progress and the next steps.

Next steps:

- An inter-laboratory comparison study for feed spiking will be performed in 2022.
- A draft guidance document is under preparation and it will be presented by the end of May to the expert group;
- The expected time for completing this project is Q4 2023.

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 is considering trigger/waiver the TG 305 bioaccumulation in fish test for manufactured nanomaterials (WPMN project).

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: Project status and milestones:	Germany 2018
<ul style="list-style-type: none"> • 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 decide on the (dis-)continuation of the projects before Oct. 2023. 	
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: Inclusion in work plan: Project status and milestones:	Austria 2019
<p>Oct. 2019 - March 2020:</p> <ul style="list-style-type: none"> • Collection of existing data, building of a scientific library for nanoscale and bulk related transformation processes under environmentally relevant conditions, data collection of environmental monitoring data with focus on transformation-relevant species. Framing the concept of NM transformation pathways in the environment. • Definition of relevant environmental media composition(s) representing both, the 	

aquatic species and conditions driving transformation and their concentrations and conditions representative for the aquatic environment.	
Sept. 2020 – Dec. 2022:	
<ul style="list-style-type: none"> • Proof of principle testing of a set of suitable NMs (sulfidation, formation of low soluble solids other than sulphide, loss of coating). Development of protocols for nanomaterial transformation testing (experimental and analysis) which are suitable for later standardization. 	
Q2 2023-Q1 2025:	
<ul style="list-style-type: none"> • Submission of first draft GD to the OECD Expert Group for review, followed by WNT reviews; • Possible submission to 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 <i>Hyalella azteca</i> Bioconcentration Test (HYBIT)	
Lead: Inclusion in work plan: Project status and milestones:	France/Germany 2019
<ul style="list-style-type: none"> • Expert Group established in summer 2019; kick-off meeting of the Expert Group was held in November 2019; • Multi-laboratory ring trial: <ul style="list-style-type: none"> ○ Pre-test (assessment of the transferability of the method) (May 2019 - November 2019); ○ Lipid extraction: During the kick-off meeting, it has been decided to initiate an interlaboratory comparison of the lipid extraction as a crucial step for the calculation of the BCF; ○ Main study: Due to the covid-19 epidemic, the experimental phase was extended until end of February 2021; • Meeting for discussion of the ring test results was held in March 2021; • Expert group and WNT commenting rounds (2023); • Earliest possible adoption of TG by OECD WNT in 2024. 	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on <i>Hyalella azteca</i> 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: Project status and milestones:	United Kingdom 2021
<ul style="list-style-type: none"> • Form Ad Hoc Expert Group to a) review existing information, b) make comments for new Test Guideline for persistence assessment, and c) address any need to make a minor revision to the Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3 (OECD, 2006) (April 2021). • Currently addressing comments and considering ways forward. 	

- UK commissioned an independent review of the method and regulatory need for the MaP test (completion end of March 2023). Topic will be on the agenda of WNT-35 for information /discussion on next steps.

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

SECTION 4
PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS

Project 4.94: IATA on Non-Genotoxic Carcinogens	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2015
<ul style="list-style-type: none"> • 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; • Three plenary meetings held in 2021, with multiple sub group meetings; • Manuscripts reviewing each hallmark block, and development of a regulatory framework being drafted Q3: 2020 - Q2: 2022; • Expectation for a meeting of the Expert Group in Q3 or Q4 2022; • Integration of assays into an IATA expected in 2022-3. 	
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: Inclusion in work plan: Project status and milestones:	United States/OECD Secr. (starting 2021)2015
<ul style="list-style-type: none"> • Project completed; additional chapter on cardiovascular system will be drafted in 2023 by the US author. 	
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: Inclusion in work plan: Project status and milestones:	Sweden 2016
<ul style="list-style-type: none"> • 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; 	

<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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 following independent data audit organized in Q3-Q4 2023; • Submission to the expert group of the validation/peer review and 1st draft of the TG 2023 Q1 2024 • It is expected that WNT and public comments rounds will then take place in Q3-Q4 2024. • Possible adoption at the WNT meeting in 2025. . 	
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
<ul style="list-style-type: none"> • Initial recommendations document approved in April 2023, project continues with the transfer of the assays to third parties laboratories, the development of testing testing strategy(ies), and the chapter on zebrafish light-dark transition assay.. 	
Subsidiary body of the JM	WNT
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: Project status and milestones:	Netherlands 2017
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<ul style="list-style-type: none"> • 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; • Data analysed and the report has been drafted; • The report has been shared Q1 2023 with the OECD new EG on genotoxicity; a peer-review will be organised as the next step in Q3 2023. 	
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: Inclusion in work plan: Project status and milestones:	Japan 2018
<ul style="list-style-type: none"> • 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. • Expectation that draft updated TG 437 and GD 160 can proceed with commenting rounds and submission for approval in 2024. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on eye irritation

Project 4.133: Study Report on the Applicability of the key event based Test Guideline 442D for in vitro skin sensitisation testing of nanomaterials	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland 2019
<ul style="list-style-type: none"> • Study report approved, project completed. 	
Subsidiary body of the JM	WNT

Expert group	Expert Group on skin sensitisation
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Project 4.139: <i>In vitro</i> genotoxicity testing for dermal exposure using 3D skin models: reconstructed skin micronucleus test and reconstructed skin Comet assay	
Lead: Inclusion in work plan: Project status and milestones:	Germany/France 2019
<p>Q1 2020: submission of validation datasets for the reconstructed skin Comet assay, for ECVAM review.</p> <p>Q2 2020: submission of validation datasets for the reconstructed skin micronucleus test, for ECVAM review.</p> <p>Q2 2021: full submission of the test methods to ECVAM for peer-review</p> <p>Q3-Q4 2023: Drafting of PRP report and submission to OECD.</p>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

Project 4.145: Guidance document on an integrated approach on testing and assessment (IATA) for phototoxicity	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2020
<ul style="list-style-type: none"> • First draft IATA document available by September 2021; • Expert Meeting in November 2021; • Commenting by Ad-Hoc Expert Group by February 2022; • Second draft IATA document available by June 2022; • Commenting by Expert Group by November 2022; • Third draft IATA document available by December 2023; • Commenting by WNT February 2023 • Revision of the draft envisaged for Q3 2023 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on phototoxicity testing

Project 4.146: New Test Guideline on toxicokinetics to accommodate testing of nano-particles	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands/ United Kingdom 2020
<ul style="list-style-type: none"> • April 2020 – September 2023: Gathering and generating experimental data ; kinetic modelling; Determine minimum requirements of the study design and development of the new TG; Preparation of a first draft of the new TG; • Second half of 2020: International workshop on the toxicokinetics of (nano)particles (probably organised in collaboration with the EU project NanoHarmony); 	

<ul style="list-style-type: none"> • Progress slower than expected due to impact of COVID on planned experimental studies and the changes in the project lead team. • December 2021: Virtual meeting of the joint Expert Group • November 2022: Nanoharmony workshop with the joint Expert Group to discuss experimental progress • Q3/Q4 2023: Development of the first draft TG/ Virtual meeting of the joint Expert Group • June/September 2024 (TBC): Draft TG submitted for comments to WNT (second milestone); • September 2024 – January 2025 (TBC): WNT commenting rounds, revision of drafts based on comments (2 commenting rounds are envisaged); • April 2025 (TBC): Approval of TG by WNT. 	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN-WNT Expert Group on Toxicokinetics of NM (TBC)

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
<ul style="list-style-type: none"> • A first draft DRP will be sent for review and commenting rounds by OECD expert groups including the VMG-NA and EDTA-AG in 2022, and WNT and this will lead to a more fully developed DRP intended to be an OECD output. This might be expected for year ending 2022, or perhaps 2023, input and comments depending; • Milestone: Presentation of the EURION cluster at the EDTA -AG meeting in May 2021. • Various chapters underway, relating to mechanisms, chemical selection, species differences, - over 16 relevant publications published to date (Feb 2022) that will provide the basis for chapters on computational evidence, adipogenesis, steatosis and receptor mechanisms such as RXR-PXR, PPARS etc. Not yet ready for consolidation or commenting. • GER (BfR) are close to completion of their draft contribution to the DRP. May be able to propose a draft in 2023. 	
Subsidiary body of the JM	WNT
Expert group	Advisory Group on Endocrine Disrupters Testing and Assessment

Project 4.148: Modification of the prediction model of the IL-8 Luc assay (OECD TG442E) to improve its performance	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2021
<ul style="list-style-type: none"> • Updated TG 442E approved in April 2023, project completed. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitization testing methods

Project 4.149: New Test guideline for identifying the T cell-mediated immunotoxic potential of chemicals using the IL-2 Luc assay	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2021
<ul style="list-style-type: none"> • TG approved in May 2023 via written procedure, project completed. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on in vitro methods for immunotoxicity testing

Project 4.150: New TG on the CYP induction (former project 4.76)	
Lead: Inclusion in work plan: Project status and milestones:	UK 2021
<p>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:</p> <ul style="list-style-type: none"> • 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 submitted February 2022. • Additional funding obtained to support the instigation of work in supplementary 3rd laboratory, starting May 2022 • January 2023: 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) • Summer 2023: Submission of the chemical augmentation report to 2 laboratories minimum and revised draft TG, to the relevant OECD expert groups for peer review. • April 2024: Potential approval of TG plus guidance document at WNT. • Indications of use is included in a chemical selection manuscript for the ED CF, and non-genotoxic 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: Project status and milestones:	United States 2022
<ul style="list-style-type: none"> • Expert Group discussions on the method validation and performance – Q2/Q3 2022 • Expert Group Peer Review organized by the secretariat – Q4 2022 • Expert Group Review on the draft TG and the peer review outcome – Q1 2023 	

<ul style="list-style-type: none"> • Expert Group discussion envisaged for March 2023 • 1st WNT Commenting Round – Q3 2023 • 2nd WNT Commenting Round – Q1 2024 • Submission for approval at WNT – April 2024 	
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
<ul style="list-style-type: none"> • 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 – Q3 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; • Public commenting rounds in 2024; <p>Possible adoption at the WNT meeting in 2025.</p>	
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
<ul style="list-style-type: none"> • 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: Project status and milestones:	United States/United Kingdom 2022
<ul style="list-style-type: none"> • Publish case study results for cosmetics (submitted) – Q1 2022 • Publish chemical case studies that cover a range of regulatory sectors (ongoing) – Q3 2022 • Propose general assessment framework for DAs for skin sensitisation quantitative risk assessment – Q4 2022 • 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) – Q4 2023 • Draft addition to GL 497 for review by the WNT – Q4 2023/Q1 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: Project status and milestones:	Japan 2022
Phase 1 (feasibility study):	
<ul style="list-style-type: none"> • 	

- Validation report and peer-review report approved in April 2023;
- WNT check point in April 2023: consultation to confirm that the leads can proceed with the development of the TG;

Phase 2 (TG development):

- The draft TG will be made available to OECD in Q2 2023;
- 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 in Q2-Q3 2023.

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
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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

Project 4.157: Support to UN GHS for modification of germ cell mutagenicity criteria in Chapter 3.5

Lead: Inclusion in work plan: Project status and milestones:	EC-JRC/Secretariat 2022
<ul style="list-style-type: none"> • 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 objective of the informal working group is to finalise a draft revised text of Chapter 3.5 and present to the sub-committee within this biennium and prior to December 2023 for possible inclusion in the tenth revised edition of the GHS. 	
Subsidiary body of the JM	WNT
Expert group	

Project 4.158: New Guidance Document on IATA for intestinal fate of orally ingested nanomaterials

Lead: Inclusion in work plan: Project status and milestones:	Italy 2022
<p>April 2022 – March 2023</p> <ul style="list-style-type: none"> – 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

- GD submission to WNT.

Subsidiary body of the JM	WNT
Expert group	

Project 4.159: Updated TG 456 for LC-MS based steroidogenesis assay

Lead: Inclusion in work plan: Project status and milestones:	France 2022
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- 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: Project status and milestones:	France 2022
<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Peer-review by internal VMG and PEPPER' scientific council December 2023 – January 2024 ○ 1st round of comments from 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: Q2 2024 ○ 2nd round of comment from WNT on validation report, and draft TG: Q3 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 4.161: New TG on Glucocorticoid receptor STTA assay

Lead: Inclusion in work plan: Project status and milestones:	France/Canada 2022
<ul style="list-style-type: none"> • 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
<p>2022:</p> <ul style="list-style-type: none"> 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. <p>2023:</p> <ul style="list-style-type: none"> 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. <p>2024:</p> <ul style="list-style-type: none"> 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 <p>2025:</p> <ul style="list-style-type: none"> 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
<p>Phase 1 (feasibility study):</p> <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> WNT check point: update and consultation of the WNT in April 2024. <p>Phase 2 (TG development)</p> <ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> Establish a clear plan in collaboration with the EG on application of evaluation framework (e.g. reference chemicals, documentation, applicability domain) – Q2 2023 Submit the supporting document for comments within the EG – Q3 2023 Adapt data interpretation procedure (as needed) and revision of the supporting document – Q3 2023 Revision of the supporting document and draft GL for public and WNT comments – Q4 2023 Final GL and supporting documents –2025 (expected duration approximately 2 years). 	
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: Inclusion in work plan: Project status and milestones:	Japan 2023
<p>Step-1:</p> <ul style="list-style-type: none"> 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: Inclusion in work plan: Project status and milestones:	NL/AT/US/LUX/ICAPO 2023
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- Establish expert group: April 2023-August 2023
- Convene EG to develop outline and draft document August 2023-December 2023
- First draft of DRP circulated within EG December 2023
- Revised draft of DRP prepared, circulated for WNT review January 2024
- Additional revisions, drafting of document April 2024
- Submitted to WNT for approval April 2025.

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: Inclusion in work plan: Project status and milestones:	France/Sweden 2023
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- 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
- Fall 2023: 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 acceptance of the project by WNT in April 2023, and no major issue during phase 2
- Q4 2023: 1st round of comments from WNT on validation report, and draft TG
- Q1 2024: 2nd round of comments from WNT on validation report, and draft TG Submission draft TG to WNT, 2024.

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: Inclusion in work plan: Project status and milestones:	France/Germany 2023
<ul style="list-style-type: none"> • 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 TG 493 ((Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) In Vitro Assays to Detect Chemicals with ER Binding Affinity): revision of performance and acceptability criteria	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom/Japan 2023
<ul style="list-style-type: none"> • Updated TG 493 approved together with the SPSF, project completed. 	
Subsidiary body of the JM	WNT
Expert group	None.

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: Inclusion in work plan: Project status and milestones:	United States through the WP Biocides 2007, revised in 2010
<p>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.</p> <p>Protocols are quantitative methods for evaluating bactericidal, mycobactericidal, fungicidal and virucidal activity of microbicides used on hard non-porous surfaces.</p> <ul style="list-style-type: none"> • 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: Inclusion in work plan: Project status and milestones:	EC (JRC), United States, Netherlands 2023
<ul style="list-style-type: none"> • Establishment of new expert group to discuss the revision of GD 34 (May/June 2023) • Expert 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 (Q3 2023). • Expert group to draft revised GD 34 (beginning Q4 2023). All communication will be done in writing and via videoconferences at this stage. • Update on progress at OECD WNT meeting (April 2024) • Draft revised GD 34 circulated to WNT for commenting (Q3 2024). • If needed/of value, a few face-to-face meeting(s) of the expert group may be organised in Q4 2023 and/or in 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: Inclusion in work plan: Project status and milestones:	Germany 2023
	<ul style="list-style-type: none"> • Finalization of draft guidance Aug. 2023; • Discussion of draft guidance in WPB September 2023; • Submit draft GD to WNT at Beginning 2024.
Subsidiary body of the CBC	WNT & WPB
Expert group	WPB

ANNEX 1**PROJECTS THAT ARE NO LONGER SUPPORTED**

Project 4.77: Feasibility study for a Guidance Document on Study Designs, to be used in revisions of Guidelines	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2013
<ul style="list-style-type: none"> • Expert meeting held on 20-21 November 2014 in Amsterdam to discuss the feasibility study; • Lead country working on the feasibility study using data from 28-d repeated dose toxicity studies; • Teleconferences of the expert group were held in September and November 2017 to present and illustrate the BMD analysis and underlying concepts; it was agreed that qualitative and quantal endpoints would have to be analysed as well, for the approach to gain more acceptance. The feasibility study is extended for another year (2018), after which it will be concluded whether or not to proceed with a Guidance Document; • Due to problems encountered with low dosing in recent studies, further analysis on the issue of impact of dosing, effects size and groups were considered, an initial update of this work was presented and discussed at the April 2020 meeting of the WNT; • Second part 2020. Perform computer simulations comparing various study designs and to address groups size, effects size in relation to continuous, quantal and ordinal (histopathological scores) data will be examined. The study design factors to be examined are: number of dose groups, number of animals, dose selection. The computer simulations will examine the impact of the various study designs on the POD (both NOAEL and BMD) and impact on classification and labelling • The primary results will be discussed in an expert group in Q3 2021 after which further adaptation/analysis will be made. • Depending on the outcome of the expert group meeting a will included in a guidance document on feasibility of study design. • This project is stopped in 2022. 	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Meeting on study designs

Project 4.98: EDTA Activity: developing a list of reference chemicals for Endocrine Active Substance metabolism	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2015
<ul style="list-style-type: none"> • Finalisation of the list in Q4 2018; 	

<ul style="list-style-type: none"> • Preparation of report to share with VMG-NA 2019/20; • Report will be annexed to project 4.147 in 2022/23 pending additional update support. 	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

Project 4.118: Update of TG 442D on in vitro skin sensitisation using animal-free serum and validation of TG 442E using human serum and human antibodies	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2017
<ul style="list-style-type: none"> • The updated TG 442D, including the option on use of human serum, was approved at the WNT in April 2018 and published in June 2018; • A dedicated workshop on the use of human products in TGs was held in March 2019; • Given the current sanitary context, works to introduce human serum to replace bovine fetal calf serum have been delayed, and other efforts have been engaged to developing defined synthetic media. Depending on progress within the short- to medium-term, the project may be reshaped and resumed. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

Project 4.119: Update of TG 455 with the introduction of a metabolic step in the ERα CALUX transactivation bioassay for ER	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2017
<ul style="list-style-type: none"> • The work has focussed on the ER CALUX with metabolic activation. Several chemicals (around 80) have been tested with and without S9, these data are currently evaluated against in vivo data. • These analyses will be ready 2Q 2022 and a discussion in an expert group (VGM NA/EDTA) is foreseen to discuss the results and next steps Q3 2022 • Depending on outcome of OECD expert group discussion planning of future work to finalise the project (4.119 and 4.120). 	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

Project 4.120: Update of TG 458 with the introduction of a metabolic step in the AR CALUX transactivation bioassay for the detection of (anti)androgenic chemicals	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2017

<ul style="list-style-type: none"> • The work has focussed on the ER CALUX with metabolic activation. Several chemicals (around 80) have been tested with and without S9, these data are currently evaluated against in vivo data. • These analyses will be ready 2Q 2022 and a discussion in an expert group (VGM NA/EDTA) is foreseen to discuss the results and next steps Q3 2022 • Depending on outcome of OECD expert group discussion planning of future work to finalise the project (4.119 and 4.120). 	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

Project 4.122: Guidance Document on hepatic clearance test methods

Lead: Inclusion in work plan: Project status and milestones:	European Commission 2017
<ul style="list-style-type: none"> • An <i>ad hoc</i> expert group will be established to scope out and develop the Guidance Document (GD). Meetings will mostly be held by TC / web conference, with sharing of documents via the OECD Clearspace; • Circulate the outline of the Guidance Document to the <i>ad hoc</i> expert group once established (July 2018); • Circulate a first draft GD to expert group in Q4 2018 • Circulate a revised draft GD to expert group in Q2 2019 • 2 commenting rounds at WNT level Q3-Q4 2019 • Final GD submitted to WNT for approval in April 2020. 	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Metabolism

Project 4.123: Review and feasibility of an Embryonic Stem Cell Test: In vitro assay detecting disruption to differentiation of rodent embryonic stem cells into cardiomyocytes using the Hand1 gene

Lead: Inclusion in work plan: Project status and milestones:	Japan 2017
<ul style="list-style-type: none"> • 1st step: Detailed Review Paper of available methods and evaluation of utility and application (Q1-Q4 2019); internal project meeting of experts selected by Japan for the drafting is on-going and review paper is waiting for presumable acceptance/publication. The draft will be submitted to WNT in Q4 2022; • This project was stoooped after the publication of the manuscript (Piersma, Aldert H et al. "Pluripotent stem cell assays: Modalities and applications for predictive developmental toxicity." <i>Current research in toxicology</i> vol. 3 100074. 13 May. 2022, doi:10.1016/j.crtox.2022.100074). 	
Subsidiary body of the JM	WNT
Expert group	

Project 4.132: A feasibility study for establishing TGs for in vitro human hepatic metabolic clearance and metabolite formation	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2018
<ul style="list-style-type: none"> • Formation of an expert group Q3 2018 (NL proposes to form an expert group for toxicokinetics) • Alignment of the set-up of the feasibility study with the draft guidance document for hepatic clearance (4.122) in close contact with EURL ECVAM Q3 2018 • Inventory of available databases and literature with hepatic clearance data for evaluation Q3+4 2018 • Circulate a first draft of the feasibility study report and commenting rounds Q1 2019 • Circulate a revised draft report Q2 2019 • Approval of final document Q4 2019-Q1 2020. • This project will be discussed at the April 2020 meeting of the WNT, together with the project on CYP induction method (project 4.76); following the publication of a scientific article in lieu of the feasibility study; • The lead country decided not to continue the development of Test Guideline in this area. In agreement with the Netherlands, the project is moved to Annex 1. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Toxicokinetics

Project 4.140: Inclusion of the LbL-3D Skin model skin irritation test to OECD test guideline 439 validated reference method	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2020
<ul style="list-style-type: none"> • The validation study report will be prepared by January, 2020 for peer-review; an evaluation of the validation study by an independent peer review panel of international experts for the LbL-3D Skin SIT method will be planned supported by ICATM; • The Independent peer review report will be completed by early summer 2020; • Discussion on-going in 2020-2021 within the Expert Group on skin irritation on the performance of the test system and on the level of similarity with RhE tissue in TG 439; • Action items and draft revised TG will be provided in Q2 in 2021. • This draft will be discussed by EG and WNT; Japan expects the revised TG 439 to be submitted for approval in April 2022. • Project stopped because test developers no longer active to support the project. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods