Work plan for the Test Guidelines Programme (TGP)

As of July 2021

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
Joint Meeting: Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology
EDTA AG: Endocrine Disrupters Testing and Assessment Advisory Group
EG: Expert Grooup
NC: National Coordinator
SPSF: standard project submission form
VMG-eco: Validation Management Group for Ecotoxicity Testing
VMG-non animal: Validation Management Group for Non Animal Testing
WNT: Working Group of the National Coordinators for the Test Guidelines Programme
WGP: Working Group on Pesticides
WPMN: Working Party on Manufactured Nanomaterial
WGB: Working Group on Biocides

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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:	WG Biocides 2018
• An Expert Group has been formed under the Working Group on Biocides; the proposed draft Guidance Document will be discussed via conference calls.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 • A draft Guidance Document is under development under auspices of the WGB but currently on hold until sufficient resources are available from the Secretariat to resume the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 1.3: New TG on Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials	
Lead: Inclusion in work plan: Project Status and milestones:	European Commission - JRC 2018
• Establishment of an Expert Group on Physical-chemical properties of nanomaterials April 2019; • Discussions and coordination within the Expert Group allowed to develop first draft generic TG and a SOP for ring trial. First trial will take place on a small scale to assess performance and applicability domain • 2020 - The arrangement for the inter-laboratory comparison (ring trial) was initiated. 7 laboratories, including JRC confirmed participation in the exercise. 7 materials were selected, one of which was analysed for homogeneity, while data for the others already exist or they are CRM. Randomly coded subsamples of materials were distributed to participant laboratories in May 2020. The TGA of the 7 materials were carried out and are annexed to the SOP. Work was delayed due to covid-19. • 2020 : In Q3 & Q4 the ILC on determination of VSSA of 7 selected materials and participation of 7 laboratories was completed (execution plus evaluation). • Results of the ILC were presented and discussed with the Advisory Expert Group (November 2020). • 2020 Q4 and 2021 Q1: A Draft ILC report was shared and commented by participating laboratories. • 2021 Q1 : ILC report to be circulated to the Advisory Expert Group for comments. • 2021 Q1 & Q2 : The ILC data will be made publicly available in peer review journal and/or JRC report . • 2021 Q1 & Q2: With support from Advisory Expert Group, decision on need and feasibility of additional steps (more data/info on degassing conditions and sample preparation; additional tests for ensuring the applicability to underrepresented materials, increasing the dataset by an additional testing phase with more laboratories and model materials).	

• First draft TG and report to be sent to WNT probably in Q3 2021.	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials (JEG-PC)

Project 1.4: New Test Guideline on particle size and size distribution of Manufactured Nanomaterials	
Lead: Inclusion in work plan: Project Status and milestones:	Germany 2018
• February 2018: Establishment of an international advisory group on particle size and size distribution of nanomaterials ; • October 2018: Decision on the test methodology, and preparation of the round robin test (SOP development, agreement of parameters, measurands and units, shipping of test materials, etc.); • March/April 2019: Start performance of the round robin test; • April 2019: Establishment of an WNT/WPMN Joint Expert Group on physical chemical properties of nanomaterials (JEG-PC); • June -August 2019: Round robin test; • September 2019 – July 2020: Delivery of data from round robin testing and: processing of results, development of a validation report; • December 2019: Meeting of the JEG-PC (OECD Boulogne); • December 2019-January 2020: 1st round of comments from the JEG-PC; • August - October 2020: 2nd round of comments from the JEG-PC; • November/December: Online JEG-PC meetings for discussion of the draft TG and validation report; • 1st WNT commenting planned for spring 2021; • Some delays due to Covid-19.	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on Physical-chemical properties of nanomaterials (JEG-PC)

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
• May 2019: Invitations distributed to verify already registered and contributing member countries and laboratories that will contribute to the experimental work. • July 2019: A first draft GD is developed and circulated to the project group for internal use for testing purposes and discussion of potential refinements and testing needs. Presentations and discussions will be held at a face-to-face meeting with the project group and participating laboratories to present and discuss the test methods and protocols considered for the GD, and their current status and test strategy regarding intra-laboratory validation. • August 2019: Launch of the intra-laboratory comparison testing.	

• December 2019: A face to face meeting was organised back to back with the WPMN, to discuss A face-to-face meeting with the project group and participating laboratories is anticipated to discuss in particular: i) the draft protocols and status of testing results; ii) SOPs and preliminary results; and iii) defining the first common dissolution testing criteria for the GD. • May 2020: the first draft GD expected to be finalised together with the intra-laboratory comparison testing at the lead institutes and additional laboratories subscribing to the testing. • The GD is expected to be submitted for approval to the WNT in 2022.	
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
• 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.	
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
• Establishment of an Expert Group. Meetings mostly via teleconference and electronic information exchange. 2-3 face-to-face meetings are also envisaged. • First Draft TG based on the scientific literature referenced below. • Iterative discussions on the first and subsequent draft versions of the TG by the Ad-Hoc Experts' Group. • 2019: Identification of testing and data generation needs in order to: i) optimize the test protocol; ii) organise the inter-laboratory comparison (ring trial); iii) if relevant and feasible, carry out a full performance validation; and iv) if relevant and feasible, further investigate the relationship between hydrophobicity (measured via the proposed method) and cellular uptake or bioaccumulation in organisms. • 2019: Expert group established and meeting held including experimental demonstration of testing.	

- 2020: Interested laboratories were identified and comments received on the project and protocols. The optimization was initiated, however, it was temporarily interrupted due to Covid-19 in spring.
- 2020: The inter-laboratory comparison (ring trial) started in autumn, 10 participant laboratories had confirmed their interest (+JRC). A set of five materials was sent together with the SOP and a test kit. The Covid-19 pandemic caused important delays and changes in participation: 4 of the confirmed laboratories declined their participation and 3 did not manage to perform the test within the deadline (fixed at end of 2020).
- 2021 Q1: Only partial results were received from 3 participants and the evaluation of these is on-going. As work restrictions remain, a re-scheduling of activities is considered and new planning is on-going.

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

2019

- Establishment of an Ad-Hoc Experts Group. Meetings mostly via teleconference and electronic information exchange. 2–3 face-to-face meetings are envisaged, if possible.
- Development of the first draft TG; iterative discussions on the draft TG by the Ad-Hoc Experts Group.
- September 2019: the Secretariat circulated a call an inter-laboratory comparison test to assess the robustness and comparability of dustiness test methods.
- December 2019: A meeting was held, back to back with the WPMN, to discuss the project in detail, in particular non-fibers, HARN, and ATEX.

Due to the COVID-19 Pandemic, significant delays were encountered and early-on proposed dates have been postponed.

2020

- 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

- 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)
- 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
- Aproval of the GD by WNT: April 2025.
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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

2020

- 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.

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 Q3 2021.
- Establishment of a repository of reference materials.

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

April 2021 – May 2022

- Establishment of a new joint WNT-WPMN Ad Hoc Expert Group and regular teleconferences for discussion and development of GD and associated experimental studies.
- Development of conceptual plan for guidance document
- Gather and analyse available experimental data
- Undertake additional experimental studies primarily to fill important data gaps
- Development of draft GD

- International workshop on approaches for determining nanomaterial concentrations in biological matrices (organised in collaboration with the EU funded project NanoHarmony) (second half of 2021)
- Regular communications with other related OECD projects to facilitate the avoidance on inconsistencies and duplication, promote harmonisation and also to identify synergies to promote efficient collaborative working and tailoring of the GD to the requirements of particular TGs and GDs under development. To include engagement with relevant existing WPMN and WNT (nanomaterial) Expert Groups to promote early input and links with other related projects.
- Commenting round of relevant WPMN and WNT Expert Groups on draft GD (April/May 2022)

June 2022 – Nov 2022

- 1st WNT commenting round on draft GD (June – Sept)
- 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 (Oct/Nov)
- Update GD on basis of comments received (Nov)

Dec 2022 – Mid Feb 2023

- 2nd WNT commenting round on revised draft GD (Dec – Jan)
- Submission of GD to WNT (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 2.46: New TG for the Detection of Endocrine Active Substances, acting through estrogen receptors using transgenic cyp 19a1b-GFP Zebrafish Embryos (EASZY assay)	
Lead: Inclusion in work plan: Project status and milestones:	France 2013
• Project completed.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

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
• 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) • April 2021: Expert group and WNT commenting rounds, TG finalization; • Earliest adoption of TG by OECD WNT (2022).	
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
• 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 will be generated during 2020-2022. These new data will be integrated into the draft acute fish toxicty IATA guidance document for circulation and discussion by VMG-Eco experts;; • Finalization of the project at WNT level is envisaged by the WNT meeting not before April 2023.	
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: 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
- 2020-2021: 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. Focus on TG 203 and TG 210 .
- 2022: WNT commenting rounds of DRP;
- 2023: 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

- A ring test including an inter-laboratory validation will be conducted in 2016-2019.
- A draft report of the phase 1 validation will be prepared and submitted to existing expert groups (FDG and/or VMG-eco) in early 2020.
- A final report of the phase 1 validation and draft test protocol, revised based on the results of the review of the expert groups, will be prepared in 2021.
- A draft report of the phase 2 validation and a revised draft test protocol will be prepared and submitted to the expert groups in autumn 2021.
- Revised draft guidance document and validation reports will be delivered by the end of 2020/ the beginning of 2022 for WNT commenting.
- Final draft guidance document will be submitted to the WNT in 2022.

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
• Inter-laboratory validation was conducted in 2018-2019. • Draft test guideline and report(s) of validation studies will be prepared and submitted to the expert groups (VMG-eco and Invertebrate expert group) in 2020.	
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
• Validation study is taking place 2017-20220: 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 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 2.60: Test Guideline: Homing flight test on honeybee (Apis mellifera L.) after single exposure to sublethal doses	
Lead: Inclusion in work plan: Project status and milestones:	France 2016
• Project completed.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on honeybee/bumblebee toxicity testing

Project 2.61: New TG RADAR assay – Rapid Androgen Disruption Adverse Outcome Reporter Assay

Lead: Inclusion in work plan: Project status and milestones:	United Kingdom/France 2017
• Q2 2018: availability of a written protocol; • Q3 2018 – Q2 2020: validation exercise in progress - CEFAS (UK): Finished: data for the 3 pro-androgenic, 4 anti-androgenic and 3 inert chemicals constituting the core list. - WatchFrog (France): Data available for all 10 core list chemicals, experiments in progress for the 6 additional chemicals. - FIWI (Switzerland): All chemicals completed. - Fraunhofer (Germany): Completing core list: 7/10 chemicals completed, end of experimental phase expected end of Q2 2020. - Idea Consulting (Japan): Completing core list: Experiments 90% complete . • Q3 2020: Completion of an integrated summary report that synthesises the data from all supporting studies; • 2020-2021: Addition of analytical chemistry results to integrated summary report; • 2021: Independent peer review of the validation study; Finalisation of the draft TG; commenting rounds within the expert group and WNT on the draft TG; • Earliest approval at the WNT in April 2022.	
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: Inclusion in work plan: Project status and milestones:	Netherlands/United Kingdom 2019
• First ring-test already completed, second ring-test with Imazapyr during Summer 2018 to Winter 2018; • OECD Expert group established in July 2019; • Ring-test 3 has been rescheduled for Summer 2021; • Training in plant propagation and experimental methods will be provided online via a series of 4 x 2 hour online sessions in April – May 2021.	
Subsidiary body of the JM	WNT
Expert group	To be determined

Project 2.63: New TG on Fish cell line acute toxicity test - RTgill-W1 cell line assay	
Lead: Inclusion in work plan: Project status and milestones:	Norway/Switzerland 2019
• pProject completed.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.64: Inclusion of thyroid endpoints in OECD fish Test Guidelines	
Lead: Inclusion in work plan**:** Project status and milestones:	Denmark 2019
2019-2020 • Establishment of an ad hoc expert group in charge of the pre-validations and validations to be performed: • Selection of promising thyroid endpoints, and validation of these in pre-validation tests including OECD TG 236, Fish Embryo Toxicity (FET) Test and the FSDT **2021:** • May 2021: submission of a draft Detailed Review Paper on thyroif endpoints **2020-2022** • 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) • Evaluation of the results and completion of a draft guidance for evaluation of thyroid endpoints • Inclusion of suitable thyroid endpoints in the OECD TG 234 protocol, and completion of a consolidated draft TG for submission to the OECD Secretariat **2023** • WNT commenting rounds • Acceptance of TG 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: Project status and milestones:	Switzerland 2019
Milestones 1. First drafts of the guideline and the validation report will be ready for Honey Bee Expert Group commenting in autumn 2021. 2. Expert group meeting/Teleconference to discuss the validation reports and draft TG in Winter 2021/2022 3. Revised validation reports and TG (based on comments) for a 1st commenting by the WNT in spring 2022. 4. 2nd WNT commenting round of the final validation report and draft TG autumn 2022. 5. Final validation report and draft TG for approval at the WNT in April 2023.	
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
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. OECD VMG-Eco and WNT commenting rounds (2022). 7. Possible adoption at WNT Meeting (April 2023)	
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

• 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 2021. • A final report of the inter-laboratory and draft of revised test guideline including the update of the scientific name will be prepared in 2022.	
Subsidiary body of the CBC	WNT
Expert group	Validation Management Group for Ecotoxicity Testing

SECTION 3
PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE

Project 3.10: New TG on dissolution rate of nanomaterials in aquatic environment	
Lead: Inclusion in work plan: Project status and milestones:	Germany (since 2020) 2014
• Conceptional development (coordination with related TG and GD developments, exchange with project associated expert group): autumn/winter 2020 • Update of SPSF considered for Nov 2020 • Update of existing protocol to determine solubility and dissolution rate using batch test: end of 2021 (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): spring 2022 • Frequent exchange with WNT projects 1.5 and 3.16 • Validation study (both on batch and dynamic testing): summer 2022 • WNT Expert Group Meeting: autumn 2022 • WNT commenting: autumn/winter 2022 • Delays are envisaged due to Covid-19.	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on ecotoxicity and environmental fate testing

Project 3.11: New TG for nanomaterial removal from wastewater	
Lead: Inclusion in work plan: Project status and milestones:	United States 2014
• Project completed.	
Subsidiary body of the JM	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: Inclusion in work plan: Project status and milestones:	United Kingdom and Spain 2014
1. 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.	

2. 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. 3. Work is being developed with Spanish resources and within the framework of the H2020 project Gov4Nano. Spain expects to incorporate their findings along 2021 and circulate a draft for comments- • A teleconference took place on 28th January 2020 to discuss progress and the next steps. • The expected time for completing this project is 2022.

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

Project 3.14: Guidance Document to support implementation of TG 312 for Nanomaterial Safety Testing	
Lead: Inclusion in work plan: Project status and milestones:	Germany/Canada 2017
• Project completed.	
Subsidiary body of the JM	WNT/WPMN
Expert group	Joint 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
• 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 March-August 2021; • Submission of TG for WNT approval in 2023.	
Subsidiary body of the JM	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
Oct. 2019 - March 2020: • 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. ***September 2020:*** • F2F meeting (Paris or Vienna) with advisory panel and nominated members from the Joint WNT/WPMN Expert Group on the Environmental Fate of Nanomaterials: agreement on the methodology to be applied, selection of transformation pathways to be included in the guidance (incl. priorization) **Sept. 2020 – Nov. 2021:** *(eventually also later, depending on COVID-19 situation and lab closures)* • 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. **Dec 2021-May 2022:** *(eventually also later, depending on COVID-19 situation and lab closures)* • Revision of draft documents and submission for approval.	
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
• The OECD ad hoc Expert Group to oversee planning and conduct of the definitive multi-laboratory ring trial has been established in summer 2019; • The kick-off meeting of the Expert Group was held in November 2019; • Multi-laboratory ring trial: o Pre-test (assessment of the transferabitlity of the method) (May 2019 - November 2019); o Lipid extraction: During the kick-off meeting, it has been decided to initiate an interlaboratory comparison of the lipid extraction as a crucials step for the calculation of the BCF; o Main study: Due to the covid-19 epidemic, some participants had to postpone their experiments. Consequently, the experimental phase, which was planned orginally to end in December 2020, was extended until end of February 2021; • Meeting for discussion of the ring test results is scheduled for March 2021;; • Development of draft TG: Q2 2021; • Expert group and WNT commenting rounds, TG finalization (Q2 2021-Q1 2022); • Earliest possible adoption of TG by OECD WNT in 2022.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on *Hyalella azteca* bioconcentration test

Project 3.18: Anaerobic Transformation of Chemicals in Liquid Manure

Lead: Inclusion in work plan: Project status and milestones:	Germany 2020
• 05/2020: Nomination of ad hoc expert group; • 06/2020-01/2021: Commenting of Draft TG by ad hoc expert group; • 2021: WNT commenting rounds, TG finalization; • 2022: Possible adoption of TG by OECD WNT.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Anaerobic Transformation studies

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
• 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). • Draft new Test Guideline for peer review based on existing SOP (April 2022). • OECD WNT meeting for acceptance of new Test Guideline (April 2023).	
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 4.76: Test Guideline for the establishment on human-derived hepatic system to investigate biotransformation and toxicity of compounds by evaluation of CYP450 induction competence	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom (formerly led by the European Commission 2013
On the basis of previous work and draft TG developed and validated under the leadership of the European Commission Joint Research Center, 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. • January 2022: 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) • June 2022: Submission of the chemical augmentation report and revised draft TG, to the relevant OECD expert groups for peer review. • November 2022/February 2023: First/second WNT commenting round • April 2023: Potential approval of TG plus guidance document at WNT. • Guidance 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	Expert Group on Toxicokinetics

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
• 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.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Meeting on study designs

Project 4.78: Updated TG 488, Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays	
Lead: Inclusion in work plan: Project status and milestones:	Canada 2013
• A 2 step update of the TG is expected : o First step is completed and the updated TG 488 was published mid-2020: Short-term revision, to improve the detection of germ cell mutations by revising the experimental design; o Longer term revision, including harmonisation with the other in vivo Test Guidelines on genotoxicity and based on additional experimental data continues. EG discussions have resumed in Q3 2020. o First WNT commenting round of the revised TG planned in Q2 2021	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

Project 4.93: new Test Guideline for the Pig-a Assay, an *in vivo* Gene Mutation Assay Promoting the 3Rs Principles	
Lead: Inclusion in work plan: Project status and milestones:	United States 2015
• DRP was approved by the WNT and will be published mid-2020 • Initiate draft TG: Q2 2020; • Public commenting on draft TG, revision as necessary: 2020-2021; • Submit revised TG to WNT: November 2021; TG considered by WNT 2022.	
Subsidiary body of the JM	WNT

Expert group	Expert Group on Genotoxicity Testing

Project 4.94: IATA on Non-Genotoxic Carcinogens	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2015
• 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; • Next plenary meeting February 2021; • Manuscripts reviewing each hallmark block being drafted Q3: 2020 - Q2: 2021; • Integration of assays into an IATA expected by Q4 2021.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Non-Genotoxic Carcinogenicity

Project 4.95: Guidance Document on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2015
Guidance Document that will support the existing genotoxicity Test Guidelines by indicating where protocol modifications and special considerations should be applied when the test item is a NM. All 5 selected nanomaterials (2x silver NPs, 2x gold NPs and 1x silica NPs) were characterised for their physicochemical properties in the pristine form, as well as suspended in the 4 cell culture media. A JRC Technical report was published: **https://ec.europa.eu/jrc/en/publication/physicochemical-characterization-gold-silica-and-silver-nanoparticles-water-and-serum-containing** The 5 cell lines chosen by the expert group were checked for their doubling times (necessary parameter in genotox). Experiment for the assessment of cytotoxicity and uptake of the 5 NPs in all 5 cell lines were performed. 2019 the technical group, established by the lead country, met to discuss the appropriate design of a ring test for the optimisation of the micronucleus test protocol on the basis of the physicochemical characterization and the cytotoxicity and uptake experiments study . The ring test should allow identifying modifications for the TGs and coming up with a proposal for a GD. This ended the first phase of the project. Second phase is led by Swansea U. and BASF, starting by further examining the preferred protocols and materials in experimental conditions. January 2020 Comparison of dispersion and testing protocols as well as scoring on-going between Swansea and BASF, anticipated end of this work: April. March 2020 lock down blocked further lab work. June 2020 Publication of JRC Report on cytotoxicity and uptake. December 2020 A micronucleus test protocol was developed and is ready to be transferred	

to other laboratories. February 2021 a report was sent to OECD Genotoxicity Expert Group; Q1 2021 Teleconference organised with the OECD Genotoxicity Expert Group to seek feedback; 2021- Possible interlaboratory trial (still to be set up and organized). New leadership required and needs communicated to WNT meeting in April 2021. In the absence of new leadership, alternatives are sought to make the most out of the work completed so far.

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

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
• Project completed; additional chapter on cardiovascular system will be drafted in 2021-2022 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

• Protocol for validation ready in October 2016 followed by validation;
• Transfer phase until January 2017;
• Validation study between March and the summer 2017;
• Statistical analysis and main validation report Q4 2017;
• Supplement to validation report with data on potency Q2 2018;
  o Statistical analysis and validation report:
  ▪ binary data: available Q1 2018;
  ▪ supplement with potency data: 2019
• ESAC peer-review completed. Preparation of a draft TG for review in Q2/Q3 2021..	

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); • ESAC peer-review delayed until at least September 2021 due to expiring mandate of current ESAC; alternative solutions sought by the lead to progress the project in 2021.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

Project 4.109: DRP on the Miniaturized versions of the Bacterial Gene Mutation Test	
Lead: Inclusion in work plan: Project status and milestones:	Belgium/United States/Netherlands 2016
• Retrospective validation/ Consolidation of existing Ames MFA data; Scientific peer review of existing data (2016 -2017); • Prospective validation if needed; Generation of additional data based on the outcome of the retrospective validation process; • Kick off meeting organised on 28 February - 1 March 2017 at OECD; • Start writing the draft DRP (Q2 2017); • Call for data sent Q1 2018; • Analysis of the collected data Q4 2018 - Q2 2019; • Expert group meeting in July 2019 (OECD, Paris) to move forward with the development of the DRP in the light of the results from the retrospective analysis; • Second call for data Q4 2019 in order to complete the database; • Reanalysis of the data in Q1-2 2020 and input from subgroups of work; • First submission of the draft DRP to WNT for comments in Q3 2020.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Miniaturised Ames Test

Project 4.115: Update of Guidance Document 28, Guidance Notes 156 and possibly TG 428 on skin absorption	
Lead: Inclusion in work plan: Project status and milestones:	EC/EFSA/Germany 2017
Teleconference meetings (at least 4): • Expert group 1st TC (Sept. 2018)/ 2nd TC (Dec. 2018): presentation by EFSA and BfR of the EFSA guidance and proposed scope of changes on the OECD Guidance Notes 156; collection of expert feedback on the GD 156 and the intended scope (pesticides only? Europe only?)	

• WNT in 2019 discussed the scope (pesticides only, and focus on GN 156 revision in 2019-2020. Leads finalised re-draft GN 156 with experts in specific areas. 3rd TC with EG held in September 2019; • The WNT recommended waiting for the changes in policies in some OECD countries before resuming the OECD activity at beginning of 2021; • Project is resuming in May 2021, next steps should include an update to GN 156 including the new state-of-play of dermal absorption estaimation across countries and revised version will be circulated for review by EG and the WNT in Q2 or Q3 2021.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Dermal Absorption or Expert Group on skin irritation.

Project 4.116: Guideline on Defined Approach(es) for Skin Sensitisation	
Lead: Inclusion in work plan: Project status and milestones:	EC/US/Canada 2017
Key milestones: • Whitepaper characterising international regulatory requirements for skin sensitisation testing, by region (completed); • Whitepaper communicating ICATM workshop outcomes and recommendations (completed); • Carry out analysis of current animal test (LLNA) data to determine performance thresholds for acceptance based on i) reproducibility of the animal test and ii) concordance with human data, where available (presented at the Special session of WNT in Dec. 2017). • Propose general assessment framework (including acceptance criteria) for DAs for skin sensitisation (discussed at the Special session of WNT in Dec. 2017). • Apply assessment framework to existing DAs that have been documented in Annex 1 of the OECD Guidance Document on the reporting of Defined Approaches to testing and assessment for skin sensitisation (OECD GD 256) and other candidate approaches and individual test methods (underway, Q1-Q2 2018). • Evaluate the feasibility of incorporating DAs (and individual test methods) in a Guideline and circulate draft Guideline and report on information supporting the validation of selected DAs to the EG and WNT for review (Oct. 2018). • Face-to-face meeting of the EG on 6-7 Dec. 2018 at OECD; further work recommended and follow-up conf. call scheduled end of Jan. 2019. • Re-analysis of LLNA study quality and analysis of human data quality in 2019; • Revised draft GL and Supporting Document will be circulated for a second written commenting round Q3 2019; • Series of TCs organised in Q4 2019- Q4 2020 to identify and discuss outstanding issues and path forward/timelines; a virtual meeting is organised on 22-23 June 2020 to tackle the remaining issues before a possible third round of review on the revised draft Guideline; • Draft GL approved by the WNT in April 2021.	
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
• Progress on on-going experiments using S9 fraction (10 chemicals, 5 positives, 5 negatives in 2 laboratories) was reported to the VMG NA (Oct. 2017); • Project was delayed due to test method lead's involvement in other TGP projects. • An update on the work is expected in 2020	

• Due to Covid19 and limited staff/personal issue is a delay. Lead propose to keep the project on the program until 2022.	
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
• Progress on on-going experiments using S9 fraction (10 chemicals, 5 positives, 5 negatives in 2 laboratories) was reported to the VMG NA (Oct. 2017);. • Project was delayed due to test method lead's involvement in other TGP projects. • An update on the work is expected in 2020 • Due to Covid19 and limited staff/personal issue is a delay. Lead propose to keep the project on the program until 2022.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

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
• 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 a manuscript in preparation that is presumably awaiting for acceptance/publication. The draft will be submitted to WNT in Q4 2021; • Establish an Ad hoc Expert Group; • Tele-conferences (at least 6) plus face to face meeting(s) to address issues identified after the first commenting round; • This draft will be discussed by EG and WNT; Japan expects to be submitted for approval in April 2023.; • 2nd step: feasibility study of the development of a Test Guideline, (timelines are not provided yet).	
Subsidiary body of the JM	WNT
Expert group	

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

milestones:	
• Kick-off meeting with the lead countries took place in February 2018, followed by a teleconference with the Expert group in April and 2018. • Case studies' proposals were discussed in June 2018. • A face to face meeting took place in March 2019 and agreed on: o the scope and outline of the guidance document; o the assays that should be considered, described/characterised in the guidance document; o how the data produced by the assays should be integrated/used and provide guidance on data interpretation; o the case studies to be included in the guidance. o the need to establish a dedicated subgroup to work on the harmonisation of DNT assessment in zebrafish; • 1st TC of WG on Developing IATA case studies on DNT organized by EFSA (20th May 2019) • The extended outline of the Guidance Document to be discussed during OECD TC (7th June 2019) • A first draft of the chapters (background and part of the guidance not linked to any experimental work) for which volunteers were identified for is expected in September 2019. • The experimental work is expected to be concluded by fall 2019; • Expert Group working on the outline of the Guidance Document in 2020; • Virtual meeting of the Expert Group in March 2020; • Virtual meeting of the Expert Group in March 2021; • Expectation to circulate a first draft of the Guidance Document in Q3 2021 for review.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on DNT

Project 4.125: DRP 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
• In 2017, the lead country will perform an extended validation study of the ToxTracker assay and use that information to draft a DRP. Depending on the validation study and DRP a SPSF for a TG for ToxTracker will be submitted. • Experimental validation work is completed and a report might be submitted to OECD in Q3 or Q4 2021.	
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

• Spring 2018: if all the data supports inclusion in TG 437, Japan and IIVS will submit all the available results; • Japan will share some of the BCOP histopathological slides to IVIS and VITO, Belgium for between laboratory reproducibility and peer review; update on progress 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; • This draft will be discussed by EG and WNT; Japan expects the revised TG 437 to be submitted for approval in April 2023.

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

Project 4.133: Detailed Review Paper 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

• Milestone 1: Compilation and critical assessment of available studies until December 2019;
  o Terminated. MNM were selected based on the conducted literature review and discussed during the first expert workshop in December 2019.
• Milestone 2: A first workshop was organised after work package 1 in December 2019 and a second workshop is planned to discuss recommendations for a future revision of TG 442D and recommendations for validation in July-September 2021;
  o The second expert workshop will be held by the end of 2021.
• Milestone 3: Report on full experimental part. Ranking of selected nanomaterials regarding suitability of use of the test method until September 2021;
  o Charcterization and testing of OECD TG 442D with selected MNM has been finished. OECD TG 442D is technically feasible. The work in regard to in vivo in vitro correlation using existing literature is ongoing.
• Milestone 4: Conclusions on the potential of TG 442D to be used for the testing of manufactured nanomaterials until November 2021;
  o Ongoing work.
• Milestone 5a: Recommendations for a future revision of TG 442D and/or for nanospecific guidance until December 2021;
  o Ongoing work.
• Based on milestones 1 to 5 the Detailed Review Paper (DRP) will be worked out until March 2022.	

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

Project 4.134: Detailed Review Paper on application and interpretation of in vitro immune-toxicity assays and definition of a tiered approach to testing and

assessment	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2019

2020-2021:

- Establish an Ad hoc Expert Group;
- tele-conferences (at least 6) plus face to face meeting(s) to address issues identified after the first commenting round;
- Discuss the regulatory needs in OECD countries as well as scope and outline of a document for integration of in vivo and in vitro methods for immunotoxicity testing;
- Discuss i) which assays are ready-to-use depending on the problem formulation, ii) issues to be addressed upon application to regulation and iii) which assay should be included in the document;
- Discuss how the data produced by the assays should be interpreted/used for a tiered approach. And draft the document;
- Discuss a tiered approach for a testing strategy in DRP;
- The revised version is provided in May, 2021.
- Tele-conferences (at least 6) plus face to face meeting(s) to address issues identified after the second commenting round
- This draft will be discussed by EG and WNT; Japan expects to be submitted for approval in April 2022.

Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Immunotoxicity (to be established)

Project 4.136: Two Defined Approaches for Ocular Irritation Predictions Based on in vitro Bottom-Up Approach Combined with Physico-Chemical Properties.	
Lead: Inclusion in work plan**:** Project status and milestones:	France 2019

2019

- Step 1: Presentation of the proposed Defined Approaches in the first instance, the two Defined Approaches from Cosmetics Europe to the Expert Group in a first webinar, and the related chemical sets; sharing of the two DAs manuscripts with the Expert Group and the WNT;
- Q3-Q4 2019 - Step 2: Discussion with the Expert Group in view of establishing a reference chemicals list;

2020

- Q1 2020 - Step 3: Re-analysis and presentation by Cosmetics Europe of the proposed Defined Approaches using the established reference chemicals list; Presentation of the Physico-chemical parameters input and analysis;
- Q2-Q3 2020 - Step 4: Review of the background supporting document that will incorporate the re-analysis and Expert Group inputs; Re-analysis of the Physico-chemical properties.

• Q4 2020 - Step 5: Re-analysis of the Performance; Presentation of the Confusion matrix. Face-to-face meeting of the Expert Group for discussion and comments to support a consolidated version of the background document; **2021** • Q1 2021: Step 6: Review of the background supporting document (comments and inclusion of the performance using confusion matrix). Initiate drafting of a Test Guideline when the Expert Group peer review is finalised. • Q2 2021: o The draft TG and updated supporting information will be provided to the OECD for circulation to the Eye irritation expert group, with a request to comment on the first draft of the Test Guideline and follow the typical process of Test Guideline development). • Q4 2021: o Depending on the comments received by the Expert group and after this first commenting round, an expert meeting may or may not need to be convened. Face-to-face meeting of the Expert Group for discussion of the substantial comments (and responses) received to support a consolidated draft version 2 of the TG. o A second draft TG would be made available to the WNT for a commenting round. **2022** • In the absence of substantial comments, a third draft TG would be available by February and possibly submitted to the WNT for approval in April 2022. •

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

Project 4.137: The kinetic Direct Peptide Reactivity Assay (kDPRA): An in chemico Method to characterize the Skin Sensitisation Potency of Chemicals	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland/Germany 2019
• Project completed.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitisation

Project 4.138: In Vitro Phototoxicity Test Using the Reconstructed Human Epidermis (RhE) for Identifying Phototoxic Chemicals Upon Exposure to Skin	
Lead: Inclusion in work plan: Project status and milestones:	United States 2019

• Project completed, Performance Standard document will be elaborated to allow the validation of similar methods.	
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**:** Project status and milestones:	Germany/France 2019
Q1 2020: submission of validation datasets for the reconstructed skin Comet assay, for ECVAM review. **Q2 2020**: submission of validation datasets for the reconstructed skin micronucleus test, for ECVAM review. **Q2 2021**: full submission of the test methods to ECVAM for peer-review **Q3 2022**: Drafting of PRP report and submission to OECD	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

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
• 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.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

Project 4.141: Revision of Appendix II in Test Guideline 442C: Amino acid Derivative Reactivity Assay (ADRA) for predicting sensitization potential

Lead: Inclusion in work plan: Project status and milestones:	Japan 2020
• Revision of Performance Standards: Since the three proficiency chemicals mentioned in item 6 are also listed in the Performance Standards, this means that the Performance Standards must also be revised. We plan to submit to the OECD a draft version of a revised Performance Standards that incorporates the above changes in August 2020; • Work to validate the proposed updates to TG 442C to extend the applicability domain conducted in 2020; • Additional testing to validate a new optimal molar concentration approach is planned in Q4 2020 and Q1 2021; • Two out of six proposals included in the SPSF are integrated in the draft TG 442C currently opened for the inclusion of the kDPRA test method (see below), and for WNT approval in April 2021. These proposals have already been discussed by the expert group and should not be impacted by the future ring trial. o the Revision of tolerance range for Reference Control C in case of using 5%DMSO as a solvent and o the inclusion of a positive control substance (Squaric acid diethyl ester), as an alternative to phenylacetaldehyde; • The validation report and draft revised TG will be provided in Q2 2021. • This draft will be discussed by EG and WNT; Japan expects the revised TG 442E to be submitted for approval in April 2022.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitization test methods

Project 4.142: Revision of OECD TG 439 to include a new me-too reconstructed human epidermis test method – KeraSkin™ skin irritation test	
Lead: Inclusion in work plan: Project status and milestones:	Korea 2020
• Project completed.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

Project 4.143: SkinEthic™ Human Corneal Epithelium (HCE) Eye Irritation Time to Toxicity Test (TTL-TTS) or identifying chemicals not requiring a classification for eye irritation and serious eye damage in TG 492	
Lead: Inclusion in work plan: Project status and milestones:	France 2020
2020: o The SkinEthic™ HCE TTL-TTS report will be finalised and will be sent as a whole package for independent peer-review. **2021**	

- Q1 2021:
  - Presentation of the proposed SkinEthic™ HCE Time-to-Toxicity, its relevance and reliability on both TTL and TTS and the related chemical sets, from the test submitter to the Expert Group on skin/eye corrosion/irritation in a first webinar.
  - The peer review panel will provide the scientific opinion and then issue its final report on the test method in Q3.
- Q2 2021:
  - The draft TG and supporting information (i.e. validation study report, and peer review panel report) will be provided to the OECD for circulation to the Eye irritation expert group, with a request to comment on the first draft of the revised version of Test Guideline 492.
  - Commenting by WNT and Expert Group by September-October.
- Q4 2021:
  - Depending on the comments received by the Expert group and after this first commenting round, an expert meeting may or may not need to be convened. Face-to-face meeting of the Expert Group for discussion of the substantial comments received to support a consolidated draft version 2 of the TG
  - A second draft TG would be made available to the WNT and the Expert Group for a commenting round.
- Q2 2022:
  - In the absence of substantial comments, a third draft TG would be available by February and possibly submitted to the WNT for approval in April 2022.

Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

Project 4.144: Update of TG 494 Vitrigel-Eye Irritancy Test Method for Identifying Chemicals not requiring Classification and Labelling for Eye Irritation or Serious Eye Damage

Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2020
• Project completed.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

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
• First draft IATA document available by September 2021; • Possible Expert Meeting in November 2021; • Commenting by WNT and Expert Group by February 2022; • Second draft IATA document available by June 2022; • Commenting by WNT and Expert Group by September 2022;	

• Possible Expert Meeting in November 2022; • Third draft IATA document available by January 2023; • Approval by WNT April 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:	United Kingdom/Netherlands 2020
• 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); • 2023: OECD workshop on the draft TG (organised in collaboration with the OECD secretariat); • June/September 2024: Draft TG submitted for comments to WNT (second milestone); • September 2024 – January 2025: WNT commenting rounds, revision of drafts based on comments (2 commenting rounds are envisaged) • April 2025: 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
• 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: F2F Presentation of the EURION cluster at the EDTA -AG meeting 2020. • Various chapters underway. GER (BfR) are close to completion of their draft contribution to to the DRP. May be able to present at EDTA May 2021.	
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 Lu assay (OECD TG442E) to improve its performance	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2021
• Revised TG442E will be submitted by Japan 2nd Q in 2021; • This draft will be discussed by EG and WNT; Japan expects the revised TG 442E to be submitted for approval in April 2022.	
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
• The IL-2 Luc assay has undergone independent peer review in 2019 and the peer review finished in June 2020. Japan submitted the validation report and peer review report to the OECD as attachments of the SPSF. • Prior to the development of a Test Guideline, Japan developed Detailed Review Paper (DRP) for in vitro immunotoxicity testing (project 4.134). Therefore, Japan wish to discuss the draft TG on IL-2 Luc assay as well as DRP with the expert group. • In 2021-2022, the DRP and TG on in vitro immunotoxicity will be shared with the OECD Expert Group for review and comments.	
Subsidiary body of the JM	WNT
Expert group	Expert Grooup on in vitro methods for immunotoxicity testing

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 WG Biocides 2007, revised in 2010
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 5.16: Guidance Document on Laboratory Assays for Evaluating the Efficacy of Biocides against Bed Bugs	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2015
• Germany replaces United States as lead country for this project. • May 2018 – 1st for WGB revision; • Q2 2021 2021 – 2nd WPB revision; • Q3 2021 – WNT/WPB commenting; • 2021/2022 WNT/WPB written procedure approval.	
Subsidiary body of the JM	WNT & WPB
Expert group	(no expert group active on this project)
Project 5.17: Guidance Documents on Testing the Efficacy of Baits against Tropical Ants	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2017
• March – May 2018 Laboratory testing • May 2018 – Jun 2018 Evaluation of Test results	

• 2019 –1st WGB revision; • Q2 2021 – 2nd WPB revision; • Q3 2021 – WNT/WPB commenting • 2021/2022 WNT/WPB written approval.	
Subsidiary body of the JM	WNT & WPB
Expert group	(no expert group active on this project)

ANNEX 1

PROJECTS THAT ARE NO LONGER SUPPORTED

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
• Finalisation of the list in Q4 2018; • Preparation of report to share with VMG-NA 2019/20; • Report will be annexed to project 4.147 in 2021.	
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
• 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 4.122: Guidance Document on hepatic clearance test methods	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2017
• An *ad hoc* 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 *ad hoc* 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 4.132: 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
• 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