

Work plan for the Test Guidelines Programme (TGP)

As of June 2022

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 Group

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

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
<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 An Expert Group has been formed under the Working Group on Biocides; the proposed draft Guidance Document will be discussed via conference calls.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 A draft Guidance Document is under development under auspices of the WGB but currently on hold until sufficient resources are available from the Secretariat to resume the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
<ul style="list-style-type: none"> Project completed, TG published on 30 June 2022. 	
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
<ul style="list-style-type: none"> Project completed, TG published on 30 June 2022. 	
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
<ul style="list-style-type: none"> • 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. • 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 1st Quarter of 2023. 	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials

Project 1.6: 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. • 1st Quarter 2020 draft report to be submitted to the Expert Group for commenting. • 2nd 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 1st 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"> • 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). • 2020: Interested laboratories have been identified and comments have been received on the project and protocols. The optimization has been initiated, however, due to Covid-19 the laboratory optimisation work and distribution of slides, supporting materials and samples had to be put on hold. • 2022: first draft TG submitted to the EG for review/comments by February; • A revised version will be prepared taking into account comment made and a revised version will be circulated together with the draft ILC results during the 3rd quarter of 2022. • The TG is expected to be submitted for approval in 2023. 	
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>2019</p> <ul style="list-style-type: none"> • 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. <p>Due to the COVID-19 Pandemic, significant delays were encountered and early-on proposed dates have been postponed.</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) • 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; TCs 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. 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; Next TC of the Expert Group in October 2022. 	
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) Potential workshop on draft GD (organised in collaboration with the OECD secretariat and potentially supported by the NanoHarmony project) with anticipated involvement to include project Ad Hoc Expert Group and relevant WPMN and WNT Expert Groups (Nov) <p>2023</p> <ul style="list-style-type: none"> 1st WNT commenting round on draft GD (Q2 2023) 2nd WNT commenting round on revised draft GD (Q3/Q4 2023) <p>2024</p> <ul style="list-style-type: none"> 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) • Mid-2022: first draft TG and draft validation report for EG commenting; • Earliest adoption of TG by OECD WNT (2024). 	
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
<p>Part 1: Update of OECD Guidance Document 23 is completed. (This part was co-lead by the United States)</p> <p>Part 2: Detailed Review Paper of use of controls in aquatic ecotoxicity tests</p> <ul style="list-style-type: none"> • 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. 	

<ul style="list-style-type: none"> • 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 • 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
<ul style="list-style-type: none"> • 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 2022. • 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 2022. • Revised draft guidance document and validation reports will be delivered by the end of 2022 for WNT commenting. • Final draft guidance document will be submitted to the WNT in 2023. 	
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 <i>Daphnia magna</i>	
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. 	

<ul style="list-style-type: none"> 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
<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 2.61: New TG RADAR assay – Rapid Androgen Disruption Adverse Outcome Reporter Assay	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom/France 2017
<ul style="list-style-type: none"> Project completed, TG published on 30 June 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, <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 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. This is on-going and next steps will be determined based on success of training; Work in progress. 	

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
<p>2019-2022</p> <ul style="list-style-type: none"> Establishment of an ad hoc expert group in charge of the pre-validations and validations to be performed: Selection of promising endpoints sensitive to thyroid hormone system disruption (THSD), and validation of these in pre-validation tests including OECD TG 236, Fish Embryo Toxicity (FET) Test, TG 210, Fish Early life-stage Toxicity Test (FELS) and TG 234 the Fish Sexual Development Test (FSDT) <p>2022:</p> <ul style="list-style-type: none"> February 2022: submission of a draft Detailed Review Paper (DRP) on “the thyroid hormone system in fish and identification of potential thyroid hormone system related endpoints for inclusion in existing OECD fish test guidelines” for review at VMG-Eco and EDTA AG. <p>2022-2024</p> <ul style="list-style-type: none"> 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 THSD endpoints Inclusion of suitable THSD endpoints in relevant fish TGs including OECD TG 234, 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 (*Osmia spp.*)

Lead: Inclusion in work plan: Project status and milestones:	Switzerland 2019
<p>Milestones</p> <ol style="list-style-type: none"> First drafts of the guideline and the validation report will be ready for Honey Bee Expert Group commenting in autumn 2022/Spring 2023. Expert group meeting/Teleconference to discuss the validation reports and draft TG in Winter 2022/Spring 2023 Revised validation reports and TG (based on comments) for a 1st commenting by the WNT in spring/summer 2023. 	

4. 2 nd WNT commenting round of the final validation report and draft TG autumn 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:	France/ United Kingdom/ Japan
Inclusion in work plan:	2020
Project status and milestones:	
<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. 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:	Japan
Inclusion in work plan:	2021
Project status and milestones:	
<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 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

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 (Apr 2025) 	
Subsidiary body of the CBC	WNT
Expert group	Expert Group Sediment-Water Toxicity Tests

Project 2.69: Revision of TG 28-219 sediment–water Chironomus test using spiked-sediment or spiked-water	
Lead: Inclusion in work plan: Project status and milestones:	Germany/Switzerland 2022
<ul style="list-style-type: none"> • Nomination of experts to participate in the ad hoc Expert Group (May 2022) • Ad hoc Expert Group to review draft revised TGs 218 and 219 (June/July 2022) • Circulation of draft revised TGs 218 and 219 version #1 for 1st WNT commenting round (Sept. 2022) • Circulation of draft revised TGs 218 and 219 version #2 for 2nd WNT commenting round (Dec./Jan. 2022/23) • Earliest WNT adoption of revised TGs 218 and 219 (April 2023) 	
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 (May/June 2022), all communication will be done in written and via virtual conferences • Draft revised GD 75 for WNT commenting (second half of 2022) • Earliest WNT adoption of revised GD 75 April 2023. 	
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"> September 2022 – February 2023: Drafting of technical annexes to Guidance Document on Aquatic Toxicity Testing of Nanomaterials. Third workshop within the framework of NanoHarmony project February – May 2023: Submission of annexes to the WPMN/WNT Expert group on ecotoxicity and environmental fate testing of MNs for commenting. June – August 2023. Final review of the annexes and submission to WNT for the first public commenting round. November 2023 – January 2024: Second public commenting round. February 2024: Final review of the annexes and submission to WNT for adoption (WNT 36). 	
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"> After April 2022: the updates and revisions are further discussed between the leading countries (US and Japan) and member countries and organizations in web meeting and electronic discussion group. At least one commenting round is scheduled before VMG-eco 2022. The draft revised version of TG240 will be submitted to VMG-eco in 2022 for further discussion and commenting round. The final draft of the revised TG240 will be submitted to WNT 2023 for approval. 	
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:	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): summer 2023 • WNT commenting: autumn/winter 2023/Spring 2024 • Delays are due to Covid-19. 	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on ecotoxicity and environmental fate testing

Project 3.12: 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.
- The experimental work has been finished (early 2022).

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 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 currently leading a Scoping review to consider how to trigger or waiver the TG 305 bioaccumulation in fish test for manufactured nanomaterials. The project is being developed within the WPMN. A draft is being prepared for discussion at the WPMN in June 2022.

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; • Expert group and WNT commenting rounds, TG finalization (Q2 -Q4 2022); • • Submission of TG for WNT approval earliest in 2023. 	
Subsidiary body of the JM	WNT
Expert group	<i>Ad hoc</i> 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 	

<p>environmental monitoring data with focus on transformation-relevant species. Framing the concept of NM transformation pathways in the environment.</p> <ul style="list-style-type: none"> • 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. <p>September 2020:</p> <ul style="list-style-type: none"> • 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. prioritization) <p>Sept. 2020 – Nov. 2021: (eventually also later, depending on COVID-19 situation and lab closures)</p> <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. <p>Dec 2021-May 2022: (eventually also later, depending on COVID-19 situation and lab closures)</p> <ul style="list-style-type: none"> • 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 <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"> • 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: <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, some participants had to postpone their experiments. Consequently, the experimental phase, which was planned originally to end in December 2020, was extended until end of February 2021; • Meeting for discussion of the ring test results was held in March 2021;; • Development of draft TG: Q2 2021; • Progress report at WMG-Eco 16 in October 2021/Q1 2022; • Expert group and WNT commenting rounds, TG finalization (Q2–Q4 2022); • Earliest possible adoption of TG by OECD WNT in 2023. 	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on <i>Hyalella azteca</i> bioconcentration test

Project 3.18: Anaerobic Transformation of Chemicals in Liquid Manure	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2020
<ul style="list-style-type: none"> Project completed; the TG will be published on 30 June 2022. 	
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
<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. Draft new Test Guideline for peer review based on existing SOP (April 2023). 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 4.78: Updated TG 488, Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays	
Lead: Inclusion in work plan: Project status and milestones:	Canada 2013
<ul style="list-style-type: none"> Project completed; updated TG 488 will be published on 30 June 2022. 	
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 <i>in vivo</i> Gene Mutation Assay Promoting the 3Rs Principles	
Lead: Inclusion in work plan: Project status and milestones:	United States 2015
<ul style="list-style-type: none"> Project completed: TG will be published on 30 June 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
<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 4.95: Guidance Document on the Adaptation of <i>In Vitro</i> Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom and Germany (previously EC until 2021) 2015
<ul style="list-style-type: none"> Study report completed and will be published in August 2022. 	
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
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> GARDskin approved and will be published in TG 442E on 30 June 2022; Work on-going to generate additional data on GARDpotency, according to ESAC recommendations; Peer-review of the additional data and report for GARDpotency will be organized in Q4 2022 at the earliest. 	
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 	

<ul style="list-style-type: none"> • 2018: revised full submission to ECVAM; • Since 2019: Addressing questions from ECVAM evaluation; • In order to proceed with the project, predictive capacity of the SENS-IS method needs to be recalculated based on the LLNA/human database and the updated reference chemicals list, which are awaited from project 4.116 (Defined Approach(es) for Skin Sensitization); • Peer review organised in Q3 2022; • It is expected that expert group meeting will then take place in Q4 2022 • It is expected that WNT and public comments rounds will then take place in 2023. • Earliest possible adoption at the WNT meeting in 2024. 	
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
<ul style="list-style-type: none"> • Project completed; DRP will be published in August 2022. 	
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
<ul style="list-style-type: none"> • Project completed; the updated Guidance Notes 156 will be published in August 2022. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Dermal Absorption or Expert Group on skin irritation.

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
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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 4.123: 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; 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 in Q3 2022 and WNT; Japan expects it to be submitted for approval in April 2024. 	
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 milestones:	EC (EFSA, JRC)/US/DK 2017
<ul style="list-style-type: none"> 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. 	

<ul style="list-style-type: none"> • A face to face meeting took place in March 2019 and agreed on: <ul style="list-style-type: none"> ○ the scope and outline of the guidance document; ○ the assays that should be considered, described/characterised in the guidance document; ○ how the data produced by the assays should be integrated/used and provide guidance on data interpretation; ○ the case studies to be included in the guidance. ○ 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; • 2nd Virtual meeting of the Expert Group in March 2021; • The case studies were reviewed by the IATA case study project members during the 2021-2022 review cycle; • 3rd Virtual meeting of the Expert Group in March 2022; • First WNT commenting round in May-June 2022; comments will be compiled and discussed within the Expert Group. 	
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
<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 are currently evaluated and a report is being prepared; • Q2 -2022 an expert meeting to discuss the results and get input on further steps; • Q3/4 refinement/finalisation of the work in line with input from the expert group. 	
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; 	

<ul style="list-style-type: none"> • 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 2022. 	
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"> • Milestone 1: Compilation and critical assessment of available studies until December 2019; <ul style="list-style-type: none"> ○ 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; <ul style="list-style-type: none"> ○ 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; <ul style="list-style-type: none"> ○ Characterization and testing of OECD TG 442D (KeratinoSens™) with selected MNM has been finished. OECD TG 442D (KeratinoSens™) is technically feasible. • Milestone 4: Conclusions on the potential of TG 442D to be used for the testing of manufactured nanomaterials until November 2021; <ul style="list-style-type: none"> ○ The <i>in vitro in vivo</i> correlation exercise could only be performed in general terms (yes/no) due to the scarcity of data and the very limited and diverse information obtained from the literature. This did not allow to produce conclusions on predictability of the assay. • Milestone 5a: Recommendations for a future revision of TG 442D and/or for nanospecific guidance until December 2021; <ul style="list-style-type: none"> ○ The recommendations included viability assessment of the cells, dispersion of nanomaterials, and use of DMSO during exposure of nanomaterials to the cell system, testing of leachates of nanomaterials, exposure time and endotoxin measurements of nanomaterials. • Based on milestones 1 to 5 a Study report was drafted and sent to OECD by the end of May 2022 for the subsequent written commenting rounds. • Written commenting rounds: <ul style="list-style-type: none"> ○ EG Skin Sens: commenting period was in June/July 2022 	

<ul style="list-style-type: none"> ○ Next steps: 1. commenting on the revised draft report by WNT (Sept. 22). A possible 2. commenting round is planned for Dec. 22. ● Study report will be submitted in due time for approval by the WNT in April 2023. 	
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
<ul style="list-style-type: none"> ● Project completed; DRP will be published in August 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
<ul style="list-style-type: none"> ● Project completed; TG will be published on 30 June 2022. 	
Subsidiary body of the JM	WNT
Expert group	Expert group on eye irritation

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
<ul style="list-style-type: none"> ● Project completed, Performance Standard document will be published in August 2022. 	
Subsidiary body of the JM	WNT
Expert group	Expert group on eye irritation

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>Q1 2023: Drafting of PRP report and submission to OECD.</p>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

Project 4.141: 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
<ul style="list-style-type: none"> • Project completed; updated TG 442C will be published on 30 June 2022. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitization 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
<ul style="list-style-type: none"> • Project completed; TG will be published on 30 June 2022. 	
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
<ul style="list-style-type: none"> • First draft IATA document available by September 2021; • Expert Meeting in November 2021; 	

<ul style="list-style-type: none"> • 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:	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); • Progress slower than expected due to impact of COVID on planned experimental studies to provide additional experimental data to support project but hoping to catch up.2023: OECD workshop on the draft TG (organised in collaboration with the OECD secretariat); • 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; • Joint Expert Group meeting held on 7 Dec 2021 with draft structure of TG presented; 	
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; 	

<ul style="list-style-type: none"> • 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"> • Draft revised TG442E was submitted by Japan 2nd Q in 2021; • This draft will be discussed by EG and WNT; Japan expects the draft revised TG 442E to be submitted for approval in April 2023. 	
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"> • The IL-2 Luc assay has undergone an independent peer review, started in 2019 and 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; DRP approved in April 2022; • Draft TG was circulated to the Expert group for a first commenting round in April 2022; comments will be addressed by the EG and next steps will depend on issues raised that need resolution. 	
Subsidiary body of the JM	WNT

Expert group	Expert Group on in vitro methods for immunotoxicity testing
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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) • Late 2022: Submission of the chemical augmentation report to 2 laboratories minimum 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. • 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"> • The Validation Management Team was comprised by members of the ICCVAM Ocular and Dermal Expert Group, which includes representatives from five US regulatory and research agencies. Our expectation is that, coupled with the peer reviewed publications already available in the open literature, the OECD Expert Group would provide additional peer review of the results summarized herein. • Updates to the test guideline will be drafted by the US in advance of the Fall 2022 expert group meeting such that it can be considered by the EG and any comments addressed in time for review and concurrence prior to the 2023 WNT meeting. 	
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 2022 • Submit the supporting document for comments – Q3 2022 • Adapt data interpretation procedure (as needed) and revision of the supporting document – Q3 2022 • Revision of the supporting document and draft GL for comments– Q4 2022 • Final GL and supporting documents – Q2 2023. 	
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 2022 • Generate additional in chemico/in vitro data (as needed) – Q3 2022 • Adapt data interpretation procedure (as needed) – Q4 2022 • Apply assessment framework to DAs with “me-too” information sources – Q1 2023 • Draft additions to GL 497 – Q2 2023. 	
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. – Q1 2023 • Incorporate DASS EG feedback on model output – Q1 2023 • Develop a publicly available and user-friendly version of the model (to be housed in the Integrated Chemical Environment) – Q2 2023 	

- Draft addition to GL 497 for review by the WNT – Q3 2023.

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
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Phase 1 (feasibility study):

- The validation study report will be finalized in early of May 2022. The summary of the validation study is attached, please refer to it for the results (Attachment No.1).
- Designation of an international ad hoc expert group (by Japan) for the peer review was completed, according to the recommendations of the partners of the ICATM.
- An international peer review will start in June 2022 and will end in Nov. 2022.
- WNT check point: written update/consultation to the WNT

Phase 2 (TG development):

- The draft TG will be made by Nov. 2022.
- The validation report, peer review report, and draft TG will be submitted to the OECD by the end of this year.
- 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 early of 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

- 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 2022 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 <p>May 2023 - December 2023</p> <ul style="list-style-type: none"> – 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 <p>February 2024</p> <ul style="list-style-type: none"> – 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
<ul style="list-style-type: none"> • Technical work, phase 1 (transferability): August 2021-March 2022 • Technical work phase 2: April 2022- August 2022 • Peer-review by internal VMG and PEPPER' scientific council August-September 2022 • Fall 2022: 1st round of comments within expert group on validation report and draft TG (discussions by teleconferences, and written exchanges), pending acceptance of the project by WNT in April 2022, and no technical issue during phase 2 • Q4 2022: 1st round of comment from WNT on validation report, and draft TG • Q12023: 2nd round of comment from WNT on validation report, and draft TG • Submission draft TG to WNT, 2023. 	
Subsidiary body of the JM	WNT

Expert group	Expert Group on in vitro ED methods
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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: March 2022- June 2022 • Peer-review by internal VMG and PEPPER' scientific council Summer 2022 • Summer/Fall 2022: 1st round of comments from expert group on validation report and draft TG (discussions by teleconferences, and written exchanges), pending acceptance of the project by WNT in April 2022 and no major issue in phase 2. • Q4 2022: 1st round of comment from WNT on validation report, and draft TG • Q12023: 2nd round of comment from WNT on validation report, and draft TG • Submission draft TG to WNT, 2023. 	
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: March 2022-May 2022 • Peer-review by internal VMG and PEPPER' scientific council: June 2022 • Summer 2022: 1st round of comments within expert group on validation report and draft TG (discussions by teleconferences, and written exchanges), pending acceptance of the project by WNT in April 2022, and no major issue during phase 2 • Autumn 2022: 1st round of comment from WNT on validation report, and draft TG • Winter 2022/2023: 2nd round of comment from WNT on validation report, and draft TG • Submission draft TG to WNT, 2023. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on in vitro ED methods

Project 4.162: Feasibility Study for Mammary Gland Whole-Mount	
Lead: Inclusion in work plan: Project status and milestones:	Denmark 2022
2022: <ul style="list-style-type: none"> • January: Received comments from USA NCall countries – • February: Amended the SPSF based on comments response to comments and 	

<p>submitted Best Practices paper for publication at journal –</p> <ul style="list-style-type: none"> • April: WNT inclusion on the workplan – • May-June-Aug-1. Part of September: Convene a kickoffkick-off meeting of the EG. Scientific papers on public health importance, technical guidance, and Best Practice methods, published in first quarter of 2022, are shared in the EG and a draft DRP is initiated based on published documents – • Q3-4: Teleconferences with EG (suggest one virtual meetings as needed each month). Discuss existing data relevant to timing, logistics of MG collection and evaluation from rats. The DRP and data reviews of WM vs pathology outcomes 5 and epithelial counts of longitudinal vs x-sectional sections will be used in the feasibility assessment. 	
2023:	<ul style="list-style-type: none"> • Q1: Draft the DRP if possible in parallel with feasibility report – • Q2: WNT NCs and EG comment on feasibility report and DRP (e.g., Teleconference with EG when needed) – • Q3-4: Create final version of DRP and feasibility report and begin development of new SPSF for WM integration if suggested. That SPSF would be submitted in Nov 2023.
2024:	<ul style="list-style-type: none"> • Q1: Final feasibility report and DRP would be submitted to WNT. Work on new SPSF would begin – • Q2: 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 Mar. 2023. <ul style="list-style-type: none"> - WNT check point: update and consultation of the WNT. <p>Phase 2 (TG development)</p> <ul style="list-style-type: none"> • The draft TG will be made by the end of Mar. 2023. • The validation report, peer review report, and draft TG will be submitted to the OECD by April 2023. • 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 June 2023. 	
Subsidiary body of the JM	WNT
Expert group	Expert Group on reproductive toxicity studies

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 5.16: 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 WP Biocides 2015
<ul style="list-style-type: none"> • Project completed, the guidance document will be published in Q4 2022.. 	
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 WP Biocides 2017
<ul style="list-style-type: none"> • Project completed, the guidance document will be published in Q4 2022.. 	
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 4.77: 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; • 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
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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 4.122: 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 4.132: 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) 	

<ul style="list-style-type: none"> • 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