

## **Work plan for the Test Guidelines Programme (TGP)**

**June 2020**

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**

<b>Project 1.1: New Guidance Document for flammability testing of Plant Protection and Biocidal Products</b>	
Lead: Inclusion in work plan: Project Status and milestones:	WG Biocides 2017
<ul style="list-style-type: none"> <li>• An Expert Working Group has been formed through the Working Group on Biocides, the proposed Guidance Document will be discussed via conference calls;</li> <li>• A draft Guidance Document was circulated for a first review in Q4 2018</li> <li>• Approval by the WGB/WNT foreseen in 2020.</li> </ul>	
Subsidiary body of the JM	TFB/WNT
Expert group	Chemistry Expert Working Group/TFB

<b>Project 1.2: Guidance Document on Bridging and Waiving of Physical/Chemistry studies of Plant Protection and Biocidal Products</b>	
Lead: Inclusion in work plan: Project Status and milestones:	WG Biocides 2018
<ul style="list-style-type: none"> <li>• An Expert Group has been formed under the Working Group on Biocides; the proposed draft Guidance Document will be discussed via conference calls.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.</li> <li>• A draft Guidance Document is under development under auspices of the WGB but currently on hold until finalisation of project 1.1.</li> </ul>	
Subsidiary bodies of the JM	WGP – WGB – WNT- WPHA
Expert group	Expert group on p-chem properties under the WGB

<b>Project 1.3: New TG on Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials</b>	
Lead: Inclusion in work plan: Project Status and milestones:	European Commission - JRC 2018
<ul style="list-style-type: none"> <li>• Establishment of an Expert Group on Physical-chemical properties of nanomaterials April 2019;</li> <li>• 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</li> <li>• 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.</li> </ul>	

<ul style="list-style-type: none"> <li>The Covid-19 crisis is delaying the laboratory work, however testing and evaluation of results should be available in September..</li> </ul>	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials

**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"> <li>February 2018: Establishment of an international advisory group on particle size and size distribution of nanomaterials ;</li> <li>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.);</li> <li>March/April 2019: Start performance of the round robin test;</li> <li>April 2019: Establishment of an WNT/WPMN Joint Expert Group on physical chemical properties of nanomaterials;</li> <li>June -August 2019: Round robin test;</li> <li>September 2019 – March 2020: Delivery of data from round robin testing and: Processing processing of results, development of a validation report ;</li> <li>December 2019: Meeting of the joint WNT/WPMN Expert Group (OECD Boulogne) .</li> <li>December 2019-January 2020: 1st round of comments from the Expert.</li> <li>A revised draft TG together with the validation report will be made available mid-2020 for WNT commenting. Some delays might need to be envisaged due to Covid-19</li> </ul>	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on Physical-chemical properties of nanomaterials

**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"> <li>May 2019: Invitations distributed to verify already registered and contributing member countries and laboratories that will contribute to the experimental work.</li> <li>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.</li> <li>August 2019: Launch of the intra-laboratory comparison testing.</li> <li>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)</li> </ul>	

June 2020

<p>SOPs and preliminary results; and iii) defining the first common dissolution testing criteria for the GD.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• The GD is expected to be submitted for approval to the WNT in 2022.</li> </ul>	
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"> <li>• 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.</li> <li>• 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.</li> <li>• 1 st Quarter 2020 draft report to be submitted to the Expert Group for commenting.</li> <li>• 2 nd Quarter 2020: Test materials for intra- and inter-laboratory testing distributed to the methods laboratories.</li> </ul>	
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"> <li>• Establishment of an Ad Hoc Experts' Group. Meetings mostly via teleconference and electronic information exchange. 2-3 face-to-face meetings are also envisaged.</li> <li>• First Draft TG based on the scientific literature referenced below.</li> <li>• Iterative discussions on the first and subsequent draft versions of the TG by the Ad-Hoc Experts' Group.</li> <li>• 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.</li> <li>• 2019: Expert group established and meeting held including experimental demonstration of testing.</li> <li>• 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</li> </ul>	

the laboratory optimisation work and distribution of slides, supporting materials and samples had to be put on hold.	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials

<b>Project 1.8: TG on Determination of the Dustiness of Manufactured Nanomaterials</b>	
Lead: Inclusion in work plan: Project Status and milestones:	Denmark/France 2019
<p><b>2019</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Development of the first draft TG; iterative discussions on the draft TG by the Ad-Hoc Experts Group.</li> <li>• September 2019: the Secretariat circulated a call an inter-laboratory comparison test to assess the robustness and comparability of dustiness test methods.</li> <li>• 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.</li> </ul> <p><b>2020</b></p> <ul style="list-style-type: none"> <li>• Validation study; review of results of the validation study by the Ad-Hoc Experts' Group Q3-Q4 2020.</li> <li>• Identification of further testing needs and final evaluation of results Q1-Q2 2021.</li> <li>• Development of the first draft GD; iterative discussions by the Ad_Hoc Experts' Group Q2 – Q3 2021.</li> <li>• Final version of the TG will be delivered to Expert group, and WNT for commenting (2022). Possible adoption of the TG by WNT: April 2023.</li> <li>• Final version of the GD will be delivered to Expert group and WNT for commenting. Possible adoption of the GD by WNT: April 2024.</li> </ul>	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group on physical-chemical properties of nanomaterials

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

<b>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)</b>	
Lead: Inclusion in work plan: Project status and milestones:	France 2013
<ul style="list-style-type: none"> <li>• Draft protocol reviewed by the Fish Drafting Group and VMG-eco in 2013; proposed time schedule for the validation study agreed during VMG-eco teleconference (2013);</li> <li>• Preliminary data analysis for Phase 1 of the validation; presentation and discussion at VMG-eco meeting in December 2014;</li> <li>• France submitted a phase 1 validation report in 2017 for discussion at VMG-Eco and presented the phase 2 of the validation study;</li> <li>• The draft version of the TG was sent to experts in July and the report of the validation report (phase 2) at the end of September. These two documents were discussed at the VMG-Eco in Q3 2018; a draft TG and validation report was circulated to the WNT for a 1<sup>st</sup> commenting round in Dec. 2018.</li> <li>• VMG-Eco supported to forward the draft TG for the EASZY for the first WNT commenting round which took place in December 2018 – January 2019.</li> <li>• The lead country will evaluate those comments in the course of 2019-2020 and amend the draft TG accordingly. An updated version of the TG is intended to be circulated in 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco
<b>Project 2.47: New TG on Determination of Effects on Earthworms in Field Studies</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2013
<ul style="list-style-type: none"> <li>• Establishment of an ad hoc Expert Group nominated by WNT in April 2013.</li> <li>• 2017-2018: validation of test design in pilot study;</li> <li>• March 2019: Meeting of extended project group at Umweltbundesamt (Dessau, Germany)</li> <li>• Q3 2020: OECD expert group commenting of draft TG and validation report</li> <li>• End of 2020/beginning of 2021: OECD Expert Group meeting planned, if needed;</li> <li>• 2021: WNT commenting round;</li> <li>• 2022: Submission of draft TG for WNT approval.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on earthworm toxicity testing
<b>Project 2.51: Guidance Document on Aquatic (and Sediment) Toxicity Testing of Nanomaterials</b>	
Lead: Inclusion in work plan: Project status and milestones:	Canada, United States 2014
<ul style="list-style-type: none"> <li>• Project completed; Guidance Document will be published mid-2020.</li> </ul>	

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

<b>Project 2.54: Guidance Document on IATA for Fish Acute Toxicity Testing</b>	
Lead: Inclusion in work plan: Project status and milestones:	Austria/ICAPO 2015
<ul style="list-style-type: none"> <li>• 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;</li> <li>• New scientific data <b>were published</b> in 2018 and 2019, <b>however, further data to support the IATA development will be generated during 2020-2022</b>. These new data will be integrated into the <b>draft acute fish toxicity IATA guidance</b> document for circulation and discussion by VMG-Eco experts;;</li> <li>• Finalization of the project at WNT level is envisaged by the WNT meeting not before April 2022.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

<b>Project 2.55: Use and analysis of control fish in toxicity studies</b>	
Lead: Inclusion in work plan: Project status and milestones:	European Commission/ICAPO 2015
<p><b>Part 1: Update of OECD Guidance Document 23 is completed.</b> (This part was co-lead by the United States)</p> <p><b>Part 2: Detailed Review Paper of use of controls in aquatic ecotoxicity tests</b></p> <ul style="list-style-type: none"> <li>• June 2015: Project Group established and preliminary discussions during kick-off TC in July 2015</li> <li>• May 2015 - February 2016: Discussion of templates for data analysis with statistician.</li> <li>• October 2015: Presentation of data analysis to VMG-Eco/Fish Drafting Group (OECD TG 203 and TG 212)</li> <li>• Since January 2016: Data collection (OECD TG 210).</li> <li>• January 2017 – April 2018: On hold whilst completing update of GD 23.</li> <li>• May 2019: Communication with statistician regarding publication of TG 203 and TG 212 data simulations and statistical simulations of available TG 210 data.</li> <li>• April – October 2020: Statistical analyses and simulations of the effect of control choice on statistical power and the calculated treatment effects in TG 210 studies.</li> <li>• October 2020: Discussion with the VMG-Eco</li> <li>• 2020-2021: Drafting of a Detailed Review Paper and development of a proof-of-concept describing what is required before a single control can be used in aquatic ecotoxicity tests.</li> <li>• 2021: WNT commenting rounds of DRP</li> <li>2022: WNT approval</li> <li>• .</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

<b>Project 2.57: Guidance Document on Juvenile Medaka Anti-androgen Screening Assay</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2016
<ul style="list-style-type: none"> <li>• A ring test including an inter-laboratory validation will be conducted in 2016-2019.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• Revised draft guidance document and validation reports will be delivered by the end of 2020/ the beginning of 2022 for WNT commenting.</li> <li>• Final draft guidance document will be submitted to the WNT in 2022.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco
<b>Project 2.58: New Test Guideline on a Short-term Juvenile Hormone Activity Screening Assay using <i>Daphnia magna</i></b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2016
<ul style="list-style-type: none"> <li>• Inter-laboratory validation was conducted in 2018-2019.</li> <li>• 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.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco/Invertebrate testing EG
<b>Project 2.59: New Test Guideline on Zebrafish Extended One Generation Reproduction Test (ZEOGRT)</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2016
<ul style="list-style-type: none"> <li>• 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.</li> <li>• Draft protocol for the ZEOGRT assay was submitted and discussed at the October 2018 VMG-Eco meeting.</li> <li>• 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 1 in Q2/Q3 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco



<b>Project 2.60: Test Guideline: Homing flight test on honeybee (<i>Apis mellifera</i> L.) after single exposure to sublethal doses</b>	
Lead: Inclusion in work plan: Project status and milestones:	France 2016
<ul style="list-style-type: none"> <li>• A last ring test was performed in summer 2019;</li> <li>• Final meeting with ring test participants: 28-29 January 2020;</li> <li>• The reports gathering the results of the different steps of the validation study will be circulated by end of February 2020 (1<sup>st</sup> report: ring tests 2016-2017; 2<sup>nd</sup> report: ring tests 2018-2019);</li> <li>• The 1<sup>st</sup> draft TG and supporting validation reports were circulated in May 2020 for a first WNT commenting round;</li> <li>• Possible meeting of the Expert Group in 2020 (virtual or F2F).</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on honeybee/bumblebee toxicity testing

<b>Project 2.61: New TG RADAR assay – Rapid Androgen Disruption Adverse Outcome Reporter Assay</b>	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom/France 2017
<ul style="list-style-type: none"> <li>• Q2 2018: availability of a written protocol;</li> <li>• Q3 2018 – Q2 2020: validation exercise in progress <ul style="list-style-type: none"> <li>- CEFAS (UK): Finished: data for the 3 pro-androgenic, 4 anti-androgenic and 3 inert chemicals constituting the core list.</li> <li>- WatchFrog (France): Data available for all 10 core list chemicals, experiments in progress for the 6 additional chemicals.</li> <li>- FIWI (Switzerland): All chemicals completed.</li> <li>- Fraunhofer (Germany): Completing core list: 7/10 chemicals completed, end of experimental phase expected end of Q2 2020.</li> <li>- Idea Consulting (Japan): Completing core list: Experiments 90% complete .</li> </ul> </li> <li>• Q3 2020: Completion of an integrated summary report that synthesises the data from all supporting studies;</li> <li>• 2020-2021: Addition of analytical chemistry results to integrated summary report.</li> <li>• 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;</li> <li>• Draft TG for approval at the WNT in April 2022.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

<b>Project 2.62: New TG on Growth Inhibition Test for the Rooted, Emergent Aquatic Macrophyte, <i>Glyceria maxima</i></b>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands/United Kingdom 2019

June 2020

<ul style="list-style-type: none"> <li>• First ring-test already completed, second ring-test with Imazapyr during Summer 2018 to Winter 2018;</li> <li>• OECD Expert group established in July 2019;</li> <li>• Ring-test 3 has been rescheduled for Summer 2021;</li> <li>• Training in plant propagation and experimental methods will be provided online and via a workshop, travel permitting, between Summer 2020 and Summer 2021.</li> </ul>	
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
<ul style="list-style-type: none"> <li>• September 2019: Formation of Ad Hoc Expert group;</li> <li>• April 2020: Circulation of Validation report and draft TG for reading by Ad Hoc Expert group</li> <li>• June 2020: Discussion of documents with Ad Hoc Expert group;</li> <li>• Summer 2020: Update of documents and written commenting round of the validation report and the draft Testguideline by the VMG-eco;</li> <li>• Autumn 2020: Discussion of the documents at the VMG-eco;</li> <li>• Winter 2020/21: WNT commenting round;</li> <li>• February 2021: Final draft documents for Approval;</li> <li>• April 2021: Approval of validation report and TG at the WNT meeting.</li> </ul>	
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
<p><b>2019-2020</b></p> <ul style="list-style-type: none"> <li>• Establishment of an ad hoc expert group in charge of the pre-validations and validations to be performed;</li> <li>• 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</li> </ul> <p><b>2020-2022</b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• Evaluation of the results and completion of a draft guidance for evaluation of thyroid endpoints</li> <li>• Inclusion of suitable thyroid endpoints in the OECD TG 234 protocol, and completion of a consolidated draft TG for submission to the OECD Secretariat</li> </ul> <p><b>2023</b></p> <ul style="list-style-type: none"> <li>• WNT commenting rounds</li> <li>• Acceptance of TG by OECD WNT</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

<b>Project 2.65: New TG on Acute Contact Toxicity Test for the solitary living Mason Bee (Osmia spp.)</b>	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland 2019
<b>Milestones</b> <ol style="list-style-type: none"> <li>1. First drafts of the guideline and the validation report will be ready for Honey Bee Expert Group commenting in autumn 2020.</li> <li>2. Expert group meeting/Teleconference to discuss the validation reports and draft TG in Winter 2020/2021</li> <li>3. Revised validation reports and TG (based on comments) for a 1<sup>st</sup> commenting by the WNT in spring 2021.</li> <li>4. 2<sup>nd</sup> WNT commenting round of the final validation report and draft TG autumn 2021.</li> <li>5. Final validation report and draft TG for approval at the WNT in April 2022.</li> </ol>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Honey bee and other bees testing

<b>Project 2.66: REACTIV (Rapid Estrogen Activity In Vitro) Assay</b>	
Lead: Inclusion in work plan: Project status and milestones:	France/ United Kingdom/ Japan 2020
<ol style="list-style-type: none"> <li>1. Completion of a comprehensive study plan (Autumn 2020).</li> <li>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).</li> <li>3. Readjustment of the protocol as a function of comments received from testing laboratories.</li> <li>4. Completion of an integrated summary report that synthesises the data from all supporting studies (late 2021).</li> <li>5. Independent peer review of the assay by the VMG-Eco group (late 2021).</li> <li>6. OECD VMG-Eco and WNT commenting rounds (2022).</li> <li>7. Possible adoption at WNT Meeting (April 2023)</li> </ol>	
Subsidiary body of the JM	WNT
Expert group	Validation Management Group for Ecotoxicity Testing

**SECTION 3**  
**PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE**

<b>Project 3.9: New GD (Decision-Tree) on agglomeration and dissolution behaviour of nanomaterials in aquatic media:</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2014
<ul style="list-style-type: none"> <li>Project completed; Guidance Document will be published mid-2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing

<b>Project 3.10: New TG on dissolution rate of nanomaterials in aquatic environment</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany (since 2010) 2014
<ul style="list-style-type: none"> <li>Conceptional development (coordination with related TG and GD developments, exchange with project associated expert group): autumn/winter 2020</li> <li>Update of SPSF considered for Nov 2020</li> <li>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")</li> <li>Development of protocol to determine dissolution rate using dynamic testing flow through method): spring 2022</li> <li>Frequent exchange with WNT projects 1.5 and 3.16</li> <li>Validation study (both on batch and dynamic testing): summer 2022</li> <li>WNT Expert Group Meeting: autumn 2022</li> <li>WNT commenting: autumn/winter 2022</li> <li>Delays are envisaged due to Covid-19.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing

<b>Project 3.11: New TG for nanomaterial removal from wastewater</b>	
Lead: Inclusion in work plan: Project status and milestones:	United States 2014
<p><b>Project status and milestones:</b></p> <ul style="list-style-type: none"> <li>May- August 2017: The round robin data set for the gold nanoparticle was assembled and analyzed by the research group;</li> <li>March- April 2017: Based on the previous round robin results a small scale test was conducted between three labs; results from the three laboratory round robins were discussed and a second practice run was scheduled;</li> </ul>	

<ul style="list-style-type: none"> <li>• June to October, 2017: Final test run completed;</li> <li>• November 2017: A teleconference of the research group took place to complete revisions to the document;</li> <li>• January- February 2018: The draft TG was distributed to WNT Expert Group in April; Laboratories willing to participate in an expanded round robin were solicited;</li> <li>• June 2018: Comments will be incorporated and a teleconference organized to finalize the commenting round;</li> <li>• November 2018: The first draft TG was circulated to the EGs for a first round of comments;</li> <li>• December 2018: The lead presented the draft TG during the Expert Meeting on Ecotoxicity and Fate of Nanomaterials that took place in Arona, Italy (12 and 13 December 2018) and received preliminary feedback;             <ul style="list-style-type: none"> <li>○ US EPA/OPPT did not provide RCOM after first WNT commenting round;</li> </ul> </li> <li>• March 2020: US EPA/OPPT has completed work for one chemical;             <ul style="list-style-type: none"> <li>○ US EPA/OPPT would need a partner to continue to move the guideline forward especially since the WNT EG has requested round robin testing of additional materials;</li> <li>○ US EPA/OPPT would help the new partner with details of their round robin for the first material, methodology input and possibility of any upcoming publication;</li> <li>○ Guideline development effort would end and a publication would be developed if another country or sponsor isn't found.</li> </ul> </li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on Ecotoxicity and Environmental Fate testing

<b>Project 3.12: New GD on assessing the apparent accumulation potential for nanomaterials</b>	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom and Spain 2014
<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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-             <ul style="list-style-type: none"> <li>• A teleconference took place on 28<sup>th</sup> January 2020 to discuss progress and the next steps.</li> <li>• The expected time for completing this project is 2022.</li> </ul> </li> </ol>	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on Ecotoxicity and Environmental Fate Testing

June 2020

<b>Project 3.14: Guidance Document to support implementation of TG 312 for Nanomaterial Safety Testing</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany/Canada 2017
<ul style="list-style-type: none"> <li>The draft GD was circulated to the Expert Group for a second round of comments in November 2018. The draft was also presented and discussed at the meeting of the Expert Group that took place in Arona (December 2018).</li> <li>The leads have incorporated inputs made. To corroborate their amendments, the leads invited (February 2019) interested laboratories to join and inter-laboratory test comparison to evaluate the mobility of nanomaterials in different soils;</li> <li>8 Laboratories were identified, and supporting material has been distributed;</li> <li>The inter-laboratory exercise took place from June 2019 to Dec. 2019, data arrived to the leads in April 2020;</li> <li>Data from the inter-laboratory test will be evaluated and presented in a report by the leads; a revised draft GD will be circulated for comments Q3 2020.</li> </ul>	
Subsidiary body of the JM	WNT/WPMN
Expert group	Joint Expert Group on Ecotoxicity and Environmental Fate Testing

<b>Project 3.15: New Test Guideline to determine the uptake of chemicals by plant roots</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2018
<ul style="list-style-type: none"> <li>An ad hoc expert group has been established in order to give further advice on the test design before final validation.</li> <li>Pre-testing in 2019/2020;</li> <li>Validation study - the aim is to test the uptake of substances according to the protocol in different crops by about 8-10 laboratories Nov.2020-April 2021;</li> <li>Submission of TG for WNT approval in 2023..</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on plant uptake of chemicals

<b>Project 3.16: Guidance Document Environmental abiotic transformation of nanomaterials</b>	
Lead: Inclusion in work plan: Project status and milestones:	Austria 2019
<p><b>Oct. 2019 - March 2020:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p><b>September 2020:</b></p>	

<ul style="list-style-type: none"> <li>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)</li> </ul> <p><b>Sept. 2020 – Sept. 2021:</b> (eventually also later, depending on COVID-19 situation and lab closures)</p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Sept 2021-March 2022:</b> (eventually also later, depending on COVID-19 situation and lab closures)</p> <ul style="list-style-type: none"> <li>Revision of draft documents and submission for approval.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Joint Expert Group on Environmental Fate Testing

<b>Project 3.17: New TG on Hyalella azteca Bioconcentration Test (HYBIT)</b>	
Lead: Inclusion in work plan: Project status and milestones:	France/Germany 2019
<ul style="list-style-type: none"> <li>The OECD ad hoc Expert Group to oversee planning and conduct of the definitive multi-laboratory ring trial has been established in summer 2019;</li> <li>The kick-off meeting of the Expert Group was held in November 2019;</li> <li>Multi-laboratory ring trial:             <ul style="list-style-type: none"> <li>Pre-test (assessment of the transferability of the method) (May 2019 - November 2019);</li> <li>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;</li> <li>Main study: Due to the covid-19 epidemic, some participants had to postpone their experiments. Consequently, the experimental phase should be finalized in December 2020;</li> </ul> </li> <li>Meeting for discussion of the ring test results is scheduled for Q1 2021;;</li> <li>Development of draft TG: Q1-Q2 2021;</li> <li>Expert group and WNT commenting rounds, TG finalization (Q2 2021-Q1 2022);</li> <li>Possible adoption of TG by OECD WNT (2022).</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	To be determined

<b>Project 3.18: Anaerobic Transformation of Chemicals in Liquid Manure</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany 2020
<ul style="list-style-type: none"> <li>05/2020 Nomination of ad hoc expert group;</li> <li>06-07/2020 Commenting of Draft TG by ad hoc expert group;</li> </ul>	

*June 2020*

	<ul style="list-style-type: none"><li>• 08/2020 Responses to comments by lead country;</li><li>• 09/2020 1st WNT commenting round;</li><li>• 11/2020 Responses to WNT comments by lead country;</li><li>• 12/2020 2nd WNT commenting round;</li><li>• 02/2021 Responses to WNT comments by lead country;</li><li>• 04/2021 Draft TG for approval at WNT-meeting.</li></ul>
Subsidiary body of the JM	WNT
Expert group	Expert Group on Anaerobic Transformation studies



**SECTION 4**  
**PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS**

<b>Project 4.73: Test Guideline on Androgen Receptor Transactivation Assays</b>	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2013
<ul style="list-style-type: none"> <li>Project completed: TG 458 will be updated and published mid-2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2013
<ul style="list-style-type: none"> <li>Project suspended and moved to Annex 1 as requested by the leads due to recurrent WNT comments related to the regulatory application of the test method.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Toxicokinetics
<b>Project 4.77: Feasibility study for a Guidance Document on Study Designs, to be used in revisions of Guidelines</b>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2013
<ul style="list-style-type: none"> <li>Feasibility study prepared mid-2014;</li> <li>Expert meeting held on 20-21 November 2014 in Amsterdam to discuss the feasibility study;</li> <li>Lead country working on the feasibility study using data from 28-d repeated dose toxicity studies;</li> <li>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;</li> <li>An update on the project was presented and discussed at the April 2020 meeting of the WNT;</li> <li>Second part 2020. Perform computer simulations comparing various study designs. This will be done in collaboration/consultation with the expert group. The aim is to reach consensus on the simulation conditions, such that the simulations may be</li> </ul>	

<p>considered to be realistic and covering the most important study types (e.g. repeated-dose, developmental). 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</p> <ul style="list-style-type: none"> <li>For each sub-part of the simulation studies (e.g. on one datatype, one study type) the outcomes will be discussed in the expert group, while revisiting the earlier discussions on top dose selection.</li> </ul> <p>2021 preparation of guidance document, with a proposal for optimal study design(s) , based on the results of the background document on the simulations. The final guidance document will be discussed with the expert group, taking into account the applicability and feasibility for the proposals to the various OECD guidelines, as well as regulatory needs and animal welfare.</p>	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Meeting on study designs

<b>Project 4.78: Updated TG 488, Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays</b>	
Lead: Inclusion in work plan: Project status and milestones:	Canada 2013
<ul style="list-style-type: none"> <li>A 2 step update of the TG is expected : <ul style="list-style-type: none"> <li>First step is completed and the updated TG 488 will be published mid-2020: Short-term revision, to improve the detection of germ cell mutations by revising the experimental design;</li> <li>Longer term revision, including harmonisation with the other in vivo Test Guidelines on genotoxicity and based on additional experimental data continues. EG discussions will resume in Q3 2020.</li> </ul> </li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

<b>Project 4.93: new Test Guideline for the Pig-a Assay, an <i>in vivo</i> Gene Mutation Assay Promoting the 3Rs Principles</b>	
Lead: Inclusion in work plan: Project status and milestones:	United States 2015
<ul style="list-style-type: none"> <li>DRP was approved by the WNT and will be published mid-2020</li> <li>Initiate draft TG: Q2 2020;</li> <li>Public commenting on draft TG, revision as necessary: 2020-2021;</li> <li>Submit revised TG to WNT: November 2021; TG considered by WNT 2022.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

<b>Project 4.94: IATA on Non-Genotoxic Carcinogens</b>	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2015
<ul style="list-style-type: none"> <li>• Uncertainty analysis and collection of relevant assays conducted in 2016-2017;</li> <li>• 3<sup>rd</sup> face to face meeting took place on 25-27 June 2018;</li> <li>• Expert Group working on the evaluation of all relevant assays identified through 1st half of 2019.</li> <li>• Integration of assays into an IATA expected by Q4 2019;</li> <li>• 1<sup>st</sup> draft IATA expected to be available Q1 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Non-Genotoxic Carcinogenicity

<b>Project 4.95: Guidance Document on the Adaptation of <i>In Vitro</i> Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials</b>	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2015
<p>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.</p> <p>All 5 selected nanomaterials (2x silver NPs, 2x gold NPs and 1x silica NPs) wer 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: <a href="https://ec.europa.eu/jrc/en/publication/physicochemical-characterization-gold-silica-and-silver-nanoparticles-water-and-serum-containing">https://ec.europa.eu/jrc/en/publication/physicochemical-characterization-gold-silica-and-silver-nanoparticles-water-and-serum-containing</a></p> <p>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.</p> <p>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.</p> <p>Second phase is led by Swansea U. and BASF, starting by further examining the preferred protocols and materials in experimental conditions.</p> <p>January 2020 Comparison of dispersion and testing protocols as well as scoring on-going between Swansea and BASF, anticipated end of this work: April.</p> <p>March 2020 lock down blocked further lab work.</p> <p>June 2020 Publication of JRC Report on cytotoxicity and uptake.</p> <p>Currently re-scheduling activities.</p> <ul style="list-style-type: none"> <li>•</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

<b>Project 4.97: EDTA Activity: Detailed Review Paper on Retinoid System</b>	
Lead: Inclusion in work plan: Project status and milestones:	Sweden/European Commission/OECD Secr. 2015
<ul style="list-style-type: none"> <li>• Oct 2017: EDTA AG meeting; feedback was to focus on some of the highlighted organ systems, or at least make some recommendations/prioritisation on pathways most ready for AOP/in vitro-method development.</li> <li>• Jan 2018: Based on the outcome of the European priority workshop for development of test methods for endocrine disruptors (2017), the following organ systems were prioritized: male and female reproductive organ system, the craniofacial/skeletal organ and central nervous systems.</li> <li>• Sweden is finalising chapters reviewing retinoid biology and focusing on male and female reproductive organ systems in 2018-2019;</li> <li>• The OECD Secr. has identified experts to draft chapters on skeletal malformations and central nervous system development.;</li> <li>• Draft sections of the DRP were circulated for comment in Q3 2019, and the resulting feedback was discussed at a Retinoid Expert Group F2F meeting held in Nov2019.</li> <li>• A TemaNORD report "<u>Retinoids in Mammalian Reproduction, with an Initial Scoping Effort to Identify Regulatory Methods</u>" was published in April 2020</li> <li>• Updated draft DRP sections were collated and the revised DRP, along with recommendations from the Retinoid EG meeting was discussed at a dedicated EDTA AG teleconference; commenting round initiated in Q2 2020; draft DRP will be consolidated in Q3 2020 with the expectation to submit for WNT approval in 2021.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	(No expert group yet active) EDTA AG

<b>Project 4.98: EDTA Activity: developing a list of reference chemicals for E-A-S metabolism</b>	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2015
<ul style="list-style-type: none"> <li>• Finalisation of the list in Q4 2018.</li> <li>• Preparation of report to share with VMG-NA 2019/20.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

<b>Project 4.99: EDTA Activity: New TG on Androgen Receptor Transactivation Assay</b>	
Lead: Inclusion in work plan: Project status and milestones:	Korea 2015
<ul style="list-style-type: none"> <li>Project completed; the updated TG 458 was approved in April and will be published mid-2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
<b>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).</b>	
Lead: Inclusion in work plan: Project status and milestones:	Sweden 2016
<ul style="list-style-type: none"> <li>Protocol for validation ready in October 2016 followed by validation;</li> <li>Transfer phase until January 2017;</li> <li>Validation study between March and the summer 2017;</li> <li>Statistical analysis and main validation report Q4 2017;</li> <li>Supplement to validation report with data on potency Q2 2018;</li> <li>Statistical analysis and validation report: <ul style="list-style-type: none"> <li>binary data: available Q1 2018;</li> <li>supplement with potency data: 2019</li> </ul> </li> <li>ESAC peer-review initiated.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation
<b>Project 4.107: New TG: Toxicogenomic analysis on 3D reconstituted epidermis for measuring skin sensitization potency – the SENS-IS assay.</b>	
Lead: Inclusion in work plan: Project status and milestones:	France 2016
<ul style="list-style-type: none"> <li>Q2-Q3 2016: first full submission of the SENS-IS method to ECVAM for evaluation</li> <li>2018: revised full submission to ECVAM;</li> <li>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);</li> <li>Subject to positive outcome of the revised submission evaluation, ESAC peer review could be organised in 2020-2021.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

<b>Project 4.109: DRP on the Miniaturized versions of the Bacterial Gene Mutation Test</b>	
Lead: Inclusion in work plan: Project status and milestones:	Belgium/United States/Netherlands 2016
<ul style="list-style-type: none"> <li>• Retrospective validation/ Consolidation of existing Ames MFA data; Scientific peer review of existing data (2016 -2017);</li> <li>• Prospective validation if needed; Generation of additional data based on the outcome of the retrospective validation process;</li> <li>• Kick off meeting organised on 28 February - 1 March 2017 at OECD;</li> <li>• Start writing the draft DRP (Q2 2017);</li> <li>• Call for data sent Q1 2018;</li> <li>• Analysis of the collected data Q4 2018 - Q2 2019;</li> <li>• 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;</li> <li>• Second call for data Q4 2019 in order to complete the database;</li> <li>• Reanalysis of the data in Q1-2 2020 and input from subgroups of work;</li> <li>• First submission of the draft DRP to WNT for comments in Q3 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Miniaturised Ames Test

<b>Project 4.114: Inclusion of laser-light based opacitometer (LLBO) in OECD TG 437</b>	
Lead: Inclusion in work plan: Project status and milestones:	Belgium 2017
<ul style="list-style-type: none"> <li>• Project completed; updated TG 437 will be published mid-2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin and Eye Irritation Testing.

<b>Project 4.115: Update of Guidance Document 28, Guidance Notes 156 and possibly TG 428 on skin absorption</b>	
Lead: Inclusion in work plan: Project status and milestones:	EC/EFSA/Germany 2017
<p>Tele-conference meetings (at least 4):</p> <ul style="list-style-type: none"> <li>• Expert group 1st TC (Sept. 2018)/ 2<sup>nd</sup> 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?)</li> <li>• 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;</li> <li>• The WNT recommended waiting for the changes in policies in some OECD countries before resuming the OECD activity at end of 2020/beginning 2021.</li> </ul>	
Subsidiary body of the JM	WNT

Expert group	Expert Group on Dermal Absorption or Expert Group on skin irritation.
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<b>Project 4.116: Guideline on Defined Approach(es) for Skin Sensitisation</b>	
Lead: Inclusion in work plan: Project status and milestones:	EC/US/Canada 2017
<p>Key milestones:</p> <ul style="list-style-type: none"> <li>• Whitepaper characterising international regulatory requirements for skin sensitisation testing, by region (completed);</li> <li>• Whitepaper communicating ICATM workshop outcomes and recommendations (completed);</li> <li>• 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).</li> <li>• Propose general assessment framework (including acceptance criteria) for DAs for skin sensitisation (discussed at the Special session of WNT in Dec. 2017).</li> <li>• 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).</li> <li>• 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).</li> <li>• 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.</li> <li>• Re-analysis of LLNA study quality and analysis of human data quality in 2019;</li> <li>• Revised draft GL and Supporting Document will be circulated for a second written commenting round Q3 2019;</li> <li>• Series of TCs organised in Q4 2019- Q2 2020 to identify and discuss outstanding issues and path forward/timelines in 2020; 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.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2017
<ul style="list-style-type: none"> <li>• 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;</li> <li>• A dedicated workshop on the use of human products in TGs was held in March 2019;</li> </ul>	

June 2020

<ul style="list-style-type: none"> <li>The work on TG 442E will continue in 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation

<b>Project 4.119: Update of TG 455 with the introduction of a metabolic step in the ER<math>\alpha</math> CALUX transactivation bioassay for ER</b>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2017
<ul style="list-style-type: none"> <li>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);</li> <li>Project was delayed due to test method lead's involvement in other TGP projects.</li> <li>An update on the work is expected in 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2017
<ul style="list-style-type: none"> <li>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);</li> <li>Project was delayed due to test method lead's involvement in other TGP projects.</li> <li>An update on the work is expected in 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	VMG-NA

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2017
<ul style="list-style-type: none"> <li>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 the draft will be submitted to WNT in Q3 2020;</li> <li>2nd step: feasibility study of the development of a Test Guideline, (timelines are not provided yet).</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	



<b>Project 4.124: New Guidance Document on Developmental neurotoxicity (DNT) in vitro assays</b>	
Lead: Inclusion in work plan: Project status and milestones:	EC (EFSA, JRC)/US/DK 2017
<ul style="list-style-type: none"> <li>• Kick-off meeting with the lead countries took place in February 2018, followed by a teleconference with the Expert group in April and 2018.</li> <li>• Case studies' proposals were discussed in June 2018.</li> <li>• A face to face meeting took place in March 2019 and agreed on: <ul style="list-style-type: none"> <li>○ the scope and outline of the guidance document;</li> <li>○ the assays that should be considered, described/characterised in the guidance document;</li> <li>○ how the data produced by the assays should be integrated/used and provide guidance on data interpretation;</li> <li>○ the case studies to be included in the guidance.</li> <li>○ the need to establish a dedicated subgroup to work on the harmonisation of DNT assessment in zebrafish;</li> </ul> </li> <li>• 1st TC of WG on Developing IATA case studies on DNT organized by EFSA (20<sup>th</sup> May 2019)</li> <li>• The extended outline of the Guidance Document to be discussed during OECD TC (7<sup>th</sup> June 2019)</li> <li>• 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.</li> <li>• The experimental work is expected to be concluded by fall 2019.</li> <li>• Submission to WNT and WGP for commenting anticipated end of 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on DNT
<b>Project 4.125: DRP on the ToxTracker assay: a stem cell-based reporter assay for mechanistic carcinogenicity hazard assessment</b>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2017
<ul style="list-style-type: none"> <li>• 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.</li> <li>• An update is expected in 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on non-genotoxic carcinogenicity
<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2018

June 2020

<ul style="list-style-type: none"> <li>• Spring 2018: if all the data supports inclusion in TG 437, Japan and IIVS will submit all the available results;</li> <li>• 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;</li> <li>• Q2 2020: submission of the additional report on between laboratory reproducibility of this proposal to EG;</li> <li>• Discussion on possible updates to TG 437 at the EG meeting in Q4 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on eye irritation

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland 2019
<ul style="list-style-type: none"> <li>• Milestone 1: Compilation and critical assessment of available studies until December 2019;</li> <li>• 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;</li> <li>• Milestone 3: Report on full experimental part. Ranking of selected nanomaterials regarding suitability of use of the test method until September 2021;</li> <li>• Milestone 4: Conclusions on the potential of TG 442D to be used for the testing of manufactured nanomaterials until November 2021;</li> <li>• Milestone 5a: Recommendations for a future revision of TG 442D and/or for nanospecific guidance until December 2021;</li> <li>• Based on milestones 1 to 5 the Detailed Review Paper (DRP) will be worked out until March 2022.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitisation

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2019
<p><b>2020-2021:</b></p> <ul style="list-style-type: none"> <li>• Establish an Ad hoc Expert Group;</li> <li>• tele-conferences (at least 6) plus face to face meeting(s) to address issues identified after the first commenting round;</li> <li>• 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;</li> </ul>	

<ul style="list-style-type: none"> <li>• 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;</li> <li>• Discuss how the data produced by the assays should be interpreted/used for a tiered approach. And draft the document;</li> <li>• Discuss a tiered approach for a testing strategy in DRP.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Immunotoxicity (to be established)

<b>Project 4.135: Revision of the TG 491 Applicability Domain for the Short Time Exposure Test Method for Ocular Toxicity Predictions</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2019
<ul style="list-style-type: none"> <li>• Project completed: updated TG 491 will be published mid-2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on eye irritation testing

<b>Project 4.136: Two Defined Approaches for Ocular Irritation Predictions Based on in vitro Bottom-Up Approach Combined with Physico-Chemical Properties.</b>	
Lead: Inclusion in work plan: Project status and milestones:	France 2019
<b>2019-2020</b>	
<ul style="list-style-type: none"> <li>• 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;</li> <li>• Q3-Q4 2019 - Step 2: Discussion with the Expert Group in view of establishing a reference chemicals list;</li> <li>• Q1 2020 - Step 3: Re-analysis by Cosmetics Europe of the proposed Defined Approaches using the established reference chemicals list; Presentation of this re-analysis to the Expert Group by webinar;</li> <li>• Q2-Q3 2020 - Step 4: Review of the background supporting document that will incorporate the re-analysis and Expert Group inputs;</li> <li>• Q 4 2020 - Step 5: Face-to-face meeting of the Expert Group for discussion and comments to support a consolidated version of the background document;</li> <li>• Step 6: Initiate drafting of a Test Guideline when the Expert Group peer review is finalised (and follow the typical process of Test Guideline development).</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert group on eye irritation

<b>Project 4.137: The kinetic Direct Peptide Reactivity Assay (kDPRA): An in chemico Method to characterize the Skin Sensitisation Potency of Chemicals</b>	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland/Germany 2019
<ul style="list-style-type: none"> <li>The method and its validation study underwent an independent peer-review (organized by the lead countries) between August 2019 and February 2020 by an international panel that included nominations from validation bodies. The revised validation report and the peer-review report have been finalized in Q1 2020.</li> <li>A draft TG for an update of TG 442c (new appendix III) will be available by mid June 2020. Next steps planned: Discussion in the EG Skin Sens (TC) / 1<sup>st</sup> WNT commenting round (June/July 2020). 2<sup>nd</sup> WNT commenting round Q4 2020 /Q1 2021 with the aim to have the draft TG ready for approval by WNT33 (April 2021).</li> <li>Follow up: once the test method has been approved by the WNT, the future role of the kinetic DPRA in the framework of “Defined Approaches For Skin Sensitisation” can be addressed.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitisation

<b>Project 4.138: In Vitro Phototoxicity Test Using the Reconstructed Human Epidermis (RhE) for Identifying Phototoxic Chemicals Upon Exposure to Skin</b>	
Lead: Inclusion in work plan: Project status and milestones:	United States 2019
<ul style="list-style-type: none"> <li>October 2019: summary report to Expert Group on Phototoxicity for comments and identification of data gaps.</li> <li>February 2020: First draft of the OECD TG on the basis of available data and circulation to the Phototoxicity expert group: Discussion of existing data for 2-3 reference methods and collection of comments on the draft TG at Expert Group on Skin and Eye Irritation meeting. It is expected that some systems will further undergo validation work to demonstrate reliability and reproducibility.</li> <li>March 2020: teleconference with Expert Groups (if needed)</li> <li>April-September 2020: Generation of new data necessary for demonstration of reliability and reproducibility in the selected testing systems</li> <li>September: Statistical analyses</li> <li>October 2020: Report to the OECD expert group, revision of the draft OECD TG to include the validation outcomes and circulation of revised draft TG to the Phototoxicity expert group.</li> <li>November 2020: Collecting comments from the expert group and revising the draft OECD TG</li> <li>January 2021: Circulation of the draft OECD TG amongst stakeholders and public comments via WNT group with follow-up implementations of revisions</li> <li>April 2021: submission of the TG at WNT meeting for approval.</li> </ul>	

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

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany/France 2019
<p><b>Q1 2020:</b> submission of validation datasets for the reconstructed skin Comet assay, for ECVAM review.</p> <p><b>Q2 2020:</b> submission of validation datasets for the reconstructed skin micronucleus test, for ECVAM review.</p> <p><b>Q4 2020:</b> full submission of the test methods to ECVAM for peer-review</p> <p><b>Q1 2022:</b> Drafting of PRP report and submission to OECD</p> <p><b>Q2 2022:</b> Discussion of the first draft of the TGs and PS with the expert group and 1st commenting by the WNT</p> <p><b>Q3 2022:</b> Second commenting round</p> <p><b>Q1 2023:</b> TGs submitted to the WNT for approval</p>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing

<b>Project 4.140: Inclusion of the LbL-3D Skin model skin irritation test to OECD test guideline 439 validated reference method</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2020
<ul style="list-style-type: none"> <li>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;</li> <li>The Independent peer review report will be completed by early summer 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

<b>Project 4.141: Revision of Appendix II in Test Guideline 442C: Amino acid Derivative Reactivity Assay (ADRA) for predicting sensitization potential</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2020

June 2020

<ul style="list-style-type: none"> <li>• 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;</li> <li>• Work to validate the proposed updates to TG 442C to extend the applicability domain is being organized. We anticipated that the revised TG 442C, Appendix II will be shared with the OECD expert group on skin sensitization. We foresee this will involve communication via email. By the end of April 2020, upon approval of the SPSF by the Working Group of the National Coordinators of the Test Guidelines Programme (WNT), Appendix II of TG 442C can be revised.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitization test methods

<b>Project 4.142: Revision of OECD TG 439 to include a new me-too reconstructed human epidermis test method – KeraSkin™ skin irritation test</b>	
Lead: Inclusion in work plan: Project status and milestones:	Korea 2020
<ul style="list-style-type: none"> <li>• An independent international peer-review on the me-too method to assess the scientific validity and similarity to the VRMs of the OECD TG439 is ongoing. The peer review report will be available in July 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	France 2020
<ul style="list-style-type: none"> <li>• Q1 2020:             <ul style="list-style-type: none"> <li>○ The SkinEthic™ HCE TTL-TTS report will be finalised and will be sent as a whole package for independent peer-review.</li> </ul> </li> <li>• Q2 2020:             <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ The peer review panel will provide the scientific opinion and then issue its final report on the test method in Q3.</li> </ul> </li> <li>• Q3 2020:             <ul style="list-style-type: none"> <li>○ 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.</li> </ul> </li> </ul>	

<ul style="list-style-type: none"> <li>○ Commenting by WNT and Expert Group by September-October.</li> <li>● Q4 2020:             <ul style="list-style-type: none"> <li>○ 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</li> <li>○ A second draft TG would be made available to the WNT and the Expert Group for a commenting round.</li> </ul> </li> <li>● Q1 2021:             <ul style="list-style-type: none"> <li>○ In the absence of substantial comments, a third draft TG would be available by February.</li> </ul> </li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2020
<ul style="list-style-type: none"> <li>● The work to revise the protocol and TG 494 will be undertaken by National Agriculture and Food Research Organization (NARO) in collaboration with National Institute of Health Sciences (NIHS). We anticipated that the revised TG 494 will be provided with the OECD expert group on skin/eye corrosion/irritation in Q3 2020;</li> <li>● A single commenting round may be sufficient before submission of the draft updated TG 494 to the WNT for approval in 2021.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin/eye irritation test methods

<b>Project 4.145: Guidance document on an integrated approach on testing and assessment (IATA) for phototoxicity</b>	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2020
<ul style="list-style-type: none"> <li>● First draft IATA document available by September 2020;</li> <li>● Possible Expert Meeting in November 2020;</li> <li>● Commenting by WNT and Expert Group by February 2021;</li> <li>● Second draft IATA document available by June 2021;</li> <li>● Commenting by WNT and Expert Group by September 2021;</li> <li>● Possible Expert Meeting in November 2021;</li> <li>● Third draft IATA document available by January 2022;</li> <li>● Approval by WNT April 2022.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on phototoxicity testing

*June 2020*



<b>Project 4.146: New Test Guideline on toxicokinetics to accommodate testing of nano-particles</b>	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom/Netherlands 2020
<ul style="list-style-type: none"> <li>• 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;</li> <li>• Second half of 2020: International workshop on the toxicokinetics of (nano)particles (probably organised in collaboration with the EU project NanoHarmony);</li> <li>• 2023: OECD workshop on the draft TG (organised in collaboration with the OECD secretariat);</li> <li>• June/September 2024: Draft TG submitted for comments to WNT (second milestone);</li> <li>• September 2024 – January 2025: WNT commenting rounds, revision of drafts based on comments (2 commenting rounds are envisaged)</li> <li>• April 2025: Approval of TG by WNT.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN-WNT Expert Group on Toxicokinetics of NM (TBC)
<b>Project 4.147: EDTA: DRP on the State of the Art of Metabolic Disruption by Chemicals</b>	
Lead: Inclusion in work plan: Project status and milestones:	NL/UK/SE/GER/DK 2020
<ul style="list-style-type: none"> <li>• A first draft DRP will be sent for review and commenting rounds by OECD expert groups including the VMG-NA and EDTA-AG in 2021, 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 2021, or perhaps 2022, input and comments depending;</li> <li>• Milestone: F2F Presentation of the EURION cluster at the EDTA -AG meeting 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Advisory Group on Endocrine Disrupters Testing and Assessment

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

<b>Project 5.6: Development of efficacy Test Guidelines and Guidance Document for public health antimicrobial biocides used on hard surfaces</b>	
Lead: Inclusion in work plan: Project status and milestones:	United States through the WG 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"> <li>• 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.</li> <li>• 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.</li> <li>• Draft TGs for fungicidal and virucidal activity of microbicides were planned for development after finalisation of the bactericidal and mycobactericidal protocols;</li> <li>• 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).</li> </ul>	
Subsidiary body of the JM	WNT & WGB
Expert group	Expert Group on Efficacy of Microbicides on Hard Surfaces
<b>Project 5.16: Guidance Document on Laboratory Assays for Evaluating the Efficacy of Biocides against Bed Bugs</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2015
<ul style="list-style-type: none"> <li>• Germany replaces United States as lead country for this project.</li> <li>• May 2018 – 1st for WGB commenting;</li> <li>• Q3 2020 – 2<sup>nd</sup> WGB commenting;</li> <li>• Q4 2020 WNT written procedure approval.</li> </ul>	
Subsidiary body of the JM	WNT & WGB
Expert group	(no expert group active on this project)
<b>Project 5.17: Guidance Documents on Testing the Efficacy of Baits against Tropical Ants</b>	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2017
<ul style="list-style-type: none"> <li>• March – May 2018 Laboratory testing</li> <li>• May 2018 – Jun 2018 Evaluation of Test results</li> </ul>	

June 2020

<ul style="list-style-type: none"><li>• 2019 –WGB commenting;</li><li>• Q4 2020 WNT written approval.</li></ul>	
Subsidiary body of the JM	WNT & WGB
Expert group	(no expert group active on this project)

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

<b>Project 4.122: Guidance Document on hepatic clearance test methods</b>	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2017
<ul style="list-style-type: none"> <li>• 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;</li> <li>• Circulate the outline of the Guidance Document to the <i>ad hoc</i> expert group once established (July 2018);</li> <li>• Circulate a first draft GD to expert group in Q4 2018</li> <li>• Circulate a revised draft GD to expert group in Q2 2019</li> <li>• 2 commenting rounds at WNT level Q3-Q4 2019</li> <li>• Final GD submitted to WNT for approval in April 2020.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Metabolism
<b>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</b>	
Lead: Inclusion in work plan: Project status and milestones:	European Commission 2013
<ul style="list-style-type: none"> <li>• Draft TG, Performance standards and validation report submitted to Secretariat in August 2014;</li> <li>• Draft TG submitted to the WNT for commenting in September 2014;</li> <li>• Discussion in expert group meeting on 11-12 May 2015 at OECD in Paris;</li> <li>• Discussion at WNT-29 in April 2017, with recommendation to proceed with the best performing method among those that were validated and a companion document describing possible uses of in vitro data on metabolism in a regulatory context.</li> <li>• Two manuscripts which address possible uses of the CYP induction methods were prepared and submitted to peer-reviewed journals. When accepted for publication, the manuscripts will be shared with WNT (probably Q1-Q2 2019) together with a draft updated Test Guideline on HepaRG.</li> <li>• The project will be on the agenda of the WNT-32 in April 2020 for discussion;</li> <li>• Project suspended and moved to Annex 1 as requested by the leads.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Toxicokinetics

<b>Project 4.132: A feasibility study for establishing TGs for in vitro human hepatic metabolic clearance and metabolite formation</b>	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands 2018
<ul style="list-style-type: none"> <li>• Formation of an expert group Q3 2018 (NL proposes to form an expert group for toxicokinetics)</li> <li>• 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</li> <li>• Inventory of available databases and literature with hepatic clearance data for evaluation Q3+4 2018</li> <li>• Circulate a first draft of the feasibility study report and commenting rounds Q1 2019</li> <li>• Circulate a revised draft report Q2 2019</li> <li>• Approval of final document Q4 2019-Q1 2020.</li> <li>• 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;</li> <li>• 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.</li> </ul>	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Toxicokinetics