September 2018

Work plan for the Test Guidelines Programme (TGP)

September 2018

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
EPOC: Environmental Policy Committee
NC: national coordinator
SPSF: standard project submission form
SSD: Streamlined Summary Document
VMG-eco: Validation Management Group for Ecotoxicity Testing
VMG-non animal: Validation Management Group for Non Animal Testing
VMG-mammalian: Validation Management Group for Mammalian Toxicity Testing
WNT: Working Group of the National Coordinators for the Test Guidelines Programme
WGP: Working Group on Pesticides
WPMN: Working Party on Manufactured Nanomaterial
TF Biocides: Task Force on Biocides

PROJECTS OF GENERAL NATURE

Project 0.1: New Guidance on Good Licensing Practices for IP elements in Test Guidelines	
Lead: Inclusion in work plan: Project Status and milestones:	EG on IP issues 2018
• A workshop was held in September 2017; an Expert Group will be formed on that basis, with additional nominations from outside Europe; • A teleconference was held in June 2018, to review a first outline of the draft Guidance Document; commenting and consolidation of the draft guidance document in Q3-Q4 2018. • Circulation to WNT for review in early 2019.	
Subsidiary body of the JM	WNT
Expert group	EG on IP issues.

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

Project 1.1: New Guidance Document for flammability testing of Plant Protection and Biocidal Products	
Lead: Inclusion in work plan: Project Status and milestones:	WG Biocides 2017
• An Expert Working Group has been formed through the Task Force on Biocides, the proposed Guidance Document will be discussed via conference calls; • A draft Guidance Document is expected to be available in Q3-Q4 2018 for a first round of review.	
Subsidiary body of the JM	TFB/WNT
Expert group	Chemistry Expert Working Group/TFB

Project 1.2: Guidance Document on Bridging and Waiving of Physical/Chemistry studies of Plant Protection and Biocidal Products	
Lead: Inclusion in work plan: Project Status and milestones:	WG Biocides 2018
• An Expert Working Group has been formed through the Working Group on Biocides; the proposed Guidance Document will be discussed via conference calls. Calls will be held as needed. • A draft Guidance Document is expected to be available in Q3-Q4 2018 for a first round of review.	
Subsidiary bodies of the JM	WGP – WGB – WNT- WPHA
Expert group	Expert group on p-chem properties under the WGB

Project 1.3: New TG on Determination of the (Volume) Specific Surface Area of Manufactured Nanomaterials	
Lead: Inclusion in work plan: Project Status and milestones:	European Commission - JRC 2018
• Establishment of an Expert Group • A first teleconference is planned before September;	

• A first draft is expected to be prepared in early 2019.	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group

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
• Establishment of an Expert Group; • October 2018: Decision on and experimental as well as conventional development of the test methodology, preparation of the round robin test (SOP development, agreement of parameters, measurands and units, shipping of test materials, etc.); • December 2018: Performance of the round robin test; • January-April 2019: Processing of results of the round robin test, completion of the draft Test Guideline; • May 2019: WNT Expert Group Meeting.	
Subsidiary body of the JM	WNT - WPMN
Expert group	Joint WNT/WPMN Expert Group

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

Project 2.39: EDTA Activity – New TG: Xenopus Embryonic Thyroid Signalling Assay	
Lead: Inclusion in work plan**:** Project status and milestones:	France 2011
• Comprehensive written validation plan, including a detailed protocol agreed by VMG-eco and participating laboratories identified in June 2012; • Inter-laboratory validation performed by France, Japan and the United States completed in March 2014; draft validation report finalised in June 2014. • Discussion of validation report for phase 1and next steps discussed at VMG-eco in December 2014. • Proposal for phase 2 of the validation and next steps discussed at VMG-eco in October 2015. • Inter-laboratory validation phase 2 performed by France, Japan and Portugal finalised in September 2016. • Preliminary outcome of phase 2 validation discussed at the meeting of the VMG-eco in October 2016. • Additional experiments performed by Belgium for the Inter-laboratory validation phase 2 finalized in April 2017. • Outcome of phase 2 validation discussed at the meeting of the VMG-eco in October 2017. • Draft TG and Phase 2 validation report have been sent to experts in June 2018 for discussion at VMG-Eco meeting in Q3 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.46: New TG for the Detection of Endocrine Active Substances, acting through estrogen receptors using transgenic cyp 19a1b-GFP Zebrafish Embryos (EASZY assay)	
Lead: Inclusion in work plan**:** Project status and milestones:	France 2013
• 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); • Preliminary data analysis for Phase 1 of the validation; presentation and discussion at VMG-eco meeting in December 2014; • France provided an update on the progress in the development of the EASZY assay in October 2015 during the last VMG-Eco, showing satisfactory results in 2 laboratories. France is continuing validation efforts by searching additional laboratories first; • One additional laboratory was identified in April 2016, preliminary results of phase 1 of the validation presented at VMG-eco in October 2016. • France submitted a phase 1 validation report in 2017 for discussion at VMG-Eco and presented the phase 2 of the validation study; • Phase 2 of the validation study has been carried out from March to early June 2018. The analysis of stock solutions and tested concentrations is in progress and will available early July; • The draft version of the TG will be sent to experts in July and the report of the validation report (phase 2) at the end of September. These two documents as well as the comments made during the first commenting round will be discussed at the VMG-Eco in Q3 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco
Project 2.47: New TG on Determination of Effects on Earthworms in Field Studies	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany 2013
• Establishment of an *ad hoc* Expert Group nominated by WNT in April 2013. • Work of the OECD Expert Group in co-operation with the SETAC Global Soil Advisory Group (GSAG). • Joint meeting of the OECD Expert Group and the GSAG at the Annual SETAC-Europe Conference in (May) 2014. • 2015: retrospective analysis of current test design; • 2017-2018: validation of test design in pilot study; • Mid-2018: evaluation of pilot study; • End 2018- Beginning 2019: : OECD Expert Group meeting planned; • Spring 2019: 1st draft TG for WNT commenting.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on earthworm toxicity testing
Project 2.50: Revision of TG 203 Fish Acute Toxicity Test	
Lead: Inclusion in work plan: Project status and milestones:	Switzerland/United Kingdom 2014
• Draft updated TG circulated to Fish Drafting Group and VMG-eco in September 2014; • Discussion of comments received and revision of draft TG at VMG-eco meeting in December 2014; • Discussion on the definition of criteria for moribund by UK experts in January 2015;	

- Consultation of the Fish drafting group to discuss a proposal for criteria for moribund by the lead countries planned for spring 2015;
- Discussion of criteria for moribund during VMG-eco meeting in October 2015;
- Teleconference with experts from VMG-Eco and the Fish Drafting group took place in May 2016 for additional discussions on clinical signs for moribund criteria, followed by an additional written commenting round;
- Discussion of criteria for moribund during VMG-eco meeting in October 2016;
- VMG-Eco could not come to an agreement regarding the inclusion of moribund in TG 203.
- Discussed at WNT-29, the need to pursue efforts to collect data from testing facilities implementing the moribund endpoint was identified as a high priority, but obstacles to accessing confidential data were identified at the VMG-eco in October 2017.
- Lead countries and Secretariat proposed a path forward in April 2018; option 2 was retained where the TG 203 will be 'modernised' and collection of clinical sign of moribundity will be proposed as optional in the TG; a guidance on the recognition of the clinical signs will be developed by the lead countries; draft updated TG 203 expected for approval in April 2019.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.51: Guidance Document on Aquatic (and Sediment) Toxicity Testing of Nanomaterials

Lead: Inclusion in work plan**:** Project status and milestones:	Canada, United States 2014

- The 1st draft was circulated to the Expert Group with a request for comments in October 2017.
- The lead countries are currently addressing comments received
- A teleconference will be organised in April/May 2018 with the OECD Expert Group with the objective to review proposed revisions and to address outstanding issues, if any.
- The revised draft is now completed and will be discussed during a teleconference with the Expert Group. If no further comments are made, the document could go for a commenting round to the WNT.
- The GD is expected to be submitted for approval at the WNT meeting in April 2019.

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

Project 2.54: Guidance Document on IATA for Fish Acute Toxicity Testing

Lead: Inclusion in work plan**:** Project status and milestones:	Austria/ICAPO 2015

- Development of a first draft Guidance Document including the FET in the threshold approach for acute fish toxicity testing (GD 126) in mid-2016, discussed by the VMG-eco in October 2016;
- Diverging views on the robustness of the FET, to be included in GD 126, were presented during the VMG-Eco meeting in October 2016.
- Written commenting round on the proposed approach was initiated by lead country and Secretariat in November 2016. Draft response to comments was discussed via teleconference in April 2017.
- New scientific data are expected to be published by Q2 of 2018. Also results from a European workshop will be published by that time. The new data and information will be integrated into the available background document and the GD 126 on the threshold approach will be updated, respectively.

• These updated versions of the background document and GD 126 will be discussed via another VMG Eco/FDG written commenting procedure by Q3 of 2018. • After this, the lead country will decide how to proceed with the project.	
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:	European Commission/United States 2015
Part 1: Update of OECD Guidance Document 23 • completed. The updated GD 23 is to be published in July 2018. **Part 2: Detailed Review Paper of use of controls in ecotoxicity tests** • June 2015: Project Group established and preliminary discussions during kick-off TG in July 2015 • May 2015 - February 2016: Discussion of templates for data analysis with statistician.. • October 2016: presentation of data analysis to VMG-Eco/Fish Drafting Group (OECD TG 203) • January 2016 - March 2017: Data collection (OECD TG 210). • January 2017 – April 2018: On hold whilst completing update of GD 23. • April 2018 – April 2019: On hold pending discussion with project group.	
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
• Demonstration studies were performed in 2016 and discussed at VMG-Eco meeting in 2016. • Japan intends to submit a preliminary test protocol by the end of 2016. • A ring test including an inter-laboratory validation will be conducted in 2016-2019. • A draft report of the phase 1 validation will be prepared and submitted to existing expert groups (FDG and/or VMG-eco) in early 2019. • 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 2019. • 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 2020. • Revised draft guidance document and validation reports will be delivered by the end of 2020/ the beginning of 2021 for WNT commenting. • Final draft guidance document will be submitted to the WNT in 2021.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco
Project 2.58: New Test Guideline on a Short-term Juvenile Hormone Activity Screening Assay using Daphnia magna	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2016

- Primary discussion of project by VMG-eco was conducted in October 2015.
- Considerations for the protocol for validation studies were discussed in October 2016. Participation of laboratories to ring-test will be organized by lead laboratory.
- Inter-laboratory validation will be conducted in 2018.
- 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 2019.
- No Ad Hoc Expert Group seems necessary. The Invertebrate Expert Group and VMG-eco can provide necessary advice.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

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

- Discussion of validation plan at VMG-Eco 12 in October 2016.
- Validation study is planned to take place 2017/2018: The aim is to test two substances according to the protocol by at least four laboratories.
- Review phase of a draft TG is currently planned to start at the end of 2018.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 2.60: Test Guideline: Homing flight test on honeybee (Apis mellifera L.) after single exposure to sublethal doses

Lead: Inclusion in work plan**:** Project status and milestones:	France 2016

- May to August 2016: Ring test experiments 2016;
- July to December 2016: Data analysis of the ring test results 2016;
- January 2017: Meeting of working group to deliver overall results;
- Second ring test organized from May to December 2017;
- January 2018: Meeting of working group to deliver overall results;
- Results of the ring test will be circulated in July 2018 (results of 2016 and 2017 experiments, as well as a first draft of the TG;
- A last intercalibration exercise, taking into account the improvements of the method, is under progress (May – September 2018). The draft report will be circulated in Q4 2018.

Subsidiary body of the JM	WNT
Expert group	Expert Group on honeybee/bumblebee toxicity testing

Project 2.61: New TG RADAR assay – Rapid Androgen Disruption Animal Replacement assay	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom/France 2017
• Q2 2018: availability of a written protocol; • Q3 2018 – Q3 2019: validation exercise completed using 5 pro-androgenic, 5 anti-androgenic and 5 inert compounds; • 2019: Completion of an integrated summary report that synthesises the data from all supporting studies (end of year 2); • 2020: Independent peer review of the assay (year 3); OECD WNT commenting rounds on a draft TG.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

SECTION 3
PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE

Project 3.9: New GD (Decision-Tree) on agglomeration and dissolution behaviour of nanomaterials in aquatic media:	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany 2014
• Until October 2014: elaboration/verification of the proposed Decision Tree; • September 2015: WNT Expert Group Meeting was held in Paris, where possible content of the GD was discussed; • October/December 2016 – discussions planned between the US and Germany on this GD and the US-led TG on dissolution rate of nanomaterials in aquatic environment (project 3.10); • July/August 2017: intended project start for drafting the GD including the installation of a project associated working group comprising inter alia of experts involved in the TG initiatives on dispersion stability (GER, A) and dissolution rate (US, DK) of nanomaterials in simulated environmental media; • September 2017 – February 2019: development of a guidance document on dissolution rate and dispersion stability in environmental aqueous media, including the use of OECD TG 318 for considerations on hetero-agglomeration and derivation of attachment coefficient • Meeting of WNT Expert Group followed by 1st draft to the WNT 1st quarter of 2019. • An Expert Meeting to discuss all the projects related to Ecotoxicity and Fate of Nanomaterials (projects 2.51; 3.9; 3.10; 3.11; 3.12; and 3.14) is being planned 12 and 13 December 2018, followed by 1st draft to the WNT 1st quarter of 2019.	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing
Project 3.10: New TG on dissolution rate of nanomaterials in aquatic environment	
Lead: Inclusion in work plan**:** Project status and milestones:	United States 2014

- September 2015: WNT Expert Group Meeting was held in Paris
- February 2016 - Finalizing the dissolution guideline document and developing the protocol that will be used for the ring test. The comments from the last Expert WG meeting were addressed/ incorporated in the latest version;
- Data collection beginning in February following the protocol; testing CuO, AgNP predispersed (75 nm), powdered 20 nm AgNP;
- October/December 2016 – discussions have taken place between US and Germany on this TG and the Germany-led GD on agglomeration behaviour of nanomaterials in different aquatic media (project 3.9).
- A first draft of the protocol/TG and ring trial proposal circulated for comments in April 2017; A teleconference was held to address outstanding issues and further comments were suggested to the document.
- The US has prepared a revised TG.
- A call for laboratories that wish to participate in the ring test will be done in June 2018.
- Validation of the method is intended to take most of 2018; results expected to be shared in 2019.
- An Expert Meeting to discuss all the projects related to Ecotoxicity and Fate of Nanomaterials (projects 2.51; 3.9; 3.10; 3.11; 3.12; and 3.14) is being planned 12 and 13 December 2018.

Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing

Project 3.11: New TG for nanomaterial removal from wastewater

Lead: Inclusion in work plan**:** Project status and milestones:	United States 2014

- May - August, 2017 - The round robin data set for the gold nanoparticle was assembled and analysed by the research group;
- March, 2017 – Based on the previous round robin results a small scale test was conducted between three labs. This was to ensure that the updated TG was clear and that all laboratory based issues with regards to the method were clear. A revised work plan and schedule was discussed by the research group.
- April, 2017 - Working drafts of the revised TG are shared with the research group. Leads were assigned to draft text for the TG. Results from the three laboratory round robin were discussed and a second practice run was scheduled
- June to October, 2017 – Final test run completed.
- November, 2017 - A teleconference of the research group took place to complete revisions to the document.
- January- February 2018 – The draft TG will be updated and distributed to WNT Expert Group in April. Laboratories willing to participate in an expanded round robin will be solicited.
- June 2018 - Comments will be incorporated and a teleconference organised to finalise the commenting round.
- September 2018- Revision of the draft TG.
- An Expert Meeting to discuss all the projects related to Ecotoxicity and Fate of Nanomaterials (projects 2.51; 3.9; 3.10; 3.11; 3.12; and 3.14) is being planned 12 and 13 December 2018.

Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing

Project 3.12: New GD on assessing the apparent accumulation potential for nanomaterials

Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom and Spain 2014
• Draft guidance was produced by October 2015; • As the draft GD was considered not to be ready for WNT commenting. The leads discussed how to further focus the scope of the project and agreed that work on the GD will focus on developing guidance specifically on how to apply TG305 to nanomaterials only. The concept of a tiered approach will remain on the work programme within the WPMN for discussion at future meetings. • Spain will continue work on incorporating nanomaterials into fish feed • The future direction for testing the accumulation of nanomaterials would benefit from a tiered approach which would reduce animal testing and allow for faster screening of nanomaterials of concern. The development of this Guidance Document is a step in the process to achieving this, but development of additional TG/GDs will be required in the future to support the lower tiers of this framework to achieve acceptance at the OECD/regulatory level. • An Expert Meeting to discuss all the projects related to Ecotoxicity and Fate of Nanomaterials (projects 2.51; 3.9; 3.10; 3.11; 3.12; and 3.14) is being planned 12 and 13 December 2018.	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing
Project 3.13: New TG *in vitro* Fish Hepatic Metabolism	
Lead: Inclusion in work plan**:** Project status and milestones:	United States and European Commission 2014
• Two new TGs, the associated guidance document and ring trial report, approved by WNT in April 2018, will be published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco
Project 3.14: Guidance Document to support implementation of TG 312 for Nanomaterial Safety Testing	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany/Canada 2017
• A preliminary draft GD has been developed by the leads and expected to be ready for the Expert Group commenting in Summer 2018; • Draft GD provided to WNT Expert Group for commenting in May 2018 • The leads expect to have the first draft available for the 1st WNT commenting in autumn 2018; • An Expert Meeting to discuss all the projects related to Ecotoxicity and Fate of Nanomaterials (projects 2.51; 3.9; 3.10; 3.11; 3.12; and 3.14) is being planned at the end of 2018 (Date to be confirmed).	
Subsidiary body of the JM	WNT/WPMN
Expert group	Joint Expert Group on Environmental Fate Testing
Project 3.15: New Test Guideline to determine the uptake of chemicals by plant roots	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany 2018

An ad hoc expert group is proposed in order to give further advice on the test design before final validation. Communication within the ad hoc expert group will be preferably via teleconferences and email and if necessary a face-to-face meeting could also be organized. 2018 – 2019 validation study The test protocol will be discussed with and explained to the participating laboratories; The aim is to test the uptake of substances according to the protocol in different crops by about 10 laboratories; The choice of laboratories, the acquisition of final support, the choice and delivery of the test substances and the procedure and slots of chemical analytics will be organized in 2018; 2019 – draft TG and validation report submission to WNT for first commenting round; • 2019 – 2020 TG approval.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on plant uptake of chemicals

SECTION 4
PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS

Project 4.73: New TG: Performance-Based Test Guideline on Androgen Receptor Transactivation Assays	
Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2013
• Validation study of the AR-CALUX method expected to be completed in early 2018 and draft validation report, draft Performance Standards, and draft Performance-Based Test Guidelines are expected for WNT review in 2019, for approval in 2020.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
Project 4.76: Performance-Based Test Guideline for the establishment on human-derived hepatic system to investigate biotransformation and toxicity of compounds by evaluation of CYP450 induction competence	
Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2013
• Draft TG, Performance standards and validation report submitted to Secretariat in August 2014; • Draft TG submitted to the WNT for commenting in September 2014; • Discussion in expert group meeting on 11-12 May 2015 at OECD in Paris; • 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. • 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 Q3-Q4 2018) together with a draft updated Test Guideline on HepaRG.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Biotransformation Assays
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
• Feasibility study prepared mid-2014; • 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.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Meeting on study designs
Project 4.78: Updated TG 488, Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays	
Lead: Inclusion in work plan**:** Project status and milestones:	Canada 2013
• First step: bring text clarifications and corrections: completed at WNT in April 2013; the updated TG 488 was approved and published in July 2013; • Second step: Further update based on additional germ cell research and harmonisation with the other *in vivo* Test Guidelines started in 2014 (Two papers supporting revisions that will be proposed to the standard design for somatic tissues to make the assay more suitable for mutation assessment in male germ cells have been published by lead country experts in the journal Mutation Research (https://doi.org/10.1016/j.mrgentox.2018.05.021 and https://doi.org/10.1016/j.mrgentox.2018.05.020)); • Additional germ cell research confirmed that TG 488 revisions are necessary to accommodate both somatic cells and the male germline, and would be ready for a first WNT commenting round in Q3 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing
Project 4.84: Amendments to the Inhalation TGs and GD to accommodate nanomaterial safety testing	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands and United States 2014
• Updated TG 412 and TG 413 were approved at WNT-29 in April 2017. • The updated GD 39 was approved at WNT-30 in April 2018. • The lead will discuss whether there is a need for updating the TG 403 (Acute Inhalation), and TG 436 (Acute Inhalation – Acute Toxic Class).	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on inhalation toxicity testing
Project 4.87: In vitro Macromolecular Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage	
Lead: Inclusion in work plan**:** Project status and milestones:	Italy 2015
• Q2 2016: considerations of the EURL-ECVAM peer-review opinion and of comments from the first WNT commenting round to revise the draft Test Guideline accordingly for a second WNT commenting round; • Q4 2016: Discussion of the current status of the project at the Expert Meeting on Eye irritation on 3-4 November 2016; request from experts to get additional information on the jack bean	

powder matrix stability and its sustainable availability to users; additional information was shared during the November 2017 meeting of the Expert Group; • In June 2018, the draft Test Guideline was circulated for review and comments; a second comments round might be organised in October 2018; the EG meeting in November 2018 will address remaining issues.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Eye Irritation
Project 4.88: Histopathology as Addendum to OECD Test Guideline 438 Isolated Chicken Eye Test for the Determination of Ocular Irritation of Detergent and Cleaning Products	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2015
• Completed, the updated TG 438 was approved at the WNT in April 2018 and published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Eye Irritation
Project 4.93: new Test Guideline for the Pig-a Assay, an *in vivo* Gene Mutation Assay Promoting the 3Rs Principles	
Lead: Inclusion in work plan**:** Project status and milestones:	United States 2015
• Prepare draft DRP and validation/Retrospective performance assessment (RPA) document: Q2 2015-Q2 2018; • Draft DRP made available end of 2017; • Expert Group to be formed and review of draft DRP (Q1 2018) • Draft validation/Retrospective performance assessment (RPA) document expected to be finalised Q2 2018 • Peer review of validation/RPA by expert group: Q3 2018 • Public commenting on draft DRP and validation/RPA document, revision as necessary: Q4 2018- Q1 2019; • Upon WNT approval of DRP/validation/RPA, initiate draft TG: Q2 2019; • Public commenting on draft TG, revision as necessary: 2020; • Submit revised TG to WNT: November 2020; TG considered by WNT 2021.	
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

- April/May 2015: Presentation of revised first draft to the WNT (April 2015), and preparation of manuscript for journal submission.
- May-July 2015: refinement of thought starter following second WNT review, and finalisation of manuscript.
- Q4 2015: development of an initial assay database/scoping document on available alternative methods in the area on non-genotoxic carcinogenicity, circulated in January 2016 to the expert group, updating in 2018;
- Kick-off face-to-face meeting: 30-31 March 2016; second meeting held on 29-30 March 2017 at OECD;
- Uncertainty thought starter paper finalised in 2017, developed uncertainty chapter finalised 2018;
- Expert Group to continue working on the development of the IATA document through 2018; face to face meeting tookake place on 25-27 June 2018.

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

Project 4.95: Guidance Document on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials

Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2015

- Initial discussion on the definition of the most appropriate parameters needed for an optimised protocol for micronucleus test was carried out in 2014. The proposal aims at developing a Guidance Document that will support the existing genotoxicity Test Guidelines by indicating where protocol modifications and special considerations should be applied when the test item is a NM.
- All 5 selected nanomaterials (2x silver NPs, 2x gold NPs and 1x silica NPs) have been characterised for their physicochemical properties in the pristine form, as well as suspended in the 4 cell culture media. A JRC Technical report has been published: **https://ec.europa.eu/jrc/en/publication/physicochemical-characterization-gold-silica-and-silver-nanoparticles-water-and-serum-containing**
- Moreover, 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 are now underway.
- Next steps on the basis of the physicochemical characterisation, and of the results of cytotoxicity and uptake experiments, for the appropriate design of a ring test will be discussed with the experts.
- This will end the first phase of the project and the results should enable the expert group to start the experimental inter-laboratory comparison study for the optimisation of micronucleus test protocol and later on to propose modifications for the TGs and come up with a proposal for a GD.

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:	Sweden/European Commission 2015
• 2015-2016: Planning of the DRP retinoid project. • 2016-2017: Contract between DG ENV and Brunel University (subcontractor, Danish Technical University) to draft an initial version of the DRP. • 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. • Oct - Dec 2017: The project was reorganized, with new project leads and a scientific writer who will draft organ system summaries. A call for references was sent out (Dec 2017) to the previously identified scientific experts. • Jan 2018: Based on the outcome of the call, available resources and the outcome of the European priority workshop for development of test methods for endocrine disruptors (2017), the following organ systems were prioritized: Female reproductive organ system, cardiovascular system, as well as filling data gaps in the existing DRP draft on the male reproductive organ system. In addition, the craniofacial/skeletal organ system will be considered, if allowed by available resources. The prioritization has been supported by the funding organization for this work (Nordic Chemicals Group) as well as by OECD SECR, DG ENV and DG ENV/JRC. • Starting from March 2018: The prioritized organ system summaries will be drafted. It is expected that the identified experts will review and refine the text provided by the scientific writer and that DG ENV/JRC will contribute with information on putative AOPs. Following this, the chapters will be reviewed by EDTA AG-members, and discussed during the EDTA AG-meeting October 2018. • Spring 2018: A call for submission of manuscript to a Virtual Special Issue (Elsevier) will be published. The intention is that the VSI will support further development of the DRP.	
Subsidiary body of the JM	WNT
Expert group	(No expert group yet active) EDTA AG
Project 4.98: EDTA Activity: developing a list of reference chemicals for E-A-S metabolism	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom 2015
• Q4 2017: Preparation of a discussion paper for the VMG-NA; • Finalisation of the list in Q4 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
Project 4.99: EDTA Activity: New TG on Androgen Receptor Transactivation Assay	
Lead: Inclusion in work plan**:** Project status and milestones:	Korea 2015
• This assay should be seen as a candidate for inclusion in the overall PBTG for ARTA, in conjunction with similar projects on the work plan (4.73 [EC]) and adopted TGs (TG 458);	

• In December 2014 the VMG-NA discussed the need for further validation to reduce the variability across laboratories; • Pre-validation report available in April 2015. • Further validation data collected and discussed by the VMG-NA in November 2016; • The validation report will be circulated to VMG-NA in 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
Project 4.100: EDTA Activity: Feasibility study for minor enhancements of TG 414 (Prenatal Developmental Toxicity Study) with ED-relevant endpoints	
Lead: Inclusion in work plan**:** Project status and milestones:	Denmark 2015
• Completed, the updated TG 414 was approved at the WNT in April 2018 and published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Reproductive Toxicity Testing
Project 4.104: Development of Guidance on good in vitro method practice	
Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2015
• Completed, the GIVIMP document was approved at the WNT in April 2018 and will be published in September 2018.	
Subsidiary body of the JM	WNT & WGGLP
Expert group	Joint Expert Group
Project 4.105: New TG: ROS Assay: An *in chemico* Method for Identifying the Phototoxic Potential of Chemicals	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2016
• Japan submitted a draft Test Guideline by Q4 2016; • OECD received first round comments and nominations from the WNT for Phototoxicity Experts in early 2017; • A teleconference of the expert group to address outstanding issues is expected in Q3 2017; • The Expert Group on skin and eye irritation discussed the assay and issues raised in the first commenting round at their November 2017 meeting; • The lead country will revise the draft TG and address issues in 2018; in parallel, a project to revise TG 432 will proceed in 2018 (new project 4.128 below); consistency between the two TGs will need to be checked in due course.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin and eye irritation
Project 4.106: New TG: Genomic Allergen Rapid Detection test for skin (GARDskin) test: An in vitro method for identification of skin sensitizers based on a genomic interpretation of the impact of chemicals on human dendritic cell-like cells (AOP key event 3).	

Lead: Inclusion in work plan**:** Project status and milestones:	Sweden 2016
• Protocol for validation ready in October 2016 followed by validation; • Transfer phase until January 2017; • Validation study between March and the summer 2017; • Statistical analysis and main validation report Q4 2017; • Supplement to validation report with data on potency Q2 2018; • Subsequent to ESAC Opinion available in 2019; it is expected that WNT commenting round(s)/expert group meeting will take place.	
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
• Second - third quarter 2016: development of a draft test guideline; • Independent peer review was postponed due to the lack of ESAC committee; • The peer review is now under progress. Subsequent to ESAC Opinion available end 2018, it is expected that WNT commenting round(s)/expert group meeting will take place in 2019. • The draft TG is expected to be submitted for approval at the WNT meeting in April 2020.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation
Project 4.108: Updated TG 442B: Local Lymph Node Assay Using Flow Cytometry (LLNA: BrdU-FCM)	
Lead: Inclusion in work plan**:** Project status and milestones:	Korea 2016
• Completed, the updated TG 442B was approved at the WNT in April 2018 and published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation
Project 4.109: DRP on the Miniaturized versions of the Bacterial Gene Mutation Test	
Lead: Inclusion in work plan**:** Project status and milestones:	Belgium/United States/Netherlands 2016
• Retrospective validation/ Consolidation of existing Ames MFA data; Scientific peer review of existing data (2016 -2017); • Prospective validation if needed; Generation of additional data based on the outcome of the retrospective validation process; • Kick off meeting organised on 28 February - 1 March 2017 at OECD; • Start writing the draft DRP (Q2 2017); • Call for data sent Q1 2018;	

• Analysis of the collected data Q2-Q3 2018; • Expert group meeting Q1 2019 to move forward with the development of the DRP in the light of the results from the retrospective analysis.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Miniaturised Ames Test
Project 4.111: Update of the repeated dose oral toxicity 90-day study (OECD TG 408) with parameters for ED	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2016
• Completed, the updated TG 408 was approved at the WNT in April 2018, and published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Reproductive Toxicty Testing
Project 4.112: Updated TG 492 on Eye Irritation testing using RhCE for LabCyte method	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2017
• Completed, the draft updated TG 492 was approved at the WNT in April 2018, and published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin and Eye Irritation Testing.
Project 4.113: New TG on Vitrigel test method for Eye Irritation Testing	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2017
• Validation and peer-review completed; • A presentation was given at the November 2017 meeting of the Expert Group, providing opportunities to raise issues and provide clarifications; • The draft TG and supporting documents are expected from the lead country in July 2018 and will be circulated for comemnts.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin and Eye Irritation Testing.
Project 4.114: Inclusion of laser-light based opacitometer (LLBO) in OECD TG 437	
Lead: Inclusion in work plan**:** Project status and milestones:	Belgium 2017
• Nov. 2017: lead country organisation presented experimental validation of the LLBO performance; issues identified and addressed at the February 2017 teleconference of the Expert Group; additional experiments will be undertaken in the UK and the US to gain confidence in the transferability of the proposed method. • Intercalibration work between the change of device still on-going in 2018.	

Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin and Eye Irritation Testing.
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 2017
Tele-conference meetings (at least 4): • Expert group 1st TC: Sept. 2018. Objective: to present supporting data (see attachment 1 under 'Essential Information' section) for updating/revising OECD TG / GD / GN[1] and relevant national/regional recommendations/approaches developed since implementation of the OECD TG428. Proposal for draft updated/revised TG / GD / GN will be presented. • Expert group 2nd TC: Q3-Q4 2018. Objective: to respond to comments received on proposed draft updated/revised TG / GD / GN and to present additional data available in other Countries. This is identified as critical step of the project, depending on data availability at Country/Organisation level, that could possibly impact on the project planning (i.e. additional TC needed and/or more time needed by the expert group for new data analysis) and the final deadline (updated OECD documents finalisation/publication). • Expert group 3rd TC: Jan 2019. Objective: to agree on the draft updated/revised TG / GD / GN for OECD/associated bodies commenting rounds (information on this step of OECD process is needed to refine the planning). • Expert group 4th TC: May 2019. Objective: to revise comments received and finalise updated/revised TG / GD / GN (to be ready for publication by July 2019).	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Dermal Absorption or Expert Group on skin irritation.
Project 4.116: PBTG on Defined Approach(es) for Skin Sensitisation	
Lead: Inclusion in work plan**:** Project status and milestones:	EC/US/Canada 2017
Key milestones: • Whitepaper characterising international regulatory requirements for skin sensitisation testing, by region (completed); • Whitepaper communicating ICATM workshop outcomes and recommendations (completed); • Carry out analysis of current animal test (LLNA) data to determine performance thresholds for acceptance based on i) reproducibility of the animal test and ii) concordance with human data, where available (presented at the Special session of WNT in Dec. 2017). • Propose general assessment framework (including acceptance criteria) for DAs for skin sensitisation (discussed at the Special session of WNT in Dec. 2017). • Apply assessment framework to existing DAs that have been documented in Annex 1 of the OECD Guidance Document on the reporting of Defined Approaches to testing and assessment	

[1] OECD test guideline (TG) 428 (2004b), OECD guidance (GD) no.28 (2004c), OECD guidance notes (GN) no.156 (2011)

for skin sensitisation (OECD GD 256) and other candidate approaches and individual test methods (underway, Q1-Q2 2018). • Evaluate the feasibility of incorporating DAs (and individual test methods) in the PBTG on the basis of the defined acceptance criteria (Q3 2018). • Draft PBTG with DAs (and individual test methods) that have proven to be adequate for inclusion (Q4 2018). • Dedicated Expert Group established, face-to-face meeting scheduled for 6-7 December 2018 at OECD.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin sensitisation
Project 4.117: Update of TG 442D on In Vitro Skin Sensitisation ARE- Nrf2 Luciferase Test Methods, including LuSens	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany 2017
• Completed, the updated TG 442D was approved at the WNT in April 2018 and published in June 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin Sensitisation
Project 4.118: Update of TG 442D on in vitro skin sensitization using animal-free serum and validation of TG 442E using human serum and human antibodies	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom 2017
• The updated TG 442D, including the option on use of human serum, was approved at the WNT in April 2018 and published in June 2018; • The work on TG 442E will continue in 2018-2019; • A dedicated workshop on the use of human reagents in TGs will be held in early 2019.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin sensitisation
Project 4.119: Update of TG 455 with the introduction of a metabolic step in the ERα CALUX transactivation bioassay for ER	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2017
• Progress on on-going experiments using S9 fraction (10 chemicals, 5 positives, 5 negatives in 2 laboratories) was reported to the VMG NA (Oct. 2017); full validation report expected in 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
Project 4.120: Update of TG 458 with the introduction of a metabolic step in the AR CALUX transactivation bioassay for the detection of (anti)androgenic chemicals	

Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2017
• Progress on on-going experiments using S9 fraction (10 chemicals, 5 positives, 5 negatives in 2 laboratories) was reported to the VMG NA (Oct. 2017); full validation report expected in 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
Project 4.121: Update of Guidance Document 150 on the interpretation of standardised test for endocrine disrupters	
Lead: Inclusion in work plan**:** Project status and milestones:	Secretariat 2017
• Completed, the updated GD 150 was approved at the WNT in April 2018 and will be published in September 2018.	
Subsidiary body of the JM	WNT
Expert group	EDTA Advisory Group
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	
Can you pls insert timelines if known. Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2017
• 1st step: Detailed Review Paper of available methods and evaluation of utility and application; • 2nd step: feasibility study of the development of a Test Guideline, (timelines are not provided yet).	
Subsidiary body of the JM	WNT
Expert group	
Project 4.124: New Guidance Document on Developmental neurotoxicity (DNT) in vitro assays	
Lead: Inclusion in work plan**:** Project status and milestones:	EC (EFSA, JRC)/US/DK 2017
• OECD Expert Group established; • Kick-off meeting with the lead countries in February 2018, followed by a teleconference with the Expert group in April 2018; Next steps (timelines not provided yet for the following milestones): • Discuss the scope and outline of the guidance (anticipated in Q4, 2018); • Define fit for purpose problem formulations (anticipated in Q4, 2018); • Discuss which assays should be included, described/characterised in the guidance (February 2018);	

• Discuss how the data produced by the assays should be integrated, interpreted/used and provide guidance (anticipated in Q2, 2019); • Discuss a tiered approach for testing and assessment and provide guidance. Tiered approach will be based on IATA and tailored on problem formulations (anticipated in Q3, 2019); • Develop case studies. Case studies' proposals have been submitted to Secretariat and will be reviewed in June 2018. The case studies will be completed once the data will be generated (anticipated in Q3, 2019).

Subsidiary body of the JM	WNT
Expert group	Expert Group on DNT

Project 4.125: DRP on the ToxTracker assay: a stem cell-based reporter assay for mechanistic carcinogenicity hazard assessment	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2017
• In 2017 we 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.	

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

Project 4.126: The Amino acid Derivative Reactivity Assay (ADRA): An In Chemico Method for Identifying the Skin Sensitisation Potential of Chemicals	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2018
• ADRA will undergo an independent peer review organized by JaCVAM during 2018, JaCVAM recommendations will be issued four to six months after completion of the peer review. • Since both the ADRA and DPRA test methods detect the same endpoints, we consider it desirable that the existing DPRA test guideline No. 442C be proposed as a Key Event Based Test Guideline, addressing the first Key Event on the AOP for skin sensitisation, which encompasses both the DPRA and ADRA test methods. Annex 1 will comprise DPRA and Annex 2 will comprise ADRA.	

Subsidiary body of the JM	WNT
Expert group	Expert Group on in vitro methods for skin sensitisation

Project 4.127: Inclusion of the LabCyte EPI-MODEL24 skin corrosion test in OECD Test Guideline 431	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2018
• A 'me-too' validation study of the LabCyteEM24 SCT was performed from February to November 2017, in accordance with the performance standard for OECD TG 431. • The validation study report will be prepared by February, 2018.	

• An evaluation of the validation study by an independent peer review panel of international experts is being planned to start in early June 2018.for the LabCyteEM24 SCT method will be planned. • The LabCyte EM24 will be proposed for in inclusion in the OECD TG 431 at the expert meeting in November 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin irritation/corrosion
Project 4.128: Revision of TG 432: In Vitro 3T3 Neutral Red Uptake Phototoxicity Test	
Lead: Inclusion in work plan**:** Project status and milestones:	OECD Secr.+ EG skin irritation testing 2018
• May – August 2018: draft revisions to TG 432; • September 2018: circulation of revised draft TG 432 to Expert Group in Skin and Eye Irritation and Expert Group in Phototoxicity for comment; • September 2018: teleconference with Expert Groups (if needed); • November 2018: Discussion of draft revisions at Expert Group on Skin and Eye Irritation meeting; • December 2018: teleconference with Expert Groups (if needed); • January 2019: circulation of final draft revised TG; • April 2019: submission for approval of revised TG at WNT meeting.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin and eye irritation/corrosion/phototoxicity
Project 4.129: Revision of OECD TG 439 as a Performance-Based Test Guideline, and include two new me-too Reconstructed human Epidermis test methods – Skin+ and epiCS	
Lead: Inclusion in work plan**:** Project status and milestones:	France/Germany 2018
• End April 2018: Approval of the SPSF & integration of me-too assays by OECD WNT; • Summer 2018: Circulation of the peer-review reports of the validation studies and distribution of the revised TG 439 for review and comments;	
Subsidiary body of the JM	WNT
Expert group	Expert Group
Project 4.130: Amendment to OECD Test Guideline 437 BCOP that includes a histopathological examination to revise the Decision Criteria for classification of chemicals requiring classification for eye hazard	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2018
• Spring 2018: if all the data supports inclusion in TG 437, Japan and IIVS will submit all the available results;	

• Japan will share some of the BCOP histopathological slides to IVIS and VITO, Belgium for between laboratory reproducibility and peer review; • Autumn 2018: submission of the additional report on between laboratory reproducibility of this proposal to EWG • Spring 2019: submission of draft revised OECD Test Guideline 437 to WNT.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin and eye irritation/corrosion
Project 4.131: Addition of the MCTT-HCETM Eye Irritation Test to the OECD Test Guideline 492 Validated Reference Method	
Lead: Inclusion in work plan**:** Project status and milestones:	Korea 2018
• Expert Group to hold a teleconference in June 2018 and discuss with Korea how to proceed, based on the validation and other supporting information, in preparation for the EG meeting in November 2018.	
Subsidiary body of the JM	WNT
Expert group	Expert Group Expert Group on skin and eye irritation/corrosion
Project 4.132: A feasibility study for establishing TGs for in vitro human hepatic metabolic clearance and metabolite formation	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2018
• Formation of an expert group Q3 2018 (NL proposes to form an expert group for toxicokinetics) • Alignment of the set-up of the feasibility study with the draft guidance document for hepatic clearance (4.122) in close contact with EURL ECVAM Q3 2018 • Inventory of available databases and literature with hepatic clearance data for evaluation Q3+4 2018 • Circulate a first draft of the feasibility study report and commenting rounds Q1 2019 • Circulate a revised draft report Q2 2019 • Approval of final document Q4 2019-Q1 2020.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on *in vitro* TK methods

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:	United States through the WG Biocides 2007, revised in 2010

Project status and milestones:	
Four new Test Guidelines based on the protocols in the current Guidance Document on quantitative methods for evaluating the activity of microbicides used on hard non-porous surfaces, which was approved in 2013. Protocols are quantitative methods for evaluating bactericidal, mycobactericidal, fungicidal and virucidal activity of microbicides used on hard non-porous surfaces. • Expert meeting (teleconference) of Expert Group on Efficacy of Microbicides on Hard Surfaces held in March and October 2016, discussing the draft TGs dealing with the bactericidal and mycobactericidal protocols. • Aim is to finalise these two draft TGs in the Expert Group in 2017/2018, followed by commenting by WGB and WNT. • Draft TGs for fungicidal and virucidal activity of microbicides will be developed after finalisation of the bactericidal and mycobactericidal protocols.	
Subsidiary body of the JM	WNT & WGB
Expert group	Expert Group on Efficacy of Microbicides on Hard Surfaces
Project 5.9: Revision of GD on Crop Field Trials and new GD on residues in rotational crops	
Lead: Inclusion in work plan: Project status and milestones:	Germany and Australia through the WG Pesticides 2008
• Completed and documents have been published. • Second Edition Guidance Document on Crop Field Trials. Series on Pesticides No. 66 / Series on Testing and Assessment No. 164. ENV/JM/MONO(2011)50/REV1 , ENV/JM/MONO(2011)50/REV1/ANN • Guidance Document on Residues in Rotational Crops. Series on Pesticides No. 97/ Series on Testing and Assessment No. 279. ENV/JM/MONO(2018)9.	
Subsidiary body of the JM	WNT & WGP
Expert group	Expert Group on Residue Chemistry
Project 5.10: New GD: Testing Efficacy of Porous and Non-Porous Treated Articles	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2011 Tier 2 activity: laboratory-based tests to substantiate claims for treated articles
• Completed, the Guidance Document was approved at the WNT in April 2018 and will be published in June 2018.	
Subsidiary body of the JM	WNT & WGB
Expert group	EBTA
Project 5.16: Guidance Document on Laboratory Assays for Evaluating the Efficacy of Biocides against Bed Bugs	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2015
• Germany replaces United States as lead country for this project. • Oct 2017 – May 2018 - revision of the draft guidance document "Draft Product Performance Test Guidelines OCSPP 810.3900: Laboratory Testing Methods for Bed Bug Pesticide Products" proposed by the EPA in 2012. • May 2018 – 1st draft GD for WNT commenting	

• Oct 2018 – 2nd revised draft GD for WNT commenting • 2019 WNT approval expected.	
Subsidiary body of the JM	WNT & WGB
Expert group	(no expert group active on this project)
Project 5.17: Guidance Documents on Testing the Efficacy of Baits against Tropical Ants	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the WG Biocides 2017
• March – May 2018 Laboratory testing • May 2018 – Jun 2018 Evaluation of Test results • July 2018 – first draft GD for WNT commenting • 3rd quarter 2018 – second revised draft GD for WNT commenting • 2019 WNT approval expected.	
Subsidiary body of the JM	WNT & WGB
Expert group	(no expert group active on this project)

ANNEX 1

PROJECTS THAT ARE NO LONGER SUPPORTED

Project 4.122: Guidance Document on hepatic clearance test methods	
Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2017
• An *ad hoc* expert group will be established to scope out and develop the Guidance Document (GD). Meetings will mostly be held by TC / web conference, with sharing of documents via the OECD Clearspace; • Circulate the outline of the Guidance Document to the *ad hoc* expert group once established (July 2018); • Circulate a first draft GD to expert group in Q4 2018 • Circulate a revised draft GD to expert group in Q2 2019 • 2 commenting rounds at WNT level Q3-Q4 2019 • Final GD submitted to WNT for approval in April 2020.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Metabolism