August 2017

Work plan for the Test Guidelines Programme (TGP)

(As of August 2017)

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

August 2017

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:	TFB 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formed through the Task Force on Biocides, the proposed Guidance Document will be discussed via conference calls; • A draft Guidance Document is expected to be available in the 3rd to 4th quarter of 2017.	
Subsidiary body of the JM	TFB/WNT
Expert group	Chemistry Expert Working Group/TFB

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

Project 2.33: New TG for a Protozoa Activated Sludge phagocytosis inhibition Test	
Lead: Inclusion in work plan: Project Status and milestones:	Germany 2009
• TG approved and validation report endorsed at WNT-29 in April 2017.	
Subsidiary body of the JM	WNT
Expert group	---
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. • Phase 2 validation report expected to be finalised in Q2 2017, pending statistical analysis in Q2 2017. • Draft TG and Phase 2 validation report will be sent to experts for discussion at VMG-Eco meeting in 2017.	

August 2017

• January 2018: Sending to WNT for the first commenting round on draft TG.	
Subsidiary body of the JM	WNT
Expert group	VMG-Eco

August 2017

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 will submit a phase 1 validation report in 2017 for discussion at VMG-Eco.	
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 2018-2019: : 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 2.48: New TG on Honey Bee chronic toxicity test (10-day feeding)	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany 2014
• TG approved and validation report endorsed at WNT-29 in April 2017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on honeybee/bumblebee 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.
- Lead countries and Secretariat will establish a path forward in the course of 2017..

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

- A workshop (non OECD event) was held in July 2014 to discuss technical aspects of preparing stable stock and test solutions and monitoring nanomaterial behaviour during the test.
- A teleconference was held on 19 January 2016 to reach an agreement on an internal draft guidance document and subsequent round-robin evaluations;
- Workgroup revised draft GD in February and March 2016; comments incorporated June – July 2016; new draft to workgroup and international conference call July/August 2016.
- Draft available for external review in June 2017 by WNT expert group and then NCs.

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

Project 2.53: New TGs on Bumble Bees Toxicity Testing

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

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- 2 TGs approved and validation report endorsed at WNT-29 in April 2017.

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

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

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

- Development of a first draft Guidance Document including the FET in the threshold approach for acute fish toxicity testing (GD 126) in mid-2016, discussed by the VMG-eco in October 2016;
- Diverging views on the robustness of the FET, to be included in GD 126, were presented during the VMG-Eco meeting in October 2016.

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- 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 mid-2017. 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 in the last quarter of 2017.
- 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

- Part 1 is divided into Parts 1A and 1B as follows:
  - Part 1A: update of Section 3.1 of GD 23
  - Part 1B: update of the remaining sections of GD 23.
- Following discussions at WNT 2016, the US will lead Part 1B and EC will lead Part 1A and Part2.

Part 1A: Update of Section 3.1

- June 2015: Ad-Hoc Expert Group established a project kick-off TC in July 2015 for Part 1A
- July – September 2015: literature search and TCs with experts to update Sections 3.1 and introductory paragraphs of Section 3. Section regarding flow-through systems added to section 2.
- Project update at Validation Management Group (VMG)-eco meeting in October 2015
- December 2015 - February 2016: 1st WNT commenting round of revised GD23 Section 3.1.
- Project update at VMG-Eco meeting in October 2016
- October 2016 - May 2017: Review and update Section 3.1 of GD 23

Part 1B: Update of the remaining sections

- June 2016: Teleconference to initiate Part 1B
- Autumn 2016: Ad-Hoc Expert Group for Part 1B established
- October 2016: Project Kick-off for Part 1B
- Project update at VMG-Eco meeting in October 2016
  October 2016 - May 2017: Review and update remaining sections of GD 23

Preliminary timelines for Part 1A and 1B

- June 2017: Section 3.1 and the other sections will be combined in one document. The responses to comments from the 1st WNT commenting round will be combined in one document
- July 2017: 2nd WNT commenting round planned
- Discussion at (VMG)-eco meeting 2017
- November 2017: 3rd WNT commenting round planned
- Finalisation of GD23 update
- Updated GD23 presented to WNT for approval in April 2018.

Part 2: Detailed Review Paper of use of controls in ecotoxicity tests

- Consolidation of historical data, assessment of data and generation of statistical simulations as necessary. Meetings will take place by teleconference as necessary. Data collection and statistical analysis will first focus on OECD TG 210
- June 2015: Ad-Hoc Expert Group established and preliminary discussions during kick-off TG in July 2015
- August 2016: Finalization of templates for data collection.
- Data collection for OECD TG 210 is ongoing.
- Presentation of data analysis to VMG-Eco/Fish Drafting Group, drafting of the DRP and WNT commenting round(s) will take place after Part 1 of the project is complete.
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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 2016-2018.
- A draft report of the phase 1 validation will be prepared and submitted to existing expert groups (FDG and/or VMG-eco) in early 2017.
- 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 2017.
- 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 2018.
- Revised draft guidance document and validation reports will be delivered by the end of 2018/ the beginning of 2019 for WNT commenting.
- Final draft guidance document will be submitted to the WNT in 2019.

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 October2016. Participation of laboratories to ring-test will be organized by lead laboratory.
- Inter-laboratory validation will be conducted in 2017.
- 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 autumn 2017.
- Revised draft test guideline and validation reports will be delivered by the end of 2017/ the beginning of 2018 for WNT commenting.
- Final draft Test Guideline will be submitted to the WNT in 2018. (earliest)

• 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 (running tests) • July to December 2016: Data analysis of the ring test results 2016; • January 2017: Meeting of working group to deliver overall results; • • May to August 2017: 2nd ringtest • August to December 2017: Data analysis of the ring test results; • January 2018: Meeting of working group to deliver overall results; • January to May 2018: Test Guideline proposal discussed within the ring test group, then, in the expert group ; • May 2018: Sending to WNT for the first commenting round on draft TG; • December 2018: Second commenting round on draft TG. • Possible approval at WNT 31 (April 2019).	
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
• Q3-Q4 2017: availability of a written protocol; • Q3-Q4 2018: validation exercise completed using 5 pro-androgenic, 5 anti-androgenic and 5 inert compounds (18 months after start date); • 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

August 2017

Expert group	VMG-Eco

SECTION 3
PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE

Project 3.7: New GD for the revised OECD TG 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany, Netherlands, United Kingdom 2012
• Guidance document approved at WNT-29 in April 2017. The R package and the user manual will also be published.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on TG 305 update
Project 3.8: Test Guideline on agglomeration behaviour of nanomaterials in different aquatic media	
Lead: Inclusion in work plan**:** Project status and milestones:	Germany 2014
• TG approved and validation report endorsed by WNT-29 in April 2017.	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on environmental fate testing
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 • July 2017 – November 2017 Conceptual development of the draft Guidance Document • December 2017 - May 2018 Meeting of the Expert Group, 1st draft GD for WNT commenting round	
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
• May to Nov. 2014: drafting of new TG on dissolution rate of nanomaterials;	

- Nov. 2014 to June 2015: draft TG distributed to volunteer laboratories for round-robin evaluation of the protocols proposed;
- September 2015: WNT Expert Group Meeting was held in Paris
- Ring test planned to start in January 2016;
- 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 are being addressed/ incorporated in the latest version;
- Data collection beginning in February following the protocol; testing CuO, AgNP predispersed (75 nm), powdered 20 nm AgNP;
- Project is 2-3 months behind schedule.
- October/December 2016 – discussions planned 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, is expected to be available in January 2017 after which validation of the method is intended to start in the course of 2017.

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, 2016 - The round robin data set for the gold nanoparticle will be assembled and analysed by the research group;
- September 2016 - February, 2017 - The research group will complete any necessary adjustments to the draft TG and create a properly formatted document for the OECD nano-expert group
- March, 2017 - A teleconference will be held where the chairs can become acquainted with the nano experts. A revised work plan and schedule will be discussed. The experts will be asked to provide additional nano and non-nano topics to be considered for inclusion in the TG. Leads will be assigned to revise the TG.
- April, 2017 - Working drafts of the revised TG are shared with the Expert Group one week prior to a teleconference when the revisions will be discussed. Leads will be assigned to draft text for the TG.
- June to October, 2017 - As necessary, additional teleconferences will be held.
- October, 2017 - A final teleconference will have the primary goal of achieving consensus on revisions to the TG. The goal is to complete revisions to the document; but if additional issues are raised, assignments will be made to research the issues and draft text for further consideration by the Expert Group.
- December, 2017 - Submission of the revised TGs and GDs to the WNT for approval.

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

- 1st Draft Guidance was prepared in October 2015 but it was not considered to be ready for WNT commenting;

- Since then a number of efforts have been made by the leads to: i) review the existing methodologies considered in the document; and ii) to do some *ex-vivo* bioaccumulation tests and ICPMS analysis that will be peer reviewed and published in the coming months.
- Based on the above work, and taking into account the recently approved GD for the OECD TG 305 (Project 3.7), a revised draft is being developed and will be made available at the end of August 2017.
- The draft will be circulated for comments to the Expert Group (September/October 2017)
- A revised draft will be prepared for a WNT commenting round in November 2017.
- It is expected to submit the Draft GD for approval to the WNT in 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

- Formation of an OECD *Ad Hoc* Expert Group to oversee planning and conduct of the definitive multi-laboratory ring trial (May 2014);
- 1st Teleconference call of OECD Ad Hoc Expert Group in vitro Fish Hepatic Metabolism in August 2014 to discuss validation plan;
- Discussion of validation plan at VMG-eco meeting in December 2014;
- multi-laboratory ring trial in November 2014 - September 2015;
- Data analysis in Q4 2015 – Q2 2016;
- F2F meeting of trial participants in Q4 2015
- Drafting of ring trial report, guidance document & 1st draft TGs in Q3 2016;
- Discussion of ring trial report, guidance document & 1st draft TGs with OECD Ad Hoc Expert Group in vitro Fish Hepatic Metabolism Q4 2016
- Discussion of progress and next steps during VMG-eco meeting in October 2016; subsequently during a teleconference with WNT expert group in January 2017.
- First WNT commenting round of TGs, validation report and guidance document initiated in April 2017;
- Discussion at VMG-Eco meeting in October 2017;TGs, guidance document finalization & submission for WNT approval (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

- May/June 2017: Drafting of Guidance Document based on the comments received within the project team;
- Nov 2017: First draft GD for submission to WNT for commenting;
- WNT 2018 approval (earliest) or 2nd commenting round.

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

SECTION 4
PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS

Project 4.2: New TG 433: Fixed Dose Procedure as Alternative to TG 403	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom 2001
• TG approved at WNT-29 in April 2017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Acute Toxicity Testing
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
• The EC has the lead in drafting a PBTG on ARTAs, including the adopted TG 458 (ARTA using EcoScreen cells), the AR-CALUX method (validation study ongoing and coordinated by EURL ECVAM), the ARTA using 22Rv1/MMTV-GR-KO cells (validation study ongoing, project 4.99 on the work plan [Korea]). • Validation study of the AR-CALUX method expected to be completed in early 2018 and draft validation report available in 2018.	
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, lead will evaluate options on how to proceed with the project.	
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; • Status report on analysis of studies in early 2016: issues reported with the lack of effects at doses tested in contract laboratories, which is problematic for the determination of BMD;	

• Project to be reviewed at WNT in 2018.	
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; • New updated TG 488 will be prepared when other genotoxicity TGs are updated; • Additional germ cell research is now in progress and it is anticipated that a draft revised TG, if necessary, would be ready for a first WNT commenting round in Q32017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Genotoxicity Testing
Project 4.79: Revision or replacement of TG 402 on Acute Dermal Toxicity Test	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom 2014
• Updated TG 402 approved at WNT-29 in April 2017. •	
Subsidiary body of the JM	WNT
Expert group	Expert group on Acute Toxicity 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. • A proposal for an updated GD 39 was shared with the WNT in April 2017, together with comments collected, issues identified will be discussed during a meeting of the Expert Group in Q3 2017 at OECD (dates to be determined).	
Subsidiary body of the JM	WNT
Expert group	Joint WPMN/WNT Expert Group on inhalation toxicity testing
Project 4.86: A new TG on SkinEthic™ Human Corneal Epithelium (HCE) Eye Irritation Test (EIT) for identifying chemicals not requiring a classification for eye irritation or serious eye damage under UN GHS	
Lead: Inclusion in work plan**:** Project status and milestones:	France 2015
• Updated TG 492 and Performance Standards Document approved at NT-29 in April 2017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Eye Irritation

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; no draft document has yet been circulated/made available at the OECD level. In November 2016, the lead experts agreed to provide all necessary information to OECD for review by countries later in 2017.	
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
• Q2 2015: o Final report of the A.I.S.E. *in vitro* ICE test method programme circulated to the OECD Expert Group on Eye Corrosion/Irritation o A proposed revision of the Test Guideline 438 to incorporate histopathology as an additional endpoint for classification of non-extreme pH and extreme pH detergent and cleaning products and surfactants circulated to the Expert Group for commenting. • November 2015: a meeting of the OECD expert group on eye irritation/corrosion was held to address comments and further revise draft Test Guideline 438 to incorporate histopathology as an additional endpoint; • The lead country will continue efforts to collect data to support the validity of histopathology as an endpoint in TG 438 in 2016; • Q3 2016: Process and incorporate suggestions and adaptions to the proposed addendum to TG 438; • Q4 2016: The analysis of reproducibility of the additional measures was not available to the expert group in November 2016; when the analytical report is available form the lead country it will be circulated, together with a proposal for an updated TG 438 to experts; further analyses underway, the outcome of which will be presented at the Expert Group meeting in November 2017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Eye Irritation
Project 4.89: Proposed Revision to OECD Guidance Document No. 160 on the Isolated Chicken Eye Test (including Histopathology)	
Lead: Inclusion in work plan**:** Project status and milestones:	Netherlands 2015
• Updated Guidance Document 160 approved at WNT-29 in April 2017.	

Subsidiary body of the JM	WNT
Expert group	Expert Group on Eye Irritation
Project 4.90: GD on IATA for Serious Eye Damage and Eye Irritation	
Lead: Inclusion in work plan**:** Project status and milestones:	United States/ European Commission 2015
• Guidance Document approved atWNT-29 in April 2017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Eye Irritation
Project 4.91: IL-8 Luc assay: An In Vitro Method for Identifying the Skin Sensitisation Potential of Chemicals	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2015
• TG approved at WNT-29 in April 2017; the TG will be merged with in TG 442E.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin Sensitisation
Project 4.92: Myeloid U937 Skin Sensitization Test (U-Sens) for identifying skin sensitization potential of chemicals	
Lead: Inclusion in work plan**:** Project status and milestones:	France 2015
• • TG approved at WNT-29 in April 2017; the TG will be merged with in TG 442E.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin Sensitisation
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
• Expert Working Group (EWG) formed (Q2 2015); • Prepare draft DRP and validation/RPA document: Q2 2015-Q4 2017; • Public commenting on draft DRP and validation/RPA document, revision as necessary: Q3 2017- Q1 2018; • DRP expected to be finalised Q2 2017, before RPA document and might be circulated for comments 1st, as ready. • Upon WNT approval of DRP/validation/RPA, prepare draft TG: Q2 2018-February 2019; • Public commenting on draft TG, revision as necessary: February 2019-November 2019; • Submit revised TG to WNT: November 2019; TG considered by WNT 2020.	
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 overview paper on available alternative methods in the area on non-genotoxic carcinogenicity, circulated in January 2016 to the expert group for their review;
- Kick-off face-to-face meeting: 30-31 March 2016; second meeting held on 29-30 March 2017 at OECD;
- Expert Group to continue working on the development of the IATA document through 2017; next face to face meeting to take place in 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 work on the definition of the most appropriate parameters needed for a good protocol and interlaboratory comparison study of the optimised protocol in 2015-2016. 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.
- <u>At the moment</u>, all 5 selected nanomaterials (2x silver NPs, 2x gold NPs and 1x silica NPs) were characterised for their physical-chemicals properties in the pristine form, as well as suspended in the 5 cell culture media. Dosimetry calculations and modelling will follow soon. 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 of the 5 NPs in all 5 cell lines are now underway.
- <u>Next steps</u>: Once the results from physical-chemical and cytotoxicity are complete, we will provide them in a mid-term report (most probably after 2017) since the expert group recommended to discuss these data and to choose the optimal condition for the NPs uptake experiments. After that discussion with the experts, we will proceed with the NPs uptake experiments that can last up to 6 months. This will end the first phase of the project and the results should enable the expert group 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 Retinoic Acid Pathway

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

- <u>2015-2017:</u> Drafting of the retinoid DRP with focus on the RAR-RXR; PPAR-RXR; and VDR-RXR signaling and metabolic pathways.

<table>
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Initial literature search (month 6)
Kick-off workshop (month 8)
Detailed time-planning for the RAR-RXR part of the DRP (month 9)
Time-plan for the initial PPAR and VDR parts of the DRP (month 10)
Time-plan for RSE and AOP efforts for the RAR-RXR part of the project (month 10)

These are all internal steps and the project will really start at OECD level with some exchange and discussions in 2017; a progress report will be presented at the EDTA Advisory Group meeting in May 2017 at OECD.

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<tr><td>Subsidiary body of the JM</td><td>WNT</td></tr>
<tr><td>Expert group</td><td>(No expert group yet active) EDTA AG</td></tr>
<tr><td colspan="2">Project 4.98: EDTA Activity: developing a list of reference chemicals for E-A-S metabolism</td></tr>
<tr><td>Lead:
Inclusion in work plan:
Project status and milestones:</td><td>United Kingdom
2015</td></tr>
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Q4 2017: Preparation of a discussion paper for the VMG-NA.

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<tr><td>Subsidiary body of the JM</td><td>WNT</td></tr>
<tr><td>Expert group</td><td>VMG-NA</td></tr>
<tr><td colspan="2">Project 4.99: EDTA Activity: New TG on Androgen Receptor Transactivation Assay</td></tr>
<tr><td>Lead:
Inclusion in work plan:
Project status and milestones:</td><td>Korea
2015</td></tr>
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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 Q3 2017.

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<tr><td>Subsidiary body of the JM</td><td>WNT</td></tr>
<tr><td>Expert group</td><td>VMG-NA</td></tr>
<tr><td colspan="2">Project 4.100: EDTA Activity: Feasibility study for minor enhancements of TG 414 (Prenatal Developmental Toxicity Study) with ED-relevant endpoints</td></tr>
<tr><td>Lead:
Inclusion in work plan:
Project status and milestones:</td><td>Denmark
2015</td></tr>
<tr><td colspan="2">

2015: Teleconference with Expert group in November 2015 to kick-off the feasibility study;
2016: Data collection to support the feasibility study, carried out by Denmark;
2017

Teleconference of the Expert Group to discuss the outcome of the study and recommendation for amendments in the TG ;
Draft final revisions as appropriate, and organise commenting rounds until the end of 2017;

2018: if proposed modifications are supported by the group, submission of the draft updated TG 414 to WNT for approval.

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<tr><td>Subsidiary body of the JM</td><td>WNT</td></tr>
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August 2017

Expert group	Expert Group on Reproductive Toxicity Testing
Project 4.101: EDTA Activity: Exploring the Concept of Developing Pathway-Based Test Method Performance Metrics: a Case Study Using Estrogen Receptor Signalling for a Computational Model	
Lead: Inclusion in work plan**:** Project status and milestones:	United States 2015
• Discussion of project by existing expert group, EDTA (composed of lead and participating organizations): October 2015 • Discussion of project by existing expert group, VMG-NA (composed of lead and participating organizations): December 2015 • Review of assay data and reference chemicals for consistency of performance across key events in the ER Pathway: early 2016 • Discussion at VMG-NA: Nov 2016 • Decision from EDTA and VMG-NA regarding the feasibility of using the proposed approach to develop a Guidance Document for methods assessing ER Pathway activity: 2017; • Submit SPSF for TG to WNT, if supported by EDTA and VMG-NA: 2018.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA
Project 4.104: Development of Guidance on good in vitro method practice	
Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2015
• Formation of a drafting group to contribute to ECVAM's endeavor to develop the first draft for review Q3-Q4 2016. • Draft document was circulated to the joint expert group and WNT/WG GLP in late 2016 for a review/commenting round; • Expert Group meeting was held to address outstanding comments in March 2017. • Second commenting round is expected in fall 2017. • Final document is expected to be submitted for WNT approval 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 will submitted a draft Test Guideline by Q4 2016; • The Expert Group on skin and eye irritation discussed this assay at their November 2016 meeting if possible. • The draft Test Guideline was circulated to WNT comment and nomination of phototoxicity experts in December 2016; phototoxicity testing will be on the agenda of the next meeting of the skin and eye irritation expert group in November 2017 at OECD.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on skin and eye irritation

Project 4.106: New TG: Genomic Assay 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 validation report Q4 2017; • ECVAM Recommendation available in 2018.	
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 by ESAC to be organised in 2017; • Depending on the outcome of the peer review, circulation of the draft TG to the WNT in 2017 or 2018.	
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
• Plan to conduct peer review after proposal is included in the TGP Work Plan for 2016; • Draft Test Guideline prepared in July 2016; • Q4 2016: Peer review panel to evaluate the within- and between-laboratory reproducibility and predictive capacity of the LLNA: BrdU-FCM; peer review report submitted in December 2016; • Revision of TG 442B submitted to expert group in May 2017; • 1st circulation of the draft TG for comments possibly by the summer 2017.	
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).	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Miniaturised Ames Test
Project 4.110: Stakeholder workshop on integrated testing strategy for developmental neurotoxicity (DNT)	
Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2016
• Workshop completed and report published as No. 261 in the OECD Series on Testing and Assessment.	
Subsidiary body of the JM	WNT
Expert group	N/A
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
Workplan/time line • Discussion of a draft updated TG 408 at the EDTA AG meeting in May 2017; if positive feedback on the proposed additional endpoints, a WNT commenting round will be organised mid-2017, and approval of the draft updated TG 408 via written procedure will be sought in 2017.	
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
• Validation and peer-review completed; • Draft updated TG 492 available possibly by the end of summer 2017, so that an Ad Hoc Expert Group can discuss inclusion of LabCyte24 EIT in OECD TG 492 at their meeting in November 2017.	
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; • Draft new TG available possibly by the end of summer 2017, so that an Ad Hoc Expert Group can discuss the draft new TG at their meeting in November 2017.	
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
Autumn 2017 • VITO nv will present at the OECD eye irritation EWG: Presentation, discussion and approval of all results (Performance Standards/validation study) and suggestion for the draft revised version of TG 437. • Submission of a draft revised version of TG 437 to WNT. • Commenting round by WNT. **April 2018** • Submission of revised OECD Test Guideline 437 to WNT.	
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: June 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: Sep 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.

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

August 2017

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 (Underway). • Whitepaper communicating ICATM workshop outcomes and recommendations (Underway). • 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 (Q1-Q3 2017 - for discussion at the expert group meeting in November 2017). • Propose general assessment framework (including acceptance criteria) for DAs for skin sensitisation (Q3 2017 - for discussion at the expert group meeting in November 2017). • Apply assessment framework to existing DAs that have been documented in Annex 1 of the OECD Guidance Document on the reporting of Defined Approaches to testing and assessment for skin sensitisation (OECD GD 256) and other candidate approaches and individual test methods (Q1-Q2 2018). • Consultation with the WNT on the outcome of the assessment described in the bullet point above and evaluate the feasibility of incorporating DAs (and individual test methods) in the PBTG on the basis of the defined acceptance criteria (Q3 2018). • Submission to the WNT of a draft PBTG with DAs (and individual test methods) that have proven to be adequate for inclusion (Q4 2018).	
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
Spring 2017 - Submission of revised SPSF and a draft revised version of TG 442D **Summer 2017** - Second draft revised version of TG 442D based on OECD comments, and - if applicable, first draft revised version of Performance Standards (PS) (No.213 in Series on Testing and Assessment) **Autumn/winter 2017** - Final revisions to the draft revised TG 442D made available for approval by the WNT, and if applicable, second and final revisions to PS made available for approval by the WNT.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on Skin Sensitisation

August 2017

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
• Circulation of proposal to update TG 442D to WNT and Expert Group for review/comments; • If comments do not impede, the TG 442D will be approved via written procedure in Q2 2017; • Validation of TG 442e using human serum and human antibodies: raising funding 2017; initiation of validation in 2 additional labs 2018: peer review of validation report Q4 2018, presentation to WNT in 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
• The results of on-going experiments (10 chemicals, 5 positives, 5 negatives in 2 laboratories) will be reported to the VMG NA (December 2017).	
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
• The results of on-going experiments (10 chemicals, 5 positives, 5 negatives in 2 laboratories) will be reported to the VMG NA (December 2017).	
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
• presentation and request for early input at the May, 2017 EDTA meeting; • draft updated document for review September 2017, • additional round of comment from the EDTA AG in late fall 2017, • final draft in early 2018.	
Subsidiary body of the JM	WNT
Expert group	EDTA Advisory Group

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 a first draft of the GD by Q4 2017; • Discuss first draft in the ad-hoc expert group; • Circulate a revised draft by April 2018; • Commenting rounds Q2 2018; • Approval of final document Q4 2018-Q1 2019.	
Subsidiary body of the JM	WNT
Expert group	Ad hoc Expert Group on Metabolism
Project 4.123: Review and feasibility of an Embryonic Stem Cell Test: In vitro assay detecting disruption to differentiation of rodent embryonic stem cells into cardiomyocytes using the Hand1 gene	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2017
• 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)/US/DK 2017
• Establish an Expert Group; • Tele-conference meetings (at least 6) plus face to face meetings to address issues identified following the first commenting round (at least 2); • Discuss the scope and outline of the guidance; define fit for purpose problem formulations; • Discuss which assays should be included, described/characterised in the guidance; • Discuss how the data produced by the assays should be integrated, interpreted/used and provide guidance; • Discuss a tiered approach for testing and assessment and provide guidance. Tiered approach will be based on IATA and tailored on problem formulations; • Provide case studies. (timelines not provided yet for the above milestones)	

August 2017

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 in November 2017.	
Subsidiary body of the JM	WNT
Expert group	Expert Group on non-genotoxic carcinogenicity

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

Project 5.6: Development of efficacy Test Guidelines and Guidance Document for public health antimicrobial biocides used on hard surfaces	
Lead: Inclusion in work plan: Project status and milestones:	United States through the WG Biocides 2007, revised in 2010
Four new Test Guidelines based on the protocols in the current Guidance Document on quantitative methods for evaluating the activity of microbicides used on hard non-porous surfaces, which was approved in 2013. Protocols are quantitative methods for evaluating bactericidal, mycobactericidal, fungicidal and virucidal activity of microbicides used on hard non-porous surfaces. • Expert meeting (teleconference) of Expert Group on Efficacy of Microbicides on Hard Surfaces held in March and October 2016, discussing the draft TGs dealing with the bactericidal and mycobactericidal protocols. • Aim is to finalise these two draft TGs in the Expert Group in 2017/2018, followed by commenting by WGB and WNT. • 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
New Guidance Document on Residues in Rotational Crops: • Development of a Guidance Document on residues in rotational crops by the RCEG; the work is led by Australia. • Expert meeting of the RCEG on 7-8 July 2015, OECD, Paris. • August-September 2016: First broad commenting round of the draft GD through WNT and WGP. • Submission to WNT and WGP for approval (anticipated in 3rd quarter, 2017). • Joint Meeting declassification (anticipated in 4th quarter, 2017). •	
Subsidiary body of the JM	WNT & WGP
Expert group	Expert Group on Residue Chemistry
Project 5.10: New TG: 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
• 2014: Beginning of Tier 2 work: Development of Guidance Document on Tier 2 laboratory-based tests used to substantiate claims for treated articles. • Contract signed in December 2014 with consultant for drafting a Tier 2 test • Review of the first draft GD (including one example protocol) by the EBTA at the October 2015 EBTA meeting in Prague.	

• Final draft GD (including two example protocols) provided on 2 December 2015. • Circulation of the draft GD to WGB and WNT for a first commenting round early 2017. • Based on the outcome of commenting round possibly submitted for approval to WNT in Q2 2017.	
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. • Jul 2017 – Jan 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. • Feb 2018 – 1st draft GD for WNT commenting • Jul 2018 – 2nd revised draft GD for WNT commenting.	
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 – Nov 2017 Laboratory testing • Nov 2017 – Jan 2018 Evaluation of Test results • Feb 2018 – first draft GD for WNT commenting.	
Subsidiary body of the JM	WNT & WGB
Expert group	(no expert group active on this project)

ANNEX 1
PROJECTS THAT ARE REMOVED AFTER TWO YEARS WHEN NO LONGER SUPPORTED

Project 2.4: New TG 2-Generation Avian Toxicity	
Lead:	United States
Inclusion in work plan:	1999
Inclusion in Annex 1	2014

- Initial draft TG in 1999; decision to conduct an avian dosing study to be considered after DRP approval (Project 2.5 completed);
- Species comparison study circulated to the expert group in April 2005;
- Avian dosing study (July 2005) and revised draft TG (November 2005) presented at VMG-eco meeting in December 2005;
- Revised draft TG used in developing a protocol for a demonstration study;
- Report of the demonstration study expected before the end of 3rd quarter 2010;
- Revised SPSF expected to be submitted for the 2011 WNT meeting;
- Progress report at the VMG-eco in November 2011;
- Experimental work expected to be completed in May 2012;
- Post study/histopathology expected end 2012;
- Validation report expected in spring 2013; the US is considering the recommendations from the Science Advisory Panel meeting held in 2013.
- General discussion during the VMG-Eco in December 2014, no concrete proposals for a way forward were presented.

Project 2.13: EDTA Activity: New TG for Mysid Life Cycle Toxicity Test	
Lead:	United States
Inclusion in work plan:	2002
Inclusion in Annex 1	2014

- First proposal for a TG submitted in 2004;
- Pre-validation work completed in the U.S. in July 2005;
- Issue discussed at the 2nd Meeting of the invertebrate expert group, on 3-4 November 2005, and progress report at the VMG-eco in December 2005;
- Preliminary ring test results available. More validation needed;
- Optimisation; US may pursue a national development of the test method depending on the interest of other member countries;
- Secretariat asked the WNT whether other countries than the US were interested in the project. If no country was interested, the project would be moved to Annex 1;
- Germany expressed interest in the project;
- Depending on the validation outcome, the SPSF will be revised and other partners will be invited to participate;
- Validation work completed (At that time there may be a need for a study comparing the copepod reproduction and development test (Project 2.1) with the mysid test;
- Comparison review between copepod and mysid;

- Outcome of additional work expected discussed at the VMG-eco meeting (November 2011)
- Experimental work expected to be completed in 2nd quarter 2012;
- Integrated Summary Report expected to be available in Spring 2013;
- Draft TG circulated for a commenting round to the WNT in July 2013; the US are considering the recommendations from the Science Advisory Panel meeting held in 2013;
- Project is put on-hold given the added value of the second generation is not clear and a life-cycle test already exist in the US.

Project 2.40: New TG: Fish Reproduction / Partial Lifecycle Test

Lead:	United States
Inclusion in work plan**:**	2012
Inclusion in Annex 1	2014

- Expert group met early September 2011 to finalise fish testing strategies and defined the place for this assay;
- Discussion at the VMG-eco in November 2011;
- A desk study comparing the sensitivity of life-stages is recommended; this will determine any further work needed to validate the test design.

Project 2.52: (New) TG including the Hypothalamo-Pituitay-Adrenal (stress) axis in fish

Lead:	United Kingdom
Inclusion in work plan**:**	2015
Inclusion in Annex 1:Project status and milestones:	**2017**

- Project on hold due to resource issues in lead country.

Subsidiary body of the JM	WNT
Expert group	VMG-Eco

Project 4.26: Cell Transformation Assay using Balb/c 3T3 cell line

Lead:	Japan
Inclusion in work plan:	2007
Inclusion in Annex 1	2014

- EC provided pre-validation and peer review reports in February 2011;
- WNT discussed the follow-up at its 2011 meeting;
- Expert meeting held on 14-15 December 2011;
- Submission of the expert group's recommendations to the WNT at its April 2012 meeting;
- WNT agreement that a few more chemicals should be tested with the BALB/c 3T3 to confirm the performance of the assay and the statistical approach used for data interpretation before a Test Guideline is developed.

Project 4.64: Transcriptional Assay for the Detection of Estrogenic and Anti-Estrogenic Compounds using the MELN Cells

Lead:	European Commission
Inclusion in work plan**:**	2012
Inclusion in Annex 1:	2015

- *In vitro* transactivation assay (2 protocols: one for a manual test method and one for a high throughput test method);
- Currently under validation;
- Expected to be integrated into an updated TG 455;
- The project was suspended due to issues with contamination of the cells.

August 2017

Project 4.52: TG for the Cytosensor Microphysiometer Test Method: an In Vitro Method for Identifying Chemicals Not Classified as Irritant, as well as Occular Corrosive and Severe Irritant Chemicals	
Lead: Inclusion in work plan: Project status and milestones	European Commission 2010
• It is understood there are other purveys of technology and given little progress has made on the project, the US does not think there is a strong argument to pursue the completion of this project based on the lack of value added for regulatory purposes.	
Project 4.102: EDTA Activity: Elaborating the Conceptual Framework for cross linkage between the human and ecotoxicology components: Three case studies to supplement GD 181	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom 2015
• • Dropped out of the work plan due to limited resources to prepare the case studies.	
Subsidiary body of the JM	WNT
Expert group	EDTA AG
Project 4.103: EDTA Activity: Species concordance and species differences considerations in extrapolation of chemical effects across species *in vitro*	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom and the Netherlands 2015
• • Dropped out of the work plan, as this will be uptaken in the revision of Guidance Document 150, but UK and Netherlands will not produce a separate OECD output or publication.	
Subsidiary body of the JM	WNT
Expert group	VMG-NA/EDTA-AG