1st July 2015

Work plan for the Test Guidelines Programme (TGP)

(As of 1st July 2015)

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. If a project is no longer supported by lead countries, it is moved to Annex 1 for two years and then deleted.

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

1st July 2015

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

There are no activities currently underway

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

Project 2.3: New GD for Avian Avoidance Studies	
Lead: Inclusion in work plan: Project status and milestones:	United Kingdom (took over from BIAC in 2004) 1999
• Given the long history of the project and difficulties to reach an agreement on a guidance document at the OECD level, the WNT agreed in April 2015 to cease the project and to make a dedicated web-page with relevant information and an appropriate disclaimer available on the public site.	
Project 2.12: EDTA Activity: TG on a Medaka Life Cycle (MLC)/Multi-generation Test (MMT)	
Lead: Inclusion in work plan:	United States + Germany + Japan 2000
• The Test Guideline on a Medaka Extended One-Generation Reproduction Toxicity was approved by the WNT in April 2015. A guidance document on histopathology techniques and evaluation has also been approved to accompany the TG.	
Project 2.31: EDTA Activity - TG on a Larval Amphibian Growth and Development Assay	
Lead: Inclusion in work plan:	United States + Japan 2009
• The Test Guideline on a Larval Amphibian Growth and Development Assay was approved by the WNT in April 2015. A guidance document on histopathology techniques and evaluation has also been approved to accompany the TG.	
Project 2.33: New TG for a Protozoa Activated Sludge phagocytosis inhibition Test	
Lead: Inclusion in work plan: Project Status and milestones:	Germany 2009
• Draft test method available (attached to the SPSF, 2009); • Small expert group established in 2010 to review the validation status of the test method; • 2012-2013: conduct of a ring test; ring test report expected by the end of 2014; • Draft Test Guideline, together with the draft ring test report, are expected for first WNT commenting round early 2015.	
Project 2.36: EDTA Activity - New TG(s): Mollusc Reproductive Toxicity Tests – Development and Validation of Test Guidelines	
Lead: Inclusion in work plan: Project Status and milestones:	Germany, United Kingdom, France, Denmark 2011

- Pre-validation of *Lymnaea* test was completed in 2012, progress report presented to VMG-eco in 2013;
- Pre-validation of *Potamopyrgus* tests completed; progress report presented at the core group meeting in April 2014;
- Validation tests for *Lymnea stagnalis* started in October 2013; validation tests for *Potamopyrgus antipodarum* started in June 2014;
- Experimental phase partially finished in October 2014;
- First results of the validation tests (nominal concentrations) were presented at the next meeting of the VMG-eco in December 2014;
- Discussion of experimental phase during VMG-eco in December 2014; VMG-Eco acknowledged that sufficient data has been gathered to demonstrate the feasibility, reliability and reproducibility of the draft SOPs. It was agreed to proceed with the drafting of the TG: one independent TG will be produced for each species
- First draft TGs expected to be ready for a WNT commenting round in June/July 2015.

Project 2.39: EDTA Activity – New TG: Xenopus Embryonic Thyroid Signalling Assay

Lead:	France
Inclusion in work plan**:**	2011
Project status and milestones:	

- 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 and next steps discussed at VMG-eco in December 2014.
- Draft validation plan of the second validation phase expected to be ready early 2015.

Project 2.44: New GD: Honey Bee (*Apis Mellifera*) Larval Toxicity Test, Repeated Exposure

Lead:	France
Inclusion in work plan**:**	2012
Project status and milestones:	

- TG 237: Honey Bee (*Apis Mellifera*) Larval Toxicity Test, Single Exposure published in July 2013;
- Development of first draft Guidance Document on Honey Bee (*Apis Mellifera*) Larval Toxicity Test, Repeated Exposure, based upon the single exposure test (TG 237);
- June-September 2013: First WNT commenting round on the draft GD;
- 29-30 October 2013: Expert Meeting at OECD in Paris;
- November 2013-January 2014: Second WNT commenting round of draft GD;
- Submission of draft GD to WNT26 in April 2014: the WNT decided that an international ring test of the proposed test method should be conducted before it can be approved;
- May 2014: Creation of a specific public web page – common to the TGP and the Pesticides Programme – that contains information on the current OECD work on bees/pollinators.
- 22-24 April 2015: Expert Meeting on honeybee toxicity testing to discuss the results of the ring-test.
- Following the expert meeting circulation of the draft ring-test report and draft revised GD for comments (2nd half of 2015)
- Expected submission to WNT for approval at WNT-28 in 2016.

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Project 2.45: New GD: Supplemental Guidance and criteria for industry for the submission of Acute Oral Avian Toxicity Data using OECD TG 223	
Lead: Inclusion in work plan**:** Project status and milestones:	United States 2012
• GD expected to be applicable to all OECD countries; • Draft document received by the Secretariat in May 2012; • WNT commenting round: August-October 2012; • Draft Guidance Document submitted for decision at the 2013 WNT meeting; • Decision of the 25th WNT in April 2013 to revise the TG 223 with respect to two issues: delayed effects of chemicals and the mortality validity criterion; • The US submitted an SPSF for the revision of TG 223 that was approved by WNT 26 in April 2014; • The US has proposed an update of TG 223 (March 2015) for circulation to WNT for comments (June 2015).	
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); • Training of participating labs to perform the EASZY assay, and conduct of studies in 2014; • Preliminary data analysis for Phase 1 of the validation; presentation and discussion at VMG-eco meeting in December 2014; • Continuation of Phase 1 of the validation during 2015.	
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; • 2016: validation of test design in ring test if necessary; • Beginning of 2017: evaluation of ring test results; • Middle of 2017: first draft TG for WNT commenting; • Approval of draft TG at WNT in 2018.	
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
• Ring-test coordinated by Germany will be organised in 2014;	

- First draft TG to be made available during the first half of 2015.
- 22-24 April 2015: Expert Meeting on honeybee toxicity testing to discuss the results of the ring-test and progress with the development of a TG.
- Following the expert meeting circulation of the draft ring-test report and TG for a first commenting round (second half of 2015)

Project 2.50: Revision of TG 203 Fish Acute Toxicity Test

Lead:	Switzerland/United Kingdom
Inclusion in work plan:	2014
Project status and milestones:	

- 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;
- Drafting of a 2nd version in the 1st half of 2015.

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

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

- A workshop (non OECD event) was held in July 2014 to discuss technical challenges associated with the current test guidelines and potential options for making them more applicable to nanomaterials. The workshop had participants from Canada (University of Alberta), United States, and Europe. Discussions at the workshop centred on technical aspects of preparing stable stock and test solutions and monitoring nanomaterial behaviour during the test.
- Another discussion (face-to-face workshop or teleconference) will be planned which will then yield agreement on a draft guidance document for comments and subsequent round-robin evaluations.
- At this time, a draft guidance document has not been reviewed and it is unlikely that a document will be ready for a WNT commenting round before the end of 2015.

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

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

- Primary leads will assemble and review the published research relevant to the development of these guidelines and identify an appropriate test strategy (months 1-3).
- An independent *ad hoc* Expert Group will be established. The Expert Group will scrutinise and comment on the first draft of the Review document (month 4).
- The Review document will be revised in accordance with the input received from the Expert Group; VMG-eco may also be consulted (month 5-6: Milestone 1: Final draft of Review document).
- Based on the recommendations of the Review, and in consultation with the Expert Group, a test protocol will be designed to identify chemicals that modulate the normal activity of the hypothalamic-pituitary-interrenal axis in fish (month 6-8: Milestone 2: Selection of test method).
- Optimization and validation of the proposed method, including a ring-test, will be conducted

following the principles outlined in OECD Guidance Document 34 (month 8-20).

- A draft Final Report describing the outcomes of the test validation procedure will be prepared. (Month 21-23).
- The Final Report will be revised in accordance with comments received from the Expert Group and VMG-eco and submitted to the WNT. (Month 24: Milestone 3: Final draft of report).

Project 2.53: New TG on Bumble Bees Toxicity Testing

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

- Preliminary ring test in 2014;
- Meeting to discuss the results of the preliminary ring test and to make a draft guideline in September 2014;
- Workshop of the ICPPR non-apis working group to organize and discuss details of the ringtest in February / March 2015;
- OECD ring test in 2015;
- Ring test results available end 2015;
- Workshop of the ICPPR non-apis working group to discuss ring test results and propose final draft guideline (based on comments and experience) end 2015.

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

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

- *May – September 2015:*
  - Convene the Ad-Hoc Expert Group and conduct initial meeting by teleconference.
  - Consolidation and review existing data to support the update of the Guidance Documents as necessary
  - Statistical simulations, if necessary, to support the update of the Guidance Documents
- Agreement on required updates (if any) to the Guidance Documents and subsequent drafting of amendments
- Meetings will take place by teleconference every 4-6 weeks during this stage and more frequently if necessary.
- Consultation of the updated Guidance Documents with the WNT (*September – November 2015*)
- Presentation to the WNT (2016 meeting) for acceptance *(April 2016).*

Project 2.55: Use and analysis of control fish in toxicity studies

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

Ad-Hoc Expert Groups will be established. Communication will primarily be by teleconferences and electronic discussions. Face-to-face meetings will be organised only when necessary and it is expected that these meetings will be satellite meetings to the VMG-Eco

Part 1: Update of OECD Guidance Document 23

- May - September 2015 – Literature review of methods available to test poorly soluble substances and update of Guidance Document 23 if necessary. Meetings will take place by teleconference every 4-6 weeks during this stage and more frequently if necessary.
- October 2015 – February 2016 – WNT commenting period (it is anticipated that there will be two

commenting rounds during this time).

- April 2016 – Updated Guidance Document 23 accepted by the WNT

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

- May 2015 – January 2016 – Consolidation of historical data, assessment of data and generation of statistical simulations as necessary. Meetings will take place by teleconference every 4-6 weeks during this stage and more frequently if necessary.
- January 2016 – September 2016 - drafting of the DRP
- September 2016 – February 2017 – WNT commenting period
- April 2017 – Acceptance of the DRP by the WNT

Project 2.56: Revision of soil toxicity TGs

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

- Proposal by ECHA – within 1 month after approval of the project by WNT (mid-May 2015);
- Review and commenting of the proposal by OECD members – 1.5 months (end June 2015);
- Teleconference – within 2 months after deadline for commenting of the proposal (sept. 2015);
- Final proposal submitted by ECHA to OECD Test Guidelines Programme – within 2 months after teleconference (Nov. 2015).

1st July 2015

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
• Development of a companion Guidance Document for the OECD TG 305. • 16-17 June 2014: Expert Meeting in Utrecht, Netherlands. • Draft GD expected in the first half of 2015 for a first review round. • Second review round and submission to WNT for approval either by the end of 2015 under written procedure or at WNT28 in 2016.	
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
• Until Oct. 2014: Experimental development of the test methods to determine the dispersibility and dispersion behaviour of nanomaterials; • November 2014-January 2015: Composing the draft TG on dispersibility and dispersion behaviour of nanomaterials; • January 2014: Project Meeting in Dessau to discuss technical aspects of the draft TG • Summer 2015: round robin test; • September 2015: WNT expert group meeting in Paris; • October 2015: Draft TG available for WNT review/comments.	
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; • January 2014: Project Meeting in Dessau to discuss technical aspects of the draft GD • April-June 2015: post-evaluation of specific aspects of the GD proposal; • September 2015: WNT Expert Group Meeting in Paris • October 2015: Draft GD available for WNT review/comments.	
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: distribute draft TG to volunteer laboratories for round-robin evaluation of the protocols proposed; • September 2015: WNT Expert Group Meeting in Paris	

- ;
- September 2015: Draft TG available for review/comments.

Project 3.11: New TG for nanomaterial removal from wastewater	
Lead: Inclusion in work plan**:** Project status and milestones:	United States 2014

- June 2014 – Expert Group established under WPMN and WNT;
- October 2014 – Final Scoping document;
- November 2014 – Potential face to face meeting (date may change to accommodate a meeting at a scheduled WPMN meeting);
- Spring 2015 – Teleconferences scheduled as needed to discuss test guideline issues;
- June 2015 – First iteration of draft test guideline for discussion and input;
- December 2015 – Second iteration of draft test guideline.

Project 3.12: New GD on assessing the apparent accumulation potential for nanomaterials	
Lead: Inclusion in work plan**:** Project status and milestones:	United Kingdom, Finland and Spain 2014

- Draft guidance by end 2014;
- Laboratory evaluation of the proposed guidance over a 6-12 month period in 2015;
- Final draft guidance planned for circulation to the WNT for a first commenting round by September 2015.

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;
- Start of multi-laboratory ring trial in November 2014 (planned to end in June 2015);
- Data analysis in Q3 2015
- Discussion of ring trial results & 1st draft TG with OECD Ad Hoc Expert Group in vitro Fish Hepatic Metabolism Q3 2015
- Discussion of ring trial results & draft TG at VMG-eco meeting in Q4 2015;
- Development of draft TG (2015-2016), WNT commenting rounds (2015-2016); TG finalization (2016).

1st July 2015

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
• 1st version circulated in October 2002; • Version 2 and compilation of comments circulated for review in June 2004; • Expert group Meeting in Germany in February 2006; the meeting established a Performance Assessment Group (PAG) to investigate the bio-statistical approaches and the overall performance of the alternative; • Progress presented at expert group meeting on acute inhalation toxicity, 7-9 November 2006, Washington D.C.; • Progress report presented at WNT 19. WNT 19 agreed on the submission of acute inhalation projects as a package; • Issue on the use of "evident signs of toxicity" has to be resolved before PAG report is finalised; • In 2013, retrospective data collected (n~500) studies on 2-4 concentrations; draft document and report in preparation for the WNT to consider; • Meeting of the Mammalian Acute Toxicity Expert Group on 8-10 September 2015 in Washington (US) to address progress made on this project.	
Project 4.5: New TG for *in vitro* SHE Cell Transformation Assay	
Lead: Inclusion in work plan: Project status and milestones:	France 2003
• Project completed with the approval of a guidance document by the WNT via written procedure in February 2015. GD to be published in the Series on Testing and Assessment in April 2015.	
Project 4.31: EDTA Activity - New TG: Human Recombinant Estrogen Receptor Alpha Binding Assays (hrERA, 2 protocols)	
Lead: Inclusion in work plan: Project status and milestones:	United States + European Commission + Germany + Japan 2008
• Project completed with the WNT approval of the Test Guideline in April 2015.	
Project 4.33: EDTA Activity - New TG: Stably Transfected Transcriptional Activation (STTA) Assay for the detection of androgenic and anti-androgenic activity of chemicals	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2008
• Draft validation report and draft TG submitted to the Secretariat in 2010; • Draft validation report submitted to the VMG-non animal in December 2010; • Peer review report available in February 2011; peer review report (with draft WNT Statement on the follow-up to the peer review) endorsed/agreed at the 2011 WNT meeting; • Discussion of chemicals to be included in an additional validation at the VMG-NA meeting in 2012; • Additional validation completed in 2013; addendum to validation report available in November 2014; • First draft TG expected to be available 1st quarter of 2015.	

Project 4.34: EDTA Activity - New TG for a stably Transfected Transactivation (STTA) Assay for the detection of anti-estrogenic activity of chemicals	
Lead: Inclusion in work plan: Project status and milestones:	Japan 2008
• Project completed with the WNT approval of the updated Test Guideline 455 in April 2015.	
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
• First draft TG submitted to the Secretariat end of June 2010 with information on the added value, scope and place in an assessment scheme, and potential Intellectual Property Rights elements; • Request for expert nomination and first WNT commenting round in July 2010; • Request for WNT comments on a revised draft in December 2010; • Draft TG revised at the expert group meeting on 29-30 September 2011 in Ispra (Italy); • Draft TG, including Performance Standards, and a Streamlined Summary Document submitted to the WNT for approval at its 2013 WNT meeting; • WNT did not approve the draft TG in April 2013 and requested clarification on the domain of applicability in the bottom-up approach; • At WNT-26 in April 2014, the US expressed interest in supporting the EC in resolving the remaining issues to seek approval of the TG by the WNT and indicated they could check if any additional data could be made available.	
Project 4.54: Validation of a Cell Transformation Assay Using Bhas 42 Cell Line for Detection of Non-Genotoxic and Genotoxic Carcinogens	
Lead: Inclusion in work plan: Project status and milestones	Japan 2010
• International validation studies completed in 2010; discussion at an expert meeting held on 14-15 December 2011 at OECD; • Submission of peer review report in 2013; draft TG circulated for a WNT commenting round at the end of 2013; • Meeting of experts and regulators in January 2014 to address comments received; • WNT endorsed the validation and peer-review report in April 2014; the document has been published in July 2014 in the Series on Testing and Assessment, as No.208; • Pending decision of Joint Meeting in November 2014 on CTAs, the draft TG might be revised and a second commenting round may take place; • The test method was transferred to a Guidance Document and is following the path of an approval via written procedure by WNT in April 2015. It is expected the Guidance document can be published around mid-2015 in the Series on Testing and Assessment.	
Project 4.58: Updated *in vivo* germ cell genotoxicity TGs (TG 478 and 483)	
Lead: Inclusion in work plan:	Canada 2011

Project status and milestones:	
• Project completed with the WNT approval of the updated Test Guidelines in April 2015.	
Project 4.59: New TG to separate the Mouse Lymphoma Assay from the current TG 476	
Lead: Inclusion in work plan: Project status and milestones:	United States, France 2011
• Project completed with the WNT approval of the Test Guideline in April 2015.	
Project 4.60: Updated TGs for *in vitro* genotoxicity assays (TG 473, 476, 487)	
Lead: Inclusion in work plan: Project status and milestones:	Canada, Netherlands, France, United States 2011
• TG 473 and TG 487 were approved by the WNT in April 2014, and published in September 2014; • Project completed with the WNT approval of the updated TG 476 in April 2015.	
Project 4.62: Revision of the introduction to the OECD TGs on genetic toxicity testing and guidance on the selection and application of the assays	
Lead: Inclusion in work plan: Project status and milestones:	Netherlands, France, Canada, United States 2011
• First draft guidance document, including the introduction, to be circulated to WNT mid-2015.	
Project 4.69: New TG: Short –Term Exposure Test (STE) for Identifying Ocular Irritants	
Lead: Inclusion in work plan**:** Project status and milestones:	Japan 2011
• Project completed with the WNT approval of the Test Guideline in April 2015.	
Project 4.71: Updated TG421/ TG422 (Reproduction/Developmental Toxicity Screening Test)/(Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test), Enhancement with ED-relevant endpoints	
Lead: Inclusion in work plan**:** Project status and milestones:	Denmark 2013
• Project completed with the WNT approval of the updated Test Guidelines in April 2015	
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
• SPSF is approved and may be merged with project 4.33 when the validation is completed. • Validation trial expected to take place in 2015-2016 and draft validation report available by the end of 2016.	
Project 4.75: New TG on human Cell Line Activation Test (h-CLAT): an in vitro method for identifying the skin sensitisation potential of chemicals	

Lead: Inclusion in work plan**:** Project status and milestones:	Japan and European Commission 2013

- Validation study carried out, peer review completed in 2014 and EURL ECVAM Recommendation to follow;
- Draft TG sent for a first WNT commenting round and its expert group on *in vitro* skin sensitisation in August 2014;
- Further analysis conducted Q4-2014;
- Revised draft TG, responses to comments and further statistical analyses of reproducibility submitted to WNT in March 2015 for discussion;
- Second commenting round will take place shortly after WNT with the view to get the TG approved by WNT via written procedure.

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 planned for 11-12 May 2015 at OECD in Paris.

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 study(ies).

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 currently under revision 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 a draft revised TG, if necessary, would be ready for a first WNT commenting round in mid-2016.

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

- July – September -2014: Collate data from partners;
- October – December 2014: Assess data and write report;
- First half of 2015: lead country to prepare a proposal for an updated TG 402, supported by the data analysed; organise a commenting round on the draft documents;
- Meeting of the Expert Group on Acute Mammalian Toxicity to be held in Washington on 8-10 September 2015.

Project 4.80: Revision of TG 431 and TG 439 to extend their applicability to coloured chemicals strongly interfering with the MTT reduction assay

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

- Project completed with the WNT approval of the updated TG 431 and TG 439 in April 2015.

Project 4.81: New TG on EpiOcular EIT for eye irritation testing

Lead: Inclusion in work plan**:** Project status and milestones:	European Commission 2014

- Project completed with the WNT approval of the Test Guideline in April 2015.

Project 4.82: Update of TG 455 for inclusion of Transcriptional ERalpha CALUX assay for the detection of (anti)estrogenic chemicals

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

- 2013-2014: on-going inter-laboratory study that will be reported in December 2014 to the VMG-NA;
- Validation report in preparation in 2015.

Project 4.83: New GD on Waiving of Bridging Mammalian Acute Toxicity Tests

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

- April 2014: submission of a draft guidance document to Secretariat (available to WNT on community site);
- Discussion with the UK on possible synergies with project 4.79 on revision or replacement of TG 402 on to Acute Dermal Toxicity;
- Expert Group to be established in Q4 2014;
    - Expert Group to take into consideration suggestions provided from member countries in addition to the information provided in the US and Canada guidance documents prior to commencing the work on preparing a draft GD
- Draft GD and internal review Q1 2015;
- Draft for first WNT review Q2 2015.
- Meeting of the Acute Mammalian Toxicity Expert Group in Washington on 8-10 September 2015.

Project 4.84: Amendments to the Inhalation TGs and GD to accommodate nanomaterial safety testing	
Lead: Inclusion in work plan**:** Project status and milestones:	United States 2014

- SPSF was approved mid-2014 taking into account modifications requested at WNT-26 for softer language as regards mandatory vs. optional required measurements in the TGs.
- Completion of draft GD(s) and amendments to TGs anticipated to take approximately 6 to 12 months for all items, depending on outcomes from WPMN and WNT reviews.
- Work will occur via teleconferences, email, and a face-to-face expert meeting to be held in October, 2015
- United States has offered to host an OECD WPMN information sharing seminar on in vivo inhalation toxicity screening methods for manufactured nanomaterials. The organizers of this project are Japan (AIST), BIAC (BASF), and the Netherlands (TBC). This seminar will be held back-to-back with an inhalation nano expert group meeting that the United States is organizing and also hosting.
- A proposal was circulated to the OECD expert group in March 2015 suggesting ways to expedite the revision of the inhalation TGs, GD 39, and GD 125.
- Teleconference of the expert group in May 2015.

Project 4.85: Revision of all TGs on skin irritation and corrosion (in vivo and in vitro)	
Lead: Inclusion in work plan**:** Project status and milestones:	Secretariat 2015

- The aim of the revision of all skin irritation and corrosion TGs is to separate the performance standards from the body of the TG, and to introduce a reference to the IATA document that contains a testing strategy, in replacement of the TG 404 supplement, which is no longer current.
- The TGs have been updated and approved by the WNT in April 2015; the project is completed.

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

- Q2 2015: finalisation of the validation study and preparation of the report, followed by independent peer-review by ESAC.
- Q3 2015: draft TG and supporting information will be provided to the OECD for circulation to the Eye irritation expert group and the WNT, with a request to comment on the draft Test Guideline.
- Q4 2015: Depending on the comments received, the expert meeting on eye irritation will address comments received at its meeting on 9-10 November 2015. Possible submission to WNT for approval in 2016.

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

- Q3 2015: first draft of the new proposed TG made available for a first WNT commenting round;
- Q4 2015: 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;
- Q1 2016: final revisions of the new proposed Test Guideline made available for discussions at the spring 2016 WNT meeting.

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:
  - Final report of the A.I.S.E. *in vitro* ICE test method programme will be circulated to the OECD Expert Group on Eye Corrosion/Irritation
  - 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 will be circulated to the Expert Group for commenting.
- Q3 2015: Convene a meeting of the OECD expert group on eye irritation/corrosion to address comments and further revise draft Test Guideline 438 to incorporate histopathology as an additional endpoint;
- Q4 2015: Process and incorporate suggestions and adaptions to the proposed addendum to TG 438;
- Jan 2016: A final draft revised Test Guideline 438 to incorporate histopathology as an additional endpoint will be submitted to WNT for adoption in April 2016.

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

- Q2 2015: A proposed revision of the Guidance Document No. 160 to incorporate histopathology as an additional endpoint for classification of non-extreme pH and extreme pH detergent and cleaning products and surfactants will be circulated to the Expert Group and WNT for comment;
- Q3 2015: Meeting of the OECD expert group on eye irritation/ corrosion to address comments and revise the draft Guidance Document No. 160 Discussion is foreseen on inclusion of the scoring system, decision tree, and the prediction model in either GD160, or in TG438;
- Q4 2015: Process and incorporate suggestions and adaptations to the proposed revision of GD160;
- Jan 2016: A revised Guidance Document No.160 to incorporate histopathology as an additional endpoint for classification of non-extreme pH detergent and cleaning products and surfactants will be submitted to WNT for adoption in April 2016.

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

- First draft IATA document available by December 2015;
- Commenting by WNT and Expert Group by February 2016;
- Possible Expert Meeting in May-June 2016;
- Second draft IATA document available by October 2016;
- Commenting by WNT and Expert Group by December 2016;
- Approval by WNT April 2017.

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

- The experiment part of IL-8 Luc assay validation study was completed in September 2014 (The attached document 2), the independent peer review by the JaCVAM started in February 2015;
- The appropriateness of generating additional information with the IL-8 Luc assay will be contingent on the outcome of the peer review by JaCVAM.

Project 4.92: Myeloid U937 Skin Sensitization Test (MUSST) for identifying skin sensitization potential of chemicals

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

- November 2014: peer-review by ESAC;
- Q2 2015: draft TG and supporting information will be provided to the OECD for circulation to the skin sensitization expert group and the WNT, with a request to comment on the new draft TG.
- Q3-Q4 2015: Depending on the comments received, an expert meeting on skin sensitisation may or may not need to be convened. Possible submission to WNT for approval in 2016.

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

- Form Expert Working Group (EWG): immediately after project approval by WNT (Spring 2015);
- Prepare draft DRP and validation/RPA document: Spring 2015-February 2017
- Public commenting on draft DRP and validation/RPA document, revision as necessary: February 2017-November 2017;
- Submit revised DRP and validation/RPA document to WNT: Nov 2017;
- Upon WNT approval of DRP/validation/RPA, prepare draft TG: Spring 2018-February 2019 (also, consider suggestions for further action on the integration question in **Attachment A**);
- Public commenting on draft TG, revision as necessary: February 2019-November 2019;
- Submit revised TG to WNT: November 2019; TG considered by WNT Spring 2020.

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.
- June-July 2015: Creation of provisional work programme for the extended WNT nominated expert group. It is expected that the membership will include the current core members, but additional relevant expertise will be identified by the drafting group in the thought starter, and expert members will be nominated by the WNT.
- September 2015: Creation and initiation of IATA NGTxC expert group, following nominations by WNT
- Kick off teleconference or face to face meeting: late 2015.

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.

Project 4.96: EDTA Activity: Deletion of TG 457

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

- The project aims at deleting TG 457, which has become redundant with the updated TG 455. The updated TG 455 now includes the agonist and the antagonist parts of the ER transactivation assay. TG 457 will be deleted in 2015.

Project 4.97: EDTA Activity: Detailed Review Paper on Retinoic Acid Pathway

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

- 2015-2017: Drafting of the retinoid DRP with focus on the RAR-RXR; PPAR-RXR; and VDR-RXR signaling and metabolic pathways.
  - 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)*

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

- Activity initiated under the Validation Management Group for non-animal tests;
- First draft document available to WNT for review late 2015.

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 (i.e. 4.33 [JP] and 4.73 [EC]);
- 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 will be discussed in December 2015 by the 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

- **2015:**
  - Review & first proposal for revision of TG 414;
  - Teleconference/face-to face meeting with Expert group
- **2016:**
  - WNT NCs and expert group 1-2nd commenting (e.g. Teleconference with EG)
  - Draft final revisions as appropriate by the end of 2016
- **2017:** if TG 414 is agreed to be revised, adoption of the rev. TG at WNT OECD

Project 4.101: EDTA Activity: Exploring the Concept of Developing Pathway-Based Test Method Performance Metrics: a Case Study Using Estrogen Receptor Signalling

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
- Presentation of draft White Paper to EDTA and VMG-NA: Dec 2016
- Consideration of concepts presented in the White Paper by lead organizations: early 2017
- 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: Dec 2017
- Submit SPSF for TG to WNT, if supported by EDTA and VMG-NA: 2018

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

- Proof of principle exercise using case studies to examine the ways in which data derived for human risk assessment can be used for for environmental risk assessment and vice versa (Integrated Risk Assessment (IRA) approaches) and how this can be applied in practice to chemicals hazard evaluation.
- Addition of case studies to the GD 181

Timelines:

- conduct 3 case studies in late 2015- early 2016;
- present these to the EDTA-AG in 2016;
- following review, propose for addition to the GD 181.

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

Outcomes and deliverables: Prioritisation of which end points and in vitro assays to be further encouraged for development by the VMG-NA and how these can inform the broader work prosed in the EDTA-AG.

- Information review and capture: Jan-June 2015
- Draft presentation to VMG-NA and EDTA-AG 2015
- Publish reviews: late 2015-early 2016
- Integration with larger scale species concordance work in EDTA-AG
- OECD commenting rounds and endorsements 2016-2017.

Project 4.104: Joint WNT-WG GLP Activity: Development of Guidance on good in vitro method practice

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

- Joint activity between the Working Group on Good Laboratory Practice and the Working Group of the National Coordinators of the Test Guidelines Programme;
- Formation of a drafting group to contribute to ECVAM's endeavor to develop the first draft for review in 2015.

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

Project 5.9: Revision of CFT GD and new GD for rotational crop field trial	
Lead: Inclusion in work plan: Project status and milestones:	United States and Germany through the WG Pesticides 2008

1) Updating of 2011 Guidance Document on Crop Field Trials
- The 2011 Guidance Document on crop field trials is being revised by the Residue Chemistry Expert Group (RCEG); the work is led by Germany.
- 12 Sept. – 31st October 2014: First commenting round by WNT and WGP.
-) Expert meeting of the RCEG on 7-8 July 2015, OECD, Paris to discuss the comments received and revise the draft GD.
- Following the expert meeting, circulation of draft GD for a second commenting round (October 2015)
- Possible Submission to WNT and WGP for approval at WNT28 and WGP31 in 2016.

2) New Guidance Document on Rotational Crops:
- The draft Guidance Document on rotational crop field trials is being developed by the Residue Chemistry Expert Group (RCEG)
- First draft GD expected in 2015 (the work is behind schedule)
- Expert meeting of the RCEG on 7-8 July 2015, OECD, Paris to address the progress of work for this guidance.

Project 5.10: New TG: Testing Efficacy of Porous and Non-Porous Treated Articles (EBTA)	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the TF Biocides 2011 Tier 1 activity completed – Tier 2 activity initiated

- Tier 1 work: First commenting round of a draft Guidance Document "Quantitative method for evaluating antibacterial activity of porous and non-porous antibacterial treated materials" (TFB & WNT, November 2012-February 2013)
- Revision of draft GD and second commenting round (October-December 2013).
- Approved by the 26th WNT meeting (9-11 April 2014)
- Declassified and published in July 2014: No. 202 in the series on Testing and Assessment; No. 8 in the series on Biocides.
- Tier 2 work: Laboratory-based tests: Development of Guidance Document on Tier 2 laboratory-based tests used to substantiate claims for treated articles.
- 30 September 2014: EBTA Meeting (Athens, Greece) discussed the Tier 2 work plan.
- Contract signed in December 2014 with consultant for drafting a Tier 2 test
- Review of a preliminary draft GD (including one example protocol) by the EBTA planned at their April 2015 meeting.
- First draft of the GD (including two example protocols) being developed by a consultant to be completed by 31 December 2015.

Project 5.13: New GD for Pesticide Terrestrial Field Dissipation Studies, including a Crosswalk between North America and European Ecoregions	
Lead: Inclusion in work plan:	Canada, USA and EFSA through the WG Pesticides 2013

Project status and milestones:	
• Development by the *ad hoc* Expert Group of: 1) OECD guidance on the conduct of pesticide TFD studies; and 2) a crosswalk between North-American and European ecoregions, to take into account the outcomes and recommendations from the March 2011 Workshop. • 17th July – 30th Sept. 2014: 1st commenting round of draft GD through the WGP and WNT. • 6th March – 27th April 2015: Second commenting round of draft GD through the WGP and WNT. • • Submission to WNT and WGP for approval by the end of 2015 under written procedure.	
Project 5.15: New GD on Storage Stability of Biocidal Products	
Lead: Inclusion in work plan: Project status and milestones:	Ireland and US through the TF Biocides 2013
• Project completed with the approval of the Guidance Document by WNT in April 2015.	
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:	United States through the TF Biocides 2015
• Draft OECD guidance document summer 2015; • Comment periods (late summer/fall); • If comments can be addressed quickly, approve at OECD WNT 2016.	

1st July 2015

ANNEX 1

PROJECTS THAT ARE REMOVED AFTER TWO YEARS WHEN NO LONGER SUPPORTED

Project 2.4: New TG 2-Generation Avian Toxicity	
Lead: Inclusion in work plan: Inclusion in Annex 1	United States 1999 2014
• Project stopped in 2014 given the complexity of the test design, the number of animals used on test, and the difficulty to transfer the test method across laboratories.	
Project 2.13: EDTA Activity: New TG for Mysid Life Cycle Toxicity Test	
Lead: Inclusion in work plan: Inclusion in Annex 1	United States 2002 2014
• Project stopped in 2014 given difficulties to demonstrate the added value of the second generation and the existence of an ASTM standard for the mysid life-cycle test.	
Project 2.40: New TG: Fish Reproduction / Partial Lifecycle Test	
Lead: Inclusion in work plan**:** Inclusion in Annex 1	United States 2012 2014
• Project stopped in 2014 given lack of resources and clear regulatory need.	
Project 2.49: Revision of OECD GD 75 on Honeybee Brood Test under semi-field conditions	
Lead: Inclusion in work plan: Inclusion in Annex 1:	Germany 2014 2015
• The project was stopped in 2015. The investigations to improve reliability of the test system failed; therefore the test cannot at this moment be upgraded to a Test Guideline.	
Project 4.26: Cell Transformation Assay using Balb/c 3T3 cell line	
Lead: Inclusion in work plan: Inclusion in Annex 1	Japan 2007 2014
• The project was stopped, given lack of interest to pursue further validation, and included in Annex 1 in 2014.	
Project 4.64: Transcriptional Assay for the Detection of Estrogenic and Anti-Estrogenic Compounds using the MELN Cells	
Lead: Inclusion in work plan**:** Inclusion in Annex 1:	European Commission 2012 2015
• The project was suspended due to issues with contamination of the cells.	