

Work plan for the Test Guidelines Programme (TGP)

July 2014

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 of a general nature are included after Section 5. *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

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

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

Project 2.1: EDTA Activity: New TG for Copepod Reproduction and Development

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| Lead: | Sweden |
| Inclusion in work plan: | 2002 |
| Project status and milestones: | |
| <ul style="list-style-type: none"> Draft guidance document was approved by the WNT-26 in April 2014. Project completed; GD will be declassified in June or July 2014 and published in the Series on Testing and Assessment. | |

Project 2.3: New GD for Avian Avoidance Studies

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| Lead: | United Kingdom (took over from BIAC in 2004) |
| Inclusion in work plan: | 1999 |
| Project status and milestones: | |
| <ul style="list-style-type: none"> Expert group meeting in May 2005 (in the margin of Lille SETAC meeting); Revised draft presented to the expert group in May 2005; Small expert group meeting in May 2006 (in the margin of SETAC meeting); Revised SPSF agreed at WNT 19. Two more expert group meetings expected; Lead country was awaiting the outcome of similar project from EFSA in the EU (Birds and Mammals Guidance Document that recommends demonstrating avoidance is sufficiently strong to ensure that lethal effects will not exceed and acceptable level); Draft GD submitted to the Secretariat on 30th November 2010; Comments from the WNT were requested in January 2011; Draft GD submitted to the WNT for approval at its 2012 meeting; Approval was delayed until an expert meeting hosted by the United Kingdom is held. The UK will host a workshop in the 2nd half of 2014 in the city of York. | |

Project 2.12: EDTA Activity: TG on a Medaka Life Cycle (MLC)/Multi-generation Test (MMT)

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| Lead: | United States + Germany + Japan |
| Inclusion in work plan: | 2000 |
| Inclusion in Annex 1 | 2014 |
| <ul style="list-style-type: none"> Bilateral work in Japan and the United States on medaka FLC/2-Gen in 2005-2006; Germany is working on a parallel project; 2007: preparation of a report comparing the various results available, based on 2 to 3 substances (TESTMETEDECO); Review of statistical issues circulated for comments in September 2007 to the fish drafting group and the VMG-eco [TESTMETEDECO]; Revised review of statistical issues submitted to the VMG-eco meeting in January 2008; Development of a TG by Japan and the United States expected at a later stage; Revised SPSF submitted by the US and Japan agreed at the 2009 WNT meeting; Discussion of the approaches proposed and best course of action by the VMG-eco in December 2009 and by the fish expert group at a meeting in June 2010; Consensus Japan/USA 27 week-Medaka Multigeneration Test presented at the fish drafting group | |

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| <p>meeting held on 9-10 February 2011 in Japan;</p> <ul style="list-style-type: none"> • Progress report at the VMG-eco meeting in November 2011; • 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; • US are considering the possibility to submit a revised draft TG to OECD for review/comments in 2014. | |
| Project 2.31: EDTA Activity - TG on a Larval Amphibian Growth and Development Assay | |
| Lead: | United States + Japan |
| Inclusion in work plan: | 2009 |
| Inclusion in Annex 1: | 2014 |
| <ul style="list-style-type: none"> • Report at the VMG-eco meeting in November 2011; • Validation expected to be completed in 2nd quarter 2012; • US are considering the recommendations from the Science Advisory Panel meeting held in 2013; • US are considering the possibility to submit a first draft TG to OECD for review/comments in 2014. | |
| Project 2.33: New TG for a Protozoa Activated Sludge phagocytosis inhibition Test | |
| Lead: | Germany |
| Inclusion in work plan: | 2009 |
| Project Status and milestones: | |
| <ul style="list-style-type: none"> • Draft test method available (attached to the SPSF); • Small expert group established in 2010 to review the validation status of the test method; • Ring test expected to be initiated in 2012 and completed in 2013; • Draft Test Guideline, together with the ring test report, are expected for first commenting round in 2014. | |
| Project 2.36: EDTA Activity - New TG(s): Mollusc Reproductive Toxicity Tests – Development and Validation of Test Guidelines | |
| Lead: | Germany, United Kingdom, France, Denmark |
| Inclusion in work plan: | 2011 |
| Project Status and milestones: | |
| <ul style="list-style-type: none"> • Annual meetings of lead countries; • Pre-validation of <i>Lymnaea</i> test was completed in 2012 (a progress report is available).; • Results of the pre-validation tests have been presented at the meeting of the VMG-eco in 2013; • Pre-validation of <i>Potamopyrgus</i> tests are now completed and have been presented at the core group meeting in April 2014; • Forthcoming validation tests are currently being organised (choice of toxicants and partner laboratories to be involved worldwide, fund-raising); • Validation is on-going for <i>Lymnaea stagnalis</i>; validation tests for <i>Potamopyrgus antipodarum</i> should start in June 2014; • First results of the validation tests will be presented at the next meeting of the VMG-eco (2014); • First draft TG expected to be ready for a WNT commenting round by the end of 2014. | |

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| Project 2.38: New TG: Growth Inhibition Test for the Rooted, Submerged Aquatic Macrophyte, <i>Myriophyllum</i> species | |
| Lead: | United Kingdom and the Netherlands |
| Inclusion in work plan: | 2011 |
| Project Status and milestones: | <ul style="list-style-type: none"> Draft TG was approved by WNT-26 in April 2014. Project completed; TG will be published in July or October 2014; Phase 1 validation report will be submitted to OECD by end of June 2014. |
| Project 2.39: EDTA Activity – New TG: <i>Xenopus</i> Embryonic Thyroid Signalling Assay | |
| Lead: | France |
| Inclusion in work plan: | 2011 |
| Project status and milestones: | <ul style="list-style-type: none"> Project approved by written procedure on 1 June 2011; Completion of a document summarising results from different demonstration studies in 2011; Project discussed at the VMG-eco meeting in November 2011; Comprehensive written validation plan, including a detailed protocol, distributed to VMG-eco and participating laboratories in June 2012; Inter-laboratory trial performed by France, Japan and the United States has been completed in March 2014. |
| Project 2.43: New TG: Sediment-Free <i>Myriophyllum spicatum</i> Toxicity Test | |
| Lead: | Germany |
| Inclusion in work plan: | 2012 |
| Project status and milestones: | <ul style="list-style-type: none"> Draft TG was approved by WNT-26 in April 2014. Project completed; TG will be published in July or October 2014. |
| Project 2.44: New TG: Honey Bee (<i>Apis Mellifera</i> L.): Brood Test | |
| Lead: | France |
| Inclusion in work plan: | 2012 |
| Project status and milestones: | <ul style="list-style-type: none"> Draft TG on larval toxicity following single exposure approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication; Draft guidance document on toxicity following repeated exposure to be circulated to the expert group for review mid-2013 and expert meeting at end of October 2013 at OECD; second WNT commenting round at the end of 2013; Draft Guidance Document will be ring-tested in 2014; Ring-test results should be presented to participants in October 2014. |
| Project 2.45: Revision of TG 223: criteria for industry for the submission of Acute Oral Avian Toxicity Data using OECD TG 223 | |
| Lead: | United States |
| Inclusion in work plan: | 2014 |
| Project status and milestones: | <ul style="list-style-type: none"> GD expected to be applicable to all countries; Draft document received by the Secretariat in May 2012; WNT commenting round: August-October 2012; |

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| <ul style="list-style-type: none"> • Draft Guidance Document submitted for decision at the 2013 WNT meeting; • Decision of the 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 a SPSF for approval at WNT-25 in April 2014; the SPSF was approved and a draft updated TG 223 will be circulated in 2014 to the WNT for review/comments. | |
| 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 |
| <ul style="list-style-type: none"> • Initial drafting of protocol, review by the Fish Drafting Group and VMG-eco and revision; proposed schedule validated during VMG-eco meeting (2013); • Training of participating labs to perform the EASZY ; testing of positive reference ligands (2) and a negative substance (1); drafting of an updated SOP; testing of selected positive and negative reference ligands (6); • Data analysis and drafting of the report by the end of 2014 for Phase 1 of the validation; • Proposal of a draft new Guideline in 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 |
| <ul style="list-style-type: none"> • Establishment of an <i>ad hoc</i> Expert Group: Request to WNT for nomination of experts sent on 22 April 2013. • Work of the OECD Expert Group in co-operation with the Setac Global Soil Advisory Group (GSAG) which meets every year in the margin of the Setac-Europe Conference (annual meeting generally in May). • First draft TG expected in the first half of 2015 and possible meeting of the OECD Expert Group and the Setac GSAG. • Joint meeting of the OECD Expert Group and the GSAG at the Annual Setac-Europe Conference in May 2015. | |
| 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 |
| <ul style="list-style-type: none"> • Ring-test coordinated by Germany will be organised in 2014; • First draft TG available in first half 2015. | |
| Project 2.49: Revision of OECD GD 75 on Honeybee Brood Test under semi-field conditions | |
| Lead: Inclusion in work plan: Project status and milestones: | Germany 2014 |
| <ul style="list-style-type: none"> • Collection of data from laboratories and evaluation from May to November 2014; • Draft updated document for two successive expert commenting rounds: first half-2015; • Guideline proposal: mid-2015. | |

| Project 2.50: Revision of TG 203 Fish Acute Toxicity Test | |
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| Lead: Inclusion in work plan: Project status and milestones: | Switzerland/United Kingdom 2014 |
| <ul style="list-style-type: none"> • Draft updated TG for review and comments in 2014. | |
| 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 |
| <ul style="list-style-type: none"> • End of 2014: circulation of first draft of guidance document for review. • March 2015: distribute draft guidance to laboratories for round-robin evaluation; • March 2016: modify draft guidance document based on results from round-robin evaluation. | |

SECTION 3
PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE

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| Project 3.7: New GD for the revised OECD TG 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure; and Addendum to Validation Report for dietary exposure | |
| Lead: Inclusion in work plan: Project status and milestones: | Germany, Netherlands, United Kingdom 2012 |
| <ul style="list-style-type: none"> • Additional Report including results using a lower feeding rate: draft Addendum to the ring test report for the 305 dietary exposure [ENV/JM/MONO(2012)20] approved by the WNT 25 in April 2013 and submitted to the Joint Meeting and EPOC for endorsement. • First draft GD expected first second 2014 for immediate commenting; • Workshop or Expert Meeting to be organised for June/July 2014 • Second commenting round third quarter 2014 • Draft Guidance Document expected to be submitted for approval to WNT early in 2015 | |
| 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 |
| <ul style="list-style-type: none"> • 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; • February 2015- June 2015: If necessary, post evaluation of single specific aspects of the TG proposal; • July/August 2015: International Expert Workshop in Berlin; • August/September 2015: Draft TG available for review/comments. | |
| Project 3.9: New GD (Decision-Tree) on dispersion and dissolution behaviour of nanomaterials in aquatic media: | |
| Lead: Inclusion in work plan: Project status and milestones: | Germany 2014 |
| <ul style="list-style-type: none"> • Until October 2014: verification of the proposed Decision Tree; • April-June 2015: post-evaluation of specific aspects of the GD proposal; • Summer 2015: Expert workshop in Berlin followed by a draft GD for 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 |
| <ul style="list-style-type: none"> • May to Nov. 2014: composing the draft 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; • July/August 2015: International Expert Workshop; • September 2015: Draft TG available for review/comments. | |

| Project 3.11: New TG for nanomaterial removal from wastewater | |
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| Lead: Inclusion in work plan: Project status and milestones: | United States 2014 |
| <ul style="list-style-type: none"> • January 2014 – Meeting via teleconference: determine direction and responsibilities, identify additional participants as needed • February 2014 – Meeting via teleconference to provide input into test guideline scoping, identify laboratory testing as needed and nanomaterial relevant issues • June 2014 – Draft scoping document for group discussion and input • 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 |
| <ul style="list-style-type: none"> • Draft guidance by end 2014; • Laboratory evaluation of the proposed guidance over a 6-12 month period in 2015; • Final draft guidance available at the end of 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 |
| <ul style="list-style-type: none"> • Formation of an OECD Ad Hoc Expert Group to oversee planning and conduct of the definitive multi-laboratory ring trial (2014); • Multi-laboratory ring trial (& independent peer review, if deemed necessary) (2014- 2016); • Development of draft TG, WNT commenting rounds, TG finalization (2016). | |

SECTION 4
PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS

| Project 4.2: New TG 433: Fixed Dose Procedure as Alternative to TG 403 | |
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| Lead: | United Kingdom |
| Inclusion in work plan: | 2001 |
| Project status and milestones: | <ul style="list-style-type: none"> • 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; • Lead country decided to withdraw this project; project moved to Annex 1; • 2010: UK informed the WNT that they want to restart the work; <i>WNT agreed that this project should stay in Annex 1 of the work plan until 2011 WNT meeting</i> • In 2013, UK invited countries’ laboratories to collect data to support the use of evident toxicity in acute inhalation toxicity in TG 433. No further information available; retrospective data collected (n~500) studies on 2-4 concentrations; draft document and report in preparation for the WNT to consider. |
| Project 4.5: New TG for <i>in vitro</i> SHE Cell Transformation Assay | |
| Lead: | France |
| Inclusion in work plan: | 2003 |
| Project status and milestones: | <ul style="list-style-type: none"> • 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 to develop a draft TG at the April 2012 WNT meeting; • Comments on the first draft TG requested from the WNT in June 2012; • Expert group meeting discussed WNT comments on 24 September 2012; • Comments on the second draft TG requested from the WNT in October 2012; • Several conference calls from December 2012 to February 2013 to address the comments of the second WNT commenting round and solve issues raised by these comments; • An additional analysis was performed to support expert agreement on the choice of the pH and the respective sensitivity and specificity of the assay; • Draft Test Guideline submitted for approval at the 2013 WNT meeting; • WNT in April 2013 postponed the approval of the draft TG until after a meeting with NC to clarify points mainly related to the validation; • A meeting took place on 14-15 January 2014 to discuss remaining issues and make proposals on the way forward; • The draft TG was not approved by WNT in April 2014; but the WNT agreed to have a guidance document describing the procedure instead, with introductory paragraph explaining the current limitations of the assay. |

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| <ul style="list-style-type: none"> • Draft GD expected for a WNT review and written procedure approval before end of May 2014. | |
| 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 |
| <ul style="list-style-type: none"> • Validation plan discussed the meeting of the VMG-non animal (2007); • Validation (complete) was presented at the meeting of the VMG-non animal (2010); • Data analysis and compilation completed in 2011; • Draft validation report submitted in November 2013 and presentation at the December meeting of the VMG-non animal; • Draft TG under preparation, based on the validation report; first draft expected mid-2014. | |
| 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 |
| <ul style="list-style-type: none"> • 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; • Draft 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; validation report to be prepared early 2014 and draft Test Guideline will follow and be ready for review at VMG-NA in December 2014. | |
| 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 |
| <ul style="list-style-type: none"> • Collection of validation data expected in 2nd quarter 2012; • Validation completed in 2013 and report will be prepared in the course of 2014. A draft Test Guideline will follow and be ready for review at VMG-NA in December 2014. | |
| Project 4.36: New TG: Comet Assay in Genotoxicity Testing | |
| Lead: Inclusion in work plan: Project status and milestones: | Japan 2008 |
| <ul style="list-style-type: none"> • The draft TG was approved by the WNT-26 in April 2014; TG should be published in July or October 2014. | |

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| Project 4.52: TG for the Cytosensor Microphysiometer Test Method: an In Vitro Method for Identifying Chemicals Not Classified as Irritant, as well as Ocular Corrosive and Severe Irritant Chemicals | |
| Lead: Inclusion in work plan: Project status and milestones | European Commission 2010 |
| <ul style="list-style-type: none"> • 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); • Performance Standards under development; • Draft TG, including Performance Standards, and a Streamlined Summary Document submitted to the WNT for approval at its 2013 WNT meeting; • The WNT did not approve the draft TG in April 2013 and requested clarification on the domain of application in the bottom-up approach; 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 4.53: GD on Skin Irritation/Corrosion and related TGs | |
| Lead: Inclusion in work plan: Project status and milestones | Germany 2010 |
| <ul style="list-style-type: none"> • The draft GD was approved at WNT-26 in April 2014; it will be declassified and published in June or July 2014 in the Series on Testing and Assessment. | |
| 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 |
| <ul style="list-style-type: none"> • International validation studies were completed in 2010; • Discussion at an expert meeting held on 14-15 December 2011 at OECD; • Final validation report and draft TG expected in 2012; • Submission of peer review report expected in 2013; draft TG circulated for a WNT commenting round at the end of 2013; • A meeting of experts took place in January 2014 to address comments received; • After revision of the draft TG a second commenting round will take place in 2014, in view of possible submission to the WNT for approval in 2015; WNT endorsed the validation and peer-review report in April 2014; it will be declassified and published in June or July 2014 in the Series on Testing and Assessment. | |
| Project 4.57: Updated <i>in vivo</i> somatic cell genotoxicity TGs (TG 474 and 475) | |
| Lead: Inclusion in work plan: Project status and milestones: | Canada 2011 |
| <ul style="list-style-type: none"> • TG 474 and TG 475 were approved by the WNT at the 2014 meeting; both TGs should be published in July or October 2014. | |

| Project 4.58: Updated <i>in vivo</i> germ cell genotoxicity TGs (TG 478 and 483) | |
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| Lead: | Canada |
| Inclusion in work plan: | 2011 |
| Project status and milestones: | <ul style="list-style-type: none"> • First expert meeting held on 1-2 March 2011; • Second expert meeting on 31 January - 2 February 2012; • Expert meeting held on 24-28 September 2012; • First WNT commenting round expected mid-2013; • Expert meeting took place in Ottawa in November 2013 to address remaining issues; • The draft updated TGs are expected to be submitted to the WNT for approval in 2015. |
| Project 4.59: New TG to separate the Mouse Lymphoma Assay from the current TG 476 | |
| Lead: | United States, France |
| Inclusion in work plan: | 2011 |
| Project status and milestones: | <ul style="list-style-type: none"> • First expert meeting held on 1-2 March 2011; • Second expert meeting on 31 January - 2 February 2012; • Third Expert meeting held on 24-28 September 2012; • Request for comments from the WNT on first draft TG expected mid 2013; • Expert meeting took place in Ottawa in November 2013 to address remaining issues; • The draft new TG is expected to be submitted to the WNT for approval in 2015. |
| Project 4.60: Updated TGs for <i>in vitro</i> genotoxicity assays (TG 473, 476, 487) | |
| Lead: | Canada, Netherlands, France, United States |
| Inclusion in work plan: | 2011 |
| Project status and milestones: | <ul style="list-style-type: none"> • TG 473 and TG 487 were approved with the publication of the biostatistical report (to be published in the Series on Testing and Assessment) by the WNT at the 2014 meeting; both TGs should be published in July or October 2014. |
| 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: | Netherlands, France, Canada, United States |
| Inclusion in work plan: | 2011 |
| Project status and milestones: | <ul style="list-style-type: none"> • First expert meeting held on 1-2 March 2011; • Second expert meeting on 31 January - 2 February 2012; • Expert meeting held on 24-28 September 2012. • Request for comments from the WNT on first draft updated introduction expected later in the TG review process; • Introduction expected to be submitted for approval together with the draft TGs • In parallel, development of a Guidance Document; 1st draft expected to be sent for WNT comments in 2014. |

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| Project 4.64: Transcriptional Assay for the Detection of Estrogenic and Anti-Estrogenic Compounds using the MELN Cells | |
| Lead: Inclusion in work plan: Project status and milestones: | European Commission 2012 |
| <ul style="list-style-type: none"> • In vitro transactivation assay (2 protocols: one for a manual test method and one for a high throughput test method); • Under validation; • Expected to be integrated to TG 455 and TG 457 (BG1Luc ER TA). | |
| Project 4.65: New TG: KeratinoSens: An <i>in vitro</i> Method for Identifying the Skin Sensitisation Potential of Chemicals | |
| Lead: Inclusion in work plan: Project status and milestones: | European Commission and Switzerland 2012 |
| <ul style="list-style-type: none"> • This method will be used to start populating the Adverse Outcome Pathway for Skin Sensitisation, which has been approved by the WNT; • Peer review completed; • Draft TG circulated to WNT for comments in November 2013; meeting of an Expert Group was held on 13-14 February 2014 at OECD in Paris to address comments received; • Second commenting round will take place in 2014, with a view to have approval of the WNT via written procedure in 2014. | |
| Project 4.66: New TG: Direct Peptide Reactivity Assay (DPRA): An <i>In Chemico</i> Method for Identifying the Skin Sensitisation Potential of Chemicals | |
| Lead: Inclusion in work plan: Project status and milestones: | European Commission 2012 |
| <ul style="list-style-type: none"> • This method will be used to start populating the Adverse Outcome Pathway for Skin Sensitisation, which has been approved by the WNT; • Peer review completed; • Draft TG circulated to WNT for comments in November 2013; meeting of an Expert Group was held on 13-14 February 2014 at OECD in Paris to address comments received; • Second commenting round will take place in 2014, with a view to have approval of the WNT via written procedure in 2014. | |
| Project 4.67: Updated TG 431: Referencing of epiCS (previously EST1000) Skin Corrosion Test in TG 431 | |
| Lead: Inclusion in work plan: Project status and milestones: | Germany 2012 |
| <ul style="list-style-type: none"> • Draft updated TG 431 approved by the WNT-26 in April 2014; TG will be published in July or October 2014. | |

| Project 4.69: New TG: Short –Term Exposure Test (STE) for Identifying Ocular Irritants | |
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| Lead: Inclusion in work plan: Project status and milestones: | Japan 2011 |
| <ul style="list-style-type: none"> • Expert group met on 29-30 September 2011 and reviewed the SPSF; • Revised SPSF and validation report submitted to WNT 24; SPSF approved; • Comments on the validation report expected from the WNT by October 2012; • Peer review report and draft Test Guideline expected in 2013; • First draft TG was circulated for a first commenting round in November 2013; • Comments received will be dealt with by the expert group in early 2014 most likely via teleconference, or face-to-face meeting if other (new) projects can justify an agenda for a face-to-face meeting; • The draft TG is expected to be submitted for approval at the WNT in April 2015. | |
| Project 4.71: Updated TG 421/TG 422 (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 |
| <ul style="list-style-type: none"> • • 2013: EG and working group established, reference data forwarded to biostatistician from the lead. Statistical analysis of data initiated, Dec. 2013. • January-March 2014: Analysis of data from lead. Collection of additional data from industry and research laboratories. These data forwarded to biostatistician and analysis initiated. • April-mid June 2014: Statistical analysis completed and development of a draft feasibility report (and first draft of a preliminary revised TG) and discussion of these documents with the working/EG group. Conference call late May-primo June. • August 2014: 1st draft of feasibility report (and the provisionally revised draft TGs) circulated to the WNT for written comments i.e. 1st commenting round (CR). • October 2014: Conference call of the working/expert group to address WNT comments (from 1st CR) and provide input to a new version of the draft feasibility report (and draft rev. TGs) • Late November 2014: draft feasibility report (and draft TG) sent to WNT for a 2nd CR. • January 2015: Conference call(s) of the expert group to address WNT comments (from 2nd CR) and input for a new version of rev. feasibility report (and draft rev. TGs). • Mid-February 2015: Draft feasibility report and draft TG revised based on WNT 2nd CR and forwarded to WNT. • April 2015: Discussion of the revised draft feasibility report (and the draft revised TG 421/422) at the WNT meeting. WNT recommendation regarding whether and how TG 421/422 should be revised, as proposed. If WNT approve the feasibility report and revision of TG 421/422 then the following schedule is envisaged: <ul style="list-style-type: none"> • June 2015: final draft revised TG 421/422 circulated to 3rd WNT CR. • Oct. 2015: Final draft TG 421/422 circulated for written WNT approval. <p>Alternatively, based on the 1st draft feasibility report circulated in August 2014, the WNT might agree to consider submission of the draft updated TGs 421/422 for approval in April 2015.</p> | |

| Project 4.72: Thyroid Scoping Document | |
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| Lead: Inclusion in work plan: Project status and milestones: | Secretariat 2013 |
| <ul style="list-style-type: none"> • Draft document circulated to the WNT for review mid-2013 and in December 2013; • Draft document approved by the WNT in 2014; document will be declassified and published in June or July 2014 in the Series on Testing and Assessment. | |
| 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 |
| <ul style="list-style-type: none"> • SPSF is approved and may be merged with project 4.33 when the validation is completed. | |
| 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 |
| <ul style="list-style-type: none"> • Validation study carried out, peer review completed in 2014 and EURL ECVAM Recommendation to follow; • Draft TG should be ready before July 2014 for a review/commenting round by the WNT and its expert group on skin sensitisation in vitro. | |
| 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 |
| <ul style="list-style-type: none"> • The validation report and peer-review report are expected to be submitted in 2014. | |
| Project 4.77: Feasibility study for a Guidance Document on Study Designs, to be used in revisions to Guidelines | |
| Lead: Inclusion in work plan: Project status and milestones: | Netherlands 2013 |
| <ul style="list-style-type: none"> • 2013: statistical evaluation of the study designs, followed by a feasibility study for a guidance document on study designs, to be used in revisions of specific Test Guidelines; • 2013: create an expert group to comment on the feasibility study, commenting via email and if needed face-to-face meeting if difficult issues; • If opinion of expert group is favourable on the development of a guidance document, an SPSF will be prepared; no further information available in 2014. | |

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| Project 4.78: Updated TG 488, Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays | |
| Lead: Inclusion in work plan: Project status and milestones: | Canada 2013 |
| <ul style="list-style-type: none"> • 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 <i>in vivo</i> Test Guidelines currently under revision • New updated TG 488 will be prepared when other genotoxicity TGs are revised. | |
| 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 |
| <ul style="list-style-type: none"> • July – September -2014: Collate data from partners; • October – December 2014: Assess data and write report; • December 2014– January 2015: Draft update to TG; • January – February 2015: OECD Consultation round, collate comments; • April 2015: Submit to WNT. | |
| 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 |
| <ul style="list-style-type: none"> • Final report of the Cosmetics Europe project will be circulated to the Expert Group on Skin Corrosion/Skin Irritation in June 2014. • Proposed revision of OECD Test Guidelines 431 and 439 to incorporate HPLC/photometry as complementary to standard photometry in these RhT test methods to expand applicability to include coloured chemicals that strongly interfere with MTT reduction will be circulated to WNT for comment in the second half of 2014. • Final draft revised Test Guidelines should be submitted to WNT for approval in 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 |
| <ul style="list-style-type: none"> • June-July 2014: draft TG and supporting information will be provided to the OECD for a review/commenting round by the WNT and its expert group on eye irritation; • July-October 2014: Performance Standards will be provided for review/commenting by the WNT and its expert group on eye irritation; • Expert meeting on eye irritation to be convened in November 2014 to discuss and address the comments received from the first circulation round; • Depending on the comments received and the outcome of the expert meeting, a revised final draft TG may be submitted to the WNT for adoption in April 2015 (at WNT27). | |

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| Project 4.82: Update of TG 455-TG 457 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 |
| <ul style="list-style-type: none"> • 2013-2014: on-going inter-laboratory study that will be reported in December 2014 to the VMG-NA. | |
| 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 |
| <ul style="list-style-type: none"> • Formation of Expert Group, Q3 2014 • International scoping discussion Q3-Q4 2014 <ul style="list-style-type: none"> ○ 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 • Final draft GD to the WNT for adoption in Q3 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, Netherlands (TBC) 2014 |
| <ul style="list-style-type: none"> • SPSF was approved taking into account modifications requested at WNT-26 for softer language as regards mandatory vs optional required measurements in the TGs. • Completion of Amendments to GD(s) and TGs anticipated to take approximately 6 to 12 months for all items, depending on outcomes from WPMN and WNT reviews. Work will largely occur via teleconferences and email. The Netherlands has offered to support a second expert workshop, if justified. | |

SECTION 5
PROJECTS RELATED TO OTHER TEST GUIDELINES

| Project 5.9: Revision of CFT GD and new GD for rotational crop field trial | |
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| Lead: Inclusion in work plan: Project status and milestones: | United States through the WG Pesticides 2008 |
| <p>1) <u>Updating of 2011 Guidance Document on Crop Field Trials</u></p> <ul style="list-style-type: none"> • The draft Guidance Document on crop field trials is being developed by the Residue Chemistry Expert Group (RCEG) • It is expected that first draft GDs will be available in early to mid-2015. <p>2) <u>New Guidance Document on Rotational Crops:</u></p> <ul style="list-style-type: none"> • The draft Guidance Document on rotational crop field trials is being developed by the Residue Chemistry Expert Group (RCEG) • It is expected that first draft GDs will be available in early to mid-2015. | |
| 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 |
| <ul style="list-style-type: none"> • The WNT approved a Guidance Document (rather than TG) at the 26th WNT meeting (9-11 April 2014); the project is completed. The GD will be declassified and published in June or July 2014 in the Series on Testing and Assessment. | |
| 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: Project status and milestones: | Canada, USA and EFSA through the WG Pesticides 2013 |
| <ul style="list-style-type: none"> • First draft GD expected for WNT & WGP commenting round in the first half of 2014; • Revision of the draft GD in the second half of 2014; • Second commenting round anticipated by end of 2014. | |
| Project 5.14: New GD for Single Laboratory Validation of Quantitative Analytical Methods in support of pre- and post-registration data requirements for biocidal and plant protection products | |
| Lead: Inclusion in work plan: Project status and milestones: | Ireland and US through the TF Biocides 2013 |
| <ul style="list-style-type: none"> • The GD was approved by the WNT at the April 2014 meeting; the project is completed. The GD will be declassified and published in June or July 2014 in the Series on Testing and Assessment. | |
| 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 |
| <ul style="list-style-type: none"> • Establishment of an <i>ad hoc</i> Expert Group on Biocide Chemistry in August 2012 (see above) | |

project 5.14);

- teleconferences of the EGBC approximately every 2-3 months;
- First draft GD on storage stability expected to be available for review by Mid of 2014;
- Number of TFB & WNT commenting round(s) as needed in 2014.

ANNEX 1

PROJECTS THAT ARE REMOVED AFTER TWO YEARS WHEN NO LONGER SUPPORTED

| Project 2.4: New TG 2-Generation Avian Toxicity | |
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| Lead: | United States |
| Inclusion in work plan: | 1999 |
| Inclusion in Annex 1 | 2014 |
| <ul style="list-style-type: none"> • 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. | |
| 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 |
| <ul style="list-style-type: none"> • 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; | |

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| <ul style="list-style-type: none"> 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 2.40: New TG: Fish Reproduction / Partial Lifecycle Test | |
| Lead: | United States |
| Inclusion in work plan: | 2012 |
| Inclusion in Annex 1 | 2014 |
| <ul style="list-style-type: none"> 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 3.5: Development of a Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3, Part 2: Bioaccumulation and Behaviour in Soils and Sediments | |
| Lead: | United States |
| Inclusion in work plan: | 2005 |
| Inclusion in Annex 1 | 2011 |
| Project 4.26: Cell Transformation Assay using Balb/c 3T3 cell line | |
| Lead: | Japan |
| Inclusion in work plan: | 2007 |
| Inclusion in Annex 1 | 2014 |
| <ul style="list-style-type: none"> 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 4.47: EDTA Activity - TG for an MCF-7 Cell Proliferation Assay for the Detection of Estrogen Receptor Agonist and Antagonist | |
| Lead: | United States |
| Inclusion in work plan: | 2010 |
| Inclusion in Annex 1 | 2013 |
| Project 4.48: EDTA Activity - TG for a Chimpanzee Recombinant Androgen Receptor Binding Assay | |
| Lead: | United States |
| Inclusion in work plan: | 2010 |
| Inclusion in Annex 1 | 2013 |