

Work plan for the Test Guidelines programme (TGP)

(June 2013)

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

Project 1.4: New TG: pH, Acidity and Alkalinity	
Lead: Inclusion in work plan: Project status and milestones:	TF Biocides 2011
<ul style="list-style-type: none">• Draft TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement.	

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

Project 2.1: EDTA Activity: New TG for Copepod Reproduction and Development	
Lead:	Sweden
Inclusion in work plan:	2002
Project status and milestones:	
<ul style="list-style-type: none"> • Pre-validation completed, expert group meeting on 3-4 November 2005; • Revised detailed ring-test plan circulated in November 2005; Ring-test between November 2005 and mid-2006; • Submission of the draft report to the invertebrate expert group and the VMG-eco; • Additional experimental work (plus report and statistical analysis) completed in 2007 (TESTDEMECO); • Validation report (Phase 1) published in 2007; • Expert group agreement on another ring test. Validation plan developed by Sweden and the US; • Validation report (phase 2) endorsed at the 2011 WNT meeting; • The US took the lead of an additional interlaboratory study; • Outcome of additional work discussed at the VMG-eco meeting (November 2011) • Comparison review between copepod and mysid; • Experimental work expected to be completed in 2nd quarter 2012; • Integrated Summary Report expected to be available in Spring 2013. 	
Project 2.3: New GD for Avian Avoidance Studies	
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 be held. • The UK to explore the feasibility – in terms of funding and experts availability – of hosting a workshop in the 1st half of 2014 (report on progress at WNT25 in April 2013) 	
Project 2.4: New TG 2-Generation Avian Toxicity	
Lead:	United States
Inclusion in work plan:	1999
Project status and milestones:	
<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.

Project 2.7: New TG for Fish Embryo Toxicity test

Lead:	Germany
Inclusion in work plan:	2005
Project status and milestones:	<ul style="list-style-type: none"> • Draft TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and published.

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

Lead:	United States + Germany + Japan
Inclusion in work plan:	2000
Project status and milestones:	<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 meeting held on 9-10 February 2011 in Japan; • Progress report at the VMG-eco meeting in November 2011; • Integrated summary report expected to be available in Spring 2013.

Project 2.13: EDTA Activity: New TG for Mysid Life Cycle Toxicity Test

Lead:	United States
Inclusion in work plan:	2002
Project status and milestones:	<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; • Optimization; 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.

Project 2.31: EDTA Activity - TG on a Larval Amphibian Growth and Development Assay

Lead:	United States + Japan
Inclusion in work plan:	2009
Project Status and milestones:	

- Report at the VMG-eco meeting in November 2011;
- Validation expected to be completed in 2nd quarter 2012;
- Validation report expected to be available in Spring 2013.

Project 2.33: New TG for a Protozoa Activated Sludge phagocytosis inhibition Test

Lead:	Germany
Inclusion in work plan:	2009
Project Status and milestones:	

- 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 the second half of 2013.
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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:	

- Annual meetings of lead countries;
- Pre-validation of *Lymnaea* test was completed in 2012 (a progress report is available).;
- Pre-validation of *Potamopyrgus* test is still ongoing and will be completed in summer 2013 (a progress report is available).
- Results of the pre-validation tests will be presented at the next meeting of the VMG-eco (2013);
- Forthcoming validation tests are currently being organized (choice of toxicants and partner laboratories to be involved worldwide, fund-raising); Validation is planned for both species in 2014.
- Invertebrate Testing Expert Meeting in June 2013 to discuss results and next steps;
- First draft TG expected to be ready for a WNT commenting round by the end of 2014.

Project 2.37: Updating TG 210: Fish Early-Life Stage Toxicity Test

Lead:	Germany
Inclusion in work plan:	2011
Project Status and milestones:	

- Draft Updated TG approved by the WNT in April 2013 and submitted to the Joint Meeting and

EPOC for endorsement, then to Council for adoption and published.

Project 2.38: New TG: Growth Inhibition Test for the Rooted, Submerged Aquatic Macrophyte, *Myriophyllum* species

Lead:	United Kingdom and the Netherlands
Inclusion in work plan:	2011
Project Status and milestones:	

- Draft test method available (February 2011, attached to the SPSF) and ring-test expected to be completed in 2011;
- Ring test report expected by the end of 2012;
- Late 2012-Early 2013: Work on this project possibly combined with the work on project 2.43 "Sediment-free *Myriophyllum spicatum* toxicity test", provided that the work progresses at the same rhythm.

Ring-test completed in 2012 and report available in April 2013. Draft Test Guideline available to be circulated for a first WNT commenting round in April-May 2013.

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

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

- 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 in 2013.

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

Lead:	United States
Inclusion in work plan:	2012
Project status and milestones:	

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

Project 2.43: New TG: Sediment-Free *Myriophyllum spicatum* Toxicity Test

Lead:	Germany
Inclusion in work plan:	2012
Project status and milestones:	

- Possible impact of sucrose on the photosynthesis inhibition will be further investigated during the Test Guideline development;
- Work on this project possibly combined with the work on project 2.38 "Growth inhibition test for the rooted, submerged aquatic macrophyte, *Myriophyllum* species", if it is the same timing.
- Draft Test Guideline circulated for a first commenting round in March 2013; deadline for response: 10th May 2013.

Project 2.44: New TG: Honey Bee (*Apis Mellifera* L.): Brood Test

Lead: Inclusion in work plan: Project status and milestones:	France 2012
<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. 	
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
<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; • 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 will draft the SPSF. 	
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 of the draft protocol: 3 months. The proposed schedule will be validated during the next VMG-eco meeting • Kick off meeting for the validation study/ Training of participating laboratories to perform the EASZY assay according to SOP: 2-3 days; • Validation of the assay by participating laboratories: a period of 2 or 3 months is planned to assess the effect of 20 selected chemicals; • Data analysis and drafting of the report in 2014; • Revised version and proposal of a 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 second half of 2013 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) 2014. 	

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; and Addendum to Validation Report for dietary exposure	
Lead:	Germany, Netherlands, United Kingdom
Inclusion in work plan:	2012
Project status and milestones:	
	<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 in June 2013;• Tentative workshop in September 2013 (exact date and venue to be determined);• Draft Guidance Document expected to be submitted for approval to WNT in 2014.

**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:	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 finalized; • 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> • UK invited countries’ laboratories to collect data to support the use of evident toxicity in acute inhalation toxicity in TG 433; • UK meetings to provide laboratories with information on data collection on 16 April 2013, 25 June 2013.
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 will take place later in 2013, dates to be confirmed.
Project 4.26: Cell Transformation Assay using Balb/c 3T3 cell line	
Lead:	Japan
Inclusion in work plan:	2007

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 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 4.31: 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 expected early 2013, followed by a peer review starting in May 2013; • Draft TG expected to be submitted for a 1st WNT commenting round in October 2013, discussed at the VMG NA 11 and submitted for a 2nd WNT commenting round by the end of 2013. • Draft Test Guideline expected to be submitted for approval at the 2014 WNT meeting
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; • Additional validation expected to be completed in 2013, if possible.
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 report and draft TG expected to be available by the end of 2013.
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"> • Short presentation on Progress at WNT 21; • Expert group meeting to review all genotoxicity methods held on 1-2 March 2011 in Paris;

- Submission of a draft validation report and draft Test Guideline early September 2012, to allow an initial review of these documents at the expert meeting on genotoxicity held on 25-27 September 2012 (Accelerate procedure requested by several EU countries);
- Revised validation report submitted early January 2013
- Peer review performed in January/February 2013
- Expert meeting on 19-21 March 2013;
- Request for WNT comments on the first draft Test Guideline expected in May 2013;
- Submission for WNT approval of the validation report, peer review report, and WNT agreement on the follow-up to the peer review at the 2013 WNT meeting.
- Validation and peer-review reports were approved by the WNT in April 2013 and will be submitted to the Joint Meeting for declassification.
- 1st WNT commenting round of the draft TG expected in June 2013.

Project 4.42: Update of TG 430: *In vitro* Skin Corrosion: Transcutaneous Electric Resistance (TER)

Lead: Inclusion in work plan: Project status and milestones	United States 2009
<ul style="list-style-type: none"> • Draft updated TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication. 	

Project 4.43: Update of TG 431: *In vitro* Skin Corrosion: Human Skin Model Test

Lead: Inclusion in work plan: Project status and milestones	United States 2009
<ul style="list-style-type: none"> • Draft updated TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication. 	

Project 4.44: TG for the use of an *in vitro* epidermal model to assess skin irritation: LabCyte EPI-MODEL24

Lead: Inclusion in work plan: Project status and milestones	Japan 2009
<ul style="list-style-type: none"> • Draft updated TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication. 	

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 and requested clarification on the domain of application of the bottom-up approach; a meeting of the eye irritation/corrosion expert group may be organised in 2013 to address remaining issues if the method is still supported.

Project 4.53: GD on Skin Irritation/Corrosion and related TGs

Lead:	Germany
Inclusion in work plan:	2010
Project status and milestones	

- Expert meeting reviewed the different types of tools that can be used in a testing strategy, and their applicability (19-21 October 2010, Berlin);
- Work plan proposed by the expert meeting to develop the draft GD and related TGs submitted for WNT comments at the 2011 WNT meeting;
- Draft GD discussed at an expert meeting on 18-19 January 2012 in Helsinki (Finland);
- Lead country is preparing a revised draft GD with the experts involved in the work;
- Discussion of the revised draft at an expert group meeting that will be held on 13-14 September 2012;
- First expert commenting round expected in September 2013;
- Expert meeting planned in November 2013 in Berlin to review the GD and comments received by then;
- WNT commenting round to take place in December 2013;
- Submission of the draft GD for WNT approval possibly expected in 2014.

Project 4.54: Validation of a Cell Transformation Assay Using Bhas 42 Cell Line for Detection of Non-Genotoxic and Genotoxic Carcinogens

Lead:	Japan
Inclusion in work plan:	2010
Project status and milestones	

- 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.

Project 4.55: GD on internal triggers for US/Canada (GD 117) and GD Supporting the TG for an Extended One Generation Reproductive Toxicity Study (draft GD 151)

Lead:	Secretariat
Inclusion in work plan:	2010
Project status and milestones	

- Draft GD approved by the WNT in April 2013 and submitted to the Joint Meeting for declassification.

Project 4.57: Updated *in vivo* somatic cell genotoxicity TGs (TG 474 and 475)

Lead:	Canada
Inclusion in work plan:	2011
Project status and milestones:	

- First expert meeting held on 1-2 March 2011;
- Second expert meeting on 31 January - 2 February 2012;
- WNT comments on first draft updated TG 474 and TG 475 requested in July 2012;

<ul style="list-style-type: none"> • Third expert meeting held on 24-28 September 2012; • Second WNT commenting round expected sometimes in 2013 for TG 474 and TG 475 respectively; • TG 474 and TG 475 expected to be submitted for WNT approval at the 2014 WNT meeting. 	
Project 4.58: Updated <i>in vivo</i> germ cell genotoxicity TGs (TG 478 and 483)	
Lead: Inclusion in work plan: Project status and milestones:	Canada 2011
<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. 	
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
<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. 	
Project 4.60: Updated TGs for <i>in vitro</i> genotoxicity assays (TG 473, 476, 487)	
Lead: Inclusion in work plan: Project status and milestones:	Canada, Netherlands, France, United States 2011
<ul style="list-style-type: none"> • First expert meeting held on 1-2 March 2011; • Second expert meeting on 31 January - 2 February 2012; • Request for comments from the WNT on first draft updated TGs 473 and 487 in April 2012. • Third expert meeting held on 24-28 September 2012 • Second request for WNT comments on TG 473 and on TG 487 mid-November 2012; • Development of a report supporting statistical issues and data interpretation expected in May 2013. • Request for comments from the WNT on first draft updated TGs 476 expected mid 2013 (together with new TG on MLA (see project 4.59)); • TG 473 and TG 487 expected to be submitted for WNT approval at the 2014 WNT meeting. 	
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
<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.	
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 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 ongoing; • Draft TG expected to be circulated to WNT for comments in 2013 (Q2). 	
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 ongoing; • Draft TG expected to be circulated to WNT for comments in early 2013 (Q2). 	
Project 4.67: Updated TG 431: Referencing of 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 TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication. 	
Project 4.68: Updated TG 431: Referencing of SkinEthic Reconstructed Human Epidermis Skin Corrosion Test in TG 431	
Lead: Inclusion in work plan: Project status and milestones:	France 2012
<ul style="list-style-type: none"> • Draft TG approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication. 	
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
<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. 	
Project 4.70: Updated TG 437/TG 438 (BCOP and ICE test methods updated for the identification of chemicals not requiring classification for eye irritation/corrosion according to the GHS):	
Lead: Inclusion in work plan: Project status and milestones:	European Commission, Netherlands, United States 2011
<ul style="list-style-type: none"> • Draft TGs and Streamlined Summary Documents approved by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement, then to Council for adoption and publication of the updated TGs. 	
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: review & first draft proposal for revision of TG 421/422. Moreover, discussion at VMG-mammalian teleconference(s) based on draft proposal. • 2014: review and refined proposal. Draft revisions of TG 421/422 will be circulated to VMG-mammalian for comments. Further revision and meeting of the VMG-mammalian and agreement on revisions needed in TG 421/422 text. Submission to WNT NCs for comments and revision as appropriate end of 2014. • 2015: adoption at OECD. 	
Project 4.72: Thyroid Scoping Document	
Lead: Inclusion in work plan: Project status and milestones:	Secretariat 2013
<ul style="list-style-type: none"> • Draft document to be circulated to the WNT for review mid-2013; • Draft document expected to be submitted to WNT in 2014 for approval. 	
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 4.74: Toxicity Testing on Immature/Juvenile Rodents	

Lead: Inclusion in work plan: Project status and milestones:	Italy 2013
<ul style="list-style-type: none"> Project proposal was provisionally approved and the SPSF will be revised to indicate that the project will start with a meta-analysis and an expert meeting to identify what might be needed; the revised SPSF will also include a more detailed discussion of the relevance of the project in the frame the assessment of risk related to children exposure, with particular reference to REACH, PPPs and Biocides data requirements. 	
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 on-going and ESAC statement expected by end 2013. 	
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 is planned to be presented to ESAC (ECVAM Scientific Advisory Committee) in March 2013, for a peer-review in October 2013, followed by a draft ECVAM recommendation and public consultation. 	
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 in November 2013. 	
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 will be submitted to JM and EPOC for endorsement and then to Council for adoption and published; Second step: Further update based on additional germ cell research and harmonisation with the other in vivo Test Guidelines currently under revision New updated TG 488 expected to be submitted to WNT approval in 2014 	

**SECTION 5:
PROJECTS RELATED TO OTHER TEST GUIDELINES**

Project 5.6: Five New TGs for Evaluating Efficacy of Microbicides Used on Non-Porous Hard Surfaces: Bactericidal – Fungicidal – Mycobactericidal – Virucidal – Sporicidal	
Lead: Inclusion in work plan: Project status and milestones:	United States through the TF Biocides 2007
<ul style="list-style-type: none"> Draft document, including four test methods (i.e. all except sporicidal), was approved as a Guidance Document by the WNT in April 2013 and submitted to the Joint Meeting and EPOC for endorsement. 	
Project 5.9: Two new GDs (Livestock residues and Rotational crops), revision of CFT GD and new Introduction to TGs Section 5A on Pesticide Residue Chemistry	
Lead: Inclusion in work plan: Project status and milestones:	United States through the WG Pesticides 2008
<ol style="list-style-type: none"> <u>New Guidance Document on livestock residues</u> <ul style="list-style-type: none"> Draft GD on Residues in Livestock submitted for comments and possible approval to the WNT by written procedure in July 2012; Draft GD, revised per WNT comments and approved in November 2012; Submitted to the Joint Meeting for declassification and further publication in both series on Testing & Assessment and Pesticides (2013). <u>Updating of 2011 Guidance Document on Crop Field Trials</u> <ul style="list-style-type: none"> RCEG meeting in New Zealand at OECD RSG on 27-28 November 2012 to discuss the updating of the 2011 CFT Guidance Document; First draft updated CFT GD expected in 2013. <u>New Guidance Document on Rotational Crops:</u> <ul style="list-style-type: none"> RCEG meeting in New Zealand at OECD RSG on 27-28 November 2012 to discuss the development of a new GD on rotational crops; First draft GD on rotational crops expected in 2013. <u>New Introduction to the Test Guidelines Section 5-A on Pesticide Residue Chemistry:</u> (i) WNT commenting round of draft Introduction in November 2012-January 2013; (ii) approved by WNT25 in April 2013; and (iii) submitted to the Joint Meeting and EPOC for endorsement. 	
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"> Expert Group on Efficacy of Biocides to Treat Articles (EBTA) established under the TFB in 2008. Review of the first draft TG by the WNT: commenting round November 2012-31 January 2013; Revision of draft TG by the project leaders; Next commenting round of draft TG and draft validation report anticipated for mid of 2013; Draft TG and draft validation report expected to be submitted to WNT 26 in 2014. 	

Project 5.11: New GD on the Testing the Efficacy of Baits against Ants	
Lead: Inclusion in work plan: Project status and milestones:	Germany through the TF Biocides 2011
<ul style="list-style-type: none"> • Draft GD approved by the WNT in April 2013 and submitted to the Joint Meeting for declassification. 	
Project 5.12: GD on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials, and possible further activities	
Lead: Inclusion in work plan: Project status and milestones:	Working Party on manufactured nanomaterials (WPMN) 2010
<ul style="list-style-type: none"> • Revised Guidance Document published in the Series on the Safety of Nanomaterials, No. 36, 2012; • Possible further work on the development of physical-chemical Test Guideline(s) for the characterisation and dosing of nanomaterials 	
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 2013; • Revision of the draft GD in the second half of 2013; • Number of additional review round(s) as needed; • Expected submission of draft GD for approval at WNT26 in 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"> • Establishment of an <i>ad hoc</i> Expert Group on Biocide Chemistry in August 2012 (the EGBC is chaired by Ireland and involves experts from Australia, Belgium, Canada, Germany, Netherlands, Sweden, US, UK and EC); • Several teleconferences of the EGBC between September 2012 and February 2013; • First draft GD on validation of quantitative analytical methods available in February 2013; • Commenting round of the draft GD through the TFB & WNT (planned April-June 2013); • Revision of the draft GD in the second half of 2013; • Number of additional review round(s) as needed; • Expected submission of draft GD for approval at WNT26 in 2014. 	
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

- Establishment of an *ad hoc* 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 2013;
- Number of TFB & WNT commenting round(s) as needed;
- Possible submission of draft GD for approval at WNT26 in 2014.

PROJECTS OF A GENERAL NATURE

Project 0.3: Updating /Maintaining TGP Web pages

Lead:	Secretariat
Inclusion in the work plan:	Continuous effort
Project status and milestones:	
<ul style="list-style-type: none"> • Thorough revision of TGP Web pages, including Endocrine Disrupters WebPages; • Public site was re-designed, and includes important information on the Test Guidelines (and draft ones), the publications in Testing and Assessment Series (and draft ones), the list of National Coordinators, animal welfare and Test Guidelines for in vitro test methods, work on endocrine disrupters, TGP workplan. 	

Project 0.5: Templates for new and revised TGs

Lead:	Secretariat + NCs
Inclusion in work plan:	2004
Project status and milestones:	
<ul style="list-style-type: none"> • Workshop held 14-16 June 2004; • 86 templates agreed by the JM; • Preparation of new or revised templates, if appropriate for all new or revised TGs; • Secretariat submitted a paper explaining the process at WNT 19; • Guidance on template preparation/revision by lead countries available in July 2008; • The Secretariat will contact NCs as new or updated TGs are adopted. 	

Project 0.7: Work on Adverse Outcome Pathways, Toxicogenomics and molecular screening

Lead:	Secretariat + IPCS
Inclusion in work plan:	2003
Project status and milestones:	
<ul style="list-style-type: none"> • Fifth meeting of the Extended Advisory Group on 7-8 June 2012 at OECD. Proposal to launch the programme for the development of Adverse Outcome Pathways (AOPs), approved by the Joint Meeting in November 2013. • A workshop “Moving Forward in Human Cancer Risk Assessment in the Genomics Era 2.0” took place on 16-17 May, organised by the University of Maastricht and ILSI/HESI; • The sixth meeting of the Extended Advisory Group, held in Paris on 14-15 May 2013. • The AOP development programme has developed its own work plan which is available to the WNT in a separate document; information including projects on the work plan and relevant documents (guidance, template and submission form) will be made publicly available. • A drafting group is working on the development of guiding principles for the high throughput screening and non-standardised test methods; • A drafting group is working on the development of a user’s manual for the AOP development work; • The 26th WNT will have a focus session on AOPs. 	

Project 0.8: EDTA Activity: Information Exchange on (Q)SAR Methods for ED Assessment

Lead:	United States
Inclusion in work plan:	2003
Project status and milestones:	
<ul style="list-style-type: none"> • Task Group established in November 2004, lead by EC/JRC/ECB; • 1st meeting in June 2005; 	

- Report to VMG-non animal in December 2006; discussion of the role of the group;
- Reorganisation of the work agreed at WNT 19;
- New group led by US EPA; meeting prior to the VMG-non animal and progress report to VMG-non animal in November 2007;
- Workshop on 17 February 2009 (with the QSAR Application Toolbox Management Group);
- Continuous activity, last report at the VMG-non animal meeting in December 2011.

Project 0.9: Development of a white paper on missing items in Guidance Document 34

Lead:	Secretariat
Inclusion in work plan:	2011
Project status and milestones:	

- Draft paper expected to be developed when resource is available;
- Possible contribution from the 2012 WNT Special Session.

ANNEX 1
PROJECTS THAT WILL BE REMOVED AFTER TWO YEARS IF NOT SUPPORTED

Project 1.1: Updated TG 120 Solution/Extraction Behaviour of Polymers in Water	
Lead:	Canada
Inclusion in work plan:	2007
Inclusion in Annex 1	2011
Project status and milestones:	
<ul style="list-style-type: none"> • (Re)-establishment of an expert group; • Teleconference on technical issues and concerns with TG 120, and on a work plan for the expert group in December 2007; • First draft revised TG was expected to be submitted to the secretariat in May 2010; Unless a draft TG is provided before the 2011 WNT meeting, the Secretariat proposes to include this project in Annex 1 (Projects that will be removed after two years if not supported). 	
Project 3.5: Development of a Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3, Part 2: Bioaccumulation and Behavior in Soils and Sediments	
Lead:	United States
Inclusion in work plan:	2005
Inclusion in Annex 1	2011
Project status and milestones:	
<ul style="list-style-type: none"> • Proposal discussed at WNT 17; • The project will be kept on hold for a couple of years due to ongoing work at ILSI and SETAC on this issue; • Unless a draft revised introduction is provided before the 2011 WNT meeting, the Secretariat proposes to move this project to Annex 1 (Projects that will be removed after two years if not supported). 	
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
Project status and milestones	
<ul style="list-style-type: none"> • Information on the added value, scope, and possible place in an endocrine disrupter assessment scheme expected to be provided by the VMG-non animal before the first commenting round; • Validation study completed in January 2011; • Validation report expected in 2012; • US expected to make a decision on whether a Peer Review will be conducted and a draft Test Guideline developed; • The project is discontinued and will be moved to Annex 1 of the workplan; • The validation report is submitted to the WNT for information and available from the Secretariat upon request. 	

Project 4.48: EDTA Activity - TG for a Chimpanzee Recombinant Androgen Receptor Binding Assay

Lead:	United States
Inclusion in work plan:	2010
Project status and milestones	
<ul style="list-style-type: none">• Information on the added value, scope, and possible place in an endocrine disrupter assessment scheme expected to be provided by the VMG-non animal before the first commenting round;• Pre-validation report expected when the pre-validation is completed.• This project is not expected to be continued after that stage, the project will be moved to Annex 1 of the workplan;• The pre-validation report is submitted to the WNT for information and available from the Secretariat upon request.	