

## UPDATED WORK PLAN FOR THE TEST GUIDELINES PROGRAMME (TGP)

(August 2008)

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Projects of a general nature are included after Section 5. Projects remain in the work plan until their publication. Each project keeps the same identification number until it is completed. If a project is no longer supported by countries, it is moved in Annex 1 for two years and then deleted. Annex 2 lists adopted Test Guidelines for which an existing template needs to be revised or a new template should be developed

### **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: endocrine disrupters testing and assessment

EPOC: Environmental Policy Committee

NC: national coordinator

SPSF: standard project submission form

VMG-eco: validation management group for ecotoxicity testing

VMG-mam: validation management group for mammalian testing

VMG-non animal: validation management group for non animal testing

WNT: Working Group of the National Coordinators for the Test Guidelines Programme

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

<b>Project 1.1: Updated TG 120 Solution/Extraction Behaviour of Polymers in Water</b>	
Lead:	Canada
Inclusion in work plan:	2007
Project status and milestones:	<ul style="list-style-type: none"><li>• (Re)-establishment of an expert group;</li><li>• Teleconference on technical issues and concerns with TG 120, and on a work plan for the expert group in December 2007;</li><li>• Draft revised TG expected to be circulated to the expert group after summer 2008; second teleconference of the expert group expected after summer 2008.</li><li>• WNT circulation of the first draft revised TG expected after summer 2008.</li></ul>

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

<b>Project 2.1: EDTA Activity: New TG for Copepod Reproduction and Development</b>	
Lead:	Sweden
Inclusion in work plan:	2002
Project status and milestones:	<ul style="list-style-type: none"> <li>• Pre-validation completed, expert group meeting on 3-4 November 2005;</li> <li>• Revised detailed ring-test plan circulated in November 2005; Ring-test between November 2005 and mid-2006;</li> <li>• Submission of the draft report to the invertebrate expert group and the VMG-eco;</li> <li>• Additional experimental work (plus report and statistical analysis) completed in 2007 (TESTDEMECO);</li> <li>• Validation report (Phase 1) published in 2007;</li> <li>• Expert group agreement on another ring test. Validation plan expected to be developed by Sweden and the US;</li> <li>• Report expected in fall 2008; It will be circulated with the draft TG to the WNT for comments.</li> </ul>
<b>Project 2.3: New GD for Avian Avoidance Studies</b>	
Lead:	United Kingdom (took over from BIAC in 2004)
Inclusion in work plan:	1999
Project status and milestones:	<ul style="list-style-type: none"> <li>• Expert group meeting in May 2005 (in the margin of Lille SETAC meeting);</li> <li>• Revised draft presented to the expert group in May 2005.</li> <li>• Small expert group meeting in May 2006 (in the margin of SETAC meeting);</li> <li>• Revised SPSF agreed at WNT 19. Two more expert group meetings expected;</li> <li>• Lead country is awaiting the outcome of similar project from EFSA in the EU.</li> </ul>
<b>Project 2.4: New TG 2-Generation Avian Toxicity</b>	
Lead:	United States
Inclusion in work plan:	1999
Project status and milestones:	<ul style="list-style-type: none"> <li>• Initial draft TG in 1999; decision to conduct an avian dosing study to be considered after DRP approval (Project 2.5 completed);</li> <li>• Species comparison study circulated to the expert group in April 2005;</li> <li>• Avian dosing study (July 2005) and revised draft TG (November 2005) presented at VMG-eco in December 2005;</li> <li>• Revised draft TG used in developing a protocol for a demonstration study;</li> <li>• Revised SPSF expected when the demonstration project is over, which is expected by end 2008.</li> </ul>
<b>Project 2.7: New TG for Fish Embryo Toxicity test</b>	
Lead:	Germany
Inclusion in work plan:	2005
Project status and milestones:	<ul style="list-style-type: none"> <li>• First draft of the TG and comprehensive background paper sent to the WNT for comments by 1 September 2006;</li> <li>• Establishment of an expert group to address comments received;</li> <li>• First teleconference of expert group on 29 January 2007: decision on further validation steps;</li> </ul>

- followed by two other conference calls;
- Meeting of the expert group on 9-11 October 2007 in Berlin;
  - Expert group addressed the issue of performance; meeting arranged by ILSI/HESI at L'Oreal in Paris in March 2008 with a session on the OECD FET;
  - Progress reported to WNT20;
  - Meeting of the expert group in May 2008 in Berlin;
  - 2-step validation approach under development by the expert group;
  - First step expected to start in September-October 2008.

**Project 2.8: EDTA Activity: Enhanced Test Guideline 211: *Daphnia Magna* Reproduction Test**

Lead: Japan

Inclusion in work plan: 2004

Project status and milestones:

- Pre-validation of the new endpoint by Japan;
- Validation plans discussed in November 2005 at an expert group meeting;
- Experimental work (Ring test) in 2006;
- Draft report circulated to VMG-eco and the invertebrate expert group for comments and submitted to the VMG-eco meeting for approval in January 2008;
- Draft updated TG, with very limited changes, approved by WNT20;
- Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008.

**Project 2.9: New TG: Collembola Reproduction Test**

Lead: Denmark

Inclusion in work plan: 2005

Project status and milestones:

- Ring test in 2005-2006;
- Circulation of the ring test report and draft TG expected by the end of September.

**Project 2.12: EDTA Activity: Development and Validation of a Fish Life-Cycle Test**

Lead: United States + Germany + Japan

Inclusion in work plan: 2000

Project status and milestones:

- 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 (TESTDEMECO);
- Review of statistical issues circulated for comments in September 2007 to the fish drafting group and the VMG-eco [TESTDEMECO- See also Project 2.16];
- Revised review of statistical issues submitted to the VMG-eco meeting in January 2008;
- Development of a TG by Japan and the United States at a later stage.

**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:

- 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 the Annex;
- Germany expressed interest in the project;
- Depending on the validation outcome, the SPSF will be revised and other partners will be invited to participate.

**2.14: Project 2.14: EDTA Activity: Development and Validation of a New TG: Fish Sexual Development Test**

Lead: Denmark

Inclusion in work plan: 2003

Project status and milestones:

- Optimization of the test methods in 2005;
- Validation plan prepared by Denmark and the fish drafting group;
- Letter sent to request nomination of laboratories by 23 June 2006;
- Pre-validation experimental work started at the end of August 2006;
- Draft report and statistical analysis finalized in 2007 (TESTMETEDECO);
- Draft report and proposals for follow-up work discussed at the VMG-eco meeting in January 2008;
- Consolidated draft Report for Phase 1 circulated to the VMG-eco on 26 June for comments by 18 August 2008;
- Phase 2 experimental work expected to start in 2008.

**Project 2.16: EDTA Activity: Development of a DRP on Fish (Long Term) Testing**

Lead: United States

Inclusion in work plan: 2002

Project status and milestones:

- First draft proposal circulated in March 2003;
- Comments received and returned to the US for revision in November 2003;
- Next revision circulated for comments in September 2007 to the Fish Drafting Group and the VMG-eco [TESTMETEDECO- See also Project 2.12];
- Revised DRP submitted to the VMG-eco meeting in January 2008, and approved by WNT 20 in 2008;
- Revised DRP expected to be published in 2008.

**Project 2.17: New TG for Avian Acute Toxicity**

Lead: United Kingdom (took over from BIAC)

Inclusion in work plan: 1999

Project status and milestones:

- Expert group meeting in May 2005;
- Statistical analysis;
- Report at WNT19 on possible combination of the TG with the US EPA Guideline 850.2100;
- Revised SPSF submitted but not discussed at WNT 19;
- Draft TG circulated to the WNT in April 2007 for comments by 30 June 2007;
- Extended expert group meeting held in September 2007 in the UK;
- 2<sup>nd</sup> round of a Reading Comprehension exercise in 2008;
- Completion of the simulation report (March 2008);
- Ring test expected to start mid 2008;

- Approval anticipated at WNT21, in 2009 (to be confirmed).

**Project 2.18: EDTA Activity: Development and Validation of a new TG: 21-Day Fish Screening Test**

Lead: Secretariat + Japan

Inclusion in work plan: 1998

Project status and milestones:

- No lead country to develop a TG;
- Validation reports (phase 1A and 1B) published (2006);
- Report on validation Phase 2 published (2007);
- Additional work initiated by CEFIC in 2007 on negative and weakly active substances;
- Candidate peer reviewers nominated by the NCs; peer review organized by Japan completed end 2007;
- Draft WNT Statement, list of technical issues to be addressed by the VMG, and preliminary draft TG circulated in February 2008;
- VMV-eco (January 2008) addressed (on a provisional basis) technical issues proposed by the Secretariat and other issues identified by the WNT at the time of the meeting;
- Fish drafting group expected to follow-up on the peer review recommendations, as appropriate;
- Draft TG sent to the WNT on 12 June 2008 for comments by 1 September;
- Fish drafting group meeting scheduled on 22-23 October 2008;
- WNT commenting round expected in November-December 2008;
- WNT approval expected at WNT 21 in 2009.

**Project 2.19: EDTA Activity: Development and Validation of Methods in Amphibians**

Lead: United States + Germany + Japan

Inclusion in work plan: 2000

Project status and milestones:

- Validation reports (Phase 1 and 2) published (2007);
- Draft validation report (Phase 3) approved by WNT 20 and expected to be published in 2008.
- Nomination of candidate peer reviewers by WNT;
- Peer review completed and report submitted to WNT in February 2008;
- WNT statement on the development of a TG agreed at the WNT meeting in April 2008;
- Meeting of the Amphibian expert group on 21-22 May 2008;
- Draft TG was circulated to the WNT on 26 June for comments by 15 September 2008;
- WNT commenting round expected in October-November;
- WNT approval expected at WNT 21 in 2009.

**Project 2.20: New TG on Determination of Developmental Toxicity of a Test Chemical to Dipteran Dung Flies**

Lead: European Commission

Inclusion in work plan: 2006

Project status and milestones:

- Draft TG submitted with the SPSF to WNT18;
- Revised Draft TG circulated to the DOTTS-group in November 2006;
- Revision of the proposal based on experts' comments early 2007;
- Revised draft TG received by the Secretariat in February 2007;
- Circulation of draft TG and validation report to the WNT for comments in March 2007;
- Circulation of a second draft in November 2007;
- WNT approval at WNT 20, in 2008;
- Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008.

<b>Project 2.22: New Test Guideline on <i>Hypoaspis Aculeifer</i> Reproduction Test</b>	
Lead:	The Netherlands
Inclusion in work plan:	2006
Project Status and milestones:	<ul style="list-style-type: none"> <li>• Experimental work finalized in July 2006;</li> <li>• Validation report and first draft TG available to the NL expert group by end of 2006;</li> <li>• NL Expert group workshop in January 2007 in Bilthoven;</li> <li>• Draft TG and validation report circulated to WNT in July 2007;</li> <li>• Second draft circulated in December 2007;</li> <li>• WNT approval at WNT 20, in 2008;</li> <li>• Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008.</li> </ul>
<b>Project 2.23: The Threshold Approach for Acute Fish Toxicity Testing</b>	
Lead:	European Commission
Inclusion in work plan:	2006
Project Status and milestones:	<ul style="list-style-type: none"> <li>• Submission of the first draft to the Secretariat in June 2008;</li> <li>• First draft sent on 8 July to the WNT for comments by 29 September 2008.</li> </ul>
<b>Project 2.24: Update of TG 209: Activated Sludge Respiration Inhibition Test</b>	
Lead:	United Kingdom
Inclusion in work plan:	2007
Project Status and milestones:	<ul style="list-style-type: none"> <li>• First draft TG submitted with the SPSF;</li> <li>• WNT circulation of the draft revised TG is expected early September 2009.</li> </ul>
<b>Project 2.25: EDTA Activity - New DRP on Molluscs Life-Cycle Toxicity Testing</b>	
Lead:	United Kingdom + Germany
Inclusion in work plan:	2008
Project Status and milestones:	<ul style="list-style-type: none"> <li>• SPSF including short review paper submitted to WNT 20</li> <li>• Circulation of consolidated draft to WNT for comments expected in April 2009.</li> </ul>
<b>Project 2.26: EDTA Activity- New TG: The 21-Day Female Stickleback Endocrine Screening Assay</b>	
Lead:	United Kingdom
Inclusion in work plan:	2008
Project Status and milestones:	<ul style="list-style-type: none"> <li>• Retrospective validation and statistical analysis;</li> <li>• Full report ready for peer review by the end of October 2008;</li> <li>• Generation of a small set of data in 2008-2009.</li> </ul>
<b>Project 2.27: EDTA Activity - New TG: Fish Short Term Reproduction Assay</b>	
Lead:	United States
Inclusion in work plan:	2008
Project Status and milestones:	<ul style="list-style-type: none"> <li>• This project should be considered together with Project 2.18</li> <li>• Information on validation and validation peer review currently considered by the fish drafting group working on Project 2.18.</li> </ul>

<b>Project 2.28: EDTA Activity - New Test Guideline on a Chironomid Life-Cycle Toxicity Test</b>	
Lead:	Germany
Inclusion in work plan:	2008
Project Status and milestones:	<ul style="list-style-type: none"> <li>• Draft TG submitted with the SPSF</li> <li>• OECD ring test expected in 2008</li> <li>• Ring testing results available end 2008/2009</li> <li>• Final draft TG expected in 2009</li> </ul>
<b>Project 2.29: New Guidance Document on Dung Beetles</b>	
Lead:	European Commission
Inclusion in work plan:	2008
Project Status and milestones:	<ul style="list-style-type: none"> <li>• Draft GD submitted with the SPSF, expected to be circulated to the WNT after summer</li> </ul>
<b>Project 2.30: Fish Testing Framework</b>	
Lead:	United States
Inclusion in work plan:	2008
Project Status and milestones:	<ul style="list-style-type: none"> <li>• Establishment of a small planning group of experts after Summer</li> <li>• Workshop expected to be held by April 2009</li> <li>• GD and recommendations expected to be completed by April 2010</li> </ul>

**SECTION 3**  
**PROJECTS RELATED TO TEST GUIDELINES ON ENVIRONMENTAL FATE**

<b>Project 3.1: New TG for Accumulation in Sediment Worms</b>	
Lead:	Germany
Inclusion in work plan:	1999
Project status and milestones:	<ul style="list-style-type: none"> <li>• Ring Test;</li> <li>• Draft TG and Ring Test Report submitted to the Secretariat in January 2007;</li> <li>• Revised SPSF agreed at WNT 19;</li> <li>• WNT circulation of the draft TG in August 2007 (comments requested by 20 October 2007);</li> <li>• Second commenting round from December to February 2008;</li> <li>• Revised draft TG approved at WNT 20, in 2008.</li> <li>• Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008.</li> </ul>
<b>Project 3.2: New Guidance for Industry Data Submissions on the Estimation of Emissions from Wood Preservatives–Treated Wood to the Environment: for wood held in storage after Treatment and for Wooden Commodities that are not covered and are not in contact with ground</b>	
Lead:	TF Biocides
Inclusion in work plan:	2001
Project status and milestones:	<ul style="list-style-type: none"> <li>• 2 Proposals for TGs (Version 1) circulated for review in February 2003 with a deadline for comment of 15<sup>th</sup> April 2003;</li> <li>• Pre-validation meeting held in September, 2004 (Berlin); pre-validation continued in 2004-2005 (5 labs in Europe);</li> <li>• Technical meeting on 8-9 June 2006 to address scientific issues associated with the two proposed TGs: (i) Leaching from wood non covered and not in contact with the ground and (ii) Leaching from wood not covered and in contact with the ground, fresh water or sea water;</li> <li>• TG (ii) adopted on 16 October 2007;</li> <li>• Need for a new template will have to be considered;</li> <li>• WNT 19 agreed on a revised SPSF;</li> <li>• Proposal to convert the draft TG (i) into a draft GD (revised SPSF);</li> <li>• Draft GD (i) discussed at the Task Force on Biocides meeting of 20-21 September 2007;</li> <li>• Final review by the Task Force on Biocides expected in September 2008;</li> <li>• Approval expected at WNT 21 in 2009.</li> </ul>
<b>Project 3.3: New TG on Phototransformation in Water (direct effects only)</b>	
Lead:	Secretariat
Inclusion in work plan:	1998
Project status and milestones:	<ul style="list-style-type: none"> <li>• Revised proposal (Version 2) was submitted by a BIAC expert in March 2005;</li> <li>• Project moved to Section “Unallocated Projects”.</li> <li>• Further discussion of deletion/continuation of this project at WNT meeting in May 2006; Secretariat provided all related documents, including a compilation of comments and revised draft proposed TG for the meeting (with project Phototransformation on Soil Surface); WNT agreed that the project should be deleted from this annex after two years (May 2008) if there is no support and no lead country during these two years;</li> <li>• WNT 19 agreed in 2007 on the need for a TG on phototransformation in surface water, which should cover direct effects only;</li> </ul>

- Consultant contracted to assist the Secretariat with the TG;
- Revised TG circulated in December 2007;
- Approval at WNT 20, in 2008;
- Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008.

**Project 3.4: New TG: Simulation Test to Assess Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater: Biodegradation in Wastewater, Activated Sludge, Anaerobic Digester Sludge, Mixing Zone for Treated Effluent and Surface Water and Mixing Zone for Untreated Wastewater and Surface Water**

Lead: United States

Inclusion in work plan: 2005

Project status and milestones:

- First draft TG available in February 2005; Proposal discussed at 17<sup>th</sup> WNT;
- Comments made by Denmark in March 2005 and others at the 17<sup>th</sup> WNT will be taken into account;
- TG proposal written and sent to the Secretariat in July 2006; proposal circulated for comment late September;
- An ad hoc international expert group formed to look at validation issues associated with this proposal;
- Comments and pending issues were presented at WNT 19;
- Circulation of responses to comments and revised Test Guideline in November 2007;
- Revised TG approved at WNT 20, in 2008.
- Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008.

**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

Project status and milestones:

- Proposal discussed at 17<sup>th</sup> WNT;
- The project will be kept on hold for a couple of years due to ongoing work at ILSI and SETAC on this issue.

**Project 3.6: Bioaccumulation test in Fish: Revision TG 305, New Guidance on the Conduct of Fish Dietary Bioaccumulation Studies**

Lead: Germany + The Netherlands + United Kingdom

Inclusion in work plan: 2008

Project status and milestones:

- Draft revised TG 305 with a reduced number of animals, and including dietary studies, expected to be available for circulation early 2009.

**Project 3.7: New TG for Bioaccumulation: Soil Test Using Terrestrial Oligochaetes**

Lead: Germany

Inclusion in work plan: 2008

Project status and milestones:

- Publication of ring test results and workshop proceedings in 2008
- Draft Proposal expected to be circulated by the end of October.

**SECTION 4:  
PROJECTS RELATED TO TEST GUIDELINES ON HEALTH EFFECTS**

<b>Project 4.1: Development of the ATC method as alternative to TG 403 for specific purposes</b>	
Lead:	Germany
Inclusion in work plan:	2001
Project status and milestones:	<ul style="list-style-type: none"> <li>• Proposal (version 1) submitted to the Secretariat in September 2004;</li> <li>• Circulated to WNT for comments in December 2004;</li> <li>• Expert group meeting hosted by 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;</li> <li>• Progress presented at the group expert group meeting on acute inhalation toxicity, 7-9 November 2006, Washington.</li> <li>• Progress report presented at WNT 19. WNT agreement on submission of acute inhalation projects as a package;</li> <li>• Expert group meeting in the US in April 2008;</li> <li>• Approval of draft TG and performance assessment report expected in 2009.</li> </ul>
<b>Project 4.5: New TG for <i>in vitro</i> SHE Cell Transformation Assay</b>	
Lead:	France
Inclusion in work plan:	2003
Project status and milestones:	<ul style="list-style-type: none"> <li>• Ongoing validation study by EC;</li> <li>• EC Phase 1 of pre-validation finalized;</li> <li>• Await the outcome of the validation study by EC (anticipated to be finished by 2<sup>nd</sup>-3<sup>rd</sup> quarter of 2008).</li> </ul>
<b>Project 4.6: Development of a DRP on Transgenic Mice</b>	
Lead:	Canada
Inclusion in work plan:	1996
Project status and milestones:	<ul style="list-style-type: none"> <li>• First version circulated to the WNT for comments in March 2005;</li> <li>• Canada made a compilation of comments and revise the draft accordingly;</li> <li>• Revised version received in May 2008;</li> <li>• Circulation of the revised version on 4 July 2008, for comments.</li> </ul>
<b>Project 4.7: New TG (487) <i>In vitro</i> Micronucleus Test</b>	
Lead:	United Kingdom
Inclusion in work plan:	2002
Project status and milestones:	<ul style="list-style-type: none"> <li>• Submission received in April 2004. First version circulated for review on 14 June 2004;</li> <li>• EC undertook a retrospective validation exercise</li> <li>• EC retrospective validation completed; EC statement endorsing the scientific validity of the test for genotoxicity testing published on 17 November 2006;</li> <li>• Revised draft TG circulated for comment on 22 December 2006;</li> <li>• Draft TG discussed at WNT 19;</li> <li>• Expert group meeting in Atlanta, USA, in October 2007;</li> <li>• Revised TG circulated for comments to WNT in December 2007.</li> </ul>

- Draft TG487 provisionally approved at WNT 20;
- Approval by WNT, Joint Meeting, EPOC and Council, and publication expected in 2009.

#### **Project 4.8: Development of a GD on Reproductive Toxicity Testing and Assessment**

Lead: Denmark

Inclusion in work plan: 1996

Project status and milestones:

- Meeting of Drafting Group in US in June/July 2003;
- Draft GD for Reproductive Toxicity (Version 1) circulated in November 2004;
- 2<sup>nd</sup> meeting in Paris on 19-21 October 2005;
- Second version circulated to the WNT for comments in December 2007;
- Approval at WNT 20, in 2008;
- GD expected to be published in 2008.

#### **Project 4.10: Update of TG 417 on Toxicokinetics**

Lead: United States

Inclusion in work plan: 2000

Project status and milestones:

- Expert group established in July 2005;
- First draft developed by the lead country and sent to the expert group for comments in November 2006.
- Comments received from the expert group by late January 2007;
- Expert group meeting in June 2008;
- Circulation of the revised first draft TG to the WNT expected in September-October 2008.

#### **Project 4.11: Update of TG 412: Repeat Dose Inhalation Toxicity**

Lead: Netherlands

Inclusion in work plan: 2003

Project status and milestones:

- First proposal available in April 2005; circulation to WNT in December 2005;
- Aspects of this project dealt with at expert group meeting for the acute inhalation studies in November 2006;
- Expert group meeting in De Bilt (Netherlands) in June 2007;
- Revised draft TG circulated to the WNT (together with the draft TG 413) in March 2008;
- Revised draft TG and responses to comments expected to be circulated after summer 2008.

#### **Project 4.12: Development of a GD on Acute Inhalation Toxicity**

Lead: United Kingdom + Germany + United States

Inclusion in work plan: 2003

Project status and milestones:

- Establishment of an expert group;
- Expert group meeting late February 2006 (see the other inhalation projects);
- GD covered TG 433, TG 436 and the revised TG 403;
- WNT18 suggested developing two separate GDs (one on acute inhalation in general, and another one providing technical guidance on inhalation testing);
- GD drafting group meeting in Berlin on 11-12 July 2006.
- Comments on the latest version of the draft GD and on the outcome of the Berlin meeting requested by the Secretariat;
- Expert group meeting on 7-9 November 2006 in Washington D.C.;

- Progress report presented at WNT 19; WNT 19 agreement on the submission of all acute inhalation projects as a package and that only one GD on acute inhalation toxicity should be developed;
- TG 433 removed from the work plan and from draft GD;
- Draft GD expected to be submitted for approval at WNT 21.

#### **Project 4.13: New TG: Transgenic Rodent *in vivo* Gene Mutation Assays**

Lead: Canada  
 Inclusion in work plan: 2005  
 Project status and milestones:

- First draft will be submitted after approval of the DRP (see Project 4.6).

#### **Project 4.14: Update of TG 403 on Acute Inhalation Toxicity**

Lead: United States  
 Inclusion in work plan: 2006  
 Project status and milestones:

- Proposal discussed at 17<sup>th</sup> WNT; more detailed SPSF submitted to the Special WNT Meeting in November 2005;
- Request for comments by end of January 2006; WNT agreed to provisionally include the project in the Workplan and that more information should be provided for the next WNT meeting;
- Revised TG available at an expert group meeting held on 22-24 February 2006 in Berlin, Germany;
- Inclusion of the project in the work plan confirmed at WNT 18;
- Expert group meeting on 7-9 November 2006;
- Expert group meeting, in De Bilt (Netherlands) in June 2007, discussed the CxT Protocol;
- Performance assessment of the CxT Protocol completed; draft report expected by the end of May 2008;
- Expert group meeting in the US in April 2008;
- Approval of draft TG and performance assessment report expected in 2009.

#### **Project 4.16: EDTA Activity: Development of a BRD to Support the Hershberger Assay**

Lead: United States  
 Inclusion in work plan: 2003  
 Project status and milestones:

- Start of the work: mid-2003;
- Draft Document available for expert review early 2007;
- Draft BRD included in the peer review package of the test method validation;
- Draft BRD circulated to EDTA TF/VMG-mam for comments by 12 February 2007;
- Revised BRD circulated to the EDTA TF/VMG-mam in December 2007;
- Revised BRD endorsed by WNT20; expected to be published in 2008.

#### **Project 4.17: New TG 426: Developmental Neurotoxicity Testing**

Lead: Secretariat  
 Inclusion in work plan: 1996  
 Project status and milestones:

- Revised proposal (Version 2) available for review: early mid-2003; circulation of 2<sup>nd</sup> version with compiled comments (deadline for comments 16 January 2004);
- Expert group meeting in Tokyo in May 2005;
- WNT Circulation of revised 3<sup>rd</sup> version of TG 426 and retrospective performance assessment (RPA);
- New revised version of TG 426 adopted by Council on 16 October 2007;

- New/updated template will have to be considered;
- Draft RPA circulated to WNT in December 2007;
- RPA declassified in May 2008; expected to be published in June 2008.

**Project 4.18: Development of a GD to support TG 451, 452 and 453 on Chronic Toxicity and Carcinogenicity**

Lead: Secretariat

Inclusion in work plan: 1997

Project status and milestones:

- Awaiting the second ILSI document in 2006;
- Secretariat received the second ILSI document in 2007;
- Discussion at WNT 19; WNT 19 agreement that GD should be developed in parallel with the revisions of TGs 450, on the basis of the two ILSI documents;
- Preliminary GD circulated to the WNT for comments in October 2007;
- Draft revised GD submitted to the Workshop on the revision of TG 451, 452 and 453 (Washington, February 2008);
- A Consultant with a small steering group is expected to add essential information to the draft GD by March 2009;
- Circulation of the revised GD expected in November 2008;
- Draft GD expected to be approved at WNT 21.

**Project 4.19: Update of TG 451, 452, and 453 on Chronic Toxicity and Carcinogenicity**

Lead: Secretariat

Inclusion in work plan: 1999

Project status and milestones:

- In 2006, Secretariat had funding to start the work;
- Strategy for revision of the TGs agreed at WNT 19;
- National positions on main issues requested by 24 July 2007;
- Workshop in Washington, in February 2008;
- Revised draft TGs 451, 452 and 453 circulated to the expert group in June.
- Draft revised TGs expected to be circulated to the WNT for comments in September and November 2008;
- Draft revised TGs expected to be approved at WNT 21.

**Project 4.22: EDTA Activity: Validation of the Hershberger Assay: Juvenile Male Model**

Lead: VMG-mam + United States (lead laboratory)

Inclusion in work plan: 2003

Project status and milestones:

- Experimental work finalized late February 2007;
- Draft validation report, prepared by the US, expected to be circulated to the VMG-mam for comments in June 2008;
- Peer review report expected in October 2008.

**Project 4.24: EDTA Activity: Update of TG 407**

Lead: Secretariat

Inclusion in work plan: 2007

Project status and milestones:

- Draft TG circulated for comments before summer 2007, together with technical issues, raised by the peer review panel, to be addressed by the VMG-mammalian, as appropriate;

- Technical issues addressed by the VMG-mam in December 2007;
- Revised draft TG circulated to WNT in December 2007;
- Approval at WNT 20, in 2008;
- Approval by Joint Meeting, EPOC and Council, and publication expected at end of 2008;
- Guidance Document on histopathology under development; expected to be approved by WNT in 2009.

#### **Project 4.25: EDTA Activity: New TG for the Hershberger Assay**

Lead: United States

Inclusion in work plan: 2007

Project status and milestones:

- Draft TG circulated for WNT comments on 12 April 2007;
- Revised draft TG expected to be circulated for comments in August 2008, when the draft validation report for the juvenile male model is available.

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

Lead: Japan

Inclusion in work plan: 2007

Project status and milestones:

- EC pre-validation;
- Await the outcome of the validation study by EC that is anticipated to be finished by 3<sup>rd</sup>-4<sup>th</sup> quarter of 2008.

#### **Project 4.27: GD for a single dose study for the derivation of an Acute Reference dose (ARfD)**

Lead: Germany

Inclusion in work plan: 2007

Project status and milestones:

- First draft circulated to the WNT on 21 November 2007;
- Compilation of comments and a revised draft GD expected to be circulated during summer 2008.

#### **Project 4.28: Extended 1 Generation Reproductive Toxicity Study**

Lead: United States + Germany + Netherlands

Inclusion in work plan: 2007

Project status and milestones:

- Establishment of an expert group;
- Retrospective assessments of 2-generation versus 1-generation test results expected by end of May 2007;
- Lead countries meeting in October 2007;
- First draft of a Test Guideline “Extended 1 Gen Reproductive Toxicity Study” circulated to the expert group for information in March 2008;
- Extension of the expert group to experts specialized in neurotoxicity and immunotoxicity;
- Draft TG circulated to the expert group and to the WNT for comments in June 2008;
- Expert group meeting expected on 15-17 October 2008;
- Circulation of the revised draft TG expected in November 2008.

#### **Project 4.29: EDTA Activity: New TG/ Stably Transfected Transcriptional Activation Assay**

Lead: Japan

Inclusion in work plan: 2007

Project status and milestones:

- Peer review report available at WNT 19;
- Draft TG circulated to WNT for comments, together with technical issues to be addressed by VMG-non animal, in July 2007;
- Technical issues addressed by VMG-non animal in November 2007;
- STTA sub-committee of the VMG-non animal established in September 2007 to deal with technical issues further addressed at the VMG-non animal in November 2007;
- Revised draft TG circulated in December 2007;
- Provisional approval at WNT20;
- Approval by WNT, Joint Meeting, EPOC and Council, and publication expected at the end of 2008.

**Project 4.30: EDTA Activity - New TG: Stably Transfected Transcriptional Activation (STTA) Assay for the Detection of Estrogen Receptors Agonists and Antagonists (LUMI-CELL® ER Assay)**

Lead: United States

Inclusion in work plan: 2008

Project status and milestones:

- Completion of the validation study expected in mid 2008;
- Peer review panel meeting expected to be convened in fall 2008;
- Draft TG expected to be available early 2009.

**Project 4.31: EDTA Activity - New TG: Human Recombinant Estrogen Receptor Alpha Binding Assays (hrERA, 2 protocols)**

Lead: United States + European Commission + Germany + Japan

Inclusion in work plan: 2008

Project status and milestones:

- Validation plan was discussed the last meeting of the VMG-non animal (2007);
- Validation is ongoing and is expected to be completed in 2008.

**Project 4.32: EDTA Activity - New TG for the H295R Cell-Based Steroidogenesis Assay**

Lead: United States

Inclusion in work plan: 2008

Project status and milestones:

- Pre-validation completed; validation ongoing and expected to be completed in 2008.

**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: Japan

Inclusion in work plan: 2008

Project status and milestones:

- Validation report and draft TG expected to be available before summer;
- Peer review expected during 2008 and peer review report available early 2009.

**Project 4.34: EDTA Activity - New TG for a stably Transfected Transcriptional Activation (STTA) Assay for the detection of anti-estrogenic activity of chemicals**

Lead: Japan

Inclusion in work plan: 2008

Project status and milestones:

- Validation study expected to be completed early 2009;
- Validation report and draft TG expected to be available mid 2009.

<b>Project 4.35: New TG for an <i>In Vitro</i> Skin Irritation Assay</b>	
Lead:	European Commission
Inclusion in work plan:	2008
Project status and milestones:	<ul style="list-style-type: none"> <li>• Validation completed;</li> <li>• EC Peer review completed;</li> <li>• Draft TG circulated on 6 June 2008.</li> </ul>
<b>Project 4.36: New TG: Comet Assay in Genotoxicity Testing</b>	
Lead:	Japan
Inclusion in work plan:	2008
Project status and milestones:	<ul style="list-style-type: none"> <li>• Final validation study expected in autumn 2010;</li> <li>• Submission of validation results and draft TG expected early 2011.</li> </ul>
<b><i>Project 4.37: New TG: Bovine Corneal Opacity and Permeability Test Method: An In Vitro Method for identifying Ocular Corrosives and Severe Irritants<sup>1</sup></i></b>	
Lead:	Unites States
Inclusion in work plan:	2008
Project status and milestones:	<ul style="list-style-type: none"> <li>• First draft TG expected to be available in July 2008 or as soon as possible after July.</li> </ul>
<b><i>Project 4.38: New TG: Isolated Chicken Eye Test Method: An In Vitro Method for Identifying Ocular Corrosives and Severe Irritants<sup>1</sup></i></b>	
Lead:	Unites States
Inclusion in work plan:	2008
Project status and milestones:	<ul style="list-style-type: none"> <li>• First draft TG expected to be available in July 2008 or as soon as possible after July.</li> </ul>
<b>Project 4.39: Update of TG 413: Subchronic Inhalation Toxicity: 90-day Study</b>	
Lead:	United States
Inclusion in work plan:	2008
Project status and milestones:	<ul style="list-style-type: none"> <li>• Discussion of the first draft at an expert group meeting in De Bilt (Netherlands) in June 2007;</li> <li>• Revised draft TG circulated to WNT (together with draft TG 412) in March 2008;</li> <li>• Revised draft and responses to comments expected to be circulated after summer 2008.</li> </ul>

<sup>1</sup> Provisional inclusion in the work plan; inclusion is expected to be confirmed at WNT 21.

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

<b>Project 5.2: EDTA Activity: Development of a DRP on Non-Animal Assays for Metabolism Assessment</b>	
Lead:	Belgium + European Commission
Inclusion in work plan:	2003-2004
Project status and milestones:	<ul style="list-style-type: none"> <li>• Start of DRP development (lead Belgium): mid-2003 ; 1<sup>st</sup> draft version presented at 2nd VMG-NA meeting;</li> <li>• 2<sup>nd</sup> revised draft circulated to EDTA TF and WNT for comments in April and May 2006; new lead: European Commission</li> <li>• Draft DRP was submitted to WNT 19 for final comments;</li> <li>• Draft DRP approved at WNT 20; expected to be published in 2008.</li> </ul>
<b>Project 5.4: New TG and Associated GD for assessing Residues in Processed Commodities: Magnitude of the Residues in Processed Commodities</b>	
Lead:	United States
Inclusion in work plan:	2003
Project status and milestones:	<ul style="list-style-type: none"> <li>• Preparatory work organised by US in late 2003;</li> <li>• Five TGs and two GD endorsed by WNT in May 2006;</li> <li>• GD published in 2006, and TGs in 2007;</li> <li>• Two new TGs approved at WNT 19. Approval by Council on 16 October 2007;</li> <li>• New/Updated templates have been considered;</li> <li>• GD on pesticide residue analytical methods published in 2007;</li> <li>• Circulation of a new Test Guideline on 5 December 2007;</li> <li>• Meeting of the residue chemistry expert group at OECD in January 2008;</li> <li>• Approval of the draft TG and GD WNT 20;</li> <li>• Draft GD expected to be published in 2008;</li> <li>• Approval of the TG by WNT, Joint Meeting, EPOC and Council, and publication expected at the end of 2008.</li> </ul>
<b>Project 5.5: EDTA Activity: DRP on Availability of <i>In Vitro</i> receptor assays in Fish for Screening of endocrine modulating activities of Environmental Chemicals</b>	
Lead:	Japan + United Kingdom + Sweden
Inclusion in work plan:	2005
Project status and milestones:	<ul style="list-style-type: none"> <li>• Proposal discussed at the 17<sup>th</sup> WNT in 2005;</li> <li>• SPSF rewritten to show more clearly the scope of the document, and approved at WNT 19;</li> <li>• Comments on the draft DRP requested from the VMG-non animal in November 2007 and from the VMG-eco in January 2008;</li> <li>• Draft DRP expected to be circulated to the WNT for comments after summer 2008.</li> </ul>
<b>Project 5.6: New TG for efficacy test methods for public health antimicrobial biocides used on hard surfaces</b>	
Lead:	Task Force on Biocides
Inclusion in work plan:	2007
Project status and milestones:	

- Validation and peer review expected in 2008;
- Submission of the draft Test Guideline for WNT approval expected in 2009.

**Project 5.7: New GD: Efficacy Test Methods for Swimming Pools and Spa Pool Sanitisers (disinfectants)**

Lead: Australia (Task Force Biocides)

Inclusion in Workplan: 2008

Project status and milestones:

- Discussion of the draft GD at the meeting of the Task Force on Biocides in September 2008.

**Project 5.8: New GD on Efficacy of Antimicrobial Treated Articles**

Lead: Task Force Biocides

Inclusion in work plan: 2008

Project status and milestones:

- Submission of the draft GD to WNT 20 for approval; WNT requested short additional text on validation status;
- Approval expected in 2008.

**Project 5.9: New TG and GD on Field Crop Trials**

Lead: United States

Inclusion in work plan: 2008

Project status and milestones:

- Work on this issue initiated in 2006;
- Residue chemistry expert group meeting at OECD on 22-23 January 2008;
- Residue Chemistry expert group meeting in the US on 5-7 May 2008 to discuss the first draft TG;
- Documents expected to be finalized in 2009.

## 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:

- Thorough revision of Endocrine Disrupters WebPages;
- Thorough revision of TGP Web pages.

### Project 0.5: Templates for new and revised Test Guidelines

Lead: Secretariat + NCs  
Inclusion in work plan: 2004  
Project status and milestones:

- 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 under development;
- The Secretariat will contact NCs regarding the Test Guidelines approved at WNT 19 and WNT 20 as soon as the guidance on template preparation is available (see Annex 2).

### Project 0.6: Update of OECD/ISO Comparison of Test Methods, Including Human Health-Related TGs

Lead: France  
Inclusion in work plan: 2003  
Project status and milestones:

- Secretariat with assistance of US and France expected to update document ENV/JM/TG/RD(99)3 as soon as ISO info is available;
- U.S. expert involved in this project is no longer available as of June 2005;
- France agreed to continue alone at WNT18 in May 2006;
- Progress report at WNT 19;
- Draft report circulated to the WNT and ISO in October 2007.
- Approval at WNT20;
- Submission of the document to the 43<sup>rd</sup> Joint Meeting for declassification in November 2008.

### Project 0.7: Miscellaneous Activities: Work on Toxicogenomics

Lead: Secretariat + IPCS  
Inclusion in work plan: 2003  
Project status and milestones:

- Advisory Group of key experts from IPCS and OECD established in December 2004
- AG developed the plan of action to explore and evaluate regulatory application of toxicogenomics;
- Progress reported to the 38<sup>th</sup> Joint Meeting in June 2005;
- Concrete work plan submitted to the 39<sup>th</sup> Joint Meeting in February 2006;
- Report on progress to the 40<sup>th</sup> JM in November 2006;
- Meeting of the extended Advisory Group on 24 May 2007 in the United States.
- Report on progress to the 41<sup>st</sup> Joint Meeting in June 2007 and to the 42<sup>nd</sup> JM in February 2008;
- Second meeting of the extended Advisory Group in June 2008, in the Netherlands.
- Report on progress to the 43<sup>rd</sup> Joint Meeting in November 2008.

**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:

- Task Group established November 2004, lead by JRC/ECB;
- 1<sup>st</sup> 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 lead by US EPA; meeting prior to the VMG-non animal and report progress to VMG-non animal in November 2007;
- Continuous activity.

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

<b>Project 3.3: Proposal for TG(s) on Phototransformation in Water</b>	
Lead:	No lead country: USA unable to continue in lead capacity
Inclusion in work plan:	1998
Inclusion in Annex 1:	2006
Project status and milestones:	<ul style="list-style-type: none"> <li>• Deletion/continuation of this project discussed by WNT 18 in May 2006; Secretariat provided WNT with all related documents, including a compilation of comments and revised draft proposed TG</li> <li>• WNT18 agreed that the project should be deleted from this annex after two years (<b>May 2008</b>) if there is no support and no lead country during these two years.</li> <li>• <i>WNT 19 agreed in 2007 on the need for a TG on phototransformation in surface water, which should cover direct effects only.</i></li> </ul>
<b>Project 2.2: Updated Guideline 205 on Avian Dietary Toxicity Test</b>	
Lead:	Netherlands (took over from BIAC in 2004)
Inclusion in work plan:	1999
Inclusion in Annex 1:	2007
Project status and milestones:	<ul style="list-style-type: none"> <li>• Netherlands took the lead for this project under the condition that progress is possible and no further delays due to major differences in opinion were anticipated;</li> <li>• Expert group meeting in May 2005 (in the margin of Lille SETAC meeting);</li> <li>• Preparation work for the revision of the draft carried out by the members of the Expert group;</li> <li>• Small expert group meeting (in the margin of SETAC meeting) in May 2006;</li> <li>• Netherlands expected to provide possible plan for further work as soon as possible before WNT19; however, it appeared that no progress was/could be made.</li> </ul>
<b>Avian Reproductive Toxicity Test (1-generation)</b>	
Lead:	Secretariat
Inclusion in Workplan:	1997
Inclusion in Annex 1:	2007
Project status and milestones:	<ul style="list-style-type: none"> <li>• As there was no longer support for this TG, WNT 19 agreed that this project should be moved to the Annex.</li> </ul>
<b>Phototransformation on Soil Surfaces</b>	
Lead:	BIAC
Inclusion in Workplan:	2000
Inclusion in Annex 1:	2007
Project status and milestones:	

- WNT requested to indicate possible regulatory needs;
- Discussion on How to deal with this project at WNT 19, in 2007;
- WNT 19 did not agree on further work on this project.

#### **Project 4.2: New TG 433: Fixed Dose Procedure as Alternative to TG 403**

Lead: United Kingdom

Inclusion in work plan: 2001

Inclusion in Annex 1: 2007

Project status and milestones:

- 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;
- 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 4.3: New TG (434) for Acute Dermal Toxicity: Fixed Dose Procedure**

Lead: United Kingdom

Inclusion in work plan: 2003

Inclusion in Annex 1: 2007

Project status and milestones:

- 1<sup>st</sup> version circulated for review in May 2004;
- Await the outcome of the Performance assessment group (see above) before a 2<sup>nd</sup> revised version is circulated;
- The lead country decided to withdraw this project.

#### **Project 0.1: Inventory of Data Requirements for Chemicals other than Pesticides**

Lead: Secretariat

Inclusion in work plan: 2001

Project status and milestones:

- Update the inventory and request for input from the WNT and Task Forces on New and Existing Chemicals by 24 November 2006;
- Submission of the revised inventory at WNT19 to support the discussion on the revision of existing TGs.

**ANNEX 2**  
**ADOPTED TEST GUIDELINES FOR WHICH AN EXISTING TEMPLATE NEEDS TO BE REVISED**  
**OR A NEW TEMPLATE SHOULD BE DEVELOPED**

<b>Project 2.6: New TG for the Determination of the Inhibition of the Activity of Anaerobic Bacteria - Reduction of Gas Production from Anaerobic Sewage Sludge</b>	
Lead:	United Kingdom
Inclusion in work plan:	2004
Project status and milestones:	<ul style="list-style-type: none"> <li>• TG adopted in January 2007. Comments provided by UK on the existing template on toxicity to microorganisms.</li> </ul>
<b>Project 2.21: New TG 225 on Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment</b>	
Lead:	Germany
Inclusion in Workplan:	2006
Project Status and milestones:	<ul style="list-style-type: none"> <li>• TG adopted by Council on 16 October 2007;</li> <li>• Need for a new/ updated template has to be considered.</li> </ul>
<b>Project 4.9: New TG 440: Uterotrophic Bioassay</b>	
Lead:	Japan and Secretariat
Inclusion in work plan:	1996
Project status and milestones:	<ul style="list-style-type: none"> <li>• TG adopted by Council on 16 October 2007.</li> <li>• Need for a new/update template will have to be considered.</li> </ul>
<b>Project 4.17: New TG 426: Developmental Neurotoxicity Testing</b>	
Lead:	Secretariat
Inclusion in Workplan:	1996
Project status and milestones:	<ul style="list-style-type: none"> <li>• TG 426 adopted by Council on 16 October 2007;</li> <li>• Need for a new/updated template has to be considered.</li> </ul>