

生態影響試験法セミナー

## 1. OECDにおける生態毒性関連 テストガイドラインの検討状況

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### 2004年4月に採択されたテストガイドライン OECD TG Programme

#### New Test Guidelines:

TG 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment;  
TG 219: Sediment-Water Chironomid Toxicity Using Spiked Water;  
TG 220: Enchytraeid Reproduction Test;  
TG 222: Earth Worm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*);  
TG 309: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test;  
TG 312: Leaching in Soil Columns;  
TG 427: Skin Absorption: In Vivo Method;  
TG 428: Skin Absorption: In Vitro Method;  
TG 430: In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER);  
TG 431: In Vitro Skin Corrosion: Human Skin Model Test;  
TG 432: In Vitro 3T3 NRU Phototoxicity Test.

#### Updated Test Guidelines:

TG 111: Hydrolysis as a Function of pH;  
TG 117: Partition Co-efficient (n-Octanol/Water): High performance Liquid Chromatography; (HPLC) Method;  
TG 202: Daphnia sp.: Acute immobilisation Test.

(Environment, Health & Safety News No. 16, July 2004)

[http://www.oecd.org/document/33/0,2340,en\\_2649\\_34365\\_1941537\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/33/0,2340,en_2649_34365_1941537_1_1_1_1,00.html)

## 2004年5月の16thWNTで合意 OECD TG Programme

TG 104: Vapour Pressure;  
 TG 123: Partition Co-efficient (1-Octanol/Water): Slow-Stirring Method;  
 TG 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test;  
 TG 221: Lemna Sp. Growth Inhibition Test;  
 TG 425: Acute Oral Toxicity: Up and Down Procedure;  
 TG 310: Ready Biodegradability – CO<sub>2</sub> in Sealed Vessels (Headspace Test);  
 TG 311: Anaerobic Biodegradation of Organic Compounds in Digested  
 Sludge – By Measurement of Gas Production;  
 Guidance Document: Part 1 of the revised introduction to the OECD Guide-  
 lines for the Testing of Chemicals Section 3 “Degradation and Accu-  
 mulation”: “Principles and Strategies Related to the Testing of De-  
 gradation Organic Chemicals”;  
 Guidance Document No. 20 on Neurotoxicity Testing.

**Finalised, to endorsement by Joint Meeting**

(Environment, Health & Safety News No. 16, July 2004)

## 2004年5月の16thWNTで報告

現在進行中の主なワークプラン

### Proposal for a New Guidance Document on Statistical Analysis

Status Report on Revision of Guidance Document No. 34  
 Status Report on Test methods for the generation of efficacy data for public  
 health antimicrobial biocides  
 Status Report on (Quantitative) Structure Activity Relationships [(Q)SARs]  
 Status Report on Avian Effects  
 Status Report on Toxicogenomics  
 Status Report on the Dung Organism Test Guidelines Development

## 2004年5月の16thWNTで合意 New Proposals

Project 2004/2.18  
Determination of the Inhibition of the Activity of Anaerobic Bacteria –  
Reduction of Gas Production from Anaerobic Sewage Sludge), UK, (M)

Project 2004/2.19  
Fish Embryo Toxicity Test, AG, (M/H)

Project 2004/2.20  
Enhanced Test Guideline 211: Daphnia Magna Reproduction Test, Jp, (M)

Project 2004/3.11  
New Guideline for a Litter Bag Test (Soil organic matter breakdown), AG, (M)

(Environment, Health & Safety News No. 16, July 2004)

**Introduction**

*The Environment, Health and Safety News is a newsletter which comes out midway between Joint Meetings, approximately every eight months. Its purpose is to provide an update on the main events and activities of the EHS Programme. Information on new publications arising from the Programme as well as dates and venues of upcoming events and meetings are given.*

*This edition is now available on the Internet as a “live-link” version.*

**☺ STAFF IN THE EHS DIVISION ☺**

Since the last Environment, Health and Safety News (No. 15, issued in November 2003), the EHS Division has seen the following changes in staffing:

- In the *Test Guidelines* area, Drew Wagner took up duty as principal administrator in February 2004. Jennah Huxley, who provided secretarial support to the team, left in May when Keri Aspegren returned from maternity leave. Pilar Prieto joined in May on secondment from ECVAM and will work with us until September 2004. Hans-Christian Stolzenberg, who replaced Anne Gourmelon during her maternity leave, left at the end of June.
- Mar Gonzalez joined the *Biosafety* team in May 2004, as did Wendy Cormier who came from the Test Guidelines team as secretarial support when Alexia O’Hare left in May. Wendy also works on Chemical Accidents.
- Fanny Blanchet de la Lande arrived in June and is working with Bob Diderich on HPV until the end of August.
- Administrative assistant Bonnie Schaefer left EHS in February 2004 and has been replaced by Lisa Eveleigh.

**TEST GUIDELINES**

The 36<sup>th</sup> Joint Meeting endorsed an approach whereby wide-ranging discussions would be conducted within the OECD, including with the members of the Working Group of the National Co-ordinators of the Test Guidelines Programme (WNT), the EDTA, and other stakeholders, on the desired focus and priorities of the Test Guidelines Programme, and the processes involved in the development and revision of Test Guidelines. The issues relating to the process of developing Test Guidelines include the impact of validation and peer review processes on the timely development of Test Guidelines, and the capacity of the Secretariat and member countries to continue to deliver practical end products in the TG Programme. The Chairman asked the Secretariat to develop a policy paper for the Joint Meeting in June 2005, following consultation with the appropriate OECD Working Groups and Task Forces. This issue was discussed at WNT16, and an Expert Consultation meeting will be organised in early 2005 to draft a report to the 38<sup>th</sup> Joint Meeting.

The draft OECD Guidance Document No. 34 on the ‘Validation and International Acceptance of New and Updated Test Methods for Hazard Assessment’ is currently under revision. Following the submission of

considerable comments on this draft document by member countries, the WNT agreed to conduct an Expert Consultation meeting to revise the draft. The USA has offered to host the meeting in October 2004. On a related note, Germany hosted an OECD Workshop on Data Interpretation Procedures (DIP) in early July 2004, based on the recommendations from the 2002 Stockholm Conference on Validation and Regulatory Acceptance of New and Updated Methods in Hazard Assessment. The outcomes of this conference will be considered in the revision of Guidance Document 34.

In April 2004, Council approved 14 new and updated Test Guidelines, which are being prepared for publication as the 15th Addendum.

#### **New Test Guidelines:**

- TG 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment;
- TG 219: Sediment-Water Chironomid Toxicity Using Spiked Water;
- TG 220: Enchytraeid Reproduction Test;
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#### **Updated Test Guidelines:**

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- TG 117: Partition Co-efficient (n-Octanol/Water): High performance Liquid Chromatography; (HPLC) Method;
- TG 202: *Daphnia* sp.: Acute immobilisation Test.

At WNT16 a number of new and revised Test Guidelines and Guidance Documents were finalised (some requiring some further minor technical amendments), and these will be provided to the Joint Meeting for endorsement. The Test Guidelines and Guidance Documents agreed by the WNT were:

- TG 104: Vapour Pressure;
- TG 123: Partition Co-efficient (1-Octanol/Water): Slow-Stirring Method;
- TG 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test;
- TG 221: Lemna Sp. Growth Inhibition Test;
- TG 425: Acute Oral Toxicity: Up and Down Procedure;
- TG 310: Ready Biodegradability – CO<sub>2</sub> in Sealed Vessels (Headspace Test);
- TG 311: Anaerobic Biodegradation of Organic Compounds in Digested Sludge – By Measurement of Gas Production;
- Guidance Document: Part 1 of the revised introduction to the OECD Guidelines for the Testing of Chemicals Section 3 “Degradation and Accumulation”: “Principles and Strategies Related to the Testing of Degradation Organic Chemicals”;
- Guidance Document No. 20 on Neurotoxicity Testing.

WNT16 also considered the priorities assigned by member countries on a number of new project proposals and agreed to add several proposals to the Rolling Workplan of the Test Guidelines Programme. These are: Project 2004/2.18 (New Guideline for the Determination of the Inhibition of the Activity of Anaerobic Bacteria - Reduction of Gas Production from Anaerobic Sewage Sludge), led by the UK, Medium (M) priority; Project 2004/2.19 (Fish Embryo Toxicity Test), led by Germany, Medium/High (M/H) priority; Project 2004/2.20 (Enhanced Test Guideline 211: *Daphnia Magna* Reproduction Test), led by Japan, Medium (M) priority; Project 2004/3.11 (New Guideline for a Litter Bag Test (Soil organic matter breakdown)), led by Germany, Medium (M) priority.

The WNT Chair, Dr. Maurice Zeeman of the USA, stepped down from that position following WNT 16. Members elected Dr. Otto Meyer from Denmark as the interim Chair until WNT 17, at which time there will be a call for nominations for a chair and vice-chair for the next three-year period.

*Forthcoming events:*

- Meeting of the Expert Group on Avian Avoidance and Dietary Toxicity, 9-10 September 2004, York, UK;
- Ad-hoc Expert Meeting on Terrestrial Plant Testing, 4-5 October 2004, Paris;
- 17<sup>th</sup> Meeting of the Working Group of the National Co-ordinators of the Test Guidelines Programme (WNT17) proposed for 12-14 April 2005;
- Expert Consultation for the revision of Guidance Document 34, Validation and International Acceptance for New or Updated Test Methods for Hazard Assessment, 13-15 October 2004, Bethesda, USA.



## ENDOCRINE DISRUPTERS TESTING AND ASSESSMENT

The validation of the Fish Screening Assay is proceeding (Phase 1B) in 14 laboratories from 7 OECD member countries. The objectives of this phase are to establish the sensitivity and reproducibility of the assay using weak chemicals with different modes of action (estrogen, androgen, aromatase inhibition), and applying the protocol in various laboratories. The results will be discussed at the Third Meeting of the Validation Management Group for Ecotoxicity Testing (VMG-eco 3) on 21-22 October in Paris.

The *Ad hoc* Expert Group on Amphibian Testing met in Paris on 28-29 June and reviewed the outcome of Phase 1 of the validation of the Amphibian Metamorphosis Assay for thyroid disruption. A common approach for the protocol has been agreed and will be applied in Phase 2, using three substances. The Expert Group will make a proposal to the VMG-eco for approval for the next validation step in September. This proposal will be accompanied by a call for possible additional participating laboratories. Phase 2 of the experimental work will be launched in November 2004.

Activities on Invertebrate Testing are on-going for the validation of a Copepod Test, that could be used (but not specifically) for the detection of endocrine disruption in aquatic arthropods; other assays are also considered and the progress made will be reviewed at a next meeting of the Ad hoc Expert Group on Invertebrate Testing (date to be agreed).

The validation program for the uterotrophic bioassay covering oestrogen and antiestrogen screening has been conducted. All reports and publications are finalised, and an independent peer review of the programme has been carried out. The peer review report has been discussed by the Peer Review Panel (PRP) and will be finalised and forwarded to the EDTA for consideration. A draft test guideline will be prepared and distributed for comment, subject to comments from the WNT.

The validation for the Hershberger bioassay covering androgen and antiandrogen screening has entered the final phase, using coded positive and negative substances. Completion is expected in September 2004. To address possible animal welfare concerns and avoid surgery, preliminary work on an alternative version has begun with completion of the initial work anticipated in October 2004. Reports for these projects will be drafted and submitted to the VMG-mammalian in December 2004.

The Validation Management Group for Non-Animal Testing (VMG-NA), previously agreed that four Detailed Review Plans (DRP) should be developed. The DRPs are anticipated to be available to the