



COUNCIL

C(2006)13
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Council

**DRAFT DECISION OF THE COUNCIL SUPPLEMENTING THE DECISION OF THE COUNCIL
CONCERNING THE MUTUAL ACCEPTANCE OF DATA IN THE ASSESSMENT OF CHEMICALS
[C(81)30/FINAL]**

(Note by the Secretary-General)

This document is submitted to Council for approval under the written procedure.

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English - Or. English

1. The scientific basis for the assessment of risks chemical substances may pose to man and the environment is provided by data on their safety. Therefore, testing is an important step in the overall chemical risk management process. The OECD Guidelines for Testing of Chemicals, which are the leading international standard for safety testing, are continuously reviewed and updated so that they remain in the forefront of science. New Guidelines are being introduced to improve risk management in member countries and/or lead to a further reduction of animal use and improvements in animal welfare. Use of the OECD Guidelines will ensure that the data derived in the safety testing of chemicals are of high quality. Furthermore, the availability of internationally harmonised test methods allows both industry and governments to save money by avoiding duplicative work. As these harmonised methods are the cornerstone of the principle of Mutual Acceptance of Data, they also contribute to eliminating non-tariff barriers to trade.

2. The Council, in its Decision C(81)30(Final) of 12 May 1981 concerning the Mutual Acceptance of Data in the Assessment of Chemicals, instructed the previously named Management Committee of the Special Programme on the Control of Chemicals, in conjunction with the Chemicals Group of the Environment Committee (renamed in 1998: Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology), to establish an updating mechanism to ensure that the Guidelines, which constitute an integral part of the aforementioned Decision, are modified from time to time as required through the revision of existing Guidelines or the development of new Guidelines.

3. Since 1981, 104 new or updated Guidelines have been adopted by the Council in eighteen Council Decisions. The most recent adoption was that of fourteen Guidelines on 13 April 2004 [C(2004)28].

4. Four draft new Guidelines proposals (123, 221, 310 and 311) and three draft updated proposals (104, 201, 425) referred to in the draft Decision in Annex 1 to this document were endorsed at the 37th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in November 2004; the revised introduction to Section 3 of the Guidelines was endorsed by the Joint Meeting on 23 September 2005 under written procedure.

5. The new and updated Guidelines were subsequently considered by the Environment Policy Committee (EPOC) [ENV/EPOC(2005)19]. EPOC agreed, under written procedure, on 6 December 2005, to recommend their submission to Council with a view to the adoption of these Guidelines.

6. A concise chronology of the development of the new and updated Guidelines is set out in Annex 2 to this document.

7. In light of the preceding, the Secretary-General invites the Council to adopt the following draft conclusions:

THE COUNCIL

- a) noted document C(2006)13;
- b) adopted the draft Decision supplementing the Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)], set out in Annex 1 to C(2006)13, and agreed to its declassification.

ANNEX 1

DRAFT DECISION OF THE COUNCIL SUPPLEMENTING THE DECISION OF THE COUNCIL CONCERNING THE MUTUAL ACCEPTANCE OF DATA IN THE ASSESSMENT OF CHEMICALS [C(81)30/FINAL]

THE COUNCIL,

Having regard to Article 5 a) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

Having regard to the Decision of Council of 12 May 1981 concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)];

On the proposal of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, and approved by the Environment Policy Committee;

DECIDES to adopt the following Guidelines¹ which become an integral part of the Decision referred to above:

Draft New Test Guidelines:

- 123 Partition Coefficient (1-Octanol/Water): Slow-Stirring Method
- 221 *Lemna* sp. Growth Inhibition Test
- 310 Ready Biodegradability - CO₂ in sealed vessels (Headspace Test)
- 311 Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production

Draft Updated Test Guidelines:

- 104 Vapour Pressure
- 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test
- 425 Acute Oral Toxicity – Up-and-Down-Procedure (UDP)

Revised Introduction to Section 3 of the OECD Guidelines for the Testing of Chemicals

- Part 1:** Principles and Strategies related to the Testing of Degradation of Organic Chemicals
- Part 2:** Bioaccumulation and Behaviour in Soils and Sediments

1. The texts of these Guidelines are available from the Environment Directorate as document [ENV/EPOC(2005)19].

ANNEX 2

CONCISE HISTORY OF THE NEW AND UPDATED TEST GUIDELINES FOR WHICH ENDORSEMENT IS REQUESTED

I. PROPOSAL FOR NEW TEST GUIDELINES

Test Guideline 123: Partition Coefficient (1-Octanol/Water): Slow-Stirring Method

1. The revised proposal for the new Test Guideline 123 "Partition Co-efficient (1-Octanol/Water): Slow-Stirring Method" was circulated to member countries for review and comment in November 2003. The Netherlands, the lead country of this project, and the Secretariat made revisions, taking into account the comments received.

2. These comments were considered by the 16th meeting of the Working Group of the National Co-ordinators of the Test Guidelines programme (WNT) in May 2004, along with additional comments on this Guideline proposal received from the US and Canada. The Meeting provisionally approved the Guideline following clarification of a small number of technical issues relating to equations. The Meeting agreed that there was no further need for the WNT to discuss the Guideline in session, and that the Secretariat would finalise the revised proposal to the WNT under written procedure, and then submit it for consideration as part of the 16th addendum to the OECD Guidelines for the Testing of Chemicals. The most recent comments received are reflected in the revised draft Test Guideline.

Test Guideline 221: *Lemna* sp. Growth Inhibition Test

3. The need for a new guideline on Lemna (TG221) was identified at the OECD Workshop on Aquatic Toxicity Testing (Copenhagen, 1995), and also in the Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals (Series on Testing and Assessment No. 11, 1998). The work, led by the UK Water Research Centre, involved two Expert meetings and an international ring test. The first Guideline proposal was circulated for review in December 1999 to the National Co-ordinators and the National Experts on Aquatic Toxicity Testing for their comments. In response, 12 countries and industry provided comments. No critical issue was raised at this commenting round. Taking into account all the comments, the proposal was revised and circulated to the National Co-ordinators for their approval in October 2000.

4. The Guideline was tabled at the 14th WNT Meeting in May 2002. The Secretariat developed a revised draft Guideline 221, and circulated it to the National Co-ordinators for approval in July 2002. At the 15th WNT Meeting in May 2003, the national coordinators agreed that an expert consultation meeting be held to resolve outstanding issues. In October 2003, an expert consultation meeting was held in Washington as an opportunity to find a solution to the disagreement on a revised Guideline 201 "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (project led by Norway) and the new Guideline 221. The consultation meeting, and also the follow-up communication among the meeting participants, resulted in revised proposals for consideration at the 16th WNT meeting in 2004. Discussions during WNT16 included issues relating to the test duration, the size of the test vessel, synchronous cell divisions, and high light intensity, amongst others. The National Co-ordinators approved the Guideline proposals for the 16th addendum in 2004.

Test Guideline 310: Ready Biodegradability - CO₂ in sealed vessels (Headspace Test)

5. In May 2000, at the 12th meeting of the National Co-ordinators of the Test Guidelines Programme, the UK proposed that a new guideline be developed, based on the ISO 14593, "Carbon dioxide (CO₂) Headspace Biodegradation Test" and validated by inter-laboratory ring-tests. The first proposal for this Test Guideline was developed by the United Kingdom and circulated for review in October 2001. A revised proposal was circulated for review in October 2003. Some of the substantial changes to the second revised version were a) adding descriptions for inhibition check and interpretation of results; and b) adding the method of soil adjustment.

6. A number of issues were flagged for discussion by the WNT, namely: reintroducing the former expression concerning the Sturm test, descriptions related to inherent biodegradability, the application of the 10-day window, and the calculation of percentage biodegradation. The 16th Meeting of the WNT agreed to adopt the revised proposal, including the deletion of one of the references identified during the meeting. This proposal was approved as amended during the Meeting, and this Guideline is proposed to be part of the 16th addendum.

Test Guideline 311: Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production

7. In May 2000, at the 12th meeting of the National Co-ordinators of the Test Guidelines Programme, the UK proposed that the new guideline be developed. The proposal had been developed based on the ISO 11734, "Evaluation of the ultimate anaerobic biodegradation of organic compounds in digested sludge – Method by measurement of the biogas production" and had been validated by inter-laboratory ring-tests. The first proposal for this Test Guideline was developed by the United Kingdom and circulated for review in October 2001.

8. The first revised proposal was circulated for review in February 2003, and then revised in line with comments received. The second revised proposal was circulated for review in October 2003, and further refinements included such changes as revising the description of the apparatus, especially the pressure measuring devices, and adding the information of calibration of the pressure-meter.

9. At the 16th WNT Meeting in May 2004, the National Coordinators considered the guideline and the meeting agreed to adopt the changes, except for one technical issue concerning the plateau phase and the normal test period. This new Test Guideline was provisionally adopted, pending the resolution of a technical issue by correspondence. The 36th Joint Meeting agreed that the Secretariat would revise the proposal under written procedure, so that it could be included in the 16th Addendum.

II. PROPOSALS FOR UPDATED EXISTING GUIDELINES**Test Guideline 104: Vapour Pressure**

10. This guideline is a revised version of the original Guideline 104, which was initially adopted in 1981 and subsequently updated in 1995. One additional method, Effusion method: isothermal thermogravimetry, is included in this new revised version. The original guideline was developed based on the EC method "Vapour Pressure" published in 1992. In 2001 an additional method designed for chemicals with very low pressures (down to 10⁻¹⁰Pa) was proposed by Germany. In the light of needs for methods, especially in relation to obtain vapour pressure for substances with low vapour pressure, other methods of this guideline are re-evaluated with respect to other applicability range.

11. Guideline 104 on “Vapour Pressure”, which was first revised in 1995, included seven measuring methods. In April 2001, Germany proposed a second update of Guideline 104 to include one additional method, namely the “Effusion method: isothermal thermogravimetry”. The 13th Meeting of the Working Group of the National Co-ordinators of the Test Guideline Programme, held in May 2001, confirmed the need for the update, and Germany took the lead in this project.

12. The first proposal for the revision of Guideline 104, developed by Germany, was circulated to Member countries for review and approval in October 2002 and subsequently revised. The revised version of Test Guideline 104, dated April 2003, was discussed at the 15th WNT meeting but full consensus was not reached. The 16th meeting of the WNT considered this latest version of the draft Guideline and agreed that the previously outstanding issues had been dealt with, and the table for reproducibility, repeatability and recommended range for each method and some editorial changes were now agreed. The guideline proposal was approved without further changes. Test Guideline 104 has been submitted for endorsement as part of the 16th addendum to the OECD Guidelines for the testing of chemicals.

Test Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test

13. The 8th WNT Meeting in 1997 accepted the revision of Guideline 201 as a project to be added to the workplan. Norway took the lead, and two Expert Group meetings were held in Oslo in 1998 and 1999. Based on the discussion at these meetings, Norway circulated a draft proposal to the members of the Expert Group in November 2000. A number of Members expressed their disagreement to using only the average growth rate as the test endpoint, and requested that area under the growth curve (AUG) and final biomass also be described as test endpoints. Experts discussed this issue through electronic communication throughout 2001, but failed to reach an agreement. In April 2002, Norway submitted to the Secretariat a revised draft proposal including amendments in a number of areas to reach a solution on this Guideline.

14. The Guidelines was tabled at the 14th WNT Meeting in May 2002. The Secretariat developed a revised draft Guideline 201 and circulated it to the National Co-ordinators for approval in July 2002. The development of this Test Guideline was done in concert with the development of Test Guideline 221. At the 15th WNT Meeting in May 2003, the national coordinators agreed that an expert consultation meeting be held to resolve outstanding issues.

15. In October 2003, an expert consultation meeting was held in Washington as an opportunity to find a solution to the disagreement on a revised Guideline 201 "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" and Guideline 221 "Lemna sp. Growth Inhibition Test". The consultation meeting, and also the follow-up communication among the meeting participants, resulted in revised proposals for consideration at the 16th WNT meeting 2004. Discussions during WNT16 included issues relating to the test duration, the size of the test vessel, synchronous cell divisions, and high light intensity, amongst others. The National Co-ordinators approved the Guideline proposals for the 16th addendum, and noted the efforts by the lead country Norway in the development of the Guidelines.

Test Guideline 425: Acute Oral Toxicity – Up-and-Down-Procedure (UDP)

16. Test Guideline 425 on the Acute Oral Toxicity-Up-and-Down-Procedure (UDP) was originally adopted in September 1998. A first revision was initiated in 1999 when computer simulations were performed to evaluate the performance of the TG 425 and to determine appropriate changes to optimize the method's performance. A statistical software package (AOT425StatPgm) to accompany the TG 425 was developed by the US EPA and it is accessible for download from the OECD and US EPA home pages. The new revised Test Guideline 425 was adopted in December 2001.

17. In January 2003, the Secretariat noted some errors in the decision logic of the software and contacted the US EPA and asked for their assistance to rectify the errors. In accordance with the US suggestions for changes, a few clarifying paragraphs have been added to the Guideline and to the software instruction manual. The WNT16 approved the revised Guideline proposal and approved its submission to the Joint Meeting for endorsement as part of the 16th addendum.

Revised Introduction to Section 3 of the OECD Guidelines for the Testing of Chemicals

18. In 1979, the Introductory Guidance to Section 3 “Summary of Considerations in the Report from the OECD Expert Group on Degradation and Accumulation”, a concise summary of the report of the ad hoc Expert Group, was published. This introduction accompanied the first set of Test Guideline proposals in this area (Guidelines 301-305).

19. During the more than two decades since the Introduction was originally drafted, there have been considerable developments in the Test Guidelines Programme and the Programme on Harmonisation of Classification and Labelling (HCL). These developments include a number of new and revised Guidelines, a Detailed Review Paper on Biodegradability Testing (1995, OECD Series on Testing and assessment No.2), and the Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures (2001, OECD Series on Testing and assessment No.33).

20. At the 14th meeting of the National Co-ordinators of the Test Guidelines Programme (the WNT), Denmark proposed the replacement of the current introduction to Section 3 with updated guidance on the subject of Degradation. The project was adopted at the 14th WNT meeting. Revised text, which described principles and strategies related to the testing of biodegradability, was developed by Denmark. It included consideration of the newly developed or revised international data interpretation and testing strategies, the applicability of OECD Test Guidelines and the guidance for interpretation of data obtained in ready, inherent and simulation tests of biodegradability.

21. In June 2003 the first part of the Revised Introduction, Annex 1, was submitted to the Secretariat. The revised draft introduction was circulated for review to the National Experts in August 2003. In April 2004, Denmark and the Secretariat revised the draft Guideline, taking into account the comments submitted by member countries and it was submitted to the 16th WNT for final approval. Following consultation, the text was revised and approved, pending two minor points of clarification of the text.

22. Prior to the finalisation of the revised Annex 1 of the Introduction, some member countries indicated that there was a need to revise the bioaccumulation part of the Introduction (Annex 2: Bioaccumulation and behaviour in soils and sediments). However, such a revision will be dependent upon a lead country to draft the necessary text and gain approval from the WNT. As such, the WNT17 meeting agreed that the revised Annex 1 of the Introduction should be provided to the Joint Meeting for approval and submitted to Council via EPOC, with the addition of a sentence indicating that the unrevised Annex 2 would be updated and submitted for approval at a later date. The WNT17 meeting agreed to the suggested changes and approved the submission of the revised draft to the JM.