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**ENVIRONMENT DIRECTORATE**
**JOINT MEETING OF THE CHEMICALS COMMITTEE AND**
**THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

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## Biocides

# HARMONISING PHYSICAL/CHEMICAL TEST METHODS REQUIRED FOR REGISTRATION/AUTHORISATION OF BIOCIDES/PESTICIDES

**6th Meeting of the Task Force, 11-12 September 2008, Dublin, Ireland**

*This document will be discussed under item 7 of the draft agenda ENV/JM/BCID/A(2008)1*

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**HARMONISING PHYSICAL/CHEMICAL TEST METHODS REQUIRED FOR REGISTRATION/AUTHORIZATION OF BIOCIDES/AGRICULTURAL PESTICIDES**

This paper reports on an ongoing analysis of the differences in EU and US test methods for basic chemistry studies required for registration/authorization of biocides/agricultural pesticides with the view of adopting or adapting these methods as OECD Test Guidelines to address biocide/ agricultural pesticide registration requirements in OECD countries.

It was prepared by Stephen Smith, from the SC Johnson company.

***ACTION REQUIRED: The Task Force is invited to:***

***(i) discuss whether there would be value in OECD working to harmonize the test methods referred to in the present document;***

***(ii) discuss relevance/role of test methods recommended by the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods in this context; and***

***(iii) nominate a lead for this activity if the TFB sees value in progressing this project and developing a work plan.***

1. Physical chemistry studies form an integral part of the data set for biocidal and pesticidal products. Important information on the physical and chemical properties of formulated products is secured from conducting these studies. In comparing the US EPA's chemistry data requirements for registration with those of the EU's Biocidal Products Directive it is possible to see some overlap in the two systems. It is also possible to see that there are separate and different test methods addressing some of these overlapping requirements and that there are opportunities to harmonise to common tests in some instances. See Table 1 for a list of overlapping studies.

2. European industry experience gained in preparation of representative product dossiers shows that a company's ability to use US physical chemistry data in EU countries differs from country to country Industry is advised that some U.S. chemistry data (methods) "may" be acceptable but it is not possible to confirm that all EU countries would accept US methods. This 'forces' industry to repeat basic chemistry studies an inefficient use of limited resources for industry and a blockage to the potential sharing of reviews by OECD Member Governments. Availability of OECD Test Guidelines would help to alleviate this inefficiency and create the potential for sharing of reviews.

3. Overlapping data requirements include Oxidizing or Reducing Action, Flammability, Explodability, Miscibility, Corrosion Characteristics, pH, Viscosity and Density. The last two methods are currently available from OECD. The TFB is invited to discuss whether it sees value in the preparation of OECD Test Guidelines for the other studies and perhaps eventually other chemistry endpoints for formulated products (analytical method validation, storage stability, etc).

4. A review and comparison of the methods of interest shows that in some cases the U.S. and EU methods reference the same CIPAC (Collaborative International Pesticides Analytical Council) test method; in such instances it may be possible to suggest that the OECD Test Guideline simply refer to the U.S., EU and CIPAC test methods as being equivalent. In other instances, the EU and U.S. require the tests run at different temperatures or a different number of trials be conducted; in such cases it would be more streamlined to merge the requirements into one test. A report on an ongoing thorough review and comparison of these methods will be provided at the TFB meeting in Dublin.

5. The objective of this exercise is not for governments to replace EU or U.S. tests with OECD tests for companies seeking only approval for the domestic market but for governments to offer companies the choice of whether to use the national or OECD method. This would allow multi-national companies the chance to secure the efficiencies of running a test (i.e., the OECD test) one time and to provide authorities the chance to share reviews. It is believed that the benefits of quicker reviews and reduced development costs will help avoid wasting precious government resources and the savings will also accrue to the consumer, with no diminution in the safety of the products.

6. The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) as proposed by the United Nations relies for communicating physical hazards on test methods recommended by the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods and described in the UN Manual of Tests and Criteria. The potential role of these methods and impact of GHS should be discussed and considered if it is agreed to progress this project.

7. The Working Group on Pesticides will be asked to discuss this issue as well at its November 2008 meeting.

**TABLE 1**
The underlined text indicates those tests for which it may be useful to develop an OECD Test Guideline (TG)

| Test Description | EPA Method | US Notes | EU/BPD Requirement | BPD Citation | EC Method | OECD TG | EU Notes(s) |
|---|---|---|---|---|---|---|---|
| Oxidizing or Reducing Action | 830.6314 | Required if contains an oxidizing or reducing agent | Oxidising properties | 3.3 | A.17. (A.21) | No OECD TG is available | NA if it can be shown product is incapable of exothermix reaction |
| Flammability | 830.6315 | Required if product contains combustible liquids | Flash point and other indications of flammability or spontaneous ignition | 3.4 | A.9, A.10, A.11, A.12. A.15, A.16 | No OECD TG is available | A.13 also possibly applicable. NA where no components are classified flammable. |
| Explodability | 830.6316 | Required if product is potentially explosive | Explosive properties | 3.2 | A.14 | No OECD TG is available | |
| Miscibility | 830.6319 | Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents | | | Not applicable | No OECD TG is available | Not required for EU. |
| Storage Stability | 830.6317 | Required (12 mos not generally not available @ submission) | Stability and Shelf-life | 3.7 | CIPAC MT 46, MT 39, MT 48, MT 51, MT 54 | | Accelerated and real time data needed |

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|---|---|---|---|---|---|---|---|
| Corrosion Characteristics | 830.632 | Required - generally not available @ submission | | | | No OECD TG is available | |
| Dielectric Breakdown Voltage | 830.6321 | Required if EP is a liquid for use around electrical equip. | | | Not applicable | No OECD TG is available | Not required for EU. |
| pH | 830.7 | Required if dispersible with water | Acidity/alkalinity and if necessary pH (1% in water) | 3.5 | CIPAC MT 31, 75 | No OECD TG is available | MT 31 if ph <4, MT 75 if pH >10 |
| Viscosity | 830.71 | Required if product is a liquid | Surface tension and viscosity | 3.10 | A.5 | OECD TG 114, 115 | OECD guideline 114 and 115 as alternate |
| Density | 830.73 | Required | Relative density | 3.6 | A.3 | OECD TG 109 | A.3 for liquids, CIPAC MT 33, MT 159 or Mt 169 for powders or granules as appropriate. |