

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

Test Guidelines Programme

**STATUS REPORT ON THREE PROJECTS COMING FROM THE PESTICIDES PROGRAMME AND
ONE FROM THE BIOCIDES PROGRAMME**

27th Meeting of the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT)

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This document contains information on progress of work for three projects carried out within the Pesticides Programme and one project carried out within the Biocides Programme.

The following two pesticide projects are part of the work of the Residue Chemistry Expert Group (RCEG):

- Updating the **Guidance Document on Crop Field Trials (CFT)** – EHS publication: No. 66 in the series on Pesticides; No. 164 in the series on Testing and Assessment.
- Developing a new **Guidance Document on Rotational Crop Field Trials (R-CFT)**.

The third pesticide project is about the development of a new **Guidance Document for Pesticide Terrestrial Field Dissipation (TFD) Studies and Crosswalk between North America and European Ecoregions**.

The biocide project is to develop a new **Guidance Document for a Tier-2 Laboratory Test used to substantiate Efficacy Claims for Biocide Treated Articles**.

ACTION REQUIRED:

The WNT is invited to:

- i) take note of progress and timelines regarding the four projects above; and*
- ii) agree on approval of the TFD & ecoregion crosswalk document via written procedure following the 2nd commenting round, if no particular issue is raised in the approval round (see paragraph 13).*

PROJECTS UNDER THE PESTICIDES PROGRAMME

Pesticide Residue Chemistry

Introduction

1. A Standard Project Submission Form (SPSF) for the development of two Guidance Documents – Crop Field Trials (CFT) and Rotational Crop Field Trials (R-CFT) – was submitted by the Working Group on Pesticides (WGP) and included in the WNT work plan in 2008 (project No. 5.9). The work has been undertaken by the Expert Group on Pesticide Residues Chemistry (RCEG) established in 2003 at the beginning of the whole pesticide residues project; the RCEG, under the supervision of the WGP-Registration Steering Group (RSG) is composed of experts from: Australia, Canada, Germany, Italy, Japan, Netherlands, New Zealand, United Kingdom, United States, European Commission, EFSA, FAO and BIAC. Since its inception and until recently the RCEG was chaired by the US EPA.

Guidance Document on Crop Field Trials (CFT)

2. A first "Guidance Document on Crop Field Trials" was published in 2011: EHS publication, No. 66 in the series on Pesticides¹; No. 164 in the series on Testing and Assessment² [[ENV/JM/MONO\(2011\)50](http://www.oecd.org/env/ehs/pesticides-biocides/pesticidespublicationschronologicalorder.htm)]. In the same time, outstanding issues related to the CFT studies were raised following an OECD survey on Maximum Residue Limits (MRL) policies in member countries (survey results published in 2010, series on Pesticides, No. 51). Further work on these issues was discussed and agreed upon at the September 2011 RSG Meeting (Ottawa, Canada). The objective was to update the Guidance Document with respect to the following points: i) crop groups and representative commodities; ii) considering the use of the proportionality principle for adjusting crop field trial values relative to application rate; and iii) further direction on the collection and preparation of field trial samples.

3. A revised draft Guidance Document on Crop Field Studies was circulated for comments on 12th September 2014 with a deadline for responses of 31st October 2014. Comments were received from: Belgium, Canada, Finland, France, Germany, Japan, Netherlands, New Zealand, Switzerland, United Kingdom, EFSA (European Food and Safety Agency) and BIAC (Business and Industry Advisory Committee to the OECD).

Guidance Document on Rotational Crop Field Trials (R-CFT)

4. A sub-group of the RCEG is developing new guidance for rotational crop field trials. The work is still at the level of the expert group; it is anticipated that a first draft document will be available for broad discussion by Mid-2015 (see below).

RCEG Meeting on 7-8 July 2015, OECD, Paris

5. A meeting of the RCEG will take place at the OECD headquarters on 7-8 July, 2015. The objective will be to progress with the development of the above two Guidance Documents – CFT and R-CFT – and resolve outstanding issues relating to these documents.

¹ <http://www.oecd.org/env/ehs/pesticides-biocides/pesticidespublicationschronologicalorder.htm>

² <http://www.oecd.org/env/ehs/testing/seriesontestingandassessmentpublicationsbynumber.htm>

Timelines

6. Following the July 2015 RCEG meeting, it is expected that a draft CFT Guidance Document will be circulated to member countries' experts (through the WNT and WGP) for a second commenting round, and a draft R-CFT Guidance Document circulated for a first commenting round.

Pesticide Terrestrial Field Dissipation (TFD)

Introduction

7. A Standard Project Submission Form (SPSF) for this project was submitted by the Working Group on Pesticides (WGP) and included in the WNT work plan in April 2013 (project No. 5.13). The work on developing guidance for terrestrial field dissipation studies and constructing an ecoregion crosswalk started with a first work plan developed by Canada and presented at the 23rd WGP meeting in November 2008. An *ad hoc* Expert Group (EG-TFD) was established in 2009 under the WGP; it is composed of experts from: Australia, Canada, Italy, Netherlands, Norway, United Kingdom, United States, the European Food Safety Agency (EFSA), and the European Commission Joint Research Centre (JRC). The EG-TFD is co-chaired by Canada, the US and EFSA.

8. A Workshop on the "Development of Harmonised International Guidance for Pesticide Terrestrial Field Dissipation Studies and Crosswalk of North American and European Eco-regions" was held on 9-11 March, 2011 in Ottawa, Canada. The workshop report published in the series on Pesticides, No. 68 is available.

9. The aim of the TFD and ecoregion crosswalk project is two-fold:

- developing guidance for the conduct of pesticide TFD studies (component 1 led by US); and
- constructing an ecoregion crosswalk (component 2 led by Canada). The ecoregion crosswalk objectives are to: (i) identify similar eco-regions between North America and Europe; (ii) provide a GIS-based decision support system to assist in the selection of regions for TFD studies; and (iii) provide background information on pesticide use areas (crop-based), soils and climate.

Guidance for pesticide terrestrial field dissipation studies and crosswalk between North America and European Ecoregions

10. The outcome of the project will be international guidance for conducting pesticide field dissipation studies and identifying similar ecoregions. A harmonised methodology, based on a conceptual model and modular approach, will be provided to conduct the study. This will allow for pesticide field dissipation/ accumulation studies conducted at foreign sites to be evaluated and considered by other countries and regulatory agencies.

11. A draft TFD Guidance Document was circulated for a first commenting round – through the WNT and WGP – in July-September 2014. Comments were received from Germany, the United Kingdom and Crop Life International. A second review round is underway; it was started on 6th March with a deadline for response of 27th April 2015.

12. The following documents have been circulated at the review rounds:

1. Draft OECD Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies.

2. **ENASGIPS model** (Europe-North America Soil Geographic Information for Pesticide Studies): a GIS (geographic information systems)-based model for identifying similar ecoregions between Europe and North America and a tool for field site selection based on concerns identified in the conceptual model.
3. **ENASGIPS user manual**: a guide for installation and running the model. The crosswalk between North America and European Ecoregions is covered in this user manual including purpose, ecoregion concept, databases, uses and running the model.

For reviewing and testing the ENASGIPS model the following instruments were provided:

- Installation instructions: details on downloading the ArcGIS software for installing and running the ENASGIPS model. Important Note: ENASGIPS model was developed under ArcGIS software (Geographic Information System) and works only under this software.
- Video/audio demo (video file): a video / audio demonstration of the ENASGIPS model; for running this demo, simply double click the file and it will run automatically with Windows Media Player.

To download the ENASGIPS model, user manual and related files, the link www.enasgips.org and password "Luvisol" (case sensitive) should be used.

Timelines

13. It is anticipated that following the current (second) review round, a revised draft Guidance Document for conducting terrestrial field dissipation studies and associated ecoregion crosswalk will be submitted to WGP and WNT for approval, either under written procedure in the second half of 2015 – provided that the written procedure is accepted by the WNT – or at the WGP and WNT meetings in April and May 2016 respectively.

PROJECTS UNDER THE BIOCIDES PROGRAMME

Tier-2 Laboratory-based test to substantiate claims for efficacy of biocide treated articles

Introduction

14. In common with many antimicrobial agents, a tiered approach to assessing the efficacy of treated articles has been proposed by OECD³. Determining the basic antimicrobial properties of active substances in antimicrobial treated articles is relatively straightforward and a harmonized approach has been presented in the "Guidance Document for Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-Porous Antibacterial Treated Materials" published in 2014: EHS publication, No. 8 in the series on Biocides⁴; No. 202 in the series on Testing and Assessment [[ENV/JM/MONO\(2014\)18](http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm)].

15. However, measuring the efficacy of a treated article in practice and determining any benefit that they might bring is significantly more complex and beyond the scope of a single, or even a few, standardized methods. This is made more difficult due to the diverse claims made for such articles. To

³ Analysis and Assessment of Current Protocols to Develop Harmonised Test Methods and Relevant Performance Standards for the Efficacy Testing of Treated Articles/Treated Materials, EHS publication, series on Biocides [[ENV/JM/MONO\(2007\)4](http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm)]

⁴ <http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm>

address this with regards to the biocidal products regulation, a guidance document⁵ has been produced for the Nordic Council of Ministers that presents a systematic approach for the evaluation of claims made for treated articles and how such claims can be evaluated.

Proposal and structure of an OECD Guidance Document

16. An OECD "Guidance Document on Tier 2 Laboratory-based Tests used to Substantiate Claims for Efficacy of Biocide Treated Articles", based on the Nordic Council document (see footnote 5) and containing two example protocols that cover major claims – simulated splash test (on textiles and plastics) and non-suspended inoculum method to simulate hand contact – is being developed by a consultant.

Timelines

17. It is anticipated that a preliminary draft Guidance Document including a first example protocol will be available in April 2015 and a full draft document including two example protocols in December 2015. It is expected that a first commenting round of the draft Guidance Document – through the TFB and the WNT – will take place in the first half of 2016.

⁵ Efficacy Assessment of Treated Articles – A guidance, Peter Askew, IMSL
<http://www.norden.org/en/publications/publikationer/2014-904/>