

US EPA ARCHIVE DOCUMENT

OECD Method Working Groups

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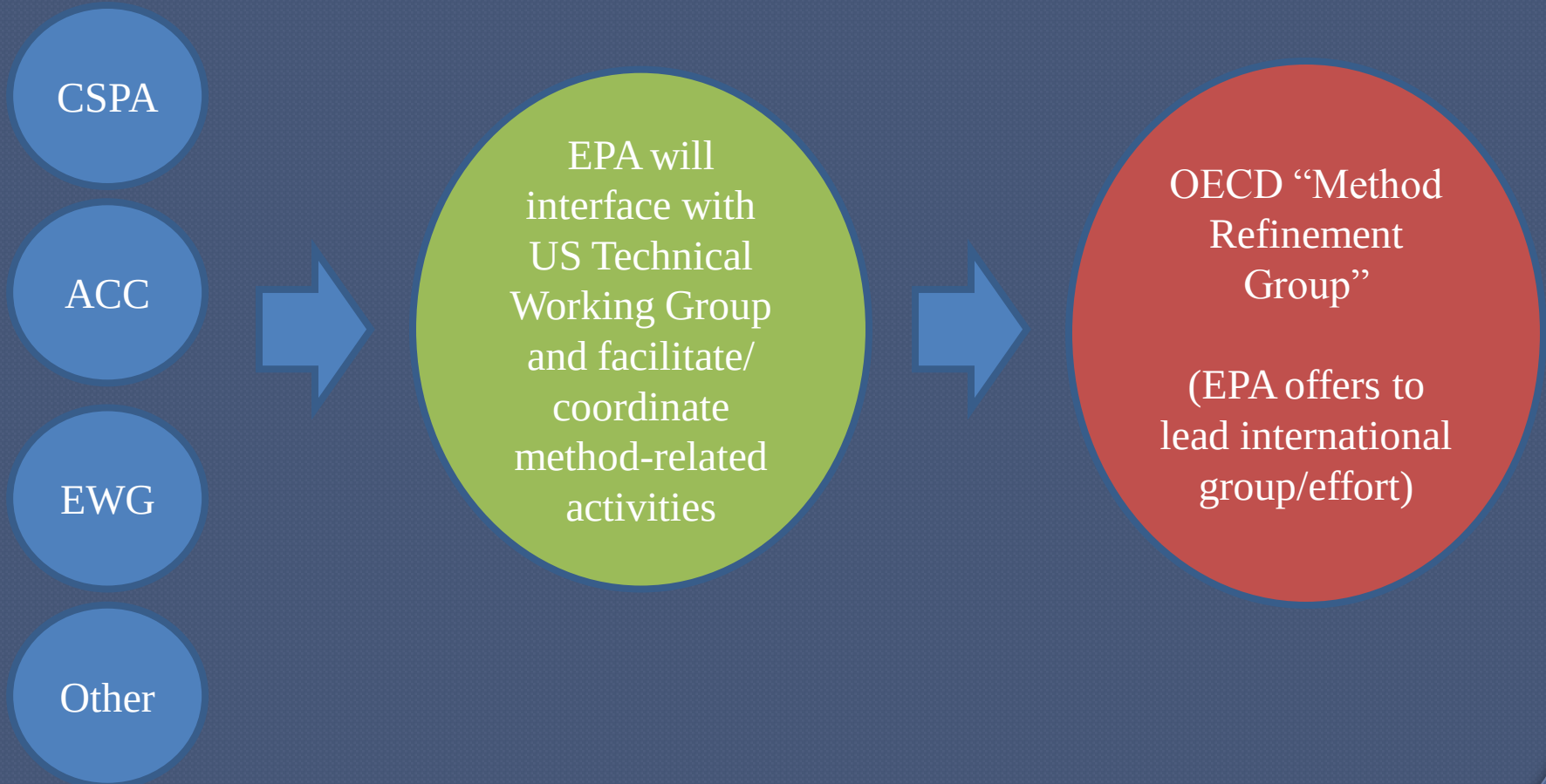
Background

● Excerpts from the OECD Guidance Document – Forward:

- “A draft *Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-porous Surfaces*, containing a Preface on guidance for the conduct of the tests and four test methods (bactericidal, mycobactericidal, fungicidal and virucidal) was approved by the 25th WNT Meeting in April 2013.”
- “The OECD member countries are encouraged to use the test methods described into this Guidance Document. The Secretariat will survey the member countries in order to get feedback on the performance of the method and technical recommendations designed to improve the procedures. For this purpose, it is anticipated that a Questionnaire will be made publicly available within one or two years (<http://www.oecd.org/env/ehs/>).”

US and OECD Working Groups

US Stakeholders



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http://www.oecd.org/chemicalsafety/testing/evaluating-the-activity-of-microbicides-used-on-hard-non-porous-surfaces.htm

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OECD Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-Porous Surfaces

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The OECD Biocides Programme and Test Guidelines Programme have been working together for several years to develop test methods for assessing the efficacy of biocidal products.

[A Guidance Document on microbiocides* efficacy testing](#) was issued in June 2013 and published in the series on Biocides (document No. 6) and series on Testing and Assessment (document No. 187). It describes quantitative methods for evaluating the activity of microbiocides used on hard non-porous surfaces. Efficacy data are part of the regulatory requirements that manufacturers/ applicants have to comply with concerning the authorisation and the placing on the market of their biocidal products.

The Guidance Document is partitioned into four sections based on the microbial agent:

- A Quantitative method for evaluating bactericidal activity of microbiocides used on hard non-porous surfaces
- B Quantitative method for evaluating mycobactericidal activity of microbiocides used on hard non-porous surfaces
- C Quantitative method for evaluating fungicidal activity of microbiocides used on hard non-porous surfaces
- D Quantitative method for evaluating virucidal activity of microbiocides used on hard non-porous surfaces

The Guidance Document will be improved in light of the experience gained. In this regard, the OECD member countries are encouraged to use the test methods described into this Guidance Document. The Secretariat will survey the member countries in order to get feedback on the performance of the method and technical recommendations designed to improve the procedures. For this purpose, a Questionnaire will be made publicly available within one or two years.

This guidance on microbiocides efficacy testing was developed by an ad hoc Group of Experts under the auspices of the OECD Task Force on Biocides and approved by the OECD Working Group of the National Co-ordinators of the Test Guidelines Programme (WNT), representing regulatory authorities. It is published in both [OECD series on Biocides](#) and [Testing and Assessment](#). The publications in these series are part of the OECD work on [chemical safety](#).

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New Workgroups

Why do we need to form new groups?

- Resolve remaining technical issues; however, the focus should be on implementation rather than method revision.
- May require limited lab work – Tomasino will highlight these.
- The international method validation process has concluded and a Guidance Document is in place – *endorsed by OECD*.
- The ultimate goal is to establish a set of internationally agreed OECD Test Guidelines.

We aim to...

- Support implementation of the OECD Guidance Documents including determining appropriate revisions.
- The Guidance Document is not legally binding.
- Provide leadership and data to secure approval as Test Guidelines

US Working Group

Formation of the US Working Group

- The group will inform US representatives to the OECD Method Refinement Group.
- Seeking to form group of technical volunteers from interested US stakeholders, particularly laboratories, which may conduct the tests.
- EPA is willing to interface with the working group and facilitate laboratory studies
- Group members should have a good understanding of how the method is performed
- Group members are encouraged to be active participants throughout the course of the initiative
- Group to be established in early 2014

OECD Method Refinement Group

Formation of the OECD Group

- OECD WNT will be informed of the initiative and formation in order to formally recognize its function and to anticipate its input.
 - WNT communication will be via the Task Force on Biocides
- Seeking an international group of technical volunteers from various OECD member countries
- U.S. is willing to/and will likely lead the effort due to EPA's interest in method implementation
- Membership will include technical experts from government, academia and industry
 - Industry participants will be nominated via BIAC in accordance with OECD policies and practices.
- The next TFB meeting is scheduled for July 2015.

OECD Method Refinement Group

- Ultimate goal is to assist in resolution of the WNT's issues for true harmonization such as deciding on a set of **test conditions** (hard water, soil load, contact time – see examples on next slide .
 - Work with the OECD Task Force on Biocides
 - Ultimately, report back to the WNT in 2015 on status, progress and resolution.

OECD Method Refinement Group

○ Excerpts from the Guidance Document:

- “Regulatory authorities may require other contact times depending on the label claims.”
- “Individual regulatory authorities may require a higher number of test carriers.”
- “Regulatory authorities may require other types and levels of soil depending on the label claims.”
- “Individual regulatory authorities may accept or ask for lower or higher water hardness for certain types of products.”
- “However, regulatory authorities may require other temperatures depending on the label claims.”

Questions/Comments

