



OECD ACTIVITIES ON EFFICACY AND TREATED ARTICLES

AMiCi WG2 workshop – Antimicrobial coatings applied in
healthcare settings – Efficacy testing.
Berlin, 7 June 2018

OECD Secretariat

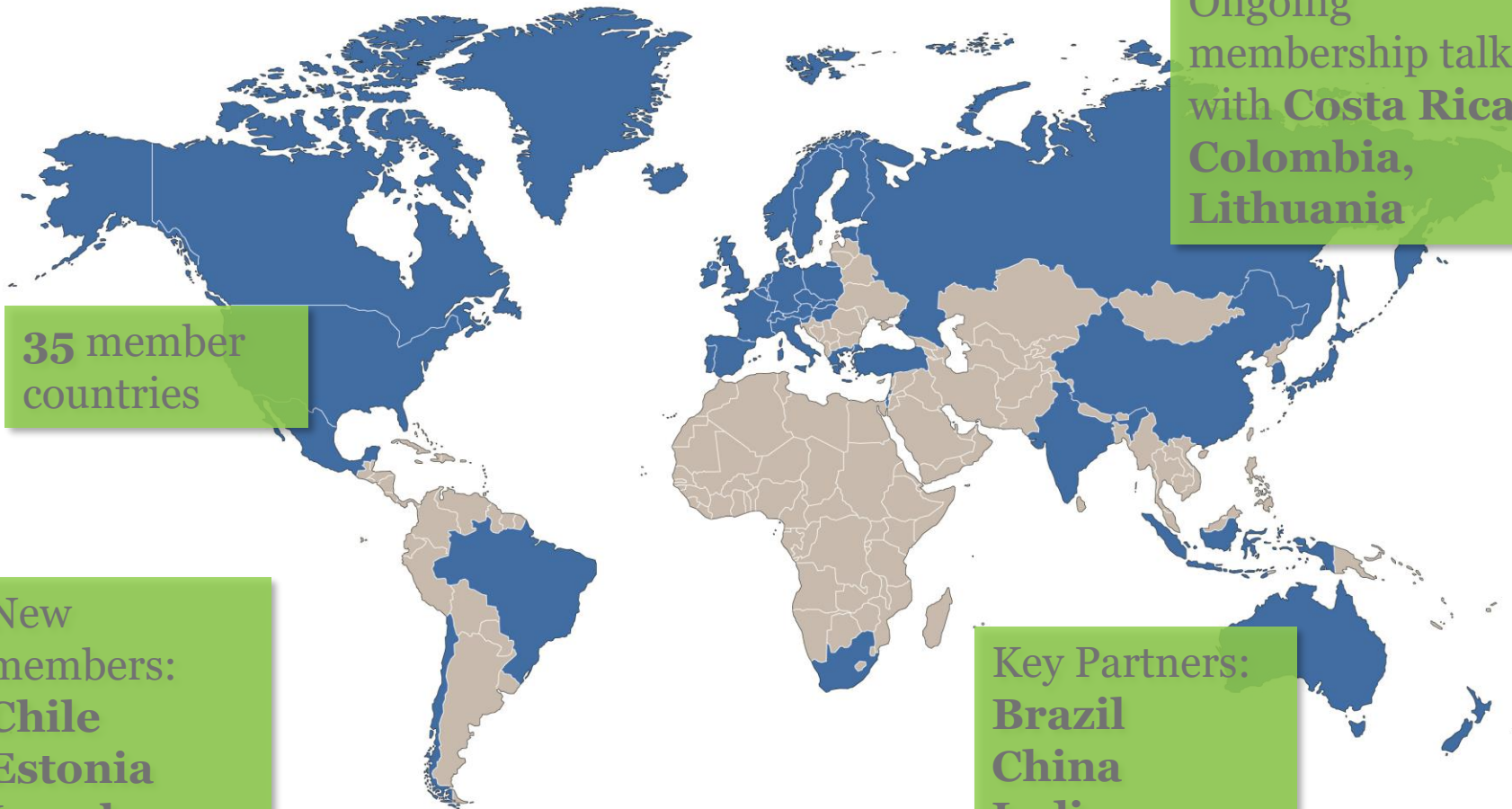


Overview

- OECD
- Working Group on Biocides
 - EBTA
 - EGCDTA
- Test Guidelines and Guidance Documents



The OECD



35 member countries

New members:
Chile
Estonia
Israel
Latvia
Slovenia

Ongoing membership talks with **Costa Rica**, **Colombia**, **Lithuania**

Key Partners:
Brazil
China
India
Indonesia
South Africa



The OECD

- ...is the global organisation that drives **better policies for better lives**
- ...analyses, measures and compares experiences and policies to give advice that helps **raise living standards** globally
- ...aims for a **stronger, cleaner, fairer world**



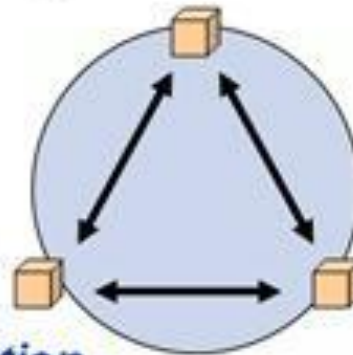
The OECD

Who drives the OECD's work?

Council

Oversight and strategic direction

Representatives of member countries and of the European Commission;
chaired by the Secretary-General; decisions taken by consensus



Committees

Discussion and implementation

Representatives of member countries and of countries with Observer status work with the OECD Secretariat on specific issues

Secretariat

Analysis and proposals

Secretary-General
Deputy Secretaries-General
Directorates



OECD/ENV/Environment, Health and Safety

Working Group of National Co-ordinators of the Test Guidelines Programme

Working Group on Good Laboratory Practice

Working Party on Exposure Assessment

Global PFC Group/ Issue Team on Sustainable Chemistry/ Ad Hoc Group on Alternatives Assessment

Working Party on Hazard Assessment

Working Group on Pesticides

Working Group on Biocides

Working Group on Chemical Accidents

Working Group on Pollutant Release and Transfer Registers

Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

Working Group for the Safety of Novel Foods and Feed

Working Party on Manufactured Nanomaterials



Working Group on Biocides

- Work Area I – Efficacy Determination
- Work area II – Evaluation of criteria other than efficacy
- Work Area III – Exposure Assessment
- Work Area IV – Work Sharing
- Work Area V – Risk Reduction
- Work Area VI – Monitoring Emerging Scientific and Policy Areas



Efficacy - Treated articles (EBTA)

Two purposes for the addition of biocides to treat articles:

- protect the materials used in the article or the properties of the article in service or,
- to introduce a new property to an article that is not related to the primary function of the article. These claims are usually health-related. Please note that in some legislations health related claims alter both the way the product is regulated and the body responsible for their registration.



Efficacy - Treated articles (EBTA)

- Analysis of current protocols to develop harmonised test methods for the efficacy testing of treated articles (2007)
- Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects (2008)



ENV/JM/MONO(2014)18
Unclassified

Unclassified

ENV/JM/MONO(2014)18

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

11-Jul-2014

English - Or. English

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

GUIDANCE DOCUMENT FOR QUANTITATIVE METHOD FOR EVALUATING ANTIBACTERIAL
ACTIVITY OF POROUS AND NON-POROUS ANTIBACTERIAL TREATED MATERIALS

Series on Testing and Assessment
No. 202

Series on Biocides
No. 8



Efficacy - Treated articles (EBTA)

- Tier I Guidance on efficacy of treated articles (2014)
- Tier II Guidance on efficacy of treated articles (approved by WNT, likely published in 2018)
- Possibly Tier III Guidance on efficacy of treated articles (field tests)



- Expert Group on Claims Development for biocides Treated Articles (EGCDTA, 2016)
 - Any claim on functionality, efficacy, or benefits from a biocidal property has public health impact
 - There is a public health concern when a claim is misunderstood



- a) Investigate claims development and regulatory benchmark tests across OECD countries;
- b) Describe principles for claims development;
- c) Describe principles of substantiating and testing such claims;
- d) Focus on claims for treated articles treated with disinfectants, e.g. for human hygiene (PT1), disinfectants and algaecides not intended for direct application to humans or animals (PT2), veterinary hygiene (PT3) and disinfectants for food and feed areas (PT4); and
- e) Estimate the chance that marketed claims correspond to the efficacy of the treated article and estimate the risk that claims are overestimating the actual efficacy of the marketed treated article



Claim development principles cover:

- i. technical aspects as possible? Is claim relevant to treated article?
- ii. legal principles with product and
- iii. socio-economic and how is that represented (or not)? The non-technical aspects may call for expertise not represented in the current EG.



of the claim assessed? Is the functionality of the environment),
 (baseline issues medical devices)

a claim presented (or not) understood?).



Test Guidelines and Guidance Documents



Test Guidelines and Guidance Documents

Oversight

- Working Group of National Coordinators of the Test Guidelines Programme (WNT)

Product

- Test Guidelines (Mutual Acceptance of Data)
- Test Guideline-related documents: Detailed Review Papers (DRPs), Guidance Documents (GDs), Validation reports and Peer review reports, etc. published in the Series on Testing and Assessment



Test Guidelines and Guidance Documents

- The testing of chemicals is labour-intensive and expensive.
- Often the same chemicals are being tested and assessed in several countries.
- The OECD Council Decision on Mutual Acceptance of Data (MAD):
 - test data generated in any member or partner country in accordance with OECD TG and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.



Test Guidelines and Guidance Documents



> A to Z

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About

Countries

Topics

> Français

OECD Home > Environment Directorate > Chemical safety and biosafety > Testing of chemicals > OECD Guidelines for the Testing of Chemicals

> Biodiversity, water and natural resource management

> Chemical safety and biosafety

> Testing of chemicals

> Assessment of chemicals

> Risk management of chemicals

> Chemical accident prevention, preparedness and response

> Pollutant release and transfer register

> Safety of manufactured nanomaterials

> Agricultural pesticides and biocides

> Biosafety - BioTrack

> Climate change

> Consumption, innovation and the environment

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OECD Guidelines for the Testing of Chemicals

The [OECD Guidelines](#) are a unique tool for assessing the potential effects of chemicals on human health and the environment. Accepted internationally as standard methods for safety testing, the Guidelines are used by professionals in industry, academia and government involved in the testing and assessment of chemicals (industrial chemicals, pesticides, personal care products, etc.). These Guidelines are regularly updated with the assistance of thousands of national experts from OECD member countries. OECD Test Guidelines are covered by the Mutual Acceptance of Data, implying that data generated in the testing of chemicals in an OECD member country, or a partner country having adhered to the Decision, in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), be accepted in other OECD countries and partner countries having adhered to the Decision, for the purposes of assessment and other uses relating to the protection of human health and the environment.

> [More about OECD Test Guidelines](#)

> [Section 1: Physical Chemical Properties](#)

> [Section 2: Effects on Biotic Systems \(Software for TG 223\)](#)

> [Section 3: Degradation and Accumulation](#)

> [Section 4: Health Effects \(Software for TG 455, TG 432 and TG 425\)](#)

> [Section 5: Other Test Guidelines](#)

> [List of Adopted Test Guidelines Including Dates of Revisions](#)

> [List of TG Addenda adopted by Council](#)

> [Draft Test Guidelines and public commenting rounds](#)

RELATED DOCUMENTS

> [Adopted Guidance and Review Documents](#)

> [Draft Guidance and Review Documents](#)

TEST GUIDELINES THAT HAVE BEEN DELETED OR REPLACED BY UPDATED VERSIONS

These obsolete Test Guidelines have been deleted in order to allow national/regional regulations that make reference to specific Test Guidelines and versions to be updated accordingly. They should not be used for new testing. They are included here because it may be useful to consult them in the framework of the assessment of substances based on old study reports. The guaranties of Mutual Acceptance of Data (MAD) would not apply if these Test Guidelines were used for new testing.

> [Section 1: Physical Chemical Properties](#)

> [Section 2: Effects on Biotic Systems](#)





Test Guidelines and Guidance Documents

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OECD Guidelines for the Testing of Chemicals, Section 2

Effects on Biotic Systems

OECD Publishing
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The OECD *Guidelines for the Testing of Chemicals* is a collection of about 150 of the most relevant internationally agreed testing methods used by government, industry and independent laboratories to identify and characterise potential hazards of chemicals. They are a set of tools for professionals, used primarily in regulatory safety testing and subsequent chemical and chemical product notification, chemical registration and in chemical evaluation. They can also be used for the selection and ranking of candidate chemicals during the development of new chemicals and products and in toxicology research. This group of tests covers effects on biotic systems.

Also available in French

English
ISSN: 2074-5761 (online)
DOI: 10.1787/20745761

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<input type="checkbox"/>	29 July 2016	Test No. 228: Determination of Developmental Toxicity to Dipteran Dung Flies (Scathophaga stercoraria L. (Scathophagidae), Musca autumnalis De Geer (Muscidae)) OECD	PDF READ
<input type="checkbox"/>	29 July 2016	Test No. 232: Collembolan Reproduction Test in Soil	PDF READ



Further Information

- Website:

<http://www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm>

and

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



Thank you for your attention !

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