# OECD Efficacy Workshop On Certain Antimicrobial Biocides

## April 22-24, 2002
## Arlington, Virginia, U.S.A.

# Workshop Summary Report

## FOREWORD

This OECD workshop was held as part of the work under the OECD Biocides Programme. It was held in Washington, 22-24 April 2002 and hosted by the United States Environmental Protection Agency (US EPA). An Organizing Committee, comprised of 14 members from the following countries and industry groups: France, UK; American Chemical Council; USA; Italy; CMCS; Germany; Czech Republic; Canada, EU and the OECD secretariat, developed the outline and scope for the workshop.

The scope of biocidal products to be covered in this workshop proved difficult to define. It was eventually decided that the workshop should cover most biocidal products bearing public health claims that are used to control micro-organisms either pathogenic to man or those which produce harmful by-products, together with materials treated with such biocidal products which also have a public health claim.

The workshop objectives were to exchange information on label claims, performance standards and efficacy testing parameters both for existing products and newly emerging ones within the scope as defined above. The final objective was to identify regulatory and scientific areas where harmonization was needed.

The Workshop was divided into plenary and break out sessions, with 5 break out groups being defined as follows: (i) biocides used on hard surfaces; (ii) biocides used on porous surfaces; (iii) biocides used in water; (iv) emerging products; and (v) treated articles (containing biocides)

**This summary report was prepared for the USA Environmental Protection Agency (Office of Pesticide Programs) by: DynCorp I&ET, Inc. , 6101 Stevenson Avenue, Alexandria, VA 22304 under EPA Contract No. 68-W-01-007.**

# Table of Contents

# *Chapter 1*
# *Revised Agenda*

**Monday 22 April**

*Location*

8:30 am ***Registration*** .....*Booth attached to Washington Ballroom*

9:00 am ***Opening Addresses/Welcome*** .....*Washington Ballroom*

**Cleo Pizana**, Chair, Special Assistant to Antimicrobials Division Director, Office of Pesticide Programs, U.S. EPA

**Frank T. Sanders**, Antimicrobials Division Director, Office of Pesticide Programs, U.S. EPA

**Geoff Wilson**, OECD Secretariat

9:30 am ***Academic Presentations*** .....*Washington Ballroom*

**Dr. Graziella Orefici**, Laboratory of Bacteriology, Instito Superiore di Sanita

**Dr. Syed Sattar**, Professor of Microbiology and Director, Center for Research on Environmental Microbiology (CREM)

**Dr. Denver Russell**, Professor of Pharmaceutical Microbiology, Welsh School of Pharmacy

10:30 am ***Break for coffee/tea*** .....*Area Outside of Washington Ballroom*

11:00 am ***Industry Perspective*** .....*Washington Ballroom*

**Dr. John Duddridge**, Rohm and Haas France SAS

**Stephen Smith**, S.C. Johnson and Son

**Kevin Mahoney**, Procter and Gamble

12:00 pm ***Regulatory Perspective***.....*Washington Ballroom*

**Dr. Dave Dillon**, Health and Safety Executive, Biocides and Pesticides Assessment Unit
**Shelley Tang**, Head, Device Registration and Assessment Section
**Michele Wingfield**, Chief, Product Science Branch, Antimicrobials Division, U.S. EPA *and* **Karen McCullagh**, Pest Management Regulatory Agency, Health Canada, Product Efficacy and Sustainability Division

1:00 pm ***Lunch***.....*Federal Hall Ballroom*

2:30 pm ***Instructions to Five Breakout Groups***.....*Washington Ballroom*

**Cleo Pizana**, Chair

3:00 pm ***Breakout groups discuss how to address the contributions of the three diverse groups, within the context of their subject area***

**Biocidal Products Used On Hard Surfaces (BLUE)** .....*Washington Ballroom*

**Biocidal Products Used On Porous Surfaces (GREEN)** .....*Madison Room*

**Biocidal Products Used In Water (YELLOW)** ..... *Van Buren Room*

**Emerging Biocidal Products (RED)** .....*Monroe Room*

**Materials Treated With Biocides Prior To First Sale (PURPLE)**.. .....*Wilson Room*

4:00 pm ***Break for coffee/tea*** .....*Area Outside of Washington Ballroom*

4:30 pm ***Resume breakout group session***
6:00 pm ***End breakout group session***
6:30 pm ***Evening Social*** ..... *Jefferson Room*
8:00 pm ***Close Social***

## Tuesday 23 April

*Location*

8:30 am ***Review Agenda for the Day*** ..... *Washington Ballroom*
**Cleo Pizana**, Chair
**Geoff Wilson**, OECD Secretariat
8:45 am ***Breakout Group Reports (15 minutes each)*** ..... *Washington Ballroom*
10:00 am ***Break for coffee/tea*** ..... *Area Outside of Washington Ballroom*
10:30 am ***Plenary Presentations on Emerging Science Issues*** ..... *Washington Ballroom*
**Dr. Michael Doyle**, The Role of Antimicrobials in Controlling Food Pathogens
**Dr. Marty Hamilton**, Performance Standards
**Dr. William Costerton**, Introduction to Biofilms
**Dr. Hans-Curt Flemming**, Extracellular Polymeric Substances: The House of Biofilm Cells
12:30 pm ***Lunch*** ..... *Federal Hall Ballroom*
2:00 pm ***Instructions to Breakout Groups*** ..... *Washington Ballroom*
**Cleo Pizana**, Chair
2:15 pm ***Breakout groups to begin working through their specific issues/work plans***
**Biocidal Products Used On Hard Surfaces (BLUE)** ..... *Washington Ballroom*
**Biocidal Products Used On Porous Surfaces (GREEN)** ..... *Madison Room*
**Biocidal Products Used In Water (YELLOW)** ..... *Van Buren Room*
**Emerging Biocidal Products (RED)** ..... *Monroe Room*
**Materials Treated With Biocides Prior To First Sale (PURPLE)**……*Wilson Room*
3:30 pm ***Break for coffee/tea***……..*Washington Ballroom*
4:00 pm ***Resume breakout group session***
6:00 pm ***Adjourn***

**Wednesday 24 April**

8:30 am ***Review Agenda for the Day*** ..... *Washington Ballroom*
**Cleo Pizana**, Chair
**Geoff Wilson**, OECD Secretariat

8:40 am ***Breakout groups' final meeting to develop recommendations***
**Biocidal Products Used On Hard Surfaces (BLUE)** ..... *Washington Ballroom*
**Biocidal Products Used On Porous Surfaces (GREEN)** ..... *Madison Room*
**Biocidal Products Used In Water (YELLOW)** ..... *Van Buren Room*
**Emerging Biocidal Products (RED)** ..... *Monroe Room*
**Materials Treated With Biocides Prior To First Sale (PURPLE)**……. *Wilson Room*

10:20 am ***Break for coffee/tea*** ..... *Area Outside of Washington Ballroom*

11:00 am ***Resume breakout group session***

11:45 pm ***Conclusions/Recommendations from 5 breakout groups*** ..... *Washington Ballroom*

1:00 pm ***Summary from the Chair*** ..... *Washington Ballroom*
**Cleo Pizana**, EPA Chair
**Geoff Wilson,** OECD Secretariat

1:30 pm ***Lunch*** ..... *Federal Hall Ballroom*

3:00 pm ***Workshop Adjourn***

# *Chapter 2*
# *Supplemental Presentations and Q & A Sessions on April 22, 2002*

## Opening Addresses/Welcome:

***Cleo Pizana – Chair, Special Assistant to Antimicrobials Division Director, Office of Pesticide Programs, U.S. EPA***

- Provided a brief introduction and welcome to the 1st OECD Efficacy Workshop On Certain Antimicrobial Biocides

***Frank Sanders – Antimicrobials Division Director, Office of Pesticide Programs, U.S. EPA***

- Described a vision for and focus for the workshop.

***Geoff Wilson – OECD Secretariat***

- Defined OECD, Organisation of Economic Cooperation and Development
- Described the objectives of the OECD Biocides Program is to help both industry and government
- In a survey of OECD countries; results showed many differences, specifically on efficacy
- Data generally required to support claims
- The program is at least 10 years old and was refocused in 2000
  - Environmental emission scenarios
  - Efficacy Activity;
    1) survey methods available
    2) Workshop on certain antimicrobials

*Presentation was not included in the workshop notebook and is included below*.

**Slide 1 :**
**OECD Efficacy Workshop On Certain Antimicrobial Biocides**

*Geoffrey Wilson*

*Organisation for Economic Cooperation and Development (OECD)*

*Geoff.Wilson@oecd.org*

**Slide 2:**
**OECD Biocides Programme – Objectives**

- To increase efficiency in the registration of biocides for both governments and industry
- To help countries reduce risks associated with biocide use

**Slide 3:**
**OECD Biocides Programme - History**

- Evolved from the Agricultural pesticides programme
- Started with a survey of OECD member countries approaches to the regulation of biocides (1997-1998)
- Programme was refocussed in 2000

**Slide 4:**
**Survey Results - General**
DIFFERENCES

- in the way biocides are categorized
- in the way biocides are regulated
- in the risk assessment approach
- in the data requirements (including efficacy requirements)

**Slide 5:**
**Survey Results – Efficacy**

- Efficacy data not required for all use categories regulated
- Importance of efficacy data for regulation variable
- Data generally required to support label claims
- Few standardised testing methods

**Slide 6:**
**OECD Biocides Programme Initiated in 1998**

- Harmonisation of data requirements
- Exposure & risk assessment
- Development of test guidelines
- Cooperation in biocides reviews
- Risk reduction activities
- Efficacy testing & acceptability criteria

**Slide 7:**
**OECD Biocides Programme**
Current Priorities

- Environmental Emmission Scenarios (wood preservatives first)
- Efficacy Activity
    - Survey of methods available
    - Workshop On Certain Antimicrobials

**Slide 8:**
**OECD Biocides Programme - Efficacy Objectives**

- Development of Guidance for Efficacy Testing and Assessment
- Harmonisation of Pass/Fail criteria

**Slide 9:**
**Overview of Efficacy Testing Methods for Biocides**

- To improve knowledge of what tests are available
- To identify areas where new tests are required
- Survey results available on OECD Website
  *http://www1.oecd.org/ehs/biocides/efficacy-overview.htm*
    - not fully comprehensive (not all product types included)
    - now somewhat out of date (published in 1998)

**Slide 10:**
**OECD Efficacy Workshop On Certain Antimicrobial Biocides**

- 22-24 April 2002, Washington, USA
- Exchange info. on label claims, performance standards and test requirements
    - for new and existing biocidal products
- Academics, Regulators and Industry
- Ultimate aim is harmonisation of key parameters related to Efficacy

**Slide 11:**
**OECD Efficacy Workshop On Certain Antimicrobial Biocides - OUTPUT**

- Workshop report
    - include reports from each B/O group
- Recommendations to:
    - Academics
    - Industry
    - Regulators
    - OECD
- Future Workshops?

**Slide 12:**
**OECD Efficacy Workshop On Certain Antimicrobial Biocides**
**OBJECTIVES**

1. To exchange information on:
   - label claims (by product categories)
   - performance standards
     (to support the label claim)
   - efficacy testing parameters
     (for developing harmonised guidance
     for methods to support the label claim)

**Slide 13:**
**OECD Efficacy Workshop On Certain Antimicrobial Biocides**
**OBJECTIVES**

2. To begin discussions on areas of emerging
   regulatory interest, such as the efficacy
   requirements of:
   - materials treated with biocides (e.g. treated textiles & plastics)

- products for spas hot bathes & dental water lines
- new claims for household products (e.g. fruit & vegetable washes)

**Slide 14:**
**OECD Efficacy Workshop On Certain Antimicrobial Biocides**
**OBJECTIVES**
3. To identify those regulatory and scientific areas where harmonisation is needed

*Workshop participants did not raise questions after this presentation was completed.*

# Academic Presentations:

***Dr. Graziella Orefici - Laboratory of Bacteriology, Instito Superiore di Sanita***

- Dr. Orefici gave the first academic presentation of the day.
- European standardization and the role of CEN
- Definition of CEN
- Standards are the main deliverable of CEN
- Scope of the CEN/TC 216
- CEN TC 216 members, university, industry, regulators, certified labs
- Contribution of different groups, each group brings a different and unique knowledge set
- Basic difficulties; normative differences in different countries, some had norms some did not, some were unwilling to change
- Test Methods: specify and fix (can be modified to fulfill specific needs)
- TC 216 horizontal working group
- Test levels: categorized into three phases
- Standards produced, completed, in process, under development
- Published standards
- Problems: tests must be validated among several labs (ring tests), expensive and time consuming and there are no grants. Standardization is not well regarded in scientific field so it makes it difficult to publish.

*Presentation was not included in the workshop notebook and included below*.

**Slide 1:**
**THE EUROPEAN EXPERIENCE:**

European standardization and the role of CEN

**Slide 2:**
**WHAT IS CEN**

- CEN is a legal association, the member of which are the National Standards Bodies (NSBs) of nineteen European Countries and six Associates, supported by a Central Secretariat based in Brussels. It is the European counterpart of ISO with which it has a standing protocol (the "Vienna Agreement") to facilitate technical co-operation.

- The principal deliverable of CEN is the European standard (EN), which must be published by each of NSBs as an identical national standard, with any pre-existing national standards in conflict being withdrawn.

**Slide 3:**
**STANDARD**

A technical specification or other document available to the public, drawn up with the cooperation and consensus or general approval of all interested parties affected by it, based on the consolidated results of science, technology and experience, aimed at the promotion of

optimum community benefits and approved by a recognized standardizing body on the national, regional or international level for repeated or continuous application, with which compliance is not mandatory

**Slide 4:**
**SCOPE OF THE CEN/TC 216**

- Standardization of the terminology, requirements, test methods including potential efficacy under in-use conditions, recommendations for use and labelling in the whole field of chemical disinfection and antiseptics. Areas of activity include agriculture (but not crop protection chemicals), domestic service, food hygiene and other industrial fields, institutional, medical and veterinary applications".

*NOTE: title and scope of CEN/TC 216 standards shall clearly express that standardization is limited to chemical disinfectant and antiseptic products and not disinfection in general.*

**Slide 5:**
**CEN TC 216**
**MEMBER AFFILIATION**

- University
- Industry
- Regulators from Ministry of Health or other National Bodies (RIVM, ISS, BSI)
- Certified Laboratories

**Slide 6:**
**CONTRIBUTION OF THE DIFFERENT GROUPS**

- Industry - Bring the market demand to the attention of the TC
- Regulation bodies - Bring the requests of national authorities to be fulfilled to put the product on the market
- University - Give the scientific support to the development of the tests
- Certified laboratories - Have, in general, the largest experience on problems regarding tests performance a good knowledge of the different products on the market

**Slide 7:**
**BASIC DIFFICULTIES**

- Normative differences in the different countries
- Countries who already had norms were very reluctant to change them

**Slide 8:**
**TC 216**


**Slide 9:**
**TEST METHODS**
Specify - Materials, methods, glassware, reagents, microorganisms, procedures, water hardness

Fix* - Microbial strains, interference substances, exposure time
*can be modified to fulfill specific needs

**Slide 10:**
**TC 216 – HWG**

- EN1040: 1997 Basic bactericidal activity
- EN1275: 1997 Basic fungicidal activity
- PrEN14347: (6/2002) Basic sporicidal activity

**Slide 11:**
**TEST LEVELS**
The tests are categorised in three phases:

- Phase 1:

Suspension tests to establish that a product (agent or formulation) has bactericidal and/or fungicidal activity without regard to specific conditions of intended use

- Phase 2 step 1:

Suspension tests to establish that a product has bactericidal and/or fungicidal, and/or sporicidal, and/or virucidal, and/or tuberculocidal etc. activity under conditions appropriate to its intended use in laboratory conditions

**Slide 12:**
**TEST LEVELS (Continued)**

- Phase 2 step 2:

Other laboratory test such as handwash and handrub tests, and test on inanimate surface to establish that products have microbicidal activity against surface attached micro-organisms (close to practical conditions)

- Phase 3:

Field tests used under practical conditions (not yet developed)

**Slide 13:**
**STANDARD PRODUCED OR UNDER DEVELOPMENT BY TC 216**

- Published 12
- Under Approval 10
- Under Development 13

| HWG | WG1 | WG2 | WG3 |
|---|---|---|---|
| 5 | 18 | 7 | 5 |

**Slide 14:**
**TYPES OF ACTIVITIES TESTED**

- Bactericidal activity 14
- Fungicidal activity 7
- Sporicidal activity 5
- Virucidal activity 5
- Mycobactericidal activity 3
- Activity against Legionella 1
- Preservation of strains 1
- Guidelines 1

**Slide 15:**
**PUBLISHED STANDARDS**

- EN 1040: 1997 – Confirmed: 2002

Chemical disinfectants and antiseptics - Basic bactericidal activity - Test method and requirements (phase 1)

- EN 1275: 1997 – Confirmed: 2002

Chemical disinfectants and antiseptics - Basic fungicidal activity - Test method and requirements (phase 1)

**Slide 16:**
**PUBLISHED STANDARDS (Continued)**

- EN 1276: 1997 – Confirmed: 2002

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics for use in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)

- EN 1499: 1997 – Confirmed: 2002

  Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2, step 2)

**Slide 17:**
**PUBLISHED STANDARDS (Continued)**

- EN 1500: 1997 – Confirmed: 2002

  Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)
- EN 1650: 1997 – Confirmed 2002

  Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics for use in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)

**Slide 18:**
**PUBLISHED STANDARDS (Continued)**

- EN 1656: 2000

  Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics for use in the veterinary field - Test method and requirements (phase 2, step 1)
- EN 1657: 2000

  Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics for use in the veterinary field - Test method and requirements (phase 2, step 1)

**Slide 19:**
**PUBLISHED STANDARDS (Continued)**

- EN 12353: 2000

  Chemical disinfectants and antiseptics - Preservation of microbial strains used for the determination of bactericidal and fungicidal activity
- EN 13697: 2001

  Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 2)

**Slide 20: PUBLISHED STANDARDS (Continued)**

- EN 13704: 2002

  Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)
- EN 12054: 2002

  Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and hanwash used in human medicine - Test method and requirements (phase2, step 1)

**Slide 21:**
**PROBLEMS**

- Each standard, before approval, should be tested in a ring trial performed in many laboratories. That means an additional committement of the laboratories, already very busy
- Developing and testing a new standard by a ring test is expensive, difficult and time consuming. The statisticians which have to evaluate the results need very specific competences
- Research in standardisation is not highly considered in the scientific field. Results of the ring tests are in general not published in high impact factor journals, grants are scarce and often given only after the work has been finished

**Slide 22:**
**PROBLEMS (Continued)**

- Regulatory body and university members have severe funding limitation therefore their partecipation to the meetings is not continuous
- Industry representatives are often marketing experts instead of microbiologists

***Dr. Syed Sattar - Professor of Microbiology and Director, Center for Research on Environmental Microbiology (CREM)***

- Dr. Sattar gave the second academic presentation of the day.
- Information covered adequately in the notebook.

*Presentation can be found in the workshop notebook .*

***Dr. Denver Russell - Professor of Pharmaceutical Microbiology, Welsh School of Pharmacy***

- Dr. Russell gave the third academic presentation of the day.
- A number of slides skipped from the notebook.

*Presentation can be found in the workshop notebook .*

*Workshop participants raised the following questions after the academic presentations:*

**Question:** Canadian question for Orefici – should OECD concern the notion of validity? Comparison w/ marriage, couple w/ a marriage license, a license doesn't necessarily determine marriage. Wants the audience to determine validity, validation of tests, feasibility of tests, and procedures of the tests.

**Answer:** Response from Orefici - need to identify the 3 components above, her second thought was how to compare different tests. If there is test data from a different test, she is unable to say if it compares to European tests. She says it is necessary to determine when comparison is necessary between different tests.

**Comment:** Response back from Canadian, question goes out to the audience - Harmonize test methods for hygienic test components also the efficacy of consumer test products (dishwashing agents, etc), question to the audience, relates to products for cleaning the skin,
**Answer:** The response was that it is outside the scope of the workshop and will be addressed in the future. Testing the efficacy of consumer products is outside the scope of this workshop.

**Question:** Again Hygiene claims made by consumer products that already have defined methods for testing how the claim is made.

**Answer:** Response is that these products are borderline and the EU hasn't developed tests to validate their claims.

**Question:** Germany - To Sattar, why the short exposure times?

**Answer:** Sattar response, contact time was to focus on the environmental contact time. When applied by sprayed or moistened rag, then the substance does not remain in contact with the microbe for as long as 10 min. If something works in a short contact time, it'll work in a longer contact time as well. Sattar was trying to model the contact time of an environmental cleaner not of something that will be soaked.

# Industry Perspective:

***Dr. John Duddridge - Rohm and Haas, France***

- Dr. Duddridge gave the first industry perspective presentation of the day.
- Changed order of slides a bit but information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

***Stephen Smith - S.C. Johnson and Son***

- Mr. Smith gave the second industry perspective presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

***Kevin Mahoney - Procter and Gamble***

- Mr. Mahoney gave the third industry perspective presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

*Workshop participants did not raise questions after the industry perspective presentations were completed.*

## Regulatory Perspective:

***Dr. Dave Dillon - Health and Safety Executive, Biocides and Pesticides Assessment Unit***

- Dr. Dillon gave the first regulatory perspective presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

***Shelley Tang - Head, Device Registration and Assessment Section***

- Ms. Tang gave the second regulatory perspective presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

***Michele Wingfield - Chief, Product Science Branch, Antimicrobials Division, U.S. EPA and Karen McCullagh - Pest Management Regulatory Agency, Health Canada, Product Efficacy and Sustainability Division***

- Ms. Wingfield and Ms. McCullough gave the third regulatory perspective presentation of the day as a joint effort.
- Information covered adequately in notebook.

*Presentations can be found in the workshop notebook .*

*Workshop participants raised the following questions after the regulatory presentations:*

**Comment:** On the notion of harmonization: Canadian government is involved due to the resource reason in the development of scientific studies to reach the goal of the one test one time, worldwide method.

# *Chapter 3*
# *Supplemental Presentations and Q & A Sessions on April 23, 2002*

## Plenary Presentations on Emerging Science Issues:

***Dr. Michael Doyle – University of Georgia, USA***

Dr. Doyle gave the first plenary presentation of the day.

- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

*Workshop participants raised the following questions after the presentation:*

**Question:** Irradiation for produce?

**Answer:** Irradiation at the level necessary turns veggies into soup.

**Question:** Works with meats?

**Answer:** Irradiated meat to decrease bacteria 5 logs "smells like a wet dog".

***Dr. Marty Hamilton – Montana State Universit, USA***

- Dr. Hamilton gave the second plenary presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

*Workshop participants raised the following questions after the presentation:*

**Question:** Jeff Brown from Biolab; about risk assessment, seems very daunting, look at the world as a series of linear equations and indeed its more complex than that. If we say that the goal is to have a 3 LR how do we do a risk assessment with different people, immuno-compromised vs. healthy for example.

**Answer:** Would require a group of experts to perform the risk assessment, need scientists, statisticians, etc to make an accurate risk assessment.

**Question:** Variation in the QCT test, to what extent is the variability due to the test versus the agent?

**Answer:** When there is an intermediate activity see a greater variability. Hasn't thought about modes of action.

**Question:** In some data the germicides weren't used at intended concentrations, risk assessment is a good idea but can't afford to wait, need to get some quantitative performance standards in place although they may be changed over time. How long until we get a risk assessment performance standard in place.

**Answer:** This will require replacing some of the science issues with policy issues. Need to strive for the ideal and will take some political effort as well as scientific.

**Question:** Risk assessment project is very ambitious, like the cancer risk assessment, suggest a more modest project, do a hazard assessment instead of a risk assessment.

**Answer:** Hazard assessment is a good place to start but the epidemiology should be more accessible due to the fast action of microbes vs. cancer.

**Question:** Do you totally remove microbes or just harmful ones?

**Answer:** No answers.

**Question:** (comment) Disinfection will only decrease a small percentage of infectious disease and we don't know how much that percentage will be.

**Answer:** Should get this data and if it turns out that the percentage decrease is small it may not be worth the effort.

***Dr. William Costerton – Montana State University, USA***

- Dr. Costerton gave the third plenary presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

*Workshop participants raised the following questions after the presentation:*

**Question:** UK, role of persisters in biocides.

**Answer:** A biofilm is attacked by an antibacterial agent and persisters remain until the agent goes away then start growing again and living off the remains of the dead bacteria. It may be that these persisters see the agent coming and are able to change their genetic code to become resistant.

***Dr. Hans-Curt Flemming – University of Muelheim in Germany***

- Dr. Flemming gave the fourth plenary presentation of the day.
- Information covered adequately in notebook.

*Presentation can be found in the workshop notebook .*

*Workshop participants did not raise questions after this presentation was completed.*

# *Chapter 4*
# *Hard Surfaces*
# *Breakout Group Report*

During the OECD Workshop, several breakout groups convened to exchange information on label claims, performance standards, and efficacy testing parameters. These breakout groups began discussions on areas of emerging regulatory interest and began to identify those regulatory and scientific areas where harmonization is needed. The information presented in this chapter reflects the two reports developed by the Hard Surfaces Breakout Group on April 23rd and April 24th, respectively. A list of the participants comprising this breakout group is provided at the end of the chapter.

## Report 1

The Hard Surfaces Breakout Group proceeded with discussion based on the following assumptions.

1. All hard surface biocide products (HSBP) will be regulated.

2. All HSBP used in areas such as hospitals, institutions, food areas, and household products will require efficacy testing.

3. Each governing body will define the acceptable use areas.

Objectives for the Workshop – Hard Surfaces

- Standard methods for efficacy
- Establish criteria for an acceptable test method
- Standard test microorganisms
- Establish Performance Standards
- Unify Regulatory claims
- Coordinated Protocol Reviews
- Encourage more encompassing tests rather than for specific organisms
- Consider developing monographs for end-use products containing specific actives
- Understand the reason for the lack of harmonization today
- What is good/bad about the current test methods?
- Mutual recognition and criteria
- Longevity and importance of standardizing organizations
- Establishing adequate level of protection

- What differences can exist for countries but still have harmonization
- Establish standardized label guidance

Types/Categories of Products – Hard Surfaces

| | US | EU | Canada |
|---|---|---|---|
| • Bactericidal | X | X | X |
| • Fungicidal | X | X | X |
| • Virucidal | X | X | X |
| • Mycobactericidal | X | X | X |
| • Tuberculocidal | X | X | X |
| • Sporicidal | X | X | X |
| • Non-Food Sanitizer | X | | X |
| • Food Contact Sanitizer | X | | X |

Public Health Label Claims- Hard Surfaces

- Kills
- Kills (99.9%, 99.99%, 99.999%)
- Reduces
- Destroys
- Eradicates
- Eliminates
- Fights
- Germicidal
- Antibacterial
- Antimicrobial
- "Bug" + cidal
- Active against (species)
- Controls
- Disinfects
- Hygienically cleans
- Inhibits
- Guards against
- Protects against
- Residual
- Long lasting
- Cleans/Disinfects
- Washes/Disinfects

*Workshop participants did not raise questions after this presentation was completed.*

# Report 2

**Hard Surfaces Breakout Group**

- Basic Assumptions
- Objectives
- Categories/Types of Biocide Products
- Test Method Wish List
- Commonly Used Claims
- Options to Consider
- CEN 13697/QCT-1/QCT-2
- Recommendations

**Hard Surfaces Breakout Group - Test Method Wish List**

- Quantitative with defined inoculum level
- Ideal carrier- material (i.e. stainless steel), design (concave/flat)
- Defined soil load
- Reproducible
- Standard growth and recovery media
- Suited for range of actives
- Standard source of test organism
- Standard interfering substances
- Standard propagation of test organisms

**Hard Surfaces Breakout Group - Test Method Wish List - Cont'd...**

- Represent practical conditions
- Realistic contact time
- Sensitivity
- Statistically valid - number of replicates
- Defined microorganisms
- Standard method of detection (counts)
- Defined number of batches/lots

**Hard Surfaces Breakout Group - Test Method Wish List - Cont'd...**

- Controls: viability, sterility, neutralization, toxicity
- Easy to automate

**Hard Surfaces Breakout Group - Recommendations - Communication**

- Formally create OECD network to foster communication (OECD)
- Continue/formally create an OECD Technical Work Group to move all Hard Surface Breakout Group harmonization recommendations forward with diverse participation of regulators, academics, industry (OECD, regulators)
- Communicate activities to other countries, regulatory areas (OECD, regulators)

**Hard Surfaces Breakout Group - Recommendations - Science**

- Utilize a risk based evaluation to establish adequate level of protection to set performance criteria (industry, academics)
- Perform comparison of quantitative carrier tests -QCT-1, QCT-2, CEN 13697 (e.g. Gold Standard) (academia, industry)
- Identify standard quantitative test methods (regulators, industry, academics)
- All methods should be validated through round robin/ring/collaborative trials (regulators, industry, academics)

**Hard Surfaces Breakout Group - Recommendations - Process**

- Develop a fast track process for harmonized reviewing and accepting new/modified test methods (regulators, industry, academia)
- Evaluating the feasibility of extending efficacy test results into existing/harmonized label guidelines (regulators, industry, academia)
- Develop a process for mutual recognition of science (efficacy) reviews including standard report templates/summaries/formats and electronic submission (regulators, industry, academia)
- Develop a process for transition to new method/performance criteria (i.e. grandfather in existing products/data) (regulators)

*Workshop participants raised the following questions after the presentation:*

**Question:** From ASTM's point of view, the comparison of standards contains a lot of items, question to EPA, what is the next step forward, as scientists, we feel that results are much more reproducible using quantitative techniques instead of qualitative methods with dilution.

**Answer:** Michele Wingfield's answer – It's a long process to incorporate new guidelines. QCT1 and QCT2 test methods are being evaluated and will be incorporated into existing guidelines.

**Question:** As we go forward we need a commitment globally from regulatory agencies so that the science can address the question and gain rapid acceptance.

**Answer:** Geoff Wilson– OECD has a test guidelines program in which tests are evaluated and formulated to be incorporated into the OECD guideline and this will help getting a test accepted internationally.

# Participants

**HARD SURFACES (BLUE)** ***Washington Ballroom***

| NAME | | AFFILIATION | COUNTRY |
|---|---|---|---|
| Diane FALBO | **CHAIR** (OC) | Industry | US |
| Bert van KLINGEREN | **Rapporteur** (OC) | Academic | EU |
| Brigid KLEIN | **Rapporteur** | Industry | US |
| | | | |
| Frantisek RETTICH | (OC) | Regulator | Czech Republic |
| Ingeborg SCHWEBKE | (OC) | Regulator | EU |
| Andre CRAAN | | Regulator | Canada |
| Mary FITZPATRICK | | Regulator | EU |
| Ulla FALK | | Regulator | EU |
| Myra CHENG | | Regulator | US |
| | | | |
| Kristy SANCHUCK | | Industry | Canada |
| Stephen SMITH | | Industry | US |
| Bob ISRAEL | | Industry | US |
| Mary BENNNET | | Industry | US |
| Martin JONES | | Industry | EU |
| Mithu SEN | | Industry | EU |
| Florian LICHTENBERG | | Industry | Switzerland |
| | | | |
| Rhonda JONES | | Academia | US |
| Eliot HARRISON | | Academia | US |
| Jurgen GEBEL | | Academia | EU |
| Radu CRAINIC | | Academia | EU |
| | | | |

# *Chapter 5*
# *Porous Surfaces*
# *Breakout Group Report*

This breakout group began discussions on areas regarding porous surfaces and began to identify those regulatory and scientific areas where harmonization is needed. The information presented in this chapter reflects the two reports developed by the Porous Surfaces Breakout Group on April 23rd and April 24th, respectively. A list of the participants comprising this breakout group is provided at the end of the chapter.

## Report 1

**Porous Surfaces Break-Out - Report # 1**
Fundamental questions to define scope of group:

- What is a porous surface?
- What level of porosity is relevant?

Surfaces Discussed

- 'soft' surfaces
    - Fabrics/textiles, leather, carpets, sponges, etc..
- hard porous (rough) surfaces
    - concrete, ceramics, natural stone, etc…
- in-between
    - un-sealed wood, rubber/latex, etc…

**Porous Surfaces Break-Out - Report # 1**
Relevant Use-Areas

- Fabrics/Textiles
    - Laundry (domestic, commercial, hospital)
    - Hard-to-launder fabrics (drapery, upholstery)
    - Carpets
- Wood – cutting boards, flooring, counters, animal stalls and related surfaces in veterinary field
- Food Processing areas?
- Building Materials – ceiling tiles, drywall

**Porous Surfaces Break-Out - Report # 1**

- Product Types & Methods of Application
    - Liquids, Powders, Sprays, Tablets, Foams, Gels, Wipes, Gaseous Products, Dry Solvents
- Brainstorm List of Label Claims
    - Target organisms
- Bacteria, virus, fungi, spores, prions, protozoa, blood borne pathogens

- Specific organisms
- Broad terms – germs/microbes

**Porous Surfaces Break-Out - Report # 1**

- Brainstorm List of Label Claims
- Related claims
    - disinfects, sanitizes, destroys, inactivates, kills,
    - removes, washes away, reduces, eliminates
    - quantification: e.g. kills/removes 'x' % of 'y'
    - safety related: reduces level of 'x' to a safe level, improves safety, reduces risk of 'disease y'
    - disease related: prevents spread of disease, kills 'organism x' which causes 'disease y'
    - General: antimicrobial, antibacterial, hygienic, biocidal

**Porous Surfaces Break-Out - Report # 1**

Next Steps

- Define scope and related boundaries of discussion for break-out group
- List of existing protocols for porous surfaces
- Issues/problems related to porous surfaces
- Ideas/priorities for harmonization

*Workshop participants did not raise questions after this presentation was completed.*

# Report 2

**Porous Surfaces Break-Out - Report # 2**

Relevant Use-Areas

Fabrics/Textiles (1st focus area)

- Laundry (domestic, commercial, hospital)
- Hard-to-launder fabrics (drapery, upholstery)
- Carpets

Wood – (2nd focus area) cutting boards, flooring, counters, animal stalls and related surfaces in veterinary field

Food Processing areas? (outside scope)

Building Materials – (outside scope)

**Porous Surfaces Break-Out**
Fabrics/Textiles
Laundry (Machine Wash)

| | EU | US | Canada | Other |
|---|---|---|---|---|
| Domestic | No | Yes<br>DIS/TSS-13 | Yes<br>T-1-215 | Japan<br>JL1902 |
| Commercial | No | Yes<br>DIS/TSS-13 | Yes<br>T-1-215 | Japan<br>Germany<br>Austria |
| Hospital | Standard[1] | Standard[1] | Standard[1] | Japan<br>Germany |

[1] Standard in place designating parameters for treatment using HACCP

- Related Claims: Sanitizes, Disinfects, Antibacterial, Kills 99.9% of germs/bacteria, in Japan specific SEK symbol

**Porous Surfaces Break-Out**
Fabrics/Textiles
Hard to Launder Fabrics (Drapery/Upholstery)
Related Claims: Sanitizes, Disinfects, Antibacterial, Kills 99.9% of germs/bacteria

- US: AOAC Sporicidal Test (silk suture loop)
- US/Canada: non-Food Contact Sanitizer (DIS/TSS-10, T-1-215) with fabric carrier
- Germany: DVG Virucidal test

Carpets – Related Claims: Sanitizes, Antibacterial, Kills 99.9% of germs/bacteria

- US: DIS/TSS-8, Canada: T-1-215

**Porous Surfaces Break-Out**
Porous Material Challenges

- Representative Materials for Carrier Testing
    - Properties and Interactions with biocide
    - Porosity, penetration of product
    - Suggest grouping of materials to be covered by a few representative materials for testing
- Organic soil levels
    - expected to be higher than for a hard surface
- Recovery of bacteria more difficult than hard surfaces
- Interaction with other products
    - May be specific to laundry additives

**Porous Surfaces Break-Out**
Porous Material Challenges

- Method of Inoculation
- Drying conditions of fabric carrier after inoculation
- Possible influences if material is pretreated with biocide (i.e. a treated material)
- Amount of fabric/product ratio
- Extraction of product (simulate mechanical extraction)
- Microbial attachment properties

**Porous Surfaces Break-Out**
Porous Material Challenges

- Macro/micro fiber level impacts
    - e.g. Entrapment of bacteria in fibers
- Dry or wet carrier prior to treatment
- Conditions during exposure period
- Laundry: Temperature, wash volume, fabric load, soil level, water hardness, product concentration…

**Porous Surfaces Break-Out**
Opportunities for Harmonization

- Long term: Research required related to porous surface issues to develop 'best' test
- Intermediate: Modifications to existing protocols to address concerns
- Short term: Convene expert working group(s) to identify opportunities for harmonization in methodology, pass/fail criteria, and label claims

**General Recommendations**

- Carrier test preference is to be quantitative (limitations regarding certain surfaces, must be statistically valid)
- Use of a phased approach is important to demonstrate inherent biocidal activity (e.g. in suspension) recognizing difficulties in demonstrating activity on certain surfaces
- Consider modification of Quantitative Carrier test (Sattar's) using representative porous materials
- Periodic review of protocols

**Recommendations to OECD**

- OECD to involve and facilitate coordination of national, regional and international standard setting organizations
- OECD to facilitate development of expert working groups

**Recommendations to Academia**

- To work with other stakeholder in implementing research proposals
- To reinforce basic and applied research in disinfection testing and epidemiology
- Research Priorities:
    - Families of materials (identification of standard materials)
    - Microbe attachment considerations re porous surfaces
    - Influence of materials in
    - Test Organism Selection (relevant surrogates)
    - Methodology to assess an endpoint/hygiene standards

**Recommendations to Regulators**

- Openness to implement recommendations for harmonization
- Provide input into expert working groups to ensure harmonized methods, pass fail criteria will be acceptable for implementation
- Input to the harmonization of regulatory and label terminology

**Recommendations to Industry**

- To fund research
- Continue to encourage harmonization

*Workshop participants did not raise questions after this presentation was completed.*

# Participants

**POROUS SURFACES (GREEN)** ***Madison Room***

| NAME | | AFFILIATION | COUNTRY |
|---|---|---|---|
| Kevin MAHONEY | **CHAIR** (OC) | Industry | Canada |
| Stephen TOMASINO | **Rapporteur** | Regulator | US |
| Reinhart BOEHM | **Rapporteur** | Academia | EU |
| | | | |
| Pierre MARIS | (OC) | Regulator | EU |
| Graziella MORACE | | Regulator | EU |
| Gina WONG WON | | Regulator | Canada |
| Chiu LIN | | Regulator | US |
| Gerard DONZÉ | | Regulator | Switzerland |
| | | | |
| John RIGARLSFORD | | Industry | EU |
| Rich SEDLAK | | Industry | US |
| Joseph RUBINO | | Industry | US |
| Howard CASH | | Industry | US |
| Beatriz RODRIGUEZ | | Industry | Mexico |
| Jurgen SCHWEMMER | | Industry | Switzerland |
| Robin DIAS | | Industry | US |
| | | | |
| John HOLAH | | Academia | EU |
| Susan SPRINGTHORPE | | Academia | Canada |
| Reinhart BOEHM | | Academia | EU |
| | | | |

# *Chapter 6*
# *Water*
# *Breakout Group Report*

This breakout group began discussions on areas regarding biocides used in water and began to identify those regulatory and scientific areas where harmonization is needed. The information presented in this chapter reflects the two reports developed by the Water Breakout Group on April 23rd and April 24th, respectively. A list of the participants comprising this breakout group is provided at the end of the chapter.

## Report 1

**Biocides used in Water Breakout Group report**
Water products considered within the scope:

- swimming pools
- spas/hot tubs
- Biofilms
- tap water systems

**Water products considered within the scope:**

- water systems used in RV's
- water used in food prep.
- emergency water treatment
- humidifiers and stand alone air conditioners

**Water products considered within the scope:**

- dental water lines/hemodialysis water systems.
- Will be discussed as an example of an emerging product/use

**Approach for discussions**

- Identify current label claims for certain water biocides
- Discuss whether claim can be related to performance? Yes or No.
    - Yes= there is an established test method which defines performance OR if there is a reasonable expectation that a test method could be modified to support claim.
    - No = claim is too vague/general; not clear how it would be confirmed by test method; there is no test method

**Current label claims –swimming pools, spas & hot tubs**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Kills harmful bacterial | No | Kills is vague/not well defined. Which bacteria? |
| Disinfectant | Yes | Test methods exist e.g. AOAC Disinfectant; EPA DIS/TSS – 12 PMRA Standard |
| Sanitiser | Yes | Test methods exist – see above. |
| Bactericide | Yes | Test methods exist – see above. Need a greater scope |
| Algaecidal | Yes | Toxins related to public health |
| Controls harmful organisms | No | Too vague. |
| Fungicidal | Yes | Method Development is possible/straight forward |

**Current label claims – spas/hot tubs**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| See swimming pool claims | | |
| Controls Pseudomonas | Yes | |
| Controls Legionella | Yes | |

**Current label claims – emergency water treatment**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Disinfection | Yes | Xlog10 knockdown in Y minutes against Z organisms; could easily be developed as a suspension test |
| Bactericidal | Yes | Xlog10 knockdown in Y minutes against Z organisms; could easily be developed as a suspension test |
| Control of pathogenic organisms | No | Further discussion of issues related to claims |
| Giaria/cryptosporidium | Yes | Methods under development |

**Current label claims – humidifiers & air conditioners**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Antimicrobial | No | |
| Bactericidal | Yes | Defined by drop in organisms over defined time period |
| Legionella | No | |

**Current label claims – antibacterial washes**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Cholera | Yes | |
| Salmonella | Yes | |
| Kills harmful bacteria | No | Terms are too vague; cannot be linked to specific test method or outcome |
| Kills germs | No | Terms are too vague; cannot be linked to specific test method or outcome |

**Current label claims – tap water**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Disinfection | Yes | |
| Legionella | Yes | |
| Biofilms | No | Methods exist, but are not codified and they are complex and $$$$$$$$ |

**Current label claims – water used in food preparation**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Controls pathogens | No | Terms are too vague; cannot be linked to specific test method or outcome |
| Sanitisers | Yes | |
| Bactericidal | Yes | |
| Fungicidal | Yes | |

**Current label claims – in DUWL and hemodialysis**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Prevents, eliminates, reduces biofilm | No | Terms are too vague; cannot be linked to specific test method or outcome |
| Legionella | Yes | |
| Pseudomonas | Yes | |
| Decontaminantes | No | Terms are too vague; cannot be linked to specific test method or outcome |

**Current label claims – toilet/flushing water e.g. in RV's**

| Claim | Performance Link? | Explanation/further discussion? |
|---|---|---|
| Hygienic | No | Terms are too vague; cannot be linked to specific test method or outcome |
| Kills harmful organisms and bacteria | No | Terms are too vague; cannot be linked to specific test method or outcome |
| Kills 99.9% of bacteria | Yes | |

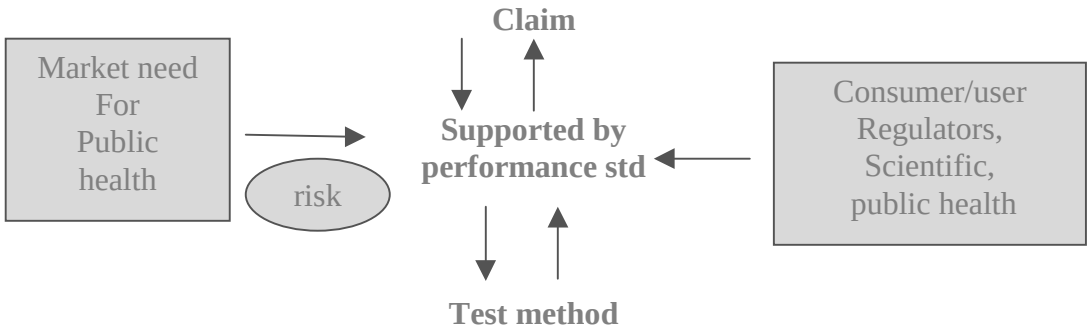
**Recommendations**

**Stay tuned!**

*Workshop participants did not raise questions after this presentation was completed.*

# Report 2

**Schematic Flow Diagram**




**Risk assessment is a key consideration in development of performance standards**
**The goal is to reduce risk to acceptable levels**

**Performance characteristics**

- Immediate/residual activity
- Time to effectiveness
- Lab v. field (in use) data
- Level of control
- Absolute v. relative
- Log reduction

**Issues/problems related to label claims**

- Use of products on sites for which they are not registered
- Lack of global harmonized meaning of disinfectant/sanitizer
- Duration/contact time for product
- Lack of clarity of claim/confidence in methodology (e.g. bacteriostatic neutralizer)
- Non-uniformity and appropriateness of test organism
- Claim must be supported by use directions (extended labelling
- Irresponsible use of terms such as “germs”
- Directions not clear to end user

**Issues/problems related to label claims**

- Application procedure not clear
- Linkage between claim words and performance
- Terms don't have the same meaning in all languages
- Use of word safe
- Claim vocabulary meaningful to user (user specific)
- Details on extent/site of activity and applicability

**Proposed label claims for emerging products**

- Reduces the minimum concentration of chlorine in pool/spa (combination treatment systems)
- Giardia (eliminates or reduces threat)
- Reduces heterotrophic bacterial counts to <200 CFU/ml (dental unit water line (DUWL))
- Reduces biofilms (DUWL)
- Protects your health (AC units)

**Examples of emerging products/claims**

- DUWL – dental unit water line
- Beads that release biocides (silver) to treat water
- Electrolytic chlorinators for water (pools/spas/remote potable water)
- Cartridge devices that release silver for water purification for consumption

**Recommendations-label claims**

- Develop common vocabulary for
- Sanitizer
- Disinfectant
- Develop label claims, where possible, that are more descriptive (a verb that describes what the product does, duration of control)
- Develop label claims, where possible, regarding secondary effects (indirect and combined; physical and chemical effects)

**Recommendations-label claims**

- Develop a cross walk between existing claims and established/acceptable methods
- Where less non-scientific terms are used for marketing terms the specified level of control must be equivalent to the highest established performance standard
- General guidance for establishing label claims for conventional products
- General guidance for establishing label claims for new and emerging products (goal to reduce non-scientific terms)

**Recommendations – Performance Standards**
**Recommendations -Test Methods**

- To develop a guidance by which test methods/testing strategies should be performed and reported
- Based on GEP = good experimental practice
- Including both process and content

**Recommendations – Test Methods**

- Develop a mechanism for the ongoing exchange and capture of information related to test methods, leading to establishing a current database.
- Institute an international funding mechanism for development of required test methods.

*Workshop participants did not raise questions after this presentation was completed.*

# Participants

**WATER (YELLOW)** ***Van Buren Room***
**(includes swimming pools, spas, hot tubs, biofilms & dental water lines)**

| NAME | | AFFILIATION | COUNTRY |
|---|---|---|---|
| Karen McCULLAGH | **CHAIR** (OC) | Regulator | Canada |
| Graziella OREFICI | **Rapporteur** (OC) | Regulator | EU |
| Michelle COTTRILL | **Rapporteur** | Regulator | US |
| | | | |
| Ingrid HAUZENBERGER | | Regulator | EU |
| Bob HARTOG | | Regulator | EU |
| Brendan DOLAN | | Regulator | EU |
| Amy RISPIN | | Regulator | US |
| | | | |
| David ASHWORTH | | Industry | EU |
| Roy VORE | | Industry | US |
| Geoff BROWN | | Industry | North America |
| Mike BALDRY | | Industry | EU |
| | | | |
| Hans-Curt FLEMMING | | Academia | EU |
| Bob HARTOG | | Academic | EU |
| Jean BARBEAU | | Academia | EU |
| William COSTERTON | | Academia | US |
| Eugene COLE | | Academia | US |
| | | | |

# *Chapter 7*
# *Emerging Products*
# *Breakout Group Reports*

This breakout group began discussions on areas of emerging products and began to identify those regulatory and scientific areas where harmonization is needed. The information presented in this chapter reflects the two reports developed by the Emerging Products Breakout Group on April 23rd and April 24th, respectively. A list of the participants comprising this breakout group is provided at the end of the chapter.

## Report 1

**Emerging Products**

active vs. end-use formulations
benefit?
who decides there is a need for emerging products (consumer? industry?)?
other issues – resistance (area of concern)
no established test methods/performance standards

**Label Claims**

- "kills germs"
- "residual claims" (dry/wet) – continual biocidal effect
- air-ducts
- material preservation
    - false sense of security
- "disinfects/sanitises"
- kills 99.9%…
    - what does it mean to consumers?
    - starting inoculum?
    - driven by regulatory definition/performance standard
- "removes biofilm" / "prevents formation" (or) → dental water lines; swimming pools; food processing (water)
- "extra hygiene"
- "sanitary"
    - market driven claims
    - range of claims
    - specific claims/relevancy
        - laundry-faecal E. coliform bacteria
        - sanitiser washes-food-borne pathogens
    - "green" products-in-can preservatives

- establish site/pest relationship
- which pathogens?
- link to need
- issue du jour – HBV, HIV, HCV, CJD, TB, Anthrax
  – emerging pathogens
  – MRSA
- list all organisms on label?
- removal claims-not always regulated (is in USA)
- air sanitizers
- carpet sanitiser-powder

- "antibacterial"
  - indirect or implied claims-"freshness"
  - qualified vs. unqualified claims

**Terminology**

CEN-Agreement on terms not to use

↳ supported by test methods

- significant effect?
- limit amount of wording
- more informative
- different consumer base worldwide (cultural difference-application)
- pictograms
- generic vs. specific claims
- label space

<focus group studies> ~ consumer surveys

**Performance Standards**

- set by regulatory authorities?
- Standard development organizations (SDO's)

  ↳ develop the methodologies-reproducibility not the performance standard (in USA)
- establish need
- log reduction
- measure effect of product contribution to health (risk reduction)
- surveillance (post authorization /registration)
- variability – intra/inter laboratory
  – meet efficacy target
  – geographical differences in activity
- round-robin testing → validation (precision)
- number of labs necessary to be statistically valid

Recommendation!

- Consumer education – read the label
  – other hygienic practice

– consider the source
– real risk?
– hygiene vs. cleaning
– industry/government partnership

- Communicating Risk

| Recommendation |
|---|

- quantitative risk assessment
    - inter-government task force-WHO/FAO/FDA
    - infectious disease
    - BENEFIT!
    -

**Terminology**

| Recommendation: ACTION ITEM |
|---|

- Working document on terminology

Recommendation:
Based on risk assessment/need

- Epidemiology (primary risk factors)
- Health benefit (reduce illness)

| | |
|---|---|
| 1. Hazard Assessment<br>2. Environmental Exposure<br>3. Dose response<br>4. Risk Assessment | - Inventory of present scheme<br>- Field test<br>↳ Before/after comparison |

Laboratory Experimentation

↓

Modeling

↓

Field tests

*Workshop participants did not raise questions after this presentation was completed.*

# Report 2

**INITIAL THOUGHTS**

1. Brainstorm the ideal criteria for designing methods for emerging products.
2. Design a model method for fruit and vegetable produce rinses.

**PROGRESS IN THIS AREA**

- The discussion on the selection of target microorganisms for emerging products test methods lasted for over an hour.
- Started discussing other desired parameters.
    - Once the group started prioritizing this list, the discussions became a little more focused.

**IDEAL PARAMETERS FOR NEW TEST METHODS**

| Essential Elements | Nice to Have |
|---|---|
| • One or more relevant microorganisms<br>• Standardized maintenance of test organisms<br>• Test organisms must be widely available<br>• Defined Contact time, contact temperature, interfering substances, pH, hard water (diluent)<br>• Inoculum-to-treatment ratio (simulate real world)<br>• Density of Inoculum<br>• Quantitative Measurement<br>• Appropriate Neutralizers<br>• Appropriate Controls | • "Natural" consortium of organisms<br>• "Known test organism, even if not relevant for field of application (Research & Development)<br>• Include biofilm<br>• Dose Response Curves (Kinetic assessment) |

**SPECIAL SITUATIONS**

- If the method is for biofilm reduction/control, must include a biofilm representative of the use situation.

- If the method is for residual activity (dry or moist), must be addressed in the test method.

**MEASURES TO EVALUATE PRIOR TO CONDUCTING TEST**

- Compatibility of the test product to the intended packaging container, equipment, supplies, surfaces used in the test.
- Test organism compatibility to surfaces used in the test.

**WAYS TO MEASURE PRECISION OF METHOD**

- Conduct testing in multiple labs (preferably 2 or 3).
- Develop database which stores information on multiple products so that the reproducibility of the method is assessed.
- Plan for acquiring repeatability/reproducibility data via a "new methods database"

**RECOMMENDATIONS ON AREAS TO HARMONIZE**

- The group has recommended seven areas for future harmonization.
- Conduct a science based assessment of risk to provide evidence of the need for the new product.
- Ideally, this would include:
- Hazard assessment
    - Exposure assessment
- Dose Response
- Overall Microbial Risk Assessment based on three measures above

**RECOMMENDATIONS ON AREAS TO HARMONIZE**

- Test methods should include ideal parameters described above, as appropriate to the type of product
- Recognize a need for flexibility in this area.
- Terminology
- Working document on terminology, building on OECD glossary and ASTM efforts.

**RECOMMENDATIONS ON AREAS TO HARMONIZE**

- Involve standards setting organization in the collaborative process (product conception-to-regulatory authorization) for new emerging product areas.
- Develop Educational Programs
- Increase knowledge of consumers on the proper use and benefits of biocides. This should be a joint academia/industry/regulatory effort.
- Increase awareness for regulators/industry/academia on global efforts for development of emerging products.

**RECOMMENDATIONS ON AREAS TO HARMONIZE**

- OECD or other Standards Development Organizations should work towards harmonizing guidance for efficacy test methods. Similar to work conducted on tox methods. The ultimate goal would be to harmonize test methods.

**PARKING LOT ISSUES**

- Future discussions on gray areas regarding cleaning or removal related claims.
- Hygienic
- Sanitary
- Future funding for academic research and participation collaborative efforts.

# Process For Introducing Emerging Products
# Collaborative Process Including Regulators, Academia & Industry

| OBJECTIVES | GOALS | STRATEGIES | MEASURES |
|---|---|---|---|
| Establish Need | • Propose Mode of Transmission<br>• Describe Potential Benefits<br>• Confirm User Groups Interest | 1. Risk Identification<br>2. Epidemiological Data<br>3. Literature<br>4. Expert Collaboration<br>5. User Group Surveys<br>➢ Willingness to pay | • Baseline Risk<br>➢ Exposure, illness<br>• Intervention Points<br>• Consequences<br>➢ Medical costs, missed work days, missed school days, pain & suffering, |
| Develop Global Testing Strategy | • Incorporate Global Regulatory Requirements<br>• ID Existing Global Methods or Develop Methods to Simulate Use | 1. Develop Coordinated Test Plan Incorporating Regulatory and Application tests<br>2. Execute Lab ID, Qualification and Validation Program<br>3. Identify Synergies for Coordination of Regional Needs<br>4. Expert Collaboration | • Required Regulatory Tests (CEN suspension, etc)<br>• Key Elements of Consumer Experience<br>➢ Organisms, exposure, surface, temp, mechanical energy, etc.<br>• Regional Variations |
| Set Performance Standard | • Determine Minimum Efficacy Target | 1. Compare to Existing Standards and Practices<br>2. Quantitative Risk Assessment<br>3. Expert Collaboration | • Log reduction<br>➢ %, X Fold<br>• Statistical confidence |
| Confirm Efficacy | • Establish Testing Capability<br>• Validate New Methods<br>• Develop Submission | 1. Execute Testing Program.<br>2. Submit Registration Data | • Testing Capability Confirmed<br>➢ Correct endpoint<br>➢ Reproducible and Reliable<br>• Completed Dataset |

| ↑ INDUSTRY | *FACILITATES* ↑ | ↓ REGULATORS | **OWN** ↓ |
|---|---|---|---|
| Review Submission and Proposed Label Claims | • Confirm Technical Robustness of Submission Dataset<br>• Verify Claims are Meaningful and Supportable. | 1. Regulatory Review<br>2. Negotiation of Claims | • Data Consistent with Coordinated Test Plan<br>➢ Appropriate Lab, Procedures<br>• Data Meet Performance Stds<br>• Claims Consistent with Data |

Emerging Products - Harmonization

Short Term-

- Co-recognition of Methods
- Allow removal/cleaning claims
- Legitimacy of using risk assessment for establishing needs, benefits, claims
-

Longer Term-
Single Global Registration

*Workshop participants did not raise questions after this presentation was completed.*

# Participants

**EMERGING PRODUCTS (RED)** ***Monroe Room***

| NAME | | AFFILIATION | COUNTRY |
|---|---|---|---|
| Michele WINGFIELD | **CHAIR** (OC) | Regulator | US |
| Hans-Joachim ROEDGER | **Rapporteur** (OC) | Industry | EU |
| Dave DILLON | **Rapporteur** (OC) | Regulator | EU |
| | | | |
| Fred BISSONNETTE | | Regulator | Canada |
| Mary RAPHAEL | | Regulator | Canada |
| Kimmo KARHI | | Regulator | EU |
| Ulrike KOWALSKI | | Regulator | EU |
| Emily MITCHELL | | Regulator | US |
| | | | |
| Richard WALTERS | | Industry | US |
| Robert KIEFER | | Industry | US |
| Graham LLOYD | | Industry | EU |
| Thomas WARSCHEID | | Industry | EU |
| Jim KAIN | | Industry | US |
| Kazuya ISHII | | Industry | Japan |
| | | | |
| A D RUSSELL | | Academia | EU |
| Michael DOYLE | | Academia | US |
| Marty HAMILTON | | Academia | US |
| Paul TERPSTRA | | Academic | EU |
| | | | |

# *Chapter 8*
# *Treated Materials*
# *Breakout Group Report*

This breakout group began discussions on areas regarding treated materials and began to identify those regulatory and scientific areas where harmonization is needed. The information presented in this chapter reflects the two reports developed by the Treated Materials Breakout Group on April 23rd and April 24th, respectively. A list of the participants comprising this breakout group is provided at the end of the chapter.

## Report 1

1) Scope – Public Health Claims
   - Aesthetic Claims e.g. Odour/Odor

   NOT INCLUDED – Preservation of the Material

2) Many Matrices + Many Applications (So Complex)

3) Information Exchange

4) Biggest Challenges were – Activity over time
   - Durability
   - Level of Performance

5) Few Test Methods

6) Major Test Organisms – Bacteria
   - Fungi
   - Algae

7) Resistance v Tolerance

   Agreed unlike Antibiotics true resistance rarely seen.

8) How Do Biocides Work In/On these Products?

   Two broad biocide types – Diffusive/Migrating v Bound

   And – therefore what impact on testing method?

9) Terminology – Tried to agree on terminology for claims.

   Not total success but progress – Agreed to Park as this only inhibited way forward.

10) Focus now to be on Methods

    Based around matrix covering control/effect, organisms, duration, product type

11) Proposed Halfway house to harmonis(z)ation

    One efficacy data package but varying requirements by Countries e.g. log 2 or 3 reduction may be required

    BUT at least Industry would quickly know from the efficacy data where their product would be accepted.

FINAL GOAL STILL –

One Product/One Test/One World

*Workshop participants did not raise questions after this presentation was completed.*

# Report 2

**AIMS**

- Exchange Information
- Discussed Inhibition to Harmonisation
- Decided : 3 major Control Situations
  - Cidal/Kill
  - Inhibition/Stasis of Growth
  - Inhibition Stasis of Metabolism (Odour)
- Decided to move to towards Harmonisation via a staged process (Halfway House).

**METHODOLOGY**

- Reviewed Available test methods
- Decided on Tiered Approach
- Phase 1 – Simple Efficacy
- Phase 2 – Simulated Use
- Phase 3 – Field/End Use

Grouped Critical Parameters for Phase 1 Test

Phase 1 - Critical Parameters

**SAMPLE**

- Controls – Untreated/Treated (+ve if possible)
- Preparation – Sanitise/Sterilise etc
- Size & Weight
- Wettability
- Porosity
- Replicates

**INOCULUM**

- Gram +ve & -ve (K.pneumoniae, E.coli, S.aureus - std strains)**
- Preparation
- Bioburden

**Can change to meet use conditions

**EXPOSURE OF MICROBE**

- Fluid (Nutrients +/-)
- Temperature
- pH
- Time of exposure
- Soiling
- Volume/Surface area
- Humidity
- Static/Dynamic test
- Inoculum Delivery Method (Drip/Spray/Dip etc)

**RECOVERY**

- Efficiency of Recovery must be determined.
- Recovery fluid
- Neutraliser
- Volume
- Method of Recovery (Must be efficient but non damaging)
- For example – Shaking or Sonication
- Quantitative viable cells – Plate count, MPN, ATP etc

**DATA**

- Initial cells – untreated/treated
- Post contact cells – untreated/treated
- Precision/Bias/Validation
- Average log reduction (Log $t_x$ - log $t_0$)

**NEXT STEPS**

- Take Phase 1 tests and adapt for simulated use (Phase 2)
- Cidal v Static (nutrients) + Label Claim
- Duration + Conditions of Use
    - Time
    - Use ("Wear the Sock")
    - Wash or Weather ("Wash the Sock")
    - Sequence of Wash/Weather (may be important)
    - Microbe(s) type may be important

**LIMITS OF CURRENT METHODS**

- All Wet/Liquid
- Validation of Inactivation
- Biofilm Bacteria (as inoculum & post exposure)
- No resistance/tolerance data
- Potential lack of recovery of total population

**RECOMMENDATIONS**

The working group recommends that OECD member states should use agreed terms and harmonise the acceptable claims.
More specifically the term 'antibacterial' becomes a sub-division (or set) of 'antimicrobial' and does not necessarily imply a public health claim

~~The working group recommends that OECD member states should use agreed terms and harmonise the acceptable claims.~~

~~More specifically the term 'antibacterial' becomes a sub-division (or set) of 'antimicrobial' and does not necessarily imply a public health claim~~

The working group recommends an acknowledgement that treated materials may be

part of an overall hygienic practice rather than substitutes for products that sanitise, disinfect or sterilise.
Accordingly, different performance standards are necessary for showing a benefit for treated materials. Member states may harmonise performance standards in relation to claims.

The working group recommends that any anti-microbial claims for treated materials **MUST** be supported by scientifically sound quantitative efficacy data.

The working group recognizes that a tiered approach to testing is necessary in order to substantiate the range of efficacy claims for treated materials.

The working group recommends that methods to be used in Tier I testing must include the critical parameters identified by this group, as appropriate.

The working group recommends that for a tiered testing approach the critical parameters identified by the group for Tier I should be adopted for the needs of subsequent testing.

**FUTURE NEEDS**

- Dry methods
- Fungal methods
- Biofilm challenge
- Recovery efficiency
- Resistance development

*Workshop participants did not raise questions after this presentation was completed.*

# Participants

**TREATED MATERIALS (PURPLE)** ***Wilson Room***

| NAME | | AFFILIATION | COUNTRY |
|---|---|---|---|
| Malcolm GREENHALGH | **CHAIR** (OC) | Industry | EU |
| Andrée CREMIEUX | **Rapporteur** (OC) | Academic | EU |
| Hang TANG | **Rapporteur** | Regulator | Canada |
| | | | |
| Jun YOSHIDA | | Regulator | Japan |
| Shelley TANG | | Regulator | Australia |
| Cherie GOEWIE | | Regulator | EU |
| Sandro SALVI | | Regulator | EU |
| Edmund PLATTNER | | Regulator | EU |
| | | | |
| Sue PRICE | | Industry | US |
| William HANRAHAN | | Industry | US |
| Mark WIENCEK | | Industry | US |
| Tom AROELLA | | Industry | Canada |
| Peter STUTTE | | Industry | EU |
| John DUDDRIDGE | | Industry | EU |
| | | | |
| Syed SATTAR | | Academia | Canada |
| Paul RASCHLE | | Academia | Switzerland |
| Peter GILBERT | | Academia | EU |
| Hiroki KOURAI | | Academia | Japan |
| Jean FRENEY | | Academia | EU |
| | | | |

# *Chapter 9*
# *Workshop Summation*

## Notecard Questions & Responses

## April 22, 2002

1) **Question for Michele Wingfield**: I believe that you said for fresh produce model that you must use 5 outbreak strains for the 3 pathogens (0157; L.mono; Salm. Sp.) How do you maintain consistency as these fresh isolates may well vary in resistance, and this will change as they are subcultured? From John Rigarlsford, (UK).

   Answer: Maintain stock cultures at –70C and restrict number of subcultures. *Dr. Doyle*

2) **2 questions for regulatory representatives from USA, EU, Canada & for Dr. Doyle**:
   A. Are claims of reducing spoilage of foodstuffs considered "public health claims"?

      Answer: If responsible organism is a pathogen to humans or animals then yes. If the responsible organism is not a pathogen then it not considered a public health claim. *Karen McCullagh*

      Answer: Spoilage microorganisms and spoilage of food stuffs are not a public health issue, hence no public health claim. However, reducing food borne pathogens is a public health issue, hence warrants public health claims. *Dr. Doyle*

   B. Is there (or should there be) be differentiation between claims of direct reduction of microbes on food vs. reducing microbes on inanimate surfaces which then contaminate the food?

      Answer: In Canada not right now. This is a good question that needs to be considered by product assessment & audit authorities. *Karen McCullagh*

      Answer: Need to establish the relevance of object of inanimate surface to transmission of food borne pathogen to provide evidence for public health claim. For example, need to provide evidence that a toothbrush or sponge is a vehicle for transmitting pathogens resulting in human illness in order to justify public health claims of reducing pathogens on antimicrobial-impregnated toothbrushes or sponges. *Dr. Doyle*

3) **General question:** We talked about "benefits", what kind of use benefits should we look for to be able to say that the antimicrobials work?

> Answer: It is difficult to quantify the benefits of the use of antimicrobials but the best way to do this is to imagine what would happen if they were not used. Antimicrobials are used in many areas but two examples that spring to mind are their use in hospitals and kitchens. In these two places, in particular, the use of disinfectants helps prevent disease and food poisoning. An even more obvious example is the use of antimicrobials in drinking water, you only have to look at the diseases associated with unsafe drinking water to see the benefits of the use of these types of biocidal products *Geoff Wilson*

## April 23, 2002

1) **General question:** What mechanisms are the regulatory bodies of the attending countries using to monitor developments on biocide bacterial resistance and cross resistance to antibiotics? What techniques are used to understand the actual scientific developments on the issue versus popular press reports on the subject?

> Answer: In Europe, at present, there is no standard approach to the points raised in this question but when the Biocidal Products Directive is in full operation issues such as those mentioned will be addressed by the Regulatory Committee - the Standing Committee on Biocidal Products. *Geoff Wilson*

## Final Comments from Geoff Wilson

**Biocidal Products - Efficacy Issues**
Other Biocidal Product Types
Another Workshop?
- Product Type?
- Where?

Geoff.Wilson@oecd.org

**Follow-up Actions**
•Workshop Report (including summary of each Breakout Group Report) to be published on OECD Password Protected website
•Conclusions and Recommendations reported to:
- Biocides Steering Group
- Working Group on Pesticides
- Joint Meeting

•Input to OECD Biocides Programme

*Workshop participants did not raise questions after this presentation was completed.*

## Post-Workshop Organizing Committee Meeting

- Discussed the directions to the breakout groups about getting their recommendations to the OECD and then who would be responsible once the recommendations are received.

- Cleo Pizana suggested that an overall recommendations section be developed for implementation ideas and placed in the forefront of the meeting summary so that it would not get lost, Geoff Wilson seconded, and the breakout leaders agreed that their overall implementation recommendations should be pulled out of the breakout reports – The following were requested to be included in the new section:

    - OECD should send out a request to industry, academia, and the government organizations for a one year staff commitment (detailee) of one person from each of the segments (industry, academia, and government) to work on advancing the recommendations from the workshop; or
    - OECD should establish a working group from industry, academia, and the government organizations to advance the recommendations

- Establish a separate work chair implementation area on the secure web site which will have the distinct issues/problem-areas and progress listed. This will be a distinct portion of the web site that can then be opened to get to the specific work groups or areas of interest for discussion.

- Organizing committee agreed to contact their respective OECD country representatives to inform them of the success of the conference and to promote further efforts by the OECD in this direction.

- Graziella Orefici has sent an e-mail indicating an interest in hosting the next Biocide workshop in Rome.

# *Chapter 10*
# *Final List of Workshop Participants*


Tom **AROELLA**
Thomson Research Associates
95 King St. E., Suite 400
Toronto, ON M5C 1G4
Canada

Tel : +1 416 955 1881
Fax : +1 416 955 1887
E-mail : tom@ultra-fresh.com

David **ASHWORTH**
Global Development Manager
Performance Chemicals for Detergents and Formulators Europe
E-EVD/MM
BASF Limited
Ruddington Fields Business Park
Mere Way
NG11 6JS Ruddington, Nottingham
United Kingdom

Tel : +44 115 912 4583
Fax : +44 115 912 4592
E-mail : david.ashworth@basf-biocides.co.uk

Dr. Michael **BALDRY**
Inveresk Research
Client and Regulatory Services
EH33 2NE Tranent
United Kingdom

Tel : +44 1875 618484
Fax : +44 1875 614555
E-mail : michael.baldry@inveresk.com

Dr. Jean **BARBEAU**
University of Montreal
Department of Stomatology, Faculty of Dentistry
P.O. Box 6128, Centre-ville
Montreal, Quebec H3C 3J7
Canada

Tel : +1 514 343 2366
Fax : +1 514 343 2233
E-mail : jean.barbeau@umontreal.ca

Mary **BENNETT**
Ecolab Inc
840 Sibley Memorial Highway
St. Paul, MN 55118-1708
United States

Tel : +1 651 306 5813
E-mail : mary.bennett@ecolab.com

Frédéric **BISSONNETTE**
Pest Management Regulatory Agency
Efficacy and Sustainability Division
Canada

E-mail : fbissonn@hc-sc.gc.ca

Prof. Reinhard **BÖHM**
Universität Hohenheim
Institut für Umwect und Tierhygiene –460
D-70593 Stuttgart
Germany

Tel : +49 711 4592427
Fax : +49 711 459 2431
E-mail : boehm@uni-hohenheim.de

Geoffrey **BROWN**
Biolab Inc.
627 E. College Ave.
Decatur, GA 30031
United States

Tel : +1 404 378 1761 ext. 230
Fax : +1 404 370 7485
E-mail : GBrown@BioLabinc.com

Dr. Howard **CASH**
Lonza, Inc
79 Route 22 East
Annandale, NJ 08801
United States

Tel : +1 908 730 1593
Fax : +1 908 730 1546
E-mail : hcash@lonza-us.com

Myra **CHENG**
California Department of Pesticide Regulation
1001-I Street
P.O. Box 4015
Sacramento, CA 95812
United States

Tel : +1 916 324 3940
E-mail : mcheng@cdpr.ca.gov

Dr. Eugene **COLE**
Brigham Young University
Department of Health Sciences
229-C Richards Building
Provo, UT 84602
United States

Tel : +1 801 422 7491
Fax : +1 801 378 4388
E-mail : gene_cole@byu.edu

Dr. J.W. **COSTERTON**
Director, Center for Biofilm Engineering
Room 366 EPS Building
Montana State University
Bozeman MT 59717
United States

Tel : +1 406 994 1960
Fax : +1 406 994 6098
E-mail : bill_c@erc.montana.edu

Michele **COTTRILL**
US EPA
Environmental Science Center
701 Mapes Road
Fort Meade, Maryland 20755-5350
United States

Tel : +1 410 305 2955
E-mail : cottrill.michele@epa.gov

Dr. André **CRAAN**
BGIVD
Finance Building
Health Canada
Therapeutic Products Directorate
Postal Locator 0202B9
Tunney's Pasture
Ottawa, ON K1A 1B9
Canada

Tel : +1 613 954 6731
Fax : +1 613 941 1183
E-mail : andre_craan@hc-sc.gc.ca

Prof. Andrée **CREMIEUX**
MICRAAM
Faculté de Pharmacie, 27 Bd Jean Moulin
13385 Marseille CEDEX
France

Tel : +33 4 91 78 29 51
Fax : +33 4 91 79 41 30
E-mail : micraam@pharmacie.univ-mrs.fr

Robin **DIAS**
The Clorox Company
7200 Johnson Drive
Pleasanton, CA 94588
United States

Tel : +1 925 425 6801
Fax : +1 925 425 6382
E-mail : robin.dias@clorox.com

Dr. David **DILLON**
Health and Safety Executive
Biocides and Pesticides Assessment Unit,
Magdalen House, Bootle
L20 3QZ Merseyside
United Kingdom

Tel : +44 151 951 4104
Fax : +44 151 951 3317
E-mail : dave.dillon@hse.gsi.gov.uk

Dr. Brendan **DOLAN**
Pesticide Control Service
Dept. Agriculture and Food, Abbotstown,
Castleknock
Dublin 15
Ireland

Tel : +353 1 607 2611
Fax : +353 1 820 4260
E-mail : brendan.dolan@agriculture.gov.ie

Dr. Gérard **DONZÉ**
Federal Office of Public Health
3003 Bern
Switzerland

Tel : +41 31 323 4109
Fax : +41 31 324 9034
E-mail : Gerard.donze@bag.admin.ch

Dr. Michael **DOYLE**
University of Georgia

Tel : +1 770 228 7284
E-mail : mdoyle@cfs.griffin.peachnet.edu

Dr. John **DUDDRIDGE**
Rohm and Haas France SAS
Regulatory
European Laboratories, Rohm and Haas France SAS
Rue L.V. Beethoven, Sophia Antipolis
Valbonne
France

Tel : 0033493955375
Fax : 0033493654471
E-mail : JDuddridge@rohmhaas.com

Debbie **EDWARDS**
Antimicrobials Division (7510C)
Office of Pesticide Programs, US Environmental Protection Agency, 1200 Pennsylvania Avenue
Washington, DC 20460
United States

Tel : +1 703 308 7891
E-mail : edwards.debbie@epa.gov

Diane **FALBO**
S.C. Johnson and Son, Inc.
Microbiology Department, M.S. 0125, 1525 Howe Street
Racine, WI 53403
United States

Tel : +1 262 260 3726
Fax : +1 262 260 2512
E-mail : dmfalbo@scj.com

Ulla **FALK**
European Commission
Directorate-General Environment, Unit C-3
200, rue de la Loi, Bu-5,2-57
B-1049 Bruxelles
Belgium

E-mail : ulla.falk@cec.eu.int

Dr. Mary **FITZPATRICK**
KemI
Box 1384
S-171 27 Solna
Sweden

Tel : +46 8 783 1258
Fax : +46 8 735 7698
E-mail : maryf@kemi.se

Dr. Hans-Curt **FLEMMING**
IWW
Moritzstrasse 26
D-45476 Muelheim
Germany

Tel : +49 208 40303400
E-mail : HansCurtFlemming@compuserve.com

Prof. Jean **FRENEY**
Hôpital Edouard Herriot
Laboratoire central de microbiologie
3 Place d'Arsonval
69437 Lyon Cedex 03
France

Tel : +33 4 72 11 07 68
E-mail : jean.freney@chu-lyon.fr

Dr. Jürgen **GEBEL**
Hygiene-Institut der Uni Bonn
Sigmund-Freud-Str. 25
53127 Bonn
Germany

Tel : +49 228 287 4022
Fax : +49 228 287 9522
E-mail : juergen.gebel@ukb.uni-bonn.de

Dr. Peter **GILBERT**
University of Manchester
Oxford Road
M13 9PL Manchester
United Kingdom

Tel : +44 161 275 2361
Fax : +44 161 275 2360
E-mail : mbpsspg2@man.ac.uk

Dr. Chérie **GOEWIE**
CTB-Board for the authorisation of pesticides
Stadsbrink 5, NL-6707 AA Wageningen, P.O. Box 217
NL-6700
AE Wageningen
Netherlands

Tel : +31 317 471856
Fax : +31 317 471899
E-mail : c.e.goewie@ctb.agro.nl

Malcolm **GREENHALGH**
Avecia Limited
Research Department, Biocides Business Centre, P.O. Box 42, Hexagon House, Blackley
M9 8ZS Manchester
United Kingdom

Tel : +44 161 721 1022
Fax : +44 16 17 21 41 73
E-mail : malcolm.greenhalgh@avecia.com

Dr. Marty **HAMILTON**
Montana State University
Center for Biofilm Engineering
366 EPS Building
Bozeman, MT 59717-3980
United States

Tel : +1 406 994 5387
Fax : +1 406 994 6098
E-mail : marty_h@erc.montana.edu

William **HANRAHAN**
Microban Products Co.
11515 Vanstory Dr.
Huntersville, NC 27078
United States

Tel : +1 704 875 0806
Fax : +1 704 875 0810
E-mail : b.hanrahan@microban.com

Eliot **HARRISON**
122 C Street, NW, Suite 740
Washington, DC 20001
United States

Tel : +1 202 393 3903 ext. 14
Fax : +1 202 393 3906
E-mail : Eharrison@lewisharrison.com

Bob **HARTOG**
TNO Voeding
Utrechtseweg 48, P.O. Box 360
3700 AJ Ziest
Netherlands

Tel : +31 30 69 44 728
Fax : +31 30 69 44 901
E-mail : hartog@voeding.tno.nl

Ingrid **HAUZENBERGER**
Federal Environment Agency
Spittelauer Lände 5
A-1090 Vienna
Austria

Tel : +43 1 313 04 5917
Fax : +43 1 313 04 655
E-mail : hauzenberger@ubavie.gv.at

Dr. John **HOLAH**
Campden and Chorleywood Food Research Association (CCFRA)
Chipping Campden,
GL55 6LD
Chipping Campden
United Kingdom

Tel : +44 (0) 1386 842041
E-mail : j.holah@campden.co.uk

Kazuya **ISHII**
Manager, Task Force for ICCA
Japan Chemical Industry Association
Kazan Bldg
2-4 Kasumigaseki 3-chome,
Chiyoda-ku
Tokyo 100-0013
Japan

Tel : +81 3 3580 1367
Fax : +81 3 3580 1383
E-mail : kishii@jcia-net.or.jp

Dr. Bob **ISRAEL**
Johnson Wax Professional
8310 16th Street
Sturtevant, WI 53177-0902
United States

Tel : +1 262 631 4437
Fax : +1 262 631 4067
E-mail : Robert.Israel@jwp.com

Martin **JONES**
Unilever Research
Quarry Road East, Bebington
CH63 3JW Wirral
United Kingdom

Tel : +44 151 641 3028
Fax : +44 151 641 1837
E-mail : Martin-V.Jones@Unilever.com

Rhonda **JONES**
Scientific and Regulatory Consultants, Inc.
P.O. Box 1014, 102 1/2 S. Chauncey Street
Columbia City, IN 46725
United States

Tel : +1 260 244 6270
Fax : +1 260 244 6273
E-mail : rjones@srcconsultants.com

Jim **KAIN**
The Procter and Gamble Co.
11530 Reed Hartman Highway
Cincinnati, OH 45241
United States

Tel : +1 513 626 6640
Fax : +1 513 626 3522
E-mail : kain.dj@pg.com

Kimmo **KARHI**
Senior Officer
Registration of Biocides (Toxicology)
Säästöpankinranta 2 A, 8th floor
P.O. Box 210
FIN-00531 Helsinki
Finland

Tel : +358 9 3967 2728
Fax : +358 9 3967 2797
E-mail : kimmo.karhi@sttv.fi

Robert **KIEFER**
Consumer Specialty Products Association
900 17th Street, NW, Suite 300
Washington, DC 20006
United States

Tel : +1 202 872 8110 x 7308
Fax : +1 202 872 8114
E-mail : rkiefer@cspa.org

Brigid **KLEIN**
CSPA

Tel : +1 202 872 8110 x 7309
E-mail : bklein@cspa.org

Prof. Hiroki **KOURAI**
Ministry of Economy, Trade and Industry
Department of Biological Science and Technology
2-1 Minamijosanjima-cho
770-8506 Tokushima
Japan

Tel : 81-88-656-7408
Fax : 81-88-656-9148
E-mail : kourai@bio.tokushima-u.ac.jp

Dr. Florian **LICHTENBERG**
c/o Office fédéral de l'environnement, des forêts et du paysage
Departement fédéral de l'environnement, des transports, de l'energie et de la communication
CH-3003 Berne
Switzerland

Tel : +41 31 322 69 55
Fax : +41 31 324 79 78
E-mail : Florian.Lichtenberg@lonzagroup.com

Dr. Chiu **LIN**
Food and Drug Administration
Division of Dental, Infection Control, and General Hospital Devices
Center for Devices and Radiological Health, 9200 Corporate Blvd
Rockville, MD 20850
United States

Tel : +1 301 443 8913
Fax : +1 301 480 3002
E-mail : cxl@cdrh.fda.gov

Graham **LLOYD**
CEFIC
Steptoe & Johnson
5, Telford Gardens, Brewood
GB-Staffordshire ST19 9ED
United Kingdom

Tel : +44-1902 851425
Fax : +44-1902 851188
E-mail : glloyd@steptoe.com

Kevin **MAHONEY**
Procter and Gamble
P.O. Box 355, Station A
Toronto, ON M5W 1C5
Canada

Tel : +1 416 730 5919
Fax : +1 416 730 4449
E-mail : mahoney.kp@pg.com

Pierre **MARIS**
AFSSA
BP 90203
35302 Fougères
France

Tel : +33 2 99 94 78 78
Fax : +33 2 99 94 78 80
E-mail : p.maris@fougeres.afssa.fr

Karen **MCCULLAGH**
Pest Management Regulatory Agency
Health Canada, Product Efficacy and Sustainability Division, Sir Charles Tupper Building, 2720 Riverside Drive, Room 735E (6607E)
Ottawa, Ontario K1A 0K9
Canada

Tel : +1 613 736 3765
Fax : +1 613 736 3770
E-mail : karen_mccullagh@hc-sc.gc.ca

Emily **MITCHELL**
US EPA
Office of Pesticide Programs
Ariel Rios Bldg, Mail Code 7596C, 1200
Pennsylvania Ave. N.W.
Washington, D.C. 20460
United States

Dr. Graziella **MORACE**
Instituto Superiore della Sanità
Laboratorio di Virologia
Viale Regina Elena, 299
00161 Roma
Italy

Tel : +39 06 49 90 32 41
Fax : +39 06 49 90 20 82
E-mail : morace@iss.it

Dr. Graziella **OREFICI**
Laboratory of Bacteriology
Instituto Superiore di Sanità, Viale Regina Elena, 299
00161 Rome
Italy

Tel : +39 06 4990 2333
Fax : +39 06 4938 7112
E-mail : gorefici@iss.it

Cleo **PIZANA**
US EPA
Antimicrobial Division, 7510C
Office of the Pesticide Programs, 1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460
United States

Tel : +1 703 308 6431
Fax : +1 703 308 6467
E-mail : pizana.cleo@epa.gov

Dr. Edmund **PLATTNER**
Federal Ministry of Agriculture, Forestry, Environment and Water Management
V/3
Stubenbastei 5
A-1010 Vienna
Austria

Tel : 00 43 1 51522-2346
Fax : 00 43 1 51522-7352
E-mail : edmund.plattner@bmlfuw.gv.at

Sue **PRICE**
3M Company
879 East 7th Street, Building 290-04-01
St. Paul, MN 55106-3837
United States

Tel : +1 651 736 3461
Fax : +1 651 736 9278
E-mail : smprice1@mmm.com

Mary **RAPHAEL**
Health Canada
Therapeutic Products Directorate
Canada

Tel : 1 613 736 3746
E-mail : mary_raphael@hc_sc.gc.ca

Dr. Paul **RASCHLE**
EMPA
Swiss Federal Laboratories for Materials Testing and Research Microbiology
Lerchenfeldstrasse 5
CH-9014 St. Gallen
Switzerland

Tel : +41 71 2747 347
Fax : +41 71 2747 694
E-mail : paul.raschle@empa.ch

Frantisek **RETTICH**
National Institute of Public Health
Srobárova 48
100 42 Prague 10
Czech Republic

Tel : +420 2 6708 2283
Fax : +420 2 6708 2566
E-mail : rettich@szu.cz

John **RIGARLSFORD**
DiverseyLever Ltd
Osier Drive, Sherwood Park, Nottinghamshire
NG15 0DS
United Kingdom

Tel : +44 1623 728 027
Fax : +44 1623 728 069
E-mail : john.rigarlsford@diverseylever.com

Amy **RISPIN**
US EPA
Office of Pesticide Programs (7506C), Ariel Rios Building, 1200 Pennsylvania Ave.
Washington, DC 20460
United States

Tel : +1 703 305 5989
Fax : +1 703 308 1850
E-mail : rispin.amy@epa.gov

Dr. Hans-Joachim **RÖDGER**
Lysoform GmbH
Kaiser Wilhelm Str. 133
12247 Berlin
Germany

Tel : +49 30 77 992 211
Fax : +49 30 77 992 219
E-mail : dr.roedger@lysoform.de

Beatriz **RODRIGUEZ**
Proctor and Gamble
Mexico

E-mail : rodriguez.bm@pg.com

Joseph **RUBINO**
Reckitt Benckiser Inc.
1 Philips Parkway
Montvale, NJ 07645
United States

Tel : +1 201 573 6083
E-mail : joseph.rubino@reckittbenckiser.com

Dr. Denver **RUSSELL**
Welsh School of Pharmacy
Cardiff University
CF10 3XF Cardiff
United Kingdom

Tel : +44 (0)29 208 75812
Fax : +44 (0)29 208 74149
E-mail : RussellD2@Cardiff.ac.uk

Dr. Sandro **SALVI**
Biolab
Via Bruno Buozzi 2
20090 Vimodrone (Milano)
Italy

Tel : +39 02 2507 1525
Fax : +39 02 2504 333
E-mail : sandro.salvi@biolab.it

Kristy **SANCHUK**
Manager Pesticide Regulations
Technical Support
S.C. Johnson and Son Limited
1 Webster Street
Brantford, Ontario N3T 5R1
Canada

Tel : +1 519 758 6555 ext. 7317
Fax : +1 519 758 6652
E-mail : ksanchuk@scj.com

Frank **SANDERS**
US EPA
7510C, Ariel Rios Building, 1200 Pennsylvania Ave., N.W.
Washington, DC 20460
United States

Tel : +1 703 308 6411
E-mail : sanders.frank@epa.gov

Dr. Syed **SATTAR**
Faculty of Medicine, University of Ottawa
Ottawa , ON K1H 8M5
Canada

Tel : +1 613 562 5800 x8314
Fax : +1 613 562 5452
E-mail : ssattar@uottawa.ca

Dr. Ingeborg **SCHWEBKE**
Robert-Koch-Institut
Nordufer 20
13353 Berlin
Germany

Tel : +49 1888 754 2237
Fax : +49 1888 754 2612
E-mail : schwebkei@rki.de

Dr. Jürgen **SCHWEMMER**
Arbeitskreis der Desinfektionsmittelhersteller in der Schweiz (ADA)
Schweizer Gesellschaft für Antisepsie AG
Lysoform AG
Gaswerkstrasse 1
CH-5200 Windisch/Brugg
Switzerland

Tel : +41 56 441 69 81
Fax : +41 56 442 41 14
E-mail : dr.schwemmer@lysoform.de

Richard **SEDLAK**
Soap and Detergent Association, The
Technical and Internatioanl Affairs
1500 K Street, NW, Suite 300
Washington, DC 20005
United States

Tel : +1-202-662-25-23
Fax : +1-202-347-41-10
E-mail : rsedlak@sdahq.org

Mithu **SEN**
Procter and Gamble
Vle C. Pavese 385
00144 Rome
Italy

Tel : +39 06 5097 2036
Fax : +39 06 5097 6036
E-mail : sen.s@pg.com

Stephen **SMITH**
S.C. Johnson and Son
1525 Howe Street
Racine, WI 53403-2236
United States
Tel : +1 262 260 0619
Fax : +1 262 260 4716
E-mail : srsmith@scj.com

Susan **SPRINGTHORPE**
University of Ottawa
Centre for Research on Environmental Microbiology
451 Smyth Road
Ottawa, ON K1H 8M5
Canada
Tel : +1 613 562 5800 ext 8313
Fax : +1 613 562 5452
E-mail : sspring@uottawa.ca

Peter **STUTTE**
Sanitized
Switzerland
Tel : +41 34 427 16 15
E-mail : Peter.Stutte@sanitized.com

Hang **TANG**
Pest Management Regulatory Agency
Sir Charles Tupper Bldg , 2720 Riverside Dr.
Ottawa, ON K1A 0K9
Canada
E-mail : hang_tang@hc-sc.gc.ca

Shelley **TANG**
TGA
Conformity Assessment Branch
P.O. Box 100
Woden ACT 2606
Australia
Tel : +61 2 6232 8793
Fax : +61 2 6232 8785
E-mail : shelley.tang@health.gov.au

Prof. Paul **TERPSTRA**
Wageningen University
Consumer Technology and Product Use
Wageningen
Netherlands
Tel : +31 317 483277/482088
Fax : +31 317 482593
E-mail : paul.terpstra@tech.hhs.wau.nl

Dr. Stephen **TOMASINO**
US EPA
7503, 701 Mapes Rd.
Fort Meade, MD 20755-5350
United States
Tel : +1 410 305 2976
E-mail : tomasino.steve@epa.gov

Dr. Bert **VAN KLINGEREN**
National Institute for Public Health and the Environment (RIVM)
Postbox 1
3720 BA
Netherlands
Tel : +31 30 274 2905
Fax : +31 30 274 4414
E-mail : b.van.klingeren@rivm.nl

Dr. Roy **VORE**
Avecia Inc.
Pool and Spa Products, Biocides Research and Development Center
235 Cherry Lane
New Castle,DE 19720
United States
Tel : +1 302 472 1316
E-mail : roy.vore@avecia.com

Richard **WALTER**
Dow
E-mail : RWWALTER@DOW.com

Dr. Thomas **WARSCHEID**
Freie Hansestadt Bremen
Amtliche Materialprüfungsanstalt (MPA)
Leiter der Abteilung 4
Mikrobiologie
Paul-Feller-Straße 1
28199 Bremen
Germany
Tel : +49 421/5 37 08-0 Durchwahl
Fax : +49 421/5 37 08-10
E-mail : warscheid@mpa-bremen.de

Dr. Mark **WIENCEK**
Milliken and Company, M-401
920 Milliken Road
Spartanburg, SC 29304
United States
Tel : +1 864 503 6260
Fax : +1 864 503 1365
E-mail : mark.wiencek@milliken.com

Geoff **WILSON**
OECD
ENVIRONMENT DIRECTORATE
2, rue André Pascal
75016
Paris
France
Tel : +33 1 45 24 16 78
Fax : +33 1 45 24 16 75
E-mail : Geoff.WILSON@oecd.org

Michele **WINGFIELD**
US EPA
Office of Pesticide Programs, Antimicrobials Division (7510C), Ariel Rios Building, 1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
United States
Tel : +1 703 308 6349
Fax : +1 703 308 8481
E-mail : wingfield.michele@epa.gov

Gina **WONG WON**
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, ON K1A 0K9
Canada

E-mail : gina_wong_won@hc-sc.gc.ca

Jun **YOSHIDA**
Deputy Director, Ministry of Health, Labour and Welfare
Office of Chemical Safety, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau
1-2-2 Kasumigaseki, Chiyoda-ku
100-8916 Tokyo
Japan

Tel : 81-3-3595-2298
Fax : 81-3-3593-8913
E-mail : yoshida-jun@mhlw.go.jp

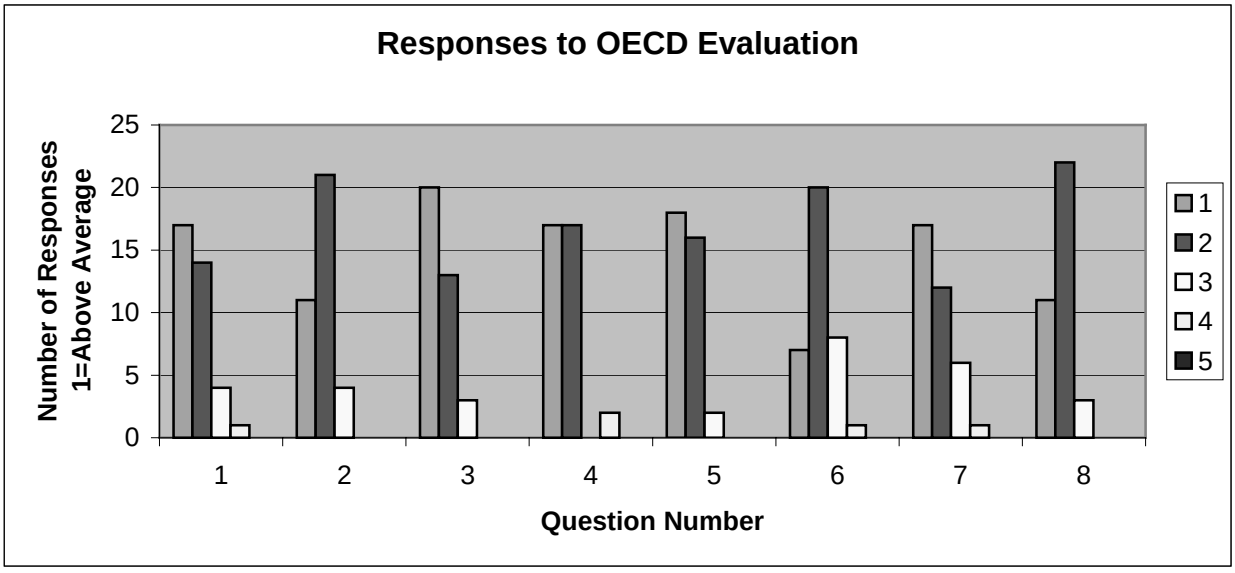
# *Chapter 11*
# *Evaluation Results*

## Evaluation Questions

| |
|---|
| **1) The registration process and other logistical requirements at the conference were well organized.** |
| **2) The set up of the meeting rooms was conducive to the conference format and presentations.** |
| **3) The workshop was organized and flowed smoothly.** |
| **4) The plenary presentations provided clear, thorough and useful information on relevant topics.** |
| **5) The information provided during the plenary session was presented in a timely manner.** |
| **6) The information provided to assist the Breakout sessions was presented in a clear, sufficient manner.** |
| **7) The workshop allowed me to make contacts I will use in the future.** |
| **8) The workshop generated useful goals for future workgroup interaction.** |

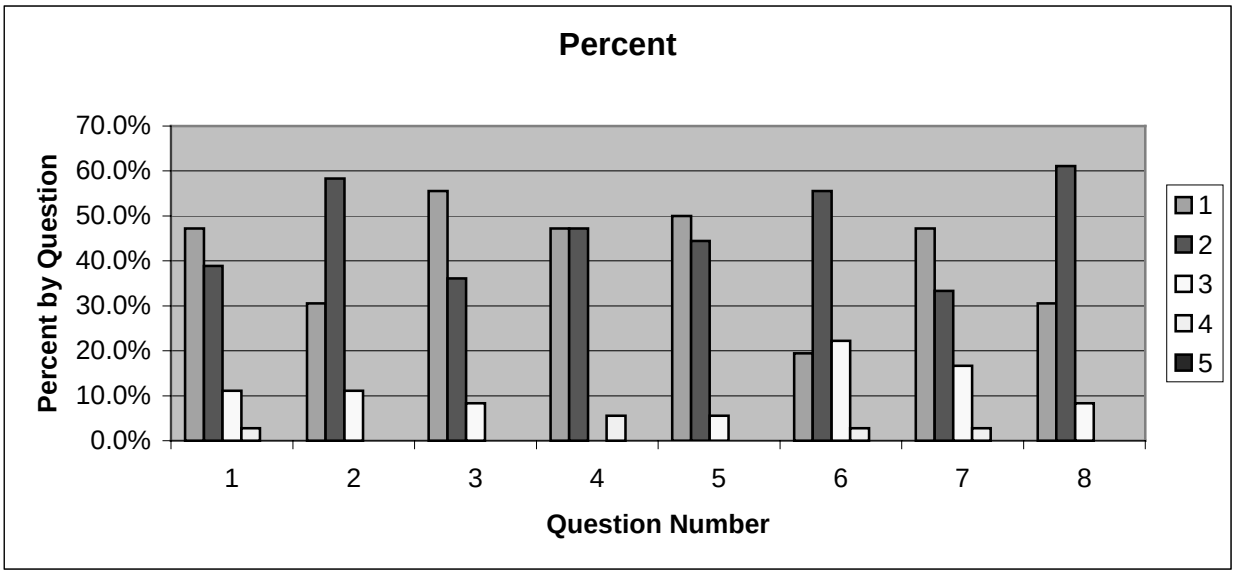
## Evaluation Results

**Number of each # (1-5) response for each question on the OECD evaluation**



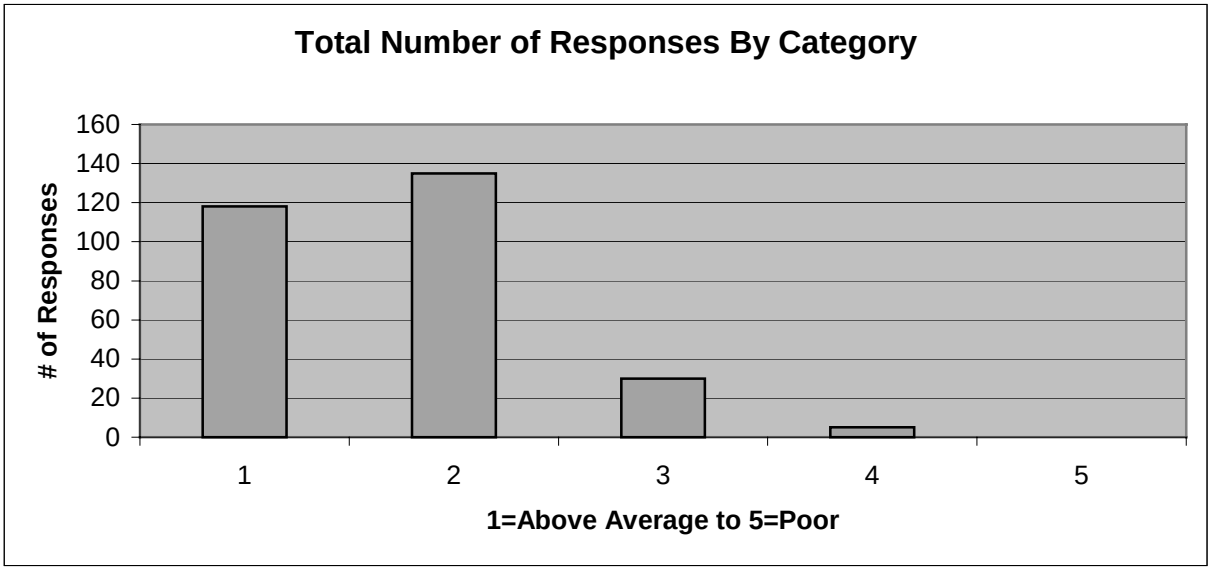

1 = Above Average, 5 = Poor

**Percent of each # (1-5) response for each question on the OECD evaluation**




1 = Above Average, 5 = Poor

**Total number of each # (1-5) response for all 8 questions on the OECD evaluation**



# Comments from OECD Evaluations

**Denver Russell** – 1) OECD help with expenses at any future meeting should be considered, especially for academics and speakers. 2) Breakout presenters should be encouraged to give computer-generated summaries, etc in appropriate size print. 3) Coffee and lunch breaks are sacrosanct, being most useful for informal discussions. Thus, formal lectures should not be permitted to extend beyond stipulated period.

**Howard Cash** – It appears a solid base has been created. But much more needs to be discussed before real harmonization is achievable. Lack of resources may be the worst problem – even competing cultural bias of what is appropriate and competing regulatory schemes are manageable if proper support is available from governments/industry or a combination.

**SA Sattar** – Generally a good successful effort. Looking forward to a follow-up. OECD – please consider providing academics with financial support to attend future meetings on this topic

**Geoffrey Brown** – Allow individuals from industry to choose their particular breakout session. Designate regulators that have substantive expertise in the breakout area in which they attend.

**John Hulah** – A good starting point and the process should develop. There should have been more interaction between the 5 groups, especially for the delegates who could have offered expertise in more than one area. The initial selection of expertise should have had delegate input. Thank you for your efforts and I look forward to future input.

**Anonymous** - Since I was not so familiar with this field it was quite pitty my contribution during the breakout. For the efficacy issue, I think that we should learn about pesticides groups experience harmonizing. Efficacy testing if any. Also, we should learn about new chemical TF's experience of MANC (mutual acceptance of notification) and GHS.

**Anonymous** - Insufficient time in breakout group, a daunting task. Day to day timing was excellent. Should have been more EPA presence – especially in break out sessions.

**Roy Vore** – The "nomination" process in the first email was confusing. Once I got past that the organization was well thought out. The discussions in the break out groups and the informal discussions were extremely valuable. Even though I am familiar with BPD these discussions helped explain some of the background logic that is not transparent to a US focused microbiologist.

**Frederic Bissonnette** – Breakout groups should have started earlier in the day. It's hard to think straight after 4 hours of presentations.

**Anonymous** - Conference room ceiling too low, limited the height of the presentation screen. Computer/beamer needed for breakout groups.

**Richard Walter** – I believe we have all learned more about our area, regional and global biocide needs, the methods used/needed to define activity of formulations and the needs of regulators in antibacterial products. We need to continue we need to address the items that have been parked.

**Shelley Tang** – I found the workshop very useful in setting the groundwork for a harmonization proposal. I think the work of the breakout groups need to continue as only an outline was developed in the time available. It was very encouraging to see the enthusiasm evident at the workshop.

**Dave Dillon** – I found the conference to be well organized and run – the chairs to facilitate the overall conference proceedings in plenary did an excellent job in communicating information on domestics, itinerary changes and were outstanding in keeping things running to time. (if there were any gliches/problems – they were not obvious) Plenary presentations were all well prepared and delivered and facilitated great, stimulating discussions in breakout. One minor gripe was that more time perhaps needed in breakout to conclude discussions and then prepare reports. I thoroughly enjoyed the event.

**Anonymous** - Excellent meetings with significant progress towards harmonization goal.

**Bob Hartog** – For me the workshop was very informative and inspiring! Should be continued. The use of biocidal products for public health purposes is only part of hygienic programs. Such programs should be developed carefully and carried out strictly. This should be underlined in user instructions of biocidal products to guarantee proper performance and expected effects.

**Anonymous** - For people with non “English” background, please speak loud, clear and slowly.

**Robert Kiefer** – Agendas not distributed prior – unsure of start time for workshop on Monday morning. Need copies of ALL presentations. I would like to be a part of any follow-up/working group activities related to biocide efficacy for the OECD. Look forward to future projects/work products. Great workshop!

**John Rigarlsford** – Meeting rooms too hot and AC too noisy. More time was needed for breakout sessions, cut back on plenary sessions. More opportunity to contribute to other breakout groups would have been nice. Evening social events should be considered to encourage networking. Overall, thanks to the organizers. I trust that this is the first of many such meetings and I would be willing to play a more active role in future meetings.