IBRG International Biodeterioration Research Group

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Introduction of the European Antibacterial Industry

By Robbie Coffin

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Introduction

- Biochemistry BSc Hons
- 7 years in industry
- Quality Management & Research and Development at IMSL
- Secretary General – IBRG (April 2019)

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IMSL

- Consultancy and Testing Laboratory in Hampshire, U.K
- Treated articles – ISO 22196/JIS Z2801, ISO 201743, OECD Porous/Non-Porous Method, IBRG Methods
- Odour Testing – Textile
- PT 11 & 12 testing

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IBRG

- Formed in 1968
- Test Method Development
- Close relationship with SIAA – Current President Tadashi Tsuchyia

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Activities within the IBRG

- Wet-State Preservation
- Dry-State Preservation
- Functional Fluids
- Treated Articles

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IBRG Methods

- Determining the Resistance of Paints and Coatings to Algal Growth
- Tier 1 Basic Efficacy Method for Biocidal Active Substances used to Preserve Aqueous Based Products
- Tier 1 Polymer Dispersion Method
- Tier 1 Wet State Paint Method
- Tier 1 Metal Working Fluids Method
- Tier 1 Basic Efficacy of Biocidal Active Substances used to Preserve Aqueous Based Cooling Fluids
- Tier 1 Basic Efficacy of Biocidal Active Substances used to Prevent Biofilms in Aqueous Based Cooling Fluids
- Tier 1 Basic Efficacy of Biocidal Active Substances used as Slimicides in Aqueous Based Paper Pulps
- Tier 1 Textile Method – Antibacterial Properties

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Biocidal Products Regulation

- Replaced the BPD (Directive 98/8/EC)
  - From 1st September 2013 (EU) 528/2012.
- Regulates both active substances and biocidal products.
- Classification of biocides into 22 Product Types (PTs).

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Main Group 1: Disinfectants	Main Group 2: Preservatives	Main Group 3: Pest Control	Main Group 4: Other Biocidal Products
PT1 1: Human hygiene	**PT 6: Preservatives for products during storage**	PT 14: Rodenticides	PT 21: Antifouling products
PT 2: Disinfectants and algicides (Not for human or animal application)	**PT 7: Film Preservatives**	PT 15: Avicides	PT 22: Embalming and taxidermist fluids
PT 3: Veterinary Hygiene	**PT 8: Wood Preservatives**	PT 16: Molluscides, vermicides and products to control other invertebrates	
PT 4: Food and Feed Areas	**PT 9: Fibres, leather, rubber and polymerised materials preservatives**	PT 17: Piscidies	
PT 5: Drinking Water	**PT 10: Construction Materials**	PT 18: Insecticides, acaricides, and products to control arthropods	
	PT 11: Preservatives for liquid-cooling and processing systems	PT 19: Repellents and attractants	
	PT 12: Slimicides	PT 20: Control of other vertebrates	
	PT 13: Working or cutting fluid preservatives		

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Tiered Approach

- **Tier 1: Proof of Principle** defines the basic industry standard tests that determine efficacy of an antibacterial treated article in a controlled laboratory environment.
- **Tier 2: Simulated Use** defines the translational tests that mimic end-use scenarios, environments and incubation times.
- **Tier 3: In-Use Evaluation** substantiates direct health benefit claims or supports marketing initiatives by the development of clinical trials that take place in end-use environments under real-world conditions.

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Understanding the Problem

- Basic methods are useful during invention, development and product QA.
- More realistic models needed to understand potential benefit and support product registration.
- Field trials to assess impact.

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Biocidal Products Regulation

- Antimicrobial coatings (AMCs) are recognised as Biocidal Products (PT 2).

2	Disinfectants and algaecides not intended for direct application to humans or animals.	Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools aquariums, bathing and other waters, air conditioning systems; w'alls and floors in private, public and industrial areas and in other areas for professional activities. Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

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Biocidal Products Regulation

- BPR is concerned with chemical action.
  - An AMC that exploits physical effects will be exempt.
    - Modified topography.
    - Certain photo-activated systems.
    - Bacterial 'fly paper'.
- However,

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Biocidal Products Regulation

- Attractants and repellents are covered.
- Biological agents and enzymes are covered.
- Natural products are covered.
- AMCs manufactured outside EU are covered.
- Nano-materials are covered.
    - The nano-form of a registered active substance will require separate registration,
    - But, aggregated nano-particles may not.

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Biocidal Products Regulation

- If the effect (even if physical) exploits a novel chemical then this may need to be registered under REACH.
    - If the quantity exceeds 1 t / year.
    - A biocidal active substance must always be registered with the BPR no matter what the quantity (even when imported as part of an AMC).

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Biocidal Products Regulation

- Costs.
  - Very high for a new active substance (€1M - €3M).
  - Expect costs in the region of €100K to use an existing active substance.
    - Letter of access for that active substance.
    - Efficacy data.
    - Potential licensing fees.
    - Registration review costs.
    - Consultants to prepare dossier / IUCLID submissions.

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Thank you

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