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Regulatory requirements for antimicrobial surfaces

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Overview

- European & UK Regulations
- US Regulations (and Canada)
- Australia, Japan, MEA and others
- Differences and Similarities
- Barriers to Innovation
  - Costs, Marketing and Markets

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Antimicrobial Effects

- Three broad divisions.
  - Disinfectants and sterilisation.
  - A treatment intended to protect the properties of a material, extend durability or protect the function of an article.
  - A treatment intended to add new properties or functions to an article not related to its primary use (antimicrobial surfaces – AMS).

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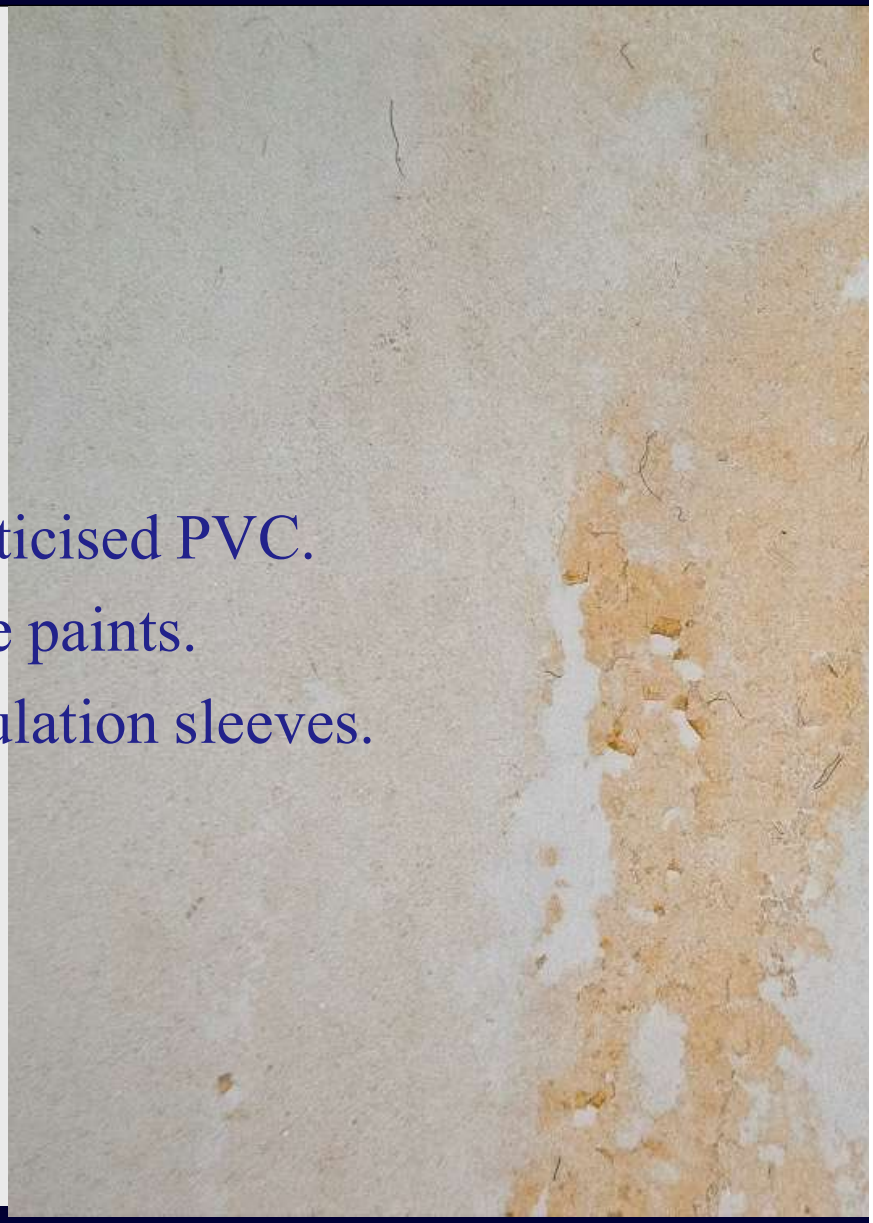
Protect Properties

- Examples
  - Prevent deterioration of plasticised PVC.
  - Extend the lifespan of façade paints.
  - Stop arcing on electrical insulation sleeves.
  - Prevent odour.



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Protect Properties

- Measuring the effect.
  - In most instances this can be done using typical examples of the materials it is intended to be used with.
  - *The untreated material must show the pattern of deterioration that the treatment is intended to prevent in any tests used.*
  - Wide range of tests and ageing scenarios available that can be used.

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Protect Properties

- Consequences of the failure of a product.
  - Readily observed.
    - A shower curtain goes mouldy and cracks
    - A painted wall needs redecorating sooner than expected due to visible fouling by growth.
    - Sports clothes start to smell after being used a few times.
  - Complaints, no re-sales *etc* up the supply chain.

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Add New Properties

- Examples of AMS:
  - Keyboard treated to prevent bacterial growth.
  - Hospital bedside cabinet treated to kill germs on contact.
  - Door handles that prevent cross-infection.

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Add New Properties

- The very act of introducing antimicrobial properties is often perceived as desirable.
- Articles often address hypothetical hazards.
- The majority intend to improve hygiene.
- It is often unclear to the consumer / user / clinician / manager what benefit is intended.

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Add New Properties

- Measuring the effect.
  - In most instances this can only be done using the final article (AMS).
  - The need for the treatment must be justified (is there a significant hazard?).
    - Prevents growth – do they grow under the conditions of use and, if so, does this present a problem?
    - Is the presence of viable microorganisms on the article a significant issue in practice?

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Add New Properties

- Supporting a claim.
  - No standard tests – the effect should be demonstrated in a realistic simulation.
  - The scale, speed and duration should be relevant to the hazard being targeted.
  - Durability?

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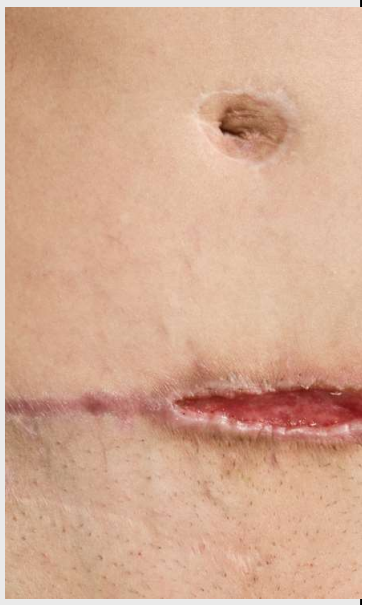
Add New Properties



- Consequence of failure of an article.
  - Cannot be observed directly.
    - Are bacteria growing on the keyboard?
    - Did MRSA deposited by skin contact die between one touch event and the next?
    - Is the sponge free of hazardous bacteria?
    - Did the infection rate go down?

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Regulation of AMS

- Regulation varies from country to country.
- Except for within the EU (& UK), there is no consistent approach.
  - Basic toxicity and ecotoxicity data is similar.
  - OECD is working towards harmonisation.
  - Requirements for efficacy data varies (a lot).

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EU 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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Biocidal Products Regulation

- Antimicrobial surfaces (AMS) 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 AMS 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.
- AMS 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 AMS).

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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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UK BPR

- Replaced the EU BPR on 1st January 2021
  - as a consequence of the UK leaving the EU.
- Regulates both active substances and biocidal products (22 PTs).
- Mirrors the EU BPR at present.
  - Divergence is anticipated over time.
    - Registration under both EU and UK BPR schemes.
  - Costs are time based and are unclear at present.

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USA

- Regulated by the US EPA.
  - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
- Regulates both active substances and biocidal products.
- Treated Article Exemption - 40 CFR 152.25(a).

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USA – TA Exemption

- Treated articles are exempt from registration if :
  - The active substance they contain is registered,
  - And they do not make a public health claim.
- However, the articles / surfaces we are interested in do, by definition, make such a claim.
- They will be regarded as biocides.

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USA

- A new active substance will require the usual toxicity, ecotoxicity data *etc*.
- Efficacy (and durability) will need to be demonstrated using a protocol agreed with the EPA.
- PRIA* 4 process for approval of protocol.

* Pesticide Reporting Improvement Act

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USA – PRIA4

- Forces a 90 day review period.
- Expect costs of *ca* $15K for the PRIA.
- Anticipate 3–4 cycles of the review process.
- Often needs a consultant.
- Agreed protocol must be executed by an agreed laboratory to GLP.
    - High costs.

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USA

- Will almost certainly lead to registration as a non-food-contact sanitizer.
- Not transferable to EU.
    - The definition and parameters are not recognised under the BPR.
- May not even be transferable to Canada.

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Japan

- SIAA certification scheme.
  - Kohkin brand mark.
    - Driven by historical and widespread *E coli* food poisoning outbreaks (70's and 80's).
  - Two standard methods trigger the brand mark
    - Do not describe performance in practice and the **presence** of an antibacterial agent is regarded as the benefit.
  - No additional requirements for healthcare.

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Australia

- Similar registration programme as USA / EU for active substances and biocidal products.
- No registration required for AMS for non-professionals uses (considered as domestic disinfectants).
- Healthcare will require registration / proof of efficacy *etc* (detail not available yet).

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MEA, India & Pakistan

- Few countries have a biocide registration programme.
- Some require 'toxic' materials used as non-agricultural pesticides to be registered.
- No registration requirements for AMS.
- Some hospitals ask for data to ISO 22196 but it is mainly used for marketing.

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Kenya

- The Pest Control products Board (PCPB) regulates all uses of biocides as well as pesticides.
- Efficacy data using the methods produced by IBRG is required for biocidal active substances used in paints.
- It is not clear whether AMS are regulated, but it does appear that they are using BPR as guidance.
- It is likely that neighbouring states will follow.

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Turkey

- Have a registration programme based on the EU BPR.
- No apparent requirement for registration of AMCs though, as long as the active substance is approved.
- Data from ISO 22196 appears common.

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Turkey – Antimicrobial Paints

- Ministry of Health
- List of approved active substances for T-BPR PT2 although not all are actually relevant to AMS
- ISO 22196 bacterial and fungi
- Stability of Active Substance in-can gives the shelf life that can be claimed
    - < 20% reduction give 2 year shelf life 'claim' 3 monthly analysis

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Asia / Pacific

- Sri-Lanka and Malaysia have a complex and demanding biocide registration programme.
- No apparent requirement for registration of AMS though as long as the active substance is approved.
- Taiwan, Indonesia and China have a less complex programme but not for AMS although China is interested in the BPR approach.
  - Threshold levels in a standard method (GB/T 20944.1-2007)

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Asia / Pacific

- South Korea have a full biocide registration programme based on the EU BPR which commenced 1st January 2019. It is not clear yet how this will impact on AMS, but they announced in February 2019 that health related claims would be covered.

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Differences and Similarities

- In many cases the core toxicity / ecotoxicity requirements are very similar.
- The approach to efficacy can be very different.
- EU BPR is the most demanding scheme.
  - Strong emphasis on demonstrating performance under realistic conditions and supporting claims.
  - Risk / benefit is a major factor in the assessment process.

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Costs, Marketing and Markets

- Cost and complexity of registration is a major barrier for AMS development.
  - New active substances will be very costly to bring to market and there is enormous pressure on the key ones in current use (*eg* silver ion and ZPT).
- Launching into less regulated markets can provide faster / early returns on investment,
  - but only if the effects claimed are real and beneficial.
  - Unsubstantiated / unrealistic claims damage the perception of AMCs.

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Costs, Marketing and Markets

- Rigid specifications / matching claims into existing categories can limit innovation.
  - Claim driven models potentially deliver more value as long as the benefits are significant.
- Cost : benefit.
  - Disinfectants / sanitizers *vs* AMCs.
- Value *vs* cost.
  - The lack of credible and robust field data is a major issue for many regulators, especially in the EU.

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Costs, Marketing and Markets

- Wide application may prove to be non-viable.
  - Development and regulation costs and complexity.
  - Poor / limited impact in trials to date.
  - Limited opportunity to recover costs.
- Target interventions for max. impact on HAIs.
  - Cost – justify based on savings on HAIs.
  - Protection of antibiotics (target multi-drug resistance).
  - Contact surfaces with maximum potential for cross contamination.
  - Tie in with infection control policies where possible.