BAM
Bundesanstalt für Materialforschung und -prüfung

Sicherheit in Technik und Chemie

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Biocide resistance risk assessment

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www.bam.de

Biocide resistance – legal background

EU biocide product regulation **(EU) Nr. 528/2012**

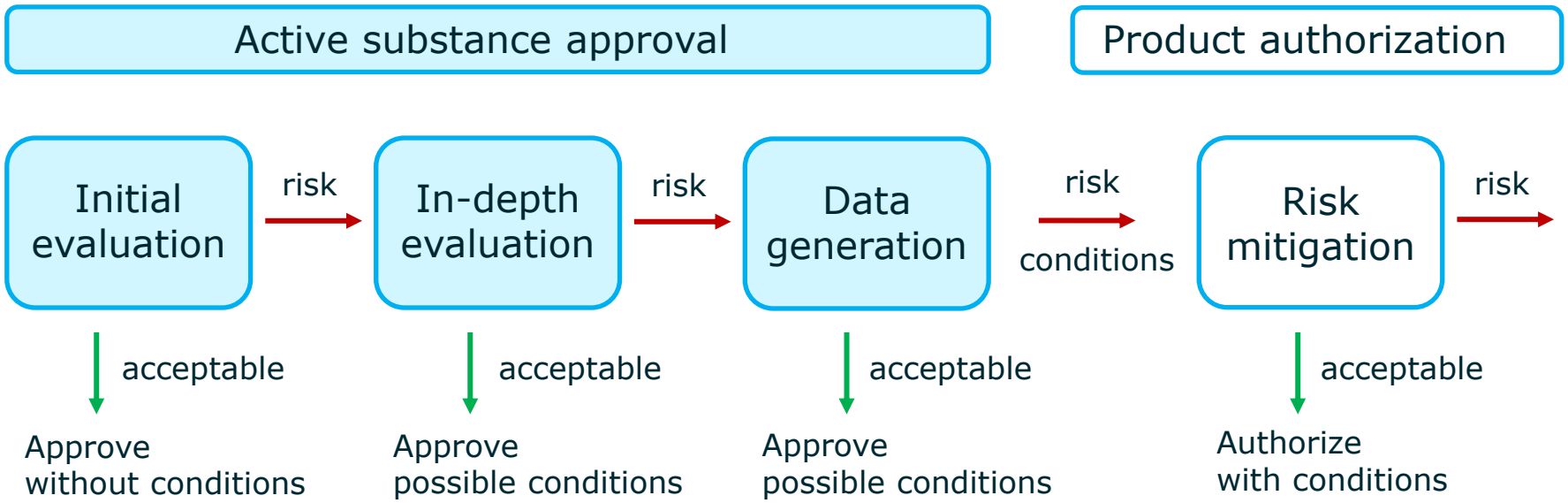
BPR Article 19.1.b.ii) **Conditions for granting an authorisation**

The biocidal product has no … **unacceptable resistance or cross-resistance**…

Garnet-Marlen Kroos (JKI) → insecticides stock protection
Ralf Dieckmann (BfR) → microorganisms
Christiane Stahr (UBA) → insecticides/rodenticides
Ingeborg Schwebke (RKI) → disinfectants
Ilka Zerfass & Martin Krüger (BAuA) → regulation
Frank Schreiber (BAM) → microorganisms preservatives

Biocide resistance risk assessment

Potential tiered approach



Initial evaluation

- **Previous experience** → list of suspects, novel active substance
- **Type of inhibition** → growth during use
- **Mode of action** → single biochemical target site
- **Stability** → stable substance dilutes around application site

List of questions to be answered with yes or no:

Does the mode of action involve a single biochemical target site?

In-depth evaluation

Impact

If resistance occurs

Human health upon exposure with resistant strains

Loss of efficacy

Likelihood

of resistance to occur

Association to risk factors category:

Biocide
Target organisms
Use

In-depth evaluation

Biocide

Past experience
Efficacy
Stability of substance
MoA
Resistance mechanism
Mutation supply rate
Horizontal gene transfer

Target organism

Adaptive potential
Stability of resistance
Metabolism
Survival stages (tolerance)
Cross-resistance
Dispersal

Use

Repeated application
Homogeneity
Production volumes
Protected goods
Environmental stability

In-depth evaluation

List of questions to be answered with yes or no:

For example, **Type of application**:

Is there a high number of repeated applications to obtain control?
→ Yes → Priority score: High
→ Likelihood: Medium

Possibility to calculate a score for this category

In-depth evaluation

Biocide

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Target organism

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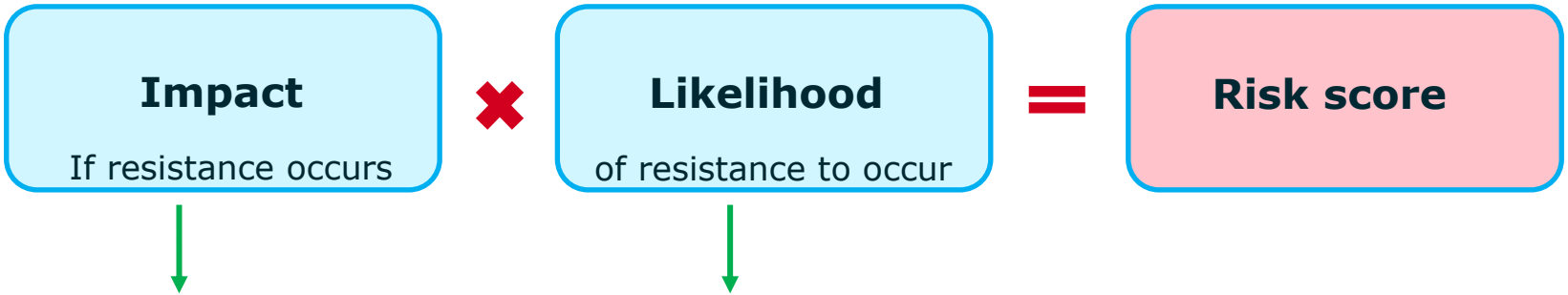
In-depth evaluation



Health

Loss of efficacy

Association to risk factors category:

Biocide
Target organisms
Use

Biocide resistance risk assessment

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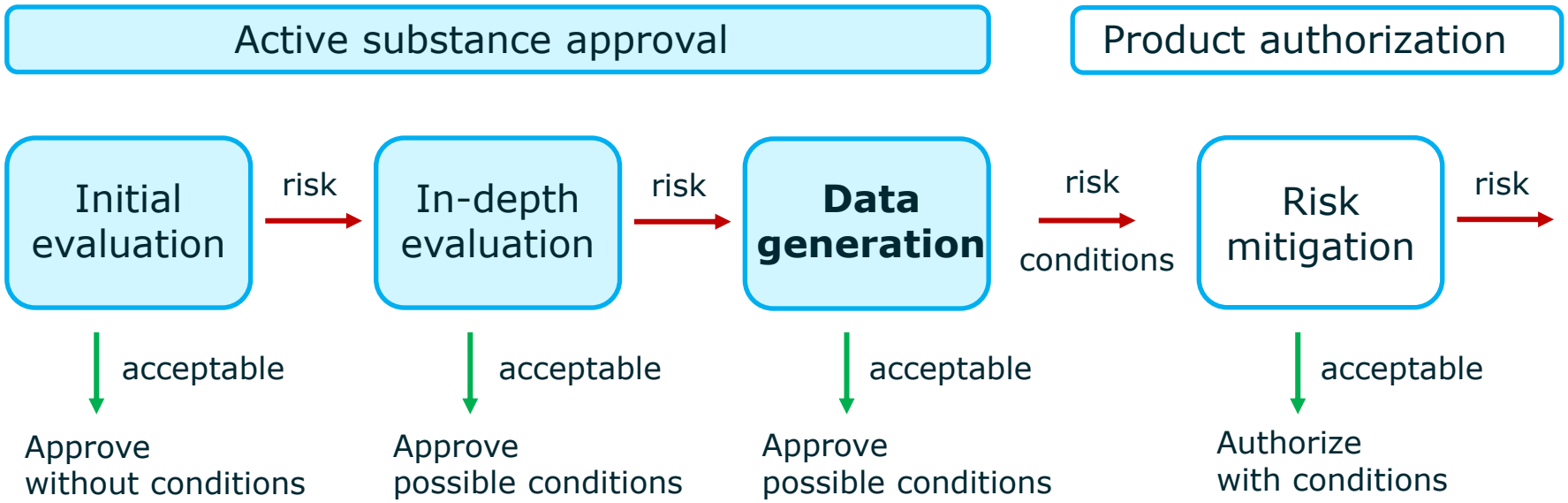

Data generation

Biocide

Past experience
Efficacy
Stability of substance
MoA
Resistance mechanism
Mutation supply rate
Horizontal gene transfer

Target organism

Adaptive potential
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Use

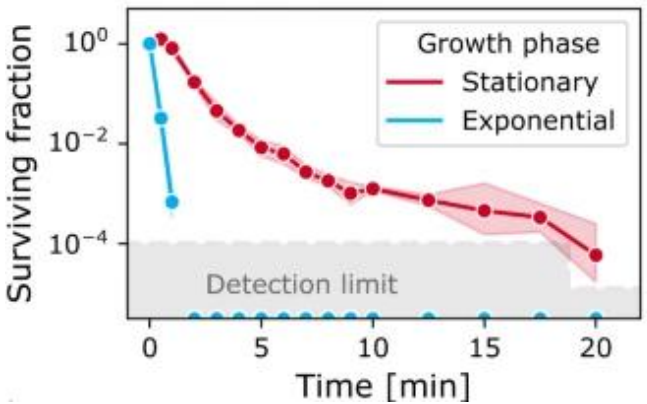
Type of application
Homogeneity
Production volumes
Protected goods
Environmental stability

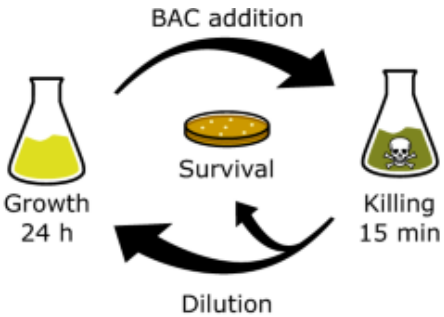
Data generation

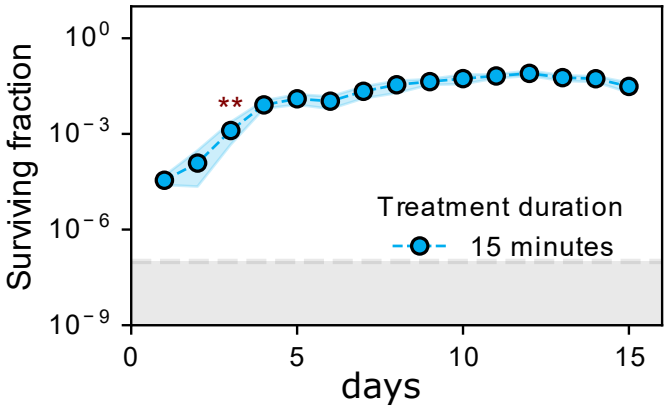
nature COMMUNICATIONS

Persistence against benzalkonium chloride promotes rapid evolution of tolerance during periodic disinfection

Niclas Nordholt[1], Orestis Kanaris[1], Selina B. I. Schmidt[1] & Frank Schreiber[1]







Data generation – Biocide resistance standard

WIPANO

Federal Ministry for Economic Affairs and Energy

BioResTest project

Development of a laboratory method to assess resistance development of microorganisms to biocides

Data generation – Biocide resistance standard

Laboratory test method

Antimicrobial surfaces

Surface disinfection

Data generation – Biocide resistance standard

Laboratory test method

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DR. BRILL + DR. STEINMANN
INSTITUTE FOR HYGIENE AND MICROBIOLOGY

Antimicrobial surfaces

ISO 22196

Measurement of antibacterial activity on plastics and other non-porous surfaces

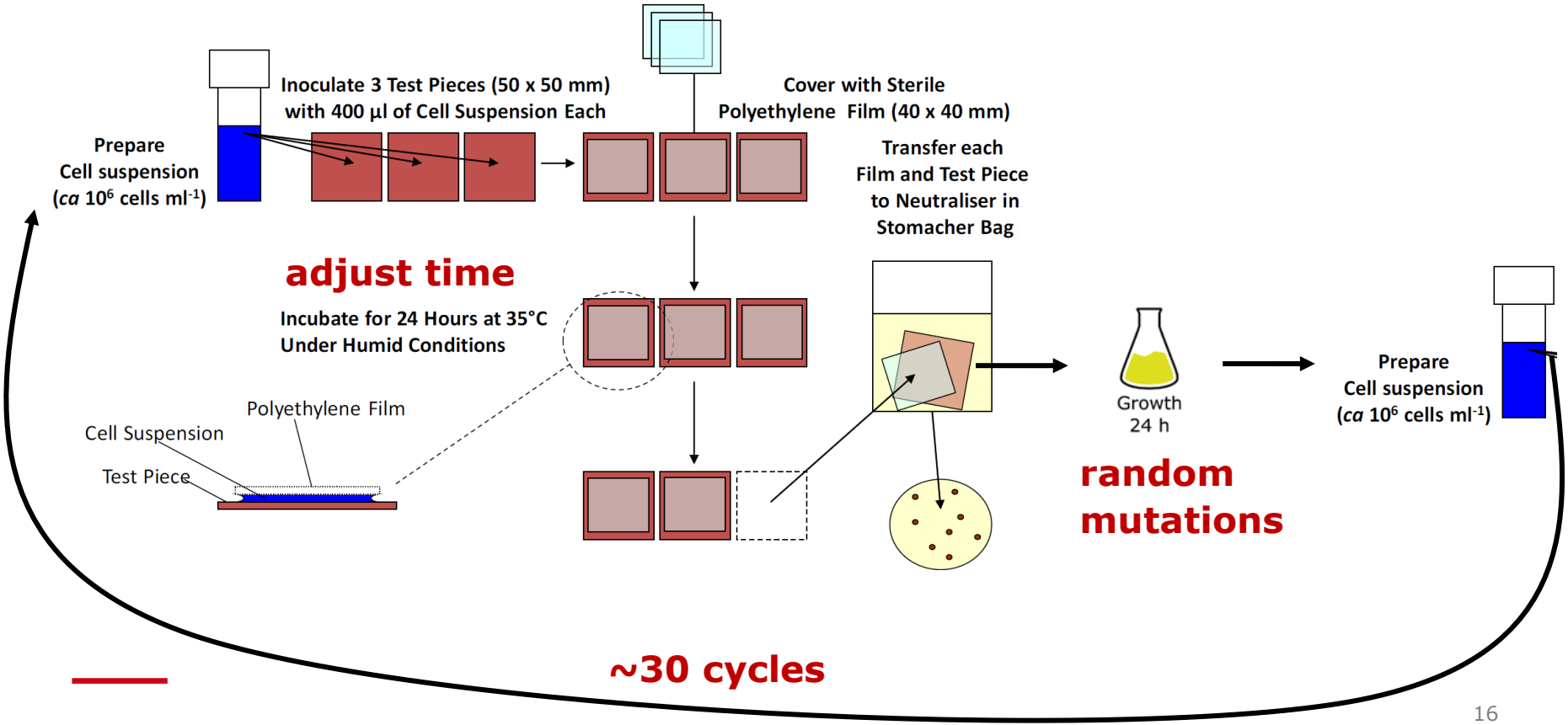
Surface disinfection

EN 13697; EN 16615

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants …

4-field test (mechanical action)

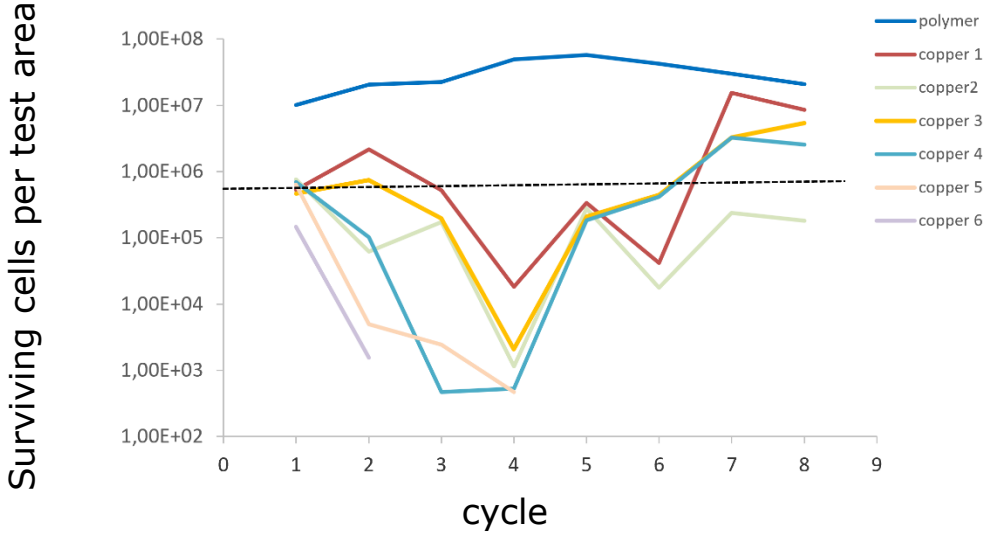
BioResTest - Antimicrobial surfaces ISO 22196



Data generation – Biocide resistance standard

Pseudomonas aeruginosa

evolving for survival on copper



Limitations and outlook

- Serve data gaps

- Quantitative link between dissemination of resistant strains and impact on humans

- release assessment of resistant organisms
- exposure assessment to humans
- assessment of impacts on humans

- Define **‘unacceptable’** resistance

- International standards (ISO TC330)

Acknowledgements

Team

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