Requirements for Efficacy Testing of Treated Articles according to EU biocides legislation

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When does an Antimicrobial Coating fall under EU biocides legislation?

- A biocidal claim is made, and
- An active substance was added with the intention of imparting a biocidal function, and
- It is made available on the market or used within the EU

claim?

Basically, any statement that a coating has a biocidal function.

What is a biocidal function?

- …… the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. (Art. 3a)

EU biocidal products regulation

- Only authorised **biocidal products (BP)** may be sold and used
- **Active substances (AS)** are evaluated and approved on EU level

- **Treated articles (TA)** may only be treated with an approved AS

Biocides Regulations for AMC

- The coating itself is a biocidal product (BP)

  → has to be authorised when made available on the EU market or used within the EU

- The articles treated with the coating can be a treated article (TA):

  →the active substance has to be authorised within the EU (for the right product type and use)

  →The article has to be labelled (if a claim is made)

Borderline between BP and TA

- The article treated with the coating can be a biocidal product itself (if it has a primary biocidal function), or
- The article can be a treated article (if the biocidal function is secondary).

Efficacy testing

Both a treated article and a biocidal product can be liquid or solid. This is decisive for testing!

- For liquids: no methodological difficulties
- For solid articles: quite a challenge

What is efficacy testing about?

- The claim made needs to be supported by efficacy tests which show that the BP/TA holds what it promises
- Problem: unclear claims are difficult to test

Example: an ”antimicrobial” kitchen surface.

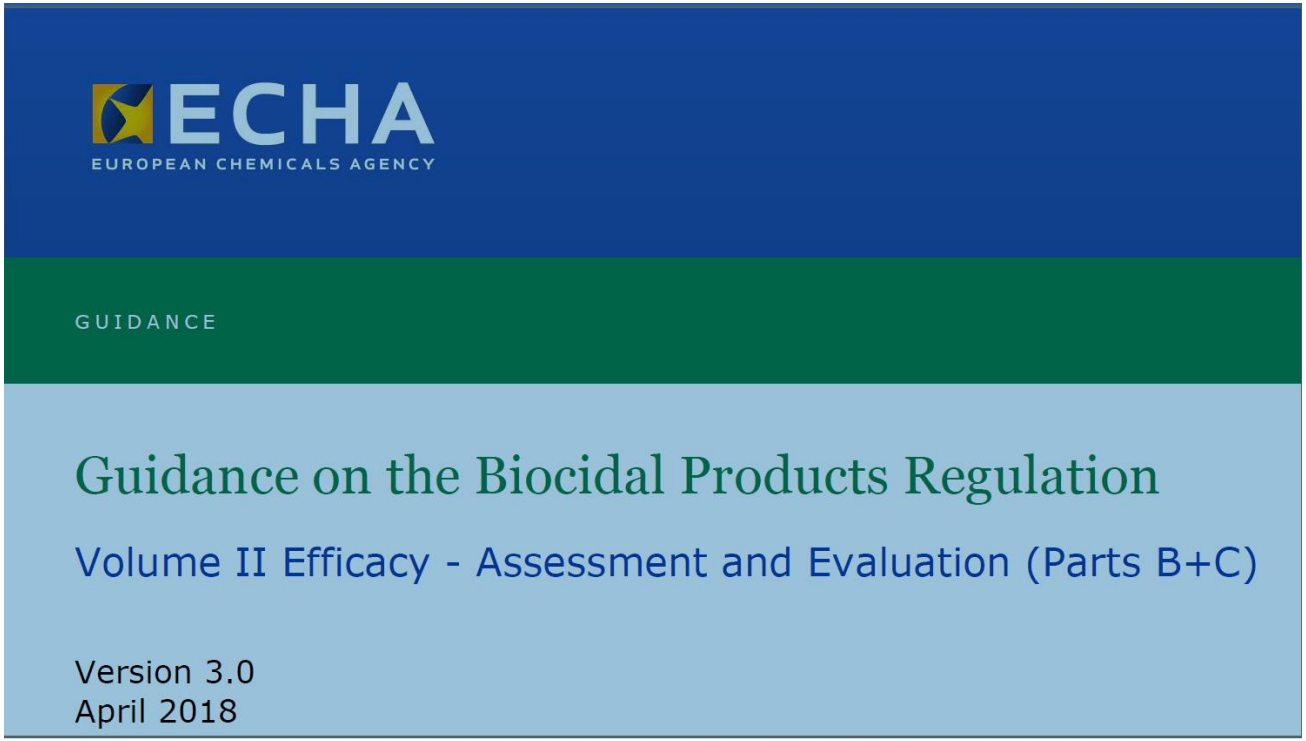
What is to be protected: the material? The user?

The material: usually not prone to microbial deterioration if properly assembled.

The user: claim insinuates protection against cross-contamination with pathogens.

What is usually tested is prevention of bacterial growth or killing over a period of 24h in humid conditions.

EU-guidance for Efficacy Testing



https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

Unclear claims are impossible to test

- From the guidance on claims

  "….Claims should comprise of the description of the problem and the way it is suggested to be solved by the biocidal treatment. Claims include information given in an active substance dossier, information on the label of a product, information provided on a web-site or in product-associated leaflets. All claims should be consistent. …"

An important distinction

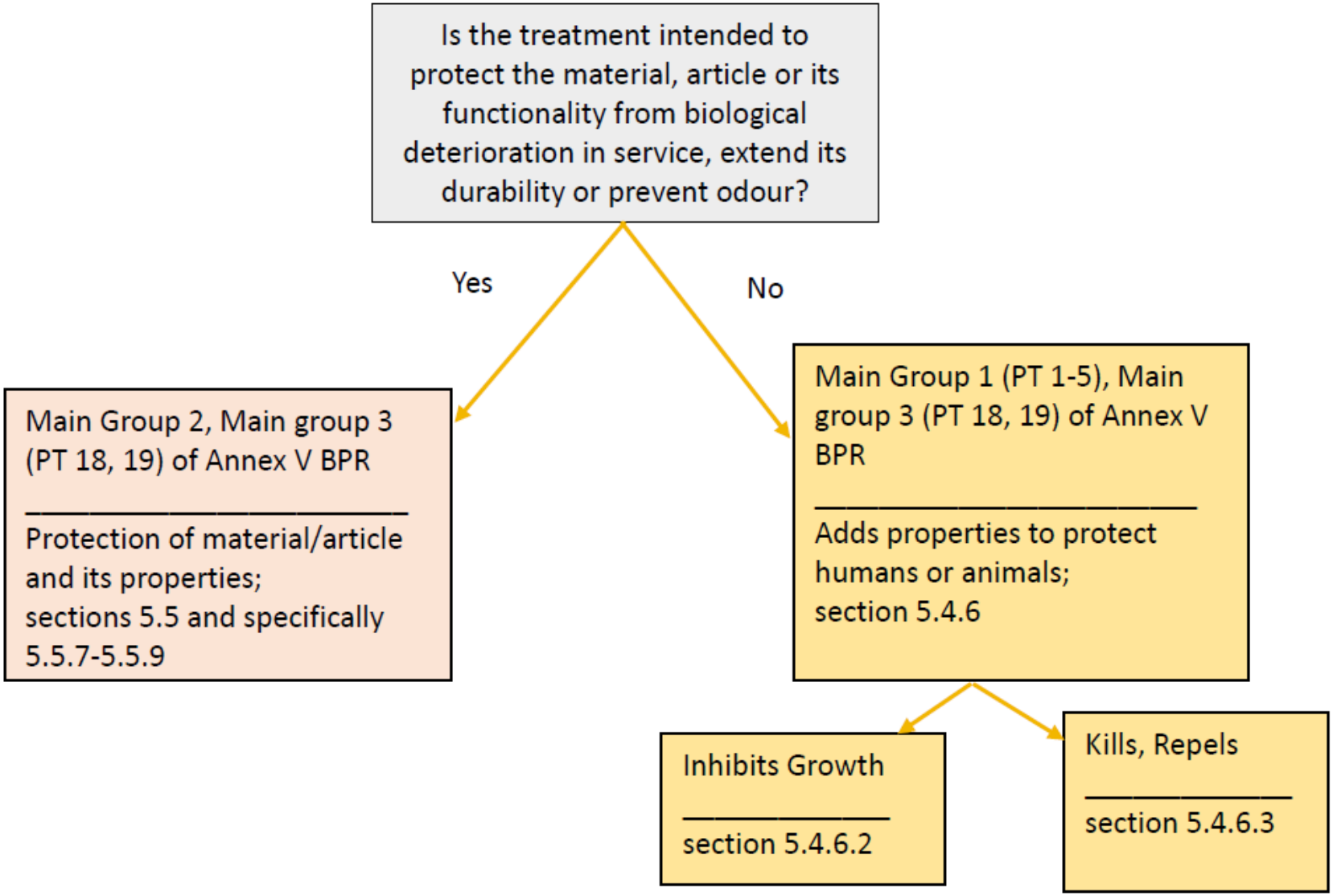
Allocation to EU product types

- Main group 1: Disinfectants → basic purpose to protect humans and animals
- Main group 2: Preservative → basic purpose to protect materials

Unclear claims: often ignore allocation to a main-group and disguise the purpose of the treatment. Efficacy tests for preservatives are done with materials which are not prone to bacterial degradation or with organisms which are not damaging the material.

From the Guidance

Figure 1: Decision scheme to distinguish between claims for material protection and claims for protection of humans and animals



Efficacy testing

- …needs to be done under normal conditions of use (regardless if preservation or hygienic purposes are intended)

- → that is if a coating is used on a surface, the service life conditions of the surface have to be simulated as realistically as possible

Normal conditions of use

In case the material is to be protected, testing for:

- UV, weathering, wearing, washing, abrasion, etc.

In case the user is to be protected, testing for:

- The type of contamination and the speed which would be required to avoid cross-contamination
- Humidity, soiling

Efficacy testing of TA/BP with a health claim

Tailored approach:

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Tailored approach:

"…The testing strategy entirely depends on the specific claim made. In the majority of cases, a claim can only be made for a specific type of final article, as use area and use conditions are decisive for describing the problem which the biocide must solve, and to demonstrate efficacy in exactly those conditions is necessary. …"

Efficacy testing of TA/BP with a health claim

Tiered approach:

- Tier 1 - Proof of principle: Tier one tests should document the efficacy of the incorporated biocide in the relevant matrix against relevant target organism(s) under relevant conditions (e.g. humidity, temperature).
- Tier 2 - Simulated Use: Tier two tests should document the efficacy of the incorporated biocide in the relevant matrix under real-life conditions (e.g. way of contamination, cleaning regimes, time to take effect) and the duration of the effect.

Efficacy testing of TA/BP with a health claim

Tiered approach:

Depending on the claim made (e.g. “kills bacteria on door-handles, reduces cross contamination”, “prevents mosquito-born deseases”), even Tier 3 testing can be necessary:

- Tier 3 - In-Use Evaluation/Field studies: To substantiate health benefit claims, treated and untreated articles would be tested via statistically designed use trials by a representative user group.

Determining the purpose of a treatment

Precondition: a clear problem description!

- Which organisms are relevant? Which life stages?
- How much humidity is involved?
- In which way are the organisms deposited/transferred?
- What influence has the carrier matrix on the release of the antimicrobial agent?
- What is the speed of the effect required?

Tailored testing

Example 1 bedside cabinet: reduce cross-contamination by ”killing on contact”

- Exactly the same material as used for the bedside-cabinet should be tested
- Relevant pathogens should be chosen (bacteria, ev. viruses?)
- The pathogens should be deposited via simulated skin-contact or via simulated aerosol
- Test conditions should be dry
- Relevant speed and kill-rate should be demonstrated (deviated from problem description)

Tailored testing

Example 2 air-conditioning unit: avoid spreading of legionella and/or mould-spores

- Exactly the same material as used for the AC-unit should be tested
- Relevant pathogens should be chosen (bacteria, ev. mould-spores?)
- Spreading via aerosol should be simulated
- Humid test-conditions, temperatur relevant for AC-system
- Relevant growth reduction should be demonstrated (deviated from problem description)

EU Claims matrix for TA

- In parallell to (liquid) disinfectants: claims matrix for BP to treat articles with disinfectant properties

Claim	Use conditions	Purpose	Performance standard
Killing on contact	Dry	To prevent cross-contamination with pathogens	Log 3 reduction within 5-60 minutes
Prevents bacterial/fungal growth	wet	To prevent contamination with pathogens	Prevents growth

Conclusions

- Clear distinction between material protection and protection of humans or animals
- Approval of the active substance for the right PT and use necessary
- Claims should reflect a solution to a real problem and be specific
- Solid articles require testing which is specific for the treated article in question, applying relevant matrices and simulating relevant use-conditions.

Thank you for your attention!