
BioGenius®

Challenges with the Guidance on the Biocidal Products Regulation (Volume II: Efficacy) for PT18 (Insecticides) and PT19 (Repellents and Attractants) – a Laboratory Perspective

BioGenius®
Dr. Catherine Linn

Agenda

- **Company profile - speaker's background**
- Guidance on the biocidal product regulation - chronology
- Test designs
- Test planning
- Conclusion

Independent service laboratory BioGenius GmbH

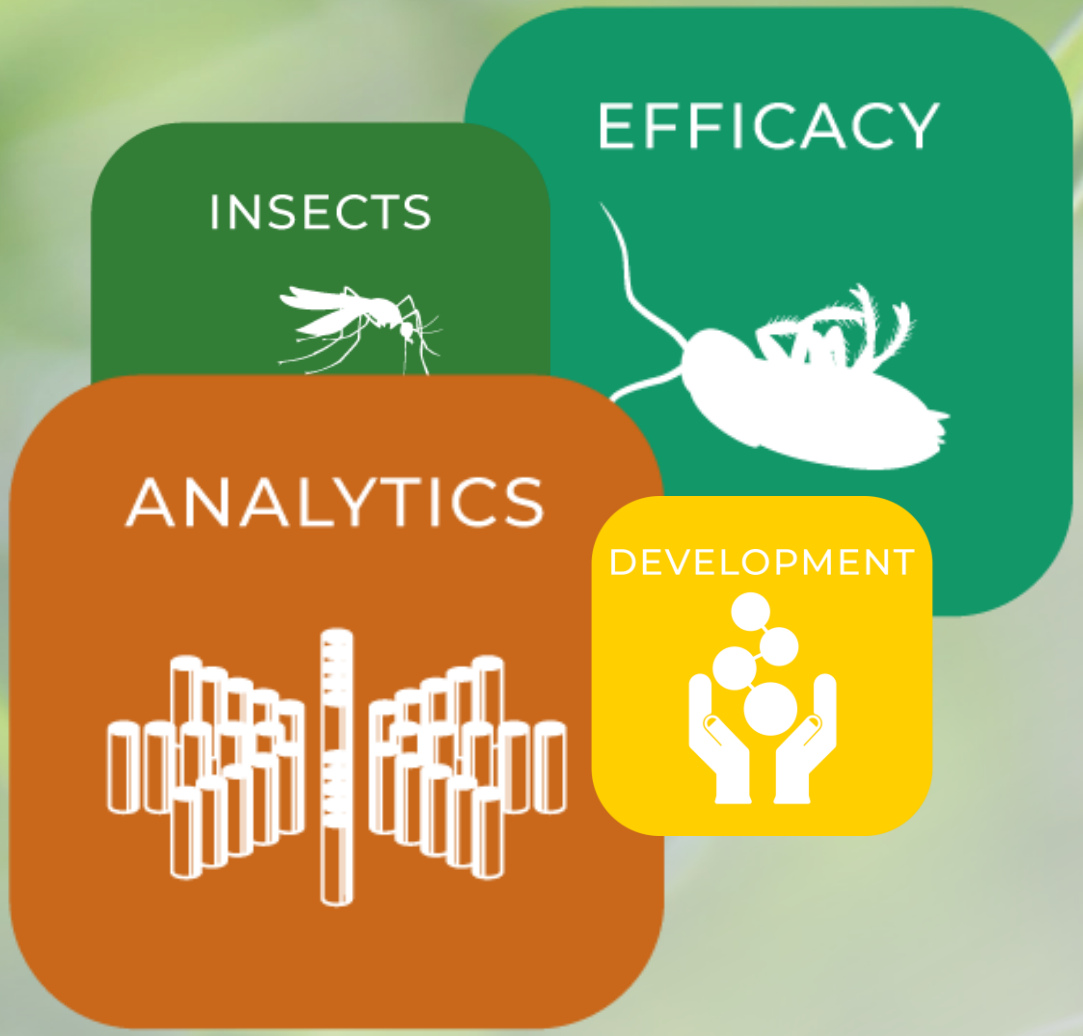
Formation in 2004

2.800 m² laboratory space

750 clients all over the world

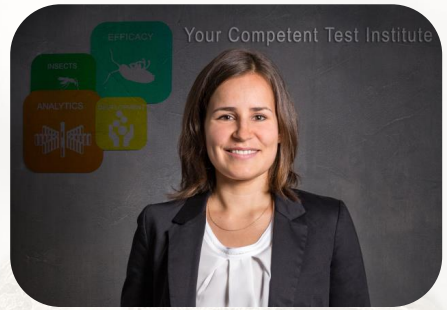
27 employees with higher education in chemical analysis, application technology and biology

More than 19 years of experience in international product registration



BioGenius Services

Speaker‘s background



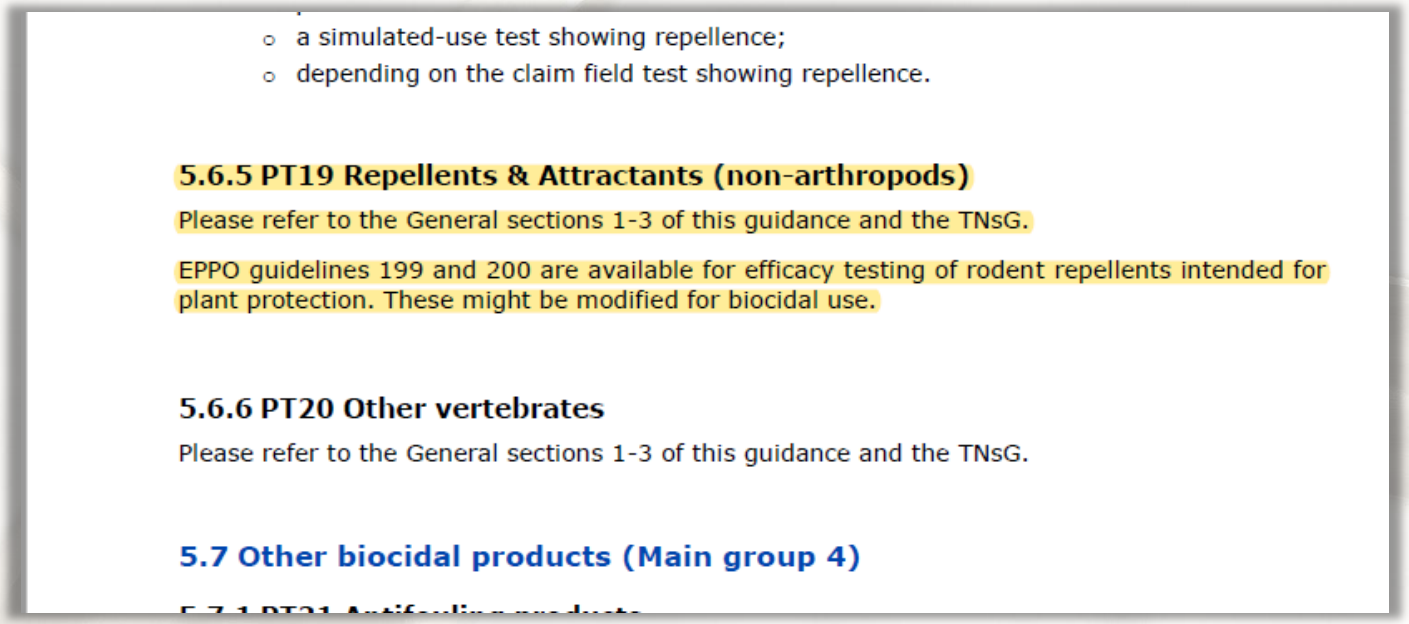
Dr. Catherine Linn

- > 7 years experience as project manager for efficacy testing (PT18/PT19)
- Technical support for customer
- Coordination of tests

Guidance on the Biocidal Products Regulation

Chronology:

- Version 1.0 (Febr 2017)
- Version 2.0 (Dec 2017)
- Version 3.0 (April 2018) - up to here: PT19 practically not described



- a simulated-use test showing repellence;
- depending on the claim field test showing repellence.

5.6.5 PT19 Repellents & Attractants (non-arthropods)

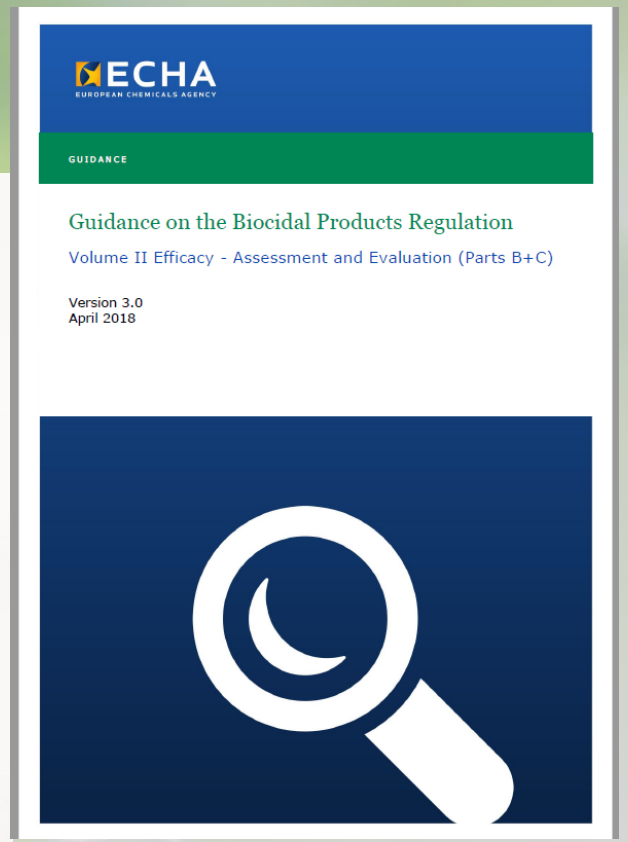
Please refer to the General sections 1-3 of this guidance and the TNsG.

EPPO guidelines 199 and 200 are available for efficacy testing of rodent repellents intended for plant protection. These might be modified for biocidal use.

5.6.6 PT20 Other vertebrates

Please refer to the General sections 1-3 of this guidance and the TNsG.

5.7 Other biocidal products (Main group 4)



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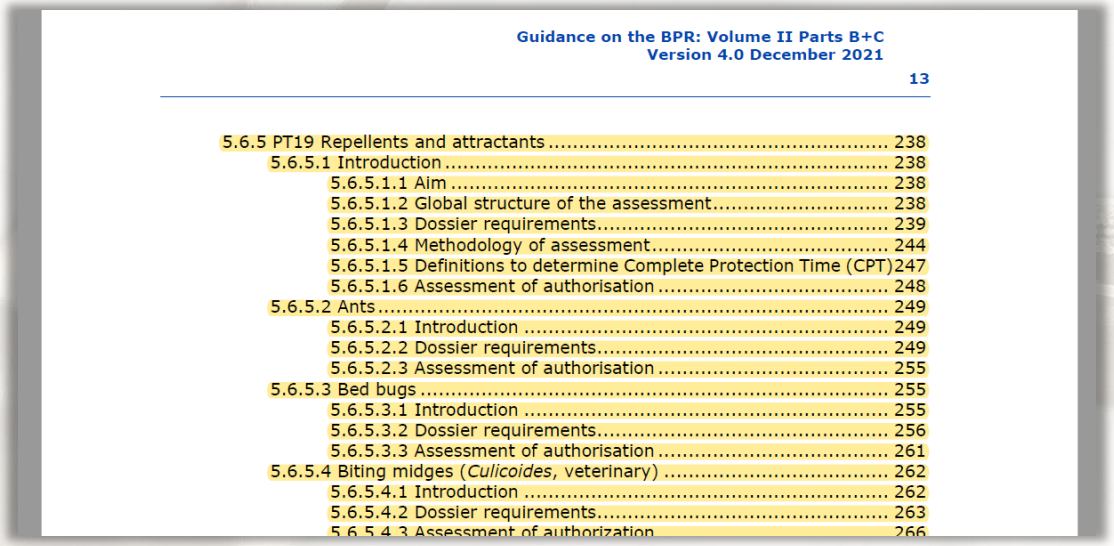
- Version 4.0 (Dec 2021): PT19 added, further tests, more detailed



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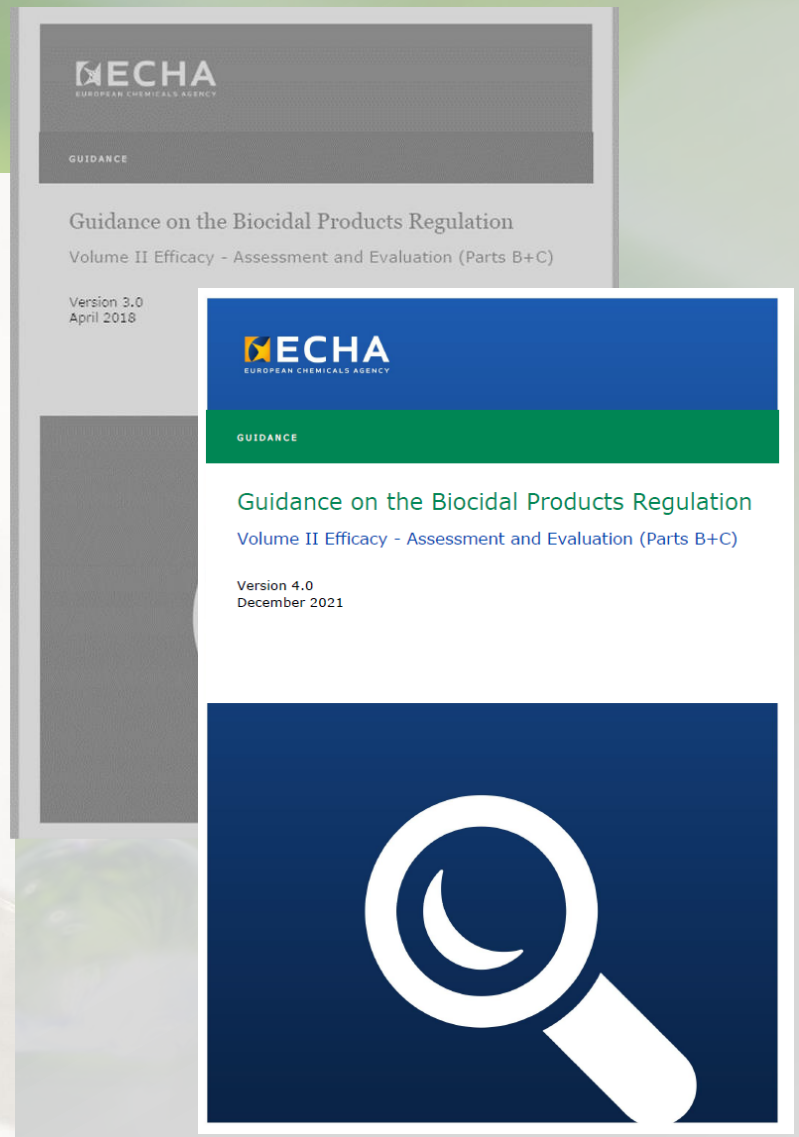

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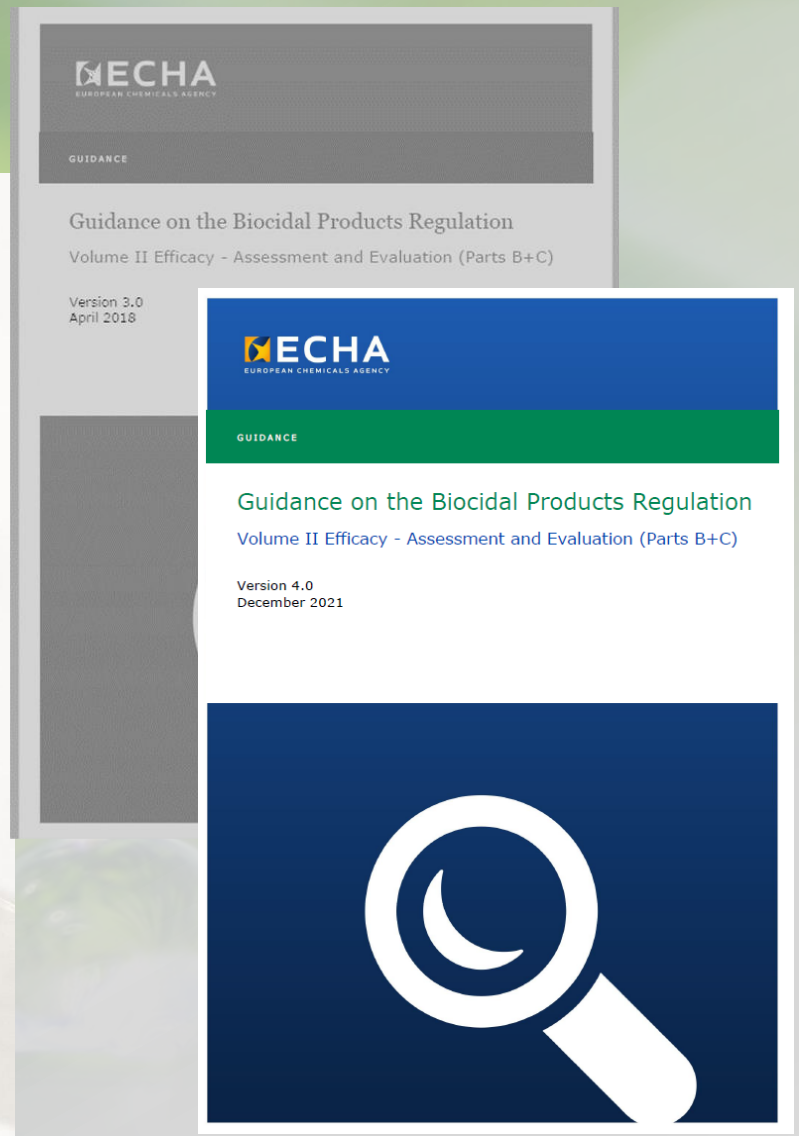
Figure 14: Room test volunteer wearing a light beekeeper suit, gloves and white hospital booties and one arm is protected by a "tube" of flexible material

After each efficacy test, the room needs to be cleaned thoroughly before the next test is initiated.

5.6.5.9.2.2.1.2.5 Efficacy assessment



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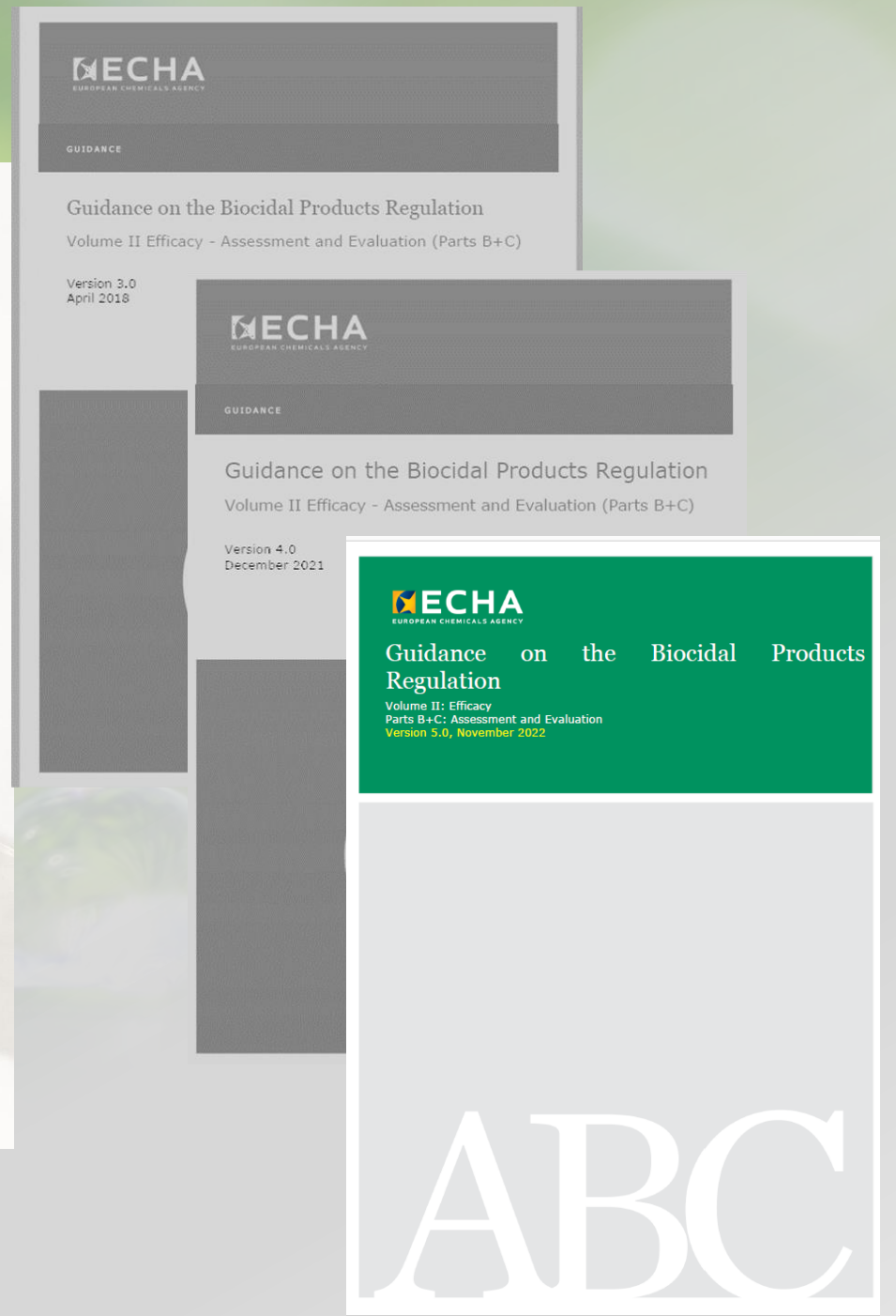

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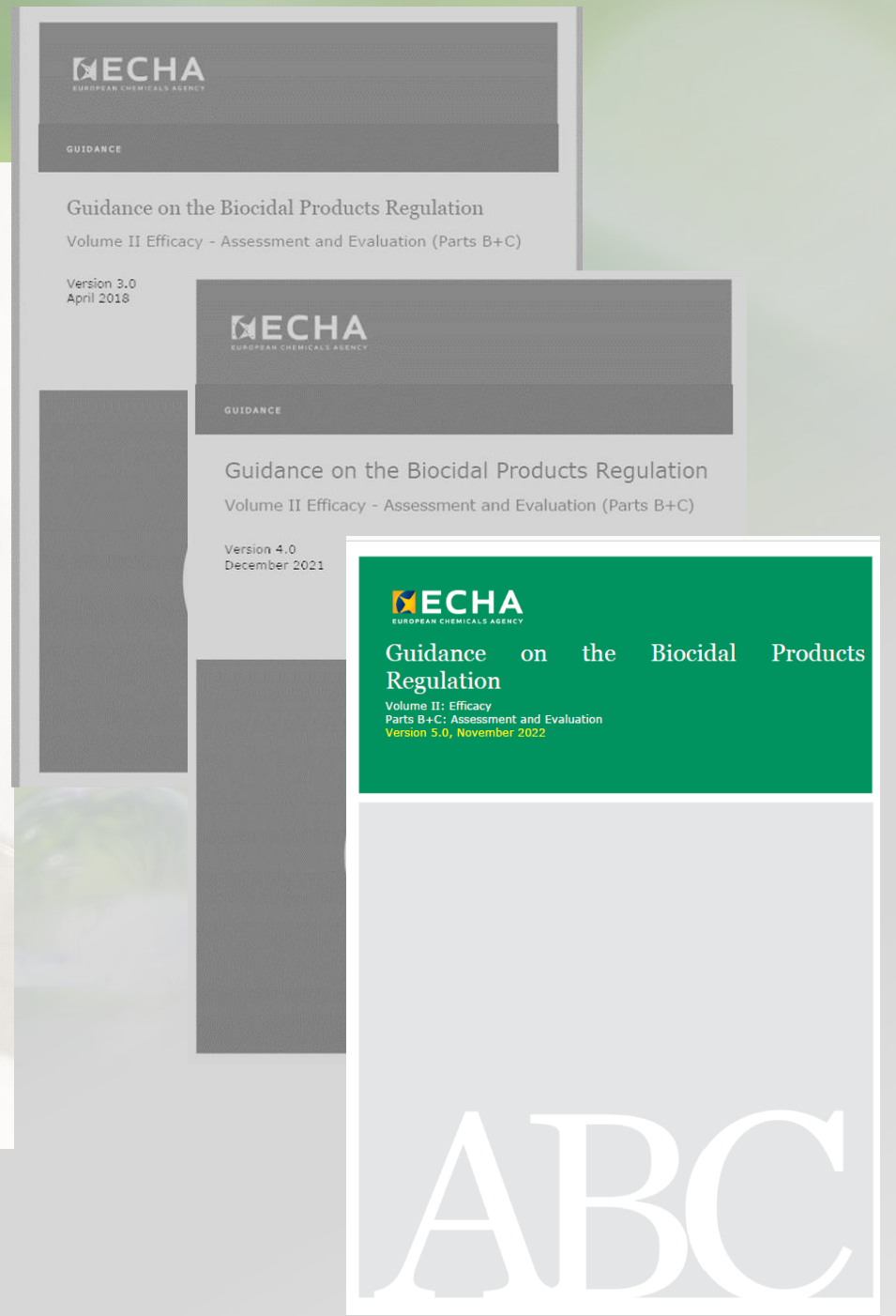
→ always test according newest release of guideline!



Test designs in Guidance on the Biocidal Products Regulation

Lab-test

Simulated-use test

Field test

(Images: BioGenius)

Complexity

Test designs in Guidance on the Biocidal Products Regulation

Well described passages: Mosquito repellent testing

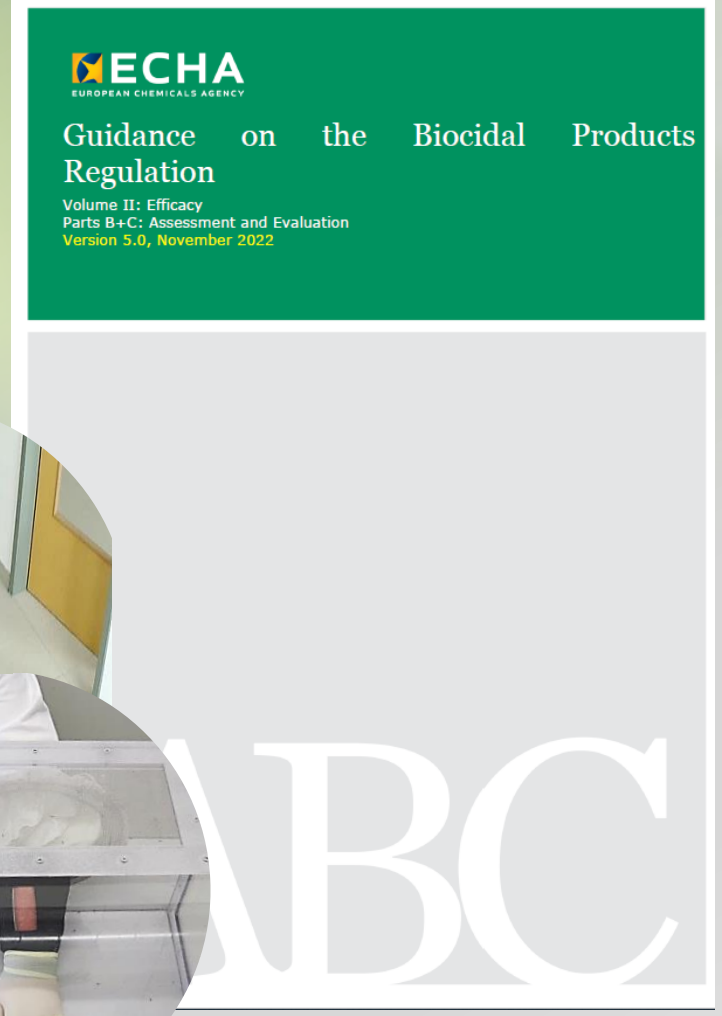
5.6.5.9.2.2.1 Products intended for use as topical repellents for human skin
- **5.6.5.9.2.2.1.2.2 Arm-in-Cage test**
- **5.6.5.9.2.2.1.2.3 Arm-to-Cage test**
- **5.6.5.9.2.2.1.2.4 Room test**

5.6.5.9.2.2.2 Repellents applied on clothing both for humans or animals

5.6.5.9.2.2.3 Products intended for use as topical repellent for animals

5.6.5.9.2.2.4 Products intended for use as general surface treatment

5.6.5.9.2.2.5 Products intended for use as spatial repellents
- **5.6.5.9.2.2.5.1.1 Landing/probing inhibition test**
- **5.6.5.9.2.2.5.1.2 Reduction of entry into an area**



(Images: BioGenius)

Test designs in Guidance on the Biocidal Products Regulation

Well described passages: Example Tick repellent testing

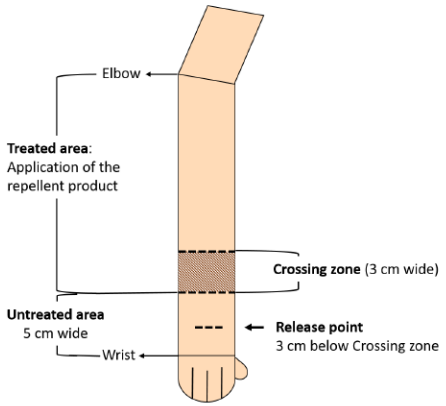


Figure 15: Upper side of a human test arm in a simulated-use test to show repellency against ticks. Dotted lines (release point, start and end of the 3 cm crossing zone) mark the lines that are drawn on both the control and the test arm before the test.

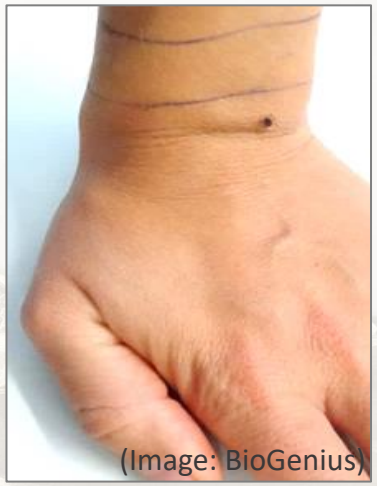
The following criteria for repellence should be used:

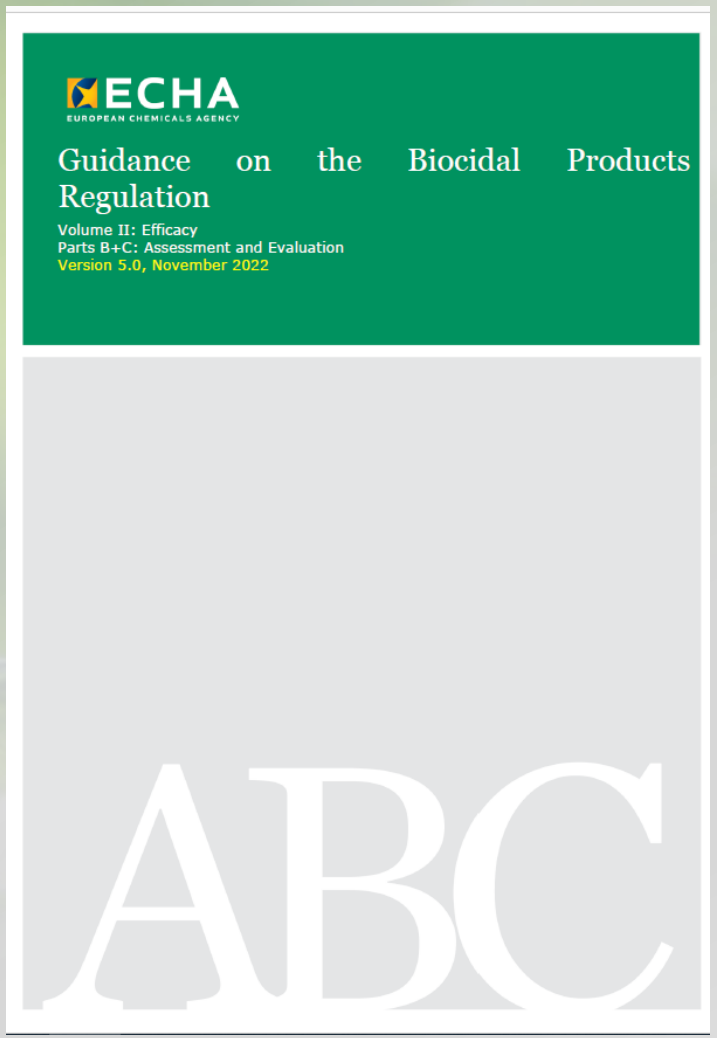
A tick is not repelled when it, within the 3 minutes observation time, either

- Crawls onto the treated area and remains there for 1 min, or
- Enters the treated area and further crawls across the 3 cm crossing zone within less than 1 min after entering the treated area.

A tick is repelled when it, within the 3 min observation time, either

- does not crawl into the treated area, i.e. stays on the untreated area or drops off from the untreated area of the treated arm after contacting the start line of the crossing zone (repellent border), or
- crosses the start line of the crossing zone (repellent border), but turns back into the untreated area within less than 1 min after entering the treated area, or


(Image: BioGenius)



Test designs in Guidance on the Biocidal Products Regulation

Poorly described passages: Example PT18 against Mites

of the claimed residual period). Exposure time should, preferably, be comparable to the time the mites might reasonably be expected to be in contact with a treated surface under practical conditions and assessors will take this factor into consideration when evaluating the data. Treated surfaces should include at least two porous and one non-porous substrate, representing surfaces that might, typically, be treated for mite control (e.g. plywood, painted plywood, textile fabric, according to the label claim). Mortality is normally assessed after 1 day up to 14 days post-exposure.

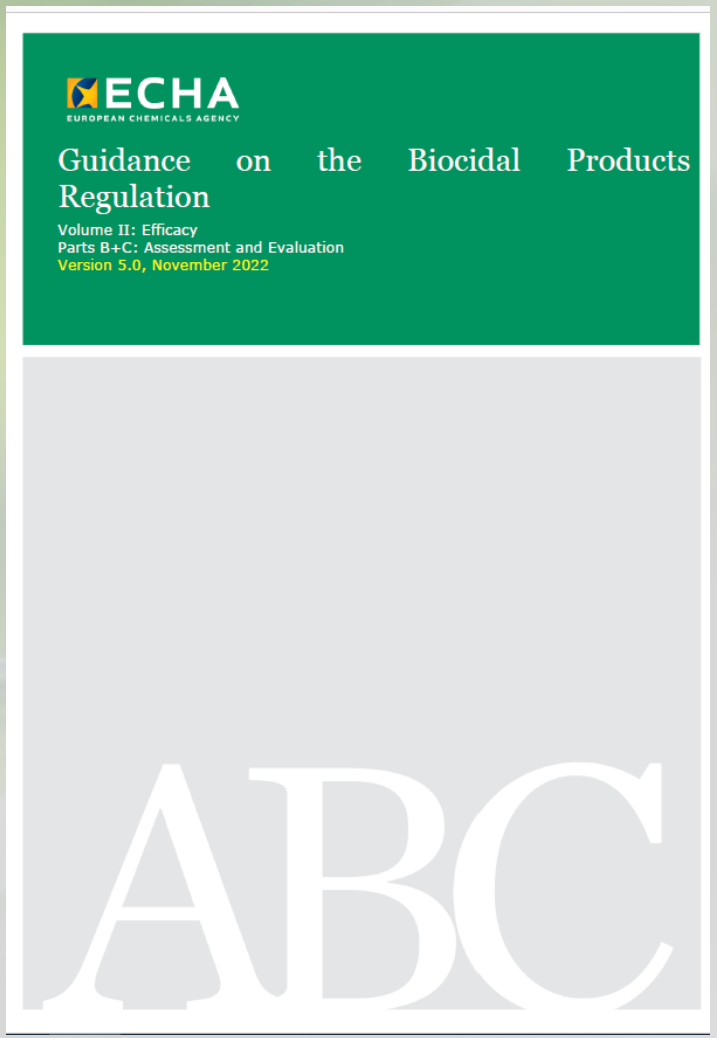
Simulated use tests

These tests are designed to mimic the practical use situation. For products that knockdown and kill mites simulated-use tests should be performed in which the product is applied according to the instruction for use. When products for general surface treatment are tested the mites must have a choice to be in contact with the biocide or not. The results should be compared to a control test, without biocide.

5.6.4.8.2.3 Requirements per type of claim

Specific mites: when specific mite species are mentioned in the claim (e.g. dust mite, red mite) both laboratory and simulated-use tests are required with the target species.


(Image: wikimedia.org)



Test designs in Guidance on the Biocidal Products Regulation

Poorly described passages: Example PT18 against Fleas

A control treatment without biocide with the same number of replicates should be included in all laboratory trials.

Simulated use studies

These tests are designed to mimic the practical use situation. The test should be performed according to the label claim.

Simulated-use tests can be waived if a robust field trial is submitted.

5.6.4.9.2.3 For claims made for products intended to be used as space spray treatments

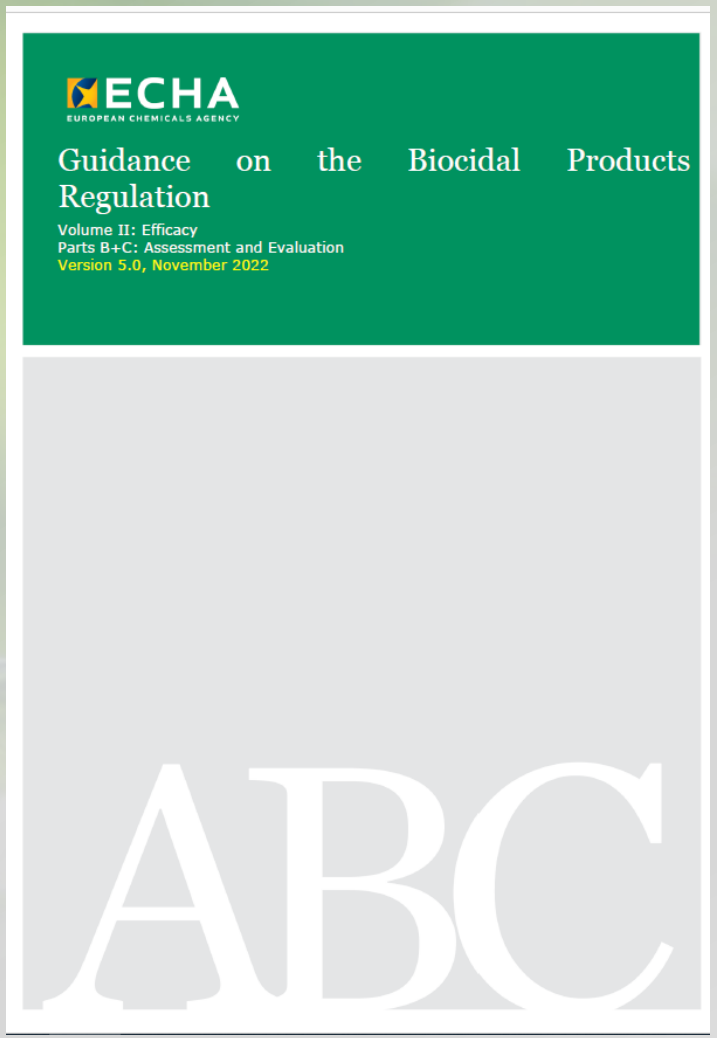
Some insecticides against fleas can be used in foggers. For the evaluation of these insecticides different types of laboratory, simulated-use tests and field tests can be used.

The efficacy test design should be defined for the available treatment method.

5.6.4.9.3 Assessment of authorisation

5.6.4.9.3.1 Norms and criteria

(Image: Wikipedia)



Test planning

How to proceed?

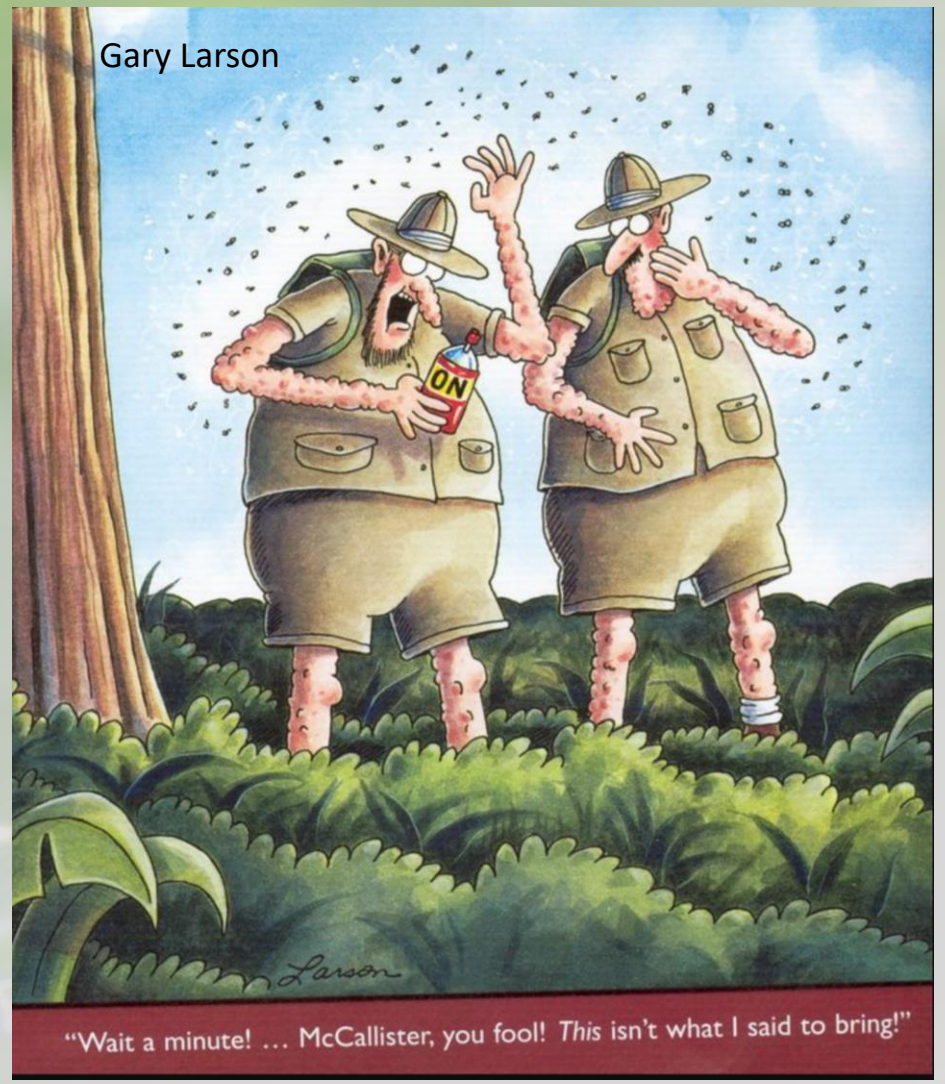
- Check relevant chapter in guideline
- Check BPR guideline if test described for similar species
- Check what is generally required for other species
- Check if other established guidelines are available
- Prepare a study plan to hand in to authority (e.g. pre-submission meeting)
- Adjust authorities' requirements to test set-up
- Start testing




Conclusion

- Guidance on the Biocidal Products Regulation constantly under revision
- Check what is required / be flexible
- Prepare a study plan to hand in to authority before test start
- Adjust test set-up to authorities' requirements

Conclusion – Never loose your focus and choose the right test!



Which PT: PT18 or PT19 or something else?

If PT19: Test for Attractant or Repellent?

Thank you!

BioGenius®

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