Technical Agreements for Biocides

Efficacy (EFF)

April 2024

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Preface

The Technical Agreements for Biocides (TAB) collects the general agreements of the Working Group (WG) which have not yet been included in any other BPR related guidance. These WG agreements are not the official view of ECHA, nor are they legally binding.

The TAB is publicly available in the public S-CIRCABC Interest Group[1].

Starting from May 2022[2], version numbers are assigned to single TAB entries and not the entire TAB document. The starting point ("version 1") for version numbering are entries in the TAB document published in July 2020. Changes to these entries are implemented as new entries with the same reference number but a higher version number. For entries where more than one version may be applicable, due to different applicability timelines for active substances and products, all applicable versions are provided.

The applicability of a TAB entry depends on the type of the entry and is shown separately for each entry. Publication date (i. e. reference date) and applicability dates are given as presented in Table 1 below. For more information on rules regarding applicability of guidance and TAB entries, see BPC-31 document "Applicability time of new guidance and guidance-related documents in active substance approval", CG document Doc. no. CG-33-2019-07 and CA document CA-July12-Doc.6.2d. Links to these documents are provided in footnotes to the table below.

For entries published more than two years before May 2022, the following text is included instead of publication dates: "*Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products*".

[1] https://webgate.ec.europa.eu/s-circabc/w/browse/ae26a5d2-a19b-42b8-a173-19bef3375d49

[2] Date of change to a TAB database system to manage the efficacy TAB entries.

Table 1: Type of TAB entries and applicability dates

	Applicability of the TAB entry	
Type of entry in the TAB	**(A) for active substance approval**	**(B) for product authorisation**
a) Editorial changes of the existing guidance	As of the publication date, for all dossiers (independent of the submission date of the dossier)	As of the publication date, for all applications (independent of the submission date of the application)[3,4]
b) Clarification/interpretation of the existing guidance (clarification/explanation)		
c) New guidance as new technical scientific advice is given which triggers new data requirements	Applicants: for dossiers submitted to the eCA 6 months after the publication of the TAB entry; eCAs: for CARs submitted to ECHA 6 months after the publication of the TAB entry; with specified exceptions[5]	For applications submitted to the eCA 2 years after the publication of the TAB entry[6]
d) New guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements)		
e) New guidance not triggering new data requirements where: • no guidance was available at all for a certain issue • new guidance is correcting major mistakes of former guidance • new guidance is considerably more reliable than former guidance.	As of the publication date, for all dossiers (independent of the submission date of the dossier)[5]	

[3] CG document CG-33-2019-07, "Date of applicability of: A) Technical Agreements of Biocides (TAB) entries and B) Conclusions of the Working Groups on the technical questions referred from CG" is available here: https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/00cafca0-81f6-44c2-8aaf-05cb1cbcff93/CG-33-2019-07%20AP%2014.3%20Date%20of%20applicability_TAB%20entries_CG%20quest_rev1.pdf; Please note that "publication date" in Table 1. equals to "reference date" in the CG-33-2019-07 document.

[4] In case the application is already at the peer review, applicability should be discussed on a case-by-case basis by the eCA and the applicant.

[5] The document "Applicability time of new guidance and guidance-related documents in active substance approval" agreed at the BPC-13 meeting is available here: https://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf/0b9c0634-eb54-4805-8b5e-b95f09a05632

[6] CA document CA-July12-Doc.6.2d, "Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products" is available here: https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf

Procedure

TAB is a living document that will be updated over time. Any suggestions on the need to change the content can be sent at any time to BPC-WGs@echa.europa.eu.

Proposals to include, revise or delete entries will be open for commenting by the EFF WG members in the frame of the commenting on the general minutes of each EFF WG meeting, where TAB entries agreed upon at the WG meetings will be included in the minutes. After the general minutes have been commented on, revised and agreed upon, ECHA will update the TAB document, if necessary, and publish it in S-CIRCABC. The procedure does not involve discussions at the WG. However, the TAB entry may be discussed at the WG, if necessary.

1. Virucidal activity against enveloped viruses

Version 2 (WGII2016, WGIII2022)

Is modified Vaccinia Virus Ankara (MVA) acceptable test organism to prove virucidal activity of biocidal products used as disinfectants in PT1, 2, 3 and 4?

MVA representing enveloped poxviruses is a sufficient test organism to confirm efficacy against enveloped viruses for biocidal products used in PT1: *Human hygiene* as hand disinfectants (hygienic and surgical), PT3: *Veterinary hygiene* as skin disinfectants, e.g. teat disinfection with a claim against enveloped viruses and also for biocidal products used as hard surface disinfectants in PT2: *Disinfectants and algaecides not intended for direct application to humans or animals* and PT4: *Food and feed area*.

Type of entry:	c) New guidance, as new technical scientific advice is given which triggers new data requirements
Publication date:	03/11/2022
Date of applicability for active substances:	03/05/2023
Date of applicability for products:	03/11/2024

Limited virucidal activity

Version 1 (WGII2016): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Please note that this is not the most recent version of the entry – see the latest version above.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022).

Is modified Vaccinia Virus Ankara (MVA) acceptable test organism to prove virucidal activity of biocidal products used as disinfectants in PT1, 2, 3 and 4?

MVA representing enveloped poxviruses is a sufficient test organism to confirm efficacy against enveloped viruses for biocidal products used in PT1: *Human hygiene* as hand disinfectants (hygienic and surgical) and PT3: *Veterinary hygiene* as skin disinfectants, e.g. teat disinfection with a claim against enveloped viruses.

Regarding biocidal products used in PT4: *Food and feed area* it is necessary to point out that for the time being a claim against enveloped viruses is not accepted. For biocidal products used in other PTs a virucidal activity within the meaning of full virucidal activity can only be claimed, i.e. against both enveloped and non-enveloped viruses.

2. PT14: Applications for changes with lower concentration of an active substance or new applications for product authorisations

Version 2 (WGIV2016, WG-IV-2021)

What kinds of efficacy data are requested as a part of an application for a change of PT14 biocidal products authorisation with a lower concentration of an active substance as well as for a new application for product authorisation, if palatability data from a product with the same formulation (except a higher concentration of the active substance) are available?

1. Products containing warfarin, chlorophacinone and coumatetralyl (FGARs):

   Efficacy has to be demonstrated in laboratory choice and field tests or semi-field and field tests following the current Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C), chapter PT14 Rodenticides.

2. Products containing bromadiolone, brodifacoum, difenacoum, difethialone and flocoumafen (SGARs):

   Efficacy of the 'old' formulation has to be demonstrated in laboratory choice and field tests, or semi-field and field tests following the current Guidance on the BPR:

Volume II Efficacy - Assessment and Evaluation (Parts B+C), chapter PT14 Rodenticides.

In case a complete efficacy data package for the 'old' formulation has been submitted including at least 20% of palatability in the laboratory tests and the product composition remains unaltered except lower concentration (≥25ppm) of an active substance only new field tests are required.

In case the palatability in the 'old' formulation is lower than 20%, new laboratory choice and field tests or new semi-field and field tests with the product under authorisation are required.

For products with active substance concentration <25ppm, new laboratory choice and field tests or new semi-field and field tests are required.

For any other change in product composition, e.g. bait formulation, that can affect bait attractiveness, other than lower concentration of an active substance, efficacy and palatability have to be demonstrated in new laboratory choice and field tests or new semi-field and field tests.

Type of entry:	c) New guidance, as new technical scientific advice is given which triggers new data requirements
Publication date:	30/05/2022
Date of applicability for active substances:	30/11/2022
Date of applicability for products:	30/05/2024

PT14: Applications for major changes with lower concentration of an active substance

Version 1 (WGIV2016): Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

Please note that this is not the most recent version of the entry – see the latest version above.

What kind of efficacy data are requested as a part of application for major change of PT14 biocidal products with lower concentration of an active substance?

Based on current experience the following approach applies:

- laboratory tests

  palatability - in choice tests it should absolutely be validated (criteria of 20 % should be met without exceptions) and the same amount of bait as well as challenge diet should be provided.

  Proposal for laboratory tests:

  – systematic comparison between laboratory tests with old and new formulation to check the increase of palatability (valid if active substance is the only change);
  – longer exposure time accepted only if palatability > 20 % and no signs of animal suffering.

- field tests[7]: efficacy must be demonstrated according to the claims for two reasons:
  – environmental risk assessment takes into account the application rate per surface unit, then quantities applied in the field tests has to be considered;
  – in case of high infestation, bait stations should be checked and refilled more often than every 2/3 days or once a week;

  Proposal for field tests:

[7] Only for roof rat (Rattus rattus) it is acceptable to demonstrate efficacy:
– in two or more well-conducted semi-field trials, in regions where infestations of roof rats are quite rare, or
– two (or more) well-conducted field trial(s) in regions with infestations of roof rats.

- quantities in bait stations must follow the label claims, particularly in case of an active substance decrease.

In case a complete efficacy data package for the 'old' formulation has been submitted including at least 20% of palatability in the laboratory tests and the product composition remains unaltered except lower concentration (≥25 ppm) of an active substance only new field tests are required.

In case the palatability in the 'old' formulation is lower that 20%, choice and field tests are required.

For products with active substance concentration <25 ppm, choice and field tests are required.

For any other change in product composition other than lower concentration of an active substance, efficacy and palatability have to be demonstrated in choice and field tests.

3. Devices generating the active substances by electrolysis

Version 1 (WGV2016): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Should the devices generating the active substances by electrolysis be taken into account when authorising biocidal products?

If the active ions are produced in situ by electrolysis the device can affect the efficacy. Therefore, at product authorisation stage the efficacy tests should always be done with the electrodes in a specified device or devices with a defined output range. Information on how the device is protected for under- and overdosing should also be given. However, it shall be noted that the device itself is not subject to product authorisation.

4. PT18: Shelf life of bait products

Version 1 (WGV2016): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Could 'a long period storage' agreed for PT14 products be accepted with reference to the requirements on palatability studies corresponding to more than 24 months also for PT18 biocidal products?

The palatability testing defined for PT14 products can also be applied to PT18 biocidal products. Therefore, efficacy testing should only be provided for the following cases:

- bait products with preservatives that claim a shelf life longer than 24 months;
- bait products without preservatives that claim a shelf life longer than 12 months;
- bait products for which the degradation of the active content is >10% and assessment of the degradation on the efficacy is needed to substantiate the shelf life claim.

For bait products with a shorter shelf life claim than stated above, no efficacy tests of aged bait (i.e. product at the end of maximum storage) have to be provided. For these products it is sufficient to provide tests on fresh bait (i.e. newly produced product).

5. PT18: Insecticide against crawling and flying insects intended to be used in aircrafts

Version 1 (WGI2017): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

In the context of the authorisation of an insecticide (against crawling and flying insects) intended to be used in aircrafts, shall a field test (i.e. in the specific environment of aircraft in realistic settings) be submitted?

There is currently no guideline available that describes a possible set-up for semi-field trials in a laboratory. For biocidal products authorised as insecticides for aircraft disinsection semi-field tests in line with the WHO guidelines (specific to mosquitoes) simulating realistic conditions of use, using cabin crew training sites or decommissioned aircrafts shall be submitted.

6. PT1-5: Co-formulant(s) being a potential active substance in disinfectant products

Version 1 (WGII2017): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Note: This TAB entry had been modified and implemented in Volume II, Parts B+C efficacy guidance (3 November 2022).

How to exclude or confirm that a co-formulant in a disinfectant product is a potential active substance?

In case during evaluation phase of biocidal product containing one or more co-formulant(s) the evaluating Competent Authority regards one or more of the co-formulant(s) to be an additional active substance the applicant should provide a justification on its function in the formulation and how this will not influence efficacy of the product. Only in cases where a justification is not conclusive tests should be provided to demonstrate the 'non-activity' of the co-formulant(s). The following strategy has been developed[8].

A) Three kinds of tests have been identified. The eCA may request one, two or all of them, as necessary and appropriate.

Test 1: The biocidal product without active substance is tested.

The active substance(s) are replaced by water or, when justified, any other suitable substance(s). The test should be performed at the recommended concentration of the product.

If the active substance(s) cannot be replaced for whatever reason, the concentration of the product without active substance has to be decreased accordingly[9].

In cases where in this test a high lg reduction is seen, further tests 2 with each co-formulant under question would be required to verify which co-formulant is causing this effect.

Test 2: Each co-formulant under question is tested alone.

The concentration (of the co-formulant) in the test has to be adapted to the relative amount of the co-formulant in the biocidal product[10].

Test 3: The biocidal product without the co-formulant is tested.

[8] The conclusions of the test performed according to this strategy are only valid when at least one active substance is identified.
[9] Example: Amount of the active substances is 30g/100g in the biocidal product. Concentration used for claiming bactericidal activity is 2.0 %. Concentration in Test 1 should be 2% of 70.0g = 1.4 %.
[10] Example: Amount of the co-formulant is 3.0g/100g in the biocidal product, concentration used for claiming bactericidal activity is 3.0 %, concentration of the co-formulant in Test 2 should be 3% of 3.0g=0.09 %.

Two products are tested in parallel: the biocidal product and the same product, but without the co-formulant that should be replaced by water or, when justified, any other suitable substance(s). Separate testing may be performed for each co-formulant under question removing only one co-formulant at a time. The test should be performed at the recommended concentration of the product.

Any deviation from a test method above must be clearly described and a justification for any deviations provided.

B) Each test should be performed as a (modified) Phase 2, step 1 test. For all tests it is requested to show a definite lg reduction considering the detection limits of the respective tests, i.e. within the detection limits precise lg reduction values need to be given such as 2.68 lg instead of <5.00 lg. The EN tests may be adapted accordingly, if necessary. For instance, extra dilution steps will be needed for these tests to show lg reductions around 3.00 and 3.50.

C) Generally, these tests should be performed with bacteria.

D) Test 3 should be performed under the test conditions (interfering substance/soiling, contact time) used for a product claim, demonstrating that the product without the co-formulant is still efficacious under use conditions.

Since both tests, 1 and 2 are tests without active substance the conditions should not be as severe as under use conditions. These Phase 2 step 1 tests should be performed with proportionate amount of interfering substance and with the longest contact time claimed for the product.

E) In all tests the pH of the test solution should be adjusted to the pH of the biocidal product.

F) To demonstrate in tests 1 and 2, that the co-formulants under question are not active substances the lg reduction should be at least 2 lg lower than the required lg reduction in the EN Phase 2 step 1 test performed. For test 3, the lg reduction of the two products should be similar, i.e. show no more than 1.50 lg difference.

G) Schematic overview of possible test results and conclusions

Test	Test product*	Result (lg reduction)	Conclusion
Test 1	BP without AS	<3**	all CFs are not active substances in this product
		≥3**	one or more or the combination of the CF might have biocidal activity in the product
Test 2	Only CF	<3**	this CF is not an active substance in this product
		≥3**	this CF might be acting as an active substance in this product
Test 3	BP without CF	≥3.5**	this CF is not an active substance in this product
		<3.5**	this CF might be acting as active substance

* BP = biocidal product; AS = active substances; CF = co-formulant.
** lg reduction in an EN Phase 2 step 1 tests for bacteria (EN1276; EN13727; EN1656).

7. PT4: Disinfection of packaging before filling

Version 1 (WGII2017): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022).

What are the testing requirements for aseptic packaging applications (PT 4) before filling in relation to:

The following data should be provided to demonstrate efficacy of a product for aseptic packaging applications:

1. Efficacy should be demonstrated by validation of the product in the disinfection process using aseptic filling devices and packaging material that are representative for the intended use of the product[11]. Phase 2, step 1 and phase 2, step 2 tests are not required;
2. A negative control with all claimed target organisms should be performed (with e.g. water) to demonstrate that the high temperature alone is insufficient to achieve sufficient control of microorganisms. Since it might be expected that bacterial spores survive the use conditions, it can be possible to exclude a negative control for bacterial spores if sufficient scientific justification is provided;
3. Products are efficacious under certain conditions, e.g. temperature, concentration, contact time, etc. Products can be tested in aseptic filling machines that meet/use the (worst-case) conditions for the product to be efficacious. The conditions to be taken into account and reflected in the test report:
    - surface temperature;
    - concentration;
    - amount of product applied;
    - contact time;
    - relative humidity;
    - dose/application rate;
    - inner surface properties of the packaging.
4. Generally, only bacterial spores survive these conditions, while vegetative bacteria and yeasts will be killed in the negative control. Therefore, demonstrating efficacy against bacterial spores (e.g. *Geobacillus stearothermophilus*) is sufficient for an efficacy claim against other groups of microorganisms for aseptic filling applications. However, when the negative control shows survival of any other target organisms (e.g. fungal spores) these should also be tested by validation of the product in the disinfection process.

[11] Test protocols for hygienic/aseptic devices according to class III, IV and V have been published by the Association of German Machinery and Plant Constructions (VDMA). Taking into account the data requirements listed in this TAB, appropriate test protocols to demonstrate efficacy can be developed based on these VDMA methods.

8. Room disinfection - how to ensure the proper use

Version 1 (WGV2017): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022).

Should the advice for biological validation[12] and, in cases where there are monitoring methods available, also for chemical validation[13] be included in the use instruction in the SPC?

Yes, this advice should be given to validate the use instructions for the vaporisation regime (dosing, temperature, humidity, concentration in the air, and contact time during each phase) for specific circumstances of the room (volume, presence of furniture, equipment, cables etc.).

If room disinfection with vaporised biocidal product is claimed, it is highly recommended to include in the use instructions in the SPC the advice that biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

In case there are methods available for chemical monitoring the active substance in the air or on surfaces, it is highly recommended to include in the use instructions in the SPC the advice that besides biological validation chemical validation should be performed. In case of hydrogen peroxide this can be done with H_2O_2 test strips, or with a device that measures ppm H_2O_2 in the air.

9. Textile disinfection

Version 1 (WGV2017): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Note: These TAB entries are implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022).

9.1 Efficacy testing

What kind of efficacy tests should be performed for biocidal products used as disinfectants for textile either or not in combination with detergents?

For biocidal products used as disinfectants in combination with detergents, e.g. in the pre- and main-wash the following approach should apply:

- Phase 2 step 1 test should be done in combination with the detergent and disinfectant. All claimed disinfectant/detergent combinations and the claimed conditions should be tested, unless worst case conditions can be justified (e.g. testing only lowest and highest concentrations of same disinfectant/detergent combination).

[12] Biological validation demonstrates which dosing and parameters for vaporisation (temperature, humidity, concentration in the air, and contact time during each phase: preparation, conditioning, disinfection, and terminal phase) should be used for optimal disinfection of the room in question, i.e. sufficient killing of organisms on all surfaces in the room. Biological validation is performed by monitoring efficacy against a challenging test organism (e.g. *Geobacillus stearothermophilus* spores) during the room disinfection process. Chips with spores are placed at places that are difficult to reach. After the disinfection, the chips can be processed according to, for instance, the AFNOR test NF T72-281.

[13] Chemical validation demonstrates which dosing and parameters for vaporisation (temperature, humidity, concentration in the air, and contact time during each phase: preparation, conditioning, disinfection, and terminal phase) should be used for optimal disinfection of the room in question, i.e. sufficient active substance (according to the dosing instructions) on all surfaces in the room. Chemical validation is performed by monitoring the amount of active substance in the air (or on the surfaces) during disinfection.

- Phase 2 step 2 test should be done according to EN 16616. Furthermore as a minimum the disinfectant/detergent combination should be tested. In principle all claimed disinfectant/detergent combinations and the various conditions claimed should be tested, unless worst case conditions can be justified (e.g. testing only lowest and highest concentrations of same disinfectant/detergent combination).

For biocidal products used as disinfectants and applied separately without a detergent, e.g. disinfection in the last rinse for textile the following approach should apply:

- Phase 2 step 1 test should be performed without a detergent.
- In case a disinfectant is applied in a such way that it does not come into contact with a detergent, a justified suitable test procedure for the Phase 2 step 2 test should be provided, e.g. a modified EN 16616 test without detergent, with justification for the use of soiling that mimics the clean conditions. To demonstrate efficacy in this modified test, test organisms should be added at the same step of the process as the disinfectant.

For combined cleaner-disinfection products used as disinfectants for textile the following approach should apply:

- Phase 2 step 1 and Phase 2 step 2 tests should be done with the combined cleaner-disinfection product (without adding an extra detergent since the detergent is already included in the product).

Table 1. Efficacy testing versus disinfection at various steps of the washing process.

Disinfection in	Presence detergent/disinfectant in washing step	Testing	Test conditions
Pre-wash*	detergent and disinfectant	Phase 2, step 1 Phase 2, step 2	Detergent and disinfectant at use concentration Temperature and contact time as in use instructions Dirty conditions
Main wash*	detergent and disinfectant	Phase 2, step 1 Phase 2, step 2	Detergent and disinfectant at use concentration Temperature and contact time as in use instructions Dirty conditions
Last rinse*	disinfectant	Phase 2, step 1 Phase 2, step 2	Temperature and contact time as in use instructions Clean conditions**

* Steps of the assumed washing cycle are: 1) pre-wash, 2) main wash, 3) rinse.
** EN 16616 describes dirty conditions only. When clean conditions are in line with the intended use testing can be done with a modified EN test with justified modifications.

9.2 Test organisms for elevated temperatures

What test organisms should be used for textile disinfection at elevated temperatures?

The recommended test organisms for efficacy testing of textile disinfection processes are listed in Table 2. Depending on the intended claims the following test organisms can be chosen to be tested at the claimed temperature. Minimally a bactericidal and yeasticidal claim should be made for textile disinfection.

Table 2. Overview of test organisms versus temperature

Claimed temperature (T)	BPR Guidance	EN 16616	Recommendation
T < 40ºC	Organisms as indicated in EN 16616	*Pseudomonas aeruginosa* *Escherichia coli* (K12) *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans* *Aspergillus brasiliensis* *Mycobacterium terrae* *Mycobacterium avium*	Organisms as indicated in EN 16616
40ºC ≤ T < 60ºC*	*Enterococcus faecium*	*Pseudomonas aeruginosa* *Escherichia coli* (K12) *Staphylococcus aureus* *Enterococcus hirae* *Candida albicans* *Aspergillus brasiliensis* *Mycobacterium terrae* *Mycobacterium avium.*	*Pseudomonas aeruginosa,* *Escherichia coli* (K12) *Staphylococcus aureus* ***Enterococcus faecium*** *Candida albicans* *Aspergillus brasiliensis* *Mycobacterium terrae* *Mycobacterium avium*
T ≥ 60ºC	*Enterococcus faecium*	*Enterococcus faecium*	*Enterococcus faecium*

* Volume II Efficacy, Assessment + Evaluation (Parts B+C), section 5.4.0.4.4 is still applicable: "When efficacy against mycobacteria, yeasts and fungal spores is claimed and no temperature resistant strains are available, the standard test organisms should be tested at the maximum temperatures for which the test is validated." These tests (Phase 2 step 1 tests) should be done in addition to the tests above when the claimed temperature is higher than the maximum validated temperature for that test organism (standard organisms as for <40 ºC).

10. PT4: Applicability of the Mechanical Engineering Industry Association (VDMA) guidelines for evaluation of disinfection of packaging before filling

Version 1 (WGII2018): Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022)

Can the detailed guidelines developed by the German Food Processing Machinery and Packaging Machinery Association (1-6) be applied in efficacy evaluation of "Disinfection of packaging before filling" as described in point 7 of this TAB document?

The use "Disinfection of packaging before filling" can be described using the combined description of class III, IV and V machines from VDMA guidelines (1).

The microbiological challenge test (2) is acceptable as the minimum efficacy requirement. As already mentioned in point 7 of this document a negative control should be performed, in order to demonstrate that high temperature alone is insufficient to achieve sufficient control, and there is a need for a biocidal product. The negative control may be excluded

for the tests with bacterial spores, under condition that sufficient justification is provided. In addition, a validation similar to EN standards may be requested.

More detailed information than that described in VDMA document (3) should be included in the test report, e.g., dose of disinfectant, relative humidity, contact time, temperature, information on cleaning of the materials prior to the disinfection procedure and surface properties of packaging material.

References[14]:

1. Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application. VDMA Nr. 2, English edition July 2007. https://nuv.vdma.org/documents/256988/1036554/FS_2_2000_2nd+ed+2006_english.pdf
2. Guide to Checking the Microbiological Safety of Hygienic Filling Machines of VDMA Classes IV and V. VDMA Nr. 12. English edition August 2008. https://nuv.vdma.org/documents/256988/1036554/FS_12+2007+English.pdf
3. Code of Practice Filling Machines of VDMA Hygienic Class V: Testing the Effectiveness Packaging Sterilization Devices. VDMA Nr. 6, English edition September 2008. http://www.vdma.org/documents/256988/1387903/Download1
4. External Sterilization of Packaging Materials VDMA Nr. 14, English edition July 2007. http://nuv.vdma.org/documents/256988/1036554/FS_14_2006_English.pdf
5. Code of Practice Testing Aseptic Plants: Sterilizing the Sterile Zone in a Machine Interior VDMA Nr. 8. English edition March 2004. https://nuv.vdma.org/documents/256988/1036554/FS_08_2003_English.pdf
6. Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods Minimum requirements and basic conditions for operation in accordance with specification VDMA Nr. 10, English edition November 2005. http://www.vdma.org/documents/256988/1388294/Download1

11. Room disinfection – claimed and tested room size

Version 1 (WGIV2018): Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

Note: This TAB entry had been modified and implemented in Volume II, Parts B+C efficacy guidance (3 November 2022)

What room size should be tested for a room outside of the description in NF T 72-281?

For biocidal products having claims for room disinfection it was noticed that the rooms to be disinfected vary from rather small to quite large, e.g. in food and feed areas.

For a claimed room size outside the description in NF T 72-281 the room sizes indicated in Table 1 should be tested. It is strongly recommended to follow the test set-up in NF T 72-281 for all tested volumes.

Table1: Room size to be tested versus room size claimed

Claimed volume (m^3)	Volume (m^3) to be tested in a semi-field trial
<30	claimed volume(s)**
30 – 150	30 – 150*
>150	claimed volume(s)*

* According to NF T 72-281 test (version 2014)

** Fixed volumes are tested and claimed, or a volume range is claimed based on a test in the maximum volume.

In addition, the following sentence concerning mandatory (micro)biological (and chemical, if applicable) validation should also be included in the SPC: *"The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter."*

[14] The reader should check the website of the Mechanical Engineering Industry Association (VDMA): http://www.vdma.org for new or updated standards.

12. PT1-5: Efficacy testing of stored disinfection products during shelf life

Version 1 (WGV2018): Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022)

What should be taken into account for efficacy tests in case the active substance concentration decreases with more than 10% during shelf life of the biocidal product?

If the active substance concentration decreases with more than 10% during shelf life of the biocidal product, efficacy tests should be performed demonstrating efficacy of stored product (see TAB-APCP, point 2.4). In general, efficacy shelf life tests are acceptable if, at least one of the following issues is addressed:

- Efficacy shelf life test should preferably be performed with aged products that have been stored for the complete claimed shelf life.
- In some cases, it is also acceptable when efficacy shelf life tests are performed with fresh product[15] with an active substance concentration comparable to the concentration measured in a stored product after the claimed shelf life. In those cases, a robust justification and/or a clear indication from the physico-chemical assessment is required which explains why age-related changes in co-formulants would not have an effect on efficacy of the aged product, and why reduction in the quantity of active substance would be the only issue to be addressed.

13. PT6-13: Relevant test bacteria for preservatives

Version 1 (WGVI2018): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

What kind of bacteria as test organisms are required for a general bacteriostatic/bactericidal claim?

Bacteria as target organisms are more relevant in liquid matrices (PTs 6, 11, 12, 13) than in solid matrices (PTs 7, 9, 10). Thus, this conclusion is applicable to liquid matrices.

1. For a general bacteriostatic/bactericidal claim valid data proving efficacy against both:
   a. at least one Gram-negative, and
   b. one Gram-positive test organism,
   with a total of at least four test organisms is required.
2. When mixed consortia (Gram-negative and Gram-positive bacteria in the same consortium) are used, data submitted on the consortium as a whole will be accepted.
3. *Pseudomonas* spp. is a mandatory Gram-negative test organism for liquid matrices to preserve.

   In case that, in an efficacy test, the chosen *Pseudomonas* spp. does not grow, but the other test bacteria do (only relevant if species are tested separately, not if they are tested as consortia), this could be accepted if it can be justified that *Pseudomonas* is not relevant in that specific case, but the other test organisms are.

[15] If efficacy is demonstrated with fresh product according to the requirements for the particular use, an efficacy shelf life test can be a Phase 2 step 1 test. The test can be performed with the claimed organism most difficult to kill under the most difficult conditions (a robust justification should be provided based on the fresh product data). The most difficult conditions are the conditions for which the highest product dose is required.

14. PT4: Differentiation of target organisms by contact time and dosage

Version 1 (WGII2019): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022)

Can contact time and dose be differentiated for different target organisms?

Bacteria and yeast are mandatory target organisms for PT4. For non-professional users it is not feasible to differentiate bacteria and yeast as target organisms.

The professional users may discriminate between bacteria and yeast, and in the food industry the target organisms may differ between applications and production lines. Therefore, contact time and dose can be differentiated for bacteria and yeast for professional users, if sufficiently justified in the PAR.

15. Applicability of Phase 2, step 2 tests for different surface applications methods

Version 1 (WGIII2019): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Note: This TAB entry had been modified and implemented in Volume II, Parts B+C efficacy guidance (3 November 2022).

Which Phase 2, step 2 test is applicable for generating efficacy data for disinfectants applied on the surfaces by the respective application method?

The following Phase 2, step 2 tests should be used for the respective application methods:

Application group	Application method	Exemplary use instructions	Phase 2, step 2 test	Wipe/mop test material
Spraying	1. Spraying 2. Pouring 3. Foaming	Make sure to wet surfaces completely by spraying the product onto the surface to be disinfected. After spraying, the required contact time has to be respected until further treatment, e.g. wiping to dry the surfaces.	Tests without mechanical action, e.g. EN 13697	-
Wiping with specified wipes	Wiping with ready-to-use wipes.	Wipe the surface to be disinfected. Make sure to wet surfaces completely.	Test with mechanical action, e.g. EN 16615	Specified wipe material. In case several wipe materials are included, testing should at least be carried out with a representative worst-case wipe material (the choice of worst-case material needs to be justified). If this is not feasible, at least one wipe material should be tested with all test organisms and the remaining wipe materials at least with the
	Wiping with specified wipes, which are soaked on site by the user.	Soak the wipes with product/spray product on the wipe until completely soaked and then wipe the surface to be disinfected. Make sure that the surface is completely wet after the wiping step. Example: specified wipes are provided in dry form in a bucket. Prior to use, the user pours the liquid product in the bucket and lets the wipes soak	Test with mechanical action, e.g. EN 16615	

				most resistant test strain of each target organism group.
Wiping with unspecified wipes	Applying product onto wipe followed by wiping	Apply, e.g. spray, pour product onto wipe until it is soaked and then wipe the surface to be disinfected. Ensure that the surface is completely wet after the wiping step.	Test with mechanical action, e.g. EN 16615	Testing should be carried out with the standard wipe listed in EN 16615.
	Applying product onto surface followed by wiping*	Apply, e.g. spray, pour product onto the surface to be disinfected and then wipe the surface. Ensure that the surface is completely wet after the wiping step.	Test with/without mechanical action, e.g. EN 16615/EN 13697	Testing should be carried out with the standard wipe listed in EN 16615 (if mechanical action is intended).
Mopping with specified mops	Mopping with ready-to-use mops	Mop the surface to be disinfected. Make sure to wet surfaces completely.	Test with mechanical action, e.g. EN 16615	Testing should be carried out with the standard wipe listed in EN 16615.
	Mopping with specified mops, which are soaked on site by the user.	Soak the mop with the product and then mop the surface to be disinfected. Ensure that surface is completely wet after the mopping step.	Test with mechanical action, e.g. EN 16615	
Mopping with un-specified mops	Applying product onto mop followed by mopping	Soak the mop with the product and then mop the surface to be disinfected. Ensure that surface is completely wet after the mopping step.	Test with mechanical action, e.g. EN 16615	Testing should be carried out with the standard wipe listed in EN 16615.
	Applying product onto surface followed by mopping*	Apply (Spray/Pour) product onto the surface to be disinfected and then mop the surface. Ensure that surface is completely wet after the mopping step.	Test with/without mechanical action, e.g. EN 16615/EN 13697	Testing should be carried out with the standard wipe listed in EN 16615 (if mechanical action is intended).
Others	Brushing	Make sure to wet surfaces completely when applying the product onto the surface by brushing.	Tests without mechanical action, e.g. EN 13697	-

*Cases where the product is applied onto surface by spraying/pouring, followed by wiping/mopping of the surface, are identified as exceptions, because wiping/mopping in such cases is considered as a way of distributing the product without any real mechanical action. For these exceptions EN 13697 is considered applicable. Applicant is responsible for indicating whether wiping or mopping is only for distribution of the product or whether mechanical action is involved.

16. Growth quantification or determination of filamentous fungi

Version 1 (WGIV2019): Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

How to assess the growth of filamentous fungi in non-filterable matrices unsuitable for visual examination (by a naked eye)?

The use of colony-forming unit (CFU) assessment for filamentous fungi proves to be inadequate due to expected inconsistencies in CFU count in comparison to the true microbiological load. Some of the alternative methods depending on the matrix assessed may to some extent be insufficient to demonstrate growth of filamentous fungi. Thus, in such cases the assessment of growth should be based on a combination of CFU assessment

and one of the suited, additional methods performed in parallel. The following list of methods poses examples of additional detection methods:

- Microscopical assessment of matrix samples to demonstrate if spores have grown into hyphae. It is recommended to provide at least 8 images per replicate in a respective study report. If hyphae are observed in each replicate, then growth is confirmed. Only complex hyphal structure may be regarded as growth in contrast to the first initial hyphae strands spreading out of the spore, which may not be regarded as growth.
- Detection of matrix degradation, e.g. loss of viscosity, or of biological marker molecules linked to fungal growth, e.g. ergosterol measurement, ATP analysis, or CO_2 development in the matrix (controls should be included such as 'non-treated but inoculated matrix' and both 'non-treated and non-inoculated matrix'). At least three replicates should be performed. Each measurement protocol has to be robust and described in detail. Raw data has to be provided.

Growth or metabolic activity has to be demonstrated in both the CFU assessment and the chosen additional method.

17. PT6-13: Tiered approach to testing preservatives

Version 2 (WGI2024)

Note: This TAB is not applicable to PT 8.

What efficacy tests are required for authorisation of biocidal products belonging to Main Group 2: Preservatives?

In accordance with the Guidance on the BPR, Volume II Efficacy - Assessment and Evaluation, Parts B+C, a tiered approach is to be followed for preservative efficacy testing.

Nevertheless, all three test tiers are not systematically necessary. Appropriate and valid tier 2 tests supporting the claimed use can be submitted to demonstrate the efficacy of a preservative biocidal product. In this case, tier 1 tests can be waived. For each intended use, efficacy needs to be demonstrated in tier 2 tests, in at least one relevant matrix and against all intended target organism groups.

Regardless if only tier 2 or both tier 1 and tier 2 tests have been submitted, the efficacious dose will always be derived from tier 2 tests only. In case tier 3 tests (field tests) are submitted instead of tier 2 tests, additional laboratory evidence (tier 1 tests) needs to be submitted and both the tier 3 test and the laboratory evidence will be taken into account when setting the efficacious dose, unless the applicant can comprehensively justify why it is not possible to mimic relevant basic environmental conditions in a laboratory setting.

What are the requirements for tier 2 efficacy tests for preservatives? – Part 1: Simulated ageing.

According to the Vol. II, Parts B+C efficacy guidance efficacy should be demonstrated under "real life conditions". For tier 2 tests, a special focus is put on simulating ageing[16] of the tested system (both treated matrix and untreated control). Typically, the following procedures/factors should be employed to generate tier 2 data for preventive treatment, depending on the specific uses applied for and the potential efficacy-reducing factors that can be expected in these uses[17]. The choice of ageing methods used in the respective efficacy tests has to be justified by the applicant based on the expected in-use conditions.

[16] In this document, the generic term "ageing" includes all relevant environmental factors that can cause loss of the biocidal effect in a treated matrix, such as e.g. weathering, UV exposure, extended storage, leaching, soiling, or washing and cleaning regimens.

[17] This is a non-exhaustive list. Other ageing modes, which have not been named here, may be necessary depending on the individual use and ageing factors encountered in that context.

- PT 6 – Accelerated ageing of the claimed treated matrix at elevated temperatures or storage at ambient temperature[18].
- PT 7 – Exposure to air (to allow the evaporation of volatile components), humidity, UV irradiation, leaching in water, accelerated ageing at elevated temperatures, or a relevant combination thereof[19]. Alternatively, outdoor ageing, if relevant.
- PT 9 – As for PT 7. For treated textiles, washing cycles should be considered if relevant.
- PT 10 – As for PT 7.
- PT 11 – Usually not relevant.
- PT 12 – Usually not relevant.
- PT 13 – Accelerated ageing of the claimed treated matrix at elevated temperatures or storage at ambient temperature and addition of appropriate soiling[20].

In certain cases, ageing procedures can be omitted if ageing is demonstrably not relevant for the specific use, for example:

- For curative treatment, ageing generally is not relevant and can be omitted when generating the efficacy data.
- Products intended for short-term preservation (e.g. short-term preservation of white water in PT 6) would not require tests with an aged matrix if the article is preserved only for periods that are covered by the submitted biological testing.
- When the product is dosed into the treated matrix continuously or repeatedly in intervals shorter than the duration of the biological testing (such as typically in PT 11 or 12).

In any case, when ageing procedures are waived, a justification should be included in the respective dossier.

After the required ageing procedures have been performed[21], the standard challenge test described for tier 1 in the guidance and its appendices (e.g. IBRG PDG 16-007 for the preservation of aqueous-based products in PT6) could be performed to generate tier 2 data.

What are the requirements for tier 2 efficacy tests for preservatives? – Part 2: Other aspects.

In certain cases, only one challenge can be considered sufficient, if multiple challenges are not relevant for the specific use, e.g. a PT 6 product is used right before packaging for the preservation of a treated article in a tightly sealed container until the first opening and the treated article is not intended to be preserved after opening the can.

Furthermore, care should be taken to simulate in-use conditions in tier 2 tests. Hence, solid matrices should usually not be tested on agar plates in tier 2 tests. Agar holds high amounts of available water, while humidity in most real-life applications is a limiting factor

[18] Ageing protocols for the test matrices should be adapted from section 2.6.4.1 on storage stability in Volume I (Parts A/B/C, version 2.1) of the BPR guidance. Storage at any of the combinations of temperature and test duration described in the guidance section on accelerated storage or at ambient conditions for at least 6 months is considered sufficient to demonstrate efficacy within the usual shelf life (including periods longer than 6 months) of any preserved articles (from the production of the treated article until the first opening).

[19] Ageing protocols already established for paints/coatings (e.g. ASTM D4587, EN ISO 16474-2/3, BS 3900-G6 Appendix E) or wood preservation (e.g. EN 73, EN 84, EN 152 Annex F) can also be adapted to other solid matrices.

[20] A standard setup for accelerated ageing at elevated temperatures could be 7 days at 40 °C. Soiling should always be added and can be performed as in IBRG FFG16-001.4: add 1% of 1% yeast extract solution.

[21] In some cases, an untreated matrix may become spoiled by microbial growth during the ageing process and will therefore not be suitable for use during the challenge test. Such cases should be recorded and the affected sample(s) should be replaced by a fresh sample of the same matrix as the untreated control for the challenge test.

on bioavailability and thus efficacy of biocides. Furthermore, even very pure agar often contains unspecified amounts of nutrients that are nevertheless sufficient to support microbial growth. If it is necessary to simulate soiling that would cause biological growth in practice, it should be added separately in a controlled way.

Likewise, biocides for liquid matrices must be tested in a matrix that is relevant for the respective use. To simulate soiling that would be encountered in the in-use conditions, very low amounts of defined nutrients may be added. In some cases, a combination of ageing and soiling will be appropriate. Testing of preservatives in microbiological nutrient media is not relevant to demonstrate efficacy and should not be employed.

Type of entry:	b) Clarification/interpretation of the existing guidance (clarification/explanation)
Publication date:	03/04/2024
Date of applicability for active substances:	03/04/2024
Date of applicability for products:	03/04/2024

PT6-13: Tiered approach to testing preservatives

Version 1 (WGV2019) Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

What efficacy tests are required for authorisation of biocidal products belonging to Main Group 2: Preservatives?

When testing preservatives, the tiered approach should be followed in accordance with the Guidance on the BPR, Volume II Efficacy - Assessment and Evaluation (Parts B+C). Nevertheless, it does not necessarily mean that all three tiers are necessary in each case. When appropriate and valid Tier 2 tests supporting the claimed use are submitted to demonstrate efficacy of a preservative biocidal product, Tier 1 tests are not needed and can be waived. In case that Tier 3 tests (field tests) are submitted instead of Tier 2 tests, additional laboratory evidence (Tier 1 or Tier 2 tests) needs to be submitted, unless the applicant can comprehensively justify why it is not possible to mimic relevant conditions of use in a laboratory setting.

What are the requirements for Tier 2 efficacy tests for preservatives?

Vol. II, Parts B+C efficacy guidance specifies the requirements for Tier 2 tests stating that efficacy should be demonstrated under "real life conditions". A special focus is put on simulating ageing[22] of the treated matrix. Typically, the following ageing procedures are relevant for preventive Tier 2 tests, depending on the specific uses applied for[23]. Other ageing modes, which have not been named here, may be necessary in dependence of the individual use.

- PT 6: Long storage of the claimed treated matrix at ambient temperature or accelerated ageing at elevated temperature[24].
- PT 7: Evaporation in air, leaching by water, UV irradiation, temperature-related ageing, or a relevant combination thereof[25]. Alternatively, outdoor ageing, if relevant.
- PT 9: As for PT 7. For treated textiles, washing cycles should be considered.
- PT 10: As for PT 7.

[22] In this document the generic term "ageing" includes all relevant factors that can cause loss of the biocidal effect in a treated matrix, e.g. weathering, UV exposure, extended storage, leaching, or washing and cleaning regimens.
[23] This is a non-exhaustive list.
[24] Ageing protocols can be adapted from Volume I, Parts A+B+C of the BPR guidance - chapter on storage stability.
[25] Ageing protocols already established for wood preservation (e.g. EN 73, EN 84, EN 152 Annex F) can also be applied to other solid matrices.

- PT 11: Usually not relevant.
- PT 12: Usually not relevant.
- PT 13: Temperature-related ageing and addition of appropriate soiling[26].

In certain cases, ageing procedures can be omitted if ageing is demonstrably not relevant for the specific use, e.g. a PT 6 product would not require tests with an aged matrix if the matrix is preserved only for periods that are covered by biological testing anyway (typically 1-6 weeks).

Apart from ageing procedures, care should be taken to simulate realistic conditions in Tier 2 tests. Hence, solid matrices should usually not be tested on agar plates in Tier 2 tests. Agar holds high amounts of available water, while humidity in most real life applications is a limiting factor on bioavailability and thus efficacy of biocides. Furthermore, even very pure agar often contains unspecified amounts of nutrients that are nevertheless sufficient to support microbial growth. If it is necessary to simulate soiling that would cause biological growth in reality, it should be added separately in a controlled way.

Likewise, biocides for liquid matrices must be tested in a matrix that is relevant for the respective use. To simulate soiling that would be encountered in the real-life use, very low amounts of defined nutrient media may be added. Tests of preservatives in microbiological nutrient media are not relevant to demonstrate efficacy.

18. PT18: Efficacy requirements for an insecticide to be used in stables

Version 1 (WGI2020) Entry published more than 2 years before the publication date of this TAB document, i.e. currently applicable for both active substances and products.

Can sticky traps be used as an appropriate and reliable method to estimate and monitor population of flies in stables?

Use of sticky traps is an appropriate and reliable method to monitor population of flies in stables when generating field data. The use of another indirect measure like the Danish Pest Infestation Laboratory (DPIL) fly index or spot cards is acceptable as well.

What are the appropriate efficacy criteria for field trials of an insecticide to be used against flies in stables?

In the field trials, the efficacy criteria (reduction of the population) should be ≥80%, because of short generation times and possible resistance development. Deviations might be accepted in well justified cases.

19. PT2 and PT4: Hard surface disinfection and differentiation of virucidal claims

Version 2 (WGI2020, WGIII2022)

Should different virucidal claims be allowed for hard surface disinfection in PT2 and in PT4?

1. For disinfectants used in healthcare and non-healthcare areas in PT2 (e.g. hotels, public sanitary, homeless shelters, public transport or clean rooms for production of pharmaceuticals) by professional users in addition to the currently accepted virucidal claim, also the limited spectrum virucidal activity and the activity against enveloped viruses can be claimed;

[26] E.g. as done in IBRG FFG16-001.4: add 1% of 1% yeast extract solution

2. For disinfectants used in non-healthcare areas in PT2 by the general public only a virucidal activity and activity against enveloped viruses can be claimed;
3. For disinfectants used in PT4 (e.g. food industry, kitchens in restaurants or homes, shops like butchers and grocery shops where food is processed, etc.) by professional users and by the general public a virucidal activity and activity against enveloped viruses can be claimed.

Type of entry:	c) New guidance, as new technical scientific advice is given which triggers new data requirements
Publication date:	03/11/2022
Date of applicability for active substances:	03/05/2023
Date of applicability for products:	03/11/2024

PT2: Hard surface disinfection and differentiation of virucidal claims

Version 1 (WGI2020)

Please note that this is not the most recent version of the entry – see the latest version above.

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022)

Should different virucidal claims be allowed for hard surface disinfection in PT2?

1. For disinfectants used in healthcare and non-healthcare areas (e.g. hotels, public sanitary, homeless shelters, public transport or clean rooms for production of pharmaceuticals) by professional users in addition to the currently accepted full virucidal claim, also the limited spectrum virucidal activity and the activity against enveloped viruses can be claimed;
2. For disinfectants used in non-healthcare areas by the general public only a full virucidal activity and activity against enveloped viruses can be claimed.

Type of entry:	c) New guidance as new technical scientific advice is given which triggers new data requirements
Publication date:	10/07/2020
Date of applicability for active substances:	10/01/2021
Date of applicability for products:	10/07/2022

20. PT5: EN 1276 and EN 14476 test requirements for active chlorine-based disinfectants

Version 1 (WGI2020)

Note: This TAB entry is implemented already in Volume II, Parts B+C efficacy guidance (3 November 2022)

Are efficacy tests in accordance with EN 1276 and EN 14476 obligatory for PT 5 active chlorine-based disinfectants?

According to the Guidance on the Biocidal Products Regulation Vol. II Efficacy - Assessment and Evaluation (Parts B+C) version 3.0 (April 2018), passing modified EN 1276 and EN 14476 tests is a basic requirement for PT 5 disinfectants.

Based on the current information there is enough evidence that the active chlorine-based products (most widely used water disinfectants), cannot pass these tests at typical use concentrations that have long been established. In addition, it was acknowledged that the

active chlorine concentration in drinking water cannot be increased to a level that passes these criteria. Consequently, the modified EN 1276 and EN 14476 tests mentioned in the guidance are considered as not obligatory for PT 5 active chlorine-based disinfectants. Efficacy of such products should be demonstrated with a simulated-use test and/or a field test.

Type of entry:	e) New guidance, considerably more reliable than former guidance
Publication date:	10/07/2020
Date of applicability for active substances:	10/07/2020
Date of applicability for products:	10/07/2022

21. Disinfection without mechanical action - a minimum volume of product necessary to ensure sufficient wetting

Version 1 (WGIII2020)

How much product is needed to wet the surface completely and to keep the surface wet for the contact time, or part of it?

It is acceptable that there might be a difference between drying time and volume of product containing volatile active substance in the EN 13697 test and in practice. Therefore, in practice, it is accepted that the non-porous hard surface does not necessarily remain wet during the claimed contact time.

A minimum volume of product should be added to the non-porous hard surface to ensure sufficient wetting over the whole treated surface for disinfection without mechanical action. For volumes lower than 18 ml/m^2 a robust justification and/or efficacy data is needed.

Type of entry:	d) New guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done
Publication date:	30/05/2022
Date of applicability for active substances:	30/11/2022
Date of applicability for products:	30/05/2024

22. PT18: Crack and crevice treatment - test requirements for biocidal products with a crack and crevice treatment claim

Version 1 (WGIII2021)

What kind of simulated use test should be provided in the context of product authorisation of e.g. an "insecticide against crawling insects with crack and crevice treatment" when using the definition of "the application of a small amount of insecticide directly into cracks and crevices where insects hide or where they may enter"?

To demonstrate the efficacy of a product with a crack and crevice treatment claim, the results of the efficacy tests should meet the pass criteria for a product intended for use as general surface treatment.

For crack and crevice treatment the following test setup is proposed:

- The trial is performed in the laboratory, in a test chamber simulating the real conditions of use, by treating cracks and crevices of a designed "furniture", releasing insects, and counting their knockdown and/or mortality, according to the

claim. The furniture which represents the cracks and crevices should be put in the test chamber before its treatment in order to simulate the real condition of use.

- The duration of exposure and results in terms of knockdown and/or mortality should be consistent with the requirements for the species in the efficacy guidance Vol. II, Parts B+C, PT18 Chapter and in accordance with the product's claim. Also, an acclimatization period is required, consistent with the ecology of the target species.
- Depending on the dose expression, e.g. in g par linear meter, and the mode of application, e.g. space between cupboard and floor; cracks in the wall, etc., the space between panels in the furniture should be adapted to the claim and should be relevant regarding the target organisms claimed. The material of the treated surface (porous, non-porous) is not relevant, as the goal is to evaluate the mortality of hidden insects which are directly treated by the product.

Only for a crack and crevice treatment with a residual efficacy claim:

- The insects have the choice not to be in contact with the product and are not forced to be in contact with the treatment to reach water and food sources. In addition, sufficient untreated shelter should be available to the target species (either an untreated section in the test furniture or an additional crack and crevice shelter in the test arena, which can be placed after acclimatization).
- The treated surfaces, e.g. porous and non-porous tiles, inserted into the designed furniture, or treating directly on the furniture surface, should be representative for the surface types claimed. For a general claim (without specific claimed surface types) both porous and non-porous surfaces need to be tested separately, in line with the requirements for that target species in the efficacy guidance Vol. II, Parts B+C, PT18 Chapter. If such guidance is missing for the target species, 2 porous surfaces and 1 non-porous surface need to be tested.

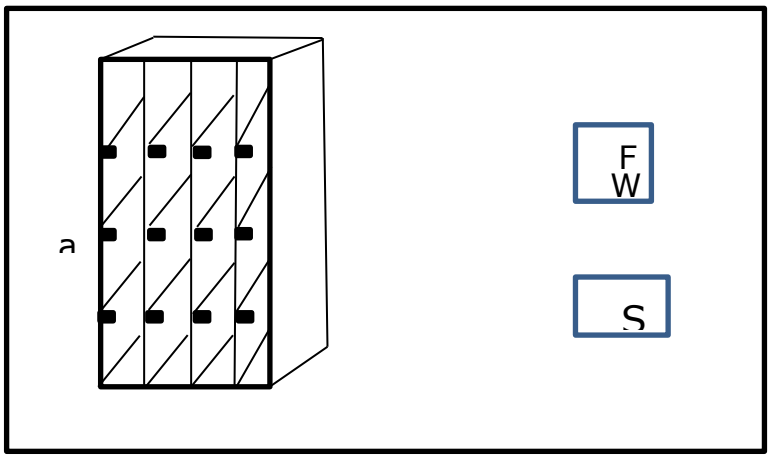


Figure 1: Example of a test arena with a designed "furniture" for the simulated-use test for testing crack and crevice treatment against crawling insects. Treated tiles are inserted into the entry of the simulated use furniture. The location of the additional shelter, food and water are just examples.

Other test designs than the example presented in Figure 1 can be accepted if the protocol is scientifically valid.

Type of entry:	c) New guidance as new technical scientific advice is given which triggers new data requirements
Publication date:	30/05/2022
Date of applicability for active substances:	30/11/2022
Date of applicability for products:	30/05/2024

23. PT18: Evaluation of attractants in bait products

Version 1 (WGIII2021)

What kind of efficacy tests should be provided in the context of evaluation of attractants in PT18 bait products?

Efficacy evaluation of attractants (PT19) in PT18 bait products should be done in accordance with the requirements for bait products given in the efficacy guidance Vol. II, Parts B+C, PT18 Chapter.

In the case where no requirements for PT 18 bait products have been defined in this chapter, the efficacy should be proven in:

- a palatability laboratory choice test for bait products whose mode of action requires oral consumption of the product by the target organism. The test should demonstrate the palatability of the fresh product and the product at the end of the claimed maximum storage period. In the test, the test organisms should have a choice between a non-toxic food source (challenge diet, either the non-toxic bait or a non-toxic food source known to be a strong feeding source for the test species) and the bait product;
- a simulated-use test according to the claim;
- a field trial according to the claim.

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

An insecticidal product (PT18) containing an attractant (PT19) is normally considered to be "sufficiently effective" if the following results are achieved:

The laboratory palatability choice test (bait and alternative food):

- at least 95% of the test insects have been killed at a given time.

The required results in simulated-use and field tests:

- ≥ 90% mortality at the end of the test period according to the SPC and the label claim.

Deviating requirements for special claims:

Outdoor use:

- a field trial is mandatory to demonstrate ≥ 90% mortality at the end of the test period according to the SPC and the label claim.

Use in stables:

- a field trial is mandatory to demonstrate ≥ 80% mortality at the end of the test period according to the SPC and the label claim.

Nest kill claim:

a field trial is mandatory to demonstrate 100% mortality at the end of the test period according to the SPC and the label claim.

Type of entry:	c) New guidance, as new technical scientific advice is given which triggers new data requirements
Publication date:	30/05/2022
Date of applicability for active substances:	30/11/2022
Date of applicability for products:	30/05/2024

24. Efficacy testing for disinfectants at elevated use temperatures

Version 1 (WGI2022)

How to assess the efficacy of disinfectants at elevated temperatures ≥40°C in case of organism groups where no standardised thermotolerant test organisms are available?

Note: This agreement is not intended to overrule existing or future agreements on testing strategies for specific uses, like e.g. aseptic filling or laundry disinfection.

The following agreement covers only organism groups for which no standardised thermotolerant organism is described in the guidance. Where such organisms already are described (e.g. *E. faecium* for bacteria), the relevant tests should be performed at the intended use temperature with these organisms as required by the guidance.

In cases where no standardised thermotolerant representative organism exists for the intended use temperature, the following tests should be performed in a first step:

- Use-specific tests (e.g. P2S1 and P2S2) with usual standard organisms of the claimed organism groups at claimed use temperature (e.g. test temperature of 60°C if this temperature is claimed for the use), with an additional water control (20°C or the highest temperature where water controls are valid; corresponding to control A in CEN P2S1 disinfection standards) to demonstrate cell vitality. In complex simulated use tests (e.g. dishwasher test), the temperature should be measured frequently over the duration of the test to ensure that the intended use temperature is reached and maintained.

Case A: In case all controls of the standard organisms are valid at the intended use temperature and all other test requirements are fulfilled, the test can be accepted without any further requirements and a claim against the tested organism group should be accepted.

Case B: In case all standard test organisms of a target organism group are killed by the intended use temperature in the relevant tests (P2S1 and P2S2), a chemical-biocidal effect cannot be established. If the respective group is mandatory for the use, the mandatory status is waived and the group is considered optional because the standard organisms are not relevant to a chemical-biocidal claim at the intended use temperature. This means that there is no requirement to authorise these organisms, but they also cannot be named in the SPC as target organisms based on these data on standard organisms. This means, e.g. if *Candida albicans* is killed at 60°C there is no need to test any further; however yeast should not be listed anymore as target organisms in the SPC.

If however, the applicant intends to maintain the claim for case B, the following additional data can be used to support the claim for organisms groups for which no thermotolerant organism is described in the guidance: P2S1 tests with one thermotolerant representative of the respective organism group at the intended use temperature[27]. The applicant should

[27] If in rare cases the water control at the intended use temperature does not contain enough surviving organisms to demonstrate the required lg reduction, an additional water control at a lower temperature can be performed. As long as this control is valid and the other requirements are fulfilled there are two options:

a. If there still are survivors in the water control at the intended use temperature and a chemical biocidal effect can be demonstrated, the claim can be granted.
b. If there are no survivors in the water control at the intended use temperature, no chemical effect of the biocide can be demonstrated. If a chemical effect is demonstrated for at least one other group of target organisms, a descriptive sentence can be included for the thermally inactivated target organisms in section "Other information" of the SPC with clear reference to the affected uses: "A biocidal effect against [Group of target organisms] could not be demonstrated due to thermal inactivation of the test organisms at XX°C during YY min contact time."

This rule also applies in cases where standardised thermotolerant test organisms already are available (bacteria, viruses, bacterial spores).

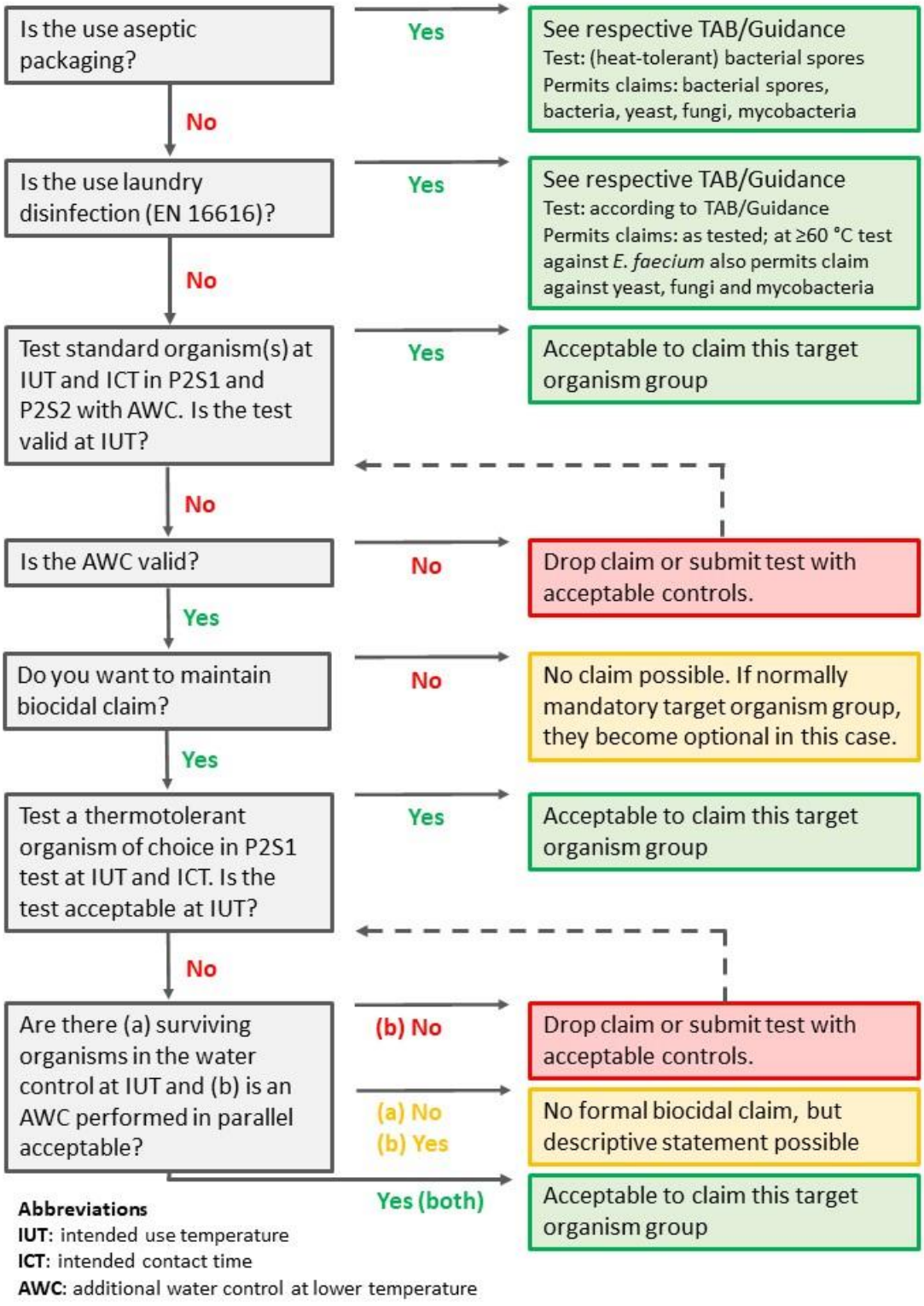
justify why the chosen test organism is considered a representatively tolerant organism for the intended application. The following thermotolerant species are examples that may be used for tests at elevated temperatures:

Yeasts: *Ogataea polymorpha* (syn. *Candida thermophila*) [Shin et al., International Journal of Systematic and Evolutionary Microbiology 2001, 51, 2167-70; Lehnen et al., BMC Microbiology 2019, 19:100]

Fungi (spores): *Aspergillus fumigatus* [Araujo et al., Medical Mycology 2006, 44, 439-443; Hagiwara et al., PLoS ONE 2017, 12(5):e0177050; O'Gorman et al., Nature 2009, 457, 471-475]

Mycobacteria: *Mycobacterium hassiacum* [Schröder et al., International Journal of Systematic Bacteriology 1997, 47, 86-91; Haas et al., BMC Research Notes 2020, 13:140]

Graphic depiction of proposed workflow for disinfectant testing at elevated temperatures for organism groups without thermotolerant standard organisms.



Type of entry:	c) New guidance as new technical scientific advice is given which triggers new data requirements
Publication date:	30/05/2022
Date of applicability for active substances:	30/11/2022
Date of applicability for products:	30/05/2024

25. PT1-5 Use concentration and contact time

Version 1 (WGIII2023)

PT1-5: Biocidal products against various groups of target organisms with different use concentrations and contact times within the same use.

How to determine the use concentration and contact time of the biocidal products with a variety of different test concentrations and contact times against the various groups of target organisms within the same use?

Rule 1:

The product used against the obligatory target organisms only, e.g. bacteria and yeasts, should have within the same use the same use concentration and contact time for all of them based on the provided test data. The worst-case test data, from phase 2, step 1 (P2S1) and phase 2, step 2 (P2S2) tests, should be used to determine these parameters[28]. In example 1 the product used against obligatory organisms gets a use concentration of 5% and a contact time of 5 minutes.

Example 1: Test results and dosage recommendation: PT2 - health care, obligatory organisms bacteria and yeasts.

Target organism	Test	Result		Test	Result		Conclusion	
		Time (min)	Conc. (%)		Time (min)	Conc. (%)	Time (min)	Conc. (%)
Bacteria	P2S1	4	2	P2S2	5	3		
Yeasts	P2S1	5	4	P2S2	5	5		
							5	5
Enveloped viruses	P2S1	1	2	P2S2			5	5
Fungi	P2S1	5	5	P2S2	5	10	5	10

Rule 2:

If also optional target organisms are claimed, the product can never be used having a shorter contact time and/or lower use concentration within the same use compared to these foreseen for the obligatory target organisms[29]. The background for this proposal is that a disinfectant must work as a minimum against the obligatory organisms. Therefore, the product can never have a shorter contact time or a lower use concentration against optional target organisms claimed as the basic efficacy cannot be guaranteed at this contact time and use concentration*.

In example 1 the product used against the obligatory organisms in health care surface disinfection have a contact time of 5 minutes and a use concentration of 5%. To be used against enveloped viruses the contact time of 1 minute and the use concentration of 2% is sufficient. Based on these data the dose recommendation for all organisms claimed is: 5 minutes and the use concentration of 5%. Thus, the product used against enveloped viruses will not get a separate dosage recommendation.

[28] Exceptions can be made in some cases, e.g. in PT 3 for specific disinfection (see section: 'Disinfection of manure, litter and other substrates for veterinary use' in the Vol. II, Parts B+C) and PT 4 (see entry: Differentiation of target organisms by contact time and dosage (PT4) in the TAB), this will be evaluated by the eCA on case by case basis.

[29] Biofilm should not be seen as a target organism in this context but as an additional use.

Rule 3:

If optional target organisms are claimed within the same use and the product needs to have a higher in-use concentration to pass the relevant criteria, it will get a separate dosage recommendation. The same applies if a longer contact time is necessary for the product to be used against the optional target organisms. The product will get a separate contact time to be used against these optional organisms.

In example 1 the product used against fungi need a higher dosage than the obligatory organisms. Thus, the product used against fungi gets a separate dosage recommendation of 10%.

As recommendation for efficacy testing

The contact time or use concentration in the efficacy tests of the optional target organisms should preferably be identical to the contact time or use concentration of the obligatory organisms. Otherwise, the dosage recommendation will become as in example 2, which may lead to confusion in practise.

Example 2: Test results and dosage recommendation PT2 - health care, obligatory organisms (bacteria and yeasts) and optional organisms (fungi).

Target organism	Test	Result		Test	Result		Conclusion	
		Time (min)	Conc. (%)		Time (min)	Conc. (%)	Time (min)	Conc. (%)
Bacteria	P2S1	5	3	P2S2	5	6	15	6
Yeasts	P2S1	15	1	P2S2	15	2	15	6
Fungi	P2S1	15	3	P2S2	60	3	60	6*

* The product is efficacious against fungi at a concentration of 3% and 60 minutes contact time. However, due to the fact that the product is efficacious against the obligatory organisms at the concentration of 6% it is not possible to lower the concentration in the recommended dose.

Type of entry:	b) Clarification/interpretation of the existing guidance (clarification/explanation)
Publication date:	11/12/2023
Date of applicability for active substances:	11/12/2023
Date of applicability for products:	11/12/2023

26. Defining growth in untreated controls

Version 1 (WGII2023)

What are the minimum requirements for growth in untreated controls when quantified as CFU?

Growth means an increase over the recovery directly after inoculation, which is statistically significant and greater than 0.5 log. Statistical significance is usually determined by the Student's t-test. A p-value <0.05 (95 % confidence level) is highly recommended, p <0.1 (90% confidence level) may in exceptional cases be used if justified (e.g. identifying outliers, or lowest concentration with a biocide showing growth).

Type of entry:	c) New guidance as new technical scientific advice is given which triggers new data requirements
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Date of applicability for active substances:	12/06/2024
Date of applicability for products:	12/12/2025