Guidance on the Biocidal Products Regulation
Volume II Efficacy - Assessment and Evaluation (Parts B+C)

DRAFT PUBLIC Version 3.0 (Section 5.x.x PT5 ONLY)
xxxxxxxxx 201x
LEGAL NOTICE

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C)

Reference: ECHA-17-G-03-EN
Cat. Number: ED-04-17-144-EN-N
DoI: 10.2823/175784
Publ. date: xxxx 2018
Language: EN

© European Chemicals Agency, 2018

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers) using the Guidance feedback form. The feedback form can be accessed via the ECHA website or directly via the following link:

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland
DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Comment</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1.0</td>
<td>First edition</td>
<td>February 2017</td>
</tr>
</tbody>
</table>
| Version 2.0 | Update to add a new Appendix for PT8  
The text has been revised as follows:  
• To add a new Appendix 12  
• To revise section 5.5.8.3 to remove footnote 28  
• To re-number Appendices after the new Appendix to 13-24 and revise all cross references to these Appendices. | Xxxx 2017 |
| Version 3.0 | Update to section 5.4.5 PT5 Disinfectants in Drinking water  
The text has been revised as follows: | Xxxxx 2018 |

2
PREFACE

The Guidance on the Biocidal Products Regulation (BPR) is to be applied to applications for active substance approval and product authorisation as submitted from 1 September 2013, the date of application (DoA) of the Biocidal Product Regulation (the BPR).

This document describes the BPR obligations and how to fulfil them.

The scientific guidance provides technical scientific advice on how to fulfill the information requirements set by the BPR (Part A), how to perform the risk assessment and the exposure assessment for the evaluation of the human health and environmental aspects and how to assess and evaluate the efficacy to establish the benefit arising from the use of biocidal products and that it is sufficiently effective (Parts B & C).

In addition to the BPR guidance, the Biocidal Products Directive (BPD) guidance and other related documents are still considered applicable for new submissions under the BPR in the areas where the BPR guidance is under preparation. Furthermore these documents are still valid in relation to the applications for active substance approval or applications for product authorisation under the BPD that may still be under evaluation. Also the Commission has addressed some of the obligations in further detail in the Biocides competent authorities meetings documents which applicants are advised to consult. Please see ECHA Biocides Guidance website for links to these documents: [https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation].

Applicability of Guidance


---

1 Link available under Working Procedures (right column) [https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee]
# Table of Contents

1. **Table of Contents**
2. LEGAL NOTICE .................................................................2
3. DOCUMENT HISTORY ..........................................................3
4. PREFACE ..............................................................................4
5. LIST OF ABBREVIATIONS .....................................................12
6. GLOSSARY OF TERMS ..........................................................14
7. 1. GENERAL INTRODUCTION ..............................................18
8. 2. CLAIMS ...........................................................................18
9. 3. GENERAL CONSIDERATIONS FOR THE DEVELOPMENT AND REPORTING OF EFFICACY DATA
10. 4. ACTIVE SUBSTANCE APPROVAL .......................................18
11. 5. PRODUCT AUTHORISATION ..............................................18
12. 5.1 EVALUATION OF EFFICACY AT PRODUCT AUTHORISATION STAGE ........................................18
13. 5.2 PRODUCT FAMILIES .....................................................19
14. 5.3 TREATED ARTICLES ....................................................19
15. 5.4 DISINFECTANTS (MAIN GROUP 1) .....................................19
16. 5.4.0 General ......................................................................19
17. 5.4.0.1 Introduction ............................................................19
18. 5.4.0.2 Dossier requirements ..............................................20
19. 5.4.0.3 Label claim ..............................................................21
20. 5.4.0.3.1 Target Organisms ..................................................21
21. 5.4.0.3.2 Areas of Use ........................................................22
22. 5.4.0.3.3 Sites of Application ...............................................22
23. 5.4.0.3.4 Directions for use (Methods of application) ..........23
24. 5.4.0.3.5 Other interfering parameters ..................................23
25. 5.4.0.4 Efficacy testing ......................................................23
26. 5.4.0.4.1 Tiered approach ....................................................23
27. 5.4.0.4.2 Standard test methods ..........................................25
28. 5.4.0.4.3 Data requirements ...............................................27
29. 5.4.0.4.4 Relevant factors of the test procedure ......................29
30. 5.4.0.5 General data requirements ........................................32
31. 5.4.0.5.1 Test range .............................................................32
32. 5.4.0.5.2 Claim for several areas of use ..................................32
33. 5.4.0.5.3 Biocidal products with biostatic effect ......................32
34. 5.4.0.5.4 Malodour control ..................................................33
35. 5.4.0.5.5 Changes in ingredients .........................................33
36. 5.4.0.5.6 Treated articles ....................................................33
37. 5.4.0.5.7 Biocidal Product Families ......................................33
38. 5.4.0.6 Resistance ...............................................................33
39. 5.4.0.7 Assessment of application for authorisation ................33
40. 5.4.0.7.1 Decision making ..................................................33
41. 5.4.0.7.2 Assessment ........................................................33
42. 5.4.1 PT1 Human hygiene biocidal products .........................34
43. 5.4.2 PT2 Disinfectants and algaecides not intended for direct application to humans or animals .........................34
44. 5.4.3 PT3 Veterinary hygiene biocidal products ......................34
45. 5.4.4 PT4 Food and feed area disinfectants ............................34
46. 5.4.5 PT5 Drinking water disinfectants ..................................35
47. 5.4.5.1 Introduction ............................................................35
5.4.5.2 Disinfection at the drinking water suppliers and their water distribution systems .................................................. 35
5.4.5.2.1 Introduction .................................................................. 35
5.4.5.2.2 Data requirements .......................................................... 36
5.4.5.3 Disinfection of raw water for individual supply (1-2 premises) ... 37
5.4.5.3.1 Introduction .................................................................. 37
5.4.5.3.2 Data requirements .......................................................... 37
5.4.5.4 Disinfection in collective drinking water systems ... 39
5.4.5.4.1 Introduction .................................................................. 39
5.4.5.4.2 Data requirements .......................................................... 39
5.4.5.5 Disinfection of water in reservoirs ........................................ 43
5.4.5.5.1 Introduction .................................................................. 43
5.4.5.5.2 Data requirements .......................................................... 43
5.4.5.6 Disinfection of water of undefined quality for small scale use (up to 5 L/person/day) .......................................................... 44
5.4.5.6.1 Introduction .................................................................. 44
5.4.5.6.2 Data requirements .......................................................... 44
5.4.5.7 Disinfection of water for animals .......................................... 45
5.4.5.7.1 Introduction .................................................................. 45
5.4.5.7.2 Data requirements .......................................................... 45
5.4.6 Materials and Articles Treated to Protect Humans or Animals ........... 47
5.5 PRESERVATIVES (MAIN GROUP 2) ........................................... 47
5.6 PEST CONTROL (MAIN GROUP 3) ............................................. 47
5.7 OTHER BIOCIDAL PRODUCTS (MAIN GROUP 4) ......................... 47
APPENDIX 1. CLAIMS MATRICES ................................................. 48
APPENDIX 2. STANDARDS AND TESTING METHODS FOR EFFICACY-TESTING OF DISINFECTANT BIOCIDAL PRODUCTS (PT 1-5) .................................................. 49
APPENDIX 3. TABLE OF REFERENCE TEST ORGANISMS (PT 1-5)................................. 58
APPENDIX 4. OVERVIEW OF STANDARDS, TEST CONDITIONS AND PASS CRITERIA (PT 1-5) 61
APPENDIX 5. EXAMPLES OF VIRUSES SORTED ACCORDING TO THEIR PRESENCE IN THE HUMAN BODY IN CASE OF VIRUS INFECTION ............................................. 62
APPENDIX 6. SELECTION OF RECOMMENDED TESTS FOR SOLID MATERIALS (EXCLUDING WOOD-PRESERVATIVES) .......................................................... 64
APPENDIX 7. SELECTION OF RECOMMENDED TESTS FOR LIQUID MATERIALS .............. 64
APPENDIX 8. COMMONLY USED METHODS TO MEASURE THE EFFECTS OF PRESERVATIVE/CURATIVE ACTION IN LIQUID MATRICES .............................................. 64
APPENDIX 9. COMMONLY USED METHODS TO MEASURE THE EFFECTS OF PROTECTING MATERIAL ............................................................................................... 64
APPENDIX 10. COMMONLY USED METHODS TO MEASURE ANTIMICROBIAL ACTIVITY 64
APPENDIX 11. INFORMATION ON THE PRINCIPLE TARGET ORGANISMS FOR PT 8 AS OUTLINED IN THE DOCUMENT (5.5.8) .......................................................... 64
APPENDIX 12. ANNEX A OF EN 599-1 AND EN 14128 .......................................................... 65
APPENDIX 13. LABORATORY STUDIES FOR RODENTICIDES : BAiT CHOICE TEST ........ 65
APPENDIX 14. FIELD TRIAL FOR RODENTICIDE BAITs ....................................................... 65
APPENDIX 15. LIST OF CURRENTLY AVAILABLE STANDARD TEST METHODS FOR RODENTICIDES .......................................................... 65
APPENDIX 16. ADDITIONAL INFORMATION ON LABEL CLAIMS ........................................ 65
APPENDIX 17. SPECIES GRID ...................................................................................... 66
APPENDIX 18. LIST OF CURRENTLY AVAILABLE STANDARD TEST METHODS FOR
PRODUCT TYPE 18 INSECTICIDES/ACARICIDES AND PRODUCT TYPE 19
REPELLENTS/ATTRACTANTS (AS FAR AS THEY CONCERN INSECTS AND OTHER
ARTHROPODS) ............................................................................................................. 66
APPENDIX 19. EFFICACY GUIDELINE WITH COCKROACH; FIELD TRIAL .............. 67
APPENDIX 20. CURRENT ANTIFOULING COATINGS ....................................................... 67
APPENDIX 21. PUBLISHED PAPER (CEPE ANTIFOULING WORKING GROUP) .......... 67
APPENDIX 22. EXAMPLE OF HOW AN OVERALL FOULING ASSESSMENT MAY BE CARRIED
OUT FOR PANEL TESTING IN MARINE WATERS .................................................. 67
APPENDIX 23. PT 22 ACTIVE SUBSTANCES IN THE REVIEW PROGRAMME ........ 67
APPENDIX 24. ASSESSMENT GRID FOR TESTS ON HUMAN BODIES ......................... 67

Figures

Figure 1: Decision scheme to distinguish between claims for material protection and
claims for protection of humans and animals .......................................................... Error
Figure 2: The various phases of a cycle of disinfection of an automatic process
........................................................................................................................................ Error
Figure 3: A Test for Antibacterial Activity in Wet Conditions ................................. Error
Figure 4: Simulated Splash Model Non-Porous Materials ......................................... Error
Figure 5: Simulated Splash Model Porous Materials .................................................. Error
Figure 6: Printing Model .............................................................................................. Error
Figure 7: Decision scheme for the distinction between preservation/curative action and
disinfection .................................................................................................................. Error
Figure 8: Example of a Simulated Growth Test ......................................................... Error
Figure 9: An Example of an Agar Plate Based Test .................................................... Error
Figure 10: OECD/IBRG Tier 1 Textile Test ................................................................. Error
Figure 11: Life cycle of subterranean termites ............................................................ Error
Tables

1 Table 1: Example ready-to-use disinfectants with/without pre-cleaning.*
2 ! Bookmark not defined.
3 Table 2: Example concentrated disinfectants
4 ! Bookmark not defined.
5 Table 3: Example surface disinfectants ready-to-use: more PT's
6 ! Bookmark not defined.
7 Table 4: Example insecticide: take target organisms and application method into account.
8 ! Bookmark not defined.
9 Table 5: Example anti-fouling product: Different ratio's of two (or more) active substances.
10 ! Bookmark not defined.
11 Table 6: Example anti-fouling product: Different ratio's of two (or more) active substances.
12 ! Bookmark not defined.
13 Table 7: Number of sampling points
14 ! Bookmark not defined.
15 Table 8: Number of sampling points
16 ! Bookmark not defined.
17 Table 9: Protection of Humans or Animals – Example Claims, Problems and Testing Approaches
18 ! Bookmark not defined.
19 Table 10: Basic Requirements for a Valid Test Protection of Humans or Animals
20 ! Bookmark not defined.
21 Table 11: Examples
22 ! Bookmark not defined.
23 Table 12: Basic Requirements for a Valid Test Protection
24 ! Bookmark not defined.
25 Table 13: Odour: Example Claims, Problems and Testing Approaches
26 ! Bookmark not defined.
27 Table 14: Different categories and the related product codes
28 ! Bookmark not defined.
29 Table 15: User categories
30 ! Bookmark not defined.
31 Table 16: Wood categories
32 ! Bookmark not defined.
33 Table 17: Wood product categories
34 ! Bookmark not defined.
Table 18: Application aim
Table 19: Different field of uses
Table 20: Method of application
Table 21: Examples of target organisms for wood preservatives
Table 22: Examples of claim matrix based on the application codes for product
Table 23: Preventive treatments: List of available standards and others methods used in wood preservation
Table 24: Curative treatments: List of available standards used in wood curative treatments (based on EN 14128)
Table 25: Toxicity ranking of known active substances used in anticoagulant rodenticides based on LD 50 (acute) data of brown rats and house mice compiled from CA-Reports, ranking from high (1) to lower toxicity (3)
Table 26: Target organisms versus test organisms
Table 27: Overview guidelines on termites
Table 28: CEN European standards
Table 29: Other test methods and guidance documents
Table 30: Reference Test Organisms
Table 31: Examples of viruses
Table 32: Selection of recommended tests for solid materials (excluding wood preservatives)
Table 33: Selection of recommended tests for liquid materials
Table 34: Commonly Used Methods to Measure the Effects of Preservative/Curative Action in Liquid Matrices
Table 35: List of standards
Table 36: Components Making Up a Label Claim
<table>
<thead>
<tr>
<th>Table 4</th>
<th>Example of linking table claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 38: PT 18 Crawling Insects</td>
<td>Error</td>
</tr>
<tr>
<td>Table 39: PT 18 Flying Insects</td>
<td>Error</td>
</tr>
<tr>
<td>Table 40: PT 19 – Repellents &amp; Attractants</td>
<td>Error</td>
</tr>
<tr>
<td>Table 41: Acronyms and Abbreviations</td>
<td>Error</td>
</tr>
<tr>
<td>Table 42: General</td>
<td>Error</td>
</tr>
<tr>
<td>Table 43: Crawling Insects: Cockroaches</td>
<td>Error</td>
</tr>
<tr>
<td>Table 44: Crawling Insects: Termites</td>
<td>Error</td>
</tr>
<tr>
<td>Table 45: Crawling Insects: Other Crawling Insects</td>
<td>Error</td>
</tr>
<tr>
<td>Table 46: Flying Insects</td>
<td>Error</td>
</tr>
<tr>
<td>Table 47: Insecticides Against Textile and Stored Product Pests</td>
<td>Error</td>
</tr>
<tr>
<td>Table 48: Repellents &amp; Attractants</td>
<td>Error</td>
</tr>
<tr>
<td>Table 49: Current Antifouling Coatings</td>
<td>Error</td>
</tr>
<tr>
<td>Table 50: Example of categorisation of fouling coverage into ratings from 0 to 4</td>
<td>Error</td>
</tr>
<tr>
<td>Table 51: Example of weighting of ratings</td>
<td>Error</td>
</tr>
<tr>
<td>Table 52: Example of categorisation of overall efficacy</td>
<td>Error</td>
</tr>
<tr>
<td>Table 52: PT 22 active substances in the review programme</td>
<td>Error</td>
</tr>
</tbody>
</table>

Table 4: Example of linking table claims
NOTES to the reader:

In this document text cited from the Biocidal Products Regulation (EU) No 528/2012 is indicated in **green boxes**.

⚠️ This symbol highlights text to be noted.

Section 5.6 and sub-sections for PT10, PT11, PT12, PT15, PT16, PT17, PT19 (non-arthropods) and PT20: please refer to the General sections 1-3 of this guidance and the TNsG.
## List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFNOR</td>
<td>Association française de normalisation; French national organisation for standardisation <a href="http://www.afnor.org/">http://www.afnor.org/</a></td>
</tr>
<tr>
<td>AS</td>
<td>Active substance</td>
</tr>
<tr>
<td>BP</td>
<td>Biocidal product</td>
</tr>
<tr>
<td>BPD</td>
<td>Biocidal Products Directive 98/8/EC</td>
</tr>
<tr>
<td>BPR</td>
<td>Biocidal Products Regulation (EU) No 528/2012</td>
</tr>
<tr>
<td>BS</td>
<td>British standard</td>
</tr>
<tr>
<td>CA/CAs eCA</td>
<td>Competent Authority/Competent Authorities</td>
</tr>
<tr>
<td></td>
<td>- Evaluating CA (eCA) is the Competent Authority that evaluates the application for an active substance approval or an application for a Union authorisation.</td>
</tr>
<tr>
<td></td>
<td>- Receiving CA is the Competent Authority that receives an application for a National Authorisation.</td>
</tr>
<tr>
<td>CAR</td>
<td>Competent Authority Report, (also known as the assessment report).</td>
</tr>
<tr>
<td>CEN</td>
<td>Comité Européen de Normalisation; European Committee for Standardisation <a href="http://www.cen.eu/">http://www.cen.eu/</a></td>
</tr>
<tr>
<td>CFU</td>
<td>Colony forming units</td>
</tr>
<tr>
<td>CIP</td>
<td>Cleaning-in-Place</td>
</tr>
<tr>
<td>CT</td>
<td>Concentration x Time</td>
</tr>
<tr>
<td>CV</td>
<td>Critical value</td>
</tr>
<tr>
<td>DIN</td>
<td>Deutsches Institut fuer Normung; German national organisation for standardisation <a href="http://www.din.de/">http://www.din.de/</a></td>
</tr>
<tr>
<td>DVG</td>
<td>Deutsche Veterinaemedizinische Gesellschaft; German Veterinary Medical Society <a href="http://www.dvg.net/">http://www.dvg.net/</a></td>
</tr>
<tr>
<td>EN</td>
<td>European Standard</td>
</tr>
<tr>
<td>EPPO</td>
<td>European and Mediterranean Plant Protection Organization <a href="http://www.eppo.org">www.eppo.org</a></td>
</tr>
<tr>
<td>ESL</td>
<td>Estimated service life</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Explanation</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>EU</td>
<td>European Union + Norway, Iceland and Lichtenstein Please note the BPR applies to the European Economic Area (EEA) and thus all references to the EU in the text should be understood as EEA (EU + Norway, Iceland and Lichtenstein)</td>
</tr>
<tr>
<td>GLP</td>
<td>Good laboratory practice</td>
</tr>
<tr>
<td>KD</td>
<td>Knock down</td>
</tr>
<tr>
<td>KD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Knock down for 50% of the group of tested animals</td>
</tr>
<tr>
<td>KT&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Knock down time for 50% of the group of tested animals</td>
</tr>
<tr>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Lethal dose for 50% of the group of tested animals</td>
</tr>
<tr>
<td>MAD</td>
<td>Mutual acceptance of data</td>
</tr>
<tr>
<td>prEN</td>
<td>Draft European Standard</td>
</tr>
<tr>
<td>PAR</td>
<td>Provisional assessment report</td>
</tr>
<tr>
<td>PEG</td>
<td>Partner expert group</td>
</tr>
<tr>
<td>PT</td>
<td>Product-type</td>
</tr>
<tr>
<td>SPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>TC</td>
<td>Technical Committee</td>
</tr>
<tr>
<td>TM</td>
<td>Technical Meeting</td>
</tr>
<tr>
<td>TNsG</td>
<td>Technical Notes for Guidance</td>
</tr>
<tr>
<td>TVC</td>
<td>Total viable count</td>
</tr>
<tr>
<td>UC</td>
<td>Use Class</td>
</tr>
<tr>
<td>VAH</td>
<td>Verbund fuer Angewandte Hygiene; Association for Applied Hygiene <a href="http://www.vah-online.de/">http://www.vah-online.de/</a></td>
</tr>
<tr>
<td>VOC</td>
<td>Volatile organic compound</td>
</tr>
</tbody>
</table>
## Glossary of Terms

<table>
<thead>
<tr>
<th>Standard term</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity against enveloped viruses (see also Virucidal activity and Limited spectrum virucidal activity)</td>
<td>A claim for hygienic hand and skin disinfectants with activity against enveloped viruses only.</td>
</tr>
<tr>
<td>Algaecide</td>
<td>A product or active substance used to control (inhibit the growth) or kill algae.</td>
</tr>
<tr>
<td>Algaecidal activity</td>
<td>The capability of a product or active substance to produce a reduction in the number of viable algae cells under defined conditions.</td>
</tr>
<tr>
<td>Antimicrobial product</td>
<td>A product which prevents the growth of/reduces the number of/mitigates the growth of micro-organisms</td>
</tr>
<tr>
<td>Bactericide</td>
<td>A product or active substance which irreversibly inactivates vegetative bacteria under defined conditions.</td>
</tr>
<tr>
<td>Bactericidal activity</td>
<td>The capability of a product or active substance to produce a reduction in the number of viable bacterial cells of relevant test-organisms under defined conditions</td>
</tr>
<tr>
<td>Bacteriostatic activity</td>
<td>Capability of a product or active substance to inhibit the growth of bacteria under defined conditions</td>
</tr>
<tr>
<td>Biocidal product/Biocide</td>
<td>BPR Article 3(1)(a): — any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, — any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. A treated article that has a primary biocidal function shall be considered a biocidal product.</td>
</tr>
<tr>
<td>Biofilm</td>
<td>An accumulation of microbial cells immobilised on a substratum and embedded in an organic polymer matrix of microbial origin</td>
</tr>
<tr>
<td>Biostatic product</td>
<td>A product which inhibits the growth of micro-organisms under defined conditions</td>
</tr>
<tr>
<td>Curative effect on biofilm</td>
<td>The biocide is added after the biofilm is formed and acts on biofilm stability, facilitating the biocide interaction with cells – it may or may not act as detergent and detach the biofilm from the surface</td>
</tr>
<tr>
<td>Disinfectant within PT 2, 3, 4 and 5</td>
<td>A disinfectant is a product that reduces the number of micro-organisms in or on an inanimate matrix achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose</td>
</tr>
<tr>
<td><strong>Standard term</strong></td>
<td><strong>Explanation</strong></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Disinfection within PT 2, 3, 4 and 5</td>
<td>Disinfection is the reduction of the number of micro-organisms in or on an inanimate matrix achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose</td>
</tr>
<tr>
<td>Skin disinfection within PT1</td>
<td>Skin disinfection is the reduction of the number of micro-organisms on skin, achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose</td>
</tr>
<tr>
<td>Efficacy</td>
<td>The ability of a product or active substance to produce an effect as described in the label claims made for it, when used under actual use conditions.</td>
</tr>
<tr>
<td>Flowcondition (for biofilm)</td>
<td>Biofilm is formed on supports of different nature placed along a tube or a chamber where the medium (inoculated and/or fresh) is circulated in a closed (reservoir-pump-tubing) or open (reservoir-pump-tubing-outlet) system</td>
</tr>
<tr>
<td>Fungicide</td>
<td>A product or active substance which irreversibly inactivates fungi (vegetative mycelia, budding yeasts and/or their spores) under defined conditions</td>
</tr>
<tr>
<td>Fungicidal Activity</td>
<td>The capability of a product or active substance to produce an effect as described in the label claims made for it, when used under actual use conditions</td>
</tr>
<tr>
<td>Fungistatic activity</td>
<td>The capability of a product or active substance to inhibit the growth of fungi under defined conditions</td>
</tr>
<tr>
<td>Hygienic hand disinfectants</td>
<td>A hygienic hand disinfectant is a hygienic handrub disinfectant or a hygienic handwash disinfectant</td>
</tr>
<tr>
<td>Hygienic handrub disinfectant</td>
<td>Product used for post-contamination treatment that involves rubbing hands, without the addition of water, which is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora</td>
</tr>
<tr>
<td>Hygienic handwash disinfectant</td>
<td>Product used for post-contamination treatment that involves washing hands with water, which is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora</td>
</tr>
<tr>
<td>Limited spectrum virucidal activity (see also Virucidal activity and Activity against enveloped viruses)</td>
<td>Limited spectrum virucidal activity is a claim for hygienic hand and skin disinfectants using Adenovirus and Murine Norovirus as test organisms, thus including activity against the test viruses and all enveloped viruses (see Appendix 5).</td>
</tr>
<tr>
<td>Log reduction / log&lt;sub&gt;10&lt;/sub&gt; reduction / log reduction</td>
<td>Reduction presented in a logarithmic scale. Example 1: when a disinfection reduces 10^8 bacteria to 10^2 bacteria, this is a log reduction of 6. Example 2: when a disinfection reduces 5.10^7 fungal spores to 8.10^7 fungal spores this is a log reduction of 3.79.</td>
</tr>
<tr>
<td>Microbes/micro-organisms</td>
<td>Bacteria (including vegetative cells bacterial spores and mycobacteria) fungi (including yeasts, moulds and fungal spores) algae, viruses (including bacteriophages), protozoa (including cysts and other permanent states), etc.</td>
</tr>
<tr>
<td>Mycobactericide</td>
<td>A product or active substance which irreversibly inactivates mycobacteria under defined conditions</td>
</tr>
<tr>
<td>Standard term</td>
<td>Explanation</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Mycobactericidal activity</td>
<td>The capability of a product or active substance to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions</td>
</tr>
<tr>
<td>Neutraliser</td>
<td>A chemical agent or formulation which suppresses the residual activity of an disinfectant within a test but does not inhibit or inactivate micro-organisms</td>
</tr>
<tr>
<td>Performance standard</td>
<td>Regulatory or scientific standard for biocides that is either quantitative or qualitative (that may also be specified in the test method) by which a decision is taken on the acceptability of a claim.</td>
</tr>
<tr>
<td>Preventive effect on biofilm</td>
<td>The biocide is present before the biofilm is formed and may act both on cell viability and/or on cell adhesion/biofilm maturation</td>
</tr>
<tr>
<td>Product type (PT)</td>
<td>Product types (PT) are defined in BPR annex V</td>
</tr>
<tr>
<td>Sporicide</td>
<td>A product or active substance which inactivates dormant bacterial spores under defined conditions</td>
</tr>
<tr>
<td>Sporicidal activity</td>
<td>The capability of a product or active substance to produce a reduction in the number of viable bacterial spores of relevant test organisms under defined conditions</td>
</tr>
<tr>
<td>Sporistatic activity</td>
<td>The capability of a product to inhibit the germination of dormant bacterial spores under defined conditions</td>
</tr>
<tr>
<td>Static condition (for biofilm)</td>
<td>Biofilm is formed on supports such as microplates without agitation after an incubation time that depends on the microorganism considered</td>
</tr>
<tr>
<td>Surgical hand disinfectants</td>
<td>A surgical hand disinfectant is a surgical handrub disinfectant or a surgical handwash disinfectant</td>
</tr>
<tr>
<td>Surgical handrub disinfectant</td>
<td>Product used for preoperative treatment that involves rubbing hands, without the addition of water, which is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound</td>
</tr>
<tr>
<td>Surgical handwash disinfectant</td>
<td>Product used for preoperative treatment that involves washing hands with water, which is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound</td>
</tr>
<tr>
<td>Treated article</td>
<td>A treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products</td>
</tr>
<tr>
<td>Tuberculocide</td>
<td>A product or active substance which irreversibly inactivates Mycobacterium tuberculosis under defined conditions</td>
</tr>
<tr>
<td>Tuberculocidal activity</td>
<td>The capability of a product or active substance to irreversibly inactivate Mycobacterium tuberculosis, demonstrated by the capability to produce a reduction in the number of viable cells of the test organism Mycobacterium terrae under defined conditions</td>
</tr>
<tr>
<td>Virucide</td>
<td>A product or active substance which irreversibly inactivates viruses under defined conditions</td>
</tr>
<tr>
<td>Standard term</td>
<td>Explanation</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Virucidal activity (see also Limited spectrum virucidal activity + Activity against enveloped viruses) | The capability of a product or active substance to produce a reduction in the number of infectious virus particles of relevant test organisms under defined conditions.  
“Full spectrum” virucidal activity is a claim for biocidal products using relevant test organisms and thus showing activity against the enveloped and non-enveloped viruses. |
| Yeasticide                                                                   | A product or active substance which irreversibly inactivates yeast under defined conditions                                                                                                                    |
| Yeasticidal activity                                                         | The capability of a product or active substance to produce a reduction in the number of viable vegetative yeast cells of relevant test organisms under defined conditions.                                           |
1. General Introduction

2. Claims

3. General considerations for the development and reporting of efficacy data

4. Active substance approval

5. Product authorisation

5.1 Evaluation of efficacy at product authorisation stage

The Product Authorisation stage is the point in the evaluation process where the efficacy of the biocidal product should be looked at for the full range of claims made. More test organisms or different uses can be relevant as compared to active substance approval. At this stage, it is not the properties of the active substance which are of interest, but instead the properties of the fully formulated product, which may contain more than one active substance.

Therefore, this is the stage at which a full evaluation of the efficacy of the formulated product should be carried out, and where the efficacy is evaluated in relation to the label claims made for the product. This evaluation should include all relevant target species (or representative species), the effects of using the product, the duration and speed of effect (including ageing and weathering if relevant), any claims for residual action, together with any other specific claims.

At biocidal product authorisation, the applicant must clearly describe the uses for which the product is intended when it is used under normal conditions, at the appropriate application rate and in accordance with the use instructions.

This information is required to allow a proper evaluation of the efficacy to be carried out, and must include, for every product type separately:

- The purpose of the biocide (e.g. prevent destruction of material by insect infestations, decrease of bacterial contamination on surfaces);
- The function of the product (e.g. bactericide, fungicide, rodenticide, insecticide);
- The organism(s) to be controlled;
- The effects on representative target organism(s) (e.g. attracting, killing, inhibiting);
- Any products, organisms or objects to be protected;
- The concentration at which the active substance will be used (the use concentrations for different targets should be stated for each use and method of application, if appropriate. Applicants should also indicate if the use concentrations should be different in different parts of EU);
- Description of the instructions of uses.

Commented [SJ1]: PEG CONSULTATION NOTE
The text shaded PINK is not in the scope of the consultation and not open for commenting: it is the introductory sections for Section 5 and is included for reference ONLY. The full text of Volume II is available on the ECHA Biocides Guidance website
At the product authorisation stage, efficacy must be demonstrated against all claimed target organisms. Use against additional target organisms (i.e. which were not supported at the active substance approval stage) may be applied for at this stage.

For biocidal products used to treat articles, it is important to categorise possible wide ranges of uses into sets of similar materials and use-conditions. Please see sections 5.3, 5.4.2 and 5.5 for more details.

5.2 Product families

5.3 Treated articles

5.4 Disinfectants (Main group 1)

5.4.0 General

5.4.0.1 Introduction

This guidance describes the nature and extent of data which should be available to support the label claims for biocidal products within the Main Group 1: Disinfectants. This group covers 5 product types as described in Annex V of the BPR:

MAIN GROUP 1: Disinfectants

These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air-conditioning systems; and walls and floors in private, public, and industrial areas; and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product type 3: Veterinary hygiene

---

2 This is taken to mean the disinfection of air itself. Disinfectants sprayed or vaporised into the air (e.g., room disinfection by vaporised biocides) are normally for the purpose of disinfecting surfaces and not the air itself. Disinfectants for air conditioning systems disinfect the surfaces or liquids in these systems, not the air coming out of it.
Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

**Product type 4: Food and feed area**

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

**Product type 5: Drinking water**

Products used for the disinfection of drinking water for both humans and animals.

Products in this main group are meant for the control of micro-organisms, such as bacteria (including vegetative cells, spores and mycobacteria), fungi (including moulds and yeasts), and viruses (including bacteriophages), algae and protozoa. Control may be carried out on inanimate surfaces or skin or in liquids. Note that the term "disinfectant" used for main group 1 should be read as a generic term and not according to the definition in the glossary of terms. This means that next to disinfectants it can also include products with biostatic activity.

The most important fields of use include medical, veterinary, food, feed and drinking water sectors. Applications in public, commercial and industrial areas, where application is to inanimate surfaces without direct contact with food, are included in Product type 2. If contact between disinfected inanimate surfaces and food is possible (e.g. food industry, private and restaurant kitchens), applications are included in Product type 4.

Disinfectants for medical instruments and medical equipment that are considered medical devices are covered under the Medical Device Directive 93/42/EEC (see 3.9.1 for more information). More borderline cases with other Directives or Regulations are noted elsewhere in this Guidance Document and are defined or described in other legislation or guidance.

Cleaning products which are not intended as biocides, including liquid detergents, washing powders etc. are excluded from these product types and thus this guidance is not applicable (Annex V of BPR).

Treated articles with claimed disinfecting properties or function can also fall within PTs 1 to 5: when such articles have a primary biocidal function they are considered biocidal products (see Competent Authority (CA) document⁴). These articles can include a wide variety of goods, with different applications, matrices etc. This guidance deals mainly with efficacy testing of (liquid) biocidal products; the methodology for testing (solid) treated articles can be quite different. See section 5.4.4.3 of this Guidance for details of a valuable guidance.

A "Glossary of Terms" is at the beginning of the document.

**5.4.0.2 Dossier requirements**

The following aspects are relevant for the evaluation of the efficacy of biocidal products within PT1-5:

1. The label claim and instructions for use
2. Efficacy data of the product
3. The possible occurrence of resistance, cross-resistance or tolerance.

---

³ CA-Sept13-Doc
5.4.0.3 Label claim

For each product, clear label claims should be provided. When the label itself cannot contain all the necessary information, any accompanying leaflet should also be considered. To simplify the text only the term "label claim" will be used below.

The types of efficacy claims made for a disinfectant/ biocidal product depend upon, among other things, the types of micro-organisms the disinfectant targets (e.g. fungal spores, yeasts, mycobacteria, bacteria or bacterial spores) and the disinfectant's intended use (e.g. in hospitals, in contact with food, in animal houses, in homes). Label claims and recommendations for use, including concentration and contact time, must be supported by the results of bactericidal, fungicidal, etc. tests appropriate to the area of application, which are normally performed on the basis of the specific standards.

Complete instructions for use are an integral part of the label.

The information on the product label should fully correspond with the uses pre-defined at the authorisation stage and reflected in the corresponding version of the SPC. Applicants must indicate clearly on the product's label the spectrum of antimicrobial activity claimed.

Examples of the common fields of applications are presented in the claim matrices which are a set of tables linked to this guidance document (see Appendix 1 for more information). The Claim Matrices are not intended to be exhaustive, but the majority of uses are included.

5.4.0.3.1 Target Organisms

The target organisms for which claims are made should be specified on the product label.

As the claimed antimicrobial efficacy for disinfectant products will encompass a large spectrum of potential target organisms, it is not necessary or indeed feasible to include all possible micro-organisms in an efficacy test designed to support a label claim. Instead, the types of target organism the product is intended for are mentioned, for example, fungal spores, yeasts, viruses, algae, protozoa, (myco)bacteria or bacterial spores.

Specific species are mentioned on the label where they are the only or most relevant organisms, or where they have a different susceptibility to biocides than the rest of the group. For instance, mycobacteria are less susceptible than other bacteria and it is only relevant to control them in certain situations such as tuberculosis wards.

In general it is not possible to claim against specific single species without claiming (and demonstrating) efficacy against the group of organisms (e.g. no claim against Mycobacterium tuberculosis without also making a general bactericidal claim, no claims against HIV without a general claim against enveloped viruses). However, there are some cases in which it can be justified that a claim only for a single or a small number of species is made (such as bacteriophages in the milk industry, or fungi Aspergillus fumigatus in poultry housing). Claims against specific organisms or groups of organisms should not be made, if they imply a false impression of superiority of a product; for example, a claim against MRSA should not be made for a bactericidal product, because MRSA do not present a specific challenge for disinfectants.

Standard test methods normally specify one or more representative species that should be tested per group of organisms for which the claim is made. For instance, a bactericidal product should be tested on gram-positive and gram-negative bacteria, a fungicidal product should be tested on yeasts and fungal spores. The species used are

---

4 Details on how to fill out the SPC are available in the ECHA Technical Guide and SPC Editor.
representative species that take into account their relevance to practical use, susceptibility for disinfectants and adequacy for laboratory testing. The test organisms and strains which should be used are normally stated in standard efficacy test methods, i.e. according to EN 14885 or OECD-guidance. When it is not possible to use standard test methods for efficacy testing and other tests are used instead, the test organisms listed in Appendix 3 should be employed. If test organisms other than those listed in Appendix 3 are used, their relevance should be justified. Wherever possible strains should be selected from international collections (their genetic stability should be checked regularly). The preservation procedures must be clearly described (EN 12353). Other test organisms, in addition to those specified in the test standards, can also be tested. When efficacy against specific additional species is claimed, efficacy tests with those species should also be performed. In general, claims should not be made against the specific reference species used in a standard test as this can give a misleading impression that the product shows activity beyond that covered by the general (e.g. bactericidal, fungicidal) claim. Mentioning specific organisms on the label is still a subject of discussion between Member States. The above sections reflect the position at the time that this guidance is written.

5.4.0.3.2 Areas of Use

Disinfectants are used almost everywhere that people want to “eliminate” or inhibit (for static products) micro-organisms. They are used to kill or irreversibly inactivate or inhibit bacteria, fungi and viruses on animate and inanimate surfaces and matrices, in hospitals, households, schools, restaurants, offices, swimming pools, kitchens, bathrooms, dairy farms, on medical and dental equipment, eating utensils and at many other locations. In some cases biostatic products are used which only inhibit microorganisms (see section 5.4.0.5.3 of this guidance). Applicants should clearly indicate the intended areas of use for the product on the label, for example, areas of use could include (not exhaustive):

- Hospital and other medical areas;
- Domestic use;
- Institutional use (offices, schools etc.);
- Industrial applications, e.g. food, cosmetic, pharmaceutical industry etc.;
- Restaurants and large-scale/canteen kitchens;
- Veterinary areas (animal housing, animal health care, teat or hoof disinfection etc.);
- Recreational areas.

5.4.0.3.3 Sites of Application

In addition to the types of efficacy claimed (e.g. bactericidal, fungicidal, tuberculocidal) and the intended area of use, the applicant must specify the use patterns for which the disinfectant is recommended on the label.
Broad examples of use patterns (not exhaustive) could include areas such as:

- Use on intact skin;
- Use in hospitals, operating theatres, isolation wards, etc.;
- Use in food manufacturing, retailing, processing areas etc.;
- Use in animal housing and equipment, e.g. pigs, sheep, poultry etc.;
- Use on work surfaces, cutting boards etc.;
- Use on fabrics or textiles;
- Use on toilets, bathrooms, sinks, etc.;
- Use against micro-organisms associated with human or animal waste;
- Use in air conditioning systems;
- Use in swimming pools, spas, aquariums and bathing waters;
- Use in tanks, pipelines, equipment soak or bottle wash.

5.4.0.3.4 Directions for use (Methods of application)

The label claim must specify the application method of the product. For disinfectants there is a broad range of application methods (e.g. wiping, aerosol, spraying). The in-use concentration of the solution and the contact time, which are essential for safe and effective use, should be described on the label. Any other directions for use should also be specified, such as whether the surface should be cleaned first, and claims regarding the number of times a prepared use solution can be used (or re-used) before a fresh solution must be prepared.

The application method can have a strong influence on the efficacy of a product, therefore the testing of a product should be appropriate for the application method. If specific equipment is used for application of the product (e.g. vaporisers) this should be taken into account when testing the product for efficacy. Equipment used in laboratory tests or small scale tests may (of necessity) be different from that employed in practice. This is especially the case when biocidal active substances are generated in situ using large scale equipment, such as electrolysis. In cases where small scale tests cannot be extrapolated to actual use conditions a large scale test with the equipment should be done.

5.4.0.3.5 Other interfering parameters

Any other circumstances that can influence the efficacy of a product should be mentioned on the label (e.g. temperature or pH requirements). For example, when a surface should be cleaned before applying the biocide and a no rinsing step is involved, or that alkaline cleaning fluids should not be used with acidic biocides, and vice versa.

5.4.0.4 Efficacy testing

For efficacy testing of disinfectants in general only quantitative tests methods should be used.

5.4.0.4.1 Tiered approach

For efficacy testing of disinfectants a tiered approach is recommended. The following tiers can be distinguished (in accordance with EN 14885):

- Phase 1 tests are quantitative suspension tests to establish that a product (or an active substance) has bactericidal, fungicidal etc. activity without regard to specific conditions of intended use. Phase 1 tests cannot be used for any product claim.
- Phase 2 comprises two steps:
Phase 2, step 1 tests are laboratory suspension tests in which the ultimate purpose is to establish at what concentrations the product meets specified requirements under "in-use" conditions. In these tests, in-use conditions (e.g. temperature, contact time, interfering substances) are considered in the test method.

Various laboratory methods have been developed for biocide activity testing. Although these experiments differ in their design and experimental detail, they are all based on the principle of adding a test inoculum to the disinfectant (or vice versa) and taking samples at specified times. The biocide in each sample is then neutralised and the survival of the organisms assessed. In practice, the methods can be classified into two groups, according to how the end-point of the test is determined:

**Quantitative tests**

Samples of untreated and biocide-treated cells are plated on nutrient medium after neutralisation. After incubation, the number of colony forming units is determined and the log\(_{10}\) reduction in viable counts is determined.

**Capacity tests**

The biocide is challenged successively with the test organism at defined time intervals. This type of test can be used for instance for swimming pools and toilet disinfectants which are challenged by new bacteria periodically. Following each inoculation, samples are taken, and after a suitable contact period has elapsed, the biocide is neutralised and the sample incubated in a suitable growth medium to determine the surviving microorganisms. The result is expressed as the amount of the accumulated inoculum that was required to produce the "failure".

Phase 2, step 2 tests are simulated use or practical tests, performed under rigorous conditions within the laboratory, which mimic real-life conditions, for instance by pre-drying the micro-organisms onto surfaces. These tests are used in a second testing stage. After measuring the time-concentration relationship of the disinfectant in an in-vitro test (phase 2, step 1), these practical tests are performed to verify that the proposed use dilution is likely to be adequate in real-life conditions. For several uses standardised, simulated use tests exist (surface disinfection, hand wash or rub, instrument disinfection) but there are no standard tests available for many others.

Longer-lasting activity is claimed for some products. When these products are applied to surfaces, it is common that they will not be completely removed or rinsed off after application. This might lead to longer-lasting activity of the biocide on the surface.

Likewise, some products are used for maintenance via continued release of low levels of biocidal product. Both effects can be determined by appropriate efficacy tests.
Phase 3 Field or in-use tests

In-use testing involves the antimicrobial evaluation of the product under actual conditions of use on specified surfaces or materials in a specified environment. As with standard and non-standard laboratory methods, representative organisms or a suite of organisms of concern may be used. Validated methodologies for these types of tests are currently not available, although some are in development.

The practical use conditions under which a product can be used can be very variable and are therefore difficult to standardise. Field tests, although not standardised, can however give valuable additional information on the efficacy of the product, provided that the studies are scientifically robust, well reported and provide a clear answer to the question. In these types of test, a control treatment without biocide should be included. Where this is not possible, efficacy should be judged on a comparison of the situation before and after application.

Until validated standards are prepared, the responsibility for determining the acceptability of data derived from field trials in support of the claim will lie with the CA, taking into account the guidance given in EN 14885.

5.4.0.4.2 Standard test methods

Ideally, data should be generated using internationally or nationally recognised testing methods (CEN, OECD, ISO, etc.). Several international standard test methods currently exist for disinfectant products. Recommended standard tests are presented in Appendices 2 and referenced in Appendix 4 to this guidance document.

If there are no guidelines available for the specific use of a product, or guidelines are not suitable, the applicant may use other methods (such as intra-company Standard Operating Procedures), where the studies are scientifically robust, well reported and provide a clear answer to the question. In addition, the test methods used, together with the test conditions, should be clearly and fully described and must address the efficacy claim that appears on the product label. The use of existing guidelines, with modifications to make the guideline more suitable for the specific product or use conditions, is also possible. EN 14485 provides guidance on modification of standards (EN 14485, section 4.2 version 2014).

At the time of publication of this guidance document, a broad range of CEN methods are available. OECD has several phase 2/step 2 test methods developed for the efficacy testing of disinfectants to be used on hard surfaces which have been published as Guidance Documents. Available tests are presented in Appendix 2 and referenced in Appendix 4. The use of CEN test methods is highly recommended, where these are available and relevant. However it should be noted that although this Guidance is mainly based on EN standards, there are some cases where there are discrepancies compared to the EN tests. In such cases the ECHA Guidance should be followed as the leading guidance. OECD test methods may be used if, for example no CEN standard is available.

These methods, described below, typically give a standard set of test parameters, test organisms and pass criteria. Where specific conditions apply for a field of use, such as high/low level soiling, high/low temperatures, relevant contact times etc. these conditions should be included in the efficacy tests.
CEN Standard Test Methods
A Technical Committee (TC 216) was established in the European Committee for Standardisation (CEN), to produce harmonised European methods for testing the activity of disinfectants used in medical, veterinary, food, industrial, domestic and institutional areas. The standards are based on suspension tests (phase 1 and phase 2, step 1) and some simulated use tests like surface tests (phase 2, step 2).

European standard EN 14885 gives information on the application and interpretation of European Standards for the testing of chemical disinfectants within product types 1, 2, 3 and 4 of the Directive / Regulation.

This document outlines the various standards currently available and provides guidance as to the choice of a suitable standard that may be used to demonstrate the effectiveness of disinfectants in particular situations (such as medical, veterinary and food hygiene) and on the interpretation of results from such tests in making and supporting efficacy claims.

In EN 14885 products intended for domestic use are grouped with products for use in food and industrial areas, and therefore the tests specified are not always relevant to domestic areas. For instance, the virus test EN 13610 only tests against bacteriophages. In these cases, the test from the medical area should be used where relevant. In cases where no test method is available for one area of use (e.g. sporicidal test in the medical area), a test from another area can be used instead, provided that the test parameters (soiling, temperature, etc.) are adapted to the intended use area (for further guidance on the use of tests see EN 14885 section 4.2).

The application of disinfectants to water systems such as swimming pools, spas, and drinking water is not addressed in EN 14885. For the evaluation of activity against Legionella in aqueous systems (water used in cooling towers and water for general purposes, like spas, pools, showers and other uses) a quantitative suspension test is available (EN 13623).

EN 14885 includes guidance on how a phase 3 field trial should be conducted. This guidance is intended to advise on the factors to be taken into account and controlled when performing a field trial.

The use of CEN test methods is highly recommended, provided that the methods are applicable for the use of a product. In some cases, the method can be adapted (other contact times, soiling, etc.) to fit the use conditions. Any deviation from a standard must be clearly described and a justification for any deviations provided.

OECD Standard Test Methods
The OECD publishes practical test methods (comparable to phase 2, step 2 tests (1.4.1.3) or phase 3 (1.4.1.4)) for testing the efficacy of disinfectants on non-porous surfaces within the “Series on Testing and Assessment” or the “Series on Bioicides”, respectively. Currently, all available methods have been issued as OECD Guidance Documents. Guidance Documents are, however, not covered by the Mutual Acceptance of Data (MAD) principle and are advisory in nature. Further developed OECD Test Guidelines might become available in the future. As European Standards are not available for all types of applications yet, the use of OECD methods is recommended provided that the methods are appropriately reflecting the use of a product. Again, the methods can be adapted (other contact time, soiling, etc.) to better fit the use conditions, provided that any deviations from the standard are clearly described and justified.

Please note that in the OECD Guidance Documents on disinfectants, the volume of disinfectant solution added to the surface is very high compared to what is normally done in practice. This test protocol can only be used for uses where the volume of disinfectant solution per surface area is similar to the intended use (e.g. flooding).
Other Standard Test Methods

While CEN standards and, in case no CEN standard is available, OECD methods are highly recommended, there are circumstances in which these tests cannot be applied, i.e. they are not available, or relevant to a particular product or use pattern. In those cases other test methods can be used.

Other test methods, for example VAH (former DGHM), DVG, AFNOR, US-EPA, AOAC or ASTM methods, are available and might be used when no international standard is available for a specific application. Where these methods lack predefined test parameters, target organisms or pass criteria, the applicant has to provide evidence why the chosen parameters are appropriate for the intended application.

Where no standard tests are available, suitable test protocols may be designed (and justified) by the applicant, but these should be discussed with and agreed by the CA before testing takes place.

5.4.0.4.3 Data requirements

Label claims and recommendations must be supported by the results of tests appropriate to the area of application.

In each test the composition of the product to be tested should be clearly described, including the identity and function of the active substances specifying quality and quantity in the formulation. In addition, because the co-formulants can affect the efficacy of the product, they must also be clearly described including identity and function.

Alternatively, the formulation can be identified by a retrievable reference name or number. In such cases (i.e. it may only state a code for the product for the purposes of confidentiality), the composition of the tested product should be provided separately. As the formulation may affect the efficacy of the product, the composition of the product tested should be the same as the product under consideration. If not, justifications should be provided for any differences, and these will be assessed on a case-by-case basis.

As phase 1 tests do not take practical use conditions into account, they are not considered acceptable to support claims during product authorisation. In general, phase 1 tests are used during the development of the product, for inclusion of active substances on the “Union list of approved substances” under the BPR or to prove that a co-formulant has no biocidal activity.

In general, at least phase 2, step 1 and step 2 tests are required to support label claims during product authorisation. The phase 2, step 1 test will provide basic information on the efficacy of the product (in a standard test), while phase 2, step 2 tests investigate the effects of more in-use factors (such as drying of target organisms). The combination of phase 2, step 1 and step 2 tests will generally provide a robust data package to demonstrate the efficacy of a product. Deviations from the tiered approach should be justified.

In some cases, for example when disinfection is done in suspension under real use conditions (because the target organisms are suspended in a liquid already or will be suspended during the process due to mechanical action, for example, in CIP), a phase 2, step 1 test is sufficient on its own, as this already simulates practical conditions.

In other cases a phase 2, step 2 test may be replaced by a phase 3 test where a phase 2, step 2 test is not appropriate. In general, a phase 3 test will be done in combination with a standard phase 2, step 1 test, as phase 3 tests are often variable.

Where in-use conditions cannot be simulated, phase 3 tests are required (e.g. drinking water disinfection with ionisation equipment).

If more than one test method is available and applicable in phase 2, step 2 to substantiate a label claim for efficacy, it is sufficient to provide data from only one of the test methods. The test method selected should be one which best represents the way in
which the product is used. For example, in the case of a disinfectant used for "hard, non-porous surfaces by spraying", the test method should be one for such surfaces without mechanical action and with representative conditions of use, such as contact time, soiling, temperature and test organisms.

It is not mandatory to perform the tests under obligatory test conditions of the standards if the claimed use conditions of the products are different from these obligatory tests conditions.

Tests have to be performed with relevant target organisms, which are selected in accordance with the standard and the intended use of the product. This is further discussed in Section 1.3.1 of this Guidance. A list of standard test organisms is given in Appendix 3.

The concentrations used in testing should be selected to demonstrate the threshold of product efficacy. Suspension tests should be performed with several dose rates, including at least one rate lower than the effective rate. Competent Authorities (CAs) will evaluate dose response data generated in these tests in order to assess if the recommended dose is appropriate (i.e. the concentration is not too high, or at the minimum) to achieve the desired effect.

For biocidal products which claim a biostatic effect (bacteriostatic, fungistatic, etc. i.e. the ability to inhibit growth of bacteria, fungi etc. without killing them) the efficacy should be shown by suspension tests and simulated use tests (e.g. surface tests). The suspension test and simulated use test should be performed with and without neutralisation and with a water control (where water is tested instead of the product). The results from this testing should show that the product prevents growth of the test micro-organism (i.e. a lower level of test organism compared to the water control) but does not necessarily inactivate them (the micro-organisms survive in the test without neutralisation).

Biocidal products that claim a biostatic effect bear the risk of development of organisms with temporary or permanent reduced susceptibility (resistance). For this reason, efficacy of these types of products has to be examined carefully.

In case of in situ production of the active substance or when an apparatus is used to dose the active substance in the right amount to the water, the report should contain information on safety measurements concerning over and under dosing.

Other products, which do not have biocidal or biostatic activity, might fall within the scope of the BPR, Article 3 1 (a) "with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action". No EU standards are available for these types of product yet, so applicants should provide a method following the principles of this guidance and based on scientific evidence. During development of new tests, or when an applicant is considering using a non-standard test or using novel testing methods, they should discuss this with the CA as to the acceptability and applicability of the test.

In the following sections, guidance on the requirements per product type and use will be given.

Detailed but non-exhaustive lists of the most relevant product applications and uses of biocides, together with the required test methodology, are given in the claims matrices which are a set of tables linked to this guidance document (see Appendix 1 for more information).

For uses and claims that are not specifically mentioned in this document the requirements will be set on a case by case basis by the CA.
5.4.0.4.4 Relevant factors of the test procedure

Formulation of the tested product

A product authorisation is given to a single biocidal product with a defined composition or to a group of products making up a biocidal product family (BPF) and having similar uses, the same active substances, similar composition with specified variations and similar levels of risk and efficacy.

With respect to a single product the efficacy of its specific formulation should be demonstrated. Therefore it is important that the formulation tested is clearly reported in each test report (or provided alongside the test report with a statement that it is the formulation which has been tested). The formulation details should specify the active substances and co-formulants present, together with their respective concentrations, and should confirm that all tested formulations contain the same co-formulants and concentrations. Any deviations should be mentioned and justified in a statement or in the relevant efficacy reports. Where there are deviations in the formulation from that in the product for which authorisation is sought, the tests will only be considered relevant where it is evident that the deviations have no effect on efficacy. In cases where this is not evident, a confirmatory study with the organisms that is most difficult to control should be proposed.

Within the BPF the minimum level of efficacy over the whole potential range of products should be demonstrated and the permitted variations in composition and intended uses should be explicitly identified.

The test formulations should be chosen in such a way that they cover the whole potential range of products. The test formulations should include at least a product with the lowest concentration of active substance. A justification should be given whether co-formulants influence the efficacy. When co-formulants might influence the efficacy, the worst case concentration of co-formulants (i.e. low concentration of a co-formulant that might have a positive effect on efficacy, high concentration of a co-formulant that might have a negative effect on efficacy) should be tested. See also 1.5.7 for more information on testing BPF.

Hard Water Claims

The degree of hardness of the water used to dilute the disinfectant may affect its performance (by the presence of metal ions such as Ca$^{2+}$ and Mg$^{2+}$). Generally the harder the water is, the less effective the diluted disinfectant will be. Therefore, test programmes which require that products are diluted with potable water must be diluted in water of standard hardness as defined in the corresponding test standard, for the purpose of efficacy testing.

It follows that any product that carries label claims for effectiveness in hard water must be tested by the appropriate method in water with defined hardness at the level claimed.

Presence of Interfering Substances

When disinfectants are applied to either inanimate surfaces or skin or liquids, substances may be present on the surface or in the liquid, which may affect the disinfectant's activity.

The nature, amount and condition of the soiling present will affect the efficacy of a disinfectant.

In many cases residual contamination must be expected and in some situations (e.g. in the treatment of blood spillages) disinfectants are specifically used to decontaminate soiling, to prevent infection transfer and to assist in safe disposal.

Blood, urine, faeces, food debris, fats and oils, dust and proteinaceous materials are the most likely organic soilings to be encountered. Limescale, milkstone and soil are the most common inorganic soilings.
Where claims are made for use under soiled or dirty conditions, the use concentrations of the product must be determined from tests performed in the presence of suitable soiling materials. Soiling materials commonly used in efficacy test methods include albumin serum, blood, yeast and yeast extract.

In practice, with exception of a few situations (e.g. clean rooms), the presence of soiling on surfaces or in liquids to be disinfected cannot be ruled out. For this reason, a small amount of interfering substance should always be included during the testing of the product. In the CEN methods this is called "under clean conditions". Tests under clean conditions can be used when the surface is clean before disinfection. This is for instance the case when the label states that cleaning prior to disinfection is necessary. When a product claims combined cleaning and disinfection, the product should be tested under dirty conditions (see Appendix 4 for more information). Also, where the label only states excessive dirt should be remove, and the surface is still soiled after that (e.g. in the meat industry), soiling for dirty conditions should be used. Please note that in some cases EN 14885 is not always sufficient to meet BPR requirements.

When a product is to be recommended for certain uses where the soiling is of a specific type (such as soap film residue or hard water scum), the product must be tested in the presence of that specific soiling type. If more soiling types are relevant for the use of the product (e.g. a product must be used in the beverage industry, in meat industry or in kitchens), pre-testing should be done to determine the most challenging soiling type. Extended testing with the most challenging soiling type will be sufficient to cover all the others.

As an exception to the rule, products to be used in cleanrooms do not require additional soiling in the test. A cleanroom has a controlled level of contamination that is specified by the number of particles per cubic meter at a specified particle size. The soiling level in cleanrooms is so low that even testing under clean conditions for the EN tests is still over-dosing of soiling compared to cleanrooms. For these uses the high load of test organisms can be seen as soiling. Tests without soiling will only be accepted when the label states the specific use in clean rooms which are classified according to ISO 14644-1 in class 1 to 9 or according to GMP EU classification in Grade A to D.

Generally, soiling will reduce the efficacy of the disinfectant, and where soiling is present, longer contact times, higher concentrations, pre-cleaning or a combination of these elements may be necessary.

Temperature

Generally, disinfection performance increases with temperature, although this depends on the active substances and the effect on individual species may vary depending on the specific properties. Therefore, the test temperature should be representative of those encountered during the intended use of the product (e.g. low temperature in animal housing, higher temperature in CIP). Some biocides are used in chemothermal disinfection, for instance, some CIP treatments are done under temperatures of 60-80°C. Also for these uses the products should be tested at the use temperature.

If products (PT 2-4) are tested with high temperatures above 40°C heat resistant reference test organisms must be used. Enterococcus faecium must be used as the only test organism for claiming bactericidal activity. For a virucidal claim the only test organism must be Murine Parvovirus. For a sporicidal claim the test organism can be spores of, for example, Bacillus cereus or Clostridium sporogenes.

For mycobacteria, yeasts and fungal spores no relevant test organisms for high temperatures are available. Most yeasts and fungal spores are already irreversibly inactivated by high temperature (>40°C) in the control without active substance. However, ascospores of several fungi can become heat resistant and can cause problems in, for instance, the food industry.
When standard tests with relevant temperature resistant strains become available for mycobacteria, yeasts and fungal spores, these should be used.

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.

For specific claims against heat resistant species (e.g. *Talaromyces flavus*) efficacy tests with these organisms should be provided. In these tests a control without biocide should be included which shows survival of the test organisms at the high test temperature.

It is possible that the concentration needed to pass the test is higher for the organisms tested at lower temperature than for the temperature resistant organisms tested at higher temperature. In that case a justification should be given on how the test results reflect the use concentration in the use instruction on the label.

**Contact Time**

The contact time of a product on a surface etc. is an important aspect in the evaluation of the efficacy of disinfectants. In general, the longer the contact time, the more effective the disinfectant is. In trials where test organisms are taken from treated samples for further analysis, the contact time between the biocide and the test organisms should be stopped. Neutralisers, membrane filtration or subculture techniques are used to prevent residual carry-over of active substances. Neutralisation is discussed further in section 1.4.4.6 of this Guidance.

Some disinfectants act very quickly, whereas others require an extended contact time to achieve adequate performance. Mycobacteria, bacterial spores, fungal spores and non-enveloped viruses take longer to be irreversibly inactivated than most vegetative microorganisms.

The contact time that is practical in real life use should be taken into consideration when testing. In phase 2 and phase 3 tests the product should pass the test at the contact time recommended on the product label.

**Neutralisation**

Neutralisers are used to stop the product’s activity in trials where the test organisms are taken from treated samples for further analysis, such as plate count following biocidal treatment. An effective neutraliser for the test product should be identified, and evidence demonstrating the effectiveness of the neutraliser against the product under test, and showing that the neutraliser itself does not have antimicrobial activity, must be included in a test report. Membrane filtration or subculture techniques can be used to stop the product’s activity, in combination with or instead of chemical neutralisation. These other methods are covered by the term “neutralisation” as used in this guidance.

Appropriate controls for determining the efficacy of the procedure to stop the product’s activity after the contact time should be performed.

**pH**

The prevailing degree of acidity or alkalinity during disinfection can also affect the performance and choice of disinfectant. Therefore, the pH of the product at the use concentration (diluted) as used in the test must be included in the test report.

**Texture of Surfaces**

Smooth impervious surfaces are easier to disinfect (and also to clean) than rough or pitted ones. In some circumstances the micro-organisms might be protected from the action of disinfectants by being protected in porous surfaces. Clumps of micro-organisms may also be more difficult to inactivate, as cells inside are protected by dead micro-organisms on the outside. Recently porous surface tests have been developed (CEN) to test under these conditions.
Bacteria and fungi can adhere to surfaces forming biofilms. In biofilms susceptibility is decreased (the bacteria are in a different physical state) and penetration of biocide can be difficult to achieve due to the matrix surrounding the bacteria. This makes bacteria in a biofilm more difficult to inactivate.

Repetition
In general test results become more reliable when the tests are done in replicates (e.g., repeated in time, in more test objects). Replicates should be performed as required in the appropriate EN standards and where appropriate, internal standards or reference substances should be included.

EN 14885 section 5 (parts b, c and d) state the following information on precision of the test methods (repetitions):

- For standardised tests, or adaptation of a standard test, it is recommended to repeat the test and/or include an internal standard and/or performing the test in a second and/or third laboratory. When doing the latter the second laboratory (and any further laboratory) might only repeat the test which is regarded as the most relevant one with the least susceptible test organism(s). If results from two or more laboratories are used, each laboratory has to specify one result, e.g., “R = > 5.2 lg (EN 13727-instrument disinfection)”. Then the mean of the results of all laboratories is calculated assuming each laboratory’s result as equivalent. Results with lg “more than” are set as this figure, e.g., “> 5.2 lg” is used for calculation as “5.2 lg”. All lg values are converted to real numbers, e.g., 5.2 lg to about 158,000. The mean is the arithmetic mean of these converted numbers. If one of the testing laboratories obtains a result less than the required lg reduction, the product must pass if further tests by three other laboratories demonstrate a pass. The calculations above cannot be done with tests where pass criteria are not expressed as lg reduction.

- In case of repetition of the test it is unnecessary to repeat the test with all testorganisms but only with the least susceptible to the product under test.

- If two or more tests are carried out to support a claim of performance (e.g., phase 2, step 1 and phase 2, step 2) and the ensuing recommendation for use, the tests may be ranked according to their order of relevance, i.e., their ability to predict the product’s performance under real life conditions. In case of a ranking only the result of the most relevant test may be repeated taking into account advice 3). If a ranking is not possible only the results of the test showing the highest minimum active concentration should be repeated.

5.4.0.5 General data requirements

5.4.0.5.1 Test range
Tests (phase 2, step 1) should be performed at a range of concentrations in order to verify that the use concentration is suitable for the desired effect (e.g., not too high or not at the minimum effective level).

5.4.0.5.2 Claim for several areas of use
In cases where the product is intended for several areas, it is usually acceptable to perform the tests from only one area, as long as the test is performed with the worst case test conditions (temperature, log reduction, interfering substances, etc.) and the test with the highest/most stringent pass criteria is used. In case the strains are different between the PTs all the strains must be tested.

5.4.0.5.3 Biocidal products with biostatic effect
For biocidal products with a biostatic effect (bacteriostatic, fungistatic, etc.), the efficacy should be shown by suspension tests and simulated use tests (e.g., surface tests). The suspension test and simulated use tests should be performed with and without...
neutralisation. The results from these tests should show that the product prevents
growth of the test organism (no increase in numbers compared to the negative control)
but does not necessarily inactivate them (survival of the test organism in the test
without neutralisation).

5.4.0.5.4 Malodour control
There are specific requirements for products claiming control of organisms that cause
malodour. Phase 2, step1 and step 2 tests should be performed with odour producing
micro-organisms. A justification for which bacteria, fungi, etc. are relevant to the
intended use should be provided. Along with these laboratory tests, an odour test should
be performed. The CA will decide on a case-by-case basis whether the product will
receive authorisation.

5.4.0.5.5 Changes in ingredients 5
When small changes are made to the non-active ingredients in a product, it is not always
necessary to repeat all the tests with the new formulation. The applicant may provide a
description of the changes and the effects that they have on the efficacy of the product.
In the case of a minor change, a robust justification might be sufficient (to be decided by
the CA). In other cases, new efficacy tests will have to be provided. This can be either a
full set of efficacy tests or a test with the least susceptible organism in the former test.

5.4.0.5.6 Treated articles
See Section 5.3 for guidance on Treated Articles.

5.4.0.5.7 Biocidal Product Families
When authorisation is requested for a product family, efficacy should be demonstrated
for the whole group but not necessarily of each product. More information is available in
Section 5.2 Product Families.

5.4.0.6 Resistance
See section 3.2 for guidance on resistance.

5.4.0.7 Assessment of application for authorisation

5.4.0.7.1 Decision making
Biocidal Product Regulation 528/2012 (Annex VI) stipulates rules for decision making for
biocides.
The test results must meet the requirements of the standards or other criteria for
acceptance which are described below per type of use. Where a product does not
conform to these criteria, the applicant should provide a justification in the application as
to why the product should still be recommended for authorisation. The CA will decide on
a case-by-case basis whether the product will receive authorisation.

5.4.0.7.2 Assessment
The CA assessor/expert assesses the performance of the product as demonstrated in the
submitted efficacy tests against the label claims made for the product and the above
criteria. If the product is judged to be sufficiently effective in laboratory (and, where
relevant, field) tests, the product will be recommended for authorisation as far as
efficacy is concerned.

In exceptional cases the applicant may provide justification as to why the specified
acceptance criteria are not met but the product is still acceptable. The CA will evaluate

---

5 For this section, the product family concept of the BPR is not yet taken into account.
the justification on a case-by-case basis, possibly in consultation with the other CAs, and decide whether it is acceptable or not.

The following sections give more specific dossier requirements per type of disinfectant.

5.4.1 PT1 Human hygiene biocidal products

5.4.2 PT2 Disinfectants and algaeicides not intended for direct application to humans or animals

5.4.3 PT3 Veterinary hygiene biocidal products

5.4.4 PT4 Food and feed area disinfectants
5.4.5 PT5 Drinking water disinfectants

5.4.5.1 Introduction

Product type 5 contains biocidal products used for the disinfection of drinking water for both humans and animals. The definition of drinking water is in accordance with Article 2 of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. In this Guidance (and section) the term drinking water for humans is not only used for water that will be consumed directly by humans but also for other uses of water coming out of the plumbing system like showering, cooking, etc.

When disinfection is done in the water system while it is in service and the water itself is also disinfected, this is included in PT5. When water systems are disinfected in closed circuits, after which the system is washed with clean water, this is disinfection of the pipework only and is as such included in PT4.

Disinfectant products can be added to drinking water, intermittently by shock dosing or continually dosing. The purpose of this type of disinfection is to disinfect the water in order to prevent transmission of water-borne diseases via drinking water. Water-borne transmitted pathogens can be bacteria, viruses, yeasts, fungal spores or protozoan parasites. Disinfection is only one aspect of drinking water treatment. Application of drinking water disinfectants is accompanied with the responsibility to also control any toxic disinfectant by-products. Treatment substances should only be added for specific hygienic or technical reasons, limiting application to the minimum volumes that are absolutely necessary for achieving the targeted effect (principle of minimisation) and only under conditions optimising their efficacy.

Disinfection within PT5 can be divided into six application groups:

1. Disinfection at the drinking water suppliers and their water distribution systems
2. Disinfection of raw water for individual supply (1-2 premises)
3. Disinfection in collective drinking water systems
4. Disinfection of water in reservoirs
5. Disinfection of water of undefined quality for small scale use (up to 5 L/person/day)
6. Disinfection of water for animals

In the sections below a detailed description of each group as well as the requirements and acceptance criteria for most common uses are specified. For other uses and claims that are not specifically mentioned the requirements will be set on a case-by-case basis by the CAs.

5.4.5.2 Disinfection at the drinking water suppliers and their water distribution systems

5.4.5.2.1 Introduction

This is the disinfection of water during drinking water treatment in water plants of drinking water suppliers during transport in between drinking water suppliers, and prior to distribution into (part of) the communal piping system (referred to as primary disinfection in this guidance). This group also includes products that are added by drinking water suppliers to the previously-treated water already in the public distribution systems.
network to ensure that an adequate disinfectant residual is maintained throughout the system (referred to as secondary disinfection in this guidance).

Following physical treatment of water, primary disinfection describes the main disinfection method employed to inactivate waterborne pathogenic micro-organisms. Primary disinfection is often supplemented by downstream secondary disinfection to maintain a residual level of disinfectant within the distribution system in order to assure good quality of drinking water to the point of compliance i.e. the consumer's tap as determined in the Drinking Water Directive.

5.4.5.2 Data requirements

Test methods

For product authorisation of drinking water disinfectants used by the drinking water suppliers and in water distribution systems, the tiered approach as described in section 5.4.0.4. of this Guidance is preferred.

For primary disinfection next to a suspension test, a simulated use test should be performed. For suspension tests EN phase 2, step 1 tests are preferred. Since for most target organisms there are no specific EN tests for drinking water disinfection, tests should be modified to reflect the use conditions with respect to soiling, temperature range and contact time. EN tests from food and industrial area (see EN 14885) can be modified (see 'Test conditions' on next page). For virucidal activity EN 14476 can be modified.

For the simulated use test a detailed appropriate test method is given in the test method "Quantitative determination of the efficacy of drinking water disinfectants" (see Appendix 2 Table 29). The test is performed on an adapted test rig. A disinfectant neutralizer or filter system is required to stop a reaction between disinfectant and test organisms.

Currently the simulated-use test can only be performed in the test lab in Germany where the test was developed, as only there the required test set up is available. Alternative methods will be considered and are acceptable provided they are scientifically justified and will be evaluated by the CA on a case-by-case basis. Please note that monitoring data can only be accepted as supplementary data since this data does not offer the possibility to calculate log reduction to evaluate the disinfection.

For secondary disinfection a simulated-use test is required with relevant use conditions with respect to temperature, soiling and contact time.

For an overview of available EN tests see Appendices 2 and 4.

Test organisms

Drinking water disinfectants used on site at the drinking water suppliers and water distribution systems should be at least sufficiently effective against bacteria and viruses. Efficacy tests with these organisms should always be provided. For all other groups of organisms (Protozoa, etc.), data only have to be provided when activity against those organisms is claimed. The test organisms used in efficacy tests are normally stated in the applicable standard test methods or the test method "Quantitative determination of the efficacy of drinking water disinfectants". For drinking water disinfectants used on site at drinking water suppliers and water distribution systems Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae and Escherichia coli should be tested. In an EN suspension test the efficacy against enteroviruses and norovirus should be tested. In the simulated use test bacteriophages are used as an indicator for human viruses as given in the test method "Quantitative determination of the efficacy of drinking water disinfectants".

An overview of reference test organisms is given in Appendix 3.

Test conditions
It is important that the efficacy tests are carried out with the contact time as claimed on the label, and also that the claimed contact time is a realistic value.

Suspension tests may be modified considering the type of disinfectant application and considering especially that the test needs to be performed reflecting the worst-case conditions (temperature, soiling, contact time, mineralization, pH). Further details can be taken from Appendix 4. For suspension tests the maximum contact time is 30 minutes. For simulated use tests contact time of either 10 or 25 minutes should be applied.

Laboratory tests should be carried out with appropriate soiling. For primary disinfection it can be expected that soiled water is used e.g. surface water. Therefore, for this use the laboratory tests should be done under dirty conditions. Secondary disinfection is done on clean water, simulated by clean test conditions. Appendix 4 states the appropriate soiling for PT5.

The applicant should provide the rational for the choices made.

Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated use tests have been carried out (using the required test organisms and test conditions), and when the pass criteria for the tests have been met.

Where pass criteria are available in the standard test these should be met. For PT5 products the required log reductions in suspension tests are referenced in Appendix 4.

The pass criteria for the simulated-use test are stated in the test (see Appendix 2 Table 29). The same criteria are valid for both primary and secondary disinfection.

Deviations from the pass criteria are possible, but must be justified in the application. If the simulated use test passed but the suspension test did not pass, the applicant needs to justify why the concentration used in the simulated use test should be considered as the effective dose.

The Competent Authority will evaluate any justification on a case-by-case basis, consulting the other Competent Authorities where appropriate, and decide whether it is acceptable or not.

5.4.5.3 Disinfection of raw water for individual supply (1-2 premises)

5.4.5.3.1 Introduction

These are disinfectants intended to be used for private water supply, (i.e. any water supply which is supplied to a property that is not provided by a water supplier). Most of these supplies are situated in remote, rural parts of a country and can originate from a range of sources including wells, natural springs and watercourses.

5.4.5.3.2 Data requirements

Test methods

For product authorisation of drinking water of individual supply the tiered approach as described in section 5.4.0.4.1 of this Guidance is preferred.

Next to a suspension test a simulated use test should be performed. For suspension tests EN phase 2, step 1 tests are preferred. Since for most target organisms there are no specific EN tests for drinking water disinfection, tests should be modified to reflect the use conditions with respect to temperature range, soiling and contact time. EN tests from food and industrial area (see EN 14885) can be modified (see ‘Test conditions’ on next page). For virucidal activity EN 14476 can be modified.
For the simulated use test, a detailed appropriate test method is given in the test method “Quantitative determination of the efficacy of drinking water disinfectants”. The test is performed on an adapted test rig. A disinfectant neutralizer or filter system to stop a reaction between disinfectant and test organisms is required. Currently the simulated-use test can only be performed in Germany. Alternative methods will be considered and are acceptable provided they are scientifically justified and will be evaluated by the CA on a case-by-case basis.

For an overview of available EN tests see Appendices 2 and 4.

Test organisms

Drinking water disinfectants of raw water for individual supply should be at least sufficiently effective against bacteria and viruses. Efficacy tests with these organisms should always be provided. For all other groups of organisms (Protozoa, etc.), data only have to be provided when activity against those organisms is claimed.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods or the test method “Quantitative determination of the efficacy of drinking water disinfectants”. For drinking water disinfectants used in private drinking water supply systems *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus hirae* and *Escherichia coli* should be tested.

In EN suspension tests efficacy against enteroviruses and norovirus should be tested. In the simulated use test, bacteriophages are used as an indicator for human viruses as given in the test method “Quantitative determination of the efficacy of drinking water disinfectants”.

An overview of reference test organisms is given in Appendix 3.

Test conditions

It is important that the efficacy tests are carried out with the contact time as claimed on the label, and also that the claimed contact time is a realistic value.

Suspension tests may be modified considering the type of disinfectant application and considering especially that the test needs to be performed reflecting the worst-case conditions (temperature, soiling, contact time, mineralization, pH). Further details can be taken from Appendix 4. For suspension tests the maximum contact time is 30 minutes.

For simulated use tests contact time of either 10 or 25 minutes should be applied.

Laboratory tests should be carried out with soiling for dirty conditions as defined in Appendix 4. Depending on the water source interfering substances may be variable and require modifications of the soiling in the efficacy tests. The applicant should provide the rational for the choices made.

Further details can be taken from Appendix 4.

Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated use tests have been carried out (using the required test organisms and test conditions), and when the pass criteria for the tests have been met.

Where pass criteria are available in the standard test these should be met. For PT products the required log reductions in suspension tests are referenced in Appendix 4.

The pass criteria for the simulated-use test are stated in the test.

Deviations from the pass criteria are possible, but must be justified in the application. If the simulated use test passed but the suspension test did not pass, the applicant needs to justify why the concentration used in the simulated use tests should be considered as the effective dose.
The Competent Authority will evaluate any justification on a case-by-case basis, consulting the other Competent Authorities where appropriate, and decide whether it is acceptable or not.

5.4.5.4 Disinfection in collective drinking water systems

5.4.5.4.1 Introduction

This is disinfection in collective drinking water systems like hospitals and other health care facilities, hotels, penitentiary institutions, etc. In these large plumbing systems water might become contaminated with *Legionella* spp. In addition to physical techniques (heating, UV treatment, etc.) chemical disinfection is sometimes allowed in some EU countries.

5.4.5.4.2 Data requirements

Test methods

For product authorisation of drinking water disinfectants in collective drinking water systems the tiered approach as described in section 5.4.0.4.1 of this Guidance is preferred.

The following requirements are set for biocides to be used as disinfectant in collective drinking water systems:

Laboratory tests

Basic efficacy of the product should be demonstrated in suspension tests (phase 2, step 1).

Studies should show that the product can accomplish a log reduction of 5 against bacteria and a log reduction of 4 against *Legionella pneumophila* specifically. This can be done in laboratory tests (e.g. suspension tests EN 1276 and EN 13623). Tests should be modified to reflect the use conditions with respect to soiling, temperature range and contact time (see Appendix 4).

The suspension tests can be waived when simulated use or field trials are available in which the concentration of *Legionella* spp. is high enough to show log reduction of 5 (min. 10^5 cfu/L).

Simulated use tests

A simulated use test should be performed but is only mandatory in cases where a log reduction of 4 cannot be demonstrated in a field trial due to low levels of *Legionella* spp. in the drinking water or in the suspension test.

A detailed description for simulated use test is given in the test method “Quantitative determination of the efficacy of drinking water disinfectants. Currently this test can only be performed in Germany. Alternative methods will be considered and are acceptable provided they are scientifically justified: they will be evaluated by the CA on a case-by-case basis. If this test cannot be used according to the scope of the test an alternative method can be presented. CAs will examine the eligibility of the proposed alternative. As the test method “Quantitative determination of the efficacy of drinking water disinfectants” does not cover *Legionella* spp., an experimental method to simulate a system with hot water is given in the test method “Efficiency of disinfection treatment against *Legionella* spp. in drinking water network and hot water system - Evaluation using a pilot unit scale 1” (see Appendix 2 Table 29).
Field trials
Field trials (historic and in use monitoring) should always be provided especially for products with long and continuous use. See below under Test Conditions/Field Trials for further details.

Test organisms
PTS products for collective drinking water systems should be at least sufficiently effective against bacteria and specifically against *Legionella* spp. Since the control of *Legionella* spp. in collective drinking water systems is of major importance, efficacy against *Legionella* spp. (field tests) and *Legionella pneumophila* (suspension tests or simulated use tests) should always be demonstrated in addition to general test against bacteria. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only need to be provided when an efficacy against those organisms is claimed.

Test conditions
Laboratory tests
It is important that the efficacy tests are carried out with the contact time as claimed on the label, and also that the claimed contact time is a realistic value.

Suspension tests may be modified considering the type of disinfectant application and considering especially that the test needs to be performed reflecting the worst-case conditions (temperature, soiling, mineralization, pH). Further details can be taken from Appendix 4. For suspension tests the maximum contact time is 24 hours.

Since the water treated in collective drinking water system is clean water coming from a drinking company, laboratory tests should be carried out with soiling for clean conditions as defined in Appendix 4.

Simulated use tests
The tests are carried out with the standard contact time (10 or 25 minutes) or as claimed on the label. Tests should be carried out with soiling for clean conditions as defined in Appendix 4.

Field Trials
LOCATIONS
A field trial should be performed at a minimum of 3 locations.

The drinking water quality in the different EU countries may differ. In some EU countries disinfectants like chlorine are included as standard, whilst in other countries disinfectants are only added during outbreaks of pathogens. Therefore some EU countries will only accept field trials carried out within their own country or in locations with comparable water specifications. In general, however, tests are not performed in all EU countries. Therefore, in all field tests the quality of the tested drinking water should be clearly specified and documented. The comparability of this water to the drinking water in each country should be clearly described and justified, accordingly. Ultimately, the Competent Authority will decide whether the test is acceptable or not.

Only locations with 100 or more operational draw-off points (downstream of the application spot) are acceptable. A location is a collective drinking water system which is treated by the product. Also a part of a collective drinking water system, for instance a wing of a building or only the cold water system, can be seen as a test location as long as it contains 100 or more operational draw-off points.
1. DURATION OF THE TEST

When the apparatus is in continuous or discontinuous use (so no single applications) the duration of the test is one year per location, starting from the first sampling round after starting the apparatus. When, due to starting problems etc., the first months do not give the required result, the test should be extended to ensure a duration of one year starting from the point at which a stable situation is reached. In this way at least a year of test results can show that the product is capable of controlling *Legionella* spp.

2. DIFFERENT TYPES OF WATER

It is recommended that the locations are spread over the country, this is to ensure that the product is tested on different types of water (hardness, organic material, etc.). For this purpose information should be provided on the quality of the provided water at the different locations. In principal this information is available through the water suppliers.

3. *LEGIONELLA*

Before starting a test it should be clear that the installation to be treated is contaminated with *Legionella* spp. bacteria (≥1000 cfu/L). For this purpose information should be provided on (recent) problems with *Legionella* spp., like results from sampling in the past and performed cleanings, etc. The system should not be artificially contaminated.

4. SAMPLING POINTS

The amount of sampling points per location depends on the amount of draw-off points (taps and other outlets) in the installation. The table below should be used.

<table>
<thead>
<tr>
<th>Number of draw-off points (outlets)</th>
<th>Number of sampling points</th>
</tr>
</thead>
<tbody>
<tr>
<td>101 – 200</td>
<td>6</td>
</tr>
<tr>
<td>201 – 400</td>
<td>8</td>
</tr>
<tr>
<td>401 – 800</td>
<td>10</td>
</tr>
<tr>
<td>801 – 1600</td>
<td>12</td>
</tr>
<tr>
<td>&gt; 1600</td>
<td>14</td>
</tr>
</tbody>
</table>

5. EFFICACY

The tuning of the apparatus from which the disinfectant is dosed should be recorded at the time of sampling.

6. The following measurements should be performed:

   - zero measurement: measurement of *Legionella* spp., total hardness, pH, organic contamination of the water and residues of active substances from previous treatments before the disinfection treatment is started.
• *Legionella* spp., monthly sampling, norm value 100 cfu/l (90%-percentile with a maximum of 1000 cfu/l);

• total hardness, Ca, Mg; sampling once per four months, depending on the variation a higher frequency might be necessary; also data from the water supplying companies can be collected;

• pH, monthly sampling on both standard sampling points, or data from the water supplying companies can be collected.

**ACTIVE SUBSTANCES**

To determine the amount of active substance in the water, the relevant substances should be measured monthly. In general the active substance of the used biocidal product should be measured monthly. The sampling points as stated in Table 8 of this section should be taken. Especially the first and the most far away sampling point are of importance, in order to ensure that enough product reaches the end of the system. These data are especially relevant for the efficacy assessment of in situ generated products and can also be used in other areas (e.g. for toxicological and environmental risk assessment).

**GENERAL REQUIREMENTS FOR STUDY REPORTS**

Every study report should contain a good description of the material (location, number of draw-off points, sampling points, history of *Legionella*, etc.), the method (starting date, tuning of the apparatus from which the disinfectant is dosed) and the results (including 0-measurement). In the study reports of the field tests the results should be interpreted per location. Remarks such as high values above the norm, should be mentioned and explained. The report should contain a conclusion.

**APPARATUS**

In case of in situ production of the active substance or when an apparatus is used to dose the active substance in the right amount to the water, the report should contain information on safety measurements concerning over and under dosing. Continuous measurement of the dosed active substance should be established.

**Acceptance criteria**

A product will be assessed to be sufficiently effective if the required laboratory, simulated use and field tests have been carried out (using the required test organisms and test conditions), and when the pass criteria for the tests have been met.

Where pass criteria are available in the standard test these should be met. For PT5 products the required log reductions in suspension tests are referenced in Appendix 4.

The pass criteria for the simulated-use test are stated in the test (see Appendix 2 Table 29).

For the evaluation of the results of the measurements in the field trial, the norm values used are mentioned above under Test Conditions/Field Trials. Per location, 90% of the measurements should fulfil the requirements. Over all locations together, 90% of the locations should fulfil the requirements.

Deviations from the pass criteria are possible, however they must be justified in the application.

The Competent Authority will evaluate any justification on a case-by-case basis, consulting the other Competent Authorities where appropriate, and decide whether it is acceptable or not.
5.4.5.5 Disinfection of water in reservoirs

5.4.5.5.1 Introduction
This is disinfection of water stored in tanks and reservoirs, for instance on ships, mobile homes, or in small tanks as in a dentist’s chair. It is presumed that these tanks start filled with water of drinking water quality. The disinfection product should maintain the quality of the water over time. When the product is also intended to disinfect water from other sources (e.g. ground water, spring or surface water) this should be clear in the claim for the product. It should also be specified whether the tank should be cleaned before disinfection or not. The claimed use should be specified in the SPC.

5.4.5.5.2 Data requirements

Test methods
For product authorisation of drinking water disinfectants in reservoirs the tiered approach as described in section 5.4.0.4.1 of this Guidance is preferred. Next to a suspension test a simulated use test should be performed.

For suspension tests EN phase 2, step 1 tests are preferred. Since for most target organisms there are no specific EN tests for drinking water disinfection, tests should be modified to reflect the use conditions with respect to soiling, temperature range and contact time. EN tests from food and industrial area (see EN 14885) can be modified (see 'Test conditions' below). For virucidal activity EN 14476 can be modified. Efficacy suspension tests should be provided with two concentrations: the concentration of the product as dosed (start concentration) and the active substance concentration obtained in the field at the end of the claimed period of use.

For disinfection of water in reservoirs it is mandatory to provide a simulated-use test. Such tests are required in order to demonstrate proper distribution of the disinfectant in the reservoir. In the absence of a standard method, the applicant should provide a testing proposal which needs to be agreed by the eCA in advance. Alternatively, for products with one active substance that can easily be measured, efficacy can be demonstrated using a field test in which the amount of active substance and the amount of organisms is measured several times during the test period.

In some cases efficacy against biofilm is of importance in this use. For testing efficacy against biofilms see section 5.4.2.11 of this Guidance.

Test organisms
Drinking water disinfectants for reservoir water should be at least sufficiently effective against bacteria and viruses. Tests with these organisms should always be provided.

For all other groups of organisms (e.g. *Legionella* spp. or Protozoa) tests only have to be provided when efficacy against these organisms are claimed.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods. An overview of reference test organisms for PT5 is given in Appendix 3.

Test conditions
It is important that the tests are carried out with the same contact time as claimed on the label. The claimed contact time has to be a realistic value. Therefore, the applicant has to clearly indicate how long the disinfectant can guarantee the quality of the water in
the reservoir. When started with raw water it should be indicated at what time after the
treatment the water can be used.

If protozoa are claimed, tests with longer contact times relevant for protozoa are
acceptable.

When starting with water of drinking water quality, tests should be carried out with
soiling for clean conditions as stated in Appendix 4. For this type of product (if tested
under clean conditions), the applicant needs to clearly indicate to the user that the
reservoir should be clean before filling it with fresh and clean water.

When starting with raw water, tests should be carried out with soiling for dirty conditions
in accordance with the test requirements (see Appendix 4).

Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and
simulated use tests have been carried out (using the required test organisms and test
conditions), and when the pass criteria for the tests have been met.

Where pass criteria are available in the standard test these should be met. The required
log reductions in suspension tests are referenced in Appendix 4.

Deviations from the pass criteria are possible, however they must be justified in the
application.

The Competent Authority will evaluate any justification on a case-by-case basis,
consulting the other Competent Authorities where appropriate, and decide whether it is
acceptable or not.

5.4.5.6 Disinfection of water of undefined quality for small scale use (up to 5
L/person/day)

5.4.5.6.1 Introduction

This is disinfection of for instance, individual emergency water supply or other water that
might be contaminated in places where no clean drinking water is available. This means
water not originally coming from the drinking water suppliers. This is only intended for
water that is used directly for drinking or preparing food after disinfection, therefore for
small scale use (up to 5 L/person/day).

5.4.5.6.2 Data requirements

Test methods

For this use it is in most cases acceptable to demonstrate efficacy in a suspension test
only. For suspension tests EN phase 2, step 1 tests are preferred. Since for most target
organisms there are no specific EN tests for drinking water disinfection, tests should be
modified to reflect the use conditions with respect to soiling, temperature range and
contact time. EN tests from food and industrial area (see EN 14885) can be modified
(see 'Test conditions' on the next page). For virucidal activity EN 14476 can be modified.
For an overview of available EN tests see Appendix 2.

If a pre-treatment for turbidity is needed, such as filtration, this should be part of the
test conditions. This needs to be clearly instructed on the SPC of the product in the
section "Instructions of use" together with the exact treatment duration. This
responsibility lies with the applicant.

If no pre-treatment for turbidity is involved the field trials should be performed. Field
trials should be performed with different raw water (mineralisation, TOC, temperature,
pH) in which turbidity is considered.
Test organisms

Drinking water disinfectants of "water with undefined quality (small scale use)" should be at least sufficiently effective against bacteria and viruses. For all other groups of organisms tests only have to be provided when efficacy against the organisms that are claimed. The test organisms used in efficacy tests are normally stated in the applicable standard test methods. An overview of reference test organisms is given in Appendix 3.

Test conditions

A suspension test needs to be performed reflecting worst-case conditions (temperature, soiling, contact time, mineralization, pH). The test should be done with the claimed contact time but no longer than 30 minutes. The suspension test (EN phase 2, step 1 - food area) should be carried out with soiling for dirty conditions (see Appendix 4).

For the field trial at least three types of raw water should be tested. Information on mineralisation, TOC, temperature, pH and turbidity should be given.

Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and field tests have been carried out (using the required test organisms and test conditions), and when the pass criteria for the tests have been met.

Where pass criteria are available in the standard test these should be met. For PT5 products the required log reductions in suspension tests are referenced in Appendix 4.

Deviations from the pass criteria are possible, however they must be justified in the application.

The Competent Authority will evaluate any justification on a case-by-case basis, consulting the other Competent Authorities where appropriate, and decide whether it is acceptable or not.

5.4.5.7 Disinfection of water for animals

5.4.5.7.1 Introduction

This is disinfection of water in animal housing used as drinking water for animals and for other uses in animal houses (cleaning, preparing feed, etc.). When products are used to disinfect water for both humans and animals, requirements according to sections 5.4.5.2 to 5.4.5.4 are also applicable. The origin of the water in water systems for animals can differ, e.g. groundwater, surface water (dirty), or water from drinking water suppliers (clean). The intended use should be specified on the SPC.

5.4.5.7.2 Data requirements

Test methods

For efficacy testing of disinfectants for water for animals the tiered approach as described in section 5.4.0.4.1 of this Guidance is preferred. Next to a suspension test also a simulated-use test or field test (phase 3) should be performed, to provide information under in-use conditions. In some cases efficacy against biofilm is of importance in this use. For testing efficacy against biofilms see section 5.4.2.11 of this Guidance. For suspension tests EN phase 2, step 1 tests are preferred. Since for most target organisms there are no specific EN tests for drinking water disinfection, tests should be modified to reflect the use conditions with respect to soiling, temperature range and contact time. EN tests from food and industrial area (see EN 14885) can be modified (see 'Test conditions' on next page). For virucidal activity EN 14476 can be modified.
For the simulated use test a detailed appropriate test method is given in the test method “Quantitative determination of the efficacy of drinking water disinfectants”. The test is realised on an adapted test rig. A disinfectant neutralizer or filter system to stop a reaction between disinfectant and test organisms is required. Currently this test can only be performed in Germany. Alternative methods will be considered and are acceptable provided they are scientifically justified and will be evaluated by the CA on a case-by-case basis.

Since drinking water for animals can be obtained from a variety of different sources, e.g. surface water (lakes, rivers), underground water pumped from wells, human drinking water, rain water, etc., several kinds of water should be tested. Alternatively, it should be indicated on the label under which conditions the product can be used.

**Test organisms**

Drinking water disinfectants of water for animals should be at least sufficiently effective against bacteria. For all other groups of organisms tests only have to be provided when efficacy against the organisms are claimed. The test organisms used in efficacy tests are normally stated in the applicable standard test methods. An overview of reference test organisms is given in Appendix 3.

**Test conditions**

It is important that the efficacy tests are carried out with the contact time as claimed on the label, and also that the claimed contact time is a realistic value.

Suspension tests may be modified considering the type of disinfectant application and considering especially that the test needs to be performed reflecting the worst-case conditions (temperature, soiling, contact time, mineralization, pH). Further details can be taken from Appendix 4. For suspension tests the maximum contact time is 30 minutes.

Laboratory tests should be carried out with soiling for clean or dirty conditions as defined in Appendix 4. Depending on the water source that has to be disinfected the test should be performed under either clean or dirty (e.g. undefined or pumped up water) conditions.

Field tests should be done in animal housing. A testing proposal needs to be provided taking into consideration relevant parameters, such as type of water to be treated (e.g. water originating from the public distribution system or surface water), pre-cleaning of the “distribution system”, pre-treatment of the water (e.g. physical treatment such as filtration) and application of food additives or antibiotics which will be evaluated by the CA on a case-by-case basis.

**Acceptance criteria**

A product will be assessed to be sufficiently effective if the required laboratory tests, or when applicable, field tests have been carried out (using the required test organisms and test conditions), and when the pass criteria for the tests have been met.

Where pass criteria are available in the standard test these should be met. For PT5 products the required log reductions in suspension tests are referenced in Appendix 4.

The pass criteria for the simulated-use test are stated in the test (see Appendix 2 Table 29). Field trials should demonstrate sufficient efficacy and the microbiological burden should stay below an acceptable level according to the relevant legislation. Deviations from the pass criteria are possible, however they must be justified in the application.

The Competent Authority will evaluate any justification on a case-by-case basis, consulting the other Competent Authorities where appropriate, and decide whether it is acceptable or not.
5.4.6 Materials and Articles Treated to Protect Humans or Animals

5.5 Preservatives (Main group 2)

5.6 Pest Control (Main group 3)

5.7 Other biocidal products (Main group 4)
Appendix 1. Claims Matrices

The claims matrices are a set of tables linked to this guidance document: these documents are available on the ECHA Biocides Efficacy Working Group webpage [http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/efficacy].

The claims matrices linked to this document are intended to cover biocidal products covered under the scope of Product Type 1, 2, 3, 4, 5 and for Treated Articles.

The claims matrix is a tool for the applicant and CAs. It is intended to capture the information that is needed in the authorisation dossier, to adequately describe typical combinations of products, formats of application of the products, as well as target sites. It also includes the claims made and the requirements for testing these claims (in terms of methodology and appropriate performance standards) for a product to be used in this way.

The reader should note that the matrices are not exhaustive in terms of use patterns, scenarios and test methods.

The claims matrix must be used together with the relevant sections within the efficacy guidance document so as to provide both applicants and CAs alike with clear direction as to the nature and extent of the efficacy data required to support a claimed effect. The claims matrix acts as a guide to the information required when compiling an efficacy dataset for a PT1, PT2, PT3, PT4 biocidal product and for Treated Articles.

To note:

- Each row (entry) within the matrices is not independent and can be linked to other entries.
- These matrices only address biocidal claims made for these products.
- The claim matrix will be updated regularly according to the state-of-the-art.
Appendix 2. Standards and testing methods for efficacy-testing of disinfectant biocidal products (PT 1-5)

The methods for testing efficacy referenced within this guidance document are enlisted below. The use of European Standards (Table 28) is highly recommended if available and appropriate for the respective application. Should no European Standard for an application be available yet and an adaption of an existing standard is not possible according to the rules laid down in EN 14885, other test methods and guidance documents (Table 29) may be used. In cases where the below mentioned methods are inappropriate to demonstrate efficacy of a product for special applications, methods from other national or international standardisation bodies may also be employed. These include for example, OECD, AOAC, ASTM or ISO methods. It is recommended to agree such testing strategies with the evaluating CA before tests are performed.

Tests should be carried out according to the respective latest edition of a standard. Please check the respective web sites for the latest information.

Table 1: CEN European standards

<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
<th>PT</th>
<th>Scope/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 1276</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1)</td>
<td>1,2,4,5</td>
<td>This European Standard specifies a method for testing bactericidal activity by assessing reduction in the number of viable bacterial cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 1499</td>
<td>Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2, step 2)</td>
<td>1</td>
<td>This European Standard specifies a test method simulating practical conditions for establishing whether a hygienic handwash product reduces the transmission of transiently contaminating microorganisms when used to wash the artificially contaminated hands of volunteers.</td>
</tr>
<tr>
<td>EN 1500</td>
<td>Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)</td>
<td>1</td>
<td>This European Standard specifies a test method simulating practical conditions for establishing whether a hygienic handrub product reduces the transmission of transiently contaminating microorganisms when rubbed onto the artificially contaminated hands of volunteers.</td>
</tr>
</tbody>
</table>

6 The CEN does not sell or distribute standards or any other deliverable. All European Standards (EN) and drafts (prEN) as well as other approved documents are directly available for purchase from the CEN national standardisation bodies.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
<th>PT</th>
<th>Scope/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 1650</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas - Test method and requirements (phase 2, step 1)</td>
<td>1,2, 4, 5</td>
<td>This European Standard specifies a method for testing fungicidal or yeasticidal activity by assessing reduction in the number of viable mould spores and/or yeast cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 1656</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)</td>
<td>3</td>
<td>This European Standard specifies a method for testing bactericidal activity by assessing reduction in the number of viable bacterial cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 1657</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)</td>
<td>3</td>
<td>This European Standard specifies a method for testing fungicidal or yeasticidal activity by assessing reduction in the number of viable mould spores and/or yeast cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 12353</td>
<td>Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporidical, fungicidal and virucidal (including bacteriophages) activity</td>
<td>1,2, 4, 5</td>
<td>This method specifies how to keep test organisms used and defined in European Standards for the determination of bactericidal, mycobactericidal, sporidical, fungicidal and virucidal (ind. bacteriophages) activity of chemical disinfectants and antiseptics drawn up by CEN/TC 216.</td>
</tr>
<tr>
<td>EN 12791</td>
<td>Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)</td>
<td>1</td>
<td>This European Standard specifies a test method simulating practical conditions for establishing whether a product for surgical hand disinfection reduces the transmission of the microbial flora on hands when used for the treatment of clean hands of volunteers.</td>
</tr>
<tr>
<td>EN 13610</td>
<td>Chemical disinfectants - Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1)</td>
<td>4</td>
<td>This European Standard specifies a method for testing virucidal activity against bacteriophages by assessing reduction in the number of infectious bacteriophage particles in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>PT</td>
<td>Scope/Remarks</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------------------------------------</td>
<td>----------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>EN 13623</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against <em>Legionella</em> of chemical disinfectants for aqueous systems - Test method and requirements (phase 2, step 1)</td>
<td>2, 4, 5</td>
<td>This European Standard specifies a method for testing bactericidal activity against <em>Legionella</em> by assessing reduction in the number of viable <em>Legionella</em> cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 13624</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)</td>
<td>1, 2</td>
<td>This European Standard specifies a method for testing fungicidal or yeasticidal activity by assessing reduction in the number of viable mould spores and/or yeast cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 13697</td>
<td>Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 2)</td>
<td>2, 4</td>
<td>This European Standard specifies a method for testing bactericidal and/or fungicidal or yeasticidal activity by assessing reduction in the number of viable bacterial cells and/or mould spores and/or yeast cells dried on a steel carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 13704</td>
<td>Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)</td>
<td>4</td>
<td>This European Standard specifies a method for testing sporicidal activity by assessing reduction in the number of viable bacterial endospores in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 13727</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)</td>
<td>1, 2</td>
<td>This European Standard specifies a method for testing bactericidal activity by assessing reduction in the number of viable bacterial cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14204</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)</td>
<td>3</td>
<td>This European Standard specifies a method for testing mycobactericidal activity by assessing reduction in the number of viable mycobacterial cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
</tbody>
</table>

7 EN 13704 is under review and the revised standard will include veterinary and human health care areas.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
<th>PT</th>
<th>Scope/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 14347</td>
<td>Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1)</td>
<td>1, 2, 3, 4</td>
<td>This European Standard specifies a method for testing sporicidal activity by assessing reduction in the number of viable bacterial endospores in suspension under defined conditions. The method is declared as a phase 1 test but, but based on its requirements, it can serve as a suspension test (comparable to phase 2, step 1) until revised/additional CEN methodology for testing sporicidal activity becomes available. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14348</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)</td>
<td>1, 2</td>
<td>This European Standard specifies a method for testing mycobactericidal activity by assessing reduction in the number of viable mycobacterial cells in suspension under defined conditions. The method is also applicable to demonstrate tuberculocidal activity only. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14349</td>
<td>Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)</td>
<td>3</td>
<td>This European Standard specifies a method for testing bactericidal activity by assessing reduction in the number of viable bacterial cells dried on a steel carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14476</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (phase 2, step 1)</td>
<td>1, 2, 4, 5</td>
<td>This European Standard specifies a method for testing virucidal activity by assessing reduction in the number of infectious virus particles in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14561</td>
<td>Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)</td>
<td>2</td>
<td>This European Standard specifies a method for testing bactericidal activity by assessing reduction in the number of viable bacterial cells dried on a frosted glass carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14562</td>
<td>Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)</td>
<td>2</td>
<td>This European Standard specifies a method for testing fungicidal or yeasticidal activity by assessing reduction in the number of viable mould spores and/or yeast cells dried on a frosted glass carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>PT</td>
<td>Scope/Remarks</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------</td>
<td>----</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>EN 14563</td>
<td>Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)</td>
<td>2</td>
<td>This European Standard specifies a method for testing mycobactericidal activity by assessing reduction in the number of viable mycobacterial cells dried on a frosted glass carrier under defined conditions. The method is also applicable to demonstrate tuberculocidal activity only. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14675</td>
<td>Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)</td>
<td>3</td>
<td>This European Standard specifies a method for testing virucidal activity by assessing reduction in the number of infectious virus particles in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 14885</td>
<td>Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics</td>
<td>1, 2, 3, 4, 5</td>
<td>This European Standard specifies the European Standards, i.e. test methods, to which products have to conform in order to support the claims for microbicidal activity which are referred to in this document. It also specifies terms and definitions which are used in European Standards. It is applicable to products for which activity is claimed against the following microorganisms: vegetative bacteria (incl. mycobacteria and Legionella), bacterial spores, yeasts, fungal spores and viruses (incl. bacteriophages).</td>
</tr>
<tr>
<td>EN 16437</td>
<td>Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)</td>
<td>3</td>
<td>This European Standard specifies a method for testing bactericidal activity by assessing reduction in the number of viable bacterial cells dried on a wood carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
<tr>
<td>EN 16438</td>
<td>Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)</td>
<td>3</td>
<td>This European Standard specifies a method for testing fungicidal or yeasticidal activity by assessing reduction in the number of viable mould spores and/or yeast cells dried on a steel carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.</td>
</tr>
</tbody>
</table>
EN 16615: This European Standard specifies a method for testing bactericidal and/or yeasticidal activity by assessing reduction in the number of viable bacterial and/or yeast cells dried on a PVC carrier under defined conditions. The test applies to products that are used for disinfecting non-porous surfaces by wiping and includes ‘ready-to-use wipes’ which are impregnated with a microbicidal solution.

EN 16616: This European Standard specifies a method for testing microbicidal activity of a disinfection process for the treatment of contaminated textile. The procedure is carried out by using a washing machine and microbicidal activity is assessed as the reduction in the number of viable test organisms, such as bacterial, mycobacterial or yeast cells and mould spores, dried on a cotton carrier under defined conditions.

EN 16777: This European Standard specifies a method for testing virucidal activity by assessing reduction in the number of infectious virus particles dried on a steel carrier under defined conditions. The approach can be applied to formulated products or to biocidal active substances.

Table 2: Other test methods and guidance documents

<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
<th>PT</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM E2196</td>
<td>Standard Test Method for Quantification of Pseudomonas aeruginosa Biofilm Grown with Medium Shear and Continuous Flow Using Rotating Disk Reactor</td>
<td>2, 3, 4</td>
<td>This test method is used for growing a reproducible Pseudomonas aeruginosa biofilm in a continuously stirred tank reactor (CSTR) under medium shear conditions. In addition, the test method describes how to sample and analyse biofilm for viable cells. Available via: <a href="http://www.astm.org/Standard/">http://www.astm.org/Standard/</a> or the national standardisation bodies</td>
</tr>
<tr>
<td>ASTM E2274</td>
<td>Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants</td>
<td>2, 3</td>
<td>This test method is designed to evaluate sanitizing/disinfectant laundry detergents/additives for use in top-loading automatic clothes washing operations. This test method is designed predominantly to provide testing with representative vegetative bacteria but can also be designed to accommodate the testing of fungi and viruses. Available via: <a href="http://www.astm.org/Standard/">http://www.astm.org/Standard/</a> or the national standardisation bodies</td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>PT</td>
<td>Remarks</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------------------------------------------</td>
<td>------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ASTM E2406</td>
<td>Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants for Use in High Efficiency Washing Operations</td>
<td></td>
<td>This test method is designed to evaluate sanitizing/disinfectant laundry detergents/additives for use in high efficiency (HE) automatic clothes washing operations that typically utilize very low wash water volumes. This test method is designed to provide testing with representative vegetative bacteria but can also be designed to accommodate the testing of fungi and viruses. Available via: <a href="http://www.astm.org/Standard/">http://www.astm.org/Standard/</a> or the national standardisation bodies.</td>
</tr>
<tr>
<td>ASTM E2562</td>
<td>Standard Test Method for Quantification of <em>Pseudomonas aeruginosa</em> Biofilm Grown with High Shear and Continuous Flow using CDC Biofilm Reader</td>
<td>2,3,4</td>
<td>This test method specifies the operational parameters required to grow a reproducible <em>Pseudomonas aeruginosa</em> biofilm under high shear. The resulting biofilm is representative of generalized situations where biofilm exists under high shear rather than being representative of one particular environment. Available via: <a href="http://www.astm.org/Standard/">http://www.astm.org/Standard/</a> or the national standardisation bodies.</td>
</tr>
<tr>
<td>DIN SPEC 10534</td>
<td>Food hygiene - Commercial dishwashing - Hygiene requirements, testing</td>
<td>4</td>
<td>This document is a summary of the standards DIN 10510, DIN 10511, DIN 10512 and DIN 10522. It specifies hygiene requirements relating to the design, construction and operation of commercial ware washers and in particular provides information on their hygienic and proper operation, on cleaning and disinfection of wash ware and on care and maintenance of the machinery. It describes the methods for testing hygienic operation. Available via: <a href="http://www.beuth.de/en/">http://www.beuth.de/en/</a> or the national standardisation bodies.</td>
</tr>
<tr>
<td>DVG Guidelines</td>
<td>Guidelines for the testing of disinfection procedures and chemical disinfectants; Original title: Richtlinien für die Prüfung von Desinfektionsverfahren und chemischen Desinfektionsmitteln</td>
<td>3,4</td>
<td>DVG Guidelines specify methods for testing activity of chemical disinfectants against bacteria, yeasts and fungal spores, viruses, and parasites. They apply to the veterinary and the food sector, such as animal husbandry, veterinary practices, meat production/fod of animal origin, and large-scale/canteen kitchens (except ward kitchens catering patients). DVG Guidelines are published by the German Veterinary Medical Society (DVG). Available in German via: <a href="http://www.desinfektion-dvg.de">http://www.desinfektion-dvg.de</a>.</td>
</tr>
<tr>
<td>ISO/TS 15883-5</td>
<td>Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy</td>
<td>2,3,4</td>
<td>ISO 15883 relates to a series of standards that specify the required performance levels of Washer-Disinfectors. Part 5, the Technical Specification (TS), describes a method to generate biofilm formed by <em>Pseudomonas aeruginosa</em>. Available via: <a href="http://www.iso.org/iso/home.htm">http://www.iso.org/iso/home.htm</a> or the national standardisation bodies.</td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>PT</td>
<td>Remarks</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>----</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>NF T722-281</td>
<td>Methods of airborne disinfection of surfaces - Determination of</td>
<td>2,3,4</td>
<td>This French standard specifies a method for testing microbicidal activity of airborne disinfection processes. The tested product is diffused, e.g. in gaseous form or as an aerosol, to reduce the number of relevant test organisms, such as bacteria, bacterial spores, yeasts, and fungal spores. Available in French via: <a href="http://www.afnor.org/en">http://www.afnor.org/en</a> or the national standardisation bodies</td>
</tr>
<tr>
<td>Nordic Working Paper</td>
<td>Efficacy Assessment of Treated Articles: A guidance</td>
<td>1,2,3,4</td>
<td>The document provides guidance on efficacy testing of biocides used in treated articles. The presence and relevance of existing standard test methods is described and, where they do not exist or where they do not provide sufficient support, the nature of the data required will be described. The document was published by the Nordic Council of Ministers. Open access via: <a href="http://www.norden.org/en/publications/publikationer/2014-904/">http://www.norden.org/en/publications/publikationer/2014-904/</a></td>
</tr>
<tr>
<td>OECD Series on Biocides No. 4</td>
<td>Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants and Field Testing (Series on Testing and Assessment No. 170 and Series on Biocides No. 4)</td>
<td>2</td>
<td>The document provides guidance on setting up a strategy for efficacy testing of pool and spa disinfectants in a laboratory scale testing phase and a field testing phase in a full-size swimming or spa pool. Open access via: <a href="http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm">http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm</a></td>
</tr>
<tr>
<td>OECD Series on Biocides No. 8</td>
<td>Guidance Document for Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-Porous Antibacterial Treated Materials (Series on Testing and Assessment No. 202 and Series on Biocides No. 8)</td>
<td>1,2,3,4</td>
<td>The document provides guidance for testing the basic antibacterial performance of porous (textile) and non-porous (plastic) materials that have been treated with a biocide with the intention of introducing antibacterial/hygienic properties into that material. Open access via: <a href="http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm">http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm</a></td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>PT</td>
<td>Remarks</td>
</tr>
<tr>
<td>-----------</td>
<td>-------</td>
<td>----</td>
<td>---------</td>
</tr>
<tr>
<td>VAH</td>
<td>VAH certification of chemical disinfection procedures; Original title: VAH-Zertifizierung chemischer Desinfektionsverfahren</td>
<td>1, 2</td>
<td>VAH Standard methods specify methods for testing activity of chemical disinfectants against bacteria (incl. mycobacteria), yeasts, and fungal spores. They apply to testing products used for disinfection in public facilities (medical and other) and, in the event of substantiated medical indications, also in the private home. VAH Standard methods are published by the Association for Applied Hygiene (VAH). Available in German via: <a href="http://www.mhp-verlag.de/en/home/">http://www.mhp-verlag.de/en/home/</a></td>
</tr>
<tr>
<td>UBA</td>
<td>Quantitative determination of the efficacy of drinking water disinfectants</td>
<td>5</td>
<td>This document provides a guidance for testing the bactericidal and virucidal activity in drinking water in a simulated use test. <a href="https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/150629_version_2._quantitative_determination_of_the_efficacy_of_drinking_water_disinfectants.pdf">https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/150629_version_2._quantitative_determination_of_the_efficacy_of_drinking_water_disinfectants.pdf</a></td>
</tr>
</tbody>
</table>
Appendix 3. Table of Reference Test Organisms (PT 1-5)

This table (Table 30) is given as a general overview of relevant test organisms for testing disinfectants in accordance with the BPR.

This table comprises mainly those reference test organisms that are included in the EN norms covered by EN 14885. Furthermore, strains are listed that are recommended for some uses (e.g. endoparasites from DVG standard).

The reader can check the website of the CEN (European Standardization Organizations): www.cen.eu for new and updated standards.

Since the EN systematics of WG’s 1 to 3 does not fit exactly to the BPR PT scheme, in borderline cases an indicated reference test organism might be used for other PTs as well. In cases where there are discrepancies between this ECHA guidance and the guidance in EN 14885, the ECHA Guidance should be followed as the leading guidance. However, EN 14885 can be followed with satisfactory justification to meet the requirements of the BPR.

Tests with test organisms in addition to those mentioned below are acceptable, if adequate scientific evidence is submitted on which the relevance of the test organism to the field of use can be judged.

Table 3: Reference Test Organisms

Key for Table 30:
* X = basic requirement to claim activity against micro-organism;
(X) = basic requirement for specific use as described in the table below in brackets;
O = optional;
** the strain ATTC 16404 was previously classified as Aspergillus niger but after reclassification in 2008 it is now classified as Aspergillus brasiliensis;
*** for a limited spectrum virus claim in PT1 Poliovirus does not have to be tested;
**** in EN suspension tests efficacy against enteroviruses and norovirus should be tested.
### Micro-organisms

<table>
<thead>
<tr>
<th>Micro-organisms</th>
<th>PT1*</th>
<th>PT2*</th>
<th>PT3*</th>
<th>PT4*</th>
<th>PT5*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus ATCC 6538</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa ATCC 15442 (not for teat disinfection)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O</td>
</tr>
<tr>
<td>Enterococcus hirae ATCC 10541 (not for teat disinfection)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O</td>
</tr>
<tr>
<td>Escherichia coli ATCC 10536 (teat disinfection)</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella Typhimurium ATCC 13311</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactobacillus brevis DSM 6235</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterobacter cloacae DSM 6234</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterococcus faecium ATCC 6057 (for T ≥40°C)</td>
<td>(X)</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proteus vulgaris ATCC 13315 (not for teat disinfection)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptococcus uberis ATCC 19436 (teat disinfection)</td>
<td>(X)</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legionella pneumophila ATCC 33152 (PT2: pools, hot tubs; PT4: drinking water systems, PT5: in collective drinking water systems)</td>
<td>(X)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legionella pneumophila ATCC 43108</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Yeasts</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Candida albicans ATCC 10231</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O</td>
</tr>
<tr>
<td>Saccharomyces cerevisiae ATCC 9763 (breweries)</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saccharomyces cerevisiae DSM 70487 (breweries)</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fungal spores</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspergillus brasiliensis** ATCC 16404</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O</td>
</tr>
<tr>
<td><strong>Viruses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polio virus type 1, LSc-zab (Picornavirus)</td>
<td>X***</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenovirus, type 5, strain Adenoid 75, ATCC VA-5.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>O***</td>
</tr>
<tr>
<td>Murine norovirus, strain S99 Berlin</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X***</td>
<td></td>
</tr>
<tr>
<td>Murine parvovirus, strain Crawford, ATCC VR-1346 (for T ≥40°C)</td>
<td>(X)</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bovine Enterovirus Type 1, ECEID - Virus ATCC VR-248</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotavirus (pools, hot tubs)</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterovirus, e.g. Coxsackievirus B4 or B5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Enveloped Viruses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVA = Modified Vaccinivirus Ankara (teat disinfection)</td>
<td>X</td>
<td>(X)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bacteriophages</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacteriophage P001 DMS 4262 (milk industry)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Bacteriophage P008 DMS 10567 (milk industry)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Mycobacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mycobacterium terrae ATCC 15755</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Commented [SE2]: PEG CONSULTATION NOTE
The text shaded **PINK** is not in the scope of the consultation and **not open** for commenting: it is for reference ONLY.
### Micro-organisms

<table>
<thead>
<tr>
<th></th>
<th>PT1</th>
<th>PT2</th>
<th>PT3</th>
<th>PT4</th>
<th>PT5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mycobacterium avium ATCC 15769</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(PT1 and PT2 claim for mycobactericidal: both, tuberculocidal: M. terrae only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bacterial spores</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spores of Bacillus cereus ATCC 12826 (bee hives)</td>
<td></td>
<td></td>
<td>(X)</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Spores of Bacillus subtilis ATCC 6633 (bee hives)</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>(X)</td>
</tr>
<tr>
<td>Spores of Clostridium sporogenes ATCC 7955</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Spores of Geobacillus stearothermophilus (for $T \geq 60^\circ C$)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O</td>
</tr>
<tr>
<td><strong>Endoparasites</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oocysts of <em>Eimeria tenella</em> strain Houghton (chicken farms)</td>
<td></td>
<td></td>
<td></td>
<td>(X)</td>
<td></td>
</tr>
</tbody>
</table>

Commented [SE2]: PEG CONSULTATION NOTE

The text shaded PINK is not in the scope of the consultation and not open for commenting: it is for reference ONLY.
Appendix 4. Overview of standards, test conditions and pass criteria (PT 1-5)

The overview is presented in a number of tables which are available on the ECHA Biocides Efficacy Working Group webpage [http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/efficacy].

These tables provide an overview of available phase 2,1 and 2,2 EN standards which are applicable for testing the efficacy of disinfectant biocides. This overview is not exhaustive. For other or more specific uses and tests other than EN standards, reference should be made to the relevant sections of this guidance.

It should be noted that although this Guidance is mainly based on EN standards, there are some cases where there are discrepancies amongst the EN tests and in such cases the ECHA Guidance should be followed as the leading guidance. Where noted these are identified in the table.

The reader is strongly advised to check whether there are new versions of the standards on the website of the CEN: www.cen.eu.

It should be noted that if tests other than CEN standards (notably when no CEN tests are available) are used, and pass criteria are available, these should be met (unless stated differently in this guidance). When the test does not provide pass criteria, the criteria in this table can be taken into account as guidance for what level of reduction is normally required.

In all cases, deviations from these standards are possible but should be justified in the application.

Regarding the table for PT5, it should be noted that the text in Section 5.4.5 (PT5) of this Guidance document is only "preliminary draft text" and has not been reviewed or revised to address written PEG comments received and the section is currently under review within the "Disinfectants Project". In the meantime, the "preliminary draft text" is available to readers for information and it is for this reason that a table for PT5 is included, but this will be reviewed when Section 5.4.5 of the Guidance is reviewed.
Appendix 5. Examples of viruses sorted according to their presence in the human body in case of virus infection

These viruses may contaminate hands, instruments, other surfaces and textiles.

**NOTE 1** This list is not exhaustive.

**NOTE 2** Enveloped viruses are in **bold**.

**Table 4: Examples of viruses**

<table>
<thead>
<tr>
<th>Blood</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterovirus</td>
<td><strong>Hepatitis C virus (HCV)</strong></td>
</tr>
<tr>
<td>Filoviridae</td>
<td><strong>Hepatitis Delta virus (HDV)</strong></td>
</tr>
<tr>
<td>Flavivirus</td>
<td><strong>Human Immunodeficiency Virus (HIV)</strong></td>
</tr>
<tr>
<td>Herpesviridae</td>
<td><strong>Human T Cell Leukaemia Virus (HTLV)</strong></td>
</tr>
<tr>
<td>Hepatitis A Virus (HAV)</td>
<td>Parvovirus B 19</td>
</tr>
<tr>
<td><strong>Hepatitis B virus (HBV)</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Respiratory tract</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus (Mast-)</td>
<td><strong>Influenza Virus</strong></td>
</tr>
<tr>
<td>Coronavirus</td>
<td><strong>Paramyxoviridae</strong></td>
</tr>
<tr>
<td>Enterovirus</td>
<td>Rhinovirus</td>
</tr>
<tr>
<td>Herpesviridae</td>
<td>Rubella Virus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neuronal tissue, ear, nose &amp; eye</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus (Mast-)</td>
<td><strong>Human Immunodeficiency Virus (HIV)</strong></td>
</tr>
<tr>
<td>Enterovirus</td>
<td>Polyomavirus</td>
</tr>
<tr>
<td>Herpesviridae</td>
<td>Rabies Virus</td>
</tr>
<tr>
<td>Measles Virus</td>
<td>Rubella Virus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gastro-intestinal</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus (Mast-)</td>
<td>Enterovirus</td>
</tr>
<tr>
<td>Caliciviridae</td>
<td><strong>Hepatitis A Virus (HAV)</strong></td>
</tr>
<tr>
<td>Coronavirus</td>
<td><strong>Hepatitis E Virus (HEV)</strong></td>
</tr>
<tr>
<td>Astrovirus</td>
<td>Rotavirus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skin, breast and/or milk</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterovirus</td>
<td><strong>Human T Cell Leukaemia Virus (HTLV)</strong></td>
</tr>
<tr>
<td>Herpesviridae</td>
<td>Papillomavirus</td>
</tr>
<tr>
<td>Human Immunodeficiency Virus (HIV)</td>
<td><strong>Poxviridae</strong></td>
</tr>
</tbody>
</table>
### Spleen and lymph nodes (see also blood)

<table>
<thead>
<tr>
<th>Human T Cell Leukaemia Virus (HTLV)</th>
<th>Human Immunodeficiency Virus (HIV)</th>
</tr>
</thead>
</table>

### Dental procedure

<table>
<thead>
<tr>
<th>Adenovirus(Mast-)</th>
<th>Enterovirus</th>
<th>Herpesviridae</th>
<th>Hepatitis B virus (HBV)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hepatitis C Virus (HCV)</th>
<th>Hepatitis Delta Virus (HDV)</th>
<th>Human Immunodeficiency Virus (HIV)</th>
</tr>
</thead>
</table>

### Urogenital tract

<table>
<thead>
<tr>
<th>Hepatitis B Virus (HBV)</th>
<th>Herpesviridae</th>
<th>Human Immunodeficiency Virus (HIV)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Human T Cell Leukaemia Virus (HTLV)</td>
</tr>
<tr>
<td></td>
<td>Papillomavirus</td>
<td>Polyomavirus</td>
</tr>
</tbody>
</table>

### Reference:

Appendix 6. Selection of recommended tests for solid materials (excluding wood-preservatives)

Appendix 7. Selection of recommended tests for liquid materials

Appendix 8. Commonly Used Methods to Measure the Effects of Preservative/Curative Action in Liquid Matrices

Appendix 9. Commonly Used Methods to Measure the Effects of Protecting Material

Appendix 10. Commonly Used Methods to Measure Antimicrobial Activity

Appendix 11. Information on the principle target organisms for PT 8 as outlined in the document (5.5.8)

8 These tests are not necessarily appropriate for all claims and materials. Tests have to be chosen depending on the claim made, the materials used and the conditions of use foreseen for the treated material/article.

9 These tests are not necessarily appropriate for all claims and materials. Tests have to be chosen depending on the claim made, the materials used and the conditions of use foreseen for the treated material/article.

10 Please note: The methods listed are not necessarily appropriate in all cases. Their applicability depends on the claim made, the materials used and the conditions of use for the treated material/article. These methods are listed to give an overview for the assessor when and where a method is meaningful to demonstrate a claim and where its limits are.

11 Please note: The methods listed are not necessarily appropriate in all cases. Their applicability depends on the claim made, the materials used and the conditions of use for the treated material/article. These methods are listed to give an overview for the assessor when and where a method is meaningful to demonstrate a claim and where its limits are.

12 Please note: The methods listed are not necessarily appropriate in all cases. Their applicability depends on the claim made, the materials used and the conditions of use for the treated material/article. These methods are listed to give an overview for the assessor when and where a method is meaningful to demonstrate a claim and where its limits are.
Appendix 12. Annex A of EN 599-1 and EN 14128

Appendix 13. Laboratory studies for rodenticides: bait choice test

Appendix 14. Field trial for rodenticide baits

Appendix 15. List of currently available standard test methods for rodenticides

Appendix 16. Additional information on label claims
Appendix 17. Species grid

Appendix 18. List of currently available standard test methods for product type 18 insecticides/acaricides and product type 19 repellents/attractants (as far as they concern insects and other arthropods)
Appendix 19. Efficacy guideline with Cockroach; field trial

Appendix 20. Current Antifouling Coatings

Appendix 21. Published paper (CEPE Antifouling Working Group)

Appendix 22. Example Of How An Overall Fouling Assessment May Be Carried Out For Panel Testing In Marine Waters

Appendix 23. PT 22 active substances in the review programme

Appendix 24. Assessment grid for tests on human bodies