

SUPERSEDED GUIDANCE - NEWER VERSION AVAILABLE

Transitional Guidance on the Biocidal Products Regulation

Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants

May 2016

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Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants

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PREFACE

This Transitional Guidance is to be applied to applications for active substance approval and product authorisation submitted under the Biocidal Product Regulation (EU) No 528/2012 (the BPR). This document describes the BPR obligations and how to fulfil them

A "Transitional Guidance" is usually a document that has been initiated under the "old" Biocidal Products Directive 98/8/EC, however this Guidance has been developed under the BPR.

This Transitional Guidance document has been developed by the Efficacy WG of the Biocidal Products Committee (BPC) and has undergone a full ECHA consultation. The document is waiting for inclusion into the Volume II Part B of the new BPR guidance structure, but because it has been finalised before the relevant new BPR guidance document (i.e. Vol II Part B) has been fully developed, it is being made available as a Transitional Guidance document until such time as the relevant new document is ready for publication.

This Transitional Guidance deals with the evaluation methodology of efficacy tests for disinfectants for the national and Union authorisations of products under the EU Biocidal Products Regulation 528/2012 (BPR).

This Transitional Guidance replaces part of the Appendices to section 7 (page 111 to 134) from the Technical Notes for Guidance (TNSG) on Product Evaluation in support of Directive 98/8/EC (Biocidal Product Directive - BPD).



NOTES ON THE TEXT:

- Section 1: the General Introduction is written for disinfectants in the Main Group 1 (PT 1 to 5). This section has been commented on in a Commission public consultation and revised accordingly.
- Section 3: detailed guidance for PT2 was endorsed by the Technical Meeting in 2012, and Competent Authorities (for Biocides) meeting in May 2013. Some revisions of these sections have been incorporated after the Commission public consultation and revised accordingly.
- Sections 2, 4 and 5: the detailed guidance on PT1, 3 and 4 is now incorporated in this guidance document. This was reviewed by a working group of several Competent Authorities and stakeholders.
- Section 6: a preliminary draft for PT 5 is included in this guidance: this has not been reviewed or revised to address written PEG comments received. Since the consultation was launched a "Disinfectants Project" has been initiated which will address PT 5 and will also address the PEG comments received. The project will provide a draft guidance document which will undergo an ECHA consultation in 2016. In the meantime, the "preliminary draft text" for PT 5 in section 6 is available to readers.

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NOTES to the reader:

This Transitional Guidance will be reformatted (sections numbers, table numbers etc.) and re-organised (Table of contents, list of Abbreviations, Glossary etc.) when it is incorporated into the New Guidance Structure.

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.

List of Abbreviations

Abbreviation	Explanation
AFNOR	Association française de normalisation; French national organisation for standardisation http://www.afnor.org/
AOAC	Association of Official Analytical Chemists http://www.aoac.org/
ASTM	American Society for Testing and Materials http://www.astm.org/
ATCC	American Type Culture Collection http://www.lgcstandards-atcc.org/
BP	biocidal product
BPD	Biocidal Products Directive 98/8/EC
BPR	Biocidal Products Regulation (EU) No 528/2012
CA/CAs	Competent Authority/Competent Authorities
CEN	Comité Européen de Normalisation; European Committee for Standardisation http://www.cen.eu/
CIP	Cleaning-in-Place
DIN	Deutsches Institut fuer Normung; German national organisation for standardisation http://www.din.de/
DVG	Deutsche Veterinaermedizinische Gesellschaft; German Veterinary Medical Society http://www.dvg.net/
EN	European Standard
EPPO	European and Mediterranean Plant Protection Organization www.eppo.org
ISO	International Organization for Standardisation http://www.iso.org/
MAD	Mutual Acceptance of Data
OECD	Organisation for Economic Co-operation and Development http://www.oecd.org/
prEN	Draft European Standard
PT	product-type
SPC	Summary of Product Characteristics
TC	Technical Committee
TM	Technical Meeting
TNsG	Technical Notes for Guidance
US-EPA	United States Environmental Protection Agency http://www.epa.gov/
VAH	Verbund fuer Angewandte Hygiene; Association for Applied Hygiene http://www.vah-online.de/

Glossary of Terms

Standard term	Explanation
Activity against enveloped viruses (see also Virucidal activity and Limited spectrum virucidal activity)	A claim for hygienic hand and skin disinfectants with activity against enveloped viruses only.
Algaecide	A product or active substance used to control (inhibit the growth) or kill algae.
Algaecidal activity	The capability of a product or active substance to produce a reduction in the number of viable algae cells under defined conditions.
Antimicrobial product	A product which prevents the growth of/reduces the number of/mitigates the growth of micro-organisms
Bactericide	A product or active substance which irreversibly inactivates vegetative bacteria under defined conditions
Bactericidal activity	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
Bacteriostatic activity	Capability of a product or active substance to inhibit the growth of bacteria under defined conditions
Biocidal product/ Biocide	BPR Article 3(1)(a): <ul style="list-style-type: none"> – 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. <p>A treated article that has a primary biocidal function shall be considered a biocidal product.</p>
Biofilm	An accumulation of microbial cells immobilised on a substratum and embedded in an organic polymer matrix of microbial origin
Biostatic product	A product which inhibits the growth of micro-organisms under defined conditions
Curative effect on biofilm	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
Disinfectant within PT 2, 3, 4 and 5	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

Standard term	Explanation
Disinfection within PT 2, 3, 4 and 5	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
Skin disinfection within PT1	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
Efficacy	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.
Flow condition (for biofilm)	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
Fungicide	A product or active substance which irreversibly inactivates fungi (vegetative mycelia, budding yeasts and/or their spores) under defined conditions
Fungicidal Activity	The capability of a product or active substance to produce a reduction in the number of viable vegetative yeast cells and mould spores of relevant test organisms under defined conditions
Fungistatic activity	The capability of a product or active substance to inhibit the growth of fungi under defined conditions
Hygienic hand disinfectants	A hygienic hand disinfectant is a hygienic handrub disinfectant or a hygienic hand wash disinfectant
Hygienic handrub disinfectant	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
Hygienic handwash disinfectant	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
Limited spectrum virucidal activity (see also Virucidal activity and Activity against enveloped viruses)	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).
Log reduction / log ₁₀ reduction / lg reduction	Reduction presented in a logarithmic scale. Example 1: when a disinfection reduces 10 ⁸ bacteria to 10 ² bacteria, this is a lg reduction of 6. Example 2: when a disinfection reduces 5.10 ⁷ fungal spores to 8.10 ³ fungal spores this is a lg reduction of 3.79.
Microbes/micro-organisms	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.
Mycobactericide	A product or active substance which irreversibly inactivates mycobacteria under defined conditions
Mycobactericidal activity	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

Standard term	Explanation
Neutraliser	A chemical agent or formulation which suppresses the residual activity of an disinfectant within a test but does not inhibit or inactivate micro-organisms
Performance standard	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.
Preventive effect on biofilm	The biocide is present before the biofilm is formed and may act both on cell viability and/or on cell adhesion/biofilm maturation
Product type (PT)	Product types (PT) are defined in BPR annex V
Sporicide	A product or active substance which inactivates dormant bacterial spores under defined conditions
Sporicidal activity	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
Sporistatic activity	The capability of a product to inhibit the germination of dormant bacterial spores under defined conditions
Static condition (for biofilm)	Biofilm is formed on supports such as microplates without agitation after an incubation time that depends on the micro-organism considered
Surgical hand disinfectants	A surgical hand disinfectant is a surgical handrub disinfectant or a surgical hand wash disinfectant
Surgical handrub disinfectant	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
Surgical handwash disinfectant	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
Treated article	A treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products
Tuberculocide	A product or active substance which irreversibly inactivates <i>Mycobacterium tuberculosis</i> under defined conditions
Tuberculocidal activity	The capability of a product or active substance to irreversibly inactivate <i>Mycobacterium tuberculosis</i> , demonstrated by the capability to produce a reduction in the number of viable cells of the test organism <i>Mycobacterium terrae</i> under defined conditions
Virucide	A product or active substance which irreversibly inactivates viruses under defined conditions
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.

Standard term	Explanation
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

1.1 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 algacides 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 air¹, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algacides 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

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.

¹ This is taken to mean the disinfection of air itself. Disinfectants sprayed or vaporised into the air (e.g. room disinfection by vaporised biocide) 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 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) document ²). 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 1.5.6 of this Guidance for details of available guidance.

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

1.2 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.

1.3 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

² [CA-Sept13-Doc](#)

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 SPC³. 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 claims 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.

1.3.1 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 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.

³ Details on how to fill out the SPC are available in the ECHA Technical Guide and SPC Editor.

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.

For some areas of use there are minimum requirements for the groups of organisms for which efficacy should be demonstrated. For instance, for products used for animal transport vehicles efficacy against bacteria, yeasts and viruses should be demonstrated. For these products it is obligatory to test all required organisms. Per section, a sub-section on test organisms provides information on the minimum requirements for that use.

1.3.2 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 1.5.3 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.

1.3.3 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.

1.3.4 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.

1.3.5 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*.

1.4 Efficacy testing

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

1.4.1 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 quantitative suspension tests to establish that a product has bactericidal, fungicidal, virucidal etc. activity, simulating practical conditions appropriate to its intended use.

- Phase 2, step 2 tests are quantitative laboratory tests, often using carriers or living tissues with dried-on micro-organisms, simulating practical conditions to establish that the product has bactericidal, fungicidal, virucidal etc. activity.
- Phase 3 tests are field tests under practical conditions.

1.4.1.1 Phase 1

Phase 1 tests are laboratory suspension tests to establish the basic activity of the product or active substance. These tests may be used during the development of the product, but are not accepted for product authorisation. However, a phase 1 test can be used to demonstrate that a co-formulant does not have any biocidal activity in the product.

1.4.1.2 Phase 2, step 1

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 log₁₀ 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 micro-organisms. The result is expressed as the amount of the accumulated inoculum that was required to produce the "failure".

1.4.1.3 Phase 2, step 2

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.

1.4.1.4 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 actual 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.

1.4.2 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.

1.4.2.1 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 available standards 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 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 adaption 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.

1.4.2.2 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 Biocides", 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).

1.4.2.3 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.

1.4.3 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 tests 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.

1.4.4 Relevant factors of the test procedure

1.4.4.1 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 contro 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.

1.4.4.2 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.

1.4.4.3 Presence of Interfering Substances

Where 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 removed, 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.

1.4.4.4 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 low 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.

1.4.4.5 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 micro-organisms.

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.

1.4.4.6 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.

1.4.4.7 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.

1.4.4.8 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.

1.4.4.9 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.

EN14885 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 shall 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 test-organisms 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.

1.5 General data requirements

1.5.1 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).

1.5.2 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.

1.5.3 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).

1.5.4 Malodour control

There are specific requirements for products claiming control of organisms that cause malodour. Phase 2, step 1 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.

1.5.5 Changes in ingredients ⁴

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.

1.5.6 Treated articles

This section concerns treated articles and should be read in conjunction with the CA Note for Guidance "Frequently asked questions on treated articles", CA-Sept13-Doc.5.1.e, Revision 1 December 2014 ⁵.

A treated article according to Article 3(1)(l) of the BPR is any substance, mixture or article which has been treated with or intentionally incorporates one or more biocidal products. A biocidal product, in contrast, is any substance or mixture with a biocidal

⁴ For this section, the product family concept of the BPR is not yet taken into account.

⁵ [CA-Sept13-Doc](#)

function. Pursuant to Article 3(1)(a) a treated article with a primary biocidal function is considered a biocidal product.

Article 3 Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'biocidal product' means

- 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.

Liquids fulfil the substance or mixture definition. Consequently, liquids may only be considered as treated articles if they do not intend to control any harmful organism. In contrast, solid treated articles are defined by their shape and function rather than by their chemical composition. Thus, solid treated articles fulfil the definition of a biocidal product if they have a primary biocidal function.

The term "primary biocidal function" is not further defined in the BPR, but in the CA document, it is described as "a biocidal function of first rank, importance, or value compared to other functions of the treated article".

Thus, considering the different product types for PTs 1-4, the following examples would be considered as biocidal products and not treated articles. For PT 1 or 3, disinfecting wipes would be regarded as biocidal products⁶. For PT2, paints and coatings intended to prevent microbial settlement and growth in order to provide a hygienic environment would likewise be regarded as biocidal products⁷. Other PT 2 applications which could fall under either category, depending on their primary function could include for instance textiles, tissues, masks, or other articles or materials in which a biocidal product has been incorporated with the purpose of adding disinfecting properties to these articles and materials. For PT 4, examples are materials or articles which come into contact with food or feed and are treated with or incorporate a biocide; whether such articles are to be regarded as biocidal products again depends on their primary function. PT 5 applications are usually biocidal products. Further product examples are given in Appendix 1 of the CA document.

Treated articles, if not biocidal products, do not require efficacy assessment under the BPR. However, active substances and biocidal products incorporated into treated articles may require assessment of their efficacy in treated articles as part of the active substance approval and biocidal product authorisation processes (if such uses are applied for).

⁶ See CA document Appendix 1

⁷ See CA document Question 8

Generally, there is no difference in efficacy testing of treated articles or biocidal products. For instance, wet state preservatives (PT 6) or a hand disinfectant (PT 1) are usually both tested in a liquid matrix, the first matrix is a treated article, the latter is a biocidal product; only the performance standards are different in these examples. Specific requirements apply, however, when the efficacy of solid material or articles has to be tested. A test under practical conditions of use (step 3 test) is mandatory. In contrast to preserving claims, where standard materials under certain standard conditions of use can be tested, testing for disinfecting claims has to be specific for every single article. For these types of claims, the specific conditions of use are to be considered when designing the efficacy testing; for example, a polymer coating used for a hospital bedside cabinet has to be tested for the specific contaminating situation of a hospital bedside cabinet, including cleaning schemes and soiling situation; efficacy has to be shown compared to an untreated bedside cabinet. Bacteriocidal effects have to take effect very quickly to show an advantage compared to an untreated cabinet, where droplets of blood or saliva will dry out quickly and not either be contaminating any more. Please read more about how to design such tests in BPR Vol II Efficacy Parts B+C, Section 5.3⁸.

As long as there is no specific EU guidance on efficacy testing of treated articles, the following document should be used:

- Nordic Working Paper "Efficacy Assessment of treated articles: A guidance" concerning data requirements and acceptance criteria for treated articles⁹.

Furthermore, there are two OECD test methods available:

- Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects (OECD Series on Biocides No. 1);
- Guidance Document for Quantitative Method for Evaluating Antibacterial Activity of Porous and Non-Porous Antibacterial Treated Materials (OECD [Series on Testing and Assessment No. 202 and Series on Biocides No. 8](#))

1.5.7 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 Vol II Efficacy Parts B+C, Section 5.2 Product Families ¹⁰.

1.6 Resistance

The topic of resistance is discussed in the general part of the TNsG on Product Evaluation (Section 6). In the biocidal product dossier information on resistance should be given.

Additionally, in support of the review for each active substance, information on resistance is given in the Competent Authority Report (CAR) of this active substance.

Resistance will be assessed on the basis of expert judgement.

⁸ Vol II Efficacy Parts B+C is under development and will incorporate this document before publication, at which time the cross reference will be updated and the footnote will be removed.

⁹ <http://norden.diva-portal.org/smash/get/diva2:702967/FULLTEXT01.pdf>

¹⁰ See footnote 10

1.7 Assessment of application for authorisation

1.7.1 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.

1.7.2 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 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.

2. PT 1 Human hygiene biocidal products

2.1 Introduction

Product type 1 contains 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.

Products applied on human skin may be assigned to either biocidal, medicinal or cosmetic products or even to medical devices. If the product under investigation is within the scope of the Medicinal Products Directive (2001/83/EC), the Cosmetic Products Regulation ((EC) No 1223/2009) or the Medical Devices Directive (93/42/EEC), it is excluded from the BPR for the respective use.

Products for disinfection of damaged skin (e.g. wound disinfection) or disinfection of undamaged skin before a medical treatment of a patient (e.g. pre-operative skin disinfection before surgery and disinfection before injection) and products with a claim of medicinal use, are always medicinal products (covered by the Directive 2001/83/EC on medicinal products for human use).

Biocidal products within PT1 are mainly hand disinfectants, which can include disinfection of wrist and forearm.

When applying for authorisation for a biocidal product within PT1 a detailed description of the intended use should be given, to prevent authorisation of medicinal products, or cosmetic or medicinal uses, as biocides (e.g. the claim "skin disinfection" is insufficient).

For products that fall under the BPR the data requirements described in the following sections apply.

2.2 Hand disinfectants

2.2.1 Introduction

Hand disinfectants can be divided in hygienic handwash, hygienic handrub, surgical handwash and surgical handrub products. Handwash products are intended to be used with water, handrub products are intended to be used without the addition of water. Hand disinfectants can include disinfection of wrist and forearm. Products include liquids, gels, wipes, etc.

Hand disinfectants can be used in a wide variety of areas such as hospitals and other health care institutions, food, beverage and other industry, private homes, etc.

In the sections below 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.

2.2.2 Data requirements

2.2.2.1 Test methods

For efficacy testing of hand disinfectants, the tiered approach as described in section 1.4.1 of this Guidance is preferred. For hygienic handwash, hygienic handrub, surgical handwash and surgical handrub phase 2, step 1 and step 2 tests are required. Phase 2, step 1 tests are available for all relevant test organisms and required depending on the claim made. For a claim without specification of the area of use the phase 2, step 1 for medical area should be used.

For bacteria a phase 2, step 2 test is available for these uses and therefore mandatory. For other organisms phase 2, step 2 tests will be mandatory when they become available. For an overview of available EN tests see Appendices 2 and 4.

Disinfectant towelettes/wipes

For hand disinfectant wipes, phase 2, step 1 tests should be done preferably with the liquid extracted from the wipe or, if difficult to extract, use the liquid as it is before it is added to the wipes. Phase 2, step 2 tests for hand disinfection (modified EN 1500) should be tests with the wipe applied on volunteers hands according to the intended use. The wipes should be used on full hands and not on the fingertips only. In addition, a test must be performed that shows that either the wipe will still disinfect if the wipe dries out or that the wipe stays wet long enough to disinfect according to the claim. In addition, the use directions can address these issues, for instance, stating on the label that only wet wipes are efficacious or giving expiry dates for re-sealable packages if appropriate according to the intended use conditions.

2.2.2.2 Test organisms

Hand disinfectants intended for general hygiene purposes should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided. For hand disinfectants intended for use in industrial environments to prevent spoilage of products, in some cases also prevention of bacteria and yeast infections is of importance, for example, in food and cosmetic industry. In other industries it may be justified that only efficacy against bacteria is sufficient.

For all other groups of organisms tests have to be provided only when activity against those specific organisms is claimed.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods.

Additionally to the obligatory species, other species can be used if there are valid scientific arguments to justify their use, such as a need to show activity against specific organisms of concern in a human health environment, especially emerging health risks, or in specified industries.

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

2.2.2.2.1 Virucidal activity

For products used as hygienic hand disinfectants a differentiation in the virucidal activity is made.

The claims can be:

- full virucidal activity;
- limited spectrum virucidal activity;
- activity against enveloped viruses.

For each claim different test organisms should be tested.

The EN 14476¹¹ test for virucidal activity gives the opportunity to either test for full or limited spectrum virucidal activity for hand disinfectants. For full virucidal activity Poliovirus, Adenovirus and Murine Norovirus should be tested. Limited spectrum virucidal activity is a claim for hygienic handrub and hygienic handwash products using Adenovirus and Murine Norovirus as test organisms, thus including activity against the test viruses and all enveloped viruses (see Appendix 5 for a list of relevant viruses). Activity against enveloped viruses is currently being discussed to be included in EN 14476¹² (test virus: MVA = Modified Vacciniavirus Ankara).

When only the limited spectrum virucidal activity or activity against enveloped viruses is demonstrated the label claim cannot be "virucidal". The SPC should clearly state which of the possible virucidal claims was demonstrated.

Non-professionals may not understand the difference between a virucidal claim and a limited spectrum virucidal claim. Therefore, the instructions for non-professionals should be carefully worded. National hygiene agencies should decide how this can be communicated to the public and how the label claim (in the SPC) should be phrased to prevent misuse (e.g. limited spectrum products will not be efficacious during an outbreak of Hepatitis A virus or Enterovirus).

2.2.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The contact time can be found in the relevant EN tests. In general the contact times are:

- for hygienic handwash and handrub products the contact time is between 30 and 120 seconds;
- for hygienic handwash and handrub products used in medical area the contact time is usually 30 seconds for bactericidal, yeasticidal activity and activity against enveloped viruses;

¹¹ The current published version is EN 14476: 2013

¹² At the time of publication of this Transitional Guidance, prEN 14476:2011 is under development and has been submitted to CEN.

- for surgical hand disinfection products the contact time should not exceed 5 minutes.

It must be assured that the disinfected hands stay wet during treatment (e.g. by applying enough product or by applying the product several times if the volume necessary is too much to apply at once).

Phase 2, step 1 tests should be carried out with soiling (interfering substances) for clean or dirty conditions depending on the intended use and according to the relevant EN tests, i.e. EN 13727 and EN 13624 (medical and veterinary area) or EN 1276 and EN 1650¹³ (industrial, domestic, institutional area). Dirty conditions in phase 2, step 1 tests are mandatory for handwash applications. For handrubs, clean conditions in phase 2, step 1 tests suffice if use instructions state that the product must be applied on visibly clean hands.

For handwash products the phase 2, step 1 tests should be performed with a dilution of the product to take into account that the product is used on wetted hands. This is described for bacteria in test EN 13727 and a similar approach should be taken for other organisms.

Phase 2, step 2 tests are performed without additional soiling according to EN 1499, EN 1500 or EN 12791. The soiling needed for clean and dirty conditions can be found in the relevant EN phase 2, step 1 tests and in the Table of Pass Criteria and EN Standards available on the ECHA Biocides Efficacy Working Group webpage (see Appendix 4 for more information). Note that dirty conditions for products used in hospitals and health care differ from those in other areas of use.

2.2.3 Acceptance criteria

A product in PT1 will be assessed to be sufficiently effective if the required laboratory 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 PT1 products the required \log_{10} reductions are referenced in Appendix 4 or EN14885.

Since the test methods for these types of products are generally established, deviations are not foreseen. If, however, deviations are considered necessary, they must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

2.3 Other skin and scalp disinfection

For other skin and scalp disinfection products the overlap with medicinal and cosmetic products is significant. Only products that are not covered under either of these directives can be considered as PT1 disinfectants.

2.3.1 Data requirements

2.3.2.1 Test methods

For other skin disinfection products the tiered approach as described in section 1.4.1 of this Guidance is preferred: phase 2, step 1 and step 2 tests are required.

The same phase 2, step 1 tests as required for hand disinfectants can be used.

¹³ These tests will be adapted for hand disinfectants.

Currently, there are no European phase 2, step 2 standard tests available for other skin disinfectants. However, test protocols may be designed by adapting existing standards (e.g. CEN methods involving volunteers) in a way that mirrors the respective application.

Newly designed test protocols should be timely discussed with and agreed by the CA before tests are carried out.

Deviations from the existing/future standards should always be mentioned and justified.

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

2.3.2.2 Test organisms

Disinfectants for other skin and scalp should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For phase 2, step 1 tests the standard organisms of these tests should be tested.

For phase 2, step 2 tests either the standard organisms of these tests can be tested or the normal occurring micro flora in volunteer tests.

For all other groups of organisms tests only have to be provided when activity against those specific organisms is claimed.

Justification for the used test organisms should be provided.

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.

2.3.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label. The claimed contact time has to be a realistic value and should be justified for the use.

Phase 2, step 1 and phase 2, step 2 carrier tests should be carried out with BSA as soiling (interfering substances) for clean or dirty conditions depending on the intended use. Simulated-use studies with volunteers are in general performed without additional soiling.

The soiling needed for clean and dirty conditions can be found in the relevant EN tests (see EN 14885, medical area) and referenced in Appendix 4.

2.3.2 Acceptance criteria

A product in PT1 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 PT1 products the required \log_{10} reductions are referenced in Appendix 4 or EN14885.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3. PT 2 Disinfectants and algaecides not intended for direct application to humans or animals

3.1 Introduction

Product type 2¹⁴ contains disinfectants and algaecides not intended for direct application to humans or animals. This includes *inter alia*:

- 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 such as 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 air¹⁵, 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.

The data requirements (test standards and test organisms) and assessment criteria for the most common uses are specified below. Detailed but non-exhaustive lists of the most relevant product applications and uses of disinfectants within PT2, together with the relevant test methodologies are given in the claims matrices which are a set of tables linked to this guidance document (see Appendix 1 for more information).

All of the possible uses in this PT cannot be covered in the matrices. For other, less common, uses and claims that are not specifically mentioned, there is often no international standard tests available. Where this is the case, the applicant should provide tests that show the efficacy of the product and a justification for the use of these tests. The assessment of these products will be based on expert judgement and will be handled case-by-case.

3.2 Data requirements

There are some general data requirements that apply to all uses in PT2, and these are described below. There are also specific data requirements that apply to different types of use, and these are described in the sections covering those uses.

The intended uses of the disinfectant determine which tests will be required to support the product. Tests that most closely reproduce the practical application conditions should be selected.

In general it is not known which organisms are present on a surface or matrix to be disinfected. Therefore a disinfectant must have a broad spectrum of activity, in order to control all of the organisms that may be present.

¹⁴ This includes biostatic products.

¹⁵ This is taken to mean disinfection of air itself. Disinfectants sprayed or vaporised into the air (e.g. room disinfection by vaporised biocide) are generally for the purpose of disinfecting surfaces and not the air itself. Disinfectants for air conditioning systems disinfect the surfaces in these systems, not the air coming out of it.

3.2.1 Use in health care

For general applications in the medical sector, the products should be at least sufficiently effective against bacteria and yeasts (which are responsible for most common nosocomial infections). Additionally, efficacy against other organisms can be claimed.

Products intended to disinfect surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient, must be tested with a contact time of maximum of 5 minutes. The same applies when the contact time of the product must be limited for practical reasons. Products for other surfaces than those stated above, may be tested with a contact time of a maximum of 60 minutes.

3.2.2 Tuberculosis departments

If the product is to be used in tuberculosis departments, the product should be efficacious as a general disinfectant used in health care (efficacy against bacteria and yeast), but tuberculocidal activity or mycobactericidal activity must also be demonstrated.

3.2.3 Cleanrooms

Products to be used in cleanrooms only differ in the data requirements for the interfering substance to be used in the tests. 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 metre 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 8 or according to GMP EU classification in Grade A to C.

3.2.4 Products against viruses

Products against viruses must be effective against viruses with and without an "envelope" (protein or lipid mantle). Products can claim virucidal efficacy if efficacy against non-enveloped viruses has been proven. Such products can be regarded as efficacious against enveloped and non-enveloped viruses.

The Phase 2 step 2 virus test described in EN 14476, should be used for testing products against viruses used in domestic areas. For testing products used in veterinary hospitals either EN 14476 or EN 14675 can be used. For products used in the medical area, a phase 2 step 2 test is under development, see prEN 16777.

3.3 Disinfectants for hard surfaces (in PT2)

3.3.1 Introduction

Biocides can be used to disinfect hard surfaces in areas such as hospitals (including veterinary hospitals, dental facilities etc.), industry, institutions or private homes. These surfaces may be tables, floors, walls, the outsides of machinery and hard furniture, etc. Products are often wiped or sprayed onto the surfaces and may be washed or wiped off after a certain contact time.

The testing requirements for some specific uses of hard surface disinfectants are discussed in separate sections, for example, toilets, room disinfection with vaporised biocide, immersion of equipment into the product, etc. As the areas of use can be as

diverse as private homes to operating theatres, the test requirements might vary depending on the area of use.

3.3.2 Data requirements

See general data requirements for PT2 (see sections 1.5 and 3.2 of this Guidance). A detailed, but non-exhaustive list of the most relevant product applications and uses of hard surface disinfectants and the required test methodologies are given in Claims Matrix PT2, table for "Hard surfaces": the claims matrices are a set of tables linked to this guidance document (see Appendix 1 for more information and also Appendix 4).

3.3.2.1 Test methods

For efficacy testing of hard surface disinfectants, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a hard surface disinfectant:

- a quantitative suspension test (phase 2, step 1);
- and a quantitative surface test (phase 2, step 2),
both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Tests in phase 3 are optional, as no validated test methods are available yet. Several methods for testing the efficacy of hard surface disinfectants are available. Appendices 2 and 4 give a list of recommended test methods.

The following documents are recommended for surface disinfection:

- EN 14885: gives an overview of which EN phase 2, step 1 and step 2 tests to use for different uses,
if CEN standards are not relevant or available for the use or organisms claimed the following documents are recommended if appropriately reflecting the application:
- OECD guidance for the testing of chemicals: Quantitative method for evaluating activity of microbiocides used on hard non-porous surfaces (these are surface tests which would be considered phase 2, step 2 tests),

The use of the specified tests is strongly recommended where they are relevant and appropriate. Where the tests are not appropriate to the product, other tests can be used, although a justification for the relevance of the tests used should also be provided.

It is preferred that tests should be selected that correspond to the use area of the product (e.g. tests from medical areas for use in hospitals and tests for industrial areas for use in cosmetic industry). Where the product is intended for use in several areas it is acceptable to perform the tests specified for only one of the areas, as long as the test with the highest/most stringent pass criteria is used. In some cases where the worse case cannot be clearly identified all areas must be tested.

Currently validated surface tests with and without mechanical action are available (EN and OECD). Validated surface tests with mechanical action have been developed, and should be used for products that are intended to be used with mechanical action (EN 16615).

Where specific conditions apply for a field of use, such as high/low level soiling, high/low temperatures, relevant contact times etc. (see section 1.4.4 of this Guidance), these conditions should be included in the efficacy testing.

Disinfectant towelettes/wipes

For disinfectant wipes, the phase 2, step 1 tests should be done preferably with the liquid extracted from the wipes, or if difficult to extract, use the liquid as it is before it is added to the wipes. Phase 2, step 2 tests should be tests with mechanical action. These tests are available for bacteria and yeasts. For testing other organisms surface tests can be done with liquid extracted from the wipes (not the original liquid), with a justification of the volume that is applied per square centimetre. In addition, a test must be performed that shows that either the wipe will still disinfect after the wipe dries out or that the wipe stays wet long enough to disinfect according to the claim. In addition, the use directions can address these issues, for instance, stating on the label that only wet wipes are efficacious, defining the surface area each wipe can disinfect (e.g. 0.5 m²), or giving expiry dates for re-sealable packages.

3.3.2.2 Test organisms

The test organisms used in efficacy tests are normally stated in the applicable standard test methods. For use in veterinary health care the target organisms in the test for the veterinary area (PT3) should be used.

If standard tests are not used (there will normally need to be a justification for this), the test organisms used to support a general claim should be demonstrated to be equivalent to the reference test organisms given in Appendix 3.

Tests with test organisms other than those mentioned in Appendix 3 are acceptable, if adequate scientific evidence is submitted on which the relevance of the test organism to the field of use can be judged.

Also see the general data requirements PT2 for specific claims and minimum requirements in health care.

3.3.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, where relevant, field tests have been performed (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.

If the test does not provide these criteria, the general criteria referenced in Appendix 4 or EN 14885 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.4 Soft furnishings

3.4.1 Introduction

Disinfectants for use on soft furnishings are intended to be used on fabrics in the home, institutional environment, healthcare and healthcare facilities. These can be used to treat porous soft surfaces such as curtains, sofas, upholstery, mattresses and carpets. The products are often sprayed onto the surfaces.

3.4.2 Data requirements

See general data requirements in sections 1.5 and 3.2 of this Guidance. A detailed, but non-exhaustive list of the most relevant product applications and uses of soft furnishing disinfectants and the required test methodology is given in Claims Matrix PT2, table for

“Soft furnishings”: the claims matrices are a set of tables linked to this guidance document (see Appendix 1 for more information) .

3.4.2.1 Test methods

For efficacy testing of surface disinfectants for use on soft furnishing the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a surface disinfectant:

- a quantitative suspension test (phase 2, step 1);
 - and a quantitative surface test (phase 2, step 2);
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Tests in phase 3 are optional as no validated test methods are available yet.

Where possible, the phase 2, step 1 test should be selected from EN 14885 from the table that corresponds to the use area of the product (e.g. test from medical area for use in hospitals and test for domestic areas for use in private homes).

The phase 2, step 2 surface carrier test can be derived from adaptation of CEN TC 216 surface tests. Instead of a hard surface carrier, carriers could be made of suitable fabric types. ISO 20743 can also be used, or other quantitative methods including textile as carrier. EN16616 is not relevant since this is done in washing machines.

3.4.2.2 Test organisms

The same test organisms as given for hard surfaces should be tested. See section 3.3.2.2 of this Guidance and Appendix 3.

3.4.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, where relevant, field tests have been performed (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 tests these should be met.

If the test does not provide these criteria, the general criteria referenced in Appendix 4 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.5 Room disinfection with vaporised biocide

3.5.1 Introduction

Room disinfection involves the reduction and inactivation of micro-organisms on the surfaces of the walls, floor and ceiling of the room, as well as on external surfaces of the furniture and equipment present in the treated room. The product is applied by airborne diffusion of an aerosol, a smoke, a vapour or a gas. The technical characteristics of the diffuser equipment play a central role, ensuring a homogeneous distribution of the biocide product in the volume of the room and reaching all surfaces (including ceilings and the undersides of horizontal surfaces), therefore the diffuser equipment contributes in a decisive way to the efficacy of the product. Manual spraying is not covered in this section, but under hard surface disinfection (see section 3.3 of this Guidance).

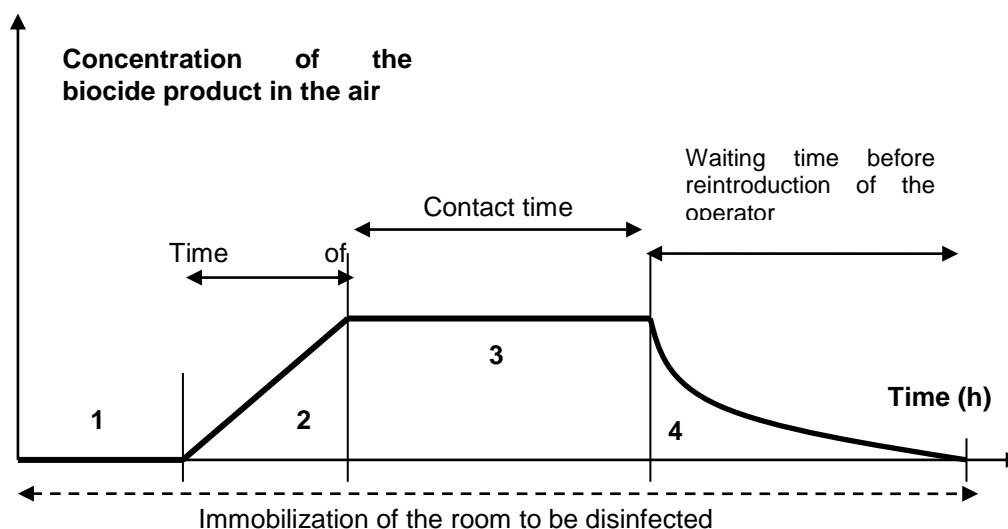
Room disinfection may not disinfect the inside parts of furniture, and will not disinfect the air itself, so these uses are not considered in this section. Room disinfection is therefore closely related to surface disinfection without mechanical action. As this causes complications in cases of organic contamination, cleaning of surfaces is necessary prior to room disinfection.

Process

The application of the product consists of four phases:

- (1) the preparation phase (required depending on type of active substance and application procedure), during which the environmental conditions (relative humidity, temperature) are modified to an optimal level for the product;
- (2) the conditioning phase, during which the product is diffused into the room, in order to reach the effective concentration;
- (3) the disinfection phase, which corresponds to the contact time required to obtain the expected level of efficacy;
- (4) the terminal phase, which includes aeration of the room to remove any disinfectant present in the air, or other procedures for inactivation of the active substance, before access of people or animals into the room can be permitted (see Figure 1 below).

Figure 1: The various phases of a cycle of disinfection of an automatic process



Phases of the cycle:

- 1: preconditioning (optional)
- 2: diffusion
- 3: phase of contact
- 4: aeration

Particular attention must be given to the dispersal time and contact time. The dispersal time is the time necessary to reach a target concentration of the product in the air and on the surfaces to be disinfected in a given volume, while the contact time is the time necessary to reach the expected efficacy.

Note: the various phases of the cycle presented are theoretical and can be adapted according to the process. The maintenance of a concentration of biocide in the

atmosphere may be achieved by the regular introduction of additional biocide during the contact phase.

3.5.2 Data requirements

3.5.2.1 Test methods

Airborne disinfection differs from direct application of liquids to surfaces. Therefore the EN phase 2, step 2 standards for surface disinfection are not applicable for room disinfection. The tiered approach is still possible, however, by using different test methods.

The following tests are normally required for a room disinfectants:

- when applicable, a quantitative suspension test (phase 2, step 1);
- semi-field trial such as European standard based on NF T 72-281 (EN standard in preparation) for disinfection using airborne application (phase 2, step 2).

The CEN phase 2, step 1 tests are suitable as suspension tests under clean or dirty conditions, although only applicable for products that can be tested in suspension (e.g. not for gasses). These tests are not sufficient on their own, and should be combined with a semi-field trial for disinfection using airborne application. Where it is not possible to test the product in a suspension test, the semi-field trial will be sufficient.

NF T 72-281 was developed by AFNOR (the French standardisation body) in 1986, and updated in 2009. This standard was taken as a start to develop a new EN standard on airborne disinfection of surfaces (decision taken within the framework of CEN TC 216 in November 2012). This semi-field method evaluates the efficacy of disinfectants when vaporised in a room (automatic diffusion process) or when sprayed in the direction of a surface (manual application). Only application by vaporisation is discussed in this section. Once this method has been finalised and adopted at European level, any method variations should be taken into account.

3.5.2.1.1 Basic principles of room disinfection

Inert and dry carriers infected with a known number of micro-organisms (bacteria, fungi, yeasts, mycobacteria, spores and viruses including bacteriophages) are placed in a room of defined volume, temperature and relative humidity. The size of the test room should be relevant to the claims for the product. The carriers used are often stainless steel, but other relevant (generally non-porous) materials can also be used, such as glass or plastic.

When the disinfection of textiles (curtains etc.) and other materials (e.g. wallpaper, filters in flow cabinets) is claimed, appropriate carriers should be used to demonstrate efficacy.

The inoculated carriers must be placed in a vertical position with inocula facing away from the diffuser. Their distance to the diffuser depends on the room dimensions (for instance: see Appendix B of NF T 72-281). The test method defines obligatory test conditions for parameters that may influence the success of the disinfection.

This test includes the use of milk in order to maintain viability of the micro-organisms on the carriers during the test. Depending on the area of use, suitable interfering substances should be tested (e.g. blood for use in hospitals).

Similar carriers are placed in a second room nearby which is not treated with diffused product, to act as controls.

Additional tests can be performed to simulate specific conditions that are encountered in the practice and to fit with label instructions. In this case, all experimental conditions

should be described clearly in the test reports. The standard lists the information that must be included in the final report.

3.5.2.1.2 Diffuser

As mentioned earlier, the disinfection efficacy is closely related to the technical characteristics of the diffuser. Section 5 “intended uses and efficacy” of the [Guidance on information requirements for biocides](#). (Volume II Efficacy, part A) requires applicants to take into account the technical equipment used, together with the product to be authorised.

A detailed description of the equipment and its characteristics must be provided in sufficient detail to distinguish it from other equipment:

- equipment name and model;
- diffusion principles (e.g. fogging, vapour, fumigation) and particles size distribution of aerosols or powder;
- description of the diffusion performance of the equipment (e.g. volume to disinfect, diffusion speed);
- description of the ambient conditions (e.g. humidity, temperature) in which the process can be used;
- diffusion time for a specific volume;
- precautions for over and under-dosing.

The product authorisation will only be granted for use with the equipment described in the application. After authorisation, any modification to the equipment should be validated and reported to the CA for evaluation.

For major modifications that can affect the efficacy (e.g. pipe, pump, nozzles), it should be demonstrated that the efficacy of the process has not been affected (e.g. by a new study on the most resistant organism).

For minor modifications that do not change the efficacy of the process, only a notification of the modifications to the equipment must be provided.

3.5.2.1.3 Contact time

As room disinfection may necessitate a long period of treatment, the contact time to be tested is not defined. The testing should demonstrate efficacy at a contact time proposed for the intended use. This should be relevant to practical use and depends on substance concentration, volume of room, power of the diffuser equipment, etc... All of these parameters should be stated on the product label or in a technical information sheet

3.5.2.2 Test organisms

Since room diffusion is used to disinfect hard (and soft) surfaces, the same organisms should be tested as for hard surface disinfection (section 3.3 of this Guidance). Appendix 3 contains a table of reference test organisms.

The general data requirements for PT2 for specific claims and minimal requirements in health care also apply for room disinfection with vaporised biocide.

3.5.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, (semi) field tests have been performed (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 tests these should be met.

If the test does not provide these criteria, the general criteria referenced in Appendix 4 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.5.4 Notes

3.5.4.1 Limitations

Any limitations of the procedure should be specified in the application.

Literature has shown that disinfection by vaporised biocide may not be as effective on wet surfaces (lower concentration of the product) or inside closed cupboards and closets (where the vapour cannot penetrate). Therefore carriers should be tested under these conditions, and if efficacy is not proven, the label instructions should provide appropriate information (such as stating that cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks and toilet bowls) should be disinfected with suitable alternative products.

Other factors which may influence the efficacy of the process in the practical use such as the equipment, furniture, special structures (e.g. bumps on the walls) or special materials (copper in hydrogen peroxide procedures), including environmental conditions (e.g. temperature, relative humidity) which may affect the success of the disinfection, have also to be considered. The conditions of a sufficient vaporisation should also be specified.

3.6 Swimming pools, spas and hot tubs

3.6.1 Introduction

Disinfectants are used to treat water in swimming pools, spas and hot tubs. These may be public pools (which may be used by many people daily) or household pools or tubs (which might be used only occasionally). An intermediate situation consists of facilities in hotels, housing complexes or sports clubs, where the bather load may be lower than in a fully public facility, but still high compared to private, domestic facilities.

Disinfectant products can be added to a pool continuously, intermittently, by shock dosing or through generation *in situ*. Large public facilities may have dedicated staff to maintain the pool using automated control systems, whereas smaller pools may be treated using manual methods by janitorial staff. Private pools may be treated by individual householders, supplemented in some cases by professional pool treatment personnel. Disinfection is only one aspect of pool maintenance and other activities, such as ensuring the correct pH and the removal of pollutants by oxidation, flocculation and filtration, are essential to ensure adequate water quality.

The principal purpose of the use of disinfectants is to treat the water to prevent the water-borne transmission of pathogens between pool users. Supplementary purposes are to ensure the aesthetic quality of a pool (by ensuring that algae do not result in turbid water or unsightly and slippery microbial growth on pool surfaces, such as the floor and walls of the pool) and to prevent microbial slime and biofilm formation in pipework and related equipment.

This section only deals with disinfection of the pool water and the pipework and related equipment containing pool water. The disinfection of hard surfaces surrounding the pool is covered in section 3.3 of this Guidance.

3.6.2 Data requirements

See PT2 general data requirements in sections 1.5 and 3.2 of this Guidance.

A detailed, non-exhaustive list of the most relevant applications and of appropriate test methodology is given in Claims Matrix PT2, table for "Swimming pools": the claims matrices are a set of tables linked to this guidance document (see Appendix 1 for more information).

3.6.2.1 Test methods

For efficacy testing of pool disinfectants the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a pool disinfectant following a tiered approach:

- a quantitative suspension test (phase 2, step 1);
- simulated-use tests with pool water or a surface test (phase 2, step 2)*;
- and a field test (phase 3)**;

all simulating practical conditions appropriate to its intended use (temperature, contact time, soiling/bather load etc.).

* A phase 2, step 2 test may be appropriate in cases where a product has a specific use in surface disinfection. Otherwise, a simulated use test is appropriate for products intended to disinfect the water in a pool or spa.

** In some cases the field trial can be waived. The OECD guidance document (described below) is based on experience with hypochlorous acid/hypochlorite. Therefore, it is acceptable that for products based on hypochlorous acid/hypochlorite the field test is waived and only laboratory test data are provided. In some other cases, waiving the phase 3 test can also be justified.

The OECD "Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants in Laboratory and Field testing" (OECD Series of Testing and Assessment No 170, version dated 08 October 2012) describes laboratory and field test methods, conditions and criteria needed to demonstrate efficacy of a pool disinfectant. The protocol for field tests should be agreed between the applicant and CA before a field test is initiated.

For products that are used for specific purposes such as disinfecting pipework, filters and filter media, it may be more appropriate to test using the EN 14885 methods for the disinfection of surfaces in institutional applications.

3.6.2.2 Test organisms

Besides bacteria and viruses, protozoa can also be of importance in swimming pools. Fungi may pose a health hazard on wet surfaces surrounding the pool and can cause slime build up in pipework. OECD guidance lists the organisms that normally should be tested. Although algae and protozoa in pools are, in general only a problem when maintenance of the pool is not carried out properly, data against algae and/or protozoa should be provided where claims against these targets are made.

3.6.3 Acceptance criteria

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

When pass criteria are available in the standard tests these should be met.

The OECD guidance document sets out criteria for laboratory and field tests. However, it may be noted that there is a current OECD project review underway to look at criteria for laboratory and field tests.

Where these criteria are not met, the applicant can provide a justification as to why the product should still be considered acceptable. However, the CA will evaluate any justifications on a case-by-case basis, consulting the other CAs as necessary, and will decide whether it is acceptable or not.

The OECD guidance document contains more details on factors to be considered.

3.7 Toilets

3.7.1 Introduction

Biocides can be used to disinfect toilet bowl surfaces in diverse environments including, hospitals, industry, institutions or households. Toilet bowl biocides are available in a wide variety of forms, such as liquids, foams, powders, gels, pastes and tablets.

These products are often applied via pouring around the inside rim of the toilet bowl surfaces with the area scrubbed after a minimum contact time.

Other products are applied in the toilet permanently. They can be attached over the rim of the toilet bowl, stuck directly onto the side of the toilet bowl, placed directly in the cistern (water reservoir), or attached by other means. These products are normally discharged when the toilet is flushed.

Hard surfaces on the inside of toilets are covered by this section. Surfaces on the outside and toilet seats, lids etc. are covered by section 3.3 "hard surfaces" of this Guidance.

The use of biocides in chemical toilets, most commonly found on airplanes, trains, and in portable toilets, is not covered in this section, (see section 3.13 of this Guidance).

3.7.2 Data requirements

See PT2 general data requirements in 1.5 and 3.2.

A detailed, non-exhaustive list of the most relevant applications and of appropriate test methodology is given in Claims Matrix PT2, table for "Toilet bowls": the claims matrices are a set of tables linked to this guidance document (see Appendix 1 for more information).

3.7.2.1 Test methods

For efficacy testing of toilet disinfectants the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a hard surface disinfectant:

- a quantitative suspension test (phase 2, step 1);
- and a quantitative surface test (phase 2, step 2);

both simulating practical conditions appropriate to its intended use (temperature, soiling, contact time, etc.).

Several test methods for quantitative suspension and surface tests are available.

Appendix 2 gives a list of recommended test methods. The following documents are recommended for surface disinfection:

- EN 14885: gives an overview of what EN phase 2, step 1 and step 2 test to use for different uses,

if CEN standards are not relevant or available for the use or organisms claimed the following documents are recommended if appropriately reflecting the application:

- OECD guidance for the testing of biocides: Quantitative method for evaluating activity of microbiocides used on hard non-porous surfaces (these are surface tests which would be considered phase 2, step 2 tests).

The use of the specified tests is strongly recommended where they are relevant and appropriate. Where tests are not appropriate to the product other tests can be used, although a justification for the relevance of the tests used should also be provided.

For products intended to be added to the water reservoir or hanging down from the rim of the bowl, the concentration of the product (or at least the active substance) in the water before, between and after flushing should be determined. This can be done by an analysis of the water under in-use conditions or, for products where all parameters are defined, by calculation. The laboratory efficacy tests should be performed using these concentrations.

Tests in phase 3 are optional.

When efficacy against biofilm is claimed a simulated-use test or field test has to be provided, next to a phase 2, step 1 test. See section 3.11 of this Guidance for test methods.

3.7.2.2 Test organisms

The same test organisms as for hard surfaces should be tested. See section 3.3.2.2 of this Guidance and Appendix 3.

Products will normally only target bacteria and, optionally, yeasts and viruses. Fungi and spores are usually not relevant in the toilet bowl but when efficacy is claimed testing is required.

3.7.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, where relevant, field tests have been performed (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 tests these should be met.

If the test does not provide these criteria, the general criteria referenced in Appendix 4 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.8 Air-conditioning systems

3.8.1 Introduction

Disinfection of air-conditioning systems is similar to hard surface disinfection since only the surfaces in the system are disinfected and not the air itself. The difference with general surface disinfection is that the surfaces are mostly hidden inside the system and cannot be reached easily without taking it apart (for instance for air-conditioning systems in cars, dismantling the system would not be desirable).

In general, disinfectants for air-conditioning systems are applied by airborne diffusion of an aerosol, a smoke, a vapour or a gas. The biocide is applied to an operating air-conditioning system at the inlet of the system. This way the biocide is sucked into and passes through the whole system.

Preservation of cooling liquids is not covered under PT2 but rather within PT11 (preservatives for liquid cooling and processing systems).

3.8.2 Data requirements

For products that are applied by airborne diffusion of an aerosol, smoke, vapour or gas the same test methods and test organisms should be used as for room disinfection. Therefore, the same data requirements as for section 3.5 of this Guidance (Room disinfection with vaporised biocide) are applicable here.

The following tests are normally required for a disinfectant for air-conditioning systems:

- when applicable, a quantitative suspension test (phase 2, step 1);
- semi-field trial such as NF T 72-281 for disinfection using airborne application (phase 2, step 2).

See section 3.5 of this Guidance for specifications.

In the semi-field test the carriers inoculated with test organisms are placed in the air-conditioning system at the beginning and at the end of the system. When it is not possible to put carriers in the system they should be placed between the biocide application site and the inlet of the system and at the end of the system, in the out-flowing air. If carriers at both sides fulfil the criteria it can be assumed that the surfaces in between are also disinfected sufficiently.

For products that are applied by manual spray, the test methods and test organisms used for hard surface disinfection should be employed. See section 3.3 of this Guidance (Hard surface disinfection) for data requirements.

In addition to these data, the applicant should provide a justification that the spray apparatus is capable of reaching all (hidden) surfaces of the air conditioning system.

3.8.3 Acceptance criteria

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

The same pass criteria can be used as for other surface disinfection (section 3.3.3 of this Guidance). The criteria referenced in Appendix 4 can be used as guidance for what level of log₁₀ reduction is normally required. Deviations from these are possible, but have to be justified in the application.

3.9 Equipment disinfection by immersion

3.9.1 Introduction

Although instrument or equipment disinfection can be considered equal to hard surface disinfection, it differs from the intended use in section 3.3 of this Guidance because it is mainly applied by immersion of the equipment or instruments in the biocide solution or by filling equipment with the solution (disinfection of inner surfaces). The products are intended for equipment used, for example, in health care facilities, laboratories and industry. The requirements for products to be used for CIP are not included in this section and can be found in section 5.3 of this Guidance.

Some of the products used for disinfection of medical instruments, which are to be used specifically for diagnostic and/or therapeutic purposes for human beings, do not fall under the scope of the BPR. Disinfectants that are specifically used for the disinfection of medical devices or a group of medical devices (anaesthetic equipment, endoscopes, surgical instruments, incubators) are covered under the Medical Device Directive

93/42/EEC. However, some disinfectants have a broader claim, for example, disinfection of instruments and surfaces. They are so called 'dual use products' as their distinct claims are covered by more than one legislative instrument. The BPR states that such biocidal products should comply, in addition to the requirements laid down in the BPR with the relevant essential requirements set out in Annex I to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

3.9.2 Data requirements

3.9.2.1 Test methods

For efficacy testing of equipment disinfectants the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for an instrument disinfectant:

- a quantitative suspension test (phase 2, step 1);
- and a quantitative carrier test (phase 2, step 2);

both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Methods for testing efficacy of equipment or instrument disinfectants are available.

Appendix 2 gives a list of recommended test methods. The following document is recommended for instrument disinfection:

- EN 14885: gives an overview of which EN phase 2, step 1 and step 2 test to use for different uses.

The use of the specified tests is strongly recommended where they are relevant and appropriate.

For use in industry and institutional areas, no specific tests for instrument disinfection are given in EN14885. Nevertheless, phase 2, step 1 suspension tests from the industry and institutional areas can be used, by employing area specific soiling. For phase 2, step 2 tests, the instrument tests for medical areas are most appropriate. Soiling specific to the area of intended use should be employed.

3.9.2.2 Test organisms

For general disinfection of medical (including dental and veterinary) equipment, instruments, and equipment and other instruments which are used in contact with skin or mucous membranes (e.g. instruments for pedicure), efficacy against bacteria, yeasts, viruses and fungal spores must be demonstrated. For instruments and equipment used in laboratory and industry the test organisms specified for hard surfaces should be tested.

See section 3.3.2.2 of this Guidance and Appendix 3.

3.9.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, where relevant, field tests have been performed (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 tests these should be met.

If the test does not provide these criteria, the general criteria referenced in Appendix 4 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.10 Textiles

3.10.1 Introduction

Biocides can be used to treat textiles and fabrics in hospitals, health care facilities, industry, institutions or private homes, when relevant micro-organisms (pathogenic, spoiling) in the textiles have to be reduced. These products can be in the form of laundry products which combine detergent and biocide or can be specialised products in the form of laundry additives which are added to the wash cycle or as finishing products (e.g. fabric softeners) which are added in the last rinsing step or as pre-treatment.

Typically contaminated clothes, linen or other washable textiles are treated in an appropriate washing machine. The biocide is added in concentrated form and diluted in the machine with water according to the specification of the manufacturer to get a defined concentration in the machine. The automated chemical-thermal process normally comprises an (optional) initial pre-treatment step for heavily soiled laundry, followed by the main washing step (at a defined temperature and defined contact time) and 3 to 4 rinsing steps with cold water.

In some cases laundry can be treated through a hand-wash process in diluted biocide, which can take the form of a pre-soak (after which, machine washing is used), a hand wash only, or through soaking to disinfect textiles before they are destroyed (e.g. in an infectious disease outbreak situation).

Biocidal laundry products, either as combined biocide/detergent/conditioner or as special additives, are available for either targeted pre-treatment of contaminated articles or for whole-wash use.

3.10.2 Data requirements

See PT2 general data requirements in sections 1.5 and 3.2 of this Guidance. A detailed, non-exhaustive list of the most relevant applications and of appropriate test methodology for is given in Claims Matrix PT2, table for "Laundry products": the claims matrices are a set of tables linked to this guidance document (see Appendix 1 for more information).

3.10.2.1 Test methods

For efficacy testing of textile disinfectants the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a textile disinfectant:

- a quantitative suspension test (phase 2, step 1),
- a quantitative carrier test involving carriers made of test fabric (cotton, polyester) (phase 2, step 2),

Both should simulate practical conditions relevant to its intended use (concentration of the product, temperature, soiling, different fabrics, contact time, etc.). This includes the application of a normal washing procedure (including detergent) as a control.

Currently, the following types of test are available:

- phase 2, step 1 suspension tests as described in EN 14885,

- phase 2, step 2 tests involving
 - a full-scale laundry machine test (EN 16616)
 - for products not intended to be used in washing machines, small scale laboratory setting (e.g. for pre-soaking in a bucket) may be considered (e.g. ASTM E4206 or ASTM E2274).

In the phase 2, step 2 tests fabric is contaminated with test organisms and then exposed to the disinfectant.

The EN tests are strongly recommended where available and appropriate.

3.10.2.2 Test organisms

Textile disinfection products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

When disinfection is done at high temperatures (>40 °C) relevant test organisms for these temperatures should be used as described in section 1.4.4.4 of this Guidance.

An overview of reference test organisms, also for high temperatures, is given in Appendix 3.

3.10.2.3 Test conditions

For products intended to be added to washing machines, information on the following in-use conditions should be provided:

- the concentration of the product in the water during disinfecting process (i.e. washing or rinsing). The water volume used can differ between wash and rinse cycle and different washing programmes, but also between washing machines;
- the water to textile ratio in the test is an important factor that should reflect the in-use conditions;
- the temperature during the disinfection process (high when added in wash process, low in rinse process);
- the contact time (differs between various washing programmes and washing machines).

The laboratory tests should be performed under these conditions. The conditions for effective disinfection can normally only be carried out in professional washing machines.

If the exact conditions cannot be met, for example, in household machines, reasonable worst case conditions must be tested.

Worst case conditions, e.g.:

- the lowest temperature;
- the highest volume of water (i.e. maximum dilution of the product);
- the shortest contact time;
- the maximum load of laundry (i.e. smallest water to textile ratio).

When phase 2, step 2 tests involving fabric test carriers are performed, both the micro-organisms remaining on the test carriers, those released into the washing liquid and those transferred to previously uncontaminated control carriers should be assessed.

Manual soaking or pre-soaking can be done at room temperature but for some intended uses the temperature might start high and will cool down during the contact time (e.g.

where hot water is used, which cools naturally). This should also be taken into account in the tests.

3.10.2.4 Soiling

The interfering substance most appropriate for the in-use conditions should be used. For instance, blood for products used in the medical area and protein for products used in industry, institutional and domestic areas are recommended. The soiling on a domestic product for use in pre-soak (dirty clothes) will be very much higher than the soiling present for a post-wash rinse additive (clean clothes). For products used during pre-soak and wash, tests should be done under dirty conditions. For products used during post-wash rinse, tests should be done under clean conditions.

3.10.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, where relevant, field tests have been performed (using the required test organisms and test conditions), and when the pass criteria for the tests have been met. When the product is intended to be used in combination with or directly after a detergent, a clear effect of the disinfectant alone should be demonstrated. There should be a significant difference (+log 2) between disinfectant+ detergent and the detergent alone.

EN and VAH tests provide pass criteria.

No acceptance criteria have been specified in the ASTM standards for laundry (ASTM E 2406-04 or ASTM E 2274-09).

If the test does not provide pass criteria, the general criteria referenced in Appendix 4 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.11 Biofilms

3.11.1 Introduction

A biofilm is a complex aggregation of micro-organisms usually distinguished by the excretion of a protective and adhesive matrix attached to a solid surface in contact with a fluid. The matrix may incorporate other components derived from the environment.

Once the first cell succeeds in attaching to a surface and a biofilm starts to form, growth of the biofilm may become very fast, as subsequent free floating bacteria find it much easier to attach to the developing matrix.

Biofilms can grow in areas such as inside water tanks and the distribution pipelines of hospitals, hotels, industries and, in general, in any water systems which have temperatures and nutrients adequate for microbial growth.

The consequences of biofilm formation in a water system or facility may be severe depending on environmental conditions and any safety and performance requirements.

In healthcare facilities, biofilm contamination of medical equipment or water systems may increase the risk of nosocomial infections; in industrial facilities biofilm may cause microbial contamination of production (pharmaceuticals, cosmetics, etc.); in other situations biofilms may be responsible for significant reduction of the performance of water systems by obstructing normal flow or they may induce corrosion of the pipelines.

Several factors may contribute to biofilm formation, with important factors including the chemical composition and roughness characteristics of the pipe, tank or tube circuit.

Bacteria in biofilms are more resistant to disinfection than planktonic bacteria of the same species, as the presence of extracellular polymeric substances can act as a physical barrier to the biocide. This matrix may hamper biocidal penetration to the lower layers of the biofilm or may interact with the biocide and neutralise it. Additionally, the physiological state of the bacteria in the biofilm differs from bacteria in suspension, which can also influence the susceptibility of the bacteria to biocides. Complex communication systems are often also present that allow increased tolerance of members of the biofilm community to be initiated.

Two types of activities of biocides against biofilm can be identified:

- 1) Prevention of biofilm formation: the biocide acts on biofilm formation (i.e. in this case the biocide is present before the biofilm is formed and may affect the early adhesion of cells to the surface or the viability of the cells);
- 2) Biofilm disinfection ("curative"): the biocide acts on a mature biofilm (i.e. when the biofilm is already present on a surface and the biocide interacts with the biofilm-embedded cells, with a -cidal effect). Biocidal products of this type may also achieve detachment of the biofilm (possibly in conjunction with physical action).

In case where the biofilm is not removed as a result of the biocide treatment, it should be followed by mechanical removal of the biofilm.

Industry is increasingly developing new technologies for prevention, inactivation and/or detachment of biofilms and/or inactivation of biofilm embedded organisms, for example through the use of UV light, water ionization or impregnated or coated materials and new biocides which claim specific efficacy against biofilms.

3.11.2 Data requirements

There are currently no standard laboratory tests available to verify the efficacy of biocides against biofilms. As this is an area in which the science is developing rapidly, the information below should be considered as general guidance reflecting the state of knowledge at the time of writing this Guidance.

Tests to demonstrate the efficacy of disinfectants according to EN and OECD are based on simpler models than are found in biofilms. The available surface/carrier tests are not representative of biofilm models, as they do not consider the presence of extra cellular polymeric substances which act as a physical barrier to the biocide.

Other characteristics of the biofilm and biocidal product should be taken into account. For example, if biocide impregnated materials claim a preventive effect on biofilm formation, the prevention of biofilm formation should be demonstrated, taking into consideration the half-life of the impregnating substance which may differ depending on the material characteristics. The active substance may be released from the surface and/or may be inactivated by environmental factors.

A standard suspension test can only be used to confirm basic activity of the product against the claimed organisms in a tiered approach.

A suggested general approach could be:

- 1) a suspension test: any biocide claiming to act on biofilm, has to be first evaluated in standard suspension test (preferably EN);
- 2) a simulated use efficacy test to demonstrate the ability of the product to exert a controlling effect on the biofilm under either static condition or under flow conditions depending on the use pattern (claim). This controlling effect can be to destroy and detach, inhibit or prevent the formation of a biofilm;
- 3) a field trial, where the biofilm is formed under (simulated) use conditions.

These tests should be performed in sequence to obtain more complete information on the activity of the product on biofilm.

For biofilm disinfection (curative) a suspension test (as for (1) above) and suitable robust data from either a simulated use test (2) or field trial (3) should be performed. If there are no robust data from a simulated use test (2), a field test (3) is mandatory.

For biofilm prevention the approach is different to that for biofilm disinfection, as the biocide is present before the biofilm is formed and may affect the early adhesion of cells to the surface or the viability of the cells. In this case the suspension test (1) may not be useful since the product might not have a –cidal effect.

3.11.2.1 Test methods

3.11.2.1.1 Suspension tests

The first step in the tiered approach is a suspension test. The CEN phase 2, step 1 tests are suitable as suspension tests. This test is only applicable for products that can be tested in suspension and which have a –cidal effect.

3.11.2.1.2 Simulated use tests

Standard laboratory tests to verify the efficacy of biocides against biofilms are not currently available. Therefore, before performing a biofilm test, the methods should be agreed with the CA.

Applicants should provide a method following the principles in this guidance and based on scientific evidence. During development of the tests CAs of member states should be consulted to make sure that the tests are acceptable.

Biofilms can be formed and evaluated in static or flow conditions. The way the biofilm is formed has an effect on the susceptibility of the biofilm to biocides: biofilms formed under flow conditions are generally more resistant to biocides than biofilms formed under static conditions.

The conditions under which the biocidal products will have to operate should also be taken into account. Under static conditions the disinfectant operates without the aid of the removal effect of a fluid flow or shear stress. Under flow conditions the contact time might be shorter when shock dosing is used.

Static tests are less expensive and easier to standardise, but flow tests are generally closer to the real use scenarios.

In both cases, the reproducibility and repeatability of results over time should be ensured; so a method that allows a series of observations, rather than a single observation, should be employed.

Laboratory tests for evaluating the efficacy of biofilm disinfectants should emulate the critical factors of a real-world environment. In most instances, a biofilm will not be comprised of a single species and tests based on consortia relevant to the end use should be employed when simulating actual use.

In cases where only efficacy against biofilms formed under static conditions is claimed (e.g. use in tanks without flow) it is sufficient to only test against these biofilms.

Examples of methods for testing under flow and static conditions are described below, but other protocols are available in literature or may be under development.

3.11.2.1.3 Static condition assay

Standard laboratory tests to verify the efficacy of biocides against biofilms formed under static conditions are not currently available. However, literature describes several methods of how to create a biofilm in the laboratory under static conditions.

An example of a semi-quantitative method for biofilm evaluation is the microplate test, where a biofilm is formed in static conditions and the amount of biofilm can be quantified by spectrophotometric measurements. The amount of living cells in the biofilm before and after treatment can also be determined. In this case, the disinfectant operates without the aid of the removal effect of a fluid flow or shear stress.

A positive aspect of such an assay is that it is a low cost, easy-to-conduct test, that allows several replicates and/or the testing of several conditions (several biocide concentrations, more species, etc.) to be performed, which would provide the basis for a more accurate and closer-to-reality test.

This method consists of the formation of a biofilm by the species of interest on the bottom of 96 well plates (the material and coating of the plates should be specified); the disinfectant may be present before (preventive effect) or after (inhibition/removal effect) the biofilm is formed. The amount of biofilm (biomass) is quantified after staining of the adherent material and spectrophotometric measurement. Detecting chemicals such as ATP to measure bacterial viability may also be used.

3.11.2.1.4 Flow condition assay

Standard laboratory tests to verify the efficacy of biocides against biofilm formed under flow conditions are not currently available. However, systems to generate a standard biofilm have been developed by CEN (CEN ISO/TS 15883-5:2005 Annex F) and ASTM (ASTM E2196 and ASTM E2562). Using either of these reproducible biofilms, a method for the assessment of prevention and/or elimination of biofilm in terms of viable cells reduction and bacterial biomass reduction can be carried out.

The CEN method consists of the production of a standard *Pseudomonas aeruginosa* biofilm inside a Teflon tube, using a flowing system to simulate a real world situation.

ASTM E2196 and ASTM E2562 standards use biofilm rotating disc reactors, which are especially suited for high shear forces.

The biofilm is then treated with a disinfectant to evaluate the biocidal capacity to remove or to reduce the biofilm.

Other carrier types (e.g. silicon, steel, PVC, etc.) can be selected and used depending on the biofilm development system, and the experimental conditions can be adapted to compare the efficacy of different treatments in preventing biofilm formation.

A reference substance of known activity must be tested in parallel (e.g. chlorine dioxide, sodium hypochlorite).

3.11.2.1.5 Field trials

As for other situations in which biocides are used, only field tests (phase 3 tests) are fully representative of the activity of the biocide on biofilms, but these tests are difficult to standardise, and such tests should be complemented by laboratory suspension or simulated use tests, which have a higher degree of robustness and reproducibility.

A field trial should reproduce the in-use conditions of the worst-case situation of the intended uses.

Prevention and/or elimination of biofilm (in terms of viable cells reduction and bacterial biomass reduction) should be demonstrated by sampling before and after disinfection.

A field test can be waived if a suitably robust simulated use test, which adequately mimics the in-use conditions is provided. A robust test could for instance be a complex pipe system, in which natural biofilm formation takes place, either in combination with the addition of standard organisms or not.

3.11.2.2 Test organisms

The choice of micro-organisms for a test is relevant, since the use of only one organism per test is limiting and may not be fully representative of the real events leading to micro-organism aggregation (biofilms in settings where disinfectants are used, are normally multi-microbial, i.e. composed of several different species). Moreover, contaminants from environmental sources may be embedded in the biofilm matrix which may reduce the disinfectant's efficacy.

Bacteria are not the only inhabitants of biofilms, as both fungi and algae may also inhabit biofilms. Protozoans that consume bacteria may feed on biofilms. Protozoan oocysts and virus particles can become entrapped in a biofilm and later detach, returning to the environment.

In a suspension test, the standard organisms per claimed group (bacteria, fungi, etc.) should be tested.

For a general claim of efficacy against biofilms, as a minimum, bacteria should be tested in laboratory biofilm tests. When action against other groups of organisms (e.g. fungi, algae etc.) is claimed these should be tested as well.

In suspension tests the standard organisms should be tested (see Appendix 3).

Pseudomonas aeruginosa, *Staphylococcus aureus* and *Legionella* spp. are acceptable test organisms for the laboratory biofilm tests. Mixtures of test organisms for producing biofilms are only acceptable as additional tests as it is difficult to standardise such methods.

In simulated use or field trials the biofilm may be formed *in vivo* with naturally occurring micro-organisms.

3.11.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, where relevant, field tests have been performed (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 tests these should be met.

If the test does not provide these criteria, the general criteria referenced in Appendix 4 can be taken as guidance for the level of reduction required. Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

3.12 Soil

Disinfection of soil and other substrates (in playgrounds) with biocides is not common (and so far not claimed for Annex I of the BPD or the "Union list of approved substances" of the BPR). This is more often done for plant protection. Therefore, plant protection guidelines and EPPO standards on soil treatments should be referred to for test methods. The use of the test methods should be justified with the application.

3.13 Other uses in PT2

Several other uses are mentioned in the description of PT2: wastewater and hospital waste disinfection, algaecides for swimming pools and indoor/outdoor aquatic area (aquaria / garden ponds), foot baths in swimming pools, chemical toilets, disinfection of air. No data requirements and acceptance criteria for these uses are currently available.

However, the general principles for efficacy evaluation in PT2 are applicable for these other uses. Efficacy data should be adequate to demonstrate efficacy and suitability for

the intended use, based on laboratory and/or practical data from existing and/or proposed new quantitative studies. If desired the design of any proposed efficacy tests may be agreed between the applicant and the CA taking into account all relevant conditions of use. Such factors include consideration of the organisms to be controlled, requirements for biocidal or biostatic effects, contact time and temperature and the nature and presence of interfering substances.

Specific requirements should also be set on a case by case basis by the CA as appropriate for specific claims.

4. PT 3 Veterinary hygiene biocidal products

4.1 Introduction

Product type 3 contains biocidal 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 are also included.

Some of the products in PT3 are on the borderline with veterinary medicinal products or cosmetic products. If the product under investigation is within the scope of the Veterinary Medicinal Products Directive (2001/82/EC as amended by 2004/28/EC) it is excluded from the BPR for the respective use. When a product only has a cosmetic claim (e.g. cleaning skin, hoofs, paws) and no reference is made to any biocidal claim (e.g. skin disinfection, activity against microorganisms), it is excluded from the BPR.

Borderline cases are discussed in more detail in the respective sections below.

Following a decision taken at the CA meeting in May 2015 (CA-May -2015-Doc 8.3) products applied for general disinfection of surfaces in the medical area (medical practices, hospitals) as well as of surfaces in veterinary practices associated with examination and operation/treatment of the animals are assigned to PT 2, whereas products for specific veterinary hygiene purposes (e.g. products with specific claims against a target organism only relevant in the veterinary area) are considered to be in PT 3.

In the sections below 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.

4.2 Disinfectants for hard surfaces in PT3

4.2.1 Introduction

Biocides can be used to disinfect hard surfaces, both porous and non-porous, in areas such as animal housing (stables, cages, housing for pets, etc.), animal transportation vehicles (including tyres), hatcheries, etc. These surfaces may be tables, floors, walls, the outsides of (milking) machinery (including milking robots and milking clusters/claws) and hard furniture, equipment, boots, etc. Products may be applied by spraying, wiping, foaming or soaking, and may be washed or wiped off after a certain contact time. Boots and tyres may be disinfected by walk-through, drive-through bath or mat, or even by a machine (boot wash station), etc.

The testing requirements for some specific uses of hard surface disinfectants are discussed in separate sections, for example, beehives.

Disinfection of inner surfaces of pipelines or reservoirs for milk, water or feed for animals are considered food and feed contact surfaces and are therefore considered PT4 (see

section 5.3 of this Guidance). Outer surfaces of milking equipment are considered in this section.

4.2.2 Data requirements

4.2.2.1 Test methods

For efficacy testing of veterinary hard surface biocidal products, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a hard surface disinfectant:

- a quantitative suspension test (phase 2, step 1);
- and a quantitative surface test (phase 2, step 2);

both simulating practical conditions appropriate to its intended use (temperature, soiling, porous or non-porous surfaces, contact time, etc.).

Field tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Several methods for testing the efficacy of hard surface disinfectants are available.

Appendices 2 and 4 give a list of recommended test methods.

The following documents are recommended for surface disinfection:

- EN 14885: gives an overview of which EN phase 2, step 1 and step 2 tests to use for different uses;
- DVG guideline (relevant for testing against endoparasites and virucidal activity on porous and non-porous surfaces, as long as no EN tests are available).

The use of the specified tests is strongly recommended where they are relevant and appropriate. Where the tests are not appropriate to the product, other tests can be used, although a justification for the relevance of the tests used should also be provided.

Since OECD tests are not specified for veterinary use, they are not specifically recommended.

In the veterinary area very often rough, porous surfaces have to be disinfected (i.e. wood, concrete, rough plastic materials). When tests for porous surfaces are available it is recommended to use these tests for general surface disinfection in veterinary areas.

For boot, tyre, and equipment disinfection by immersion in a bath, information should be provided on how long the efficacy of a bath can be guaranteed (time period, number of boots etc. passing through). Challenging efficacy tests (capacity tests, see section 1.4.1.2 of this Guidance) should be done, simulating the consecutive challenge not only by micro organisms but also by soiling. A test with relevant organic soiling should be provided in order to ensure that biocidal product can be challenged successfully with the test organism until the end of the claimed period of use. 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 is measured several times during the test period. Efficacy (suspension) tests should be provided with the concentration of the product tested (in the suspension test) and the active substance concentration obtained in the field at the end of the claimed period of use.

A product can be applied by airborne diffusion of an aerosol, a smoke, a vapour or a gas, with the intention to disinfect the surfaces of the walls, floor and ceiling of the room, as well as external surfaces of the furniture and equipment present in the treated room. For these products the test methods are described in section 3.5 of this Guidance. These tests should be adapted to fit the conditions (soiling, etc. see section 4.2.2.3 of this Guidance) for veterinary use.

When efficacy against a biofilm is claimed, a simulated-use test or field test has to be performed, along with a phase 2, step 1 test. See section 3.11 of this Guidance for test methods.

Where no phase 2, step 2 or phase 3 tests are provided this must be justified in the application for authorisation and will be evaluated on a case-by-case basis.

The EN tests are strongly recommended where available and appropriate. For an overview of available EN tests see Appendices 2 and 4.

4.2.2.2 Test organisms

Relevant groups of organisms to be controlled in the veterinary area can be bacteria, yeasts, fungal spores, viruses, mycobacteria, bacterial spores, and endoparasites (oocysts).

Veterinary hard surface biocidal products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

Products for disinfection of veterinary instruments and/or animal transportation vehicles should not only be effective against bacteria and yeasts but also against viruses.

Activity against fungi is also required for products used in hatcheries.

For all other groups of organisms, 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. An overview of reference test organisms is given in Appendix 3.

4.2.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value, for instance:

- for surface disinfection products used on the out side of animal transport vehicles (specifically tyres) the contact time should not exceed 5 minutes;
- for disinfectants used on boots applied by spraying or walk-through bath the contact time should not exceed 1 minute;
- for disinfectants applied by dipping in bath, used on boots, materials etc. the contact time should be as claimed on the label;
- for surface disinfection products used in animal housing on floors, walls etc. the contact times as stated in the standard tests should be taken into account.

Additional contact times can be considered if appropriate and justified by the application (e.g. overnight disinfection).

Tests should be carried out with soiling for clean or dirty conditions (low or high-level soiling) in accordance with the test requirements. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary. If this is not stated on the label, the test should be done under dirty conditions. The soiling needed for clean and dirty conditions can be found in the relevant EN tests and are referenced in Appendix 4. When the test does not state two levels of soiling (e.g. porous surface test), the soiling referenced in Appendix 4 should be used.

Normally PT3 products are tested at 10°C or below since the temperature in animal housings can be low. For some uses higher temperatures are acceptable (e.g. hatcheries). Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis. Any limitations on the

temperatures at which the product should be used, and for which efficacy has been proven should be stated on the label.

4.2.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT3 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.3 Disinfection of bee hives and beekeeping equipment

4.3.1 Introduction

Disinfection of beehives is done to prevent spread of diseases from one bee population to the next.

Only disinfection of empty bee hives and beekeeping equipment, with products without a medicinal claim, is a biocidal use for general disinfection. Products used in beehives with bees, honey and brood combs are veterinary medicinal products. These products are within the scope of the Veterinary Medicinal Products Directive (2001/82/EC as amended by 2004/28/EC) and are therefore excluded from the BPR.

Important disease which can be spread via bee hives are American foulbrood (*Paenibacillus larvae*), European foulbrood, (*Melissococcus plutonius*), Nosema (*Nosema apis*, *Nosema ceranae*), chalkbrood (*Ascosphaera apis*) stonebrood (*Aspergillus flavus*) and some viral diseases. Of these diseases American foulbrood, which is an endospore-forming bacterium, is the most difficult to control.

Normal practice in case of American and European foulbrood is to clean/disinfect bee hives and beekeeping equipment and additionally disinfected by scorching with a blowtorch.

4.3.2 Data requirements

4.3.2.1 Test methods

For efficacy testing of disinfection products for beekeeping, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for disinfectants for bee hives:

- a quantitative suspension test (phase 2, step 1;
 - and a quantitative carrier test (phase 2, step 2) for porous surfaces;
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Field tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

There are no standard tests available specifically for use in bee hives. Phase 2, step 1 EN tests for veterinary area are suitable, and for sporicidal activity the EN 13704. EN phase 2, step 2 tests for veterinary area on porous material would be suitable but they are not available for all organisms yet. This can be either EN 16437 phase 2, step 2 test on

bacteria for veterinary area on porous material or DVG guidelines on rough surfaces. These tests can be adapted for other organisms.

In these tests a reference substance must be included.

Where no phase 2, step 2 tests for veterinary area on porous material are available, the available test should be adapted for this use (e.g. EN 16437 adapted for other organisms).

When the claim for the product is to replace both the cleaning/disinfection step and the flaming with a welding torch, a field trial has to be provided in which it is demonstrated that the product is as efficacious against foulbrood infected hives as is cleaning with sodium hydroxide combined with scorching with a blowtorch.

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

4.3.2.2 Test organisms

Disinfection products for bee hives should be at least sufficiently effective against bacteria and bacterial spores. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

For bacterial spores only a test for the food area is available (EN 13704). For disinfection products for beehives spores of two bacterial species should be tested. Next to the current standard test organism, *Bacillus subtilis* spores, also *Bacillus cereus* should be tested.

4.3.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value.

It must be ensured that the disinfected parts stay wet during the contact time. When residual efficacy is claimed for dried products this should be demonstrated in efficacy tests.

For disinfection of bee hives and beekeeping equipment, tests should be performed under dirty conditions (high-level soiling) used for surfaces in the veterinary area. If bee hives are not cleaned before disinfection the high-level soiling for suspension tests should be used, also in the porous surface test and tests adopted from other areas of use (e.g. EN 13704).

The soiling needed for dirty conditions can be found in the relevant EN tests and referenced in Appendix 4.

For disinfection of bee hives a temperature of 10°C or lower is acceptable. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.

4.3.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT3 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.4 Animal feet disinfection

4.4.1 Introduction

Animal feet disinfection includes hoof and claw disinfection. Products are applied in a bath, through which the animals can walk, or as wipes, foam, spray, etc. See section 4.1 of this Guidance for overlap with other EU directives.

4.4.2 Data requirements

4.4.2.1 Test methods

For efficacy testing of animal feet disinfection products, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for an animal feet disinfectant:

- a quantitative suspension test (phase 2, step 1);
 - and a quantitative carrier test (phase 2, step 2);
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Field tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

There are no standard tests available specifically for use on animal feet. Phase 2, step 1 EN tests for veterinary area are suitable. Since hoofs are made of porous material EN phase 2, step 2 tests for veterinary area on porous material would be suitable but these are not available for all organisms yet. Alternatively, DVG guideline tests on rough surfaces can be used.

The phase 2, step 2 test design must always reflect the application. When no standard test is used the test design should be discussed with, and agreed by, the CA before testing takes place.

When no phase 2, step 2 or phase 3 tests are provided this must be justified in the application and will be evaluated on a case-by-case basis.

For disinfection in a hoof bath, information should be provided on how long the efficacy of a hoof bath can be guaranteed (time period, number of animals passing through). Challenging efficacy tests (capacity tests, see section 1.4.1.2 of this Guidance) should be done, simulating the consecutive challenge not only by micro organisms but also by soiling. A test with relevant organic soiling should be provided in order to ensure that the biocidal product can be challenged successfully with the test organism until the end of the claimed period of use. When a challenge test is provided the quantitative suspension test can be waived. 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 is measured several times during the test period. Efficacy (suspension) tests should be provided with the concentration of the product tested (in the suspension test) and the active substance concentration obtained in the field at the end of the claimed period of use.

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

4.4.2.2 Test organisms

Animal feet disinfection should be at least sufficiently effective against bacteria. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

4.4.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value, therefore maximum contact times are set.

For animal feet disinfection products the contact time should not exceed 5 minutes

It must be ensured that it is possible to keep the disinfected parts wet during the contact time in practice. When residual efficacy is claimed for dried products this should be demonstrated in efficacy tests.

Tests should be carried out with high-level soiling conditions in accordance with the test requirements. Soiling conditions for animal feet disinfectants are the same as for other veterinary area disinfectants. The soiling needed for clean and dirty conditions can be found in the relevant EN tests and referenced in Appendix 4.

Normally animal feet disinfection products are tested at 10°C since feet disinfection is often carried out outside animal housings at low temperatures. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.

4.4.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT3 products the required \log_{10} reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.5 Teat disinfection

4.5.1 Introduction

Teat disinfection products are used to disinfect the teats of the udder of dairy animals (e.g. cows, sheep and goats) before or after milking. Products can be applied by dipping, spraying, foaming, wiping, etc.

See section 4.6.1 of this Guidance for overlap with other EU directives.

4.5.2 Data requirements

4.5.2.1 Test methods

For efficacy testing of teat disinfection products, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a teat disinfectant:

- a quantitative suspension test (phase 2, step 1);
- and a quantitative carrier test (phase 2, step 2), or a field test; all simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Phase 2, step 1 tests for the veterinary area, with relevant soiling for teat disinfection should be used.

No European standard phase 2, step 2 tests are available for teat disinfection. To demonstrate efficacy a phase 2, step 2 tests should be provided with a test design relevant for the use. The test design must reflect the application and should be discussed with and agreed by the CA before testing takes place.

When standard tests become available, which are relevant for teat disinfectants, it is recommended to use these tests.

Alternatively a phase 3 test, field trial, may be provided with a test design relevant for the use. The test design must reflect the application, should include a control with water instead of biocide, and should be discussed with and agreed by the CA before testing takes place.

Disinfectant towelettes/wipes

For disinfectant wipes, the phase 2, step 1 tests should be done preferably with the liquid extracted from the wipe or if difficult to extract, use the liquid as it is before it is added to the wipes. Phase 2, step 2 tests should be tests with mechanical action or, when this test is not available, with liquid extracted from the wipe (not the original liquid), with a justification of the volume that is applied per square centimetre. In addition, a test must be performed that shows that either the wipe will still disinfect after the wipe dries out or that the wipe stays wet long enough to disinfect according to the claim. In addition, the use directions can address these issues, for instance, stating on the label that only wet wipes are efficacious, or giving expiry dates for re-sealable packages.

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

Example of phase 2, step 2 tests

The phase 2, step 2 surface carrier test can be derived from adaptation of CEN TC 216 surface tests. Instead of a hard surface carrier, carriers involved could be made of material simulating the teat. Justification for the used carrier should be provided.

Cells of test organisms should be applied and fixed onto the surface in a manner which represents pre- and post-application, (dried in case of pre-milking or not dried in case of post-milking), and incubated with the product for the appropriate time (see EN phase 2, step 2 test, for example, EN 14349 or EN 16437, for growth conditions, controls, etc.). After incubation with the product the cell count reduction is evaluated and compared to a water control.

The test design should be discussed with and agreed by the CA before testing takes place.

4.5.2.2 Test organisms

Teat disinfection products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is intended to be claimed.

4.5.2.2.1 Virucidal activity

For products used as teat disinfectants a differentiation in the virucidal activity is made.

The claims can be:

- full virucidal activity or
- activity against enveloped viruses.

For each claim different test organisms should be tested.

The EN 14675 test for virucidal activity in the veterinary area tests Bovine Enterovirus Type 1 (ECBO), a non-enveloped virus. When this test is passed, full virucidal activity can be claimed.

Activity against enveloped viruses can be claimed when MVA = Modified Vacciniavirus Ankara is tested in a (modified) EN 14675 test.

When only activity against enveloped viruses is demonstrated the label claim cannot be "virucidal". The SPC should clearly state which of the possible virucidal claims was demonstrated.

4.5.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value, therefore maximum contact times are set.

For post-milking teat disinfection products the contact time is normally 1 minute but should not exceed 5 minutes.

The contact time for pre-milking teat disinfection products is normally 30 seconds or less and should not exceed 60 seconds.

Deviations from this contact time requirement must be justified in the application for authorisation and will be evaluated on a case-by-case basis.

Tests for pre-milking products should be carried out with either low or high-level soiling for veterinary surfaces, depending on the instructions given for pre-cleaning procedures.

Tests for post-milking products should be carried out with soiling for teat disinfectants in accordance with the test requirements. Soiling conditions for teat disinfectants are mentioned in the bactericidal test and should be used for the test with other organisms as well.

The soiling needed can be found in EN 1656 and referenced in Appendix 4.

For teat disinfection a test temperature of 30°C or lower is acceptable. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.

4.5.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT3 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.6 other animal corporal hygiene

4.6.1 Introduction

Disinfectants for animal corporal hygiene are used to disinfect the skin of animals. This section includes all animal skin disinfectants, which are not covered in the sections on teat or animal feet disinfection below.

A product applied on animal skin could be either a biocidal or a veterinary medicinal or a product for cleaning or cosmetic purposes. If the product under investigation is within the scope of the Veterinary Medicinal Products Directive (2001/82/EC as amended by 2004/28/EC) it is excluded from the BPR for the respective use. When a product does not have a biocidal claim (e.g. skin disinfection, activity against microorganisms claimed) but only a cosmetic claim (e.g. cleaning skin, paws) it is excluded from the BPR for the respective use.

Products for disinfection of damaged skin (e.g. wound disinfection) or disinfection of undamaged skin before a medical treatment (e.g. pre-operative skin disinfection or disinfection before injection) are always veterinary medicinal products.

When applying for authorisation for an animal corporal hygiene biocidal product within PT3 a detailed description of the intended use should be given, to prevent authorisation of veterinary medicinal products or medicinal uses, as biocides (e.g. the claim "animal skin disinfection" is insufficient).

For products that fall under the BPR the data requirements described in the following sections apply.

4.6.2 Data requirements

4.6.2.1 Test methods

For efficacy testing of animal corporal hygiene products, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for an animal corporal hygiene disinfectant:

- a quantitative suspension test (phase 2, step 1;
 - and a quantitative carrier test (phase 2, step 2);
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Field tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Phase 2, step 1 tests for the veterinary area can be used.

No European standard phase 2, step 2 tests are available for animal skin disinfection. To demonstrate efficacy a phase 2, step 2 tests should be provided with a test design relevant for the use. The test design must reflect the application and should be discussed with and agreed by the CA before testing takes place.

When standard tests become available, which are relevant for skin disinfectants, it is recommended to use these tests.

For an overview of available EN tests see Appendices 4 and 6.

Example of phase 2, step 2 tests

The phase 2, step 2 surface carrier test can be derived from adaptation of CEN TC 216 surface tests. Instead of a hard surface carrier, carriers could be made of material simulating animal skin¹⁶. Method are currently being developed, but their aptitude for the respective biocidal use/demonstration of efficacy for animal skin disinfectants remains to be proven. Justification for the used carrier should be provided.

Cells of test organisms could be applied to the surface, dried, and incubated with the product for the appropriate time (see EN phase 2, step 2 test, e.g. EN 14349, for growth conditions, controls, etc.). After incubation with the product the cell count reduction is evaluated and compared to a water control.

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

4.6.2.2 Test organisms

Animal corporal hygiene products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

4.6.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value.

It must be ensured that the test surface does not remain wet longer than the part of the animal body treated with the product, for example, by using higher (more realistic) temperatures. When residual efficacy is claimed this should be demonstrated in efficacy tests.

Tests should be carried out with high level or low level soiling conditions in accordance with the test requirements. Soiling conditions for animal corporal hygiene products are the same as for other veterinary area disinfectants. The soiling needed for clean and dirty conditions can be found in the relevant EN tests and referenced in Appendix 4.

For animal corporal hygiene products a test temperature of 30°C or lower is acceptable. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.

4.6.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use tests have been performed (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 PT3 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

¹⁶ Please take into account EU regulation 1069/2009, on animal by-products.

4.7 Disinfection of hatching-eggs

4.7.1 Introduction

Disinfection of hatching-eggs includes the disinfection of eggs before they hatch in hatcheries. Products are applied in a bath, as a spray, as wipes, fumigation, etc..

4.7.2 Data requirements

4.7.2.1 Test methods

For efficacy testing of disinfection products for hatching-eggs, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for disinfectant for hatching-eggs:

- a quantitative suspension test (phase 2, step 1);
 - and a quantitative carrier test (phase 2, step 2);
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Field tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Phase 2, step 1 tests for the veterinary area can be used.

As long as no standard phase 2, step 2 tests are available it is not obligatory to provide these tests. Phase 2, step 2 tests have to be provided as soon as standard tests are available.

When no phase 2, step 2 or phase 3 tests are provided this must be justified in the application and will be evaluated on a case-by-case basis.

For egg disinfection in a bath, information should be provided on how long the efficacy of a bath can be guaranteed (time period, number of eggs passing through). Challenging efficacy tests (capacity tests, see section 1.4.1.2 of this Guidance) should be done, simulating the consecutive challenge not only by micro organisms but also by soiling. A test with relevant organic soiling should be provided in order to ensure that biocidal product can be challenged successfully with the test organism until the end of the claimed period of use. When a challenge test is provided the quantitative suspension test can be waived. 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 is measured several times during the test period. Efficacy (suspension) tests should be provided with the concentration of the product tested (in the suspension test) and the active substance concentration obtained in the field at the end of the claimed period of use.

For products applied by airborne diffusion of an aerosol, a smoke, a vapour or a gas, with the intention to disinfect the room, as well as on external surfaces of the eggs in the room, the test methods are described in section 3.5 of this Guidance. These tests should be adapted to fit the conditions (soiling, etc. see section 4.7.2.3 of this Guidance) for veterinary use.

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

4.7.2.2 Test organisms

Disinfection products for hatching-eggs should be at least sufficiently effective against bacteria and fungi. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

4.7.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value.

It must be ensured that the disinfected parts stay wet during the contact time. When residual efficacy is claimed for dried products this should be demonstrated in efficacy tests.

Tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary. If this is not stated on the label, the test should be done under dirty conditions. Soiling conditions for of hatching-eggs disinfectants are the same as for other veterinary area disinfectants. The soiling needed for clean and dirty conditions can be found in the relevant EN tests and referenced in Appendix 4.

For disinfection of hatching-eggs a temperature of 30°C or lower is acceptable. Deviations from this temperature requirement must be justified in the application and will be evaluated on a case-by-case basis.

4.7.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory or, when applicable, simulated-use or field tests have been performed (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 PT3 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.8 Textile disinfection in PT3

4.8.1 Introduction

Textile disinfection products within PT3 are mainly used to disinfect the cloths used for teat cleaning/disinfection of dairy cattle before milking. Products are normally applied by dipping the cloth in a disinfectant solution. For other uses the requirements below should be adapted to fit the intended use.

4.8.2 Data requirements

4.8.2.1 Test methods

For efficacy testing of textile disinfection products, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for textile disinfection products:

- a quantitative suspension test (phase 2, step 1);
- a quantitative carrier test involving carriers made of test fabric (cotton, polyester) (phase 2, step 2);

both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, repeated challenges, etc.).

Field tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Test methods for textile disinfection are described in section 3.10 of this Guidance.

Currently, the following tests are available:

- phase 2, step 1 suspension tests as described in EN 14885,
- phase 2, step 2 tests involving test fabrics in:
 - a small scale laboratory setting (e.g. ASTM E2406) or;
 - a full-scale laundry machine test (pr EN 16616, or DGHM).

In the phase 2, step 2 tests fabric is contaminated with test organisms and then exposed to the disinfectant. These tests should be adapted to fit the conditions (soiling, etc. see 4.8.2.3) for veterinary use. For disinfection in washing machines a full-scale laundry machine test, according to test conditions mentioned in section 3.10.2.1.1 of this Guidance, is obligatory.

The EN tests are strongly recommended where available and appropriate. For an overview of available EN tests see Appendices 2 and 4.

4.8.2.2 Test organisms

Textile disinfection products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

When the product is intended to be used at high temperatures (>40 °C) relevant test organisms for these temperatures should be used as described in section 1.4.4.4 of this Guidance.

4.8.2.3 Test conditions

It is important that the tests are performed using the same contact time as claimed on the label.

The claimed contact time has to be a realistic value.

The contact time products intended for disinfection of textile in between milking sessions can be several hours.

Tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements for veterinary area. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary. If this is not stated on the label, the test should be done under dirty conditions. Soiling conditions for milking-textile disinfectants are the same as for teat disinfectants. The soiling needed for clean and dirty conditions can be found in the relevant EN tests and referenced in Appendix 4.

For textile disinfection a test temperature should be according to the use instructions. When the textile is immersed in a bucket with warm water it should be taken into account that the water temperature will decrease during the disinfection process. This should be reflected in the test conditions.

4.8.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT3 products the required \log_{10} reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.9 Disinfection of manure, litter and other substrates for veterinary use

4.9.1 Introduction

Manure mainly consists of urines and faeces (organic matters and intestinal bacteria) in which can also be mixed straw of litters in more or less big quantity, according to the breeding technique (partial slats or complete slats).

Manure has a potential for spreading infectious diseases and biocidal products are used to destroy some infective agents and also control microbial agents responsible of malodours.

Litters are usually used in animal housing (poultry, pigsties, etc.) and also for pets in private uses. They absorb urines and faeces. Biocidal products are mainly used to deodorize and neutralize bad smells.

4.9.2 Data requirements

4.9.2.1 Test methods

For efficacy testing of disinfects biocidal products used for manure and litter disinfection, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required:

- a quantitative suspension test (phase 2, step 1),
- and simulated-use test, or field test

all simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, mode of application, pH, etc.).

An example of a simulated-use test could be autoclaved manure or litter collected in animal housing and tested in the lab with inoculation of target organisms. A control without addition of disinfectants should be included. The test design should be discussed with and agreed by the CA before testing takes place.

In case of products claiming malodour control, the same requirements as mentioned in the section 3.2.5 of this Guidance, are required.

4.9.2.2 Test organisms

Generally, target organisms have to be representative of the veterinary area, as stated in EN 14885.

For specific uses in industry, an exception can be made when sound justification is provided. This will be evaluated on a case-by-case basis.

Taking into account the specificity of some kind of uses, it may be justified to test additional target organisms (e.g. *Brachyspira hyodysenteriae* agent of swine dysentery), special growth conditions, etc.

In case of malodour control, 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 can be performed.

4.9.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label.

The claimed contact time has to be a realistic value.

Quantitative suspension tests must be carried out with high level soiling conditions and a temperature of 10°C or less.

The test temperature should be according to the use instructions on the label and appropriate to the uses (stables, private homes, etc.).

Field and simulated-use test have to be performed according to the dose, conditions and mode of application of the product. For example, if the product is applied on top of the manure, the product does not have to be mixed with the organic matter but has to be put on top of it (to mimic the diffusion and evaluate efficacy in the same conditions as in the practice).

In case of litter, if persistence is claimed with some recommendations about the frequency of renewal, adequate simulating tests (with appropriate contribution of organic matters in the test) have to be performed.

Deviations from these requirements must be justified in the application for authorisation and will be evaluated on a case-by-case basis.

4.9.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, field (or simulated-use) tests have been performed (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 PT3 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

4.10 Other uses in PT3

Several uses of PT3 products have been specified in the above sections and data requirements and acceptance criteria for these uses are described. For products with other uses that do not fit in one of the described uses, it is up to the applicant to demonstrate efficacy in an appropriate way.

In general, the tiered approach as described in section 1.4.1 of this Guidance is preferred. Where possible the standard tests required for the described uses should be taken (e.g. EN phase 2, step 1 and step 2 tests for veterinary area). Where the tests are not appropriate for the product, other tests can be used. In that case, a justification for the relevance of the tests used should be provided. The test design should be discussed with and agreed by the CA before testing takes place. The evaluation will be done on a case-by-case basis by the CAs.

The guidance will be updated when new methods become available.

5. PT 4 Food and feed area disinfectants

5.1 Introduction

Product type 4 contains biocidal 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.

Some disinfectants applied in the food or feed area can be either biocidal product or a preservative for food or feed. If the product under investigation is within the scope of Regulations (EC) 852/2004, 853/2004 and 854/2004 on food hygiene, it is excluded from the BPR. The Regulation 852/2004 is on the hygiene of foodstuffs; the Regulation 853/2004 lays down specific hygiene rules for food of animal origin; the Regulation 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

In the sections below 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.

5.2 Disinfection of hard surfaces in food and feed area PT4

5.2.1 Introduction

Biocides can be used to disinfect hard surfaces in areas such as food industry, kitchens in restaurants or homes, shops like butchers and grocery shops where food is processed etc. These surfaces may be tables, floors, walls, the outsides of machinery, equipment, reservoirs for water or feed in animal housing etc. Products are often wiped, sprayed, foamed, applied by low to high pressure etc., onto the surface, and maybe washed or wiped off after a certain contact time.

The testing requirements for some specific uses of hard surface disinfectants are discussed in separate sections, for example, CIP, equipment and dishwashing disinfectants etc.

5.2.2 Data requirements

5.2.2.1 Test methods

For efficacy testing of food and feed area biocidal products used on hard surfaces, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for a hard surface disinfectants:

- a quantitative suspension test (phase 2, step 1);
 - and a quantitative surface test (phase 2, step 2);
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Several methods for testing the efficacy of hard surface disinfectants are available. Tests with mechanical action might be adopted from medical area, if appropriate. Appendices 2 and 4 give a list of recommended test methods.

The following documents are recommended for surface disinfection:

- EN 14885: gives an overview of which EN phase2/step1 and step2 tests to use for different uses;

if CEN standards are not relevant or available for the use or organisms claimed the following documents are recommended if appropriately reflecting the application:

- OECD guidance for the testing of chemicals: Quantitative method for evaluating activity of microbiocides used on hard non-porous surfaces (these are surface tests which would be considered phase 2, step 2 tests).

The use of the specified tests is strongly recommended where they are relevant and appropriate.

When efficacy against biofilm is claimed a simulated-use test or field test has to be provided, next to a phase 2, step 1 test. See section 3.11 of this Guidance for test methods.

A product can be applied by airborne diffusion of an aerosol, a smoke, a vapour or a gas, with the intention to disinfect on the surfaces of the walls, floor and ceiling of the room, as well as on external surfaces of the furniture and equipment present in the treated room. For these products the test methods are described in section 3.5 of this Guidance. These tests should be adapted to fit the conditions (soiling, etc. see section 4.2.2.3 of this Guidance) for use in food and feed area.

Disinfectant towelettes/wipes

For disinfectant wipe, the phase 2, step 1 tests should be done preferably with the liquid extracted from the wipe, or if difficult to extract, use the liquid as it is before it is added to the wipes. Phase 2, step 2 tests should be tests with mechanical action. These tests are available for bacteria and yeasts. For testing other organisms surface tests can be done with liquid extracted from the wipe (not the original liquid), with a justification of the volume that is applied per square centimetre. In addition, a test must be performed that shows that either the wipe will still disinfect after the wipe dries out or that the wipe stays wet long enough to disinfect according to the claim. In addition, the use directions can address these issues, for instance, stating on the label that only wet wipes are efficacious, defining the surface area each towel can disinfect (e.g. 0.5 m²), or giving expiry dates for re-sealable packages.

5.2.2.2 Test organisms

Food and feed hard surface biocidal products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For specific uses in industry, an exception can be made when sound justification is provided. This will be evaluated on a case-by-case basis.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed. Relevant groups of test organisms, next to bacteria and yeasts, can be fungi (fungal spores), viruses, bacteriophages, and bacterial spores. Bacteriophages are mainly of importance in the dairy industry.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods. For food area disinfectants *Salmonella* Thyphimurium, *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* are relevant target organisms. For products which claim general efficacy against bacteria, the standard test bacteria should be tested. For these products efficacy against *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* is assumed, because they are more susceptible than the standard test bacteria.

The EN standards for food area only include a test on bacteriophages but not on other viruses. To demonstrate a general virus claim a modified EN phase 2, step 1 test (medical area test with food area soiling) can be provided with Adenovirus and Murine Norovirus as test organism and a phase 2, step 2 test (either modified EN medical test, or DVG test or, as soon as available, an EN food area test) with Murine Norovirus.

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

5.2.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label. The claimed contact time has to be a realistic value.

Tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary. If this is not stated on the label the test should be done under dirty conditions. Note that for use in specific industries different types of soiling for dirty conditions should be used.

The soiling needed for clean and dirty conditions can be found in the relevant EN tests or EN 14885 (version 2014 or later) and referenced in Appendix 4.

If a product is intended to be used in more than one area of use (e.g. milk industry and meat industry) it is justified, after having identified the most challenging test organism, to test the relevant soiling types with this organism. That applies only per group of organisms (e.g. bacteria).

The test temperature should be according to the use instructions on the label. Food and feed area disinfectants are generally used at room temperature (test temperature 20 °C) but for some uses and claims (e.g. surfaces in cold storage rooms) low temperatures of 4 °C or 10 °C are relevant and should be tested.

5.2.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT4 products the required log₁₀ reductions are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

5.3 Disinfection of inner surfaces in PT4

5.3.1 Introduction

Biocides can be used to disinfect the inner surfaces of pipes, tanks, fillers, mixers, and other machines which come in contact with food or feed (including liquids). This includes food and feed industry, milking equipment on farms, large equipment in restaurants or shops where food is processed, etc. Inner surfaces in contact with water are discussed in the following sections.

These surfaces are disinfected by filling and circulating the biocide in the pipes, tanks, machines, etc. with disinfectant (Cleaning In Place, CIP). Also disinfection of inner surfaces of equipment by filling without circulation (not using CIP) is included in this section.

5.3.2 Data requirements

5.3.2.1 Test methods

For efficacy testing of food and feed area biocidal products used on inner surfaces using CIP, the following tests are normally required:

- quantitative suspension tests (phase 2, step 1), simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

For efficacy testing of food and feed area biocidal products used on inner surfaces by filling without circulation, the following tests are normally required for these disinfectants:

- quantitative suspension tests (phase 2, step 1);
 - and a quantitative surface test (phase 2, step 2);
- both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Several methods for testing the efficacy of inner surface disinfectants are available. Appendices 2 and 4 give a list of recommended test methods.

The following documents are recommended for inner surface disinfection using CIP:

- EN 14885 gives an overview of which EN phase 2, step 1 and step 2 tests to use for different uses;
- if CEN standards are not relevant or available for the use or organisms claimed the following documents are recommended if appropriately reflecting the application:
- OECD guidance for the testing of chemicals: Quantitative method for evaluating activity of microbiocides used on hard non-porous surfaces. (These are surface tests which would be considered phase 2, step 2 tests).

The use of the specified tests is strongly recommended where they are relevant and appropriate.

When efficacy against biofilm is claimed a simulated-use test or field test has to be provided, next to a phase 2, step 1 test. See section 3.11 of this Guidance for test methods.

When the disinfection is done with vaporised biocide a simulated-use test or a field test has to be provided. See section 3.5 of this Guidance for test methods.

5.3.2.2 Test organisms

Food and feed hard surface biocidal products should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For specific uses in industry, an exception can be made when sound justification is provided. This will be evaluated on a case-by-case basis.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed. Relevant groups of organisms, next to bacteria and yeasts, can be fungal spores, viruses, phages, and bacterial spores. Phages are mainly of importance in the dairy industry.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods. For food area disinfectants *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* are relevant target organisms. For products which claim general efficacy against bacteria, the standard test bacteria should be tested. For these products efficacy against *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* is assumed, because they are more susceptible than the standard test bacteria.

The EN standards for food area only include a test on bacteriophages but not for other viruses. To demonstrate a general virus claim a modified EN phase 2, step 1 test (medical area test with food area soiling) can be provided with Adenovirus and Murine Norovirus as test organism and a DVG phase 2, step 2 test.

When CIP is done at high temperatures relevant test organisms for these temperatures should be used as described in section 1.4.4.4 of this Guidance.

An overview of test organisms, also for high temperatures, is given in Appendix 3.

5.3.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label. The claimed contact time has to be a realistic value.

Tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary. If this is not stated on the label the test should be done under dirty conditions. Note that for use in specific industries different types of soiling for dirty conditions should be used.

The soiling needed for clean and dirty conditions can be found in the relevant EN tests or EN 14885 (version 2014 or later) and referenced in Appendix 4.

The test temperature should be according to the use instructions on the label. Food and feed area disinfectants are generally used at room temperature (test temperature 20 °C) but for some uses and claims other temperatures are relevant. For example, for surfaces in cold machinery, low temperatures of 4 °C or 10 °C are relevant and should be tested. CIP disinfection is often done at high temperatures of 40 to 80 °C. When this is the intended use the test temperature should be in accordance with the use and relevant test organisms should be used (see section 5.3.2.2 of this Guidance).

5.3.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, when applicable, simulated-use or field tests have been performed (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 tests these should be met. For PT4 products the required log₁₀ reductions tests are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

5.4 Equipment disinfection by soaking

5.4.1 Introduction

Biocides can be used to disinfect dishes, equipment, crates, boxes, etc. by soaking. This can include dishwashing disinfectants, however, normal dishwashing detergents are cleaning products and not included in the BPR. Equipment disinfection in washing machines is covered in the next section.

This can be used in areas such as food industry, kitchens in restaurants or homes, shops like butchers and grocery shops where food or feed is processed, etc.

5.4.2 Data requirements

5.4.2.1 Test methods

For efficacy testing of equipment and dish washing disinfectants the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for these disinfectants:

- a quantitative suspension test (phase 2, step 1;
 - and a quantitative surface test (phase 2, step 2);
- both tests simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Tests in phase 3 are optional, according to section 1.4.3 of this Guidance. No validated test methods are available yet.

Several methods for testing the efficacy of hard surface disinfectants are available.

Appendices 2 and 4 give a list of recommended test methods.

The following documents are recommended for equipment and dish washing disinfection:

- EN 14885: gives an overview of which EN phase2/step1 and step2 tests to use for different uses,
if CEN standards are not relevant or not available for the use or organisms claimed the following documents are recommended if appropriately reflecting the application:
- OECD guidance for the testing of chemicals: Quantitative method for evaluating activity of microbiocides used on hard non-porous surfaces. (These are surface tests which would be considered phase 2, step 2 tests)

The use of the specified tests is strongly recommended where they are relevant and appropriate.

When efficacy against biofilm is claimed a simulated-use test or field test has to be provided, next to a phase 2, step 1 test. See section 3.11 of this Guidance for test methods.

5.4.2.2 Test organisms

Equipment and dish washing disinfectants should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For specific purposes in industrial uses, an exception can be made when sound justification is provided. This will be evaluated on a case-by-case basis.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed. Relevant groups of test organisms, next to bacteria and yeasts, can be fungi (fungal spores), viruses, bacteriophages, and bacterial spores. Bacteriophages are mainly of importance in the dairy industry.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods. For dish washing disinfectants *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* are relevant target organisms. For products which claim general efficacy against bacteria, the standard test bacteria should be tested. For these products

efficacy against *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* is assumed, because they are more susceptible than the standard test bacteria.

The EN standards for food area only include a test on bacteriophages but not for other viruses. To demonstrate a general virus claim a modified EN phase 2, step 1 test (medical area test with food area soiling) can be provided with Adenovirus and Murine Norovirus as test organism and a DVG phase 2, step 2 test.

When the product is intended to be used at high temperatures (>40 °C) relevant test organisms for these temperatures should be used as described in section 1.4.4.4 of this Guidance.

An overview of reference test organisms, also for high temperatures, is given in Appendix 3.

5.4.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label. The claimed contact time has to be a realistic value. For manual dishwashing disinfectants the contact time will be short (seconds), while industrial equipment disinfection by soaking in a solution can be very long (hours).

In general dish washing disinfectants should be tested under dirty conditions, since these products are mainly used for combined cleaning and disinfection. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary. If this is not stated on the label the test should be done under dirty conditions.

Tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements.

Note that for use in specific industries different types of soiling for dirty conditions should be used. The soiling needed for clean and dirty conditions can be found in the relevant EN tests or EN 14885 (version 2014 or later) and referenced in Appendix 4.

The test temperature should be according to the use instructions on the label.

Dish washing disinfectants for manual use are normally used at 40°C and therefore tests should be done at this temperature. When the product is used at lower temperatures (e.g. only for rinsing after normal dish washing with hot water) tests can be done at 20°C. When the intended use is soaking, starting with hot water and after which the solution will cool down during the contact time, this should also be taken into account in the tests.

When disinfection is done at temperatures of 40 to 80 °C the test temperature should be in accordance with the use and relevant test organisms should be used (see section 5.4.2.2 of this Guidance).

5.4.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and, when applicable, simulated-use or field tests have been performed (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 PT4 products the required log₁₀ reductions tests are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

5.5 Disinfection in dish washing machines and crate washers

5.5.1 Introduction

Biocides can be used to disinfect dishes, equipment, crates, boxes, etc. in industrial or dishwashing machines.

This can be used in areas such as food or feed industry, kitchens in restaurants or homes, shops like butchers and grocery shops where food is processed, etc..

5.5.2 Data requirements

5.5.2.1 Test methods

For efficacy testing of equipment and dish washing disinfectants the tiered approach as described in section 1.4.1 of this Guidance is preferred.

The following tests are normally required for these disinfectants:

- a quantitative suspension test (phase 2, step 1);
- and a quantitative surface test (phase 2, step 2);
- and simulated-use or field test (phase 3) for disinfectants used in (dish)washing machines;

all tests simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.).

Several methods for testing the efficacy of hard surface disinfectants are available.

Appendices 2 and 4 give a list of recommended test methods.

The following documents are recommended for surface disinfection in dish washing machines:

- EN 14885: gives an overview of which EN phase 2, step 1 and step 2 tests to use for different uses,

The following test might be helpful for designing simulated-use or field tests:

- prDIN SPEC10534.

5.5.2.2 Test organisms

Equipment and dish washing disinfectants should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

For uses in industrial dish washers for specific purposes, an exception can be made when sound justification is provided. This will be evaluated on a case-by-case basis.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed. Relevant groups of test organisms, next to bacteria and yeasts, can be fungi (fungal spores), viruses, bacteriophages, and bacterial spores. Bacteriophages are mainly of importance in the dairy industry.

The test organisms used in efficacy tests are normally stated in the applicable standard test methods. For dish washing disinfectants *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* are relevant target organisms. For products which claim general efficacy against bacteria, the standard test bacteria should be tested. For these products efficacy against *Salmonella* spp., *Listeria* spp. and *Campylobacter jejuni* is assumed, because they are more susceptible than the standard test bacteria.

The EN standards for food area only include a test on bacteriophages but not for other viruses. To demonstrate a general virus claim a modified EN phase 2, step 1 test

(medical area test with food area soiling) can be provided with Adenovirus and Murine Norovirus as test organism and a DVG phase 2, step 2 tests.

When the product is intended to be used at high temperatures (>40 °C) relevant test organisms for these temperatures should be used as described in section 1.4.4.4 of this Guidance.

An overview of reference test organisms, also for high temperatures, is given in Appendix 3.

5.5.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label. The claimed contact time has to be a realistic value. It will depend on the contact time for the disinfection cycle in (dish)washing machines. Justification for the used contact time should be given.

In general, dish washing disinfectants should be tested under dirty conditions since these products are mainly used for combined cleaning and disinfection. Tests under clean conditions will only suffice when the label instructions state that cleaning prior to disinfection is necessary or when this is incorporated in a previous cycle of the (dish)washing machine. If this is not stated on the label the test should be done under dirty conditions.

Tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements.

Note that for use in specific industries different types of soiling for dirty conditions should be used.

The soiling needed for clean and dirty conditions can be found in the relevant EN tests or EN 14885 (version 2014 or later) and referenced in Appendix 4.

For products intended to be added to (dish)washing machines, information on the following in-use conditions should be provided:

- the concentration of the product (or at least the active substance) in the water during disinfecting process (i.e. washing or rinsing). The water volume used can differ between wash and rinse cycle and different washing programmes, but also between dish washing machines;
- the water to dishes ratio in the test is an important factor that should reflect the in-use conditions;
- the temperature during the disinfection process (high when added in wash process, low in rinse process);
- the contact time (differs between various washing programmes and washing machines).

The laboratory tests should be performed under these conditions. The conditions for effective disinfection can normally only be carried out in professional dish washing machines.

If the exact conditions cannot be met, for example, in household machines, reasonable worst case conditions must be tested.

Worst case conditions, e.g.:

- the lowest temperature;
- the highest volume of water (i.e. maximum dilution of the product);
- the shortest contact time;

- the maximum load of dishes (i.e. smallest water to dishes ratio).

The test temperature should be according to the use instructions on the label.

When the product is used at lower temperatures (e.g. only for rinsing after normal dish washing with hot water) tests can be done at 20°C. When disinfection is done at temperatures of 40 to 80 °C the test temperature should be in accordance with the use and relevant test organisms should be used (see section 5.5.2.2 of this Guidance).

5.5.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory and simulated-use or field tests have been performed (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 PT4 products the required log₁₀ reductions tests are referenced in Appendix 4.

Deviations from the pass criteria are possible, but must be justified in the application. The CA will evaluate any justification on a case-by-case basis, consulting the other CAs where appropriate, and decide whether it is acceptable or not.

5.6 Disinfection of inner surfaces in human drinking water systems

5.6.1 Introduction

Biocides can be used to disinfect surfaces in human drinking water systems (further referred to as drinking water. This can be large water systems in drinking water companies, transport pipes in between drinking water companies (semi-finished product), the communal piping system, collective drinking water systems (hospitals and other health care facilities, hotels, penitentiary institutions, etc.), and tanks and reservoirs for drinking water (for instance on ships).

When water systems are disinfected in closed circuits, after which the system is washed with clean water, it is considered to be disinfection of the pipework and is included in PT4. When disinfection is performed in water systems while they are in service and the water is also disinfected the application is considered to be included in PT5.

The drinking water systems may be new or rehabilitated drinking water pipes (e.g. in newly built or renovated houses) or systems that are in service for some time and have become contaminated during this period.

The main need to clean and disinfect the systems is to get a fresh start of the system. Cleaning and disinfection programs may be combined to treat these systems.

The systems that have been in service for some time contain biofilm and organisms to be controlled might hide in this biofilm. For instance, *Legionella* can multiply in the biofilm.

5.6.2 Data requirements

5.6.2.1 Test methods

For efficacy testing of biocidal products used on inner surfaces of drinking water systems, the tiered approach as described in section 1.4.1 of this Guidance is preferred.

For combined cleaning and disinfecting of drinking water pipes, the following test is normally required:

- a quantitative suspension test (phase 2, step 1).

When efficacy against *Legionella* is claimed, the following tests are normally required:

- a quantitative suspension test (phase 2, step 1);
- and a field test (phase 3).

all simulating practical conditions appropriate to its intended use (temperature, soiling, contact time, etc.). When ring trial validated test protocols for simulated-use tests (phase 2, step 2) become available these might replace the field trial.

When efficacy against biofilms is claimed, the following tests are normally required:

- a quantitative suspension test (phase 2, step 1);
- a simulated-use test or a field test.

5.6.2.1.1 Laboratory tests

EN phase 2, step 1 tests for the food industrial, domestic and institutional area are relevant for this use. Efficacy against *Legionella* can be tested in EN 13623 (phase 2, step 1).

See section 3.11 of this Guidance for biofilm test methods.

Appendices 2 and 4 give a list of recommended test methods.

5.6.2.1.2 Field trials

For products which claim efficacy against *Legionella*, field trials with the following requirements should be provided:

- before testing it should be established that the installation contains high numbers of *Legionella* (>100cfu/L). A zero-time measurement should be performed. Systems must not be inoculated with micro-organisms in order to perform the efficacy test;
- a field trial should be performed in a system that has been in service for some time and has become infected during this period;
- the number of sampling points per location will depend on the number of draw-off points in the installation. The table below should be used;

Table 1: Number of sampling points

Number of draw-off points (outlets)	Number of sampling points
10-100	4
101 – 200	6
201 – 400	8
401 – 800	10
801 – 1600	12
> 1600	14

* a draw-off point is a point where drinking water, household water or warm water is made available for use.

- after disinfection and subsequent washing of the system with clean water (removal of disinfectant), samples should be taken and the amount of bacteria (general) and *Legionella* in the water should be determined. Samples should be taken 48 hours and 2 weeks after disinfection;
- after treatment, water from none of the sampling points should contain more than 100 colony forming units/litre *Legionella*.

5.6.2.2 Test organisms

Biocidal products for drinking water disinfection should be at least sufficiently effective against bacteria. The test organisms used in efficacy tests are stated in the applicable standard test methods. Efficacy tests with these organisms should always be provided.

For products which claim efficacy against *Legionella*, a test with *Legionella* spp. should also be performed.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

5.6.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label. The claimed contact time has to be a realistic value.

Laboratory phase 2, step 1 tests should be carried out with soiling for clean conditions in accordance with the test requirements. The soiling needed for clean conditions can be found in the relevant EN tests and referenced in Appendix 4. Simulated-use tests should be performed with relevant soiling.

5.6.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory, or when applicable, field tests have been performed (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 these products the required log₁₀ reductions in the laboratory tests are referenced in Appendix 4. The field trial should not contain more than 100 colony forming units *Legionella* per litre.

5.7 Disinfection of inner surfaces in veterinary water systems

5.7.1 Introduction

Biocides can be used to disinfect surfaces in veterinary water systems in farms, bio-industry, etc.. These are water systems provide water for animals to drink, to prepare feed, and to use for cleaning the area. Water systems that are also suitable for human drinking water are not included in this section (see previous section of this Guidance).

When water systems are disinfected in closed circuits, after which the system is washed with clean water, it is considered to be disinfection of the pipework and is included in PT4. When disinfection is performed in water systems while they are in service and the water is also disinfected the application is considered to be included in PT5.

The water of these systems can be provided by drinking water companies but can also contain well, ground, or ditch water that is pumped up at the location, or other water. Water systems in livestock farming can be used to supply food additives or antibiotics to the animals. Therefore, these veterinary water systems may be more fouled than human drinking water systems.

5.7.2 Data requirements

5.7.2.1 Test methods

For the combined cleaning and disinfecting of veterinary drinking water pipes (e.g. water tanks, water in animal housings etc. used as drinking water for animals and for other uses in stables like cleaning, preparing feed, etc.), efficacy should be demonstrated in a

tiered approach as described in section 1.4.1 of this Guidance. This includes a phase 2, step 1 and step 2 test.

The following documents are recommended for disinfecting of veterinary drinking water pipes:

- EN 14885 gives an overview of which EN phase 2, step 1 and step 2 tests to use for different uses, the tests (bactericidal) for the food area are relevant for this use;
if CEN standards are not relevant or available for the use or organisms claimed the following documents are recommended if appropriately reflecting the application:
- OECD guidance for the testing of chemicals: Quantitative method for evaluating activity of microbiocides used on hard non-porous surfaces. (These are surface tests which would be considered phase 2, step 2 tests).

The use of the specified tests is strongly recommended where they are relevant and appropriate.

When efficacy against biofilms is claimed, a simulated-use test or field test has to be performed, as well as a phase 2, step 1 test. See section 3.11 of this Guidance for test methods.

5.7.2.2 Test organisms

Biocidal products for drinking water disinfection should be at least sufficiently effective against bacteria. The test organisms used in efficacy tests are stated in the applicable standard test methods. Efficacy tests with these organisms should always be provided.

For all other groups of organisms, data only have to be provided when activity against those organisms is claimed.

5.7.2.3 Test conditions

It is important that the tests are performed with the same contact time as claimed on the label. The claimed contact time has to be a realistic value.

Laboratory tests should be carried out with soiling for clean or dirty conditions in accordance with the test requirements for the food area. Tests under clean conditions will only suffice when the label instructions state that cleaning of the water systems prior to disinfection is necessary. If this is not stated on the label the test should be done under dirty conditions.

5.7.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory, or when applicable, simulated-use or field tests have been performed (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 these products the required \log_{10} reductions in the laboratory tests are referenced in Appendix 4.

5.8 Other uses in PT4

Several uses of PT4 products have been specified in the above sections and data requirements and acceptance criteria for these uses are described. For products with other uses, that do not fit in one of the described uses, it is up to the applicant to demonstrate efficacy in an appropriate way.

In general the tiered approach as described in section 1.4.1 of this Guidance is preferred. Where possible the standard tests required for the described uses should be taken (e.g. EN phase 2, step 1 and step 2 tests for food area). Where the tests are not appropriate for the product, other tests can be used. In that case, a justification for the relevance of the tests used should be provided. The test design should be discussed with and agreed by the CA before testing takes place. The evaluation will be done on a case-by-case basis by the CAs.

The guidance will be updated when new methods become available.

6. PT 5 Drinking water disinfectants



NOTE to the reader:

A preliminary draft text for PT 5 is included in this section: **this has not been reviewed or revised to address written PEG comments received and the section is currently under review within the ECHA "Disinfectants Project"**.

This project was initiated after the launch of the "Efficacy Assessment of PTs 1-5", and will address the efficacy assessment of PT 5, including the PEG comments received. The project will provide a draft guidance document which will undergo an ECHA consultation in 2016/2017 and the finalised agreed guidance document will replace, in whole or part, this section.

In the meantime, this Section 6 is available to readers for information and if there are other suitable means of demonstrating efficacy for PT 5 products, these may be used.

6.1 Introduction

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

When disinfection is done in the water systems while it is in service also the water is disinfected and 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 and included in PT4.

Disinfectant products can be added to drinking water, intermittently, by shock dosing or continually. The purpose of disinfection is to disinfect the water to prevent transmission of water-borne diseases via drinking water. Water-borne transmitted pathogens can be bacteria, viruses, yeasts, fungal spores and protozoan parasites. Disinfection is only one aspect of drinking water treatment. Application of drinking water disinfectants is associated with the responsibility to control 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 necessarily for achieving the targeted effect (principle of minimisation) and only under conditions optimizing their efficacy.

Disinfection within PT5 can be divided into five groups:

1. Disinfection in drinking water companies
This is disinfection of water when it enters the drinking water company, transport in between drinking water companies (semi-finished product) and prior to distribution into (part of) the communal piping system.

2. Disinfection in collective drinking water systems
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*. When physical techniques (heating, UV treatment, etc.) are insufficient chemical disinfection is allowed in some EU countries.
3. Disinfection of stationary water in reservoirs
This is disinfection of water stored in tanks and reservoirs, for instance on ships.
4. Disinfection of undefined water before drinking.
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.
5. Disinfection of veterinary water
This is disinfection of water in animal housings used as drinking water for animals and for other uses in stables (cleaning, preparing feed, etc.).

In the sections below 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.

6.2 Data requirements

6.2.1 Test methods

For an overview of available EN tests see Appendix 1.

6.2.1.1 Disinfection in drinking water companies

For product authorisation of drinking water disinfectants in drinking water companies the tiered approach as described in section 1.4.1 of this Guidance is preferred.

Next to a suspension test (EN phase 2, step 1 test) a simulated use test should be performed.

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", available on ECHA Biocides Efficacy Working Group webpage¹⁷. The test is realized on an adapted test rig. A disinfectant neutralizer or filter system to stop reaction between disinfectant and test organisms is required.

6.2.1.2 Disinfection in collective drinking water systems

For product authorisation of drinking water disinfectants in collective drinking water systems the tiered approach as described in section 1.4.1 of this Guidance is preferred.

Because the control of *Legionella* in collective drinking water systems is of major importance, efficacy against *Legionella* should always be demonstrated.

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

¹⁷ <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/efficacy>.

6.2.1.2.1 Laboratory tests

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

Studies should show that the product can accomplish a log reduction of 5 against bacteria and specifically *Legionella*. This can be done in laboratory tests (e.g. suspension tests EN 1276 and EN 13623). The suspension tests can be waived when simulated use or field trials are available in which the concentration of *Legionella* is high enough to show log reduction of 5 (min. 10^5 cfu/L).

6.2.1.2.2 Simulated use tests

A simulated use test should be performed. 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" available on ECHA Biocides Efficacy Working Group webpage¹⁸. The test is realized on an adapted test rig. A disinfectant neutralizer or filter system to stop reaction between disinfectant and test organisms is required.

6.2.1.2.3 Field trials

For products with long and continuous use (drinking water disinfection PT5) field trials with the following requirements should be provided:

6.2.1.2.3.1 Locations

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

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 part of a collective drinking water system, for instance a wing of a building or only the cold water system can be seen a test location, as long as it contains 100 or more operational draw-off points.

The drinking water quality in the different EU countries may differ. In some EU countries disinfectants like chlorine are standard included, while in other countries disinfectants are only added during calamities. Therefore some EU countries will accept only field trials in their own country or on locations with comparable water specifications. Therefore, when tests are not performed in all countries for which authorisation is applied for, the quality of the tested drinking water should be specified and the comparability of this water is to the drinking water in each country should be justified. The CA will decide whether the test is acceptable or not.

6.2.1.2.3.2 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 (see 2.6), the test should be extended to one year starting from the point that 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*.

6.2.1.2.3.3 Different types of water

It is recommended that the locations are spread over the country, this to ensure that the product is tested on different types of water. For this purpose information should be provided to the Ctgb on the quality of the provided water at the different locations. In principal this information is available through the water company.

¹⁸ <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/efficacy>.

6.2.1.2.3.4 Legionella

Before starting a test it should be clear that the installation to be treated is contaminated with Legionella bacteria. For this purpose information should be provided to the Ctgb on (recent) problems with *Legionella*, like results from sampling in the past and performed cleanings, etc..

6.2.1.2.3.5 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 (taken from appendix G of the Waterleidingbesluit).

Table 2: Number of sampling points

Number of draw-off points (outlets)	Number of sampling points
10-100	4
101 – 200	6
201 – 400	8
401 – 800	10
801 – 1600	12
> 1600	14

All sampling points should be unambiguously coded.

At each sampling round two sampling points are sampled each time (standard sampling points), preferably the sampling point next to the apparatus and the sampling point the most far away from it. These sampling points should be clearly described and the code of these points should be stated. All other sampling points should vary at each sampling round. When a sampling point shows elevated values of *Legionella* or one of the other parameters this sampling point should be sampled again the next month. The total amount of sampling points stays the same, according to the table above.

The tuning of the apparatus at the time of sampling should be recorded.

6.2.1.2.3.6 Efficacy

To be able to evaluate the efficacy the following measurements should be performed:

- zero measurement: measurement of *Legionella*, total hardness, pH, and active substances before the apparatus is put into action.
- *Legionella*, 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 waterworks companies can be collected;
- pH, monthly sampling on both standard sampling points, or data from the waterworks companies can be collected.

6.2.1.2.3.7 Active substances and metabolites (side effects)

To determine the amount of active substance in the water and any harmful metabolites, the relevant products should be measured monthly.

For anodic oxidation the following products are relevant:

- available chlorine, monthly measurements; norm value 0.3 mg/l at the draw-off points (90 %-percentile with a maximum of 0.5 mg/l)
- trihalomethanes: measurement 3 and 9 months after the apparatus is put into action, always at one draw-off point which represents the worst-case situation, normally the draw-off point the most far away from the apparatus. This concerns the parameters trichloromethane (chloroform), tribromomethane (bromoform), broomdichloormethane and dibroomchloormethane. Norm value: the total of the trihalomethanes 25 µg/l (90%-percentiel, max. 50 µg/l). The concentration broomdichloormethane should not exceed 15 µg/l.
- halogenated acetic acids: measurement 3 and 9 months after the apparatus is put into action, always at one draw-off point which represents the worst-case situation (see trihalomethanes). This concerns the parameters monochloric acid, dichloroacetic acid and trichloroacetic acid. The norm value: the total of the haloacetic acids 25 µg/L.

For copper/silver ionisation the following products are relevant:

- copper, monthly measurements; norm value 2 mg/l;
Remark: the technique cannot produce the full 2 mg/l considering the contribution of copper from other sources. An increase of the copper value of maximum 1 mg/l is considered acceptable.
- silver, monthly measurements; norm value 50 µg/l (90%-percentiel with a maximum 100 µg/l).

For chloordioxide-generators the following products are relevant:

- chlorite, monthly measurements at all draw-off points; norm value 0.2 mg/l;
- chlorate, monthly measurements at all draw-off points; norm value 0.2 mg/l;
- trihalomethanes: measurement 3 and 9 months after the apparatus is put into action, always at one draw-off point which represents the worst-case situation, normally the draw-off point the most far a way from the apparatus. This concerns the parameters trichloromethane (chloroform), tribromomethane (bromoform), broomdichloormethane and dibroomchloormethane. Norm value: the total of the trihalomethanes 25 µg/l (90%-percentiel, max. 50 µg/l). The concentration broomdichloormethane should not exceed 15 µg/l.

6.2.1.2.3.8 Evaluation criteria per location

For the evaluation of the results of the measurements the norm values as mentioned in 6.2.1.2.2.6 and 6.2.1.2.2.7 are used. Per location 90% of the measurements should fulfil the requirements. Over all locations together 90% of the locations should fulfil the requirements.

6.2.1.2.3.9 General requirements for study reports

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

6.2.1.2.4 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.

6.2.1.3 Disinfection of stationary water in reservoirs

For this use it is in most cases acceptable to demonstrate efficacy with phase 2, step 1 tests only. In some cases efficacy against biofilm is of importance in this use. For testing efficacy against biofilms see section 3.11 of this Guidance.

6.2.1.4 Disinfection of undefined water used as drinking-water

For this use it is in most cases acceptable to demonstrate efficacy with phase 2, step 1 tests only.

6.2.1.5 Disinfection of water for animals

For efficacy testing of disinfectants for water for animals the tiered approach as described in section 1.4.1 of this Guidance is preferred. Next to a phase 2, step 1 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 3.11 of this Guidance.

6.2.2 Test organisms

PT5 products should be at least sufficiently effective against **bacteria**. Efficacy test with these organisms should always be provided.

There are few exceptions to this rule:

- for products for disinfection of drinking water in drinking water companies also efficacy should be demonstrated against bacteria and viruses. This can be done in the simulated use test.
- for products for disinfection of drinking water in collective systems also efficacy should be demonstrated against *Legionella* spp..

For all other groups of organisms test 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.

6.2.3 Contact time

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. For the use as drinking water disinfectant no maximum contact times are set.

6.2.4 Soiling

The suspension test (phase 2, step 1) should be carried out with soiling for clean or dirty conditions in accordance with the test requirements. 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.

Dirty conditions: 3 g/L bovine albumin solution

Clean conditions: 0.3 g/L bovine albumin solution

6.3 Acceptance criteria

A product will be assessed to be sufficiently effective if the required laboratory, 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 4 for more information): after a contact time of 10 minutes at least a log reduction of 2 and after 25 minutes at least a log reduction of 4.

In the drinking water disinfection field tests the aim is to keep the *Legionella* concentration below 100 cfu/L. Ninety percent of all the test samples per location should show a *Legionella* concentration below 100cfu/L while the maximum *Legionella* concentration should not exceed 1000cfu/L. The test should be done on ten locations and 90% of these locations should meet this criterion.

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

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

Appendix 1. Claims Matrix

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 and 4

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 or PT4 biocidal product.

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 3) is highly recommended if available and appropriate for the respective application¹⁹. 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 4) 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, 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 3: CEN European standards

Reference	Title	PT	Scope/Remarks
EN 1276	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)	1,2,4	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.
EN 1499	Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2, step 2)	1	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.
EN 1500	Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)	1	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.
EN 1650	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)	1,2,4	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.

¹⁹ 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.

Reference	Title	PT	Scope/Remarks
EN 1656	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)	3	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.
EN 1657	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)	3	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.
EN 12353	Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including <i>Legionella</i>), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity	1,2,3,4,5	This method specifies how to keep test organisms used and defined in European Standards for the determination of bactericidal, mycobactericidal, sporicidal, fungicidal and virucidal (incl. bacteriophages) activity of chemical disinfectants and antiseptics drawn up by CEN/TC 216.
EN 12791	Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)	1	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.
EN 13610	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)	4	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.
EN 13623	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against <i>Legionella</i> of chemical disinfectants for aqueous systems - Test method and requirements (phase 2, step 1)	2,4,5	This European Standard specifies a method for testing bactericidal activity against <i>Legionella</i> by assessing reduction in the number of viable <i>Legionella</i> cells in suspension under defined conditions. The approach can be applied to formulated products or to biocidal active substances.
EN 13624	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)	1,2	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.

Reference	Title	PT	Scope/Remarks
EN 13697	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 without mechanical action (phase 2, step2)	2,4	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.
EN 13704 ²⁰	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)	4 (1, 2,3)	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.
EN 13727	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)	1,2	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.
EN 14204	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)	3	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.
EN 14347	Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1)	1,2 ,3, 4	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, 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.
EN 14348	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)	1,2	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.

²⁰ EN 13704 is under review and the revised standard will include veterinary and human health care areas.

Reference	Title	PT	Scope/Remarks
EN 14349	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)	3	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.
EN 14476	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)	1,2 (4)	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.
EN 14561	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)	2	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.
EN 14562	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)	2	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.
EN 14563	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)	2	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.
EN 14675	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)	3	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.

Reference	Title	PT	Scope/Remarks
EN 14885	Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics	1,2 ,3, 4,5	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 <i>Legionella</i>), bacterial spores, yeasts, fungal spores and viruses (incl. bacteriophages).
EN 16437	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)	3	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.
EN 16438	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)	3	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.
EN 16615	Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)	2 (4)	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	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)	2 (3, 4)	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.

Reference	Title	PT	Scope/Remarks
EN 16777	Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2)	2 (4)	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 4: Other test methods and guidance documents

Reference	Title	PT	Remarks
ASTM E2196	Standard Test Method for Quantification of <i>Pseudomonas aeruginosa</i> Biofilm Grown with Medium Shear and Continuous Flow Using Rotating Disk Reactor	2,3 ,4	This test method is used for growing a reproducible <i>Pseudomonas aeruginosa</i> 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: http://www.astm.org/Standard/ or the national standardisation bodies
ASTM E2274	Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants	2,3	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.
ASTM E2406	Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants for Use in High Efficiency Washing Operations		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.
ASTM E2562	Standard Test Method for Quantification of <i>Pseudomonas aeruginosa</i> Biofilm Grown with High Shear and Continuous Flow using CDC Biofilm Reactor	2,3 ,4	This test method specifies the operational parameters required to grow a reproducible <i>Pseudomonas aeruginosa</i> 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: http://www.astm.org/Standard/ or the national standardisation bodies

Reference	Title	PT	Remarks
DIN SPEC 10534	Food hygiene - Commercial dishwashing - Hygiene requirements, testing	4	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 warewashers 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: http://www.beuth.de/en/ or the national standardisation bodies
DVG Guidelines	Guidelines for the testing of disinfection procedures and chemical disinfectants; Original title: Richtlinien für die Pruefung von Desinfektionsverfahren und chemischen Desinfektionsmitteln	3,4	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/food 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: http://www.desinfektion-dvg.de
ISO/TS 15883-5	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy	2,3,4	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 <i>Pseudomonas aeruginosa</i> . Available via: http://www.iso.org/iso/home.htm or the national standardisation bodies
NF T72-281	Methods of airborne disinfection of surfaces - Determination of bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal and virucidal activity, including bacteriophages; Original title: Procédés de désinfection des surfaces par voie aérienne - Détermination de l'activité bactéricide, fongicide, levuricide, mycobactéricide, tuberculocide sporicide et virucide incluant les bactériophages	2,3,4	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: http://www.afnor.org/en or the national standardisation bodies
Nordic Working Paper	Efficacy Assessment of Treated Articles: A guidance	1,2,3,4	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: http://www.norden.org/en/publications/publikationer/2014-904/

Reference	Title	PT	Remarks
OECD Series on Biocides No. 1	Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects		The document guidance on efficacy testing of articles treated with antimicrobials and articles modified to exert an antimicrobial effect. http://www.oecd.org/env/ehs/pesticides-biocides/41692131.pdf
OECD Series on Biocides No. 4	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)	2	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: http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm
OECD Series on Biocides No. 6	Guidance Document on Quantitative Methods for Evaluating the Activity of Microbiocides used on Hard Non-Porous Surfaces (Series on Testing and Assessment No. 187 and Series on Biocides No. 6).	2 (4)	This document describes four quantitative methods for testing bactericidal, mycobactericidal, fungicidal and virucidal activity on steel carriers with high application volumes of liquid products. Open access via: http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm
OECD Series on Biocides No. 8	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)	1,2 ,3, 4	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: http://www.oecd.org/env/ehs/pesticides-biocides/biocidestestguidelinesandguidencedocuments.htm
VAH Standard methods	VAH certification of chemical disinfection procedures; Original title: VAH-Zertifizierung chemischer Desinfektionsverfahren	1,2	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: http://www.mhp-verlag.de/en/home/

Appendix 3. Table of Reference Test Organisms

This table (Table 5) 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 5: Reference Test Organisms

	Key for Table 5:
	* 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;
	** <i>Aspergillus brasiliensis</i> is the name of <i>Aspergillus niger</i> after reclassification in 2008;
	*** for a limited spectrum virus claim in PT1 Poliovirus does not have to be tested.

Micro-organisms	PT1*	PT2*	PT3*	PT4*	PT5*
Bacteria					
<i>Staphylococcus aureus</i> ATCC 6538	X	X	X	X	X
<i>Pseudomonas aeruginosa</i> ATCC 15442 (not for teat disinfection)	X	X	X	X	X
<i>Enterococcus hirae</i> ATCC 10541	X	X	X	X	X
<i>Escherichia coli</i> ATCC 10536 (teat disinfection)		O	(X)	X	X
<i>Escherichia coli</i> K12 NCTC 10538	X	X			O
<i>Salmonella</i> Typhimurium ATCC 13311		O		O	
<i>Lactobacillus brevis</i> DSM6235		O		O	
<i>Enterobacter cloacae</i> DSM 6234		O		O	
<i>Enterococcus faecium</i> ATCC 6057 (for T ≥40°C)		(X)		(X)	
<i>Proteus vulgaris</i> ATCC 13315 (not for teat disinfection)			X		
<i>Streptococcus uberis</i> ATCC 19436 (teat disinfection)			(X)	(X)	
<i>Legionella pneumophila</i> ATCC 33152 (PT2: pools, hot tubs; PT4: drinking water systems, PT5: in collective drinking water systems)		(X)			X
		O			O

Micro-organisms	PT1*	PT2*	PT3*	PT4*	PT5*
<i>Legionella pneumophila</i> ATCC 43108					
Yeasts					
<i>Candida albicans</i> ATCC 10231	X	X	X	X	X
<i>Saccharomyces cerevisiae</i> ATCC 9763 (breweries)				(X)	
<i>Saccharomyces cerevisiae</i> DSM 70487 (breweries)				(X)	
Fungal spores					
<i>Aspergillus brasiliensis</i> ** ATCC 16404	X	X	X	X	X
Viruses					
Polio virus type 1, LSc-2ab (Picornavirus)	X****	X			
Adenovirus, type 5, strain Adenoid 75, ATCC VR-5.	X	X		X	
Murine norovirus, strain S99 Berlin	X	X		X	
Murine Parvovirus, strain Crawford, ATCC VR-1346 (for T ≥40°C)		(X)		(X)	
Bovine Entrovirus Type 1, ECBO - Virus ATCC VR-248			X		
Enveloped Viruses					
MVA = Modified Vacciniavirus Ankara (teat disinfection)	X		(X)		
Bacteriophages					
Bacteriophage P001 DMS 4262 (milk industry)				X	
Bacteriophage P008 DMS 10567 (milk industry)				X	
Mycobacteria					
<i>Mycobacterium terrae</i> ATCC 15755	X	X			
<i>Mycobacterium avium</i> ATCC 15769	X	X	X		
(PT1 and PT2 claim for mycobactericidal: both, tuberculocidal: <i>M. terrae</i> only)					
Bacterial spores					
Spores of <i>Bacillus cereus</i> ATCC 12826 (bee hives)		O	(X)	O	
Spores of <i>Bacillus subtilis</i> ATCC 6633 (bee hives)		X	O (X)	X	
Spores of <i>Clostridium sporogenes</i> ATCC 7955		O		O	
Spores of <i>Geobacillus stearothermophilus</i> (for T ≥60°C)		(X)		(X)	
Endoparasites					
Oocysts of <i>Eimeria tenella</i> strain Houghton (chicken farms)			(X)		

Appendix 4. Overview of standards, test conditions and pass criteria

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 PT05, it should be noted that the text in Section 6 (PT 5) 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 PT05 is included, but this will be reviewed when Section 6 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 6: Examples of viruses

Blood	
Enterovirus	Hepatitis C virus (HCV)
Filoviridae	Hepatitis Delta virus (HDV)
Flavivirus	Human Immunodeficiency Virus (HIV)
Herpesviridae	Human T Cell Leukaemia Virus (HTLV)
Hepatitis A Virus (HAV)	Parvovirus B 19
Hepatitis B virus (HBV)	
Respiratory tract	
Adenovirus (Mast-)	Influenza Virus
Coronavirus	Paramyxoviridae
Enterovirus	Rhinovirus
Herpesviridae	Rubella Virus
Neuronal tissue, ear,nose & eye	
Adenovirus (Mast-)	Human Immunodeficiency Virus (HIV)
Enterovirus	Polyomavirus
Herpesviridae	Rabies Virus
Measles Virus	Rubella Virus
Gastro-intestinal	
Adenovirus(Mast-)	Enterovirus
Caliciviridae	Hepatitis A Virus (HAV)
Coronavirus	Hepatitis E Virus (HEV)
Astrovirus	Rotavirus
Skin, breast and/or milk	
Enterovirus	Human T Cell Leukaemia Virus (HTLV)
Herpesviridae	Papillomavirus
Human Immunodeficiency Virus (HIV)	Poxviridae

Spleen and lymph nodes (see also blood)	
Human T Cell Leukaemia Virus (HTLV)	
Human Immunodeficiency Virus (HIV)	
Dental procedure	
Adenovirus(Mast-)	Hepatitis C Virus (HCV)
Enterovirus	Hepatitis Delta Virus (HDV)
Herpesviridae	Human Immunodeficiency Virus (HIV)
Hepatitis B virus (HBV)	
Urogenital tract	
Hepatitis B Virus (HBV)	Human T Cell Leukaemia Virus (HTLV)
Herpesviridae	Papillomavirus
Human Immunodeficiency Virus (HIV)	Polyomavirus

Reference:

Van Regenmortel MHV et al.,Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses. Academic Press, San Diego, 2000

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