BS EN 14885:2015

BSI Standards Publication

Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics

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National foreword

This British Standard is the UK implementation of EN 14885:2015. It supersedes BS EN 14885:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/216, Chemical disinfectants and antiseptics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Antiseptiques et désinfectants chimiques - Application des Normes européennes sur les antiseptiques et désinfectants chimiques

Chemische Desinfektionsmittel und Antiseptika - Anwendung Europäischer Normen für chemische Desinfektionsmittel und Antiseptika

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 14885:2015) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 14885:2006.

EN 14885:2006 was revised to update the information on existing standards, to include standards published since 2006 and to give more details how to use the standards for making claims. CEN/TC 216 has prepared a series of standards on chemical disinfectants and antiseptics specifying requirements and test methods. The purpose of this European Standard is to specify the relationship of the various standards to one another and to claims and use recommendations.

To allow for different requirements in different areas of application, separate tests and pass criteria have been or will be prepared for each of the following three areas of application: medical, veterinary, and a group comprising food, industrial, domestic and institutional areas.

This European Standard only refers to test methods which are currently included in the work programme of CEN/TC 216 and which are described in Clause 2. It is likely that additional standards which relate to specific situations, e.g. chemical disinfection of textiles, will be produced at a later time.

This document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording and to improve its readability and thereby make it more understandable. The following is a list of significant changes since the last edition:

— some definitions were added, some were changed;

— the relevance of phase 1 tests was clarified;

— the relationship between claims for a given product and test results is described in greater detail;

— the use of standards outside their defined scope is now defined;

— the fields of application in the different areas are described in much greater detail;

— recommendations how to deal with the imprecision of the test methods are given;

— recommendations how to use the standards for proficiency testing (quality control) are given;

— the impact of changes of standards are defined;

— the main aims, scope, safety aspects, design, performance and evaluation of results of phase 3 tests (field tests) are described.

The changes mentioned above have no impact on the use of test results obtained with reference to the former version of EN 14885.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants and antiseptics in order to support claims that they have specific properties appropriate to their intended application. These laboratory methods may also be used for active substances and products under development. This European Standard is not intended to represent disinfection policy guidelines, i.e. guidelines for choosing and assessing the suitability of products for particular situations.

The CEN standards relate to only a limited range of microbial species. These have been chosen as representative species taking into account their relative resistance and their relevance to practical use. The handling properties and the microbiological safety have also been considered in choosing the test organisms.

The test methods in this European Standard are based on the current scientific state of the art. It is recognized that at the present time there is only limited knowledge regarding the relationship between the activity of products as determined by suspension as compared with surface tests, and the relevance of the results of both tests to conditions of use.

Chemical disinfectants and antiseptics should always be used responsibly. This should take into account the environmental impact of inappropriate product in-use concentrations (too high or too low) and of unnecessary use.

1 Scope

This European Standard specifies the European Standards to which products have to conform in order to support the claims for microbicidal activity which are referred to in this European Standard.

This European Standard 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 (including mycobacteria and *Legionella)*, bacterial spores, yeasts, fungal spores and viruses (including bacteriophages).

It is intended to:

a) enable manufacturers of products to select the appropriate standards to be used in order to provide data which support their claims for a specific product;

b) enable users of the product to assess the information provided by the manufacturer in relation to the use for which they intend to use the product;

c) assist regulatory authorities in assessing claims made by the manufacturer or by the person responsible for placing the product on the market.

It is applicable to products to be used in the area of human medicine, the veterinary area and in food, industrial, domestic and institutional areas.

In the area of human medicine, it is applicable to chemical disinfectants and antiseptics to be used in areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care

— in hospitals, in community medical facilities and dental institutions,

— in clinics of schools, of kindergartens and of nursing homes,

— and may also occur in the workplace and in the home. It may also include services such as in laundries and kitchens supplying products directly for the patient.

In the veterinary area it is applicable to chemical disinfectants and antiseptics to be used in the areas of breeding, husbandry, production, transport and disposal of animals. It is not applicable to chemical disinfectants used in the food chain following death and entry to the processing industry.

In food, industrial, domestic and institutional areas it is applicable to chemical disinfectants and antiseptics to be used in processing, distribution and retailing of food of animal or vegetable origin. It is also applicable to products for all public areas where disinfection is not medically indicated (homes, catering, schools, nurseries, transports, hotels, offices etc.) and products used in packaging, biotechnology, pharmaceutical, cosmetic etc. industries.

This European Standard is also applicable to active substances and products under development for which no area of application has yet been specified.

This European Standard does not refer to methods for testing the toxicological and ecotoxicological properties of products or active substances.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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)*

EN 1499, *Chemical disinfectants and antiseptics — Hygienic handwash — Test method and requirements (phase 2/step 2)*

EN 1500, *Chemical disinfectants and antiseptics — Hygienic handrub — Test method and requirements (phase 2/step 2)*

EN 1650, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas — Test method and requirements (phase 2, step 1)*

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)*

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)*

EN 12791, *Chemical disinfectants and antiseptics — Surgical hand disinfection - Test method and requirement (phase 2/step 2)*

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)*

EN 13623, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems — Test method and requirements (phase 2, step 1)*

EN 13624, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1)*

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, step 2)*

EN 13704, *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)*

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)*

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)*

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)*

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)*

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)*

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)*

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)*

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)*

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)*

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)*

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 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Some recommendations on the use of terminology in the areas of chemical disinfection and antisepsis are given in Annex A.

3.1 Chemical disinfectant or antiseptic procedures and product types

3.1.1
antiseptic
product – excluding antibiotics – that is used to bring about antisepsis

3.1.2
antisepsis
application of an antiseptic on living tissues causing an action on the structure or metabolism of microorganisms to a level judged to be appropriate to prevent and/or limit and/or treat an infection of those tissues

3.1.3
chemical disinfectant
product that is capable of chemical disinfection

3.1.4
chemical disinfection
reduction of the number of microorganisms in or on an inanimate matrix, achieved by the irreversible action of a product on their structure or metabolism, to a level judged to be appropriate for a defined purpose

3.1.5
hygienic handrub
treatment of hands by rubbing a product without the addition of water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.6
hygienic handwash
treatment of hands by washing with product and water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.7
instrument disinfection
chemical disinfection of certain instrument surfaces in the medical and veterinary areas by immersion

3.1.8
surface disinfection
chemical disinfection of a solid surface, including those of certain medical and veterinary instruments which cannot be immersed, by the application of a product with or without mechanical action

Note 1 to entry: The application includes e.g. circulation, flooding, spraying, fogging, wiping etc.

3.1.9
surgical handrub
preoperative treatment of hands by rubbing a product without the addition of water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.10
surgical handwash
preoperative treatment of hands by washing with product and water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.11
textile disinfection
chemical disinfection of textiles through the application of a product by either immersion in a solution or by processing in a washing machine

3.2 Chemical disinfectant or antiseptic action

3.2.1
bactericide
product that irreversibly inactivates vegetative bacteria under defined conditions

Note 1 to entry: The adjective derived from “bactericide” is “bactericidal”.

3.2.2
bactericidal activity
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

3.2.3
bacteriostatic activity
capability of a product to inhibit the growth of viable bacterial cells of relevant test organisms under defined conditions

Note 1 to entry: The above term is used in a standard but cannot be used for claims according to Clause 7 c).

3.2.4
fungicide
product that irreversibly inactivates fungi (moulds and yeasts) and their spores under defined conditions

Note 1 to entry: The adjective derived from “fungicide” is “fungicidal”.

3.2.5
fungicidal activity
capability of a product or active substance to produce a reduction in the number of viable yeast cells and mould spores of relevant test organisms under defined conditions

3.2.6
fungistatic activity
capability of a product to inhibit the germination of mould spores and/or the growth of viable yeast cells of relevant test organisms under defined conditions

Note 1 to entry: The above term is used in a standard but cannot be used for claims according to Clause 7 c).

3.2.7
microbicide
product that irreversibly inactivates vegetative bacteria and/or bacterial endospores and/or fungi (moulds and/or yeasts, including fungal spores) and/or viruses under defined conditions

Note 1 to entry: The above term is a general term, not to be used for claims (see Clause 7, c)).

3.2.8
microbicidal activity
capability of a product or active substance to produce under defined test conditions a reduction in the number of relevant test organisms including viable bacterial cells and/or viable vegetative yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles

Note 1 to entry: The above term is a general term, not to be used for claims according to Clause 7, c).

3.2.9
mycobactericide
product that irreversibly inactivates mycobacteria under defined conditions

Note 1 to entry: The adjective derived from “mycobactericide” is “mycobactericidal”.

3.2.10
mycobactericidal activity
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

3.2.11
phagocidal activity
capability of a product or active substance to produce a reduction in the number of infectious bacteriophage particles of relevant test organisms under defined conditions

3.2.12
sporicide
product that irreversibly inactivates bacterial endospores under defined conditions

Note 1 to entry: The adjective derived from “sporicide” is “sporicidal”.

3.2.13
sporicidal activity
capability of a product or active substance to produce a reduction in the number of viable bacterial endospores of relevant test organisms under defined conditions

3.2.14
sporistatic activity
capability of a product to inhibit the germination of bacterial endospores under defined conditions

Note 1 to entry: The above term is used in a standard but cannot be used for claims according to Clause 7.

3.2.15
tuberculocide
product that irreversibly inactivates *Mycobacterium tuberculosis* under defined conditions

Note 1 to entry: The adjective derived from “tuberculocide” is “tuberculocidal”.

Note 2 to entry: The test organism used for demonstrating the activity is *Mycobacterium terrae*.

3.2.16
tuberculocidal activity
capability of a product or active substance to produce a reduction in the number of viable cells of the test organism *Mycobacterium terrae* under defined conditions

3.2.17
virucide
product that irreversibly inactivates viruses under defined conditions

Note 1 to entry: The adjective derived from “virucide” is “virucidal”.

Note 2 to entry: The term virucide includes the inactivation of vertebrate viruses and/ or bacteriophages.

3.2.18
virucidal activity
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

Note 1 to entry: 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.

3.2.19
yeasticide
product that irreversibly inactivates yeasts under defined conditions

Note 1 to entry: The adjective derived from “yeasticide” is “yeasticidal”.

3.2.20
yeasticidal activity
capability of a product or active substance to produce a reduction in the number of viable yeast cells of relevant test organisms under defined conditions

3.3 General terms

3.3.1
additional test conditions
test conditions that are optional and not obligatory, that may be used for additional product claims and that may be found in the same standard or in an additional standard

3.3.2
Interfering substance
see “soiling”

3.3.3
neutralizer
chemical agent or formulation that suppresses the residual microbicidal activity of a product or active substance within a specific test but does not inactivate or inhibit the test organism

3.3.4
product
formulation used as a chemical disinfectant or antiseptic

Note 1 to entry: A ready-to-use product is a product used undiluted.

3.3.5
soiling
the term “soiling” is represented in the standards by the term “interfering substance”

3.3.5.1
clean conditions
conditions representative of surfaces which have been cleaned satisfactorily and/or are known to contain minimal levels of organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called “low level soiling”. The term “low level soiling” has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.5.2
dirty conditions
conditions representative of surfaces which are known to or may contain organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called “high level soiling”. The term “high level soiling” has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.6
test organism
strain of a microorganism selected for testing products or active substances within a standardized test

Note 1 to entry: For the purpose of this European Standard, the term microorganism includes vegetative bacteria, bacterial spores, yeasts, mould spores and viruses.

4 Procedures for claiming activity

4.1 Category of tests

The tests are categorised on a modular basis as follows:

— **Phase 1 tests** are quantitative suspension tests to establish that active substances or products under development have bactericidal, fungicidal or sporicidal activity without regard to specific areas of application. Phase 1 tests cannot be used for any product claim.

— **Phase 2** comprises two steps:

a) **Phase 2, step 1 tests** are quantitative suspension tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity under simulated practical conditions appropriate to its intended use;

b) **Phase 2, step 2 tests** are quantitative laboratory tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity when applied to a surface or skin under simulated practical conditions (e.g. surface, instrument, handwash and handrub tests);

— **Phase 3 tests** are field tests under practical conditions. Applicable methodologies for this type of test are not yet available, but may be developed in the future. Guidance on the design of phase 3 tests and the use of data from phase 3 tests is provided in Annex C.

NOTE In the following phase 2, step 1 is mostly shortened to “2,1” or “2/1” and phase 2, step 2 to “2,2” or “2/2”.

The phase 2, step 1 tests prove the irreversible inactivation of microorganisms. This test design provides relevant information about the activity of the product against microorganisms in suspension. Desiccated microorganisms may be stressed and may offer different challenges.

Phase 2, step 2 tests provide information about the activity against desiccated microorganisms on inanimate surfaces or on living tissues or against non-desiccated microorganisms on living tissues.

Tests shall be carried out under the minimum requirements/obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, contact time and interfering substances) shall be carried out as specified in the standard.

Phase 2, step 1 and phase 2, step 2 tests are generally needed in combination to support efficacy claims for disinfectants or antiseptics. Only in exceptional cases deviation from this principle is allowed (see relevant applications below and Annex B). Both results shall be taken into account in determination of the label claim.

4.2 General

4.2.1 In order to determine that an active substance or a product under development has microbicidal properties, it shall be tested in accordance with and shall conform to the relevant test conditions and requirements of the European phase 1 standards.

4.2.2 For the medical area see 4.3, for the veterinary area see 4.4, for the food, industrial, domestic and institutional areas see 4.5. The standards specified in 4.3, 4.4 or 4.5 may be used to support product claims of activity/conformity to this European Standard on the basis of criteria specified in those standards (minimum requirements, obligatory and/or specified additional conditions).

4.2.3 When recommendations for use are made based on the standards referenced in EN 14885 these shall be supported by test results relevant for this recommendation, e.g. a result for 30 min contact time does not allow a claim for 10 min (but a result for 10 min allows a claim for 30 min if the same product concentration is recommended for use). It is not possible to extend or shorten the time for use beyond the limits (i.e. the minimum and maximum *additional* contact times in the medical, veterinary, food, industrial, domestic and institutional areas) specified in standards referred to in EN 14885.

4.2.4 The product marketed shall be equivalent to the one tested. Equivalent means that it contains the same active substances in the same quantity and that only substances of no proven impact on the product’s activity such as fragrance or colouring are non-identical.

4.2.5 Where there is no appropriate standard for an application within a specific area, a standard from another area may be recommended for use. If later on an appropriate standard is published, this new standard shall be used.

4.2.6 Where in EN 14885 no standard exists for a specific activity in an area (e.g. medical), a standard from another area (e.g. veterinary) may be used and test conditions modified for relevance to the area of application to match the specific application. In certain cases it may be necessary or recommendable to modify even the test organism(s) to match the requirements of the area. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the standard.

4.2.7 Where in EN 14885 there is no intention to develop a test for specific product activity, the methodology in a standard specified in EN 14885 may be used and test conditions modified to match the required activity. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the standard.

4.2.8 Where in EN 14885 no standard exists that specifies the use conditions for a specific product activity in an area (e.g. activity at a temperature or contact time not specified in the obligatory or additional test conditions), a standard may be used with the relevant test condition modified for relevance to the area of application. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the standard.

4.2.9 The reduction of the number of test organisms caused by a product is generally expressed as decimal logarithm (lg) with two significant figures after the comma.

4.3 Chemical disinfectants and antiseptics for use in the medical area

4.3.1 General

In order to make a claim that a product has disinfectant properties, suitable for use in the medical area, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 1 as specified for the particular type of product and its spectrum of activity (e.g. bactericidal, fungicidal etc.).

Table 1 — Medical area – Standard test methods to be used to substantiate claims for products

<table>
<tr><td rowspan="4">Type of activity</td><td rowspan="4">Phase step</td><td colspan="8">Product Claim / Field of Application</td></tr>
<tr><td rowspan="3">Hygienic Handrub</td><td rowspan="3">Hygienic Handwash</td><td rowspan="3">Surgical Handrub or -wash</td><td colspan="2">Surface Disinfection</td><td rowspan="3">Instrument Disinfection</td><td rowspan="3">Textile Disinfection</td><td rowspan="3">Water Treatment for Control of Legionella</td></tr>
<tr><td colspan="2">mechanical action</td></tr>
<tr><td>without</td><td>with</td></tr>
<tr><td rowspan="2">Bacteri-cidal</td><td>2,1</td><td colspan="3">EN 13727 (handrub products under clean, handwash products under dirty conditions)</td><td colspan="2">EN 13727</td><td>EN 13727</td><td>EN 13727</td><td>***</td></tr>
<tr><td>2,2</td><td>EN 1500</td><td>EN 1499</td><td>EN 12791</td><td>EN 13697 [a]</td><td>*</td><td>EN 14561</td><td>*</td><td>***</td></tr>
<tr><td rowspan="2">Yeasticidal</td><td>2,1</td><td colspan="3">EN 13624 (handrub products under clean, handwash products under dirty conditions)</td><td colspan="2">EN 13624</td><td>EN 13624</td><td>EN 13624</td><td>***</td></tr>
<tr><td>2,2</td><td colspan="3">***</td><td>EN 13697 [a]</td><td>*</td><td>EN 14562</td><td>*</td><td>***</td></tr>
<tr><td rowspan="2">Fungicidal</td><td>2,1</td><td colspan="3">***</td><td colspan="2">EN 13624</td><td>EN 13624</td><td>EN 13624</td><td>***</td></tr>
<tr><td>2,2</td><td colspan="3">***</td><td>EN 13697 [a]</td><td>**</td><td>EN 14562</td><td>*</td><td>***</td></tr>
</table>

Type of activity	Phase step	Product Claim / Field of Application							
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection		Instrument Disinfection	Textile Disinfection	Water Treatment for Control of Legionella
					mechanical action				
					without	with			
Tuber culocidal	2,1	EN 14348	EN 14348	***	EN 14348		EN 14348	EN 14348	***
	2,2	***			**	**	EN 14563	*	***
Myco-bacteri-cidal	2,1	EN 14348	EN 14348	***	EN 14348		EN 14348	EN 14348	***
	2,2	***			**	**	EN 14563	*	***
Virucidal	2,1	EN 14476	EN 14476	***	EN 14476		EN 14476	EN 14476	***
	2,2	**	**	***	*		**	*	***
Sporicidal aerobic	2,1	***			*		*	**	***
	2,2	***			*	**	**	***	***
Sporicidal anaerobic	2,1	***			*		*	**	***
	2,2	***			*	**	**	***	***
Legionella	2,1	***			***		***	***	EN 13623

a See 4.3.2.6.

* Work item approved.

** No work item yet approved but relevant standards may become available in the future

*** No intention to develop a test.

As stated under 4.1, phase 2, step 1 and phase 2, step 2 tests shall be passed for any claim if standards are available. All products in the medical area shall pass the standards for bactericidal and yeasticidal activity as a minimum requirement except those products exclusively claiming activity against Legionella or fungicidal or sporicidal activity. A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in 4.3.2 and in Tables 1a, 1b, 1c and 1d. It is also stated, if for a certain field of application more than one standard shall be passed (see also Annex B).

4.3.2 Fields of application / Standards necessary to be passed for basic and additional label claims

4.3.2.1 General

In 4.3.2.2 to 4.3.2.9 the obligatory and additional standards for a defined claim are described. The Tables 1a, 1b, 1c and 1d give an overview of the standards relevant for the medical area and their main features, such as test organisms, temperature, soiling, contact time and reduction. The term “soiling” means always the soiling used within the medical area (e.g. 5.2.2.8 in EN 13727) even if a standard from another area (e.g. food) is used. In Table 1d specific aspects how to use EN 14348 for the different fields of application are laid down.

Sporicidal (aerobic and anaerobic) test methods are under development.

4.3.2.2 Hygienic handrub

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 1500 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity/Limited spectrum virucidal activity	EN 14476 (2/1)

NOTE Activity on mould spores is not regarded relevant for hygienic handrub products.

4.3.2.3 Hygienic handwash

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 1499 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity/Limited spectrum virucidal activity	EN 14476 (2/1)

NOTE Activity on mould spores is not regarded relevant for hygienic handwash products.

4.3.2.4 Surgical handrub and handwash

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 12791 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)

NOTE Activity on mould spores and viruses is not regarded necessary since surgical handrub and surgical handwash are predominantly used to reduce the number of the resident flora which does not include those microorganisms.

4.3.2.5 Instrument disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 14561 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 14562 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 14562 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1), EN 14563 (2/2)
Virucidal activity	EN 14476 (2/1)

4.3.2.6 Surface disinfection without mechanical action

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1)
Yeasticidal activity	EN 13624 (2/1)
Bactericidal / Yeasticidal	EN 13697 (2/2) [a]
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 13697 (2/2) [a]
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity	EN 14476 (2/1)
[a] This European Standard does not specify test conditions for surface disinfection (without mechanical action) in the medical area, in such case, temperature is between 4 °C to 30 °C, soiling: clean conditions or dirty condition for the medical area, contact time: 5 min or shorter for surfaces that are likely to come into contact with patients or staff close to the patient and “multitouch” surfaces, for other surfaces not longer than 60 min, lg reduction: ≥ 4,0 for bactericidal activity and ≥ 3,0 for yeasticidal and fungicidal activity, test organisms, those mentioned in the standard.	

4.3.2.7 Surface disinfection with mechanical action

European Standards to be passed [a]	
Bactericidal activity	EN 13727 (2/1)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1)
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity	EN 14476 (2/1)
[a] A phase 2, step 2 test is under development.	

4.3.2.8 Textile disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity	EN 14476 (2/1)

4.3.2.9 Water treatment for control of Legionella

See EN 13623 in Table 1a below, phase 2 step 2 tests are inappropriate, since these products are added to water.

Table 1a — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for bactericidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 1499 2,2	Minimum test conditions				
	Escherichia coli K12, NCTC 10538 (=NCIMB 10083)	Tested on the skin	between 30 s and 1 min	None	Product > reference soap with 1 min wash (P = 0,01)
EN 1500 2,2	Minimum test conditions				
	Escherichia coli K12, NCTC 10538	Tested on the skin	between 30 s and 1 min	None	Product not < Propan-2-ol 60 % vol with 2 × 3 ml/30 s each (P = 0,1)
EN 12791 2,2	Minimum test conditions				
	Normal skin flora	Tested on the skin	between 1 min and 5 min	None	<u>Immediate effect:</u> Product not < Propan-1-ol 60 % vol with n × 3 ml/3 min (P = 0,1)
					<u>3-hour effect:</u> Product not < Propan-1-ol 60 % vol ($2P$ = 0,01)
	Additional test conditions				
	None	None	None	None	<u>Sustained effect</u>: Product > Propan-1-ol 60 % vol with n × 3 ml/3 min after 3 h ($2P$ = 0,01)

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 13727 2,1	Hygienic handwash and handrub				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* K12 NCTC 10538 *Enterococcus hirae* ATCC 10541	at 20 °C	between 30 s and 1 min	Clean conditions (handrub): bovine albumin: 0,3 g/L Dirty conditions (handwash): bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0 for handrub products ≥ 3,0 for handwash products
	Surgical handwash and handrub				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* K12 NCTC 10538 *Enterococcus hirae* ATCC 10541	at 20 °C	between 1 min and 5 min	Clean conditions (handrub): bovine albumin: 0,3 g/L Dirty conditions (handwash): bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Instrument disinfection				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 When temperature is 40 °C or higher: only *Enterococcus faecium* ATCC 6057	between 20 °C and 70 °C	no longer than 60 min	Clean conditions bovine albumin: 0,3 g/L Dirty conditions bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Surface disinfection				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	between 4 °C and 30 °C	no longer than 5 min (for surfaces in contact with patient or medical staff **or** no longer than 60 min (for other surfaces)	Clean conditions bovine albumin: 0,3 g/L Dirty conditions bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	-

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 13623 2,1	Obligatory test conditions				
	Legionella pneumophila serogroup 1, Philadelphia (NCTC 11192; ATCC 33152).	30 Cooling Water	15 h Slow acting products 1 h Fast acting products	For testing, 0,05 % yeast extract solution Buffered ferrous hard water for treatment of cooling water	≥ 4,0
		20 Water for General Purposes		For testing, 0,05 % yeast extract solution Hard water for general purposes	
	The following additional test conditions are permitted:				
	Any Legionella strain, e.g. *Legionella pneumophila* serogroup 1 Benidorm (NCTC 12006, ATCC 43108)	No additional temperatures are considered relevant to this test	2 h, 6 h, 40 h, 48 h		
EN 14561 2,2	Obligatory test conditions				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	20	60 min	<u>Clean conditions:</u> bovine albumin 0,3 g/L <u>Dirty conditions:</u> bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 5,0
	The following additional test conditions are permitted:				
		10 °C-steps (max. 60 °C)	5 min, 15 min, 30 min		

Table 1b — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for fungicidal and yeasticidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 13624 2,1	Hygienic handwash and handrub				
	Candida albicans ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	at 20 °C	between 30 s and 1 min	Clean conditions (handrub): bovine albumin: 0,3 g/L Dirty conditions (handwash): bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 4,0 for handrub products ≥ 2,0 for handwash products
	Surgical handwash and handrub				
	Candida albicans ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	at 20 °C	between 1 min and 5 min	Clean conditions (handrub): bovine albumin: 0,3 g/L Dirty conditions (handwash): bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 4,0
	Instrument disinfection				
	Candida albicans ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	between 20 °C and 70 °C	no longer than 60 min	Clean conditions bovine albumin: 0,3 g/L Dirty conditions bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 4,0

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
	Surface disinfection				
	Candida albicans ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	between 4 °C and 30 °C	no longer than 5 min (for surfaces in contact with patient or medical staff **or** no longer than 60 min (for other surfaces)	Clean conditions bovine albumin: 0,3 g/L Dirty conditions bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 4,0
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	-
EN 14562 2,2	Obligatory test conditions				
	Candida albicans ATCC 10231 and *Aspergillus niger*[a] ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	20	60 min	Clean conditions: bovine albumin 0,3 g/L Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C steps (max. 60°C)	5 min, 15 min, 30 min		

[a] The name of "*Aspergillus niger* ATCC 16404 has been changed to "*Aspergillus brasiliensis* ATCC 16404".

Table 1c — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for virucidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 14476 2,1	Hygienic handrub and handwash				
	Poliovirus type 1, LSc-2ab (Picornavirus) *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine Norovirus,* strain S99 Berlin **Limited spectrum virucidal activity:** *Adenovirus,* strain Adenoid 75, ATCC VR-5 *Murine Norovirus,* strain S99 Berlin	at 20 °C	between 30 s and 2 min	Clean conditions (handrub): bovine albumin 0,3 g/L Dirty conditions (handwash): bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Instrument disinfection				
	Poliovirus type 1, LSc-2ab (Picornavirus) *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine Norovirus,* strain S99 Berlin **when Temperature is 40°C or higher, only** *Murine Parvovirus*, minute virus of mice, strain Crawford, ATCC VR-1346	between 20 °C and 70 °C	no longer than 60 min	Clean conditions: bovine albumin 0,3 g/L and/or Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Surface disinfection				
	Poliovirus type 1, LSc-2ab (Picornavirus) *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine Norovirus,* strain S99 Berlin	between 4 °C and 30 °C	no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions: bovine albumin 0,3 g/L and/or Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Textile disinfection				
	Murine Parvovirus, minute virus of mice, strain Crawford, ATCC VR-1346	between 30 °C and 70 °C	no longer than 20 min	Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	n.a.

Table 1d — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for mycobactericidal and tuberculocidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 14348 2,1	**mycobactericidal activity:** *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755 **or tuberculocidal activity**: only *Mycobacterium terrae* ATCC 15755	20	60 min	Clean conditions: bovine albumin 0,3 g/L Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps	5 min, 15 min, 30 min		
	Obligatory test conditions				
EN 14563 2,2	**mycobactericidal activity:** *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755 **or tuberculocidal activity**: only *Mycobacterium terrae* ATCC 15755	20	60 min	Clean conditions: bovine albumin 0,3 g/L Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps (max. 60 °C)	5 min, 15 min, 30 min		

EN 14348 can be used to demonstrate mycobactericidal and/or tuberculocidal activity for hygienic handrub and – wash products, surface disinfectants and disinfectants for textile. The contact times shall be adapted according to the principles described in EN 13727 and EN 13624.

4.3.3 Tests shall be carried out under the minimum requirements/obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, contact time, diluents and interfering substances) shall be carried out as specified in the standard. Additional claims which can be made are given in 4.3.2 and the Tables 1a, 1b, 1c and 1d. Products that are tested under clean conditions are generally meant to be used on visibly clean surfaces, incl. living tissues like hands.

If for a defined claim it is necessary to pass more than one standard, the test conditions shall be the same in all the standards (e.g. instrument disinfection bactericidal and fungicidal activity: 4 min contact time, clean conditions, 30 °C; these test conditions are tested in EN 13727 and EN 13624 as well as in EN 14561 and EN 14562), the contact time may be shorter than the one claimed in accordance with 4.2.3.

4.3.4 Medical devices are subject to the European Directive 93/42/EEC [2] which requires that the product carry a CE mark. Disinfectants which are intended specifically by its manufacturer to be used together with medical devices are themselves regarded as medical devices and therefore these products, as well as conforming to the instrument or surface disinfection standards in Table 1, are also required to carry a CE mark.

4.4 Chemical disinfectants and antiseptics for use in the veterinary area

4.4.1 In order to claim that a product has disinfectant properties, suitable for use in the veterinary area, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 2 as specified for the particular type of product and its spectrum of activity (e.g. bactericidal, fungicidal etc.)

Table 2 — Veterinary area – Standard test methods to be used to substantiate claims for products

Type of activity	Phase step	Product Claim / Field of Application				
		General Surface Disinfection mechanical action		Teat Disinfection	Disinfection of Equipment by Immersion	Hygienic Hand-wash and –rub; Surgical Hand-wash and -rub [a]
		without	with			
Bactericidal	2,1	EN 1656	**	EN 1656	EN 1656	EN 13727
	2,2	EN 14349 non-porous	**	***	EN 14349	EN 1499 or EN 1500 or EN 12791
	2,2	EN 16437 porous		***	***	***
Fungicidal	2,1	EN 1657	**	***	EN 1657	***
	2,2	EN 16438 non-porous		***	EN 16438 non-porous	***
	2,2	**porous	**	***	***	***
Yeasticidal	2,1	EN 1657	**	***	EN 1657	EN 13624
	2,2	EN 16438 non-porous		***	EN 16438 non-porous	***
	2,2	**porous	**	***	***	***
Mycobactericidal	2,1	EN 14204	**	***	EN 14204	***
	2,2	**non-porous	**	***	**	***
	2,2	**porous		***	***	***
Virucidal	2,1	EN 14675	**	***	EN 14675	EN 14476
	2,2	**non-porous	**	***	**	***
	2,2	**porous		***	***	***
Sporicidal	2,1	**	**	***	**	***
	2,2	**non-porous	**	***	**	***
	2,2	**porous	**	***	***	***

[a] See 4.3.2.2 or 4.3.2.3 or 4.3.2.4 for details.

** No work item yet approved but relevant standards may become available in the future.

*** No intention to develop a test.

In any case the product shall pass the standards for bactericidal activity as a minimum requirement except those products exclusively claiming fungicidal, sporicidal or virucidal activity. A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in Table 2a, 2b, 2c and 2d. If for a certain field of application more than one standard has to be passed it is indicated in notes to the tables (see also Annex B).

Table 2a — Veterinary area – Test conditions and requirements of standard test methods to be used to substantiate claims for bactericidal activity of products*)*

EN reference **Phase, step**	**Test organisms**	**Temperature** (°C)	**Contact time** (min)	**Interfering substances**	**Reduction** (lg)
	Obligatory test conditions				
EN 1656 2,1	*Pseudomonas aeruginosa* ATCC 15442 *Proteus vulgaris* ATCC 13315 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	10	30	low-level soiling: 3,0 g/L bovine albumin or high-level soiling: 10,0 g/L bovine albumin and 10,0 g/L yeast extract	≥ 5,0
	The following additional test conditions are permitted				
	Additional test organisms	4, 20, 40	1, 5, 60	Any relevant interfering substance	≥ 5,0
	Obligatory test conditions				
EN 1656 2,1 For teat disinfection	*Escherichia coli* ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Streptococcus uberis* ATCC 19436	30	5	Skimmed milk 10, g/L	≥ 5,0
	The following additional test conditions are permitted:				
	Additional test organisms	4, 20, 40	1, 30, 60	Any relevant interfering substance	≥ 5,0

EN reference **Phase, step**	**Test organisms**	**Temperature** (°C)	**Contact time** (min)	**Interfering substances**	**Reduction** (lg)
	Obligatory test conditions				
EN 14349 2,2 Non-porous surface	*Pseudomonas aeruginosa* ATCC 15442 *Proteus vulgaris* ATCC 13315 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	10	30	low-level soiling: 3,0 g/L bovine albumin or high-level soiling: 10,0 g/L bovine albumin and 10,0 g/L yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	Additional test organisms	4, 20, 40	1, 5, 60	Any relevant interfering substance	≥ 4,0
EN 16437 2,2 Porous surface	Obligatory test conditions				
	Enterococcus hirae ATCC 10541 *Proteus vulgaris* ATCC 13315 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538	10	60	low level soiling 3,0 g/L bovine albumin	≥ 4,0
	The following additional test conditions are permitted				
	Additional test organisms	4, 20, 40	1, 5, 15, 30, 120	Any relevant interfering substance	≥ 4,0

Table 2b — Veterinary area – Test conditions and requirements of standard test methods to be used to substantiate claims for fungicidal[b] and yeasticidal[b] activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
EN 1657 2,1	Obligatory test conditions				
	Candida albicans ATCC 10231 and *Aspergillus niger* [a] ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	10	30	low-level soiling: 3,0 g/L bovine albumin high-level soiling: 10,0 g/L bovine albumin and 10,0 g/L yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	Additional test organisms	4 20 40	1 5 15 60	Any relevant interfering substance	≥ 4,0
EN 16438 2,2	Obligatory test conditions				
	Candida albicans ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	10	60	low-level soiling: 3,0 g/L bovine albumin high-level soiling: 10,0 g/L bovine albumin and 10,0 g/L yeast extract	≥ 3,0
	The following additional test conditions are permitted				
	Additional test organisms	4 20 40	5 30 120	Any relevant interfering substance	≥ 3,0

a The name of "*Aspergillus niger* ATCC 16404" has been changed to "*Aspergillus brasiliensis* ATCC 16404".

b In order to claim fungicidal or yeasticidal activity for general surface disinfection or disinfection by immersion it is necessary to provide data from both phase 2 step 1 EN 1657 and phase 2 step 2 EN 16438 tests.

Table 2c — Veterinary area – Test conditions and requirements of standard test methods to be used to substantiate claims for virucidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 14675 2,1	*Bovine Enterovirus Type 1* (ECBO) ATCC VR-248	10	30	low-level soiling: 3,0 g/L bovine albumin high-level soiling: 10,0 g/L bovine albumin and 10,0 g/L yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	Additional test organisms	4 20 40	1 5 60	Any relevant interfering substance	

Table 2d — Veterinary area – Test conditions and requirements of standard test methods to be used to substantiate claims for mycobactericidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 14204 2,1	*Mycobacterium avium* ATCC 12826	10	60	low-level soiling: 3,0 g/L bovine albumin high-level soiling: 10,0 g/L bovine albumin and 10,0 g/L yeast extract	≥ 4,0
	The following additional test conditions are permitted:				
	Additional test organisms	4 20 40	1 5 10 15 30 120	Any relevant interfering substance	

4.4.2 Tests shall be carried out under the obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, interfering substances, contact time) shall be carried out as specified in the standard. Additional conditions which can be used are given in Tables 2a to 2d.

If for a defined claim it is necessary to pass more than one standard, the test conditions shall be the same in all standards e.g. for a claim of additional bactericidal activity at 4 °C, 30 min contact time under high soiling conditions, test conditions in EN 1656 and EN 14349 shall be 30 min contact time, high soiling level and 4 °C.

4.5 Chemical disinfectants and antiseptics for use in food, industrial, domestic and institutional areas

4.5.1 In order to make a claim that a product has disinfectant properties, suitable for use in food, industrial, domestic and institutional areas, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 3 as specified for the particular type of product and its claimed spectrum of activity (e.g. bactericidal, fungicidal etc.). A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in Tables 3a to 3k.

4.5.2 Tests shall be carried out under the obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, contact time, temperatures, diluents and interfering substances) shall be carried out as specified in the standard. Additional claims which can be made are given in Tables 3, 3a to 3e.

Table 3 — Food, industrial, domestic and institutional area – Standard test methods to be used to substantiate claims for products

Type and/or purpose of product	Phase, step	Activity claims				
		Bactericidal	**Fungicidal**	**Yeasticidal**	**Virucidal**	**Sporicidal**
Surface disinfectant	2,1	EN 1276 (clean conditions) and	EN 1650 (clean conditions) and	EN 1650 (clean conditions) and	***	EN 13704
Clean conditions	2,2	EN 13697 (clean conditions) [b]	EN 13697 (clean conditions) [b]	EN 13697 (clean conditions) [b]	**	***
Surface disinfectant	2,1	EN 1276 (dirty conditions) and	EN 1650 (dirty conditions) and	EN 1650 (dirty conditions) and	***	EN 13704
Dirty conditions	2,2	EN 13697 (dirty conditions) [b]	EN 13697 (dirty conditions) [b]	EN 13697 (dirty conditions) [b]	**	***
Products used for “cleaning in place”	2,1	EN 1276	EN 1650	EN 1650	EN 13610 (bacteriophages)	EN 13704
Hygienic handwash	2,1	EN 1276	***	EN 1650	***	***
	2,2	EN 1499	***	***	***	***
Hygienic handrub	2,1	EN 1276	***	EN 1650	***	***
	2,2	EN 1500	***	***	***	***
Wipes	2,1	EN 1276	***	***	***	***
	2,2	**	***	***	***	***
Products for use in breweries [a]	2,1	EN 1276 (breweries)	EN 1650 (breweries)	EN 1650 (breweries)	***	EN 13704
	2,2	EN 13697 (breweries)	EN 13697 (breweries)	EN 13697 (breweries)	**	**
Products used in the beverage and	2,1	EN 1276 (beverage)	EN 1650 (beverage)	EN 1650 (beverage)	***	EN 13704
soft drinks industry [a]	2,2	EN 13697 (beverage)	EN 13697 (beverage)	EN 13697 (beverage)	**	**
Products for use in dairies [a]	2,1	EN 1276 (dairies)	EN 1650 (dairies)	EN 1650 (dairies)	EN 13610 (phages)	EN 13704
	2,2	EN 13697 (dairies)	EN 13697 (dairies)	EN 13697 (dairies)	***	**

Type and/or purpose of product	Phase, step	Activity claims				
		Bactericidal	Fungicidal	Yeasticidal	Virucidal	Sporicidal
Products used in manufacture	2,1	EN 1276 (cosmetics)	EN 1650 (cosmetics)	EN 1650 (cosmetics)	***	EN 13704
of cosmetics [a]	2,2	EN 13697 (cosmetics)	EN 13697 (cosmetics)	EN 13697 (cosmetics)	***	***

a The obligatory conditions have to be carried out before additional conditions for a specific use.

b Where applicable.

** No work items are yet approved but relevant standards may become available in the future.

*** No intention to develop a test.

Table 3a — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods to be used to substantiate claims for bactericidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 1276 2,1	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541	20	5	Clean conditions: bovine albumin: 0,3 g/L Dirty conditions: bovine albumin: 3,0 g/L	≥ 5,0
	The following additional test conditions are permitted:				
	Salmonella typhimurium ATCC 13311 *Lactobacillus brevis* DSM 6235 *Enterobacter cloacae* DSM 6234 Other additional strains are permitted	between 18°C and 25°C	1 or 15 or 30 or 60	1 % reconstituted skimmed milk or 10,0 g/L yeast extract or 10,0 g/L sucrose or pH 5 and pH 9 buffer solutions or 5,0 g/L Sodium dodecyl sulphate	≥ 5,0

EN reference **Phase, step**	**Test organisms**	**Temperature** (°C)	**Contact time** (min)	**Interfering substances**	**Reduction** (lg)
	Obligatory test conditions				
EN 13697 2,2	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541	20	5	Clean conditions: bovine albumin: 0,3 g/L Dirty conditions: bovine albumin: 3,0 g/L	≥ 4,0
	The following additional test conditions are permitted:				
	Salmonella typhimurium ATCC 13311 *Lactobacillus brevis* DSM 6235 *Enterobacter cloacae* DSM 6234 Other additional strains are permitted	4 or 10 or 40	1 or 15 or 30 or 60	1 % reconstituted skimmed milk or 10,0 g/L yeast extract or 10,0 g/L sucrose or pH 5 and pH 9 buffer solutions or 5,0 g/L Sodium dodecyl sulphate	≥ 4,0

Table 3b — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods to be used to substantiate claims for fungicidal and yeasticidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 1650 2,1	*Candida albicans* ATCC 10231 (fungicidal) and *Aspergillus niger*[a] ATCC 16404 (fungicidal) or Candida albicans ATCC 10231 (yeasticidal)	20	15	Clean conditions: bovine albumin: 0,3 g/L Dirty conditions: bovine albumin: 3,0 g/L	≥ 4,0
	The following additional test conditions are permitted:				
	Saccharomyces cerevisiae ATCC 9763	4	1	1 % reconstituted skimmed milk	
	Saccharomyces cerevisiae DSM 70487	or 10	or 5	or 10,0 g/L yeast extract	
	var. diastaticus	or 40	or 30	or 10,0 g/L sucrose	
	Additional strains are permitted		or 60	or pH 5 and pH 9 buffer solutions	
				or 5,0 g/L Sodium dodecyl sulphate	

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 13697 2,2	*Candida albicans* ATCC 10231 (fungicidal) and *Aspergillus niger*[a] ATCC 16404 (fungicidal) or Candida albicans ATCC 10231 (yeasticidal)	20	15	<u>Clean conditions:</u> bovine albumin: 0,3 g/L <u>Dirty conditions:</u> bovine albumin: 3,0 g/L	≥ 3,0
	The following additional test conditions are permitted:				
	Saccharomyces cerevisiae ATCC 9763	4	1	1 % reconstituted skimmed milk	≥ 3,0
	Saccharomyces cerevisiae DSM 70487 var. diastaticus	10 40	5 30	or 10,0 g/L yeast extract or 10,0 g/L sucrose	
	Additional strains are permitted		60	or pH 5 and pH 9 buffer solutions or 5,0 g/L Sodium dodecyl sulphate	

[a] The name of "*Aspergillus niger* ATCC 16404" has been changed to "*Aspergillus brasiliensis* ATCC 16404".

Table 3c — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods to be used to substantiate claims for virucidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 13610 2,1	Bacteriophage P001 DSM 4262 Bacteriophage P008 DSM 10567	20	15	1 % acidic whey	≥ 4,0
	The following additional test conditions are permitted:				
		4 or 10 or 40	5 or 30 or 60	1 % reconstituted skimmed milk	≥ 4,0

Table 3d — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods to be used to substantiate claims for sporicidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 13704 2,1	Spores of *Bacillus subtilis* ATCC 6633	20	60	Clean conditions: 0,3 g/L bovine albumin	≥ 3,0
	The following additional test conditions are permitted:				
	Spores of *Bacillus cereus* ATCC 12826 Spores of *Clostridium sporogenes 51* CIP 7 939	4 or 10 or 40 75	5 or 15 or 30		≥ 3,0

Table 3e — Application of standards: dairies

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
CIP (*combined* cleaning and disinfection); e.g. tanks, pipes, filling machines	dirty surfaces, temperature > 40°C 15 min – 60 min	bactericidal fungicidal and/or yeasticidal phagocidal sporicidal	EN 1276 EN 1650 EN 13610 EN 13704	soiling: 3,0 g/L bovine albumin solution and/or 10,0 g/L reconstituted skimmed milk (dirty conditions) 40 °C 15 min and/or 30 min, and/or 60 min
CIP (disinfection after alkaline and/or acidic cleaning); e.g. tanks, pipes, filling machines	clean surfaces, room temperature or higher 5 min – 30 min	bactericidal fungicidal and/or yeasticidal phagocidal sporicidal	EN 1276 EN 1650 EN 13610 EN 13704	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumine solution and/or 10,0 g/L skimmed milk (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution and/or 10,0 g/L skimmed milk (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action (e.g. wiping)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution and/or 10,0 g/L skimmed milk (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min
NOTE 1 Wiping is with mechanical action, actually no test procedure available.				
NOTE 2 If EN 13704 is carried out under dirty conditions it is a deviation to the standard.				

Table 3f — Application of standards: food processing (e.g. meat, fish, prepared food)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. tanks, pipes, machines	dirty surfaces, 20° or ≥ 40 °C 15 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 20 °C and/or 40 °C 15 min and/or 30 min, and/or 60 min
CIP (disinfection after alkaline and/or acidic cleaning); e.g. tanks, pipes, machines	clean surfaces, room temperature or higher 5 min –30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping)	dirty surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action (e.g. wiping)	clean surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min and/or 30 min and/or 60 min
crate washers (crates, boxes, buckets, containers etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 30 min and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 10 °C and/or 20 °C 30 min, and/or 60 min
NOTE 1 Wiping is with mechanical action, actually no test procedure available. NOTE 2 If EN 13704 is carried out under dirty conditions it is a deviation to the standard				

Table 3g — Application of standards: alcoholic beverages (e.g. beer, wine)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. pipes, tanks, filler	dirty surfaces, 4 °C – 20 °C 15 min – 60 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650	soiling: 3,0 g/L bovine albumin solution or 10,0 g/L yeast extract (dirty conditions) 4 °C and/or 20 °C 15 min and/or 30 min, and/or 60 min
disinfection (CIP) after alkaline and/or acidic cleaning; e.g. pipes, tanks, filler	clean surfaces, 4 °C – 20 °C 5 min – 30 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650	soiling: 0,3 g/L bovine albumin solution (clean conditions) 4 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650 and EN 13697	soiling: 3,0 g/L bovine albumin solution or 10,0 g/L yeast extract (dirty conditions) 4 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 4 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650 and EN 13697	soiling: 3,0 g/L bovine albumin solution or 10,0 g/L yeast extract (dirty conditions) 4 °C and/or 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 4 °C and/or 20 °C 30 min and/or 60 min
NOTE If EN 13704 is carried out under dirty conditions it is a deviation to the standard.				

Table 3h — Application of standards: non-alcoholic beverages (e.g. mineral water, soft drinks)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. pipes, tanks, filler, mixer	dirty surfaces, temperature ≥ 40 °C 15 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/L bovine albumin solution or 10,0 g/L saccharose (dirty conditions) 40 °C 15 min and/or 30 min, and/or 60 min
disinfection (CIP) after alkaline and/or acidic cleaning; e.g. pipes, tanks, filler, mixer	clean surfaces, room temperature or higher 5 min – 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution or 10,0 g/L saccharose (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
surface disinfection by spraying and/or foaming (e.g. transport - filling or packaging machines, general equipment)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution or 10,0 g/L saccharose (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min
NOTE If EN 13704 is carried out under dirty conditions it is a deviation to the standard.				

Table 3i — Application of standards: food professional handling (e.g. professional kitchen)

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined surface cleaning and disinfection by spraying and/or foaming (e.g. general equipment)	dirty surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. general equipment)	clean surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined surface cleaning and disinfection with mechanical action (e.g. wiping of working surfaces)	dirty surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action (e.g. wiping of working surfaces)	clean surfaces room temperature and low temperature (10 °C) 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 10 °C and/or 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
dish washing machines (dishes, cutlery, cookware, boxes, buckets etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal	EN 1276 EN 1650	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumine solution (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min
NOTE 1 Wiping is with mechanical action, actually no test procedure available.				
NOTE 2 If EN 13704 is carried out under dirty conditions it is a deviation to the standard.				

Table 3j — Application of standards: pharmaceutical industry

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. tanks, pipes, machines	dirty surfaces, 20 °C or ≥ 40 °C 15 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 20 °C and/or 40 °C 15 min and/or 30 min, and/or 60 min
CIP (disinfection after alkaline and/or acidic cleaning); e.g. tanks, pipes, machines	clean surfaces, room temperature or higher 5 min – 30 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming [a] (e.g. general equipment)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming [a] (e.g. general equipment)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action [a] (e.g. wiping of working surfaces)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
surface disinfection with mechanical action [a] (e.g. wiping of working surfaces)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
crate washers (crates, boxes, buckets, tablets etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/L bovine albumin solution (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 3,0 g/L bovine albumine solution (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal virucidal	EN 1276 EN 1650 EN 13704 EN 14476 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min
NOTE 1 Wiping is with mechanical action, actually no test procedure available. NOTE 2 If EN 13704 is carried out under dirty conditions it is a deviation to the standard.				
[a] In clean rooms sterile and sterile packed disinfectants / detergent disinfectants have to be used.				

Table 3k — Application of standards: cosmetic industry

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
combined cleaning and disinfection (CIP); e.g. tanks, pipes, machines	dirty surfaces, 20 °C or ≥ 40 °C 15 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/L bovine albumin solution or 5,0 g/L Sodium dodecyl sulphate (dirty conditions) 20 °C and/or 40 ° C 15 min and/or 30 min, and/or 60 min
CIP (disinfection after alkaline and/or acidic cleaning); e.g. tanks, pipes, machines	clean surfaces, room temperature or higher 5 min – 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C and/or 40 °C 5 min and/or 15 min, and/or 30 min
combined surface cleaning and disinfection by spraying and/or foaming (e.g. general equipment)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution or 5,0 g/L Sodium dodecyl sulphate (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection by spraying and/or foaming (e.g. general equipment)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
combined surface cleaning and disinfection with mechanical action (e.g. wiping of working surfaces)	dirty surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumin solution or 5,0 g/L Sodium dodecyl sulphate (dirty conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min
surface disinfection with mechanical action (e.g. wiping of working surfaces)	clean surfaces room temperature 5 min – 60 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 5 min and/or 15 min, and/or 30 min, and/or 60 min

Field of application	Prerequisites in practice	Activity claims	Standards	Test conditions to support the intended use
crate washers (crates, boxes, buckets, tablets etc.)	dirty equipment temperature ≥ 40 °C	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704	soiling: 3,0 g/L bovine albumin solution or 5,0 g/L Sodium dodecyl sulphate (dirty conditions) 40 °C 1 min and/or 5 min
soaking single stage cleaning and disinfection without mechanical action (removal of loose soil prior to soaking is mandatory)	dirty surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 3,0 g/L bovine albumine solution or 5,0 g/L Sodium dodecyl sulphate (dirty conditions) 20 °C 30 min and/or 60 min
soaking disinfection without mechanical action (removal of loose soil and cleaning prior to soaking is mandatory)	clean surfaces room temperature > 30 min	bactericidal fungicidal and/or yeasticidal sporicidal	EN 1276 EN 1650 EN 13704 and EN 13697	soiling: 0,3 g/L bovine albumin solution (clean conditions) 20 °C 30 min and/or 60 min
NOTE 1 Wiping is with mechanical action, actually no test procedure available. NOTE 2 If EN 13704 is carried out under dirty conditions it is a deviation to the standard.				

5 Precision of the test methods (Repetitions)

With many of the test methods of CEN/TC 216 ring trials have been performed to determine their feasibility and to evaluate their imprecision. The results and the statistical analyses of the ring trials are summarized in each of those standards, including ensuing recommendations. The current imprecision of the standards is within acceptable tolerance. However, within the culture of best practice, the following advice should lead to improved precision.

a) The testing laboratory has to be compliant with an adequate quality assurance system (e.g. EN ISO/IEC 17025) which includes proficiency testing and the regular participation at ring trials where available.

b) Other options to further improvement are repetition of the test and/or the inclusion of 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 = > 5,23 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. “> 5,23 lg” is used for calculation as “5,23 lg”. All lg values are converted to real numbers, e.g. 5,23 lg to about 170 000. 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 (for example hygienic handrub).

c) 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.

d) 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 c). If a ranking is not possible only the results of the test showing the highest minimum active concentration should be repeated.

6 Proficiency testing

It is advisable to establish an instrument to measure the proficiency of the laboratory staff and to verify that the laboratory, under standard conditions, produces consistently results which comply with the specifications of the proficiency tests. This is often included within a laboratory quality assurance system. A proficiency test consists of performing the suspension and/or surface tests with certain established reference substances (active substances or products) at certain established concentrations.

The proficiency test is a tool for the laboratory to ensure that the whole internal processes (including strains preservation, internal procedures, qualification of the personnel, etc.) are well implemented and kept under control through periodical quality control checks.

The proficiency test should be performed periodically (at least once per year), and it should be considered part of the quality control system.

7 Minimum information for the user including labelling regarding efficacy claims and use recommendations

The manufacturer shall provide at least the following information:

a) the type and/or purpose of the product (hygienic handwash, chemical disinfectant for surfaces etc.);

b) the area and field of application:

   i) the area of application (medical, veterinary etc.);

   ii) the field of application (hygienic handrub, hard surfaces etc.);

c) the spectrum of activity (e.g. bactericidal, fungicidal); a general “microbicidal activity” cannot be claimed;

d) reference of the European Standards to which conformity is claimed (e.g. bactericidal (EN xx), fungicidal (EN xx)),

e) the recommended method(s) of application (use concentration(s), product diluent(s), volume to be applied, application procedure, contact time(s), temperature(s));

f) conditions of soiling as defined in 3.3.2.

The information a) to c) should be on the label. The other information may be given in an accompanying use instruction.

8 Changes in European Standards

8.1 Revision of European Standards

When a standard listed in Clause 2 is revised and a new edition published, it shall be used for new products or new claims for existing products. Its Foreword shall state the changes made. If no technical changes have been made it shall be stated that data obtained from the previous version are still valid.

If technical changes have been made that might impact on the results obtained when using the former version it shall be stated in the Foreword which tests using the new version shall be performed. For example, it may not be necessary to repeat all previous tests if changes refer to test conditions not effected by the technical changes in the revised version.

The above mentioned tests using the new version shall be carried out within 18 months after publication of the new version as European Standard. The publication date of the European Standard is indicated in the National Standards. After these 18 months, claims with reference to the previous are only allowed when there were no technical changes.

8.2 Impact of changes of EN 14885 on other European Standards

If EN 14885 is changed with regards to

— the interpretation of test results/ conclusion and the prerequisites for recommendations for use;

— the specification which standards have at least to be passed for a defined claim;

— the accepted level of imprecision of the test methods;

— the quality control for testing laboratories, and

— terms and definitions.

These changes shall be directly and immediately applied to all concerned standards, until they have been incorporated into the standards, e.g. at their next revision.

Annex A
(informative)

Recommendations on the use of terms and definitions in the area of disinfection and antisepsis

There are many terms which are used in the field of disinfection and antisepsis which may be confusing because these terms may have different meanings in different languages and countries.

Disinfectants and antiseptics are used to produce a state in which the number of living/viable microorganisms has been reduced to a level which:

a) is appropriate to the practical situation, e.g. a level low enough to limit the release of microorganisms in numbers which could cause transmission of infection or disease and/or could cause the deterioration of perishable goods;

b) is not necessarily sterile, i.e. free from all microorganisms including viruses.

At the present time there is no accepted definition to describe the state as defined in a) and b) above. The state is often referred to as “hygienic”, but this term can also be applied to other situations, e.g. cleaning.

Where a product which kills or inactivates microorganisms by action on their structure or metabolism is used in combination with a process of removal (i.e. washing process) of microorganisms from a surface, the total reduction of living microorganisms achieved should be sufficient to limit their release from the surface in order to prevent the transmission of infection and/or the deterioration of perishable goods under the conditions of intended application. Where this is achieved by application of a chemical product, that part of the process which involves inactivation of living microorganisms is referred to as “chemical disinfection”.

The following are other definitions which do not appear in the text of the standards but are commonly used in relation to disinfectants and antiseptics:

“Biocide” is an unspecific term applied to products related to the European “Regulation Concerning the Making Available on the Market and Use of Biocidal Products (EU) 528 / 2012” (BPR).

The terms “antibacterial, antifungal, antimicrobial, antiviral” may be used as common words (not as scientific terms). Since the mode of action is not precise, these terms cannot be used in a requirement for the activity or the efficacy of a product.

“Decontaminant/decontamination” are terms which are frequently used where radioactive substances have to be removed from organisms or items, and may be used where contaminant microorganisms are removed from items, mechanically or by a biocide. Decontamination is not a synonym of disinfection.

The term “sanitizer/sanitization” is used in some countries. No clear definition exists, so this term should be avoided in the field of antiseptics and disinfectants.

“Activity and efficacy” are both terms which relate to the effects provoked by the product (antiseptic or disinfectant) or the active substance on microorganisms. Both have to be measured if they are in the objective of a standard. Presently, it is possible to measure the activity of a product on defined microorganisms in specified experimental conditions. But efficacy implies the application of the product in order to reduce the number of present microorganisms to a level acceptable for a particular use. Efficacy is the result of the use of a product according to a defined application. No suitable methods exist presently to demonstrate with accuracy the overall effect (= efficacy) of this application of a product. In summary, it is possible to test a disinfectant (= activity), but not to evaluate disinfection.

The terms “sterility, sterile, sterilization, sterilant” fall outside the scope of activity of CEN/TC 216. Even if a product or active substance has been tested successfully for the whole spectrum of activities, including sporicidal activity, it cannot be regarded as a sterilant.

Annex B
(informative)

Recommendations on claims of activity on the basis of tests additional to or other than the tests specified in this European Standard

B.1 For any products which are included in the European "Regulation Concerning the Making Available on the Market and Use of Biocidal Products (EU) 528 / 2012" (BPR) [1], or any other relevant European directives or regulations for which specific activity is claimed, test data has to be approved by the regulatory authority and a product license obtained before the product can be marketed. In some cases it may be judged that the models specified in these standards are insufficient and/or inappropriate for the particular area of application. This can happen, for example, where disinfectants are used to treat surface-attached bio-films rather than surface-dried organisms, or the product is intended to be applied to a dry surface with mechanical action rather than by immersion or surface application without mechanical action.

B.2 In selecting an appropriate testing scheme to support a claim of specific activity the following should be considered:

a) where results of one phase and step are considered to provide sufficient information for the particular application, the other phase or phases may be omitted;

b) where claims for activity against specific organisms are made other than those called up in the European Standards e.g. *Escherichia coli* O157, these should be supported by tests against these species. Where available, strains from culture collections should be used for these tests and the test method should follow the appropriate phase 2, step 1 and phase 2, step 2 tests as closely as possible;

c) when the product dilution required to pass one phase or step is significantly higher than that required to pass the other phases or steps, the recommended use dilution should be chosen taking into account the intended use of the product in relation to the design of the tests. This can happen, for example where results from phase 2, step 1 and phase 2, step 2 tests are inconsistent with each other or with those of a valid field trial;

d) when the product dilution required to pass a test (e.g. a phase 2, step 1 test) against a particular test organism or under a particular set of test conditions (contact time, temperature etc.) is significantly higher than that required to pass the test against other test organisms and under other test conditions, the recommended use dilution should be chosen taking into account the intended use of the product in relation to the design of the tests.

B.3 In all situations as described in B.2 a) to d), the scientific or other justification for applying the scheme of testing should be given.

B.4 When required by the regulations (see B.1), approval of claims is at the discretion of the relevant regulatory authority.

Annex C
(informative)

Phase 3 tests

C.1 General

Phase 3 tests are field tests under practical conditions performed in addition to phase 2, step 1 and phase 2, step 2 tests. Validated methodology for this type of test is not available, but may be developed in the future. This annex sets out guidance in the form of factors to be considered in the design of field trials and when determining the acceptability of data derived from field trials in support of the claims made for a disinfectant or antiseptic. In the following only the term 'product' will be used.

C.2 Comparison with phase 2 tests

Phase 2 tests, both step 1 and step 2, have been developed to provide a defined set of laboratory conditions for the evaluation of the efficacy of products. These laboratory conditions simulate the actual use conditions such as contact time, temperature, soiling and site of use in a well standardized way having generally a better reproducibility. Nevertheless, there are inevitable differences between the conditions used in a laboratory test and the actual conditions of use of a product. Furthermore, the efficacy necessary to meet the requirements of a standard describing a laboratory method for the evaluation of the efficacy of a product is only a representative estimate of the standard of antimicrobial performance required in practice.

In contrast, phase 3 tests, often described as field trials, can establish directly the performance of a product under actual conditions of use. These conditions are however likely to be specific to the individual site of use and even to each individual occasion when the product is used, depending on not just the microbial challenge but the prevailing conditions under which the product is used. Hence a phase 3 test consists of a set of measurements so that the overall performance can be evaluated from a series of individual treatments.

The key feature of a phase 3 test is that it is carried out under typical operational conditions in a process in which a product is or may be used routinely, but that a series of measurements is taken according to a pre-determined plan to provide data that can be analysed statistically against defined criteria to demonstrate whether a product has the required antimicrobial performance. The site or sites of the test are usually actual sites of use, although they could be pilot or prototype installations rather than full size facilities.

Phase 3 tests typically assess performance against naturally occurring microorganisms under normal operating conditions, not against microorganisms that have been deliberately introduced and which may not be representative of the natural microflora. However, in some circumstances it may be advantageous to introduce coupons or swatches contaminated with specific microorganisms. In such cases, the deliberate introduction of additional microorganisms shall be assessed carefully in advance of the test to ensure that safety is not compromised. Contaminated materials to be introduced into a system should be prepared following the methods described in any available and relevant phase 2 tests.

If a test takes place in a small, well-controlled model system, that test should be regarded as a phase 2, step 2 test and not as a phase 3 test. However, the principles for phase 3 tests provided in this annex may provide guidance on the conduct of more complex forms of phase 2, step 2 tests.

C.3 Requirement for a Phase 3 Test

A field trial, or phase 3 test, typically requires extensive resources and the use of a new product can potentially result in unacceptable performance of a process that, prior to the test, was operating successfully. Phase 3 tests are therefore only to be performed where there are clear advantages in having such data. Appropriate phase 2 tests would usually be sufficient to demonstrate adequate efficacy for commercial or

product authorization purposes and phase 3 test data would not normally be required. This is especially the case where a product is established and has a history of demonstrated acceptable efficacy, or where the underlying technology is well known and tested.

Phase 3 tests may however usefully be undertaken in other circumstances. For example, a novel technology may lack both historic data to support claims of efficacy and suitable standardized laboratory methods for the evaluation of efficacy. In other cases, the users or operators of a specific facility or type of equipment may wish to conduct a phase 3 test to provide a robust data package to establish the efficacy of a product under their particular circumstances. Conversely, the manufacturer of a product with widespread use, such as a consumer product, may wish to conduct a phase 3 test to confirm the operational conditions under which the product has the required efficacy.

C.4 Scope of Phase 3 tests

A phase 3 test can be carried out in many different cases where a product is used. These include:

— disinfection of equipment in food, pharmaceutical or other processing plants by immersion, spraying, clean-in-place or other methods;

— disinfection of rooms, buildings, containers, transport vehicles and other enclosed spaces by spraying, mopping, vaporization or other methods;

— disinfection of catering utensils, medical equipment and other small items by immersion, washing and other processes;

— disinfection of kitchen, bathroom and other hard surfaces by spraying, mopping or other processes;

— disinfection of water systems by addition of a product, either routinely or as a shock treatment;

— disinfection of hands, tyres, boots, fabrics and other soft surfaces by washing, wiping, immersion or other processes;

— antiseptic procedures mainly in the medical and veterinary area.

This list is not exhaustive and the guidance in the annex can be applied and adapted as appropriate for individual circumstances.

C.5 Safety

Before any phase 3 testing is carried out it is necessary to identify and comply with any local legal requirements, such as those governing research and development activities with new products.

Potential risks should be identified and suitable risk management measures implemented to ensure that the phase 3 test will not give rise to any unacceptable risks. Possible risks to humans, animals, equipment, products and the environment arising from the use of the product in a phase 3 test should be identified and assessed. Toxicological and chemical risks to operators, users, bystanders and through residues in, for example, food and the environment, should be considered and documented. Potential consequences of any failure by the tested product to provide adequate control of microorganisms could include not just the risk of infection, but also product spoilage and the shutdown of plant for remedial treatment. A full size phase 3 test should not be undertaken unless the product has been shown to be effective using relevant laboratory efficacy test methods.

In addition to this risk assessment, procedures for monitoring to ensure no unacceptable risks occur and to control any problems arising during the phase 3 test should be defined and documented in advance of any testing of the product. Furthermore, the criteria for intervention or stopping the trial shall be defined, documented and agreed by all concerned parties prior to commencement of the trial. Responsibilities and

authority for decision making and any for any consequential losses or corrective actions should similarly be agreed before a phase 3 test commences.

A phase 3 test should be performed following the label instructions and other guidance on the use of the product, including any pre-treatment or ancillary treatments that are required or advised by the use-instructions. The effects of any related pre-treatment or ancillary processes on the results of the phase 3 test should be considered.

C.6 Design of a Phase 3 Test

Products and uses are diverse and each phase 3 test is likely to have specific design features. The conditions of use will vary considerably according to the intended purpose of the product. The test design and success criteria should be agreed with all relevant stakeholders before commencing a phase 3 test.

The test facility should be selected to be representative and provide a typical but real challenge to the successful use of a product. It is generally not possible to incorporate an untreated control system in a phase 3 test and so the performance of the product under evaluation would normally be compared to a different but relevant treatment.

Where a single test site is used, the product being tested should be compared with an established product under similar circumstances, usually by alternating the use of each product. For example, equipment could be disinfected with an established product for 2 weeks, and then with the product under test for 2 weeks. This process would then be repeated to give a total of 4 weeks with each product. Otherwise, separate but identical or very similar facilities can be tested in parallel using the product under evaluation and, as a comparative standard, an established product with a successful history of use in that facility. Where multiple, small scale use sites are used for an evaluation, they should be selected to be representative and allocated to the test and reference products to ensure statistical randomness. Statistical methods would normally be used in the design of a phase 3 test to establish in advance that the data generated in the test would be suitable for meaningful analysis.

The purpose of the phase 3 test is to demonstrate the efficacy of the product or disinfection process under actual use conditions. The test should be carried out for an adequate period to allow the product to be evaluated over a range of circumstances. If a product is used on a daily basis or more frequently, the duration of the test may be two months. If a product is used less frequently, the overall duration of the test is typically longer to allow for an adequate number of treatments for useful statistical evaluation. The test design should include consideration of the means, quantity, rate and timing of the dosing application and the times of sampling relative to the time(s) of dosing.

The test design should consider external and uncontrolled factors which may influence the challenges on a disinfection regime such as temperature, weather and organic and soil loading on the system, which in turn may vary according to season and between weekends and weekdays. The frequency of sampling should also be designed to provide sufficient data points over a range of circumstances while keeping the overall number of samples to be processed at a manageable level. The design should provide a set of data that would be expected to show clearly whether or not a product was sufficiently efficacious under field conditions according to predetermined criteria.

Relevant microorganisms should be selected for enumeration and a sampling protocol established. Samples should be taken not only at easily treated locations but also at places where microorganisms are likely to be found, such as in corners of equipment. Samples should be taken at representative intervals. These typically include not only after the disinfection process but, when appropriate in a periodic disinfection process, before and after any cleaning to give an indication of the challenge that the product experienced during the test period. Sampling procedures should enable acceptable recovery of viable microorganisms.

The technical procedures to enumerate microorganisms should be described. Factors to consider include neutralization and verification of the neutralization procedure, recovery of damaged but viable organisms, the appropriate culture media and incubation conditions, the number of replicates, accepted limits for counting and the interpretation of results.

In some industrial or other processes, existing measurement systems, including analyses of a final product, may be used, but supplemental testing is also likely to be needed to provide a more comprehensive assessment of the efficacy of a product. Consideration should also be given to other non-biological measures of successful disinfection, such as solution pH or turbidy. Preference should be given to objective criteria but subjective assessments such as odour or aesthetic quality may be included in the evaluation if these are important criteria for judging the suitability of a disinfection regime.

In some cases, such as evaluation of a consumer product, it may be possible for users to be unaware of the actual product being used, provided that adequate safety and use information is made available. Such blind trials can eliminate or decrease any human factors that could give a bias to any results. Nevertheless, it should be recognized that users, especially non-professional users, may apply a product slightly differently or more conscientiously when aware of a trial than under other circumstances. The robustness of any treatment to minor misuse should be considered when designing and evaluating a phase 3 test.

C.7 Performance of a Phase 3 Test

A preliminary meeting with all those involved in the test should be carried out to ensure that all of those engaged in the trial fully understand their roles and responsibilities.

Unless specified otherwise as part of the complete process, cleaning and other procedures ancillary to disinfection should be conducted in an identical fashion for all products used throughout the test.

Samples should be collected and measurements taken by suitably trained or informed personnel. Ideally, all similar samples should be taken by the same personnel throughout the trial to ensure consistency. All samples should be adequately labelled so that there is no confusion or uncertainty. It is advantageous to check periodically that sample numbering matches the appropriate sample site and to monitor the sampling process to ensure that the correct procedures are being followed.

Samples should be taken, transported, stored and analysed following generally accepted microbiological or chemical practices by suitably qualified and trained personnel.

All sampling and related equipment and materials should be stored appropriately and carefully packed away after use, ensuring that no debris is left at the sample site. It is good practice to carry out sterility and other control checks during the test to assist in identifying any anomalous results due to contaminated equipment or other process failures.

Any unusual or non-routine events that may have an impact on the results of the trials should be recorded as they occur. Similarly, any deviations from the test protocol should be recorded.

C.8 Results of a Phase 3 Test

Upon completion of the sampling and enumeration stages of a phase 3 test, statistical comparison between the efficacy of the product under evaluation and the standard product would normally be undertaken using Student's *t*-test. Unless other criteria were established during the test design, the test product shall be shown to be at least as effective as the proven established product at the test site for the measured parameters, that is not significantly less effective than the proven existing product ($p < 0,05$).

In reporting the results of a phase 3 test, the test protocol should be included, giving the agreed features and methodology incorporated into the trial design. Any deviations from the protocol should be reported. All results obtained should be included in an appendix, with identification and explanation of any data points that have been excluded from the analysis of the results. The conclusions from the test should be clearly stated.

Bibliography

[1] "Regulation Concerning the Making Available on the Market and Use of Biocidal Products (EU) 528 / 2012 (BPR)

[2] Council directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001

[3] EN 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

[4] EN 1040, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics — Test method and requirements (phase 1)*

[5] EN 1275, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics — Test method and requirements (phase 1)*

[6] EN 14347, *Chemical disinfectants and antiseptics — Basic sporicidal activity — Test method and requirements (phase 1)*

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