

Overview of (EN) standards, test conditions, and pass criteria

This table supports the Biocidal Products Regulation, Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, available in Volume II Efficacy Assessment and Evaluation (Parts B+C)¹.



NOTES to the reader:

1. The tables provide an overview of available phase 2,1 and 2,2 EN standards which are applicable for testing the efficacy of disinfectant biocides. This overview is not exhaustive. For other, or more specific uses, and tests other than EN standards reference should be made to the relevant sections of the ECHA guidance.
2. **Please note that this is a simplified overview of the requirements. It can only be used as an aide to the requirements as stated in the ECHA Guidance. Always check the respective sections of the Guidance for additional requirements.**
3. It should be noted that although the ECHA Guidance is mainly based on EN standards, there are some cases where there are discrepancies between the Guidance and EN tests and in such cases the ECHA Guidance should be followed as the leading guidance. Where noted these are identified in the table.
4. The reader is strongly advised to check whether there are new versions of the standards on the website of the CEN : www.cen.eu.
5. It should be noted that if tests other than CEN norms (notably when no CEN tests are available) are used, and pass criteria are available, these should be met (unless stated differently in this guidance).. When the test does not provide pass criteria, the criteria below can be taken into account as guidance for what level of reduction is normally required.
6. In all cases, deviations from these norms are possible but should be justified in the application.
7. Regarding the table for PT05, it should be noted that the text for PT5 of the Guidance document (section 6) is only “**preliminary draft text**” and has **not** been reviewed or revised to address written PEG comments received and the section is currently under review within the “Disinfectants Project”. In the meantime, the “preliminary draft text” is available to readers for information and it is for this reason that a table for PT05 is included in this document, but this will be reviewed when Section 6 of the Guidance is reviewed.

¹ Volume II Efficacy Assessment and Evaluation (Parts B+C) is under development and for publication in 2016. In the meantime the Transitional Guidance on Efficacy assessment of Disinfectants PT1-5 is published on the ECHA website.

 **PROCEDURE for updating this document**

This document can be updated or revised by submitting a request for review to the BPC Efficacy Working Group to the following email address: BPC-WGs@echa.europa.eu .

The request should include the following:

- Describe and explain the text to be revised giving reasons and justification for the proposed changes;
- Submit proposed revised text;
- Identify table number/name and section with page numbers of text to be reviewed and revised

PT 01						
Product type / micro-organism	Requirements¹	Test required²	Contact time³	Temp (°C)	Soiling conditions⁴	Required lg reduction
PT01 hygienic handrub						
bacteria	Basic requirement - 2,1 test	EN 13727/ EN 1276 ⁵	30 – 60 sec ⁶	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 1500	30 – 60 sec ⁶	skin T	none	≥ propan-2-ol
yeast	Basic requirement - 2,1 test	EN 13624/ EN 1650 ⁵	30 – 60 sec ⁶	20	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	30 – 60 sec ⁶	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	30 – 120 sec ⁶	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624/ EN 1650 ⁵	30 – 60 sec ⁶	20	clean / dirty	4
PT01 hygienic handwash						
bacteria	Basic requirement - 2,1 test	EN 13727	30 – 60 sec ⁶	20	dirty ⁷	3
bacteria	Basic requirement - 2,2 test	EN 1499	30 – 60 sec ⁶	skin T	none	> control
yeast	Basic requirement - 2,1 test	EN 13624/ EN 1650 ⁵	30 – 60 sec ⁶	20	dirty ⁷	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	30 – 60 sec ⁶	20	dirty ⁷	4
viruses	Optional - 2,1 test	EN 14476	30 – 120 sec ⁶	20	dirty ⁷	4
fungal spores	Optional - 2,1 test	EN 13624/ EN 1650 ⁵	30 – 60 sec ⁶	20	dirty ⁷	4
PT01 surgical hand disinfection						
bacteria	Basic requirement - 2,1 test	EN 13727	2-3 min ⁸	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 12791	2-3 min ⁸	skin T	none	≥ propan-1-ol
yeast	Basic requirement - 2,1 test	EN 13624	2-3 min ⁸	20	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	2-3 min ⁸	20	clean / dirty	4

viruses	Optional - 2,1 test	EN 14476	2-3 min ⁸	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624	2-3 min ⁸	20	clean / dirty	4

PT 02

Product type / micro-organism	Requirements ¹	Test required ²	Contact time ³	Temp (°C)	Soiling conditions ⁴	Required lg reduction
PT02 hard surfaces and other uses where EN tests are applicable, use in healthcare						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 ⁵	5 min. ⁹ /60 min	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697/ EN 16615 ²⁸	5 min. ⁹ /60 min	20	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 ⁵	5 min. ⁹ /60 min	20	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	5 min. ⁹ /60 min	20	clean / dirty	3
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	5 min. ⁹ /60 min	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	5 min. ⁹ /60 min	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 ⁵	5 min. ⁹ /60 min	20	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 13697	5 min. ⁹ /60 min	20	clean / dirty	3
PT02 hard surfaces and other uses where EN tests are applicable, use other than in healthcare						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 ⁵	5 min. ⁹ /60 min	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697/ EN 16615 ²⁸	5 min. ⁹ /60 min	20	clean / dirty	4
yeast	Optional - 2,1 test	EN 13624 / EN 1650 ⁵	5 min. ⁹ /60 min	20	clean / dirty	4
yeast	Optional - 2,2 test	EN 13697	5 min. ⁹ /60 min	20	clean / dirty	3
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	5 min. ⁹ /60 min	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	5 min. ⁹ /60 min	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 ⁵	5 min. ⁹ /60 min	20	clean / dirty	4

fungus spores	Optional – 2,2 test	EN 13697	5 min. ⁹ /60 min	20	clean / dirty	3
PT02 room disinfection (including use in healthcare)						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 ⁵	as claimed	20	clean / dirty ¹⁸	5
bacteria	Basic requirement – semi-field trial	NF T 72-281 ²⁶	as claimed	20	clean / dirty ¹⁸	5
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 ⁵	as claimed	20	clean / dirty ¹⁸	4
yeast	Basic requirement - semi-field trial	NF T 72-281 ²⁶	as claimed	20	clean / dirty ¹⁸	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	as claimed	20	clean / dirty ¹⁸	4
mycobacteria / tuberculosis	Optional – semi-field trial	NF T 72-281 ²⁶	as claimed	20	clean / dirty ¹⁸	4
viruses	Optional - 2,1 test	EN 14476	as claimed	20	clean / dirty ¹⁸	4
viruses	Optional – semi-field trial	NF T 72-281 ²⁶	as claimed	20	clean / dirty ¹⁸	4
fungi fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 ⁵	as claimed	20	clean / dirty ¹⁸	4
fungi fungal spores	Optional – semi-field trial	NF T 72-281 ²⁶	as claimed	20	clean / dirty ¹⁸	4
PT02 (instrument) disinfection by immersion or filling						
bacteria	Basic requirement - 2,1 test	EN 13727	as claimed	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 14561	as claimed	20	clean / dirty	5
yeast	Basic requirement - 2,1 test	EN 13624	as claimed	20	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 14562	as claimed	20	clean / dirty	4
viruses	Basic requirement - 2,1 test	EN 14476	as claimed	20	clean / dirty	4
fungus spores	Basic requirement - 2,1 test	EN 13624	as claimed	20	clean / dirty	4
fungus spores	Basic requirement - 2,2 test	EN 14562	as claimed	20	clean / dirty	4
mycobacteria /	Optional - 2,1 test	EN 14348	as claimed	20	clean / dirty	4

tuberculosis						
mycobacteria / tuberculosis	Optional - 2,2 test	EN 14563	as claimed	20	clean / dirty	4
PT02 textiles						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 ⁵	as claimed	as claimed ²¹	clean / dirty ¹⁹	5
bacteria	Basic requirement - 2,2 test	EN 16616/ ASTM E2406 / ASTM 2274	as claimed	as claimed ²¹	clean / dirty ¹⁹	7
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 ⁵	as claimed	as claimed ²¹	clean / dirty ¹⁹	4
yeast	Basic requirement - 2,2 test	EN 16616/ ASTM E2406 / ASTM 2274	as claimed	as claimed ²¹	clean / dirty ¹⁹	6
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	as claimed	as claimed ²¹	clean / dirty ¹⁹	4
mycobacteria / tuberculosis	Optional - 2,2 test	EN 16616/ ASTM E2406 / ASTM 2274	as claimed	as claimed ²¹	clean / dirty ¹⁹	7
viruses	Optional - 2,1 test	EN 14476	as claimed	as claimed ²¹	clean / dirty ¹⁹	4
viruses	Optional - 2,2 test	EN 16616 / ASTM E2406 / ASTM 2274	as claimed	as claimed ²¹	clean / dirty ¹⁹	?
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 ⁵	as claimed	as claimed ²¹	clean / dirty ¹⁹	4
fungal spores	Optional - 2,2 test	EN 16616/ ASTM E2406 / ASTM 2274	as claimed	as claimed ²¹	clean / dirty ¹⁹	6

PT 03						
Product type / micro-organism	Requirements¹	Test required²	Contact time³	Temp (°C)	Soiling conditions⁴	Required lg reduction
PT03 hard surfaces						
bacteria	Basic requirement - 2,1 test	EN 1656	30 min. ¹¹	10	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 14349/16437	30 min. ¹¹	10	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 1657	30 min. ¹¹	10	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 16438 ¹²	30 min. ¹¹	10	clean / dirty	3
fungal spores	Optional - 2,1 test	EN 1657	30 min. ¹¹	10	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 16438 ¹²	30 min. ¹¹	10	clean / dirty	3
viruses	Optional - 2,1 test	EN 14675	30 min. ¹¹	10	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14204	30 min. ¹¹	10	clean / dirty	5
endoparasites	Optional	DGV				
PT03 hard surfaces in transport vehicles						
Bacteria, yeasts, fungal spores, mycobacteria / tuberculosis, endoparasites	As PT03 hard surfaces		5 min. ¹¹		As PT03 hard surfaces	
viruses	Basic requirement - 2,1 test	EN 14675 ¹³	5 min. ¹¹	10	clean / dirty	4
PT03 teat disinfection						
bacteria pre-milking	Basic requirement - 2,1 test	EN 1656	30-60 sec ¹⁴	30	clean / dirty	5
bacteria post-milking	Basic requirement - 2,1 test	EN 1656	5 min. ¹⁴	30	clean / dirty	4
bacteria pre-milking	Basic requirement - 2,2 test	to be developed	30-60 sec ¹⁴	30		
bacteria post-milking	Basic requirement - 2,2 test	to be developed	5 min. ¹⁴	30		

yeast pre-milking	Basic requirement - 2,1 test	EN 1657	30-60 sec ¹⁴	30	clean / dirty	4
yeast post-milking	Basic requirement - 2,1 test	EN 1657	5 min. ¹⁴	30	clean / dirty	3
mycobacteria / tuberculosis pre/post milking	Optional - 2,1 test	EN 14204	30-60 sec/ 5 min. ¹⁴	30	clean / dirty	4
fungal spores pre/post milking	Optional - 2,1 test	EN 1657	30-60 sec/ 5 min. ¹⁴	30	clean / dirty	3
fungal spores pre/post milking	Optional - 2,2 test	EN 16438	30-60 sec/ 5 min. ¹⁴	30	clean / dirty	4
viruses pre/post milking	Optional - 2,1 test	EN 14675	30-60 sec/ 5 min. ¹⁴	30	clean / dirty	5
algae	Optional	no test available				
PT03 hoof disinfection						
bacteria	Basic requirement - 2,1 test ²⁷	EN 1656	5 min	10	dirty ¹⁵	5
bacteria	Basic requirement - 2,2 test ²⁷	EN 16437	5 min	10	dirty ¹⁵	4
yeast/ fungal spores	Optional - 2,1 test ²⁷	EN 1657	5 min	10	dirty ¹⁵	4
yeast fungal spores	Optional - 2,2 test ²⁷	EN 16438 ¹²	5 min	10	dirty ¹⁵	3
viruses	Optional - 2,1 test ²⁷	EN 14675	5 min	10	dirty ¹⁵	4/5
mycobacteria / tuberculosis	Optional - 2,1 test ²⁷	EN 14204	5 min	10	dirty ¹⁵	5
PT03 disinfection of hatching-eggs						
bacteria	Basic requirement - 2,1 test	EN 1656	as claimed	30	clean / dirty ⁴	5
bacteria	Basic requirement - 2,2 test	EN 16437	as claimed	30	clean / dirty ⁴	4
fungal spores	Basic requirement - 2,1 test	EN 1657	as claimed	30	clean / dirty ⁴	4

fungus spores	Basic requirement - 2,2 test	No standard guideline available ²⁰	as claimed	30	clean / dirty ⁴	3
other target organisms	Optional - 2,1 test	As PT03 porous surfaces				
other target organisms	Optional - 2,2 test	As PT03 porous surfaces				
PT03 textile disinfection						
bacteria	Basic requirement - 2,1 test	EN 1656	as claimed	as claimed ²¹	clean / dirty ⁴	5
bacteria	Basic requirement - 2,2 test	EN 16616 / ASTM E2406	as claimed	as claimed ²¹	clean / dirty ⁴	4
yeasts	Basic requirement - 2,1 test	EN 1657	as claimed	as claimed ²¹	clean / dirty ⁴	4
yeasts	Basic requirement - 2,2 test	EN 16616 / ASTM E2406	as claimed	as claimed ²¹	clean / dirty ⁴	3
other target organisms	Optional - 2,1 test	As PT02 textile, with PT3 soiling				
other target organisms	Optional - 2,2 test	As PT02 textile, with PT3 soiling				
PT03 disinfection of bee hives and beekeeping equipment						
bacteria	Basic requirement - 2,1 test	EN 1656	as claimed	10	clean/dirty	5
bacteria	Basic requirement - 2,2 test	EN 16437	as claimed	10	clean/dirty	4
bacterial spores	Basic requirement - 2,1 test	EN 13704	as claimed	10	clean/dirty	4
bacterial spores	Basic requirement - 2,2 test	EN 16437 adapted	as claimed	10	clean/dirty	3
other target organisms	Optional - 2,1 test	As PT03 porous surfaces				
other target organisms	Optional - 2,2 test	As PT03 porous surfaces				

PT 04						
Product type / micro-organism	Requirements¹	Test required²	Contact time³	Temp (°C)	Soiling conditions⁴	Required lg reduction
PT04 hard surfaces						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	20	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	20	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	as claimed	20	clean / dirty	3
mycobacteria	Optional - 2,1 test	EN 14348	as claimed	20	clean / dirty	5
viruses	Optional - 2,1 test	EN14476 ¹⁶	as claimed	20	clean / dirty	4
bacteriophages	Optional - 2,1 test	EN 13610 ¹⁶	as claimed	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 1650	as claimed	20	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 13697	as claimed	20	clean / dirty	3
bacterial spores	Optional - 2,1 test	EN 13704	as claimed	20	clean / dirty	3
PT04 inner surfaces without circulation						
see PT04 hard surfaces			as claimed ¹⁷			
PT04 inner surfaces by CIP						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	as claimed ¹⁷	clean / dirty	5
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	as claimed ¹⁷	clean / dirty	4
other target organisms	see PT04 hard surfaces					

Product type / micro-organism	Requirements ¹	Test required ²	Contact time ³	Temp (°C)	Soiling conditions ⁴	Required lg reduction
PT04 surfaces in drinking water systems						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
Legionella	Optional - 2,1 test	EN 13623	as claimed	20	clean / dirty	5
other organisms when claimed	Optional - 2,1 test	as PT04 hard surfaces				
bacteria and Legionella	Basic requirement field trial	See 5.6.2.1.2				
PT04 equipment disinfection by soaking						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	as claimed	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	as claimed	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed	clean / dirty	3
other organisms when claimed	Optional - 2,1 test	as PT04 hard surfaces				
other organisms when claimed	Optional - 2,1 test	as PT04 hard surfaces				
PT04 surfaces in veterinary water systems						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	20	clean / dirty	4
other organisms when claimed	Optional - 2,1 test	as PT04 hard surfaces				
PT04 disinfection in dish washing machines and crate washers						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	as claimed	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed	clean / dirty	4

bacteria	Basic requirement - 3 test	DIN SPEC10534	as claimed	as claimed	clean /dirty	?
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	as claimed	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed	clean / dirty	3
yeast	Basic requirement - 3 test	DIN SPEC10534	as claimed	as claimed	clean / dirty	?
other organisms when claimed	Basic requirement - 2,1 test	as PT04 hard surfaces				
other organisms when claimed	Basic requirement - 2,2 test	as PT04 hard surfaces				
other organisms when claimed	Basic requirement - 3 test	According to DIN SPEC 10534				

PT 05 Please note that PT5 entries are preliminary

Product type / micro-organism	Requirements ¹	Test required ²	Contact time ³	Temp (°C)	Soiling conditions ⁴	Required lg reduction
PT05 drinking water for drinking water companies, stationary water in reservoirs and undefined water						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
bacteria	Basic requirement – simulated use test	Test protocol in guidance	as claimed	20	clean / dirty	see guidance
viruses	Basic requirement - 2,1 test	EN 14476	as claimed	20	clean / dirty	4
viruses	Basic requirement – simulated use test	Test protocol in guidance	as claimed	20	clean / dirty	see guidance
other organisms when claimed	Optional - 2,1 test	as PT04 hard surfaces				
PT05 drinking water in collective systems						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean	5
Legionella	Basic requirement - 2,1 test	EN 13623	as claimed	20	clean	5
Legionella	Basic requirement - field trial	See 6.2.1.2.2				
PT05 drinking water for animals						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
other organisms when claimed	Optional - 2,1 test	as PT04 hard surfaces				
claimed organisms	Basic requirement simulated-use or field trial					

NOTES on TABLES

¹ Requirements: basic requirements are mandatory and have to be fulfilled for authorisation of a product with this intended use. In addition, other organisms claimed are optional, i.e. if the requirements for these organisms are not fulfilled these organisms will be excluded from the claim.

² EN-tests are strongly advised but not mandatory. Other tests carried out according to standard guidelines are acceptable if a clear description of the test procedure (including contact time, soiling, temperature, suitable controls, log₁₀ reduction, etc.) and justification is provided.

³ Contact time: maximum acceptable contact times are stated, at which efficacy should be demonstrated. If a shorter contact time is stated on the label, efficacy has to be demonstrated at this shorter contact time. It is recommended to only use contact times mentioned in the EN standards as obligatory or additional contact time, to keep the robustness of the test as much as possible.

⁴ Soiling conditions: low level soiling conditions are acceptable if it is stated on the label that cleaning prior to disinfection is necessary. Otherwise, and in case no prior cleaning is possible, dirty conditions have to be included in the tests.

PT 1 and 2 For hospitals and health care:

Dirty 3 g/L bovine albumin + 3 ml/L sheep erythrocytes // Clean 0.3 g/L bovine albumin.

PT 1 and 2 other uses:

Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin.

PT 2 cosmetic industry:

Dirty 3 g/L bovine albumin **and** 5g/L sodium dodecyl sulphate in separate tests.

PT2 surfaces in agricultural area (no plant protection claim):

Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin.

PT 3 general hard surface disinfectants, hoof and animal skin disinfection, pre-milking teat disinfection, and eggs in hatcheries:

Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin.

PT 3 teat disinfection

pre milking: Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin (different from EN14885).

post milking + outer surfaces of milking equipment: milk cloth: Clean/Dirty 10g/L skimmed milk.

PT 4 general:

Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin.

PT 4 milk industry:

Dirty 3 g/L bovine albumin **and** 10g/L skimmed milk in separate tests.

PT 4 meat industry:

Dirty 3 g/L bovine albumin + 3 ml/L sheep erythrocytes (different from EN14885).

PT 4 breweries:

Dirty 3 g/L bovine albumin **and** 10g/L yeast extract in separate tests.

PT 4 beverage industry:

Dirty 3 g/L bovine albumin **and** 10g/L sucrose in separate tests.

PT 5 general:

Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin.

⁵ For PT 01 or PT02-'medical applications' the required tests differ from PT01 or PT02-'non-medical' applications. The first test is for medical applications and the second is for non-medical applications. In case both types of applications are claimed, only one test has to be carried out, in which the relevant worst case test conditions (in general medical test) are included.

⁶ For hygienic handwash and handrub products used in **hospitals** the contact time is usually 30 seconds, for other uses the contact time is between 30 and 60 seconds (up to 120 seconds in case of virucidal activity). Please note that some EN tests were not developed for hand disinfection and therefore contact times shall be adapted.

⁷For handwash disinfectants it is assumed that hands will not be washed before washing with a disinfectant. Therefore, tests have to be done under dirty conditions.

⁸ The WHO states that for several products, scrubbing for 2-3 minutes reduces bacterial counts to acceptable levels. However, in the past, longer scrubbing times were accepted. Contact times of longer than 3 minutes, and up to 5 minutes, will only be authorised with a sound justification on the necessity of such long scrubbing times.

⁹ Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, must be tested with a contact time of maximum 5 min. The same applies where the contact time of the product must be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.

¹⁰ For medical equipment, tests with fungi and viruses are a basic requirement. For all other equipment, tests with fungi and viruses are optional.

¹¹ For surface disinfection in veterinary areas the normal contact time is 5 minutes. The maximum contact time is 30 minutes. For surface disinfection on animal transport vehicles the maximum contact time is 5 minutes. For disinfectants used on boots applied by spraying or walk-through bath the contact time should not exceed 1 minute.

¹² As soon as a phase 2, step 2 test for porous surfaces are available these should be used.

¹⁴ For post-milking teat disinfection the normal contact time is 1 minute. The maximum contact time is 5 minutes. For pre-milking teat disinfection the normal contact time is 10-30 seconds. The maximum contact time is 60 seconds.

¹⁵ For hoof disinfection it is not anticipated that hoofs will be cleaned sufficiently before disinfection in practice. Therefore only tests under dirty conditions are acceptable.

¹⁶ For uses where efficacy against bacteriophages only is claimed, EN 13610 can be employed. For all other PT4 uses where virucidal activity is claimed EN 14476 should be used with Norovirus and Adenovirus as test organisms.

¹⁷ The test temperature should be according to the use instructions on the label: e.g. cold =4, 10 °C, no restriction =20 °C, high temp =40, to 80 °C.

¹⁸ This test includes the use of milk as an interfering substances in order to maintain viability of the micro-organisms on the carriers during the test. Depending on the area of use, other suitable interfering substances should be tested (e.g. blood for use in 36 hospitals).

¹⁹ The interfering substance most appropriate for the in-use conditions should be used. For instance, blood for products used in the medical area and protein for products used in industry, institutional and domestic areas are recommended. The soiling on a domestic product for use in pre-soak (dirty clothes) will be very much higher than the soiling present for a post-wash rinse additive (clean clothes). For products used during pre-soak and wash, tests should be done under dirty conditions. For products used during post-wash rinse, tests should be done under clean conditions. PR 16616: The obligatory interfering substance to be tested is sterile defibrinated sheep blood (12,5 ml sheep blood per kg textile).

²⁰ As long as no standard phase 2, step 2 tests are available it is not obligatory to provide 1 these tests. Phase 2, step 2 tests have to be provided as soon as standard tests are 2 available.

²¹ When the product is intended to be used at high temperatures (>40 °C) relevant test 32 organisms for these temperatures should be used. See 1.4.4.4 of the guidance.

²² Note that in this case EN14885 differs from the EU guidance. The EU guidance is leading for biocide authorisation.

²³ According to EN1500 the test is passed when the mean reduction achieved by the hygienic handrub product under test is at least not inferior to that achieved by a reference handrub with propan-2-ol 60 % (v/v) (p=0.1).

²⁴ According to EN1499 the test is passed when the mean reduction achieved by the hygienic handwash with the product under test is larger than that achieved by a specified reference hygienic handwash (unmedicated liquid soap). (p=0.01)

²⁵ According to EN12791 the test is passed when the mean reduction achieved by the surgical handrub product under test is at least not inferior to that achieved by a reference handrub with propan-1-ol 60 % (v/v).

²⁶ NF T 72-281 is a test from AFNOR, the French standardisation body. This standard is taken as a start to develop a new EN standard on airborne disinfection of surfaces. Where available an EN test may be used for a semi-field method which evaluates the efficacy of disinfectants when vaporised in a room.

²⁷ For disinfection in a hoof bath, information should be provided on how long the efficacy of a hoof bath can be guaranteed. This can be done in a challenge test or a field test. See the guidance chapter 4.4.2.1 for more details.

²⁸ When a surface disinfectant is a wipe soaked with disinfectant liquid the product should be tested in the EN16615 test (phase 2, step 2), with mechanical action.