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English Version

## Chemical disinfectants and antiseptics - Interpretation of water controls in EN 16615:2015

Antiseptiques et désinfectants chimiques -  
Interprétation des témoins eau dans l'EN 16615:2015

Chemische Desinfektionsmittel und Antiseptika -  
Interpretation der Wasserkontrollen in EN  
16615:2015

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## European foreword

This document (CEN/TR 17825:2022) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

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## Introduction

EN 16615 was implemented in 2015 after thoroughly ring trialing the methodology. However, most of the ring trials were done with Gram positive bacteria as test organisms. After the implementation of the standard, more data was generated incl. tests with gram negative bacteria (*Pseudomonas aeruginosa*) and yeasts (*Candida albicans*). As more data became available, it was obvious that many test laboratories are facing problems in providing valid water controls corresponding to EN 16615:2015, due to the difficulty in recovering the latter two test organisms in the water control.

An exchange on methodological details between laboratories providing valid water controls and those struggling with providing such data has been agreed with a stringent timeline. Results of this scientific exchange will be considered to revise EN 16615 accordingly. Additionally, the project to revise the standard has been initiated. Meanwhile laboratories using the existing standard to generate data on disinfectants for regulatory purposes face problems in discussions with legal bodies on the validity of data to support product claims. Hence the following proposal is made for the interpretation of data according to EN 16615:2015 regarding water controls.

## 1 Scope

This document defines rules for the interpretation of data corresponding to EN 16615:2015 regarding water controls in order to avoid problems in discussions with legal bodies on the validity of data to support product claims.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

## 4 Rules for the interpretation of data regarding water controls

When testing disinfectant efficacy according to EN 16615:2015, water controls are described and the validity criteria [EN 16615:2015, 5.7.3.1. i)] are:

$N_W$  (water control) is on average  $> 10 \text{ cfu}/25 \text{ cm}^2$  on test fields 2-4

**The following change could be implemented in data evaluation:**

$N_W$  (water control) is on average  $> 10 \text{ cfu}/25 \text{ cm}^2$  on test fields 1-4,

hence, considering all 4 fields, the initially contaminated field and the three initially uncontaminated fields to determine the validity of water controls.