

**Textil – Textilier behandlade i tvätterier –
Kontrollsystem för biokontamination**

**Textiles – Laundry processed textiles –
Biocontamination control system**

Europastandarden EN 14065:2002 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 14065:2002.

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Textiles - Textiles traités en blanchisserie - Système de maîtrise de la biocontamination

Textilien - In Wäschereien aufbereitete Textilien - Kontrollsystem Biokontamination

This European Standard was approved by CEN on 23 September 2002.

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CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

This document EN 14065:2002 has been prepared by Technical Committee CEN /TC 248 "Textiles and textile products", the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.

Annexes A, B and C are informative.

This document contains a bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard : Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

EN 14065:2002 (E)

Introduction

General

The sensory cleanliness of laundry processed textiles is important for the laundry industry and their customers. Processed textiles should be visibly clean, free from stains and correctly dried or ironed; they should also be pleasant to the touch and fragrant or at least free from any unpleasant odours, etc.

Sensory cleanliness is obtained during the laundry cycle through physico-chemical treatments such as mechanical action, temperature, addition of detergents and auxiliary products, bleaching agents, dilutions and rinses in successive baths, in combination with sufficient time. With these procedures, most micro-organisms have a low probability of survival.

Nowadays the need for the prevention of microbiological contamination of individuals, products, materials or environment is of increasing significance. Consequently, assured microbiological quality becomes necessary. Therefore the laundry industry is adopting new process control techniques to assure the microbiological quality of laundered textiles.

The purpose of this standard is to provide a management system to deliver an agreed level of microbiological quality according to the intended use of the textile.

The microbiological quality of textiles is determined by their intended use, e.g. consistent with the level of risk for individuals, products, materials or an environment exposed to biocontamination. In certain cases, where very high microbiological quality is required, for example in operating theatres and immune-deficiency or burns departments in hospitals, etc., processing is completed by sterilisation.

Soiled textiles entering a laundry are contaminated with varying numbers of micro-organisms from the environment in which they have been used. In this context, the objective of the launderer is to decontaminate the textiles using a disinfecting process and then protect them from subsequent recontamination up to the moment they become the responsibility of the customer.

Good manufacturing practice in the laundry is a prerequisite for achieving microbiological quality; some countries already possess national guidelines to assist with this.

Working practices for dealing with hazards and controlling risks prior to washing should be common to all laundry operations. However from the point of maximum decontamination (by thermal, chemical and physical means) the textiles will be subject to microbiological recontamination. The awareness of a 'micro-organism exchange' is important in assessing the impact recontamination may have in the use of the textile.

Different strategies are used for controlling recontamination in terms of investment, plant design, construction and operation. Laundry operations and the market sector they supply will determine which is most appropriate.

The true performance of the complete laundry processes may only be validated after adequate in-process microbiological testing has been carried out. It may be necessary to modify plant lay out and revalidate processes as a result.

This document has been developed using the principles of a Risk Analysis and Biocontamination Control (RABC) system, presented in prEN ISO 14698-1. This method is essentially based on preventative measures, as opposed to inspection procedures on the end product.

This standard does not take into account the measures required for the protection of personnel.

Process approach

This European Standard, which describes a process approach to quality management, is consistent with ISO 9001:2000, except clause 7.3 (according to permissible exclusions given in 1.2 of ISO 9001:2000).

In the RABC system, a risk analysis has been added to a quality assurance process.

Compatibility with other quality management systems

This European Standard is compatible with other internationally recognised quality management system standards.

This European Standard may be integrated into an existing quality management system.

EN 14065:2002 (E)

1 Scope

This European Standard describes a management system for ensuring the microbiological quality of laundry processed textiles used in specifically defined sectors in which it is necessary to control biocontamination. This document describes a Risk Analysis and Biocontamination Control (RABC) system to enable laundries to continuously assure the microbiological quality of the laundered textiles.

It applies to textiles processed in laundries and used in specific sectors, e.g. pharmaceuticals, medical devices, food, healthcare and cosmetics and excludes those aspects relating to worker safety and sterility of the final product.

2 Normative references

Not applicable.

3 Terms and definitions

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

**3.1
action level**
established level of a CP monitoring variable set by the RABC team at which remedial procedures are activated to bring the laundry process back into control

**3.2
alert level**
established level of a CP monitoring variable set by the RABC team giving early warning of a change from normal conditions

**3.3
biocontamination**
contamination with viable micro-organisms

**3.4
control measure**
action or procedure required to control a biocontamination risk

**3.5
control point (CP)**
any point or step in a process at which control is applied in order to contain, eliminate or reduce biocontamination risk

**3.6
corrective action**
action to be taken, when the results of monitoring indicate that alert or action levels are exceeded, in order to restore control of the process

**3.7
flow diagram**
graphical representation of all the steps in the process

**3.8
hazard**
in the context of this standard, any element or factor that may adversely affect the achievement of the agreed microbiological quality of textiles