Module Part 6:
Special Aspects of EN 14065

Contents:

Conversion of EN 14065 -

microbiological hazard for the sector of laundry or for textile service enterprises respectively and control processes, determination of control-points, critical value, appropriate monitoring system and corrective action

Microbiological Hazard: Germtransfer

- **In** or **on** a human a big number of micro-organisms can be detected. So-called human-pathogenic germs might not only be detected at sick persons. (Germs are called human-pathogenic when they are able to cause illnesses in persons).

- In principle all sorts of micro-organisms, which can also be found in or on humans, can be detected on textiles or other human contacting objects/areas.

- Transferring germs from person to person or from objects to persons and back to objects, the hands are of particular importance. Due to a lack of hygiene, germs might be spread very fast via hands or other surfaces.

Microbiological Hazard : Diseases

once again:

- **Fortunately** a big amount of germs or toxins have to be contacted in order to cause a sickening effect!!!

- **Danger:** small amounts of germs are enough to start a reproduction in the food-product at the customer

- Primarily EN 14065 does **not** serve **protection of staff** but protects the **customer** of a textile enterprise.

microbiological hazard selection capabilities

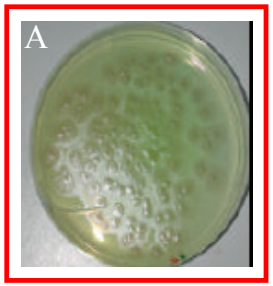
- If human-pathogenic germs are selected during a hygiene-analysis, a selection on aerobic germs for example is recommended (yeasts/fungi: *Candida**, *Aspergillus*, bacteria: *Brucella*, *Pseudomonas**, *Micrococcus*, *Corynebakterium*, *Bacillus**), optionally anaerobic bacteria (*Enterobacteriaceae*: *Escherichia**, *Klebsiella**, *Salmonella*, *Citrobacter*, *Shigella*, *Serratia**, *Listeria**, *Staphylococcus**) as well as aerotolerant anaerobic bacteria (*Enterococcus**).

  (human-pathogenic germs are underlined, only special kinds of those marked with * are pathogenic)

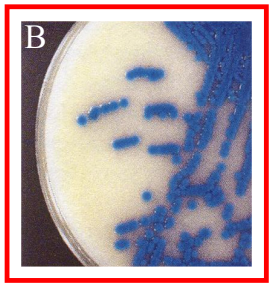
In case of problems the following germs have to be assumed within a textile service enterprise....

spectrum of germs investigation in laundries

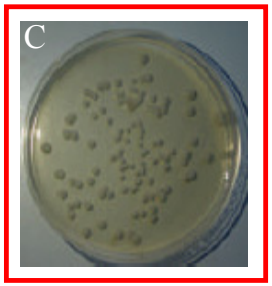
A: *Pseudomonas aeruginosa*



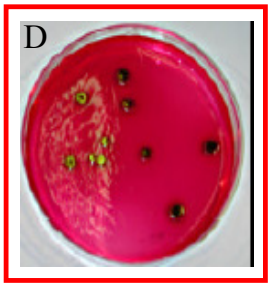
B: *Coliforme*



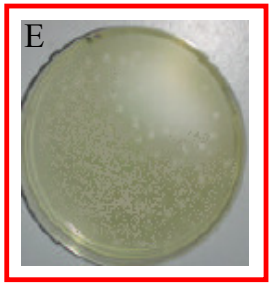
C: *Candida albicans*



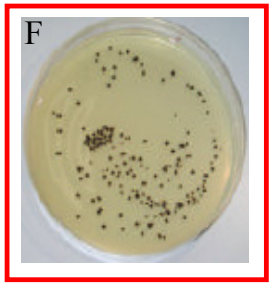
D: *Escherichia coli*



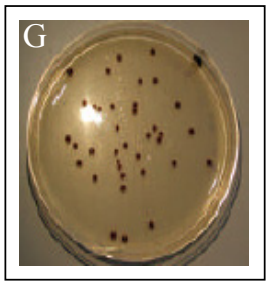
E: *Aspergillus niger*



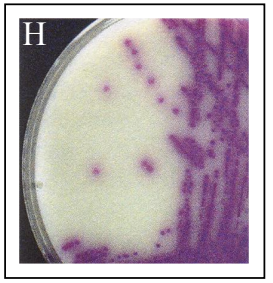
F: *Staphylococcus aureus*



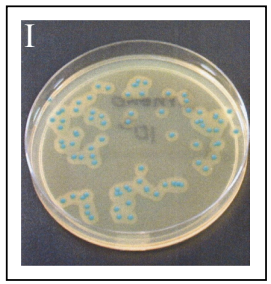
G: *Enterococcus faecium*



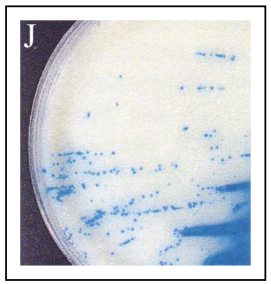
H: *Salmonella spp.*



I: *Listeria monocytogenes*



J: *Citrobacter spp.*



Pictures framed red (A to F) show yeasts, that were detected on dry ware of expedition as well.

Pictures framed black (G to J) show germs, that were detected exclusively on soiled textiles (delivery status) in textile service enterprises.

Special Aspects of EN 14065

The major amount of germs is transmitted by hands

Bio-burden of a hand-print

<u>Hand-cleaning and hand-disinfection therefore are the most important personal hygienic procedures</u>!!!

RABC-System

RABC = DIN EN 14065

=

Risk Analysis and Biocontamination Control-System

RABC-System,
Synonyms: **EN 14065,**
Control-System Bio-Contamination,
Hygiene-Managementsystem,
Quality-Managementsystem

Advantages of the RABC-System:

- a valid and accepted Quality-Management-System throughout Europe
- simple integration in established QM-Systems (e.g.. ISO 9000ff.)
- variable in application
- RABC was developed according to the approved HACCP-System

DIN EN 14065 – RABC

DEUTSCHE NORM Februar 2003

Textilien

In Wäschereien aufbereitete Textilien

Kontrollsystem Biokontamination

Deutsche Fassung EN 14065:2002

DIN

EN 14065

ICS 07.100.99; 59.080.01

- The RABC-System is published as a European Standard
- Primarily for the protection of the consumers and the final user respectively
- It does **NOT** contain biological limiting values
- Information for ordering the standard:
  http://www.beuth.de/index_en.php - or
  http://www.beuth.de/

No limiting values in EN 14065???

- **With the RABC-System a laundry or a textile service enterprise is able to ensure an agreed level of microbiological quality**

= very high adaptiveness to customer requirements

Consequently applicable for all hygienically pretentious areas

The meaning of RABC

- **risk-analysis + risk evaluation**

? ? ? ? ? ? ?

- Danger: The mischief that might appear
- Risk: The probability, that danger occurs

RABC stands for

good manufacturing practice

+ Quality-Management-System

+ Risk-Analysis

Good Manufacturing Practice (GMP)

Requirement for the implementation of the RABC-System is a good manufacturing practice in the textile service enterprise

- And what can I imagine under „ good manufacturing practice?”

Good Manufacturing Practice (GMP)

Good manufacturing practice is the appropriate textile care according to the state of the Art *.

The aim of appropriate textile care is to bring the textiles to be processed into a sensory clean condition

After processing, the textiles should be visibly clean and free of unpleasant odours.

***"State of the Art" means the technique, which allows the application under economical and technical justifiable aspects, under consideration of the cost/profit-ratio**

A hygiene-plan e.g. is a component of the good manufacturing practice!

Example of a general hygiene-plan

What	When	How	With what	What from	who
work-surface	after work	spray, with a clean cloth every day, do not dry	Product XY	e.g. spray bottle	staff

RABC-System-Implementation

The regulars of EN 14065 in principle consist of 7 maxims, according to those a corresponding system can be built

7 principles

of the

RABC-System

RABC-System-Implementation

Listing of microbiological hazard and means of control

- principle 1

(work of the RABC-group)

besides this: risk-analysis resp. -classification: small, average, high or very high risk

 example

Example Principle 1

Danger:
Ready processed textiles might be contaminated with germs by the hands of staff.

Controlling measures:
During the hygiene-monitoring, the hands of the staff, damp surfaces as well as processed dry ware are determined by contact-slides and controlled for bio-burden.

Corrective action in case of disturbance:
Regular performance of hygienic hand- and surface-disinfection, regulated by the hygiene-plan

RABC-System-Implementation

Determination of Control Points (CP)

- principle 2

only germ reducing process-steps are taken into consideration ⇒ e.g.. WSM, WSTR, drying-installations, points where a disinfection is being processed

 example

Example for Principle 2

The washer extractor is fixed as a control point.

Monitoring shall be increased.

It has to be guaranteed that germ reduction works as planned and that a case of disturbance can be detected immediately.

Facilities for visual or acoustic signal-warning are recommended as well as regular maintenance and calibration of the metering unit (e.g. temperature sensor PT100)

RABC-System-Implementation

Limiting values and tolerances for each control point

- principle 3

(in general the latest recommendations of for instance RKI, washing procedures of detergent-supplier or standards are followed)

example

Example for Principle 3

For each fixed control point limiting values resp. a tolerance range has to be established:

If necessary, national regimentations (in Germany limiting values for less germ content of dry hospital laundry are recommended by the Robert-Koch-Institute for instance) have to be taken into consideration.

Adherence of limiting values has to be tested by regular investigations.

RABC-System-Implementation

Fixing a monitoring system for each control point

- principle 4

(e.g. alarm-signal when not reaching the required temperature)

 example

Example for Principle 4

- Most of the monitoring-systems for CP should be performed continuously.

  A direct examination is preferred if the time for livelong analyses is not available. A visual inspection and physical or chemical measurements instead of microbiological analysis is preferred. Their rapid realization and the obtained results shall demonstrate that the conditions for the control of biological parameters are met.

RABC-System-Implementation

Determination of corrective action
(„Troubleshooting")

- principle 5

(e.g. inform service technician and/or house-technician, change the program, decide what to do with fail-processed textiles, document everything)

Example for principle 5

- The control over the failed process has to be regained as soon as possible.

  It must be arranged, what happens to the fail-processed textiles.

RABC-System-Implementation

Determination of controlling measures of the RABC-System

- principle 6

At least 1 x per year: re-validation! (water-examina-tions, contact-slides and also use of bio-monitors).

"Monitoring" (examination by contact slides) in shorter intervals (usually: 3 x per year)

example

Example for principle 6

- **Water examination:**
  - Total number of germs (DIN 38 411 K5), *E. coli* und coliform germs (DIN 38 411 K6)
- **Bio-indicators:**
  - Testgerms: *Staphylococcus aureus* and *Enterococcus faecium* (acc. to RKI)
- **Examination by contact-slides:**
  - Total number of germs, free of human-pathogenic germs with differentiation of food-relevant germs (*Salmonella spp., Staphylococcus aureus a*nd *Listeria monocytogenes*)

RABC-System-Implementation

- Determination of a documentation-system

  - principle 7

- documentation depends on size and type of laundry, examples are given in the annex of the standard

examples

Example for principle 7

- The documentation-system shall contain at least the RABC-manual, the operating log and the minutes of the rating-meetings.

  The complete contents of the documentation-system has to be presented in the RABC-manual. The RABC-group must be responsible for the documentation of each process-step in the laundry.

informative annexes of the standard

- Examples of good processing-conditions for the bio-contamination-control (hygiene-plan)
- Examples of microbiological hazard
- Examples of controlling measures

RABC-System-Implementation

- **Preliminaries**

- **Obligation of the management**

  - Agreement to the implementation of the RABC-System
  - Obligation of improvement of the RABC-System
  - Allocation of necessary means

RABC-System-Implementation

- **Preliminaries**

- **Establishing the RABC-Group**

  - special knowledge about working-processes and the final product (if not available, extern know how may be consulted)

  - multi disciplinary compound (e.g. production manager, plant manager, head of department, hygiene representative, workshop manager, a microbiologist)

  - Responsibility: to guide and manage the implementation of the RABC-System

RABC-System-Implementation

- **Preliminaries**

- **Making facilities and working environment available**

  - the management shall provide and register facilities for the control of bio-contamination (e.g. cleaning agents and disinfectants and if necessary, extern cleaning services)

  - the RABC-group shall register, lead and guide human and physical factors of the working environment for the control of bio-contamination (e.g. contact and confer with the production)

RABC-System-Implementation

- **Preliminaries**

- **Determination of the application of textiles**

  - the RABC-Group must document the determination of the textiles under consideration of the requirements of the customer and in dependence to the intended use ("RABC-overalls", grocers, butchers / dissectors, 50 KBE / 1 dm^2)

RABC-System-Implementation

- **Priliminaries**

- **Creating a flow chart of the laundry**

  - the RABC-Group must create a flow chart of the laundry, starting with the collection of the soiled articles up to the delivery of the articles ready for use (incl. car pool)

RABC-System-Implementation

- **Preliminaries**

- **Fixing of Process-Specification**

  - the RABC-Group has to determine a process-specification dependent on use and soiling (what is done when, where and how – e.g. disinfecting washing procedures in the washing machine.., 70 °C, per-acetic-acid etc., program for heavily soiled laundry... etc.)

RABC-System-Implementation

- **Preliminaries**

- **Establishing advanced education and training**

<u>the management shall:</u>

- determine the requirements for training the staff, which is involved in controlling the bio-hazard (usually the hygiene-representative trains the staff regarding hygiene measures)

- rate the training

- make sure that the staff realizes the meaning and importance of their operations for reaching the quality-aims

- document the education, experience, training and qualifications

RABC-System-Implementation

- **Preliminaries**

- **Determination of procurement-details**

  (the microbiological quality depends on appropriate products, which are used during the washing process. The specifications of those products must be referred to in the procurement-documents.

Furthermore helpful and feasable in advance

-Print-out of dosage- and, if possible, temperature-logs

-Hygiene-dispenser for hand-disinfection at the hand-wash-basin as well as hand-wash-basins and hygiene-dispenser at the entrance and exit of the producing areas

-Eventually certificate of disinfecting activities of the cleaning-service

Pest Control

Pest control is necessary because varmints:

- **Eat nearly everything**
- **Contaminate products**
- **Cause illness**
- **Breed very fast**
- **Are unsightly**
- **Must be controlled after implementing the RABC-System**

End of Modules

- If you have learned and understood the modules you can register for the exam