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Evaluation of one laundering process with respect to bacterial reduction according to ISO 14698-1 Appendix E.

Commissioner

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Commission

To evaluate and compare one laundering process with one reference laundering process, where a reference detergent is used, regarding the bacterial reduction. The test was performed according to ISO 14698-1 Cleanrooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods. Annex E – Guidance on validating laundering processes.

Test object

One laundering process denoted System Rodi.

Test period

The test was performed 2014-06-26 – 2014-07-14.

Test procedure

The test was performed according to ISO 14698-1 Appendix E. Two bacteria were used for inoculation:

Enterococcus hirae

ATCC 10541

Escherichia coli

ATCC 10536

Textile samples were prepared by Swerea IVF and sent to SP where the textile samples were sterilized by autoclaving.

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Day 1, 2014-07-10: At SP: Controls and test samples were prepared according to the standard. Textile samples were inoculated with the two bacteria and packaged in separate sterile packages that were put on ice and sent to Swerea IVF where the samples were stored cold during the night.

Day 2, 2014-07-11: At Swerea IVF: The textile samples were attached to the textiles in the load and washed.

Table 1 – Performed washes.

	Washing machine A	Washing machine B
First wash	Control C without bacteria System Rodi	Control C without bacteria Reference wash
Second wash	System Rodi <i>E. hirae</i>	Reference wash <i>E. hirae</i>
Third wash	System Rodi <i>E. coli</i>	Reference wash <i>E. coli</i>

Table 2 – The facts of the laundries.

	System Rodi	Reference wash
Washing machine	Electrolux Wascator FOM 71 CLS	Electrolux Wascator FOM 71 CLS
Washing programme	SS EN 60456:2005 cotton, 4,5 kg, 30 minutes main wash	SS EN 60456:2005 cotton, 4,5 kg, 30 minutes main wash
Washing temperature	30 °	30 °
Water hardness	0	Approx. 1.2 °dH
Detergent without bleaching	No detergent	85.5 g IEC A*

The textile samples were detached from the load and packaged in separate plastic bags, put on ice and immediately transported to SP.

Day 2, 2014-07-11: At SP: A new inoculation was performed for control C. The process described in the standard was performed with the exception that the textile samples were not covered by agar but laid on agar plates.

Control A from day 1 was counted after one day. The controls and samples prepared day two were inspected and the colonies were counted after three days.

Results

The results from the inspection after 3 days incubation are presented in the table below.

Table 3 – Control A

	Number of CFU /ml
<i>E. coli</i> , day 1	5.6×10^8
<i>E. hirae</i> , day 1	8.5×10^8
<i>E. coli</i> , day2	8.2×10^8
<i>E. hirae</i> , day 2	6.5×10^8

CFU = Colony Forming Units

The number of bacteria in the original suspension was $\geq 10^8$ CFU/ml.

Table 4 – Control B

	Number of CFU / ml
<i>E. coli</i> (most heavily contaminated N'1)	\geq control A (original suspension)
<i>E. coli</i> (contaminated N'2)	\geq control A (original suspension)
<i>E. hirae</i> (most heavily contaminated N'1)	\geq control A (original suspension)
<i>E. hirae</i> (contaminated N'2)	\geq control A (original suspension)

The viability of the bacteria did not change over the validation period.

Table 5 – Control C

	Type of process	Number of CFU / ml
<i>E. coli</i> (per textile sample n1)	System Rodi	n.d.
<i>E. coli</i> (filtrate n2)	System Rodi	$>8.2 \times 10^8$
<i>E. coli</i> (per textile sample n1)	Reference wash	n.d.
<i>E. coli</i> (filtrate n2)	Reference wash	$>6.5 \times 10^8$
<i>E. hirae</i> (per textile sample n1)	System Rodi	n.d.
<i>E. hirae</i> (filtrate n2)	System Rodi	n.d.
<i>E. hirae</i> (per textile sample n1)	Reference wash	n.d.
<i>E. hirae</i> (filtrate n2)	Reference wash	n.d.

n.d. = Not determined due to difficulties to count CFU from textile samples/too high numbers of CFU.

The control C is judged to fulfil the demands in the standard and the technique in the method was therefore appropriate to the process conditions.

Table 6 – Results from the samples

	Type of process	Number of CFU /ml	Reduction factor
<i>E. coli</i>	System Rodi	$>4.4 \times 10^4$	5.7×10^3
<i>E. coli</i>	Reference wash	$>3.4 \times 10^5$	7.6×10^2
<i>E. hirae</i>	System Rodi	$>1.0 \times 10^6$	1.7×10^2
<i>E. hirae</i>	Reference wash	$>2.1 \times 10^4$	8.0×10^3

The laundry process for both bacteria species and the washing procedures did not ensure reduction by a factor of at least 10^5 of the numbers of bacteria.

Evaluation

The controls A, B and C showed that the experimental conditions were fulfilled and the test was valid.

Results from the test with the System Rodi showed a reduction of the number of bacteria with the factor 5.7×10^3 for *E. coli* and 1.7×10^2 for *E. hirae*.

Results from the test with the reference wash showed a reduction of the number of bacteria with the factor 7.6×10^2 for *E. coli* and 8.0×10^3 for *E. hirae*.

It was shown that neither the reference wash nor the System Rodi ensured reduction by a factor 10^5 of the numbers of bacteria.

No clear difference between the reference wash and the System Rodi was shown.

The test results are valid for the tested samples and test conditions used only.

SPs quality system is applied, which corresponds to the requirement in SS-EN ISO/IEC 17025.

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