TNO-rapport / TNO report

V5574

Validation of the in-place cleanability of the Butterfly Valve of SODIME S.A. according to the EHEDG test procedure.

Nederlandse Organisatie voor toegepastnatuurwetenschappelijk onderzoek / Netherlands Organisation for Applied Scientific Research

SUMMARY

At the request of SODIME S.A., Chaponost, France the in-place cleanability of the Butterfly Valve was assessed according to the test procedure of the European Hygienic Engineering & Design Group (EHEDG) [Ref 1].

The test results show that the Butterfly Valve, including the EPDM gasket, is cleanable in-place at least as well as the reference pipe. The tests were conducted three times on one test object. The individual test results of the tests are comparable with each other. The Butterfly Valve complies with the hygienic criteria of the Machinery Directive 98/37/EC, annex 1 (additional essential health and safety requirements for certain categories of machinery) section 2.1 (agri-foodstuffs machinery), the hygienic requirements of EN1672 - part 2 and with the hygienic equipment design criteria of the EHEDG [2, 3, 4].

The results obtained are representative of the Butterfly Valve in the size range DN25 (1") up to DN104 (4").

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1 INTRODUCTION

At the request of SODIME S.A., Chaponost France the in-place cleanability of the Butterfly Valve was assessed according to the test procedure of the European Hygienic Engineering & Design Group (EHEDG) [Ref 1].

2 DESCRIPTION OF THE TEST OBJECT

Name of test object	: Butterfly Valve
Туре	: not applicable
Diameter of the outlet port	: SMS 51
Materials of construction	: Stainless Steel AISI 316L
Type of seal	: Gasket
Material of seal	: EPDM, FDA approved
TNO number	: 3119/03/0593

A sectional view of the test object is shown in figure 1. Further detailed information on the test object is given in Appendix A.



Figure 1. Sectional view of the butterfly valve. Specific parts relevant for the test are: 1) Disk, 2) Sectional gasket, 3) and 4) Body, 5) EPDM plug.

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3 TIME SCHEDULE

The test object arrived at TNO Nutrition and Food Research in November 2003 and was registered under TNO number 3119/03/0593. The investigation was carried out from November 2003 to December 2003.

4 MATERIALS and METHOD

Before conducting the test programme, all elastomeric components have been checked against the test strain for antimicrobial properties. Prior to testing, the test object and the reference pipe (having a 0.5 μ m Ra internal roughness) were dismantled, thoroughly cleaned and degreased by hand and steam-sterilized in-line or autoclaved at 121°C for 30 minutes.

The test object and reference pipe were reassembled with an auxiliary pipe at each end and soiled under 5 bar (gauge) pressure with a soured milk solution with spores of the test strain *Bacillus stearothermophilus* var. *calidolactis* (NIZO C953), mixed to give a final concentration of approx. 10^5 spores per cm³ in the milk. The air pressure of 5 bar was applied 3 times to the closed assembly and held at pressure for 2 minutes on each occasion. Whilst under pressure, any movable parts of the test object were operated a total of ten times. After draining and drying by flushing with dry filtered air at a velocity of 1.0 m/s (for 2 to 4 hours) until an exterior relative humidity of $\leq 0.5\% \pm 0.3\%$ was achieved, the test object was cleaned in-place in an in-place cleaning test rig (see Appendix B) by:

1. Rinsing with cold water for 1 minute;

2. Circulating a 1% (w/v) detergent solution at $63^{\circ}C \pm 2^{\circ}C$ for 10 minutes;

3. Rinsing with cold water for 1 minute.

For stages 1, 2 and 3 the mean velocity of flow in the reference pipe was 1.5 m/s. At the end of both rinsing procedures samples of the outflowing water were taken and two 5 ml portions of each were pour-plated with modified Shapton and Hindes agar (MSHA).

After cleaning the inner surface of the test object and reference pipe were covered with molten MSHA. After the agar had fully solidified the test object and reference pipe were placed in an incubator at 58°C for 16 hours.

After incubation the test object and reference pipe were examined for the presence of yellow discolouration in the agar. The degree of discolouration in the agar taken from the test object was compared to the degree of discolouration in the agar taken from the reference pipe. A detailed description of the test procedure including a figure of the test rig is enclosed in Appendix B.

5 RESULTS

The tests were conducted three times on one test object. The results of the independent tests are comparable with each other. The gasket of the test object showed no antimicrobial properties. The pressure during cleaning was 1.0 bar.

In table 1 the average yellow discolouration of the test object and reference pipe are summarized.

Test object	Average Surface finish [µm Ra]	Average discolouration (%)
Butterfly Valve		
 Housing Gasket Disk 	< 0.8 na < 0.8	<5 <5 <5
Reference pipe	0.5	20-30

Table 1. Survey of the test results of the Butterfly Valve.

na = not applicable

6 CONCLUSIONS

The test results show that the Butterfly Valve, including the EPDM gasket, is cleanable in-place at least as well as the reference pipe. The tests were conducted three times on one test object. The individual test results of the tests are comparable with each other. The Butterfly Valve complies with the hygienic criteria of the Machinery Directive 98/37/EC, annex 1 (additional essential health and safety requirements for certain categories of machinery) section 2.1 (agri-foodstuffs machinery), the hygienic requirements of EN1672 - part 2 and with the hygienic equipment design criteria of the EHEDG [2, 3, 4].

The results obtained are representative of the Butterfly Valve in the size range of DN25 (1") up to DN104 (4").

7 RECORDS

Original data sheets, protocols and the final report will be filed in the archives of TNO for 5 years after completion of the study.

8 REFERENCES

- A method for the assessment of in-place cleanability of food processing equipment, European Hygienic Equipment Design Group, Doc. 2, Second Edition March 2000.
- Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member states relating to Machinery
- EN 1672: Food Processing Machinery Basic Concepts Part 2: Hygienic Requirements, April 1997
- Hygienic equipment design criteria, European Hygienic Equipment Design Group, Doc.
 8, July 1993

9 AUTHENTICATION

We, the undersigned, herewith declare that the tests reported here were carried out according to the agreed protocols, that this report contains an accurate description of the results obtained and that the results relate only to the tested object.

Date: January 2004

Ing R.A.A. van der Meer Head of Department

Ing J. Kastelein Project Manager

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APPENDIX A

Detailed information on the Butterfly Valve.



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	6L M JEP 381 165	2059	0,78	38,10	34,80	85,00	38,00	107,00		
	6L M JEP 508 165	2060	1,28	50,80	47,50	105,00	40,00	127,00		
	6L M JEP 635 165	2080	1,38	63,50 76,20	60,20 72,20	112,00	40,00	134,00 147,00		
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APPENDIX B

A method for the assessment of in-place cleanability of food processing equipment.