Review paper
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HYGIENIC DESIGN, TESTING AND CERTIFICATION

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Abstract

With ever increasing demands for production of safe and wholesome food and the need to provide larger quantities to satisfy our growing population, it is essential that food producers and equipment manufacturers pay due regard to hygienic design and cleanability of food processing equipment.

Good hygienic design ensures that equipment can be cleaned effectively and in a reasonable time in order to maximise the efficiency of food production, ensure product safety and reduce waste.

EHEDG recognised the need to provide practical guidelines for the hygienic design of equipment and safe processing and packaging of food many years ago. As a result a large number of Sub-groups have been created to focus on specific aspects but one of the first was Test Methods. The second guideline published by EHEDG was a test for in-place cleanability of closed equipment and this screening test for hygienic design has proved very valuable to both equipment manufacturers and food producers for the manufacture and selection of hygienic equipment. Additional methods have been developed for the assessment of aseptic capability and in the Year 2000 the EHEDG Certification Scheme was launched. This provided equipment manufacturers and food producers with an independent assessment of the hygienic design of equipment and the EHEDG website contains a list of all Certified equipment.

This paper describes the test methods and assessment process for Certification of equipment according to the EHEDG Scheme.

Key words: *Hygienic design, cleaning in-place, hygienic testing, EHEDG Certification, due diligence*.

1. Introduction

Food processing equipment of poor hygienic design can result in food poisoning incidents and the ever increasing public awareness of 'food hygiene' has led to a closer focus on contamination control. Good hygienic design ensures that product soil (including microorganisms) is not retained within areas of equipment that cannot be cleaned effectively and the equipment can be cleaned in a reasonable time in order to maximise the efficiency of food production, ensure product safety and reduce waste. Equipment of poor hygienic design may be cleanable but will require additional effort at a cost that is probably uneconomic.

The European Hygienic Engineering and Design Group (EHEDG) recognised the lack of specific guidance on hygienic design and aimed to provide practical guidelines for hygienic design and assessment of cleanability of food processing equipment. EHEDG has now become internationally recognised as an authoritative source of information and has published many guidelines covering a wide range of subjects. Information contained in EHEDG guidelines has also influenced regulatory bodies in the preparation of National and International Standards. Copies of all EHEDG Guideline documents are available from www.ehedg.org.

This paper describes the EHEDG test methods for assessment of equipment and their integration within the structure of the EHEDG Certification scheme. Current activities of the Test Methods Subgroup and future objectives are also summarised.

2. Test Methods

The EHEDG Test Methods Subgroup was one of the first to be formed and the second document published by EHEDG was a method for the assessment of in-place cleanability of food processing equipment (EHEDG Document No. 2 [1]). This basic screening test for hygienic design has proved very valuable to both equipment manufacturers and food producers for the manufacture and selection of hygienic equipment. Further documents were published soon afterwards describing test methods for in-line steam sterilisabilty (EHEDG Document No. 5 [2]) and bacteria tightness (EHEDG Document No. 7 [3]) in order to address the

specific requirements for equipment intended for aseptic applications. These tests have been used for many years to assess the hygienic and aseptic capability of equipment. Other test methods were developed for the assessment of in-line pasteurisation (EHEDG Document No. 4 [4]), cleanability of moderately sized equipment (EHEDG Document No. 15 [5]), bacterial impermeability of membrane filters (EHEDG Document No. 19 [6]) and challenge tests for the evaluation of the hygienic characteristics of packing machines for liquid products (EHEDG Document 21 [7]). The test methods for in-line pasteurisation, packing machines and bacterial impermeability of membrane filters are mentioned for information only and not applied within the structure of the EHEDG Certification Scheme.

2.1 Test methods for the assessment of in-place cleanabilty

The most frequently used test method is for the cleanability assessment of small to medium sized food processing equipment intended for clean in-place (CIP) applications, such as pumps, valves, sensors, etc. The assessment is based on a comparison, in a laboratory, of the cleanability of a test item with that of a straight piece of 'reference pipe' having a known internal surface roughness and is designed to indicate areas of poor hygienic design in equipment where product or microorganisms are protected from the cleaning process. The full method is published in EHEDG Document 2.

The test procedure involves soiling the equipment and reference pipe with soured milk containing a thermophilic strain of *Geobacillus stearothermophilus* having spores which are resistant to the detergent solution used in the cleaning procedure and produce a well-defined colour reaction in the growth medium used.

The equipment to be tested and the reference pipe are cleaned and sterilised prior to filling with the soured milk containing the indicator microorganisms. The closed assembly is pressurised three times to 5 bar (or higher if required) and any movable parts of the equipment are operated under pressure to simulate in-use conditions. The soured milk is then drained and the test section dried by flushing with dry filtered air. The relative humidity of the drying air is monitored and when this is below RH 5% the test section is mounted in a purpose built test rig and a mild cleaning/rinsing procedure is initiated using a specially formulated detergent and a flow velocity of 1.5 ms^{-1}.

After cleaning, the test section is removed from the test rig and the equipment separated from the reference pipe. The equipment and reference pipe are covered with an agar based growth medium containing glucose and bromocresol purple; which is a pH sensitive dye. The growth medium is liquid when warm and solidifies when cooled. The test equipment and reference pipe are then placed in an incubator at 58 °C for 16-24 hours. During this time any spores remaining in the equipment or reference pipe will germinate and start to grow, fermenting the glucose in the agar to produce acidic end points. These acidic metabolites lower the pH of the agar and change the colour of the bromocresol purple to yellow.

After the incubation stage the equipment and reference pipe are visually examined for the presence of yellow areas in the agar. The agar extracted from the reference pipe is placed on a transparent counting grid having 5mm x 5mm graduations. To facilitate the assessment of yellow areas a colour comparison disc is used to differentiate the transition point between yellow and purple. The areas of yellow discolouration are calculated and expressed as a percentage of the total area of the reference pipe. A yellow area in the reference pipe of between 5-30% is indicative of a normal cleaning procedure. The equipment is then dismantled and the agar inspected for the presence of yellow discolouration. If yellow zones are present in the equipment the area of these are calculated and compared to the area of yellow in the reference pipe. If the yellow areas within the agar extracted from the equipment components are equal or less than the area of yellow in the agar from the reference pipe then the equipment can be classified as cleanable to the same degree as or better than the reference pipe. In the case of very small components, such as O-rings and seals, the area of yellow may be difficult to calculate accurately in order to compare with the reference pipe. In these instances a visual estimation is made and a microscopic examination of the component conducted to determine the hygienic characteristics of the surface and identify any defects. The test must be conducted a minimum of three times to determine that the yellow areas within the equipment are randomly occurring and not indicative of poor hygienic design features. If yellow zones are present in the same areas of the test item on two successive test occasions this is indicative of areas that are difficult to clean and improvements in hygienic design should be considered. In some instances it is possible to have no yellow areas in the equipment and, in this case, the equipment can be described as 'particularly cleanable'. Results from this test can also be used to compare pieces of equipment with respect to their in-place cleanability. However, this test is not indicative of performance in industrial cleaning situations and the onus is still on the user to confirm the cleanability of equipment with their products in-use.

The second cleanability test method developed by EHEDG was for moderately sized items of food

processing equipment intended for CIP cleaning applications but would be unsuitable for testing according to Document 2 due to their physical size and large internal volume, such as homogenisers, heat exchangers, etc. The assessment is also based on comparing the cleanability of the equipment with a reference pipe having a known internal surface roughness. The full method is published in EHEDG Document 15.

The test procedure involves soiling the equipment and reference pipe with a fat spread containing β-carotene food colouring and is not a microbiological based soil.

The equipment and reference pipe are cleaned prior to filling with the fat spread using a peristaltic pump. The test section is closed and pressurised 3 times to 5 bar (or higher if required) and any movable parts of the equipment are operated under pressure to simulate in-use conditions. The soiling agent is drained as much as possible using the peristaltic pump. The test section is then mounted in a purpose built test rig and a mild cleaning/rinsing procedure is initiated using a specially formulated detergent and a flow velocity of 1.5 ms^{-1}.

After cleaning, the test section is removed from the test rig and the equipment separated from the reference pipe. All internal surfaces of the equipment and reference pipe are examined for the presence of residual soil by visual inspection and swabbing the surfaces with a cotton wool swab. The swabbed area is normally 3cm x 3cm. in the case of smaller available areas to be swabbed, e.g. a seal component, then the complete surface is swabbed and this area must be indicated in the test report.

The interpretation of the results is expressed as a relative number (RN) relating to the amount of fatty film and yellow colour visible on the swab. For ease of comparison the reference pipe should contain very small amounts of residual soil. If the amounts of residual soil are randomly distributed between test occasions and equal or less in the equipment components when compared to the reference pipe then the equipment can be classified as cleanable to the same degree as or better than the reference pipe. Presence of residual soil in the same area of the equipment on three separate test occasions is indicative of areas that are difficult to clean and areas in which improvements in hygienic design should be considered. In some instances it is possible to have no visible soil remaining in the equipment and, if this result is obtained on three successive test occasions, the equipment can be described as 'particularly cleanable'. This method is less sensitive when compared to the microbiological method developed for smaller equipment due to the detection level of residual soil being much higher and the quantification of remaining soil is subjective. Whilst the procedure has been shown to be reproducible a more accurate method is required to determine the cleanability of larger items of closed equipment.

2.2 Test methods for the assessment of in-line steam sterilisability and bacteria tightness

These methods have been developed specifically for testing the aseptic capability of food processing equipment and it is recommended that in-place cleanability trials are conducted prior to these tests to verify the equipment's hygienic design.

The first method is designed to indicate whether an item of equipment can be freed internally from viable microorganisms by in-line steam sterilisation. The full method is published in EHEDG Document 5.

The test procedure involves soiling the equipment with a spore suspension of a heat resistant strain of *Bacillus subtilis* having a relatively high D-value (0.71 minutes at 121 °C) and this organism has a long record of use in assessing the sterilisation of food. Prior to testing the equipment is thoroughly cleaned and sterilised. The suspension is used to wet all the internal parts of the dismantled equipment, including surfaces in contact with each other after re-assembly (e.g. gaskets and gasket locating grooves). When the surfaces are visually dry the equipment is re-assembled. A sterilisation procedure is conducted using saturated steam at 121 °C for 30 minutes. After the sterilisation procedure a growth medium of trypticase soy broth (TSB) is introduced into the equipment through aseptic two-way valves by means of a peristaltic pump. The broth is circulated at ambient temperature (approximately 20-25 °C) for two hours every day for five days. A relatively long detection time has been chosen to allow any heat damaged spores to recover and any trapped spores to grow out of contact surfaces into the broth. If the broth remains clear after five days the equipment is classified as in-line steam sterilisable. If the broth becomes turbid and sampling confirms the presence of *Bacillus subtilis* then the equipment is unlikely to be suitable for in-line sterilisation unless modifications are made or special measures taken to avoid problems in practice.

The second method is designed to indicate that sterilised equipment will prevent the ingress of microorganisms from the outside environment to the inside product contact area. This method can be conducted directly after a successful test for in-line steam sterilisability using the same batch of broth and test circuit. The full method is published in EHEDG Document 7.

The test procedure involves coating the exterior joints of the equipment, where leakage to the inside product area may occur, twice a day with a freshly prepared suspension of *Serratia marcescens* for three consecutive days, or longer if required. The

test strain is a small, strongly motile microorganism and is capable of penetrating through small holes and crevices that are very difficult to detect using physical methods. The broth is circulated at ambient temperature (approximately 20-25 °C) for two hours each day by means of a peristaltic pump. After the soiling procedure the broth is circulated for two hours every day for a further five days to allow bacteria to fully penetrate into the test equipment and turn the broth turbid. If the broth remains clear after the 5 day detection period then the equipment is classified as bacteria tight for the duration of the soiling procedure. If the broth becomes turbid and sampling confirms the presence of *Serratia marcescens* then the equipment is not bacteria tight and, therefore, not suitable for aseptic use.

Both tests should be conducted a minimum of three times to demonstrate repeatability.

2.3 EHEDG Certification Scheme

In the year 2000 the EHEDG Certification scheme was launched and based on the assessment of equipment according to the hygienic design criteria (HDC) of EHEDG provided in Document 8 [8]. This document also describes the testing requirements for assessing the hygienic and aseptic characteristics of equipment. This scheme was mainly applied to closed equipment intended for CIP cleaning and aseptic applications. However, coinciding with the launch of the new EHEDG website in 2009, the Certification scheme was more clearly defined and expanded to include additional Certification categories for equipment used for open processing and dry material handling equipment intended for cleaning using wet or dry methods. Equipment Certified according to the new scheme is authorised to display a specific EHEDG logo according to the Certification class and the logo contains the Month and Year of Certification (Figure 1). In connection with this expanded scheme a matrix was produced to define the Certification classes applicable to specific categories of equipment and the intended cleaning procedure (Figure 2). Additionally, a Testing Scheme was established for the assessment of equipment according to Certification Type EL CLASS I, EL Class II and Type EL ASEPTIC (Figure 3). Certification of all equipment must be carried out by an EHEDG Authorised Institute [9] and is subject to contractual conditions (EHEDG Contract [10]). A list of all certified equipment is published on the EHEDG website www.ehedg.org.

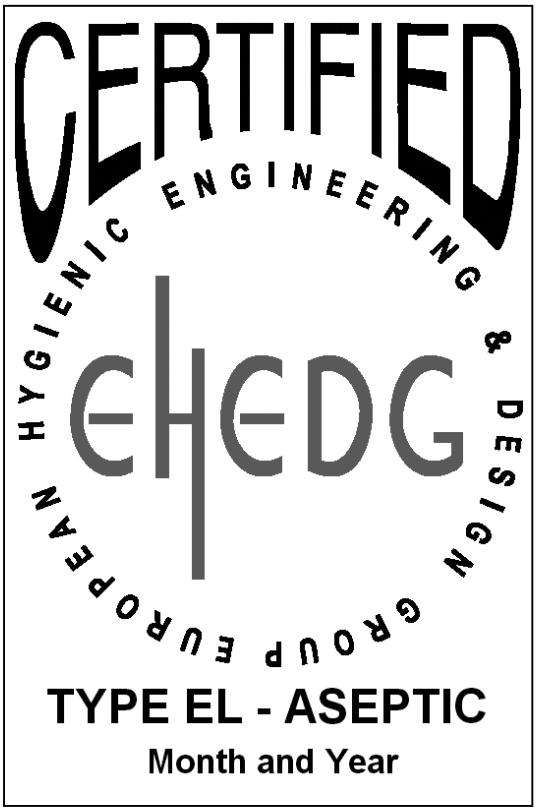

Figure 1. Example of the EHEDG Logo

European Hygienic Engineering & Design Group

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EHEDG Certification Scheme

Certificate Type*	EL CLASS I	EL ASEPTIC	EL CLASS II	ED	
Cleaning procedure	*wet*			*dry*	
	CIP cleaning, cleaning without dismantling		*cleaning with dismantling*	*automatic or manual cleaning*	
Equipment used for processes	closed / open	closed	closed / open	closed	open
Fulfilled requirements according EHEDG doc	8, (9, 10, 13, 16, 32, 35) **	8, (9, 10, 16, 32, 35) **	8, 9, 10, 13, 32, 35 **	8, 9, 22, 26, 32 **	8, 9, 22, 26, 32 **
Test method	cleanability (doc 2 or doc 15) / open process equipment without test	cleanability (doc 2 / doc 15) + sterilisability (doc 5) + bacteria tightness (doc 7)	none	none	none

* Contact EHEDG authorised institutes for design evaluations and equipment classification.
** If necessary, other special guidelines, e.g. doc 25 about mechanical seals, could be used to get more clearness about essential requirements to get an easy to clean design.

Figure 2. EHEDG Certification Scheme

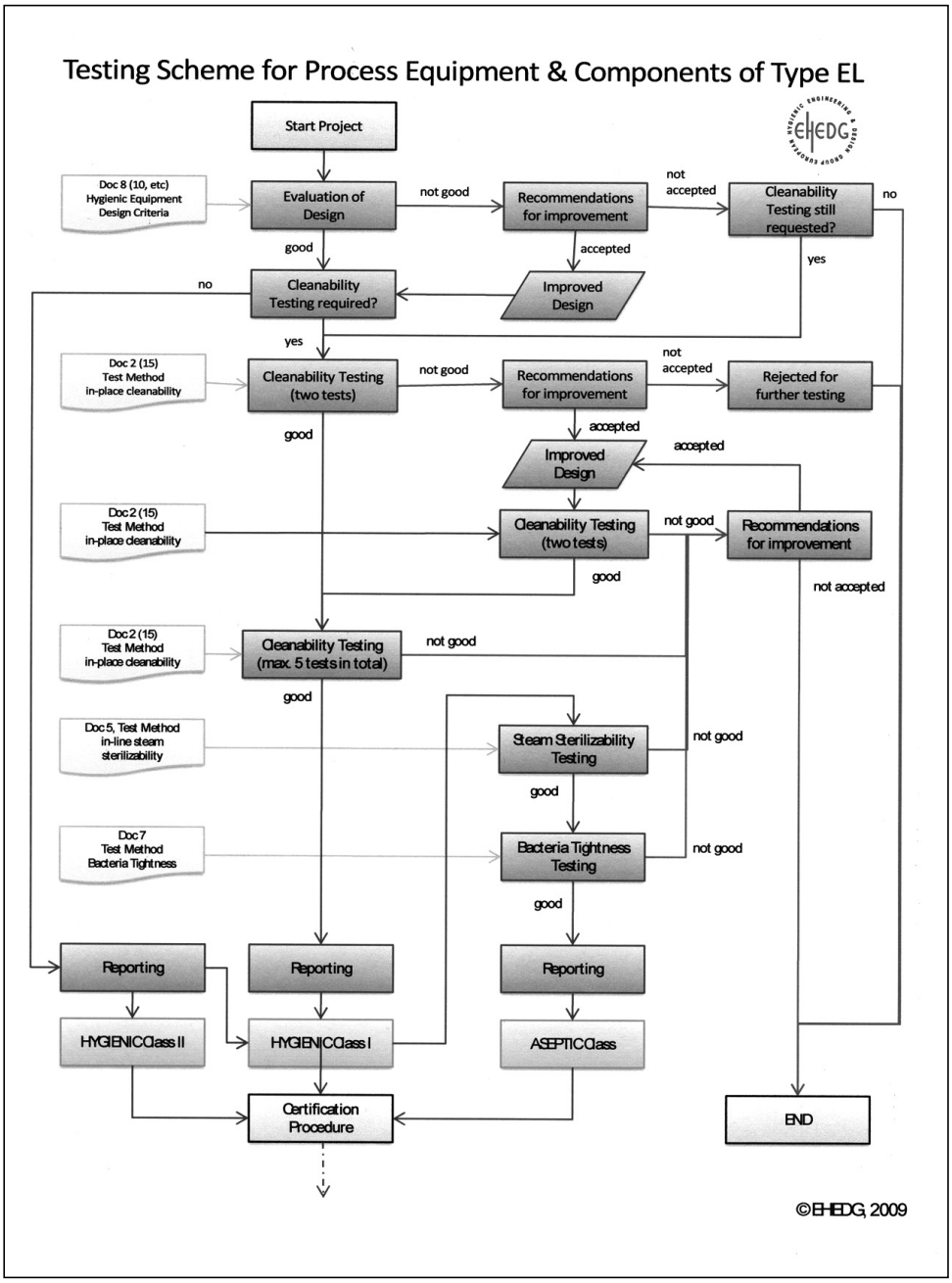

Figure 3. EHEDG Testing Scheme; EL Class I, EL Class II and EL ASEPTIC

2.4 Assessment and Testing Procedures for Certification

The assessment procedure is conducted in a number of stages. Initially, a sectional arrangement drawing of the assembled equipment and detailed drawings of sub-assemblies and components are examined according to the HDC contained in Document 8 for the principal hygienic design criteria to be met. Any other EHEDG documents applicable to the specific equipment are also used for the design review including installation considerations. Unhygienic design features, such as crevices, dead spaces and sharp internal angles can be identified at this stage and the equipment manufacturer informed of recommendations for improvement. The next stage is to conduct a physical examination of the equipment to ensure that the HDC are met in practice. This examination can reveal areas of poor hygienic design that were not apparent on the two dimensional drawings, such as the positioning of seals and control of seal compression. Additionally, surfaces are examined to check that the finishes specified have been achieved and any welds have been performed correctly and are crevice free. If the equipment fully complies with all the HDC applicable to the equipment and no static or dynamic seals are used within the

design then cleanability testing is not always required and the equipment can be Certified, examples include simple pipe bends or sensors that fully comply with the materials of construction, welding procedures, surface finish and radius requirements of the HDC and contain no crevices or dead spaces. Equipment that does not fully comply with the relevant HDC for essential technical or functional reasons or equipment containing static and dynamic seals needs to be tested according to the Testing Scheme. Testing is conducted according to the applicable test method/s up to a maximum of five tests and three successful results are necessary in order to proceed with Certification. If any spurious results are obtained during the testing then the reasons for this must be identified and the tests repeated as necessary. Provided that results of the testing are successful then the equipment can be Certified.

3. Conclusions

- The importance of testing the cleanability of food processing equipment has been highlighted by the fact that some test results have not been as expected. In some instances equipment design features or seal components have proven unhygienic even when the design appears acceptable according to the HDC. Conversely, some design features that do not meet the HDC but are required for essential technical or functional reasons may be acceptable if compensation for loss of cleanability can be demonstrated by practical testing. It is vital, therefore, to ensure that equipment is independently evaluated, inspected and tested to identify areas of poor hygienic design or confirm that certain features required for essential technical or functional reasons are indeed cleanable. Additionally, compliance with EHEDG Guidelines and the results of independent cleanability tests can provide valuable information for manufacturers to design equipment according to the requirements of the European standard for basic concepts of hygienic design (EHEDG Contract [11]) and thereby demonstrate presumption of conformity with the Machinery Directive 2006/42 EC (European Parliament and Council [12]). Test data and independent design assessments may also be used as evidence in the defence of due diligence should a case of food contamination occur.
- Current work within the Test Methods subgroup is focussed on reviewing and updating test methods documents and the new editions will be published in 2012. The group will also continue with the development of new test methods for open equipment to be cleaned with liquids and equipment to be dry cleaned. These methods will be standardised between the Authorised Testing Institutes and subsequently integrated within the Testing Scheme for Certification. However, these additional categories of equipment can currently be Certified following a successful design review, conducted by an EHEDG Authorised Institute, in accordance with all the relevant EHEDG HDC defined in the guidelines applicable to the equipment. Future considerations for the group will be the development of test methods for the assessment of tank mounted equipment and larger items of closed or semi-open food equipment.

5. References

[1] EHEDG Document No. 2, Third edition (2004). *A method for the assessment of in-place cleanability of food processing equipment.*

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