

EHEDG SubCommittee Product Portfolio

SCP – SubCommittee Procedures

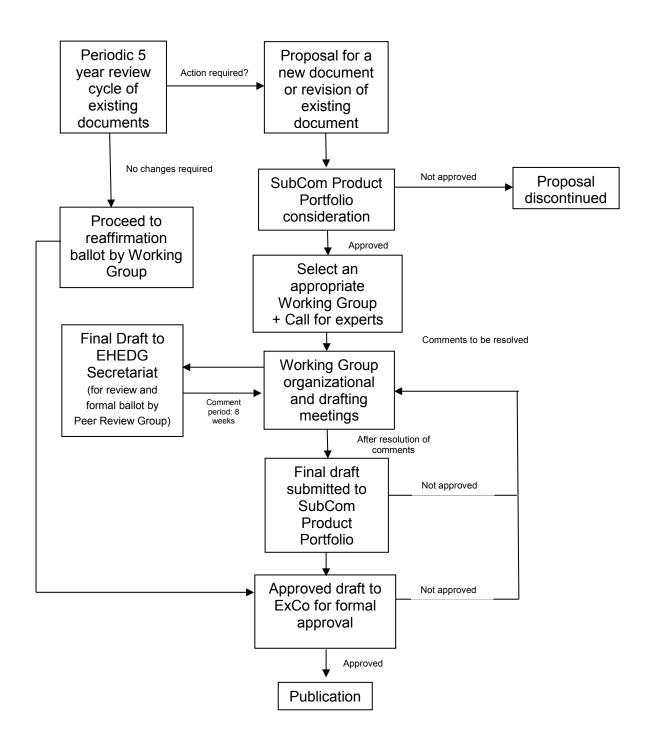


Table of Contents

| i manual on forming, tasks and duties of EnebG working Groups | |
|---|------|
| SCP 1-1 Flow Diagram for Document Development | 4 |
| SCP 1-2 Colour Scheme for Document Tracking Purposes | 6 |
| SCP 1-3 Rules for Working Groups | 7 |
| SCP 1-4 Working Group Reimbursement Rules | 17 |
| SCP 1-5 Strategic Planning | 18 |
| 2 Manual on development, life cycle policy and terms of utilization of EHEDG documents | |
| SCP 2-1 Document Proposal or Revision of Existing Document | 20 |
| SCP 2-2 Document Preparation Manual for Guidelines, Certification Procedures and Training Materials | 22 |
| SCP 2-3 Document Initial Ballot Sign-Off | 33 |
| SCP 2-4 Document Reballot Sign-Off | 34 |
| SCP 2-5 Document Life Cycle | 35 |
| SCP 2-6 Comments Template | 37 |
| 3 Manual on development, life cycle policy and terms of utilization of E Training Material | HEDG |
| SCP 3-1 Training & Education | 38 |
| SCP 3-2 Authorized Trainer Requirements | 46 |
| SCP 3-3 Agreement Training & Education | 49 |
| SCP 3-4 EHEDG Advanced Course on Hygienic Design | |
| SCP 3-6 EHEDG Training at Colleges and Universities | 57 |
| 4 Manual on principles of EHEDG product certification | |
| SCP 4-1 Authorised Testing Laboratories | 59 |
| SCP 4-2 Testing Schemes | 60 |
| SCP 4-3 Criteria for Acceptance as Authorised Testing Laboratory | 68 |
| SCP 4-4 Arbitration of Certification Challenges | 70 |
| SCP 4-5 Certification Contract | 76 |
| SCP 4-6 Equipment Evaluation Form (Appendix 3) | 80 |
| SCP 4-7 Conditions for Use of the EHEDG Certification Logo (Appendix 2) | 82 |
| SCP 4-8 Fees for Granting, Prolongation and Renewal of EHEDG Certificates | 84 |
| SCP 4-9 EHEDG Working Group Certification | 85 |
| SCP 4-10 Authorised Evaluation Officer Requirements | 88 |
| SCP 4-11 ATL Monitoring (tbd) | |
| SCP 4-12 Service Agreements between EHEDG and ATL and EHEDG and AEO | 91 |



Flow Diagram for EHEDG Document Development (Documents include Guidelines, Training Presentations and Certification Schemes)



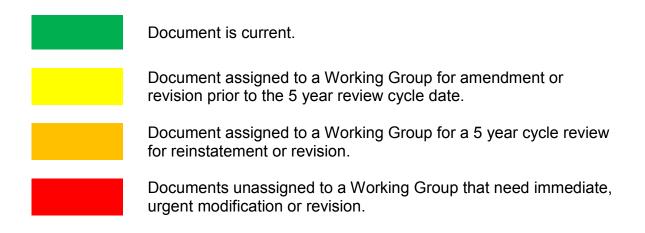


Notes Concerning the EHEDG Document Flow Process

- The proposer for a new or revision to an existing document shall submit an EHEDG Document Proposal or Revision of Existing Document form to the SubCom Product Portfolio for consideration.
- The SubCom Product Portfolio shall review the proposal. Changes or modification to the proposal shall be discussed with the proposer. The proposer shall be notified when the proposal is not accepted by the SubCom Product Portfolio with the reason for rejection.
- STEP 3 The proposer or designated lead author establishes a Working (drafting) Group with a call for experts and coordinates with the SubCom Product Portfolio advisor.
- The Working Group meets as often as necessary based on an approved budget and business plan to establish the document contents, work plan, and timescale. The activities of the Working Group are documented by minutes of the meeting circulated to all members of the Working Group, the SubCom Product Portfolio and the Secretariat.
- The Working Group ballots internally as often as necessary to resolve comments in order to arrive at a final document agreed to by consensus of the entire Working Group. Consensus shall be interpreted to mean a substantial majority of the group agrees with the final draft. Consensus does not mean unanimous agreement.
- The final WG draft is forwarded to the EHEDG Secretariat who will send the document to the members of the EHEDG Peer Review Group for review and a formal ballot for comment and consensus. Comments on the final draft should be submitted to the EHEDG Secretariat for compilation within 8 weeks. The EHEDG Peer Review Group consists of the members of ExCo, the members of SubCom Product Portfolio, all WG and Regional Section Chairmen, and the leaders of the EHEDG Test Institutes.
- After having resolved all comments of the formal ballot by the WG, a final draft of the document plus a compilation of all comments and their resolution is submitted to the SubCom Product Portfolio for approval and comment. If comments are forthcoming, they shall be submitted within 4 weeks and are to be referred to the Working Group to resolve and a new final draft is submitted to the SubCom Product Portfolio.
- The Secretariat circulates the final draft approved by the SubCom Product Portfolio to the ExCo with a recommendation to approve from the Chairman of SubCom Product Portfolio.
- STEP 9 Should the ExCo have comments to the draft, the comments shall be referred back to the Working Group for resolution by the Secretariat and the process will begin again at STEP 7.
- STEP 10 Upon formal approval of the ExCo, the document will be submitted to the Secretariat for formatting and publication.



Colour Scheme for Document Tracking Purposes (Documents include Guidelines, Training Presentations and Certification Schemes)





Rules for EHEDG Working Groups

1 Purpose

EHEDG Guidelines establish criteria for food manufacturing infrastructure (factory design, equipment, and processing).

EHEDG Certification Schemes establish the protocols by which a piece of equipment or a process is allowed to display the EHEDG logo on the equipment or associated materials.

EHEDG Training Materials establish the appropriate means to educate individuals in the approved use and interpretation of EHEDG Guidelines.

These procedures shall govern the activities of Working Groups under the oversight of the SubCom Product Portfolio related to the development, approval, revision, reaffirmation or withdrawal of EHEDG documents.

1.1 Compliance with Competition Law Rules

All SubCom Product Portfolio members and the members of all Working Groups are to comply with the EHEDG compendium on "Compliance with Competition Law Rules" to assure compliance with EU Regulations as described in Bylaw 1 and published on the EHEDG website.

2 Secretariat

The EHEDG Secretariat is responsible for maintaining the administrative support for SubCom Product Portfolio, all Working Groups (WGs) and ad hoc groups established in accordance with these procedures:

- a) Organize the WGs and ad hoc groups in consultation with the SubCom Product Portfolio.
- b) Maintain rosters of all committees, WGs, and ad hoc groups and a list of Guidelines or other documents for which it is responsible.
- c) Provide administrative support for the SubCom Product Portfolio, WGs and ad hoc groups, including secretarial services; arrange meetings; prepare and distribute meeting agendas, minutes, ballots and draft standards; and maintain adequate records.
- d) Submit proposed WG draft guidelines, testing procedures, certification procedures, and training materials, and revisions thereto, for review and conduct formal ballot by appropriate WG members.
- e) Publish approved Guidelines and approved revisions and addenda.
- f) Perform other administrative functions as required by these procedures, including oversight of compliance with these procedures, the administration of appeals and interpretations.

3 EHEDG SubCom Product Portfolio Committee

The SubCom Product Portfolio shall advise the Working Groups of necessary actions for the development and maintenance of Guidelines, Certification Services and Training Materials.



SubCom Product Portfolio consists of the Chair, the Co-Chair and appointed members representing the three product categories EHEDG Guidelines, EHEDG Certification, and EHEDG Training and Education. According to EHEDG Statutes the Chair and the Co-Chair are members of EHEDG ExCo appointed by EHEDG Board on proposal of EHEDG President for a three year term. Other members of SubCom Product Portfolio are appointed by the SubCom Product Portfolio Chair in cooperation with EHEDG ExCo.

A current member list of SubCom Product Portfolio is published on the EHEDG Website.

3.1 SubCom Product Portfolio Chair

The Chair shall:

- a) Assure that SubCom Product Portfolio meeting agendas have been prepared by the Secretariat with adequate input from SCP-members, and other interested parties.
- b) Oversee the distribution of agendas by the Secretariat in a timely fashion that will permit proper consideration of issues by SCP-members.
- c) Attend and preside at meetings.
- d) Conduct meetings in accordance with all due process requirements. On questions of parliamentary procedures not covered in these procedures, Robert's Rules of Order (latest edition) should be followed to expedite due process.
- e) Present policy issues to the SubCom Product Portfolio for consideration and action.
- f) Recommend to the SubCom Product Portfolio the replacement of non-participating members.
- g) Assign leaders to oversee the activities of WGs involved with Training Presentations and Certification Schemes.
- h) Oversee the activities of the WGs involved with Guidelines.

The Co-Chair shall assist the Chair and assume the duties of the Chair in the absence of the Chair.

3.2 SubCom Product Portfolio Responsibilities

The SubCom Product Portfolio shall:

- a) Determine policies and procedures for the committee and the WGs consistent with the general requirements of these Procedures and SCP-2-2.
- b) Administer these policies and procedures for the committee and WGs.
- c) Oversee the current inventory of EHEDG Guidelines, Certification Procedures and Training Materials; and recommend actions to assure that documents are presented for revision, reaffirmation or withdrawal every five (5) years.
- d) Evaluate requests for new Guidelines, Certification Services, and Training Materials activity for relevance to the mission and goals of EHEDG and assign the task to the appropriate WG.
- e) Assign priorities for proposed new document activity and, if necessary, to those in progress.



- f) Maintain and update as necessary the Guidance document for the preparation of Guidelines and Training Materials.
- g) Advise the ExCo of new Guidelines, Certification Services, and Training Materials based on independent research conducted by the SubCom Product Portfolio.
- h) Monitor the use and integrity of the EHEDG Logo.

Members of the SubCom Product Portfolio shall:

- a) Advise and provide the Chair and the Secretariat with appropriate information pertaining to the general application of EHEDG Guidelines, Certification Services, and Training Materials and regulatory requirements.
- b) Participate on a regular basis in SubCom Product Portfolio meetings. If a member is unable to attend these meetings, a written explanation to the Chair may be required.
- c) Respond to all correspondence or ballots requiring a reply by the identified closing date.
- d) Conduct oversight of the WGs as directed by the Chair.

3.3 Criteria for the Consideration of EHEDG Guidelines, Certification Services, and Training Materials

The SubCom Product Portfolio shall employ the following criteria when evaluating the need for new, revised or amended EHEDG Guidelines, Certification Services, and Training Materials.

- a) EHEDG, through its consensus document development activities, supports the compatibility of provisions of EHEDG Guidelines, Certification Services, and Training Materials with European regulations.
- b) Only criteria for food manufacturing infrastructure (factory design, equipment, and processing) that are available on the commercial market are eligible for consideration for new, revised or amended EHEDG Guidelines, Certification Services, and Training Materials.
- c) Demonstrated need by the proposer for the requested amendment or revision.
- d) Demonstration that the proposer is willing to be or has arranged for a chair of the document group. Lack of support by the proposer is sufficient reason to deny the request.

3.4 Actions Requiring Approval by a Majority of the SubCom Product Portfolio

The following actions require approval by a majority of the membership of the SubCom Product Portfolio whether at a meeting, by letter, or by e-mail ballot:

- a) Adoption of SubCom Product Portfolio and WG operating procedures, or revisions thereof.
- b) Approval of minutes.
- c) Approval to forward to the ExCo new, or revisions to an existing EHEDG Guidelines, Certification Services, and Training Materials for formal ExCo approval.
- d) Formation (and later disbandment) of WGs.



4 Document Working Groups (WGs)

4.1 Formation of a Working Group

The SubCom Product Portfolio may, with concurrence of the ExCo, designate WGs to expedite the work of EHEDG. The formation (and later disbandment) of a WG requires approval by a majority vote of the SubCom Product Portfolio. A list of current WGs is maintained on the EHEDG web site. The scope and duties delegated to the WG shall be approved at the time it is formed, and subsequent changes in scope or duties shall also require approval by the SubCom Product Portfolio. The charge to the WG shall clearly state whether the WG is responsible for developing the definitive content of one or more EHEDG Guidelines, Certification Services, and Training Materials and for responding to views and objections thereon.

A WG, once formed, is considered as a permanent committee. The membership may fluctuate as members join or are replaced. The WG Chair makes nominations from the EHEDG members for appointments and discharges to the WG with the consent of the SubCom Product Portfolio. In addition to interest group affiliation, the SubCom Product Portfolio may apply specific criteria in the designation of members of a WG, such as whether a candidate is knowledgeable of the specific equipment, systems or materials covered by the EHEDG document(s) assigned to the WG.

The number of members of a specified WG is not limited. Each member is considered as a voting member. There shall be only one (1) voting member per entity (i.e., company or company division, European or state agency, or university) on a WG. The determination of a company or company division for the purpose of participation on a WG shall be made by the WG Chair and based upon the type of equipment, process used, factory design, certification services, or training materials needed. For example, a company that manufactures plate heat exchangers, tubular heat exchangers, and ice cream freezers may have a voting member from each entity on the respective WG provided the equipment is manufactured by separate company divisions; similarly, a processing company that produces fluid products and dry product processing at separate operations may have a voting member from each entity.

The SubCom Product Portfolio shall review the scope, duties, work progress, and membership of all WGs annually. The Secretariat shall maintain for each WG a membership roster that includes the following information:

- a) Title of the WG and its designation;
- b) Scope of the WG;
- c) Chair and Co-Chair; and
- d) Name of members, addresses, and business affiliations, e-mail, phone, fax, etc.

4.2 Working Group Chair

The SubCom Product Portfolio shall designate a Chair and Co-Chair from the WG members. These positions are considered as permanent in order to maintain consistency; however, there is no fixed term for either of these positions. A request to the SubCom Product Portfolio for a Chair or Co-Chair will be called by the Secretariat whenever either position resigns or a request for a change has been received from at least three (3) WG members.

The WG Chair is responsible for:

a) Preparing agendas and planning for meetings necessary to carry out the function of the WG.



- b) Directing the formulation and development of the documents assigned to the WG.
- c) Draft and submit to the EHEDG Treasurer via the Secretariat and SubCom Product Portfolio an annual budget, including reimbursements, no later than November 30 for the year to come.
- d) In consultation with the Secretariat, preparing draft documents of the WG for balloting.
- e) Maintaining appropriate administrative records relating to the actions of the WG.
- f) Regular participation in WG meetings and other EHEDG meetings/functions as is deemed necessary to conduct the business of the WG.
- g) Reviewing and resolution of comments and negative ballots pertaining to WG documents.
- h) Act as the liaison and technical advisor to the SubCom Product Portfolio when interpretations of a document's criteria are needed.
- i) Select and maintain the WG membership with active members that represent and balance the concerns of the stakeholders.
- j) Prepare an annual summary of the WG's activities for the Chair of the SubCom Product Portfolio. The summary should be delivered by January 30 of the following year.

4.3 WG Responsibilities

As assigned by the SubCom Product Portfolio, the WG is responsible for:

- a) The development and maintenance of any assigned EHEDG guideline, certification procedure, or training material package within designated time-frames and target dates
- b) Responding to questions or inquiries pertaining to the documents under their purview,
- c) Commenting on international standards to promote harmonization,
- d) Informing the SubCom Product Portfolio of activities and progress on documents under development or review.
- e) Recommend to the SubCom Product Portfolio the need for new documents or revision of existing documents.

4.4 WG member responsibilities:

- a) Participate on a regular basis in WG meetings.
- b) Actively participate in the routine functions of the WG, such as soliciting comments and seeking reconciliation of viewpoints on any tentative document.
- c) Answer all correspondence requiring a reply and ballots by the closing date.

A WG member may be removed from the WG for:

- a) Two successive unexcused absences from WG meetings,
- b) Failure to respond to two consecutive WG ballots, or



c) Failure to respond to correspondence from the Chair of the WG.

Written notice to the WG committee member of this action will be provided by the Secretariat.

4.5 WG Majority Requirements

A ballot of the members of the WG shall be taken in accordance with these procedures for the approval of a draft EHEDG document or any substantive change in the content of a document to be presented to the SubCom Product Portfolio for final approval.

4.6 WG Corresponding Members

Anyone interested in participating in the activities of any WG will be, at a minimum, assigned Corresponding membership. Corresponding members are invited to actively participate in all WG activities and are encouraged to comment on all documents. Corresponding members shall not have a vote but the WG must consider their comments.

4.7 EHEDG Peer Review Group

The members of the ExCo, the SubCom Product Portfolio, other Working Group Chairs, Leaders of the Testing Institutes, and the Chairmen of each of the Regional Sections form the Peer Review Group.

The members of the EHEDG Peer Review Group shall be considered as WG Corresponding members of each Working Group. These individuals are to be included in all mailings and encouraged to provide comments whenever a WG's activities impact on their areas of responsibility so that issues of concern can be dealt with by the WG before documents are circulated for formal WG ballot.

5 Consensus and Due Process Policies

"Consensus" means directly and materially affected interest parties have reached substantial agreement. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution. This will be achieved by following the principles stated below:

- All EHEDG Documents under the oversight of SubCom Product Portfolio shall be developed according to SCP 1-1.
- WG final draft documents shall be subject to a formal review and ballot process by the EHEDG Peer Review Group.
- SubCom Product Portfolio shall supervise the document develop and review process according to SCP 1-1.
- Formal ExCo approval of all documents shall be accomplished by a ballot of the members of the ExCo and other interested parties approved by the ExCo. Voting by the ExCo occurs after the document has been developed by the assigned WG, has been reviewed and recommended for approval by the SubCom Product Portfolio as outlined in SCP 1-1.



6 Voting Procedures and Policies

6.1 Ballots

New EHEDG Guidelines, Certification procedures, or Training Materials, reaffirmation and revision of existing EHEDG Guideline, Certification procedures, or Training Materials, and the withdrawal of EHEDG Guideline, Certification procedures, or Training Materials shall be formally approved by ballot of the ExCo.

Administrative and editorial changes to that EHEDG Guideline, Certification procedures, or Training Materials which are non-substantive may be decided by a majority of the members present at a regularly scheduled meeting of the WG with concurrence of the SubCom Product Portfolio.

6.2 Voting

The ballot notification shall include:

- The purpose and intended application of the EHEDG Guideline, Certification procedures, or Training Materials;
- A copy of the complete proposed or the EHEDG Guideline, Certification procedures, or Training Materials, or relevant portion under consideration when the ExCo member has previously received the complete document;
- c) Official ballot(s) to all voting body members.

Each member of the voting body shall vote one (1) of the following positions on an original ballot:

"Approved as presented (no comment)"

(Your ballot agrees with the entire document as presented.)

"Approved, with editorial comment(s) (nonsubstantive)"

(Your ballot agrees with the intent of the document as presented but you wish to offer suggested changes that are technical or editorial in nature but are not substantive. The WG may or may not incorporate the comments at their discretion.)

"Disapproved, with substantive comment(s)"

(Your ballot does not agree substantively with some aspect of the document and you feel it should not progress until your substantive comments are resolved.)

The member shall sign and date the ballot. A typed name on an electronic ballot shall be considered as a signature. Voting by alternates or proxies is not permitted.

6.3 Resolution of a Negative, with reason ballot

To be considered, a negative ballot shall be accompanied by an explanation of the public health or hygienic design concern, with appropriate citations of regulation, if applicable, and shall include specific wording or actions that will resolve the objection.



The WG Chair shall attempt to resolve the negative ballot informally. The resolution may include wording modifications provided they do not substantially change the meaning of the original section, or clarification of a misunderstanding. When this is accomplished the negative balloter shall indicate by email that the negative ballot has been resolved and the ballot changed to "Approve".

When the negative ballot cannot be resolved the issue is to be presented for a secondary ballot. The secondary ballot shall only address the negative ballot issue. The remainder of the original document is not open for additional comment. The ballot shall show the original criteria and the proposed new criteria wording to resolve the objection. The choices as shown on the secondary ballot shall be:

"Yes, I accept the proposed (new) wording"

(Your ballot agrees with the proposed substantive change as presented in the secondary ballot.)

"Yes, I accept the proposed (new) wording, with comment"

(Your ballot agrees with the intent of the proposed substantive change as presented but you wish to offer suggested changes that are editorial in nature for consideration, not substantive changes. The WG may or may not incorporate the comments at their discretion.)

"No, I want to retain the original (ballot) wording"

(Your ballot does not agree with some aspect of the proposed substantive change and you want to retain the original wording from the original draft ballot.)

Note: These procedures may also to be used at the Working Group and SubCom Product Portfolio levels for preliminary ballots used to finalize other documents for SubCom respective ExCo consideration.

6.4 Voting Period

The voting period for ballots shall end no less than forty-five (45) days from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the Secretariat's option, when warranted.

A follow-up notification requesting immediate return of the ballot shall be sent to members whose votes have not been received within ten (10) business days before the ballot closes.

Within thirty (30) days after the close of a ballot, the Secretariat shall report the results, including all comments, to the Chair.

6.5 Majority Requirements for Actions

A ballot to be considered as valid shall have a total return by at least 80% of the ExCo members.

Approval of an EHEDG Guideline, Certification procedures, or Training Materials or reaffirmation of an existing document requires an "Approved as presented (no comment)" or "Approved, with editorial comment(s) (nonsubstantive)" vote by a minimum of 70% of the entire ExCo.



Approval of an EHEDG Guideline, Certification procedures, or Training Materials secondary ballot requires a "Yes, I accept the proposed (new) wording" or "Yes, I accept the proposed (new) wording, with comment" vote by a minimum of 70% of the casted votes.

6.6 Reporting Votes

The results of each vote on all EHEDG Guidelines, Certification procedures, or Training Materials shall be reported to the SubCom Product Portfolio as follows:

- Number of members.
- Number of members voting affirmatively.
- Number of members voting negatively with reasons.
- Number of members voting negatively without reasons.
- Number of members abstaining.
- Number of members not returning ballots.
- Listing of comments submitted.

6.7 Substantive Changes

A substantive change in an EHEDG Guideline, Certification procedures, or Training Materials is one that directly and materially affects the use of the EHEDG Guideline, Certification procedures, or Training Materials. Examples of substantive changes may include but are not limited to:

- a) Addition, deletion or revision of requirements, regardless of the number of changes;
- b) Addition of mandatory compliance with referenced standards.

7 Getting Started

7.1 New Guideline or revision of an existing Guideline

A proposal to revise an existing, or to propose a new EHEDG Guideline must first be approved by the SubCom Product Portfolio. An *EHEDG Document Proposal or Revision of Existing Document* form (SCP-2-1) should be completed and sent to the EHEDG Secretariat. If the proposal is for a new Guideline, include a proposed Scope for the document. The Secretariat will forward the proposal to the SubCom Product Portfolio. SubCom Product Portfolio will take approximately 30 days (via their ballot process) to either recommend to the ExCo approval of the proposal to be developed by the appropriate Guideline Working Group or deny further development of the proposal.

Once approved by the ExCo, the activity is conveyed to the appropriate WG; at the discretion of the WG, the actual drafting may be further assigned to a smaller Document Workgroup of subject matter experts in accordance with these procedures.

7.2 5-year life-cycle up-dates to existing EHEDG Guidelines

The Secretariat with concurrence from the SubCom Product Portfolio will notify the WG Chairs one year prior to the 5-year life-cycle anniversary date of the document to begin the process of



review and affirmation or modification of the EHEDG Guideline, Certification procedures, or Training Materials.

7.3 Working Groups

If the SubCom Product Portfolio approves development of the proposal or if the Secretariat assigns a 5-year review, the proposal is sent to the appropriate WG for development. Usually, the person who submitted the proposal becomes the Document Leader for the proposal and manages its technical revision. This person may, with the consent of the WG Chair, recruit other interested subject matter experts to assist in the proposal's development.

The drafters must develop the document in the proper format, according to the most recent guidance provided by the SubCom Product Portfolio.

The document shall be developed according to the process outlined in SCP 1-1.



Working Group Reimbursement Rules

Working Groups are comprised of experts whose know-how and expertise is recognized by the Working Group Chair to be essential to bring its work forwards.

A Working Group usually meets three or four times a year. All EHEDG Working Group work is voluntary and not remunerated. Working Group experts are neither paid for time working on a Working Group nor are they refunded for any lost income in their regular work resulting from their Working Group participation.

Travel and hotel expenses incurring on occasion of EHEDG Working Group meetings are to be assumed by the experts themselves or respectively by their companies. EHEDG will usually arrange for the meeting facilities and catering, however, the companies participating in a Working Group are welcome to host such meetings as well.

Working Group expert participants from universities and institutes without available travelling funds may apply for reimbursement of their travelling and accommodation expenses to allow them participation at the Working Group meetings. Travelling costs of company participants will be reimbursed only in exceptional cases, subject to the approval of the EHEDG Treasurer.

The Working Group expert seeking financial assistance shall submit a request for financial support to the EHEDG Secretariat within four weeks in advance of a meeting for approval by the EHEDG Treasurer. If approved, the participant is required to submit to the Secretariat a detailed travel expense report (see standard form 'Claim for Travel Expenses') together with the relevant receipts after the meeting for refund to his account. All reimbursement inquiries shall be submitted individually in advance to a meeting. Approval is granted on a case-to-case basis unless otherwise agreed with EHEDG. All requests for funding shall be within the limits set forth in the EHEDG 'Rules for Reimbursement of Travel Expenses'.

EHEDG reserves the right to limit request for funding to a maximum of three experts per Working Group provided they are from different countries and/or organizations unless otherwise agreed upon by EHEDG. All such agreements are subject to approval by the EHEDG Treasurer and – in case of doubt – require mutual consent of the EHEDG Foundation Board (N.B.: President, Vice President and Treasurer) and the Working Group Chairman who will be copied with the relevant correspondence.



Strategic Planning

1 Purpose

Strategic planning is an important, necessary function of the SubCom Product Portfolio to assure that the limited resources of EHEDG and its voluntary contributors are effectively utilized for the advancement of EHEDG Guidelines, Testing Procedures and Training Materials. The needs of the industry and the Regional Sections must be considered.

2 Document Life Cycle

Documents include Guidelines, Training Presentations and Certification Schemes. Each document developed shall have a five (5) year life cycle. At the end of that time period, the document shall be reaffirmed as written, revised to meet current industry needs, or discontinued. Each of the SubCom Product Portfolio Working Groups charged with the monitoring of those documents shall have procedures in place to assure that the documents remain current.

3 Strategic Planning

- a) SubCom Product Portfolio will maintain a three (3) year continuing strategic plan.
- b) SubCom Product Portfolio shall maintain a three (3) year rolling strategic plan. Once the original 3 year plan is established, the SubCom will evaluate the progress made on the current year's plan prior to the final ExCo meeting of the year. Based on the evaluation, the next two years of the plan will be revised as necessary and a projected plan for the third future year will be created. The current year's evaluation and the extended 3 year plan will be presented to the ExCo for concurrence.
- c) The topics and issues shall include but not be limited to the following:
 - A review of documents by industry categories to determine what the needs of that industry group may be. This may include priority scheduling for a specific document review and modification, or need to develop new documents for industry concerns not currently covered.
 - The progress of current projects under development to assure adherence to established timelines.
 - The needs and suggestions from the Regional Sections. The topics should emphasize guidelines and training materials needed by the Regional Sections.
 - Proposals from the Guidelines Working Group chairs to assure that the 5 year life cycle is adhered to and that planning for the future reviews are scheduled.
 - Proposals from WG Training & Education on the need for new or revised training materials and projections of their work progress. The proposed schedule of training sessions to be provided. The approval or removal of approved trainers available to the industry.
 - Proposals from WG Test Methods & Test Institutes on the need or establishment of new Test Institutes, any changes to the testing or certification schemes, or projection of fees.



- d) The report to the ExCo shall include a summary of the successful completion or variations in the current year's strategic plan.
- e) Upon concurrence and approval by the ExCo the strategic plan shall be distributed to all of the affected parties in January of the new year.



EHEDG Document Proposal or Revision of Existing Document

(Documents include Guidelines, Training Presentations and Certification Schemes)

| Is this a new document or revision of an existing document? | | |
|---|---|--|
| \square NEW | □ REVISION | |
| Identify docume | ent number and title: | |
| If new, provide | a draft SCOPE of the document: (use additional pages if necessary) | |
| | | |
| the existing doo | ovide the topic of the proposed revision: (include the section number in cument.) | |
| | | |
| Outline briefly t | he need/justification for the new document or proposed revision. | |
| | | |
| | | |
| Identify a lead a | author/document leader for the new document or revision: | |
| | | |
| | filiation: | |
| Phone: | | |
| E-mail: | | |



| 6. | Identify key members of the working group who have been identified? (If none, why?) | | | | |
|------|---|-----------------|---|--|--|
| 7. | Are there any cost implications to EHEDG? If so, describe. | | | | |
| 8. | | | timeline for completion of the project? | | |
| 9. | Identify | the colour co | de for the proposal: | | |
| | | | No special urgency. See completion date under item 8. | | |
| | | | Document or revision needs development as soon as possible. | | |
| | | | Document or revision urgently needed. | | |
| Nar | me of pro | poser: | | | |
| Affi | liation an | d address: _ | | | |
| Pho | one: | | | | |
| E-N | /lail: | | | | |
| | | | | | |
| Sig | nature | | Date | | |
| (For | office use | only) | | | |
| Date | e received: | | | | |
| | | by SubCom Pro | | | |
| Date | assigned | to Working Grou | ıp: | | |



Document Preparation Manual for Guidelines, Certification Procedures and Training Materials

How to use this manual

1 Introduction

This guidance document illustrates the format and verbiage that should be used to develop EHEDG Guidelines, Certification Procedures, and Training Materials to describe the hygienic concepts found therein.

EHEDG Guidelines, Certification Procedures, and Training Materials are developed to detail the hygienic principles for types of equipment, processes or factory layout; the procedures and protocols for the certification of these items; and, the training materials necessary to effectively instruct users and trainers in the correct interpretation and application of hygienic principles. It is likely that revisions and/or additions will be necessary as technology and hygienic criteria advance.

The criteria found herein are to be used as a guide for preparing new, revisions of, or amendments to existing EHEDG documents. Conformance to the suggested structure, format, symbols, and wording, as appropriate in this document will assist in the uniformity between documents and improve the review and acceptance by the stakeholder groups.

All new and revisions of documents are to be harmonized with other EHEDG documents.

The following is the recommended sequence for the text of documents. A brief explanation of the purpose and content of each section is also provided. The point system for numbering sequences in documents has been adopted by many national organizations and government agencies.

2 Document Format

All documents are to be prepared in English. Subsequent translations will be accomplished by the Regional sections as necessary.

Working Groups should write the documents in as simple terms as possible so that the intent will be understood by all non-engineer readers.

As soon as possible during the initial drafting of a document, it is to be sent to the Secretariat so that a **DRAFT** watermark, which only the Secretariat can remove, shall be added. This watermark shall remain on the document to be removed by the Secretariat immediately prior to publication.

Guidelines and Certification Schemes documents are to include the following sections in the order that they are presented below if appropriate. Training Presentation slides are encouraged to follow the suggestions as appropriate to assure conformity to the documents they represent.

A EHEDG Guideline Template is provided at the EHEDG Website Working Group Section by EHEDG secretariat. Working Groups shall use the current template for new and the revision of existing EHEDG Guidelines.



2.1 Title Page - Required

The Title Page is comprised of two actual pages as shown in Figure 1.

Page 1 includes the standardized EHEDG Guidelines graphic with the document number, document title, edition number, and date (Month and Year) centred below. The EU Flag shall be in the lower left corner and the EHEDG Logo in the lower right corner of the page.

Page 2 shall show the following information arranged as in Figure 1.

European Hygienic Engineering and Design Group

EHEDG Secretariat

Lyoner Str. 18

60528 Frankfurt, Germany

Tel: +49 69 66 03-12 17 Fax: +49 69 66 03-22 17

E-Mail: secretariat@ehedg.org

Web: www.ehedg.org

The following disclaimer is required:

THE ENGLISH VERSION OF THIS EHEDG DOCUMENT IS THE OFFICIAL VERSION. THE RESPONSIBILITY FOR THE PREPARATION, DEVELOPMENT AND ISSUANCE OF SUCH GUIDELINES LIES WITH EHEDG. DUE TO THE TECHNICAL AND GENERAL NATURE OF THE GUIDELINES EHEDG MAY NOT ASSUME ANY LIABILITY RESULTING FROM THE INTERPRETATION, APPLICATION OR USE OF SUCH GUIDELINES.



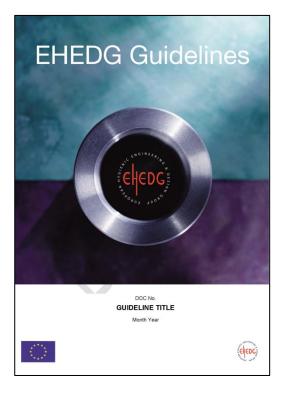




Figure 1

The title is not intended to provide the scope. The title should be concise but complete enough to identify the equipment or system being covered by the document. Titles for analogous guidelines should be similar except for the distinctive feature(s) of the equipment or system.

Beginning with page 2, all pages are to include the EHEDG logo centred in a header and a footer showing the document number, "©EHEDG", and the edition number (i.e. "Second Edition") on the left side of the footer. The page numbers shall be centred and designated as (page) of (total pages).

All documents shall include a clause proclaiming the EHEDG copyright.

2.1.1 Effective Date – Required

The effective date (Month Year) shall be forty-five (45) days following approval by the ExCo. The date shall be shown on the Cover Page.

2.2 Table of Contents – Required

A Table of Contents is to be created for each new or revised document. The table of contents shall include all sections, both numbered and non-numbered.

2.3 Disclaimer - Required

The disclaimer, as presented in Section 2.1, shall be included in all new, revised and updated documents.



2.4 Recognition and Acknowledgement - Required

The Working Group members instrumental in the development of the document shall be recognized. This section shall identify the document name, edition, document date, Working Group member names and affiliations, designation of the Working Group Chair, and any other acknowledgments as appropriate. The information shall be presented as shown in Figure 2.

All acknowledgements, other than the participants who developed the document, are to be recognized in this section.

2.5 Summary - Required

A brief summary (abstract) of the document is to be included. This summary shall be suitable for use by the Secretariat for inclusion in the document EHEDG Guidelines, Titles available and description.

2.6 Introduction - Required

This section shall provide a brief description of background information and the industry need that prompted the development of the document.

2.7 Objectives and Scope (Section 1) - Required

The scope should amplify the title. For equipment types, it should state the function and limits of the equipment and should be distinguishable from those found in other guidelines. For processes or processing environments and plant layout guidelines, it should identify the nature of the system, the subject or application, and should be distinguishable from those found in other guidelines. In both cases, the scope should be concise, but complete enough to define the boundaries of the equipment or system. The scope is the statement of intent.

At times it is appropriate to include restrictions of the guidelines in the scope. However, the limits and functions of the equipment or system cannot be overemphasized, since the scope defines the criteria necessary for the rest of the document.

2.8 Normative References (Section 2) - Required

A Normative References Section shall be included in all new and revised documents. Normative references are references to legislation, regulations or standards mandatory for the application of the document. Other references should be listed in the literature section (2.10). Once listed, the reference documents do not have to be further cited in the Fabrication Section, unless there are very specific qualifying criteria to be considered.

2.9 Definition of Terms (Section 3) - Required

Terminology and definitions should be limited to those actually used in the document. It is customary to define the product contact and non-product contact surfaces or zones. Often the method of cleaning (CIP, mechanical or manual) is included. Terms necessary to describe specific equipment or systems may be included, especially if the terms are not standard ones. Definitions are written in dictionary form with the defined terms italicized. Cyclical definitions are not permitted. For some guidelines, this section should contain a sequential (with respect to process) listing of required components and, if necessary, optional components may be listed.



2.10 General Considerations (Section 4) - Required

This section contains general topics to be considered under the scope of the document (e.g. hygienic design criteria). If these topics are already addressed in EHEDG Guidelines reference should be made to these guidelines.

2.11 Special Considerations (Section 5) – Required

This Section contains the bulk of the specialized criteria and information that comprises the intent and value of the document. The organization of the information is at the discretion of the Working Group preparing the document. See section 5 of this document for guidance on the use of pictures and illustrations.

- The guidelines should identify weak points and typical problem points in a design or process and describe how to resolve the problem(s).
- Marketing issues shall be excluded from any document's contents.

If the document is a test or certification procedure, this section should clearly specify the methods and steps in the analysis or procedure. A subsection shall be included that defines what is acceptable as proposed to what fails the test or procedure.

Installation criteria, when required, may include but is not limited to regulatory requirements; proper juxtaposition of equipment, floor, wall or ceiling clearance; and interconnections and hard wiring for required regulatory controls.

2.12 Supplemental Reading – Optional

This section includes all documents not mandatory or referenced for application of the respective guideline

2.13 Appendix (Appendices) – Optional

Any Appendix is advisory or informative unless specifically cited in the Special Consideration Section as requiring conformance. It may also include other advisory information useful for proper construction, material specifications, installation, cleaning and diagrams of the equipment or system covered by the document.

Other information that may be suitable for an Appendix is a listing of suggested further reading, appropriate websites, or a bibliography.

2.14 Key Learning Points – Required

The WG shall develop a list of key learning points from the document. The key learning points shall be towards the hygienic aspects of the guidelines. These key learning points may not be included as part of the guideline. They shall be conveyed to the Chair of the Training and Education WG in a memo or email. Also, the Training and Education WG will use the key learning points when developing a training module for the material presented in the document.

3 Abbreviations

Certain universal abbreviations are commonly used without definition. These should be in accordance with existing industry and/or military usage. It is recommended that use of less common abbreviations be limited and that they be defined the first time they appear in the document by spelling out the word(s), followed by the abbreviation in parentheses. If the



abbreviations are numerous, an abbreviation glossary may be compiled and placed in the Appendix Section of the document.

4 SI Units and Symbols Found or Potentially Used in EHEDG Documents

Table 1 - Base SI Units

| Quantity | Unit | Symbol |
|---------------------|----------|--------|
| Length | meter | m |
| Mass | kilogram | kg |
| Time | second | S |
| Electric current | ampere | Α |
| Thermodynamic | kelvin | K |
| Amount of substance | mole | mol |
| Luminous intensity | candela | cd |

Table 2 - Derived SI Units

| Quantity | Unit | Symbol | Formula |
|-------------|-------------------|--------|---------------------|
| Frequency | hertz | Hz | 1/s |
| Force | newton | N | Kg-m/s ² |
| Pressure | pascal | Pa | N/m² |
| Energy | joule | J | N*m |
| Temperature | degree celsius | °C | K - 273.15 |

Table 3 – Supplementary SI Units

| Quantity | Unit | Symbol |
|-------------|-----------|--------|
| Plane angle | radian | rad |
| Solid angle | steradian | r |



Table 4 - Units in Use with SI

| Quantity | Unit | Symbol | Definition |
|-------------|----------------------------|--------|---|
| Time | minute | min | 1 min = 60 s |
| | hour | h | 1 h = 60 min = 3600 s |
| | day | d | 1 d = 24 h = 86,400 s |
| | week, month, | | |
| | etc. | | |
| Plane Angle | degree | ۰ | 1° = (II/180) rad |
| | minute ^a | , | 1´ = (1/60)° = (11/10,800) rad |
| | second | " | $1'' = (1/60)^{\circ} = (II/648,000)$ rad |
| Volume | liter ^b | L | 1 L = 10 dL = 1000 mL |
| Pressure | Kilopascal | kPa | psi x 6.897 = kPa |
| | Pounds per in ² | psi | kPa x 0.145 = psi |
| Mass | metric ton | Т | 1 t = 1000 kg |

Table 5 - SI Prefixes

| Multiplication Factor | Scientific Notation | Prefix | Symbol |
|---------------------------|------------------------|--------------------|--------|
| 1,000,000,000,000,000,000 | 1x10 ¹⁸ | exa | Е |
| 1,000,000,000,000,000 | 1x10 ¹⁵ | peta | Р |
| 1,000,000,000,000 | 1x10 ¹² | tera | Т |
| 1,000,000,000 | 1x10 ⁹ | giga | G |
| 1,000,000 | 1x10 ⁶ | mega | М |
| 1000 | 1x10 ³ | kilo | k |
| 100 | 1x10 ² | hecto ^a | h |
| 10 | 1x10 ¹ | deka ^a | da |
| 0.1 | 1x10 ⁻¹ | deci ^a | d |
| 0.01 | 1x10 ⁻² | centi ^a | С |
| 0.001 | 1x10 ⁻³ | milli | m |
| 0.00001 | 1x10 ⁻⁶ | micro | μ |
| 0.00000001 | 1x10 ⁻⁹ | nano | n |
| 0.00000000001 | 1x10 ⁻¹² | pico | р |
| 0.000000000000001 | 1x10 ⁻¹⁵ | femto | f |
| 0.000000000000000001 | 1x10 ⁻¹⁸ | atto | а |

^a To be avoided where practical.

a Use discouraged.
b Restrict use to volumetric capacity, dry measure, or measure of fluids.
Prefix with only milli- or micro-.
c 3-A use is m² or cm².



4.1 Rules for Significant Digits and Rounding

For most instances, three or fewer decimal places are considered adequate for the implied or required accuracy of values, provided that accuracy for any value required by a State or Federal regulation is not compromised. SI units shall be considered to have three (3) significant figures and SI units shall be rounded to three (3) significant figures.)

To round to fewer digits, if the first digit discarded is less than five (5), the last digit retained is not changed. When the first digit discarded is greater than five (5), or if it is five (5) followed by one or more nonzero digits, the last digit retained is increased by one. When the first digit discarded is exactly five (5), the last digit retained is rounded up if it is odd and remains the same if it is even, provided that any value required by state or federal regulation be rounded during conversion so as not to compromise the original value.

Significant digits must be retained with consideration to the implied or required accuracy of an integral value. However, any digit that is necessary to define the specific value is significant. Zeros may be used either to indicate a specific value like any other digit and are significant, or they may indicate order of magnitude, in which case they may not be significant. The unequivocal identification of significant digits is only possible through knowledge of measurement circumstances. (Fractional IP units shall be considered to have three (3) significant figures and SI units shall be rounded to three (3) significant figures.)

4.2 Use of SI Prefixes

SI prefixes found in Table 1, are used to indicate orders of magnitude, thereby eliminating nonsignificant digits and leading zeros in decimal fractions. The selection of prefixes should be chosen so the numerical value lies between 0.1 and 1000, except that:

- Area and volume values, by convention, may require the prefixes deka, deci, or centi;
- Tabular values used in the same context should be consistent in prefix use; and
- For mechanical engineering drawings, the millimeter is used for all linear dimensions.

It is recommended that compound prefixes be avoided.

5 Pictures, Illustrations and Symbols

Document preparers are encouraged to use as many pictures and illustrations as possible to clearly present the intent of the criteria contained in the documents.

Pictures and illustrations are not intended to be engineering drawings. They are to illustrate concepts presented in the narrative portion of the documents.

When a picture or illustration from an outside source, one which is not taken specifically for the document or drawn by members of the WG, is included in the document, the WG shall obtain a signed authorization for its use from the owner of the picture or illustration. See Appendix 1.

The signed authorization shall identify the owner and state that EHEDG has the right to use the picture or illustration in any guideline, training material or certification scheme. EHEDG use shall not be deemed as an infringement upon any copyright or intellectual property right of the owner. The signed authorization shall be kept with the official WG document files.

No acknowledgement of the source will be published in the EHEDG document, unless by a mutual agreement between the owner and EHEDG.

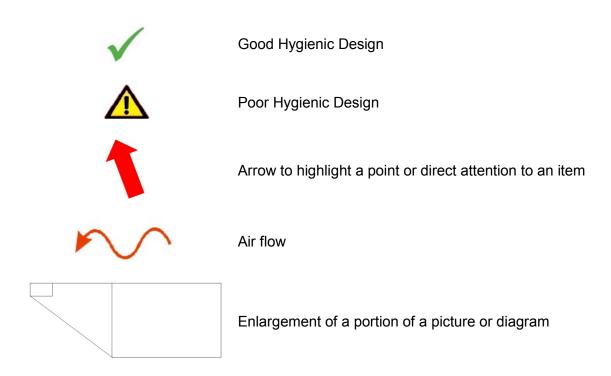


Pictures and illustrations should show examples of both good and non-hygienic examples to clearly show the differences in design principles.

5.1 Color code for EHEDG diagrams.

| Product | Dark Blue |
|--|---------------------|
| Water | Light Blue |
| Bacterial film or soil | Orange |
| Detergent | Green |
| Acid | Red |
| Disinfecting agent, steam, or sterile liquid | Purple |
| Food quality grease or oil | Yellow |
| Compressed Air | Grey or Shaded Dots |

5.2 Symbols





NOTE: In situations when there is no good hygienic design available and what is available is the best of the current technology, use no symbol and explain the details of the best available in the narrative sections of the guideline document. These explanations are to be highlighted or boldfaced in the document.

5.3 Photos

Photos intended to highlight a hygienic component or principle are preferred but shall be carefully screened so they do not include defects that are in nonconformance with the criteria in Document 8. This also includes features in the photo other than the component or principle being highlighted. If the photo cannot be edited to show only conforming features a different photo or a drafted illustration should be used. All photos and illustrations used are to be forwarded to the Chair of the SubCom Products Portfolio to be included in a database available for use in other EHEDG documents.

6 Special Considerations for Training Materials

Training materials shall be prepared in PowerPoint © format. The slide masters shall be uniform and can be obtained from the Secretariat.

Slides shall be as visually simple as possible to convey a single concept.

Presentations shall have the following slide types:

- a) Title slide
- b) Introduction and Objections. This may be one or more slides as necessary to identify the Trainer, the objectives and goals of the training course.
- c) Content of the course and identification of the main points to be covered by the training.
- d) Slides specific to the training objectives.
- e) Summary slide

As appropriate, slides shall contain speaker notes to highlight specific policies, explanatory comments, and clarifications that EHEDG wants the Trainer to convey to the course participants.

The Working Group should develop a summary of the key learning points.



Appendix 1

Sample Photograph or Illustration Authorization



| the attached photograph(s), illustration Guideline, Training Material, or Certiful Control of the control of th |), the undersigned do hereby grant EHEDG limited use of on(s), chart(s), schematic(s) or drawing(s) in any EHEDG fication Scheme. The use of these items by EHEDG for ed to be any infringement of any copyright held by the |
|--|--|
| Signature | Date |
| Company or Affiliation Name | |
| Address | |
| Attach conies of the authorized photog | graph(s) illustration(s) chart(s) schematic(s) or |

drawing(s).



EHEDG Document Initial Ballot Sign-Off

Document Title: XX Working Group: xx Chair: xx Document Date: Month / Year Version: Circulated on: Date ☐ Guideline ☐ Training Presentation ☐ Certification Scheme Deadline for receipt of comments: Date Reviewed by: (Name and company/organisation) ☐ Approved as presented (no comments) ☐ Approved with editorial comment(s) (non-substantive) ☐ Disapproved with substantive comment(s) For comments submitted EHEDG Comments template SCP 2-6 shall be used. Comments should reference a specific section or slide number and a recommendation for resolution of the

issue.



EHEDG Document Reballot Sign-Off

Document Title: XX Working Group: xx Chair: xx Document Date: Month / Year Version: Circulated on: Date ☐ Guideline ☐ Training Presentation ☐ Certification Scheme Deadline for receipt of comments: Date Note: Only the highlighted changes to the document are eligible for comment. Reviewed by: (Name and company/organisation) ☐ Yes, I accept the proposed (new) wording ☐ Yes, I accept the proposed (new) wording, with comment (EHEDG comment template (SCP 2-6) shall be used) ☐ No, I want to retain the original (ballot) wording



Document Life Cycle (Documents include Guidelines, Training Presentations and Certification Schemes)

1 Life Cycle

All documents will have a five (5) year life cycle. At the end of the 5 years the document shall be reviewed to determine if the document should be reaffirmed as written, modified to meet the current industry needs and reissued, or to be discontinued.

Six (6) months prior to the expiration date of the document, the Secretariat shall send out a notification to all EHEDG members detailing the pending expiration of the document. The notice will contain a request for input as to the future disposition of the document. See Appendix 1.

The notice period shall be at 45 days.

The Working Group shall review all of the comments received from the notice. The working group shall interpret the comments as follows;

If all of the comments indicate that the document should be reaffirmed as written, the working Group Chair shall recommend to the SubCom Products Portfolio that the document be assigned a new life cycle date and to republish the document. A no response from the General Assembly notice will be considered as a reaffirm as written comment.

If any comment is received to modify or to discontinue the document, the Working Group Chair shall convene the Working Group to resolve the comments in accordance with the procedures in SCP-1-3 Rules for EHEDG Working Groups.

Any document that has been modified or is proposed to be discontinued shall be reviewed and approved by the SubCom Product Portfolio before a recommendation is sent forward to EHEDG ExCo for formal approval.

Any document that has been approved for reaffirmation as written may be assigned a new life cycle date and reissued without EHEDG ExCo confirmation as the document has not been modified from the previously approved content.

2 Document Use

All EHEDG Documents are protected by copyright legislation.

EHEDG members are entitled to a copy of each Guideline free of charge

Non-EHEDG members may purchase copies of Guidelines by contacting the EHEDG Secretariat.

Training Materials are available only to EHEDG authorized trainers for use in training sessions. Training Materials are not available for general distribution.



Appendix 1

Notice of EHEDG 5 Year Life Cycle Review of Existing Document

(Documents include Guidelines, Training Presentations and Certification Schemes)

Members of EHEDG Peer Review Group, EHEDG is requesting your review and comment on the following document. EHEDG strives to maintain its documents to be as useful and current for the industry we serve. Your attention and response to this notice is critical to that effort. Please complete this review request by the date specified below and return it to the EHEDG Secretariat.

| Do | ument: (Document Name and Number) | | | | |
|--------------------------|--|--|--|--|--|
| Do | ument Issuance Date: (Issuance date) | | | | |
| Do | ument Scope: (Copy the Scope Section of the document) | | | | |
| Re | ew Due Date: (Due Date) | | | | |
| Re | ew Determination: | | | | |
| | Reaffirm as currently written | | | | |
| | Modify or amend the document to meet current industry need and reissue (comments required, EHEDG comment template SCP 2-6 shall be used). | | | | |
| | Discontinue or amend the document as no longer meeting current industry needs (comments required, EHEDG comment template SCP 2-6 shall be used). | | | | |
| Na | e of commenter: | | | | |
| Affiliation and address: | | | | | |
| | | | | | |
| Pho | Phone: | | | | |
| E-N | E-Mail: | | | | |
| | | | | | |
| Sig | ature Date | | | | |

Return the completed form to the EHEDG Secretariat at secretariat@ehedg.org by (date).



Template for comments on EHEDG Documents and Working Group observations

| Date: Document version: | | EHEDG Working Group: |
|-------------------------|--|----------------------|
| | | |

Document title:

| Name Initials ¹ | Clause/ Sub- Clause (e.g. 3.1) | Paragraph/ Figure/ Table/ (e.g. Table 1) | Type of comment ² ge / te / ed (see footer) | Comments | Proposed change | Resolution of comments by Working Group / reply to author of comments See note below |
|-------------------------------|--------------------------------------|---|--|----------|-----------------|--|
| | | | | | | |
| | | | | | | |
| | | | | | | |

NOTE: If the document is reformatted during the resolution of comments, provide the new location in the final document where the comment resolution is placed.

Author of comments:

| Full Name: | |
|------------------------------|--|
| Name Initials ¹ : | |
| E-Mail: | |
| Phone: | |
| Mobile: | |
| Address: | |

Template for comments on EHEDG Documents and Working Group observations, Version_02_170515

¹ abbreviation of name of author of comment; name and contact details to be stated at the end of the document

² **Type of comment: ge** = general **te** = technical **ed** = editorial



EHEDG Training & Education

1 Purpose

The Training and Education Working Group (T&E WG) is tasked with the following responsibilities:

- To develop and maintain training modules based on the criteria within EHEDG Guidelines.
- To develop and maintain quality and process control of the content and format of the training modules developed.
- To develop and maintain required minimum qualifications and skills for the designation of an Authorized EHEDG Trainer.
- Assist with training upon request and when available.

1.1 New Members

Individuals interested in becoming a member of the T&E WG shall send a request to the Chair of the T&E WG. The request should include all background information that demonstrates a knowledge of the EHEDG Guidelines and purpose, experience in hygienic design, participation as a member of any of the EHEDG Working Groups and experience with structuring or providing training. The applicant should also speak and be able to read English. The request will then be presented to the other members of the T&E WG for concurrence of accepting the request.

2 Authorities

The T&E WG is within the SubCom Product Portfolio area of responsibilities and reports to the Chair of the SubCom.

T&E WG meetings and conference calls are scheduled and conducted independently by the T&E WG Chair under the guidance of the strategic planning goals established by the SubCom Product Portfolio.

The T&E WG shall provide all members of the WG and the SubCom Product Portfolio copies of meeting and conference call minutes.

3 Training Modules

Each training module is to be based on the information and criteria presented in a published EHEDG Guideline. The individual modules may be assembled together to establish a comprehensive training course for a particular focus.

Each training module shall contain a list of key learning points established by the relevant Working Group to assure the effective and uniform transfer of the knowledge of EHEDG hygienic design principles to training course participants.



3.1 Training Module Distribution

EHEDG training modules and the key learning points will be made available to only authorized EHEDG Trainers on request by the Secretariat.

3.2 Module language

The official language for all training modules is English. However, translation into the audience native language is encouraged whenever possible.

Authorized trainers in their Regional Sections may volunteer to translate training modules into their native languages. The translators shall provide sufficient quality control to assure and certify to the SubCom Products Portfolio Chair that the translations are accurate and do not alter the intent of the EHEDG hygienic design principles or the key learning points established for the module. No information may be added or deleted from the module during the translation. All translations are to be sent to the Secretariat, who shall have the authority to share the translation with other Regional Sections.

4 Authorized EHEDG Trainer

All Authorized EHEDG Trainers shall meet the requirements of SCP 3-2 EHEDG Trainer Authorization Procedures.

The Secretariat shall maintain a list of authorized trainers.

5 EHEDG Training Programs

5.1 Training Materials

Training programs shall be conducted by EHEDG-authorized trainers as referenced in SCP 3-2. The training program shall use only approved modules provided by EHEDG.

5.1.1 Training provided by College and Universities

EHEDG supports and encourages the use of EHEDG prepared materials on hygienic design by colleges and universities as part of their curriculums. In order to maintain the integrity of the EHEDG prepared materials, it is required that any college or university individual presenting the material become an EHEDG Authorized Trainer or be able to demonstrate to EHEDG the technical knowledge to transmit the key learning points during lectures and hands-on learning exercises.

5.2 Final Test Questions

Authorized Trainers shall administer all of the test questions provided for each training module. Satisfactory completion of the training course shall be exhibited by correctly answering 70% of the test questions administered.

5.3 Training Program Logistics

EHEDG training programs shall be structured to follow the general scheme for training programs available from the Secretariat.

The training program notifications and announcements shall meet the minimum lay-out requirements established by SubCom Products Portfolio and available from the Secretariat. See Appendix 1.



5.4 Supervision of new EHEDG authorized trainers or EHEDG trainers still on their probation

To receive the support described below the programme organiser shall schedule a course with at least 10 participants.

To supervise a new EHEDG authorized trainer or a trainer still on their probation, enabling them to run the EHEDG courses independently, senior EHEDG authorized trainer are requested to support them with their knowledge. The senior EHEDG authorized trainer shall get a reimbursement for their travel and accommodation costs plus an expense allowance on request.

For the support the EHEDG training of a 1 day event, the senior EHEDG authorized trainer shall receive a compensation of € 500. For the support of an EHEDG training event of 3 days or more, the senior EHEDG authorized trainer shall receive a compensation of € 1,500.

These service costs shall be put in the budget and paid by the EHEDG regional groups.

5.5 Financing of training courses

The trainer/organizer is financially responsible for all costs associated with the presentation of the training course.

6 Royalty

All Authorized Trainers shall sign the EHEDG Authorized Trainer Royalty Contract. See Appendix 2.

All Authorized EHEDG Trainers shall remit to the EHEDG Treasurer a royalty of the total fees collected for the EHEDG training courses presented. See appendix 5.

All Authorized Trainers shall be notified in advance of any change in the royalty rate. The old royalty rate shall apply to any training course for which the Authorized Trainer can show has been contracted for and scheduled prior to the date of the rate change.

7 Participant Certification

Each participant who successfully completes an EHEDG authorized training program (see section 5.2) shall receive a certificate. See Appendix 3.

The trainer shall submit a copy of the successful participants to the secretariat. The participants may indicate if they do not wish their name to be published on the EHEDG website. See Appendix 3.



Minimum lay-out requirements for training program notifications and announcements

Front Page

- Name and logo of the organization
- EHEDG logo
- Course title

Inside

- Introduction / summary
- Target groups
- Program details and time schedule
- Trainers
- Course certificate
- Registration details
- Course fees / member discounts

Rear side

— General information (venue, travel, hotel)



EHEDG Authorized Trainer Royalty Contract

I, *name*, the undersigned hereby agree to remit to the EHEDG Treasurer a royalty as specified in SCP 3-1, Section 6. The royalty amount shall be based on the fees collected from participants in authorized training activities.

Remittance of the royalty fee along with the associated training course information to EHEDG shall be within 30 days of completion of the authorized training.

This contract shall remain in effect from the date of signing until canceled by either party.

| Authorized Trainer: | EHEDG President: |
|---------------------|------------------|
| Signature | Signature |
| Date | Date |



Certificate of Successful Completion

EHEDG Advanced Course on Hygienic Design

(Insert Participants Name)

Organized by

(Insert the name of the organization, location and date of the course)

(insert Name)

Chairman WG Training & Education

Insert Organization Logo if appropriate

(insert Name)

Trainer / Organizer



Royalty Remittance Form

| Course Title: | | | | |
|------------------------------------|---------------|--------------------------|--------|-------------------------------|
| Course Date(s): | | | | |
| Authorized Trainer: | | | | |
| Participation Fees Collected: | Roya | alty Rem | itted: | |
| Participant | Test Score | Successful Completion | | Do Not List Name on Website * |
| | | Υ | N | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Use additional pages as necessary. | | | | |
| | | | | |
| | | | | |
| | _ | | | |
| Authorized Trainer | | | Date | |



Royalties for EHEDG Training Courses (5 % of Course Revenues)

The following course fees are recommended for Western Europe and are subject to price adjustment in any other countries as customary in the particular market

| Advanced 3-Day Course in Hygienic Design | | | | | | |
|--|------------------------------|--|--|--|--|--|
| Minimum 10 participants All at-site organisation by trainers / Promotion via EHEDG Secretariat | | | | | | |
| Non-members (full price): | EUR 1,500.00 to EUR 2,000.00 | | | | | |
| Recommended EHEDG member discount | 25 % | | | | | |

| Advanced 2-Day Course in Hygienic Design | | | | | | |
|--|------------------------------|--|--|--|--|--|
| Minimum 10 participants All at-site organisation by trainers / Promotion via EHEDG Secretariat | | | | | | |
| Non-members (full price): | EUR 1,000.00 to EUR 1,550.00 | | | | | |
| Recommended EHEDG member discount | 25 % | | | | | |

| 1-Day Course in Hygienic Design | | | | | | |
|--|--------------------------|--|--|--|--|--|
| Minimum 10 participants All at-site organisation by trainers / Promotion via EHEDG Secretariat | | | | | | |
| Non-members (full price): | EUR 500.00 to EUR 750.00 | | | | | |
| Recommended EHEDG member discount | 25 % | | | | | |

| Use of EHEDG Training Material: | | | | | |
|---|---|--|--|--|--|
| Members of EHEDG WG T&E | Free of charge | | | | |
| Use of T&E material by any other party: | Upon request only, to be individually decided by T&E Subgroup | | | | |



EHEDG Authorized Trainer Requirements

1 Purpose

The Working Group Training and Education (below named "WG T&E") is responsible for the appointment and monitoring of EHEDG Authorized Trainers.

2 Qualification and Skills of Applicants

Before being accepted as an EHEDG Authorized Trainer, candidates shall provide the following:

- a) Formal application to the Chair of the WG T&E, accompanied by a CV with all relevant educational, lecturing, and teaching experience.
- b) The CV shall describe
 - the background and number of years of practical experience in evaluating the hygienic design of food processing equipment in processing plants, equipment fabrication,

or

- adequate understanding of relevant disciplines, including, a minimum of a Bachelor's degree in a relevant engineering, physical or biological science curriculum.
- Plus three (3) years' experience in relevant processing, for example, food, pharmaceutical.
- And one (1) year of the three (3) years of general experience shall be directly related to hygienic design of equipment or hygienic
- c) The applicant shall demonstrate knowledge and understanding of the EHEDG Guidelines and the principles of hygienic design.
- d) The applicant must have experience as an active member of one or more of the EHEDG Working Groups.
- e) The applicant must have successfully attended an EHEDG Advanced Training Course, including passing the final exam with a minimum score of 80 %.

3 Application Assessment

Upon receipt of an application, the WG T&E shall conduct the following assessment:

- a) Review the content of the CV.
- b) Review and contact the reference addresses listed in the applicant's CV
- c) Review the applicant's participation and contribution to a WG with the appropriate Working Group Chair(s).



d) Verify successful attendance in an EHEDG Advanced Training Course.

4 Probation

After acceptance of the application, the candidate shall conduct the following training courses on probation to demonstrate his/her ability as a trainer. The probationary training course shall be observed by one or more members of the WG T&E.

4.1

Candidates shall perform presentations during two different EHEDG Advanced Training Courses on Hygienic Engineering and Design, as follows:

4.1.1 First course

Presentation in English of at least two training course modules, with coaching and evaluation by WG T&E members.

4.1.2 Second course (self-organized)

Presentation in native language of half of the EHEDG advanced training course (self-organized) with evaluation by T&E members (simultaneous translation) plus evaluation of the training performance (by observation, by overall score of the student evaluation questionnaire and the feedback questionnaire).

5 Certification

After successful completion of above probationary training courses, the applicant will be listed as an Authorized EHEDG Trainer and may offer EHEDG Training Courses under agreed conditions (see "EHEDG Royalties").

6 Expiry of authorization

Every 5 years, on request by EHEDG Secretariat, an EHEDG authorized trainer shall provide evidence of continuing training experience, by meeting at least one of the criteria stated below:

- Active membership in the EHEDG Training and Education Working Group
- Having held at least one EHEDG advanced training course (or comparable training activity) within a period of 24 months prior to the date of request
- Successful probation according to section 4.1.2 not later than 6 months after date of request.
- Adherence to the SCP 3- series as appropriate.

If an EHEDG authorized trainer fails to provide evidence of continuing training experience EHEDG authorization will expire 6 months after date of request to provide evidence.

Except in the case of a failure to comply with the SCPs, an expired authorization could be renewed by successfully repeating probation according section 4.1.2.



Authorized Trainer Certificate

This certificate is issued following the successful completion of the application procedure according to EHEDG Document SCP 3-2 and approval by the EHEDG Working Group Training & Education

(Insert Name)

is appointed as an EHEDG Authorized Trainer on Month/Year

| Ludvig Josefsberg | Date |
|-------------------|------|
| EHEDG President | |



Agreement between EHEDG and the Members of the EHEDG Working Group "Training & Education"

EHEDG and the active members of the EHEDG Working Group "Training & Education" herewith mutually attest and agree that:

- The Working Group members commit themselves to developing new EHEDG training material, including interactive graphical aids.
- All training materials provided to the group (whether privately, company, or institution owned) shall be considered as freely given and free of any copywrite infringement use for EHEDG sanctioned activities. All training material will be published in accordance to its intended use after final release and approval of the members of the EHEDG Working Group Training & Education under the authority of SubCom Product Portfolio.
- Participants not showing up for three consecutive WG meetings without an approved absence by the WG Chair, will be removed from the Working Group.
- EHEDG training material shall be used for training purposes by EHEDG-Authorized Trainers only and shall not be shared with non-authorized companies or individual persons. However, such material may be authorized by EHEDG to be used to teach students on a non-commercial basis at institutes and universities.
- EHEDG will undertake all efforts to protect its training material from any misuse (i.e. by watermarks, password protection or whatever other appropriate measure). Further distribution of training material is not permitted without explicit permission of EHEDG Working Group Training & Education. Participants of EHEDG authorized training courses will receive hard copy of the presentation slides intended for their personal use only. No electronic files shall be distributed to course participants.
- The members of the Working Group and EHEDG agree the copyright of all training material which is commonly developed belongs to EHEDG.

| ı | have read | understand. | and a | agree to | abide by | / the | above | provisions |
|---|-------------|-------------|-------|-----------|----------|-------|-------|------------|
| | TIGVO TOGG, | anaciotana. | ana (| agi oo to | ablac b | | 40010 | |

Date / Name of Expert of the EHEDG Working Group Training & Education



Working Group "Training & Education"

EHEDG Courses on Hygienic Design

Purpose

This document describes the EHEDG Courses portfolio

1 EHEDG Basic Course on Hygienic Design Principles

1.1 Key information

1.1.1 Course title

EHEDG Basic Course on Hygienic Design Principles

1.1.2 Objectives

General objective

Provide awareness and general knowledge on hygienic design of equipment and facilities especially for food and beverages, but also for cosmetics, pharmaceutical, biotechnology and chemical industries.

Specific objectives

- Create awareness of:
 - The EHEDG organization
 - o Hygienic design
 - o Certification
- Explain Benefits and importance of Hygienic Design
- Provide general understanding on the key Hygienic Design criteria for equipment and facilities

1.1.3 Target Audience

Top management, middle managers, mechanical engineers, constructors, draughtsmen, project managers, sales-engineers, equipment purchasers, process engineers, operators, quality assurance and food safety staff, food safety regulators and auditors related with the following sectors:

- a. Equipment manufacturers
- b. Food, beverage, cosmetics, pharmaceutical, biotechnology and chemical industries
- c. Process integrators and consultants



1.2 Course structure and contents

1.2.1 General

The course is intended to create awareness of EHEDG and hygienic design principles and to give a basic understanding of the main hygienic design criteria.

1.2.2 Contents

The program should typically consist of modules of 30-60 min. The following modules are considered a priority but the course may include additional modules suitable to the audience:

- EHEDG introduction
- Legal requirements
- Hazards in hygienic engineering
- Hygienic design criteria
- Materials of construction
- Cleaning and disinfection
- Building and process lay out

1.2.3 Case studies

The inclusion of at case studies is optional, although recommended. Should they be included, they could consist of cross-sectional drawings, 3D drawings or pictures of equipment/components in order to identify hygienic design issues.

1.2.4 Length

Between 5 and 8 hours (excluding coffee and lunch times). Course can be programmed in one day or two half days.

1.3 Training materials

1.3.1 Materials

Materials used in the course shall be delivered by the Training & Education WG.

Training materials will typically consist of presentations on a slide show presentation program (e.g. Power Point), videos and animations. Optionally, technical drawings can support the presentations.

The availability of samples of equipment and components in the classroom to support the lectures is optional.

1.3.2 Handouts

Handouts will consist of:

- Course program
- Printed presentations. Two slides per page printed in color (except those presentations in which drawings are not essential that could be printed in black/white)
- List of participants



No electronic version of the presentations shall be delivered to the delegates.

1.4 Trainers

1.4.1 Requirements

Trainers participating in an EHEDG Basic Course shall be EHEDG Authorized Trainers.

Requirements for trainers are described in document SCP-3-2 EHEDG Authorized Trainer Requirements.

1.5 Fees

1.5.1 Course fees

The organizer will decide upon the course fees based on their knowledge of the local market and experience.

Discounts: EHEDG members will get a discount on the course fee of minimum 10% in accordance with SCP 3-1 Appendix 5.

1.5.2 Royalties

The organizer shall remit to the EHEDG Treasurer a royalty of the total fees collected for the EHEDG training courses presented, as established in document *SCP 3-1 Training Education WG Guidelines*.

1.6 Assessment and certificate

1.6.1 Assessment

None

1.6.2 Certificate

An attendance certificate delivered by the course organizer will be provided at the end of the course

1.7 Venue and accommodation

1.7.1 Venue

The classroom should have proper characteristics for hosting the course (comfortable, good screen, ...).

1.7.2 Accommodation

Participants are responsible for arranging their own accommodation. Course organizers should recommend convenient hotel options.

1.7.3 Other

Coffees and lunches during the course should be included in the course fee. In case the course is scheduled for two consecutive days, dinners may be included since they are an excellent opportunity for networking.



2 EHEDG Advanced Course on Hygienic Design

2.1 Key information

2.1.1 Course title

EHEDG Advanced Course on Hygienic Design

2.1.2 Objectives

General objective

Provide knowledge and insight into the hygienic design of equipment and hygienic engineering aspects especially for the food and beverage, but also for the cosmetics, pharmaceutical, biotechnology and chemical industries.

Specific objectives

- Create awareness of the EHEDG organization
- Explain Benefits and importance of Hygienic Design
- Provide understanding on the key Hygienic Design criteria for equipment and facilities, including detailed engineering concepts
- Communicate the Key Learning Points (KLPs) from all relevant EHEDG guidelines and EHEDG teaching aids such as training modules, case studies and training videos.

2.1.3 Target audience

Mechanical engineers, constructors, draughtsmen, project managers, sales-engineers, equipment purchasers, process engineers, quality assurance and food safety staff, food safety regulators and auditors related with the following sectors:

- a. Equipment manufacturers, since they will get knowledge and practical information of direct application in their activities of design and construction of equipment.
- Food, beverage, cosmetics and pharmaceutical industries, since they will get sound information and criteria for a proper equipment selection when purchasing, building process lines, designing production facilities and knowledge for more rational internal maintenance of equipment and facilities related to food safety

2.2 Course structure and contents

2.2.1 General

The course is given from a very practical viewpoint. The theoretical fundamentals of the different subjects are given in a short and concise way, continuously relating these to practice by means of examples on video, pictures or samples. Small groups are preferred for the course to be very interactive.

2.2.2 Contents

Modules to be included in the program:

- Legal requirements
- Hazards in hygienic processing



- Hygienic design criteria
- Materials of construction
- Welding stainless steel
- Static seals and couplings
- Valves
- Pumps and homogenizers
- Cleaning and disinfection
- Building and process lay out
- Installation, maintenance and lubricants
- Hygienic design criteria' for equipment processing dry materials'
- Verification of HD. Test methods and certification

The program may include additional aspects of:

- Hygienic Design aspects of typical components such as:
 - o Sensors
 - Packaging machines
- Process aspects such as:
 - o Rheology
 - Thermodynamics
 - Aseptic processes

2.2.3 Case studies

Since it's aimed to be a practical course, at least three case studies should be conducted:

- Case study 1: indicate on equipment drawings the product contact surfaces, hygienic design failures and proposal for improvement. This could be done on cross-sectional drawings and/or 3D drawings of equipment or components (valves, pumps, etc.) as well as on P&ID.
- Case study 2: same approach. Could be done on drawings or on physical equipment
- Case study 3: same approach. Should be done on physical equipment

Other exercises could be:

- Proper material selection (compliance with regulations, etc.)
- Exercise on building layout (zoning, flows of personnel and materials ...)

2.2.4 Length

Minimum 20 hours (excluding coffee and lunch times). Course can be programmed in three or four days.



2.3 Training materials

2.3.1 Materials

Training materials will typically consist of presentations on a slide show presentation program (e.g. Power Point), videos, animations and technical drawings provided by EHEDG WG Training & Education.

Samples of equipment and components should be available in the classroom to support the lectures.

2.3.2 Handouts

Handouts will consist of:

- Course program
- Printed presentations. Two slides per page printed in color (except those presentations in which drawings are not essential that could be printed in black/white)
- Case studies
- EHEDG Guideline nº 8
- EHEDG Glossary
- List of EHEDG guidelines
- List of participants

Optionally, the following contents may be included:

- EHEDG position paper on "Hygienic pipe couplings and process connections"
- EHEDG certification scheme

No electronic version of the presentations will be delivered to the delegates

2.4 Trainers

2.4.1 Requirements

Trainers participating in an Advanced Course shall be EHEDG Authorized Trainers.

Requirements for trainers are described in document SCP-3-2 EHEDG Authorized Trainer Requirements.

2.5 Fees

2.5.1 Course fees

The organizer will decide upon the course fees based on their knowledge of the local market and experience.

Discounts: EHEDG members will get a discount on the course fee of minimum 10% in accordance with SCP 3-1 Appendix 5.



2.5.2 Royalties

All Authorized EHEDG Trainers shall remit to the EHEDG Treasurer a royalty of the total fees collected for the EHEDG training courses presented, as established in document SCP 3-1 Training Education WG Guidelines.

2.6 Assessment and certificate

2.6.1 Assessment

The course trainers shall use the most recent approved Final Exam Questionnaire for the course. The exam questionnaire test will consist of 3 to 10 questions per module. Questions for the exam questionnaire will be generated by EHEDG WG Training & Education.

Successful completion of the training course shall be exhibited by correctly answering 70% of the exam questions administered.

Delegates will be given 2 min per question as an average.

Handouts can be consulted by delegates during test completion.

The course organizer shall submit a copy of the successful participants to the secretariat by using the corresponding template (see SCP 3-1 Training Education WG Guidelines).

2.6.2 Certificate

An attendance certificate delivered by the course organizer will be provided at the end of the course (regardless the completion and/or result of the test).

A "Successful Completion of the EHEDG Advanced Course on Hygienic Design" certificate will be delivered to those participants who successfully passed the exam. Apart from that, they individuals will be offered with the possibility of their name being published on the EHEDG website.

The certificate template is defined in document SCP 3-1 Training Education WG Guidelines.

2.7 Venue and accommodation

2.7.1 Venue

The classroom should have proper characteristics for hosting the course (comfortable, good screen, ...).

Industrial equipment or processes should be available for the case studies. Equipment assessed during the case studies should be representative of the current industrial situation.

2.7.2 Accommodation

Participants are responsible for arranging their own accommodation. Course organizers should recommend convenient hotel options.

2.7.3 Other

Coffees and lunches during the course should be included in the course fee. Dinners could be included since they are an excellent opportunity for networking.



EHEDG Training at Colleges and Universities

1 Purpose

EHEDG supports and encourages the use of EHEDG prepared materials on hygienic design by colleges and universities as part of their curricula. To maintain the integrity of the EHEDG prepared materials, it is required that

2 College or University Instructor

Any college or university staff member that wishes to present EHEDG materials is required to become an EHEDG Authorized Trainer or can demonstrate to EHEDG the technical knowledge to transmit the key learning points during lectures and hands-on learning exercises.

A college or university staff member who wants to provide EHEDG training other than a lecture at the university shall additionally become an EHEDG Authorized Trainer.

The individual shall comply with the provisions of SCP 3-2, EHEDG Authorized Trainer Requirements.

2.1 Demonstration of Skills and Knowledge

A college or university staff member who only provides EHEDG training materials as part of the established curriculum does not have to become an EHEDG Authorized Trainer. The individual will be required to demonstrate the appropriate skills and knowledge required by SCP 3-2, EHEDG Authorized Trainer Requirements.

3 Training Modules

Training Modules and other training materials will be provided free of charge to the approved training individuals covered by section 2.1 above.

Please note, that a college or university staff member who becomes an EHEDG Authorized Trainer shall be governed by the same royalty-rules as all Authorized Trainers.

All training individuals will protect the use of these materials and not distribute copies other than what is required for their intended purpose, to protect the intellectual property rights of EHEDG. To discourage unauthorized copying, copies of course-materials should comprise black-and-white, 2-per-page handouts only. In no case are electronic files to be distributed.

The intent of the EHEDG hygienic design principles or the key learning points (KLP) established for the module shall not be altered.

3.1 Module language

The official language for all EHEDG training modules is English. Official EHEDG translated modules can be provided and shall be used. If they are not available, the university may do the translation and this shall be submitted to EHEDG via the Secretariat.



The translators shall provide sufficient quality control to assure and certify to the SubCom Product Portfolio Chair that the translations are accurate and do not alter the intent of the EHEDG hygienic design principles or the key learning points (KLP) established for the module. No information may be added or deleted from the module during the translation.

4 Acknowledgement and Feedback

Whenever EHEDG materials are used as part of or a compliment to an established curriculum, the instructor shall acknowledge the source of the material to the students.

Upon the completion of each semester or contracted training session, the trainer shall provide the chair of the T&E Working Group with:

- 1. The number of students participating.
- 2. The amount of time devoted to the presentation of EHEDG materials.
- 3. Assessment of acceptance of the material by the students (e.g. questionnaire-results).

Suggestions for improvement of the materials are encouraged.



EHEDG Authorized Testing Laboratories

The following institutes and organisations are authorised by EHEDG to test and certify equipment:

DENMARK DTU National Food Institute

Søltoftsplads 221 2800 Kgs. Lyngby

http://www.dtu.dk/english

FRANCE ACTALIA Sécurité des aliments

Centre d'Expertise Agroalimentaire, Dept. Research

Boulevard 13 Juin 1944 14310 VILLERS BOCAGE http://www.adria-normandie.com/

GERMANY TU München Forschungszentrum Weihenstephan für Brau-

und Lebensmittelqualität Alte Akademie 3, 85354 Freising

http://www.blq-weihenstephan.de/leistungen/hygienic-design.html

NETHERLANDS TÜV Rheinland Nederland B.V. *

P.O. Box 2220, 6802 CE Arnhem http://www.tuv.com/nl/index.html

(* certification only)

SPAIN AINIA Centro tecnológico,

Departamento de Calidad y Medio Ambiente,

Parque Tecnológico de Valencia,

c/Benjamin Franklin, n° 5-11, 46980 Paterna (Valencia)

http://www.ainia.es/web/acerca-de-ainia

TAIWAN FIRDI Food Industry Research and Development

nstitute

Gongye 2nd Rd. No. 31, 5F, R3 Bldg., 70955 Tainan, Taiwan

http://www.firdi.org.tw

USA The University of Tennessee

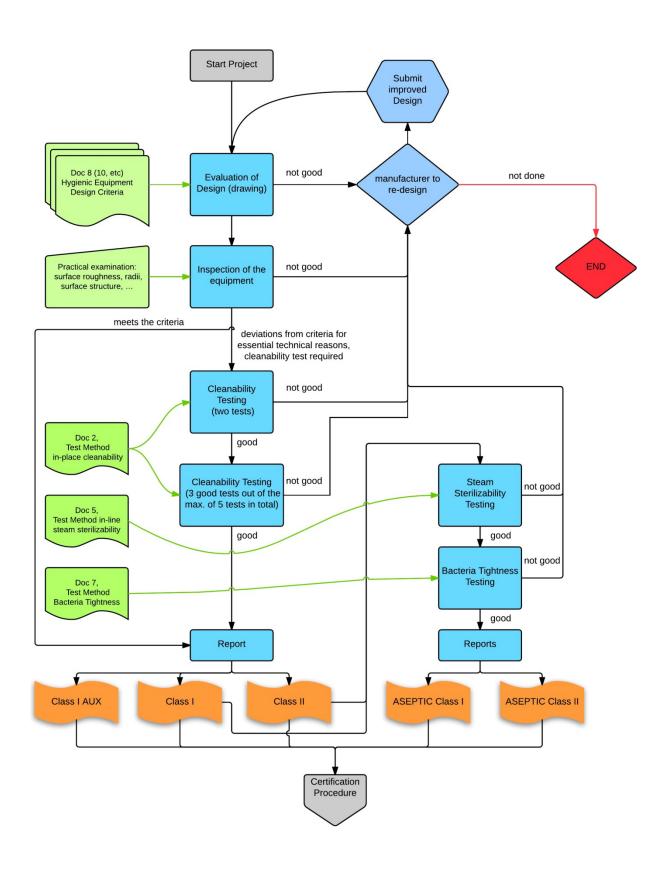
2510 River Drive, Knoxville, TN 37996-4539

http://www.utk.edu/



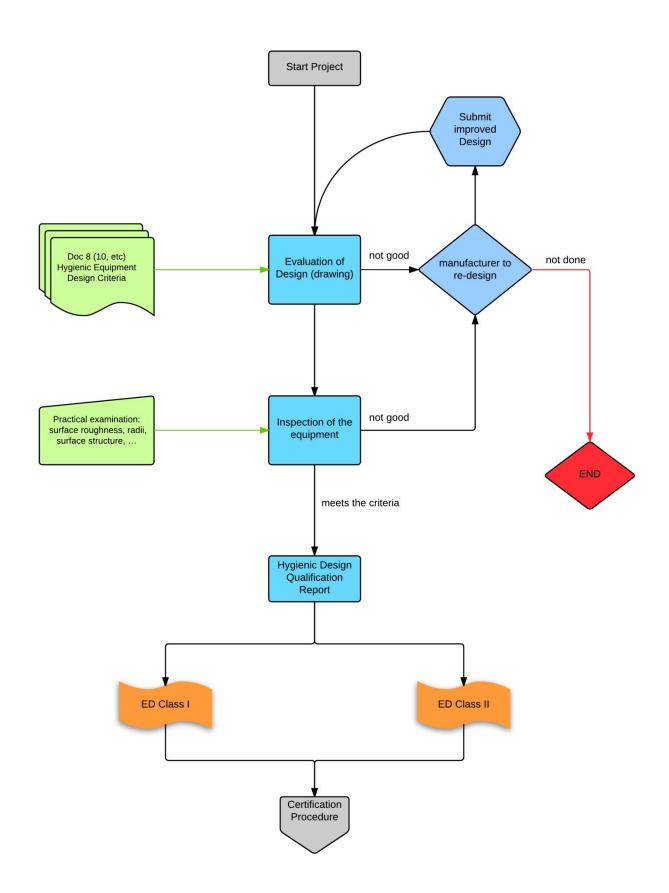
Testing Schemes

Type EL Equipment & Components Evaluation Scheme



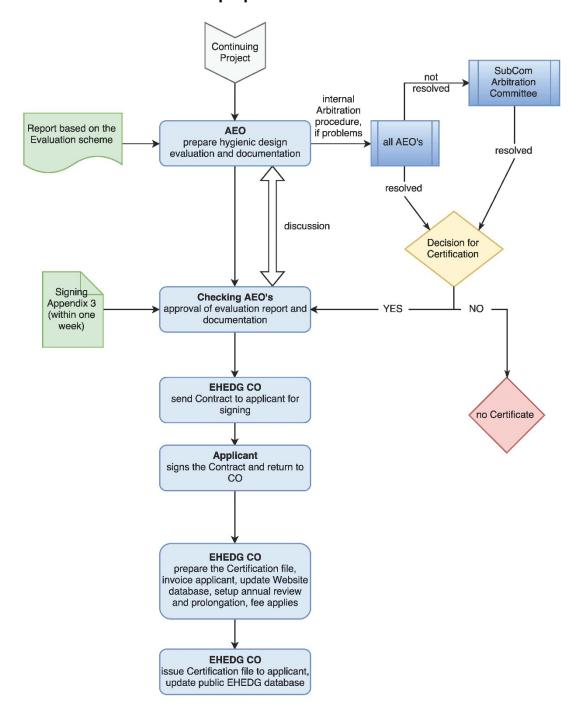


Type ED Equipment & Component Evaluation Scheme



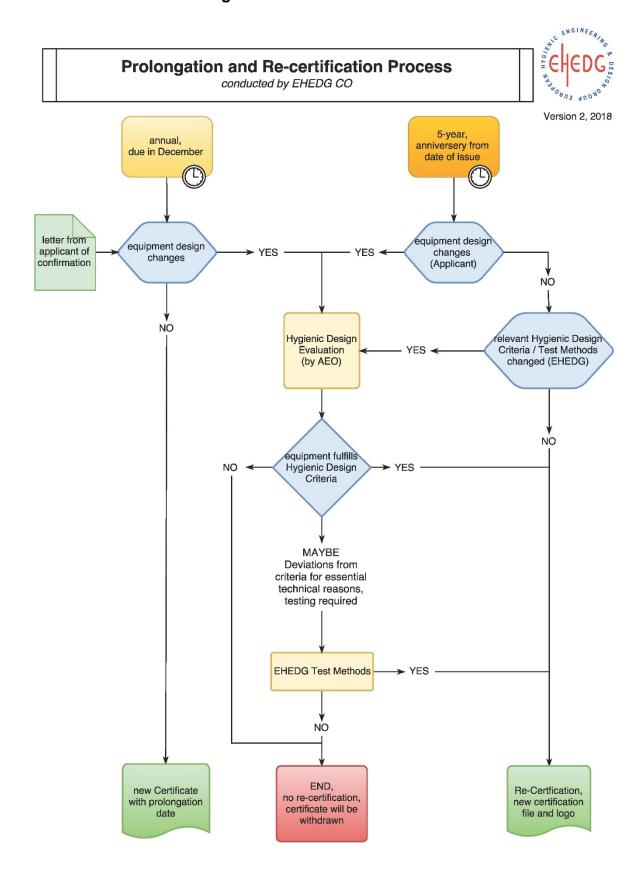


Process to prepare Certification file





Prolongation and Re-Certification Process





Certification Example

CENTROP COMPLIANCE Date of issue: day month year Valid until end: Month year **CERTIFICATE TYPE** EHEDG hereby declares that the product/-s Product/-s Trade Name from Company Name and address has/have been evaluated for compliance and meets/meet the current criteria for Hygienic Equipment Design of the EHEDG Certificate No.

> EHEDG Certification Officer Mirjam Steenaard

President EHEDG

EHEDG Secretariat Lyoner Straße 18 60528 Frankfurt am Main Germany

©EHEDG

Signed

Signed

Ludvig Josefsberg



EHEDG Certification Scheme

| Certificate Type* | EL CLASS I | EL ASEPTIC CLASS I | EL CLASS I AUX | EL CLASS II | EL ASEPTIC CLASS II | |
|---|---|--|---|---|---|--|
| Cleaning | wet | | | | | |
| procedure | cleani | ng without disma | cleaning with | n dismantling | | |
| Processes | closed | closed | open | closed / open | closed | |
| Fulfilled requirements according EHEDG doc. | 8, (9, 10, 16, 32, 35) ** | 8, (9, 10, 16, 32, 35, 39) ** | 8, (9, 13, 32, 35) ** | 8, (9, 10, 13, 32, 35) ** | 8, (9, 10, 16, 32, 35, 39) ** | |
| Design evaluation and relevant area*** | evaluation equipment equipment and relevant | | area outside on the equipment roughness Ra / radii / microscopic examination / accessibility | area inside or outside on the equipment roughness Ra / radii / microscopic examination / accessibility | area inside the equipment roughness Ra / radii / microscopic examination / accessibility | |
| EHEDG Test methods | cleanability (doc 2) cleanability (doc 2) + sterilisability (doc 5) + bacteria tightness (doc 7) | | none | none | sterilisability (doc 5) + bacteria tightness (doc 7) | |
| Equipment Examples | pipe line equipment like pumps, valves, sensors | pipe line equipment like pumps with double mechanical seal, bellow valves, sensors | auxiliary equipment like vision sensors, machine levelling feet, gear drive unit | draining channel, blender, dosing pump, tank mounted relief valve conveyor, meat mincing, slicing machine | cleaned by dismantling and sterilisable and bacteria tight like pressure relief valve with double seal | |

^{*} 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.
- *** Design evaluation is a practical step to qualify the hygienic design requirements.

Logo Samples













| Certificate Type* | ED CLASS I | ED CLASS II |
|---|--|--|
| Cleaning procedure | dry | |
| | cleaning without dismantling | cleaning with dismantling |
| Processes | closed | closed / open |
| Fulfilled requirements according EHEDG doc. | 8, (9, 22, 26, 32, 35) ** | 8, (9, 22, 26, 32, 35) ** |
| Design evaluation and relevant area*** | area inside the equipment | area inside or outside on the equipment |
| | roughness Ra / radii / microscopic examination | roughness Ra / radii / microscopic examination / accessibility |
| EHEDG Test methods | none | none |
| Equipment Examples | components of pneumatic conveying systems, diverter valve, sensor, mixer | rotary valve, hopper, mixer, mesh, metal detector |

- * Contact EHEDG authorised institutes for design evaluations and equipment classification.
- ** If necessary, other special guidelines, e.g. doc 38 about rotary valves, could be used to get more clearness about essential requirements to get an easy to clean design.
- *** Design evaluation is a practical step to qualify the hygienic design requirements.

Logo Samples:







Criteria for Acceptance as an EHEDG Authorized Testing Laboratory

1 Purpose

These procedures shall be used by SubCom Products Portfolio to evaluate the need to establish a new EHEDG Authorized Testing Laboratory (ATL); and, to evaluate the capabilities of the applicant.

2 Eligibility

- 2.1 Only EHEDG members, either an Institute or Company member, are eligible to apply to become an ATL.
- 2.2 The applicant shall submit an application to the ExCo to become a new ATL. The application shall include a business plan to demonstrate their commitment and the need to establish a local ATL in their specific geographical area; how many equipment fabrication facilities are in the proposed service area.
- 2.3 The ExCo shall accept the proposal on a probationary basis or reject the proposal if not compatible with current EHEDG needs.

3 Probationary Acceptance

- 3.1 Upon acceptance by the ExCo, the development of the proposed ATL will be assigned to the SubCom Products Portfolio, Working Group Certification (WGC).
- 3.2 The WGC shall work with the applicant in the following areas;
- 3.2.1 Development of a schedule for the implementation of the testing laboratory facilities, hiring of staff, and construction of the necessary test rig(s).
- 3.2.2 Selection of at least one Authorised Evaluation Officer (AEO) to oversee the ATL activities. The AEO shall be appointed according to the requirements of SCP 4-10 and have the following qualifications.
- 3.2.2.1 Knowledge and experience of the principles of mechanical engineering.
- 3.2.2.2 A minimum of 5 years' experience working in the field of hygienic design.
- 3.2.2.3 Knowledge and experience of EHEDG test methods and interpretation of results.
- 3.2.3 The AEO shall become an active member of the EHEDG WGC and attend at least 3 out of the last 4 sub group meetings. (Meetings are normally held twice each year.)



- 3.2.4 The AEO shall successfully complete the EHEDG Advanced Hygienic Engineering Design Course.
- 3.2.5 The AEO and nominated ATL staff shall successfully complete competency training for conducting and reporting of the test methods according to the Guidelines by another AEO designated by the WGC.
- 3.2.6 The ATL shall be accredited to ISO 17025 for conducting the identified test methods.

The WGC shall hold a meeting at the proposed ATL to witness the performance of the procedures and review the competency of staff prior to making the final recommendation to Sub Com Product Portfolio.

4 Final Acceptance

- 4.1 Upon Successful completion of the tasks in Section 3 of this SOP, the probationary application will be sent to the Chair, SubCom Products Portfolio for transmission to the ExCo with a recommendation for final approval.
- 4.2 Upon ExCo acceptance of the recommendation, the Secretariat shall notify all the interested parties and list the ATL on the EHEDG web site.
- 4.3 The ATL will become a participant in tasks as decided by the WGC, including Ring Trials.
- 4.4 The WGC shall appoint another AEO to witness the first commercial test conducted by the ATL.



Arbitration of Certification Challenges

1 Internal to EHEDG Certification Programmes

In the event of a difference of opinion between the Authorised Testing Laboratories (ATL) following discussions regarding the validity of a Certification File the following procedure shall be instigated:

- 1.1 A notification shall be submitted to SubCom Product Portfolio who will review the submitted documentation and provide written notification of the dispute to all of the interested parties.
- 1.2 SubCom Product Portfolio will contact the ATLs involved to attempt to resolve the dispute through an informal "meeting of the minds" of the differing parties. If all the parties agree with the submitted documentation and proposed resolution of the dispute as applicable, SubCom Products Portfolio will notify all parties in writing of the resolution of the dispute and attach the resolution to the certification file.
- 1.3 If SubCom Products Portfolio and the ATLs cannot agree during the informal discussions to resolve the dispute, SubCom Products Portfolio will submit the dispute documentation to the Arbitration Committee (AC) (See section 3) for review. All decisions of the AC are final and are not subject to further appeal. The certification file will include the AC decision and supporting rational. See Appendix 1.

2 External Challenge Raised by an Equipment User

- 2.1 A Challenge may be submitted only on equipment which bears a valid EHEDG Certification and an interested party believes there is a non-conformance issue with the equipment.
- 2.2 The manufacturer of the equipment shall be current in their authorisation status. The equipment shall be in actual commercial use, or in a commercial channel of sale.
- 2.3 The flowchart showing the Procedure for Resolving a Challenge of an EHEDG Certification is shown on the flow chart in Appendix 2.
- 2.4 All users of EHEDG documents (regulators, industry users, and fabricators) or purchasers of EHEDG Certified equipment are encouraged to submit a Challenge whenever non-conformance to an EHEDG document is suspected. A Challenge of non-conformance of an EHEDG Certification may be submitted to the EHEDG ExCo at any time. A current form for reporting non-conformance is available from www.ehedg.org or in Appendix 2.
- 2.5 The Challenge report will be considered by SubCom Products Portfolio upon direction of the ExCo, provided it contains all the information listed below:
 - 1. Type of the equipment, machinery, or component;
 - 2. Name of Manufacturer, Model Number or designation (required);
 - 3. Serial Number (if available);



- 4. Certificate Number and Class Type;
- 5. Address of the physical location where the observations were made (phone and
- 6. Fax numbers (when available);
- 7. Name, address, phone and fax numbers, and email address of the submitter of the Challenge.
- 8. Date of the observations;
- 9. Specify if the equipment is new or has been modified;
- 10. Specific criteria and wording from the applicable Guideline for which conformance is not met. Detailed description of the observations, with supporting quantitative measurements (whenever possible), and the reason or rationale used to determine nonconformance; and
- 11. Any other information the submitter deems pertinent to the Challenge.
- 2.6 When the submitter of a Challenge is working for a client and has a Non-disclosure Agreement (NDA) in place, the submitter shall inform their client that an issue of nonconformance has been observed and that a Challenge report must be filed. The submitter and the client shall mutually agree how to present the appropriate information required by section 2.5 in the report within the parameters of the NDA.
- 2.7 Within ten (10) days of receipt, SubCom Products Portfolio shall notify the alleged non-conforming party(ies) of the Challenge, the EHEDG Guideline criteria in question, and procedures to be followed to obtain resolution of the allegation(s). The manufacturer (including the installer(s) if appropriate) and/or user are to respond within ten (10) days to the SubCom Products Portfolio inquiry. Following the response from the manufacturer and/or user, SubCom Products Portfolio will investigate the validity of the allegation(s) and determine the responsible parties. SubCom Products Portfolio will seek the guidance and concurrence of the Chair of the EHEDG Test Methods Working Group on any aspect of the investigation of the allegations or the informal resolution.
- 2.8 SubCom Products Portfolio will prepare an Informal Challenge Resolution Proposal to seek resolution of observations which are not the result of differences of interpretation of the Guideline Document criteria. The Informal Challenge Resolution Proposal acknowledgement shall be returned to SubCom Products Portfolio within 20 working days.
- 2.9 In the case of a multiple criteria challenge, the Challenge submitter and the equipment manufacturer is obligated to accept or reject each individual proposal of the resolution.
- 2.10 Each refused proposal will require a specific, objective justification as to why it is inappropriate. No additional nonconformance issues, that were not part of the original challenge, can be added as part of the justification comments. (Any new nonconformance issue must be submitted as a new challenge.)
- 2.11 Challenge observations which are not resolved by the informal resolution process and which are clear differences of interpretation of the Guideline as written will be forwarded to the Arbitration Committee (AC) for resolution. The decisions of the AC are final and not subject to appeal.



- 2.12 Resolution of the Challenge must be completed as timely as possible upon its receipt by EHEDG dependent upon the availability of the parties involved and the time necessary for EHEDG to properly investigate the allegations. If the equipment manufacturer is determined to be the responsible party, they shall notify all purchasers of record of the inservice equipment sold. The notification shall include all units of equipment sold since the date of the last Certification. In addition, the equipment manufacturer shall keep EHEDG informed.
- 2.13 The manufacturer, when the subject of an upheld Challenge, must be able "demonstrate" that they did notify customers of record (since the last Certification File review) about the nonconformance, and if the manufacturer cannot prove that the customers of record were notified (or if EHEDG discovers that the customers were not notified), EHEDG may take "additional action" against the Certificate holder.
- 2.14 Failure to provide complete information as requested by EHEDG within 20 working days by the Challenge submitter will result in the Challenge submission being cancelled due to lack of participation by the nonresponsive participant.
- 2.15 Failure to provide complete information requested by EHEDG within 20 working days by the responsible party identified for the equipment will result in the Certification being withdrawn.
- 2.16 The revocation of a Certification will require a new Certification application for the equipment.
- 2.17 Any resolution shall include a documented plan of corrective action, mutually-agreed-upon by EHEDG and the responsible party of the confirmed nonconformance. The corrective action plan shall include scheduling of the corrective action(s) and be communicated to the interested parties.
- 2.18 If the equipment manufacturer is determined to be the responsible party;
 - 1. The Certification will immediately be removed from the EHEDG list of Certified Equipment maintained on the EHEDG website. 2. The corrective action plan shall include scheduling of any necessary confirming Recertification evaluation.
 - 2. A plan to notify purchasers of record (since the last Certification review) of the nonconformance and what actions they need to take. This plan can be demonstrated by submitting a copy of any notification letter or email and a listing of the recipients to EHEDG.
 - 3. It is acknowledged that the full resolution of the nonconformance may require the production and installation of replacement parts, and the time-frame to accommodate the completion of all necessary actions shall be scheduled within an agreed upon corrective action plan.
- 2.19 If the processor is determined to be the responsible party, they shall be notified in writing that their specific item is no longer EHEDG Certified. The Equipment manufacturer shall be notified that they are not held responsible for the modification made by the processor.
- 2.20 Throughout the evaluation and processing of the Challenge, EHEDG's responsibilities and actions include:
 - 1. A thorough review of all applications, Challenge reports and appeals with advice from the EHEDG AC, when needed.



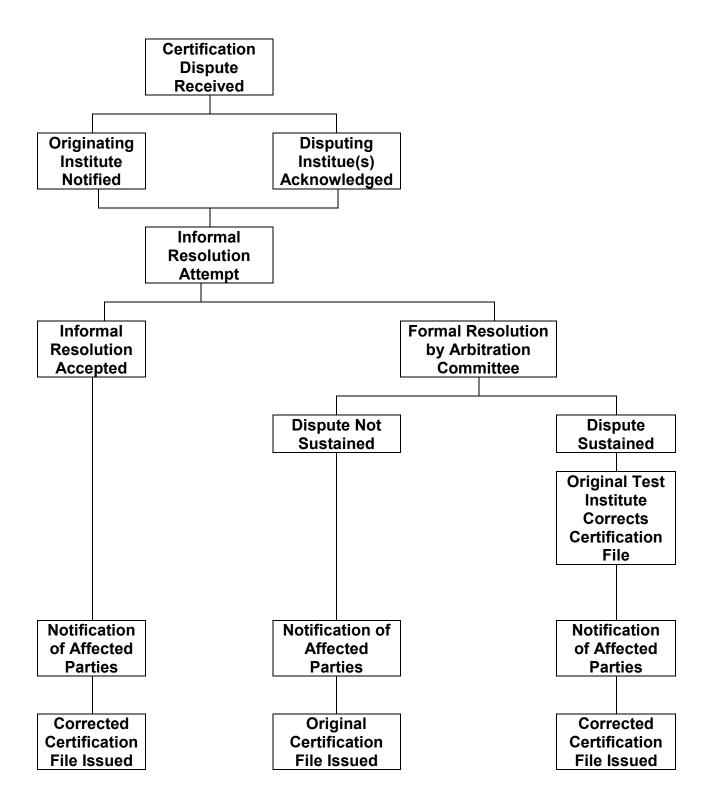
- 2. Communication of decisions to all materially affected parties and organisations.
- 3. An AC evaluation is required to substantiate that non-conformance issues have been corrected.
- 4. When a non-conformance is substantiated and the responsible party chooses not to resolve the issue(s), EHEDG will revoke the Certification.
- 5. When a substantiated Challenge is due to user modification, only the user and the equipment manufacturer will be notified.
- 6. When an EHEDG Certification is revoked, the equipment manufacturer will be required to submit a letter confirming that the use of the EHEDG Logo has been discontinued.
- 7. When a Challenge is upheld, EHEDG will investigate to determine if the error was attributable to an original Testing Institute oversight or lack of knowledge. If this is found to be the case, the AC shall direct appropriate changes to the Testing Institute procedures.
- 8. Engage legal counsel whenever necessary.

3 Arbitration Committee

- 3.1 EHEDG shall establish an Arbitration Committee (AC) comprised of eight (8) members. The members selected shall equally represent the ExCo, SubCom Product Portfolio and the Authorised Testing Laboratories. The chair is selected from one of the ExCo members. The committee members shall be knowledgeable in EHEDG Guidelines and hygienic principles. In the event of an unavoidable tie vote, the issue shall be resolved by the EHEDG full ExCo.
- 3.2 Any AC member who is a party to any Challenge or Certification dispute shall recuse him/herself from all AC deliberations and decisions related to the dispute.
- 3.3 The AC shall use the most cost-effective means to render decisions. Reviews and hearings shall be conducted electronically (e-mail, fax, WebEx, conference calls, etc.) unless an in-person meeting is specifically requested by one of the parties to the dispute. In such case, the requesting party shall assume all cost for the assembly of the AC and other affected parties.
- 3.4 When appropriate, the AC may also recommend that conflicting issues be resolved by amendment or revision to the EHEDG Guidelines or Certification schemes.



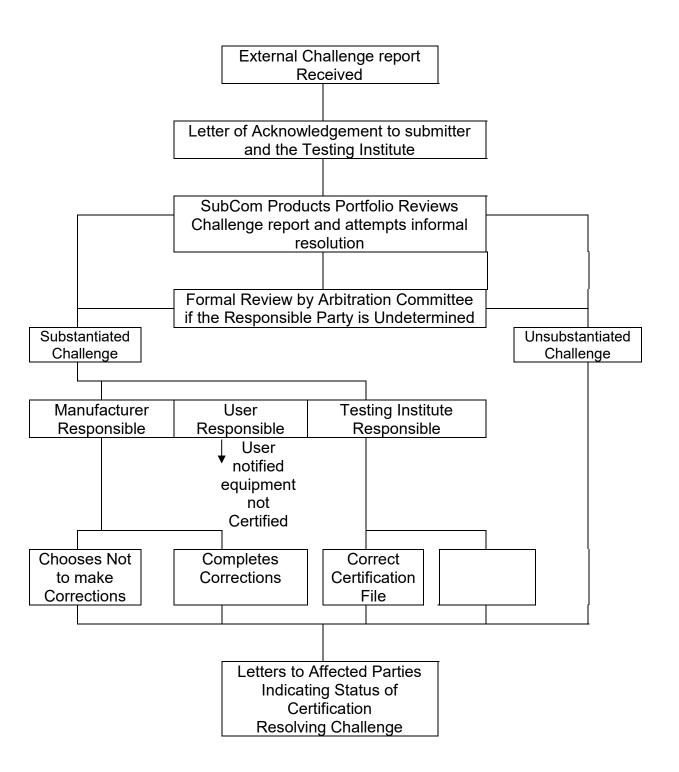
Appendix 1
Internal Certification Dispute Flowchart





Appendix 2

External Certification Challenge Flowchart





CONTRACT TO USE THE EHEDG CERTIFICATION LOGO FOR EQUIPMENT OR COMPONENTS

A Contract entered into this **(day.month.year)** between STICHTING EHEDG, an organization (foundation) existing under Dutch law, with its Secretariat at Lyoner Str. 18 in 60528 Frankfurt, Germany, herein after called "EHEDG" and **(Company name and address)**, herein after called "Company".

- Certified Equipment and Certified Components are any equipment, component, system, material or service for which EHEDG has specifically authorized the use of the EHEDG Certification Logo. The EHEDG Certification Logo is a registered mark. All existing rights in connection with or future rights through the use of the logo are exclusively reserved to the EHEDG.
- 2. EHEDG has determined that the Equipment or Components identified in Article 11 of this Contract comply with the requirements of the applicable criteria and certification classification under Appendix 1 (EHEDG Certification Type) of this Contract.
- 3. Upon execution of this Contract and payment of any outstanding fees, EHEDG authorizes the Company to use the EHEDG Certification Logo on the Equipment or Components identified in Article 11 subject to the conditions described in Appendix 2 (Conditions for Use of the EHEDG Certification Logo) of this Contract for a period of one year. The period may be extended annually by providing documentation which shows that the Equipment or Components Certified still fully meet/s the provisions of this Contract and payment of an annual prolongation fee as published on www.ehedg.org. On each fifth year anniversary of the initial Certification, the Equipment or Component Certified will be subject to a full hygienic design evaluation and testing, as appropriate, to renew the Certification
- 4. The Company undertakes the responsibility to place the Logo only on the Equipment or Components which has/have been certified as in compliance with this Contract.
- 5. It is understood and agreed that a Logo on any Equipment or Components and its/their Certification are invalid if the Equipment or Components has/have been significantly altered or been represented as being Certified for any purpose or end use other than that Certified by EHEDG. EHEDG assumes no liability for any claims arising from such alteration, misuse, or misrepresentation by the Company.
- 6. The Company assumes responsibility to inform EHEDG of any changes or modification in the design and manufacture of Certified Equipment or Components which may affect compliance with the EHEDG Criteria. EHEDG will judge whether the changes or modifications render the current Certification void. The need for review of the modified Equipment or Components depends on the modification being carried out.
- 7. EHEDG assumes no liability for any claims for damages of any kind occurring to any person or entity as a result of sale, resale, use or misuse of the Company's Equipment or Components, whether or not these are certified. The Company assumes full and complete responsibility for its use of the Logo or other representation that its Equipment or Components are Certified. EHEDG assumes no liability for any claims arising from the Company's misuse of the Logo or misrepresentation of the Certification status of its Equipment or Components.
- 8. The Company undertakes to declare in writing before the annual expiry date on the Certificate at the latest that no modifications were made on the Certified Equipment or Components, or parts thereof. If modifications have been made on the certified Equipment



- or Components, the Company is to notify EHEDG thereof who determines whether the Certified Equipment or Components needs review or not.
- 9. Certification of the Equipment or Components is subject to a full evaluation every five years from the issuance date. If the company fails to comply with the five year evaluation or fails the evaluation, the certificate will no longer be valid. At the end of this period the Certification is no longer valid and the use of the Certification Logo in relation to the Equipment or Components for which the Certification was issued is, from that moment on, strictly forbidden. However, Certification of the Equipment or Components can be reviewed to determine if the Certification could be reaffirmed as written or modified to meet the current applicable EHEDG criteria and reissued, or discontinued. The Company is responsible to initiate the review process sufficiently in advance of the renewal date to prevent a delay in certification.
- 10. The Contract may be terminated with thirty days notice by either party. The right to terminate the Contract for cause remains unaffected. Good cause is especially given, if the license fees were not paid or modifications have been carried out on the Certified Equipment or Components without prior notification. This Contract will be terminated when replaced by a mutually agreed new contract or contract revision provided by EHEDG or in case of abuse of the Logo as mentioned under article14, below.
- 11. The EHEDG Certification Logo may be used on or in connection with the following Equipment or Components:
 - (trademarks, model numbers, etc. to unambiguously identify the Equipment or Components) as shown on the drawings or copies of drawings with original (NOT copied) EHEDG stamp, dated and signed by EHEDG or the EHEDG Authorized Organization, provided that the Equipment or Components if applicable has/have means for use and/or mounting such that compliance with the EHEDG Criteria is not adversely affected. (If needed: additional remarks or conditions, based on the Evaluation Report.)
- 12. EHEDG will keep all documents and other evidence of the Company's Equipment or Components on file. The Secretariat of EHEDG will keep records of Equipment and Components that has/have been certified. EHEDG undertakes to treat all documents received from the Company as confidential.
- 13. A Certificate will be provided bearing the EHEDG Logo and applicable Certification type identification as shown on Appendix 1 of this Contract. The Certificate will be signed and dated.
- 14. Abuse of the EHEDG Certification Logo (i.e. its use under conditions conflicting with this Contract) may result in any or all of the following sanctions:
 - a. a request to immediately take corrective actions;
 - b. termination of the Contract;
 - c. indemnities and damages to the minimum amount of EUR 10,000 per case.



Examples of Abuse:

- the Company uses the EHEDG Certification Logo on Equipment, Components, drawings, brochures or other documents which have not been Certified;
- the Company uses the EHEDG Certification Logo as general information on documents:
- the Company uses the EHEDG Certification Logo on modified Equipment, Components drawings, brochures or other documents without prior notification to EHEDG:
- the Company uses the EHEDG Certification Logo on Certified Equipment or Components, drawings, brochures or other documents using another name and/or designation without prior notification to EHEDG;
- the Company uses the EHEDG Certification Logo on Equipment, Components, drawings, brochures or other documents of Equipment or Components which passed the EHEDG in-place cleaning test but do not comply with the Hygienic Design Criteria of EHEDG.
- 15. Disputes between Parties in connection with or arising out of the Contract, which cannot be resolved by arrangement between parties, shall be finally settled by arbitration in accordance with the rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbiters appointed in accordance with those rules. The place of arbitration shall be Den Haag (The Hague).
- 16. This Contract and referenced documents constitute the entire agreement between Parties and supersede all previous communications, representations or agreements between Parties with respect to the Certified Equipment or Components. No modification will be binding upon either party unless it is made in writing and is signed by duly authorized representatives of both Parties.
- 17. This Contract will be subject to Dutch law.



| For Company | For EHEDG |
|--------------|-----------|
| Company Name | |
| Name | - Name |
| Title | Title |
| Signature | Signature |
| Date | Date |

This Contract includes the following documents:

Appendix 1 - EHEDG Certification Logo type and class

Appendix 2 - Conditions for Use of the EHEDG Certification Logo

Appendix 3 - EHEDG Equipment Evaluation Form



Appendix 3

EHEDG Certification – Equipment Evaluation Form

| - | uipment: | | |
|------|--|-----------------------------------|------------------|
| Ap | plicant: | Date: | |
| Eq | uipment name: | EHEDG File Number: | |
| Тур | pe or model No/s.: | Certification Type: | |
| Oth | ner essential identification: | | |
| Ev | aluated by: | | |
| Na | me: | | |
| Ар | proved by: | | |
| Na | me: | | |
| Titl | e: | | |
| | | | |
| Da | te, Signature: | | |
| | | | |
| | | | |
| | | | |
| 1. | Results of inspection for compliance with the EHED | G Hygienic Design | |
| 1. | Criteria. | G Hygienic Design | YES □ |
| 1. | Criteria. Conclusion: | G Hygienic Design | |
| 1. | Criteria. | | YES □ MAYBE □ |
| 1. | Criteria. Conclusion: The equipment complies with the criteria. | | |
| 2. | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance presecompensation provided and convincing for Certification. | ied: ent. Evidence for | |
| | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: | ied: ent. Evidence for ion. | |
| | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance presecompensation provided and convincing for Certification. | ent. Evidence for ion. | MAYBE □ |
| | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: The equipment complies with the criteria where | ent. Evidence for ion. | MAYBE □ |
| | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: The equipment complies with the criteria where | ent. Evidence for ion. | MAYBE □ |
| 2. | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: The equipment complies with the criteria where The use of the EHEDG Certification logo is justife. | ent. Evidence for ion. | MAYBE □ |
| 2. | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: The equipment complies with the criteria where | ent. Evidence for ion. | MAYBE □ |
| 2. | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: The equipment complies with the criteria where The use of the EHEDG Certification logo is justife. | ent. Evidence for ion. | MAYBE □ |
| 2. | Criteria. Conclusion: The equipment complies with the criteria. The use of the EHEDG Certification logo is justife. Only unavoidable reasons for non-compliance prese compensation provided and convincing for Certificate Conclusion: The equipment complies with the criteria where The use of the EHEDG Certification logo is justife. | ent. Evidence for ion. | MAYBE □ |

The original of this form will be kept by EHEDG together with the application, the inspection report, the evidence provided and any other relevant documentation, as listed on the back.



| No. | Description |
|-----|-------------|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |



Appendix 2

Conditions for Use of the EHEDG Certification Logo

Upon obtaining evidence of compliance (see Appendix 1: EHEDG Certification Type), a contract shall be executed by the Company and EHEDG. The contract shall detail the Product for which Certification is provided. The Certification Logo will be dated (month and year) and will last for a period not to exceed 5 Years unless the equipment, or any part thereof, is modified, in accordance with clauses 3 and 6 of the Contract.

1. Use of the Logo and responsibility of Applicant

- 1.1. The Applicant shall represent as Certified, by use of the Logo or otherwise, only Products described in the Contract.
- 1.2. The language allowed is either "Certified by EHEDG" or "EHEDG Certified". Correct literal translations are also allowed.
- 1.3. The Logo may be printed in black or in two colours. If printed in two colours, "EHEDG" must be in red no. PMS 032 and all other text in blue no. PMS 072 (see 13, below).
- 1.4. The Logo must be used in combination with the type of Certification, such as "TYPE EL CLASS I", and the date (month in text and year in four digits) of Certification. Both must be produced below the logo in the way shown in under 13. The text, such as "TYPE EL CLASS I", must be at least 1/10 times the size of the logo and the date must be at least 1/20 times the size of the logo, but both must never be less 2 mm in height. The font must be ARIAL Rounded MT Bold or ARIAL (Western) Bold or similar and equally clear.
- 1.5. If the logo is applied directly (etching) on to the Product, this may be done without using colours. If colours are used, the colours mentioned under 4.3 must be used, as indicated. It must be ascertained that the use of the Logo on Products does not adversely affect either hygiene or food safety. Dimensional requirements are as specified under 4.4.
- 1.6. The Logo may not be cropped in any way.
- 1.7. The Logo may be used in combination with other logos or marks.
 If used in combination with other logos, it does not automatically mean that the EHEDG is linked to those organisations in one way or the other.

2. Written Authorization for Certification and Use of the Logo

The EHEDG Logo is a registered Mark. No Company or person shall apply or use the Logo in connection with a Product, or represent in any way that the Product is EHEDG Certified, until receipt of written authorization from EHEDG. EHEDG may pursue legal recourse if the Logo is misused.

3. Transfer of Authorization for Certification and Use of the Logo

No company may independently transfer or authorize the use of their certification. Upon request and with documentation of continued compliance, EHEDG may transfer authorization for continued Certification of specific Products to another Company for the purpose of a name change, change of ownership, or change of a production location. An administration fee will be charged.

4. EHEDG Acknowledgement of Certified Products

Certified Products may bear the Logo or be otherwise represented as Certified.

5. Trade Designations

A Company shall not use the letter combination "EHEDG" in its trade designation (e.g. name, model number, or other identification assigned by the Company) for a Certified or non-Certified Product. A Company shall not have a trade designation for a Certified Product that directly or indirectly states or implies an end use application for which the Product is not Certified.

6. Product modification

Any modification of the product, which has been Certified renders the Certification void for the modified products. If Certification of the modified product is desired, a new application must be submitted. If the modification proves to be relatively insignificant, the fee may be reduced or waived at the discretion of EHEDG.



7. Implementation of Revisions to Referenced EHEDG Guideline(s)

Upon adoption of a revision to any referenced EHEDG Guideline(s), mentioned in the Contract, the Company shall be encouraged to implement all changes in requirements in its Certified Products.

8. Certification of Distributors

A Company distributing a Certified Product with a trade designation other than that of the original manufacturer may apply for an extra EHEDG Certification and contract.

9. Private Labelling of Certified Products

If a Company has the intention to label Certified Products with another name and/or designation the Company shall prior to any changes notify the EHEDG thereof in writing. On written consent of the EHEDG, the Company may apply for an extra EHEDG Certification and contract.

10. Example of the EHEDG Certification Logo

The applicable logo (with Month and Year) will be provided by EHEDG.

















Fees for Granting, Prolongation and Renewal of EHEDG Certificates

The following schedule of fees shall be paid to EHEDG for the category of certificates issued.

| Due Dates | Fee |
|--|---------|
| Initial fee for first issuance or renewal of a certificate (Fee includes the first annual prolongation following issuance or renewal.) | 500 EUR |
| Fee for annual prolongation of old certificates | 150 EUR |

All above mentioned fees are not discountable.

The initial certificate will be sent to the client and published in the "Certified Equipment" list on the EHEDG website upon payment of the invoice

In subsequent years starting from the year after initial issuance of the certificate and for a period of maximum four years, annual prolongation invoices will be issued each on 30 September, unless the certificate is cancelled by either of the parties in advance for whatsoever reason. In case of non-payment of the annual prolongation invoice, the certificate will be deleted from the EHEDG website effective 31 December of the same year.

An initial invoice will be issued after renewal of the certificate which will remain published in the "Certified Equipment" list on the EHEDG website. The process will be continued by above steps as required.



EHEDG Working Group Certification

1 Purpose

The Working Group Certification (WGC) under the supervision of the SubCom Product Portfolio is tasked with the following responsibilities:

- Establish and maintain the requirements necessary to become an EHEDG Authorized Testing Laboratory (ATL) and EHEDG Authorized Evaluation Officer (AEO).
- Evaluate the capabilities and test facilities of applicants to become an ATL.
- Make recommendations to SubCom Products Portfolio for the acceptance of an applicant to become an ATL.
- Make recommendations to SubCom Products Portfolio for the withdrawal of authorization for an ATL with justification.
- Develop and maintain required minimum qualifications and skills for the designation as an EHEDG AEO.
- Make recommendations to the SubCom Products Portfolio for the acceptance of qualified individuals for the position of AEO.
- Make recommendations to the SubCom Products Portfolio for the withdrawal of qualification for an AEO with justification.
- Develop and maintain the test methods based on the criteria within EHEDG Guidelines.
- Conduct and maintain records of periodic Ring Trial testing for ATL uniformity.
- Conduct periodic uniformity meetings with the ATLs and AEOs.
- Maintain a file (log book) of all item-specific evaluation and testing procedures for internal use by ATL/AEOs.

2 Membership

- 2.1 The WGC shall consist of all AEOs, ATL representatives and any other members that the WGC deems important for the effective functioning of the Working Group.
- 2.2 The Chair and Vice Chair positions of the WGC shall be selected by a majority vote of the members and serve for a term of 2 years. The Chair and/or Vice Chair may be reaffirmed by the WGC.
- 2.3 The EHEDG Certification Officer (CO) shall attend as a non-voting, liaison observer for the certification procedures.



2.4 Decisions made by the WGC shall be accepted based on a majority vote of the members.

3 Test Methods

- 3.1 The CWG shall oversee the maintenance of the following EHEDG Documents and any further developed test method/s published by EHEDG:
 - Doc. 2, A Method for Assessing the In-place Cleanability of Food Processing Equipment
 - Doc. 5, A Method for the Assessment of the In-line Sterilisability of Food Processing Equipment
 - Doc. 7, A Method for the Assessment of Bacterial-tightness of Food Processing Equipment
- 3.2 The WGC shall maintain a log file of all evaluation and testing procedures developed for the accurate evaluation of specific types of equipment. The log file entries shall be designated by a protocol number (year-procedure number, e.g. 2017-1) and title. The log file modifications with concurrence by SubCom PP shall be made available to all ATLs, AEOs, the EHEDG ExCo, and the members of the SubCom Product Portfolio. The log file will not be made public but relevant information will be made available via the EHEDG website.

4 Ring Trials

- 4.1 The WGC will conduct a ring trial of all authorized ATLs at least every three years.
- 4.2 The WGC will establish all of the ring trial parameters and set the ring trial completion date.
- 4.3 The results of the ring trial results from all of the participating ATLs will be evaluated by an independent reviewer who is a recognized expert in hygienic design selected by the WGC with the concurrence of the SubCom Product Portfolio.
- 4.4 The summary report will be provided to the WGC and the SubCom Product Portfolio.
- 4.5 Any inconsistencies demonstrated by an ATL will be investigated to determine the cause of the inconsistency. Remedial actions will be taken as appropriate to assure that all ATLs perform at an acceptable level of accuracy and uniformity.



5 Certification Documentation File Procedures

- 5.1 Certification evaluations and testing shall be conducted according to Guidelines and the log book developed by the WGC with concurrence of SubCom Products Portfolio.
- 5.1.1 Equipment that requires a specific evaluation/testing procedure that is not currently in the log file shall be discussed and agreed within the WGC prior to evaluation and testing (See section 3.2) and the log file updated.
- 5.2 All fees associated with evaluation and testing activities shall be independently quoted and billed directly to the applicant by the ATL/AEO and all funds for such activity shall be retained by the ATL/AEO.
- 5.3 The completed Certification Documentation file and any further information necessary is to be sent to one other AEO for review (if testing was performed) or all authorized AEOs for review and concurrence (if no testing was performed).
- 5.3.1 The reviewing AEO/s shall complete the concurrence review within 14 days of receiving the file and return a signed Certificate Evaluation Form (Appendix 3, page1, of the Certification File) to the originating AEO.
- 5.3.2 Issues of non-concurrence shall be resolved by the WGC as promptly as possible.
- 5.4 The completed Certification Document file shall be sent to the CO upon completion of review and concurrence with an accompanying list of applicable documents. (Appendix 3, page 2, of the Certification File).



EHEDG Authorized Evaluation Officer Requirements

1 Purpose

The Certification Working Group for certification and testing issues (below named "WGC") is responsible for the appointment and monitoring of EHEDG Authorized Evaluation Officers (AEOs).

1.1

The AEO is a qualified, technical expert affiliated to an Authorized Testing Laboratory (ATL) for the purposes of Certifications where testing is required and is responsible for signing all design evaluation reports associated with the EHEDG certification process.

2 Qualification and skills of applicants

An EHEDG AEO, candidate shall provide the following:

2.1

A formal application to the Chair of the WGC, accompanied by a CV documenting all relevant educational, hygienic design evaluation experience and familiarity with EHEDG test procedures, with references.

2.2

The CV shall describe the background and number of years of practical experience in evaluating the hygienic design of food processing equipment in processing plants, equipment fabrication, an understanding of mechanical engineering, and the ability to read and understand engineering drawings.

2.3

The applicant shall demonstrate and maintain knowledge and understanding of the EHEDG Guidelines and the principles of hygienic design.

3 Application Assessment

Upon receipt of an application, the WGC shall conduct the following assessment:

3.1

Review the content of the CV.

3.2

Review and (if necessary) contact the reference addresses listed in the applicant's CV.

4 Probation

4.1

After acceptance of the application by the WGC and ratification by SubCom Product Portfolio, the candidate shall conduct design reviews and testing evaluations at a designated Test Institute on a probationary basis to demonstrate his/her ability as an AEO.



4.2

The probationary evaluations will be conducted for a period during which at least 4 complete equipment evaluations can be conducted.

4.3

The probationary evaluations are to be observed by one or more members of the CWG.

4.4

During the probationary period the candidate shall become familiar with the documentation requirements and approval procedures for Certification.

4.5

Should the WGC observer determine additional training is necessary, one or more additional weeks shall be scheduled.

5 Certification

Upon successful completion of the above probationary observation period(s), the applicant will become an active member of the WGC and be listed as an EHEDG Authorized Evaluation Officer qualified to conduct EHEDG design evaluations, perform testing, prepare test reports and compile documentation packages for EHEDG certification.



Authorized Evaluation Officer Certificate

This certificate is issued following the successful completion of the application procedure according to EHEDG Document SCP 4-10 and approval by the EHEDG Working Group Certification

Mr. / Ms. (Insert Name)

is appointed as an EHEDG Authorized Evaluation Officer

| Ludvig Josefsberg | | Date |
|-------------------|--|------|

EHEDG President



Service Agreements between EHEDG and Authorized Testing Laboratories and between EHEDG and Authorized Evaluation Officers

Part 1, Authorized Testing Laboratories

SERVICE AGREEMENT

between

EHEDG and (Authorized Testing Laboratory Name)

This service agreement between EHEDG and (Authorized Testing Laboratory Name), herein signified by ATL, defines the responsibilities of each party. This agreement shall remain in effect until such time as it has been cancelled by either party with 60 days' prior notice.

ATL Responsibilities:

- 1. The ATL shall be the primary contact with the prospective certification client for all testing issues.
- 2. The ATL shall be responsible for invoicing and collection of all costs associated with any testing.
- 3. The ATL shall designate and inform EHEDG who will be the official signatory authority (signer) for all test reports issued by the ATL. This signatory authority may be the TI Director or Head of Department as appropriate. A ATL may designate one or more AEOs as necessary and maintain a liaison with respect to testing protocols.
- 4. The ATL shall maintain ISO 17025 accreditation for the scope of the test methods conducted and be independently audited.
- 5. The ATL shall maintain documentation that all technicians running tests have received suitable training and are approved to conduct official testing by the EHEDG WG Certification or the affiliated AEO.
- The ATL shall participate in all ring test procedures directed by the EHEDG WG Certification.
- 7. The ATL shall maintain all testing documents
- 8. The ATL shall only conduct testing with EHEDG approved test methods and protocols (log book)
- 9. The ATL shall assure that all test reports and documentation are complete.
- 10. The completed documentation file shall be submitted to the AEO by the ATL.



EHEDG Responsibilities:

- 1. EHEDG is the sole certifying agent for all EHEDG certifications issued.
- 2. EHEDG shall maintain a list of AEOs qualified to conduct design reviews and prepare Certification documentation.
- 3. EHEDG shall obtain a signed contract with the potential certificate holder prior to certification.
- 4. EHEDG shall provide all certificate holders of record notification of the required annual prolongation and the 5-year cycle for recertification in sufficient time for the certificate holder to accomplish the required actions prior to the action date.
- 5. EHEDG shall be responsible for invoicing and collection of all certification fees.
- 6. EHEDG shall archive the official Certification file.

| 7. EHEDG shall mainta | EHEDG shall maintain the website listing of all certified equipment. | | | |
|-----------------------|--|---|--|--|
| | | | | |
| EHEDG President, | Date | Authorized Testing Laboratory Director, Date (ATL name) | | |



PART 2, Authorized Evaluation Officers

Service Agreement

between

EHEDG and (Authorized Evaluation Officer Name)

This service agreement between EHEDG and (Authorized Evaluation Officer Name), herein signified by AEO, defines the responsibilities of each party. This agreement shall remain in effect until such time as it has been cancelled by either party with 60 days' prior notice.

This agreement applies only to equipment evaluations that <u>do not</u> involve the performance of testing procedures by a Authorized Testing Laboratories ATL). When testing is performed, the AEO's activities are covered by the associated ATL Service Agreement.

AEO Responsibilities:

- 1. The AEO shall be the primary contact with the prospective certification client for all evaluation issues.
- 2. The AEO shall be responsible for invoicing and collection of all costs associated with any evaluation.
- 3. The AEO shall be the official signatory authority (signer) for all evaluation reports issued by the AEO.
- 4. The AEO shall maintain documentation of current EHEDG Authorization as an AEO.
- 5. The AEO shall maintain all evaluation documents.
- 6. The AEO shall assure that all evaluation reports are complete.
- 7. The AEO shall submit the complete documentation file to the all other AEOs for review and concurrence of the evaluation conclusions.
- 8. Reviewing AEOs shall provide the submitting AEO with a signed declaration of concurrence with the documentation file and conclusions that will become part of the official Certification file in a timely fashion.
- 9. The completed documentation file shall be submitted to the EHEDG Certification Officer by the AEO.

EHEDG Responsibilities:

- 1. EHEDG is the sole certifying agent for all EHEDG certifications issued.
- 2. EHEDG shall maintain a list of AEOs qualified to conduct design reviews and prepare Certification documentation.
- 3. EHEDG shall obtain a signed contract with the potential certificate holder prior to certification.



- 4. EHEDG shall provide all certificate holders of record notification of the required annual prolongation and the 5-year cycle for recertification in sufficient time for the certificate holder to accomplish the required actions prior to the action date.
- 5. EHEDG shall be responsible for invoicing and collection of all certification fees.
- 6. EHEDG shall archive the official Certification file.

| 7. EHEDG shall maintain the Web-site listing of all certified equipment. | | | | |
|--|----------|----------|----------|--|
| | | | | |
| EHEDG President, | Date | AEO, | Date | |