

Excerpt from the Bylaws of the VAH Disinfectant Commission

As of 1 July 2013

III Code of practice for evaluation and certification

III Art. 1 Disinfectant procedures eligible for certification

The VAH (Association for Applied Hygiene) certifies procedures for disinfection and handwashing as specified in Appendix A.

III Art. 2 Application for certification of a product and issuance of certificate

- (1) The application for certification of a disinfectant procedure has to be submitted to the Disinfectant Commission (DMK). Application forms for the different areas of application can be downloaded at <http://www.vah-online.de/application>. Certification of products is based on the Catalogue of Requirements for Including Chemical Disinfectants in the DGHM-Disinfectant List (issue 4 February 2002) or updates of these requirements (the Catalogue in German may be ordered via mhp-Verlag Wiesbaden GmbH, Marktplatz 13, 65183 Wiesbaden; www.mhp-verlag.de as well as the pertinent communications in the journal „Hygiene & Medizin“ (*note: the Catalogue of Requirements is presently being revised*). Registration and licensing procedures such as stipulated by the German Medicinal Products Act (AMG) or the Medical Device Act (MPG) are not taken into consideration. The Disinfectant Commission does not verify whether the respective product or procedure fulfils the legal trade requirements e.g. for being marketed as a medicinal drug. When submitting the application, the applicant simultaneously accepts the terms and conditions of the DMK for certifying his product. This acceptance refers to the code of practice in these by-laws and to provisions which are mentioned in the by-laws as far as they are accessible to everyone. The applicant will obtain a confirmation of receipt of the application, which then results in a contract.

- (2) a) The application form contains all active substances of the disinfectant procedure with exact weights and quantities (e.g. g/100g, g /100 ml, ml /100g, ml/100ml) according to the nomenclature rules of IUPAC. In addition, the names of the active substances used in the test reports and possibly on the labels must be specified. The substances are printed on the certificate as stated on the label. The VAH List contains the active substances groups and active substances.
b) The application must state which disinfection or handwashing procedure according to Appendix A is to be certified.

Excerpt from the Bylaws of the VAH Disinfection Commission:
Code of Practice for Evaluation and Certification, as of 1 July 2013

- c) Along with the application form, the applicant must send all the information related to the product (labels, product information, safety data sheet) to the VAH head office. If the above mentioned information states different contact times or recommended uses than those confirmed by VAH, a clear distinction must be ensured.
 - d) The application must also contain the values and their permitted deviation range of the following parameters: pH 100% (this does not apply to alcoholic products if they contain > 60% alcohol), pH 1% aqua dest., refractive index, density.
- (3) For the certification of a product it is required to present two separate, complete expert reports on the efficacy tests of the product performed according to the current "Catalogue of Requirements for Including Chemical Disinfectants in the List of Disinfectants" including the pertinent test reports written by two experts who are independent of each other. The expert reports must be signed in person, i.e. in the name of the expert. Expert reports signed by laboratories or institutes cannot be accepted. The experts and their test laboratories must not have any legal, economic, organisational or other close relationships with the applicant or amongst each other. If there is any ambiguity, the DMK is entitled to ask for an official statement on this matter from the evaluator whose most recent report carries the later date. The two expert reports including the pertinent test reports form the basis for the conformity assessment procedure and are reviewed by experts of the Disinfectant Commission. If the Disinfectant Commission has obtained other additional test results on the product submitted for certification, these results are also taken into consideration in the assessment. If the product is a transcription of a previously certified product, the provisions made in III Art. 3 will apply (4).
- (4) After the assessment procedure has been successfully by the Disinfectant Commission, a certificate is issued which is valid for three years. An application for renewal of the certificate can be filed even before validity has expired. If the requirements (see 1) have changed in the meantime, the necessary supplemental expert reports have to be presented unless otherwise stated in transitional provisions. If new expert reports and corresponding test reports are available, these must also be sent to the Commission in triplicate.
- (5) The applicant declares on oath that the products placed on the market is identical with the product samples provided to the experts for efficacy testing. In this context the applicant grants permission to the Commission to authorize a quantitative and qualitative chemical analysis of his product as well as microbiological efficacy testing in accordance with the "Catalogue of Requirements for Including Chemical Disinfectants in the List of Disinfectants" at any time – even after the certificate has been issued. The head office may perform these tests itself or commission a suitable laboratory. For the qualitative analysis of the active substances by the Disinfectant Commission the applicant has to inform the Commission about the necessary analysis methods upon request, or at least the

applicant has to state the methods which the manufacturer actually uses for quality control in the manufacturing process (in-process and batch control).

- (6) The applicant and/or the owner of the certificate are required to report any change in the composition of the certified product to the Disinfectant Commission prior to placing the altered product on the market. This obligation does not only refer to a change in the active substances but also to a change in any other substance contained in the product.
- a) If active substances (possibly excipients) are changed in quantity or type, a complete new assessment procedure is required.
 - b) If one or more additives/excipients are altered – in a quantity of less than 2 percent of weight in relation to the originally certified product – comparative (old/new) suspension tests have to be presented. These suspension tests have to be performed with the same stock. It is sufficient to use the most resistant test organism identified in the original expert report as test organism. The test should be performed at a mean contact time and with concentrations which yield numerable results. Upon request at the Disinfectant Commission, these tests may also be performed in a laboratory of the applicant provided it fulfils the pertinent quality assurance requirements. The Disinfectant Commission may require additional tests according to c).
 - c) If additives/excipients are changed to a greater extent than specified in b), the certificate holder has to verify equivalency in efficacy of the old and the new formulations by submitting a test report issued by an independent test laboratory which has tested in accordance with the procedure described in b). If the results show that the new formulation is less effective than the original formulation, equivalency may still exist. This may be demonstrated by performing tests for the actual use recommendations (test simulating practice conditions and/or suspension test). In all cases the suitability of the neutralising agent used must be verified.

In cases a) and c) the altered product must not be marketed with reference to certification. The batch numbers for the old formulation whose expiry date has not yet passed must be made known. If DMK still has scientifically justified doubts about the equivalence of the efficacy of the old and new formulations in cases b) or c) despite having performed tests, DMK is entitled to make an ad hoc decision including the demand of an entirely new evaluation.

- (7) Upon the time of notification on the alteration or withdrawal of a certificate, the certificate holder must not use the original certificate any longer and must not refer to the certificate in any way. Upon alteration of a certificate, an appropriate time limit will be set for the use of products which have already been sold. If there are serious doubts on the efficacy of a product the manufacturer is required to recall the products delivered if these contain a reference to the (original) certification.

Excerpt from the Bylaws of the VAH Disinfection Commission:
Code of Practice for Evaluation and Certification, as of 1 July 2013

- (8) At regular intervals (at least once a year), the Commission publishes an inventory of all disinfectant procedures with a valid certificate as of a fixed date in the "VAH List of Disinfectants". Additional updates are published on the Internet. If a certificate is changed or withdrawn within the period of its validity the Commission will publish this information in a suitable form (also see III Art. 5). If a certificate owner uses a certificate in breach of the stipulations in this Code of Practice, makes reference to a certificate with inappropriate factual claims or has someone else make such reference or if he advertises products this way or in a confusing manner with a certificate or has someone else advertise for him in such a manner, DMK is entitled after unsuccessfully warning the certificate owner, to disclose information about this in a suitable manner. Information from and publications by DMK according to this Code of Practice are available in professional journals (e.g. Hygiene und Medizin, Deutsche Apothekerzeitung, Pharmazeutische Zeitung) and/or on the VAH homepage on the Internet.
- (9) For certification of disinfectant procedures according to the Guidelines of the Disinfectant Commission fees will be charged which are specified in the Table in Appendix B.

III Art. 3 Test reports and expert reports, requirements on test laboratories and on experts/evaluators

- (1) Test reports must contain the results of all tests in the format of tables. Details are given in the context of the respective test method. The methodology need not be described if it was performed in accordance with these standard test methods or the respective European Standard. However, any deviance from the method must be made known and explained. Reference to the pertinent standard method or a European Standard with the date of release must be made for each test. Unless otherwise specified, the baseline microbial count of the test suspensions used must be stated in colony forming units per mL. Each test series must contain an evaluation of the results which shows the extent to which the requirements on the efficacy are being fulfilled with reference to the standard methods or European Standards.
- (2) Test reports must contain the following specifications:
- Name and address of the laboratory
 - Product name on the original marketed packaging
 - Applicant
 - Date of application/delivery of samples
 - Test period
 - Batch number and/or date of manufacture, expiry date if applicable
 - Description of product, e.g. liquid or powder, colour, appearance, odour
 - pH value of the concentrate as well as of all use concentrations recommended
 - Quantity and type of active substances according to the information provided by the manufacturer in line with the legally binding stipulations.

- (3) For retesting as a consequence of alterations in the formulation (see III Art. 2 (6)) the test report must specify which test series were performed with the product.
- (4) If expert reports are transcribed and reissued with other product names using identical formulations this must be made known by the applicant stating the name of the original product. The original test reports must be submitted.
- (5) The expert report must contain the personal letterhead of the expert and must be signed in person by the respective expert. The expert report must clearly state the name of the product, the reference to the test report and the recommended use specifications including the field of application and the active concentration-contact time relations taking into consideration scientific practice-relevant findings.
- (6) The expert compiles his/her report with reference to the test report. The expert may commission a test laboratory to perform tests and/or write test reports. The expert must be able to influence the quality assurance measures of this laboratory in order to ascertain that the tests are always performed in accordance with the state of the art of science and technology.
- (7) Each test laboratory has to undergo quality control inspections by DMK at regular intervals. Furthermore persons assigned by DMK must be granted access to the laboratory including the permission to view equipment and laboratory test records.
- (8) The expert/evaluator should meet the following profile: The expert must have experience in disinfectant testing and hospital hygiene. Experts in this context are persons who have earned a university degree for medicine or a related science and who have at least two years of experimental experience in the field of disinfectants testing.
The head office keeps an updated list of experts accredited by DMK.

III Art. 4 Conducting the evaluation process

Approval of the suitability of a disinfection process is made on the basis of the application submitted by the applicant and the expert report presented.

The application is processed according to the steps described below:

(1) Receipt

Upon receipt of the application documents, the head office will assign a reference number. This reference number is an annual consecutive number (e.g. *N12/001 for the first application in 2012*).

A file is kept by the head office for each application which contains all relevant documents including the expert reports and the test reports. In addition, the following data are recorded in a database:

Product name, field of application, manufacturer, complete address, vendor address and address for correspondence, active substances group, active substances with concentration, concentration/time ratio of the respective field of application, safety data sheet, date of application, file number, application type (new or renewed), possibly transcription/reissue notice, evaluator with date, section reviewer, date of forwarding, case administrator for the respective field of application, respective status of procedure.

(2) Forwarding

After a formal check, the request of missing documents or data and their receipt the case file is forwarded to the administrator in charge for the respective field of application (in the following referred to as *case administrator*) by the DMK Secretary.

For new applications, the case administrator must appoint two independent members of DMK as specialists to conduct the conformity assessment procedure, one of whom always is the DMK Secretary.

For new applications based on the transcription of already certified products or for the renewal of certificates conformity assessment must be performed by one reviewer only (this should not be the DMK Secretary). If the renewals, however, contain changes in the concentrations or contact times and changes according to III Art. 2 (6) a) or c), two reviewers are required. The reviewers will receive an expense allowance according to Appendix C.

(3) Confirmation of receipt to applicant:

At the same time as forwarding the case file to the case administrator, the applicant will receive a confirmation of receipt (see III Art. 2 (1) last sentence) and an invoice for 600 Euro plus VAT administration fee, which will be credited if a certificate is issued.

(4) Review:

The case administrator is granted 6 weeks for processing.

The case administrator then forwards the corresponding documents together with a report form and an accounting sheet to the reviewer of his choice. Only a person who did not participate in preparing the expert report or the test report may be selected for the conformity assessment procedure. Also, the case administrator must not always select the same reviewers for the assessment procedure. Therefore, the members of DMK should be appointed - as far as possible - in an order to be defined beforehand.

Excerpt from the Bylaws of the VAH Disinfection Commission:
Code of Practice for Evaluation and Certification, as of 1 July 2013

After feedback within three weeks and the case administrator checking the reviewer's report, the head office is informed whether any shortcomings were noticed by the reviewer or if certification can be recommended. At the same time, the last page of the reviewer's report, the accounting sheet filled in by the reviewer and confirmed by the case administrator along with the final report are forwarded to the head office. If no shortcomings are detected, certification may be completed in a silent procedure via e-mail. This means that the head office sends the case file together with all essential information to all DMK members who are asked for their consent to certification within a 7 to 14-day objection period. Should an objection be received within the deadline, a vote has to be taken within the context of a DMK meeting.

(5) Shortcomings in the expert report:

The case administrators notify the head office of shortcomings or questions in the expert report or the test reports. If these are formal shortcomings, the applicant is requested to correct these. If these are questions about the efficacy, DMK will determine which retesting is required.

(6) Resolution on issuing the certificate:

Within the context of a DMK meeting or in the silent procedure (see para. 4), the applications are presented to the DMK members with the relevant data. The vote on the resolution occurs according to I Art. 11. The DMK members who were part of preparing the expert report, are excluded from voting. If the application is rejected, DMK is to determine what information needs to be handed in later by the applicant in order to still be able to make a positive decision on the process. If there are no objections, the certificate is issued with a validity of three years.

(7) Issuing the certificate:

If DMK has agreed, an original certificate will be issued that is signed by the Chairperson of DMK.

(8) Invoicing:

The head office or the authorized accounting centre sends an invoice to the applicant (based on publicised charges).

(9) Declaration of consent for printing release:

After receiving the fee, the certificate together with a confirmation of the identity of the product, which must be signed, is sent to the applicant.

At the same time, two declarations of consent are sent to the applicant that must both be signed and sent back to the head office.

A declaration of consent (printing release with consecutive reference numbers) and a copy of the certificate are then sent to mhp-Verlag for inclusion in the current VAH List of Disinfectants.

A copy of the certificate is sent to the case administrator, one copy is included in the current VAH List file and one copy in the product file.

III Art. 5 Testing certified products on the market

- (1) The head office will perform periodic random tests on samples taken from the market, or have these performed. The date of the examinations may not be disclosed to the certificate owner in advance. The head office can perform the tests itself or commission a suitable test laboratory. The following parameters must be tested: pH 100%, pH 1% in distilled water, refractive index, density. In addition, the content of active substances can be tested with the manufacturer's method (see III Art. 2 (5)). If there are deviations, the applicant should be approached for a comment. DMK then decides whether a microbiological follow-up test is necessary, whereby especially the results of the test used for the test report presented, which were important for recommended concentration/time values, including the neutralisation, should be tested. The result of the tests are submitted to DMK together with an evaluation report. If DMK agrees with the evaluation report, the head office will inform the certificate owner of the result.

- (2) Everyone is entitled to have the effect of a product tested and to engage the head office for this purpose. If the contractee provided a security deposit for the issue of a certificate in the amount of five times the fee for a new application, the head office will buy a sample of the pertinent product on the market. Depending on the assignment, it initiates a chemical analytical or a microbiological test by an evaluator from the list in Appendix H, who will be selected by drawing lots. The extent of the expert report is determined by the contractee in consultation with the head office. In all cases, the product name must be encoded by the head office so that the evaluator does not find out the name of the product and certificate owner. The expert report is sent to the head office.

- (3) The costs of testing according to (1) are borne by DMK, the costs of (2) including compensation of expenses for processing by the contractee. The security deposit provided by the latter is offset with this. However, the certificate owner bears the costs if the tests show that
 - a) the composition of the product has been changed, but the certificate owner - contrary to regulations - did not report this change, or
 - b) the values entered in the certificate have to be raised or the contact times extended. In this case, the head office sends the results - previously made anonymous - to DMK for an opinion without disclosing the name of the certificate owner and the product name. DMK must make a decision within a deadline of 6 weeks.

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Code of Practice for Evaluation and Certification, as of 1 July 2013

The certificate owner here also might bear the potential costs for a 1/2 - page notification by DMK in at least two different professional journals (e.g. Hygiene und Medizin, Deutsche Apothekerzeitung, Pharmazeutische Zeitung).

If the certificate owner can prove that the composition has not been changed and still the case b) has occurred, he will be given the opportunity for "rectification".

- (4) The contractee according to (2) will be informed of the results of the tests - in the event of (3) a) and b), after the certificate owner has commented.

III Art. 6 Withdrawal of the certificate, suspension

- (1) In the events of III Art. 5 (3) a) and b), DMK will withdraw the certificate and after payment of the fee (see Appendix B 3 b) possibly issue an altered one.
- (2) If important reasons exist, DMK can also deny the suitability of unaltered products and withdraw the certificate. Important reasons are, for example, new scientific findings that make the effect assumed to date no longer appear valid or insufficient or the test process used to date no longer sufficient. The certificate owner and the Board of VAH must be informed of this.
- (3) DMK can withdraw the certificate of a disinfection process if the certificate owner uses the certificate contrary to the agreement concluded between DMK and him and does not cease to do so despite being warned. The certificate owner and the Board of VAH must be informed of this. Under the premises of the conditions stated in Appendix I, the company is permitted to advertise products with the VAH logo. This logo is made available by VAH. Adherence to the stated conditions must be confirmed by the company in writing. In the event of non-adherence to the conditions of using the VAH logo, VAH will issue a warning. If the warning is unsuccessful, DMK can make notification about this according to III Art. 2 (8). A further assertion of claims by VAH for the unlawful use of the VAH logo or unlawful advertising remains reserved.
- (4) If the name of the disinfection process changes but not the basis of evaluation, DMK must issue a new certificate upon application with the changed name based on the rewritten export reports.
- (5) If follow-up tests according to III Art. 5 result in doubts about the efficacy of a group of the same type of disinfectants within a certain range of effectiveness possibly related to a certain contact time or concentration, DMK is entitled to suspend the respective certificates temporarily and make notification about test results and suspension in a suitable form.

Appendix A

Disinfection and hand washing procedures included in certification (Status 15 December 2005)

(1) Hygienic hand washing:

Contact time 30 seconds or 1 minute

(2) Hand disinfection:

a) hygienic hand disinfection:

contact times 30 seconds or 1 minute

b) surgical hand disinfection

contact times 1 to > 3, 3 or 5 minutes

(3) Skin antiseptic / skin disinfection

Contact times according to skin area 15 seconds, 30 seconds or 1 minute on skin with few sebaceous glands or 10 minutes on skin with many sebaceous glands

(4) Surface disinfection

Contact times 5, 15, 30 or 60 or 240 minutes

In addition: Disinfection of fungi on untreated wood, possible contact times as above

(5) Instrument disinfection:

Contact times 5, 15, 30, 60 minutes

(6) Linen disinfection, chemical or chemo-thermal

Type of application dependent on process

Appendix B

Fees for issuing the certificate (Status 1 October 2012)

1. New application to have a certificate issued for a disinfection process (including transcriptions) and new inclusions in the List of Disinfectants:
1,800 Euro plus VAT
2. Renewal application for the certificate for a disinfection process and continued inclusion in the List of Disinfectants:
1,400 Euro plus VAT
3. Changes in formulation, changes in the area of excipients of a listed product:
 - a) 300 Euro plus VAT according to III Art. 2 (6) b)
 - b) 1000 Euro plus VAT according to III Art. 2 (6) a) and c)These fees carry the VAT valid at the time.

55% of the respective fee is allocated to application assessment and 15% each to monitoring the market in the first, second and third year.

Changes will be published timeously in the journal "Hygiene + Medizin" and on the homepage of VAH.

Appendix C

Expense allowances for certification processing (Status 1 October 2012)

1. Case administrators receive the following amounts to cover their expenses:
 - New applications (including transfers) 100 €,
 - renewals 100 €,
 - renewals with changes 100 €
 - formulation changes 100 €.
2. Reviewers receive the following amounts to cover their expenses:
 - New applications (including transfers) 125 €,
 - renewals 125 €,
 - renewals with changes 125 €
 - formulation changes 125 €.

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Code of Practice for Evaluation and Certification, as of 1 July 2013

Appendix D

Application forms are available for download at <http://www.vah-online.de/applications>)

Appendix E and F

(Confirmation of Consent (correctness of certificate and for inclusion in the VAH List of Disinfectants)) are available from the head office upon request

Appendix G

Sample certificates (are available from the head office)

Appendix H

List of accredited evaluators/experts <http://www.vah-online.de/experts>

Appendix 1

Agreement to advertise products with the VAH logo

- The product/s is/are covered by a valid certificate from VAH during the period of advertising.
- The product/s with a VAH logo are exclusively advertised with the disinfection values certified by VAH and in the areas of application certified by VAH. Disinfection values and areas of application must be clearly discernible in the advertisement. An advertisement with the VAH logo or with the statement that the product/s is/are VAH certified for other than VAH certified products is prohibited. With regard to an advertisement for several products, it must be clearly evident which of the products are VAH certified and which are not. The legally binding confirmation of Appendix E and the declaration of agreement in Appendix F of the Rules of Procedure DMK in VAH remain unaffected.
- The VAH logo is neither falsified, altered, supplemented nor used for purposes other than intended.

Adherence to the above listed prerequisites is herewith confirmed.

Place, date

Stamp, signature