FAQ – VAH-Certification and Listing of Disinfectants

General Questions

- **What is the advantage of a VAH certificate?**

  VAH-certified products are recommended, e.g., by the Robert Koch Institute (RKI) and professional societies for hygiene and infection control in Germany. The VAH certification process requires two separate expert (assessor) reports with pertinent test reports from accredited laboratories approved by VAH (*cf. below*) which are independent of each other and independent from the manufacturer. This process represents a unique quality system. Many professionals therefore make VAH certification a crucial criterion for their decisions on purchasing disinfectants.

- **Is VAH certification required for marketing a product in Germany?**

  VAH certification is an additional, but not mandatory quality mark. It is independent from formal approval processes for biocides or drugs as, for instance, according to the EU Biocidal Products Regulation (BPR) or conformity assessment procedures for medical devices.

- **Will VAH certification remain valid after approval of a product according to the BPR?**

  As an independent quality mark, VAH certification is an important quality feature for disinfectants separate from formal approval, assessment and registration processes with federal authorities. The validity of a VAH certificate is therefore independent of formal approval processes.

- **Are test reports in accordance with VAH requirements accepted for application processes for approval in accordance with BPR?**

  Test reports which meet the requirements of the VAH can be submitted for the approval process as a biocidal product, provided they are suitable for the pertinent application. For more information on the data requirements for biocidal product approval, please consult the ECHA website.

- **What is the difference between the VAH Disinfectants List and the RKI Disinfectants List?**

  The VAH Disinfectants List is the list to choose from for routine and targeted disinfection in everyday situations, for example in medical or care institutions, where disinfection is indicated. The RKI primarily lists products which fulfill requirements for use of disinfectants in specific circumstances such as outbreaks or in the event of infections with particularly hazardous pathogens and other situations where disinfection is mandated by health authorities as defined in the German Infection Control Act, §18. The evaluation of efficacy is based on scientific expert opinions and practical verification by the RKI. Detailed information on the RKI list can be found on the website.

- **Why is it not possible to certify an air-borne disinfection procedure?**

  As of today, requirements for VAH certification of air-borne disinfection procedures have not yet been defined. Please refer to the German Society of Hospital Hygiene (DGKH).

Questions on the VAH Disinfectants List (online platform)

- **How do I access the online platform of the VAH Disinfectants List?**

  The VAH List online is a platform including all products with a valid VAH certificate featuring a wide range of search options. You can access the English edition of this platform free of charge and without prior registration by activating this link https://vah-liste.mhp-verlag.de/en/

  For access to additional contents and functions such as information on test methods or the generation of favorite lists prior free registration is necessary using this link: https://vah-liste.mhp-verlag.de/en/register/

Questions on the Certification Process

- **What do I need for VAH certification of my products and who can guide me through the process?**

  All you need to know you will find in our power point presentation "How does my product get an entry in the VAH Disinfectants List" (PDF file online). For further information, please contact Ms Zimmer or Mr Zingsheim at info@vah-online.de.

- **Where do I find the application forms for certification?**

  All forms are available as PDF files from our website to fill in on your computer.

- **What are the fees for certification?**

  Current fees for certification including new certificates, renewals, and additional claims of existing certificates are published online.

- **When can I use the VAH logo?**

  You may use the VAH logo for advertising your product according to the certified use recommendations as soon as the certificate has been issued. Please contact the VAH headquarter for further information. Logos are available for the certified efficacy spectrums.

- **Why do I have to renew my certificate every 3 years?**

  This way VAH ensures that the test reports and assessment reports correspond to the current state of the art. The complete documents have to be submitted again. A renewed assessment of all documents is an additional quality measure. The process of renewal is less expensive than the first application.

- **What are the fees for test reports and the expert report?**

  The inquiry about costs for assessor reports and test reports should be directed to the assessor and the laboratory, as VAH is not involved in this preparation of these reports.

- **How long – on average – does it take to obtain a VAH-certificate?**

  The average time from submission of all necessary documents to issuance of the certificate is approximately 10 to 12 weeks for a new certificate. The length of the process varies depending on a number of factors, among them, incomplete documents and others. Frequent mistakes are listed in the next bullet point.

- **What are the main reasons why the certification process may be delayed?**

  > The application form is incomplete.
  > The expert reports and test reports submitted with the application are incomplete.
  > Formal flaws and errors such as missing pH values, differing active substances in the application and in the pertinent expert report and/or assessor's report, missing cloth specification, missing signatures in assessor's report and test report etc.
  > The note concerning the transcription of a product is missing on the expert report.
  > Documents from non-accredited laboratories are submitted.
  > The required tests methods were not performed correctly or not performed according to the current state.
  > The current requirements are not fulfilled.

- **What is the difference between a test report and an assessment report (expert opinion)?**

  An assessment report (also referred to as expert opinion) is an overall assessment of the efficacy of the product based on the pertinent test reports. The expert (assessor) states his or her recommendations for use, e.g. on the concentration-time-ratio for a particular spectrum of activity and mode of application.

  A test report contains the laboratory results from efficacy testing, performed corresponding to VAH methods and requirements.

  The detailed requirements for both types of reports are laid down in the VAH Standard Methods and Requirements (Chapter 3) and in the VAH bylaws.

- **Why do I need to submit two test reports and two assessment reports (expert opinions)?**

  The VAH requires two test reports for each product which were prepared by two laboratories which are independent of each other and independent of the manufacturer and which prove the efficacy for each claim of activity spectrum for the respective use recommendations. The laboratories have to participate in ring trials organized by VAH. The reasons for these requirements are that deviations in the test results always occur when employing biological test methods. As each test report requires a separate assessment report, two assessment reports have to be provided.

- **Which laboratories are approved?**

  In order to ensure a high level of quality, the VAH has special requirements on laboratories. Laboratories which are approved by VAH for preparing test reporting for VAH certification must be

independent of the manufacturer of the disinfectant, must be accredited according to EN ISO/IEC 17025, and must participate in VAH ring trials (interlaboratory tests) on a regular basis. A list of laboratories approved by VAH can be downloaded here. The accreditation certificate does not have to be submitted with the certification application, as this has usually already been sent to the VAH by the laboratory itself.

- **Are test reports from an accredited test laboratory outside Germany accepted?**

  Yes, VAH also accepts test reports from accredited laboratories outside Germany (see list of approved laboratories on the VAH website).

- **Can an expert write a VAH assessment report (expert opinion) based on test reports from various laboratories?**

  The assessment reports are usually written by the managing director or head of the laboratory of the corresponding laboratory. An assessment report can be issued on the basis of test reports from other laboratories if the expert has insight into the quality management system of the laboratory.

- **Where do I find experts who prepare assessment reports according to VAH requirements?**

  A list of experts who prepare assessment reports according to VAH requirements can be downloaded here.

- **Can I use test reports based on EN methods for VAH-certification? If yes, what are the requirements?**

  Please refer to the pertinent VAH communication from 2016 and obtain details from the current VAH Standard Methods and Requirements and method updates which you may download from the Website.

- **Which activity spectrums are mandatory for VAH certification?**

  For certification of a disinfectant by VAH bactericidal and yeasticidal activities are the minimum requirements. Optional claims are tuberculocidal, mycobactericidal, fungicidal, (limited spectrum) virucidal and sporicidal activities.

- **Why do I have to test more than one contact time?**

  The Disinfectants Commission requires the representation of the borderline between effectiveness and non-effectiveness.

- **Why do I have to perform an additional water control for suspension tests?**

  The water control is to be considered as a process control.

- **Why can't I certify a QAC-based handbrub?**

  VAH has issued special requirements for non-alcohol-based handrubs. Please refer to the pertinent communication on the VAH homepage which explains the requirements and provides background information.

- **Which requirements must be fulfilled for the VAH-certification of chlorine-based surface disinfectants?**

  Please refer to the pertinent VAH communication.

- **What happens to my certification if I change my formulation?**

  If active ingredients (possibly auxiliaries) are changed with respect to type or quantity, a completely new assessment is required.

  If one more more auxiliaries/additives are changed – and this at an amount of less than 2% in weight in relation to the total weight of the originally certified product – comparative (old/new) quantitative suspension tests have to be submitted.

  If auxiliaries/additives are changed to a greater extent, the certificate holder must prove the equality if efficacy of the old and new formulations by submitting a test report prepared by an independent test laboratory.

  Details are laid down in the VAH Bylaws III §2 (6).

- **I have a concentrate and I would like to market this as a ready-to-use product and/or as a presaturated wipe system. Which documents do I need for the application?**

  1. Apply for a ready-to-use product: Submit two transcribed assessment reports with original test reports and comparative investigations with the quantitative suspension test. The suspension tests must be carried out with the same batch. It is sufficient to test the most resistant test organism from the original test report. The test should be carried out by one of the two assessors at a medium contact time and in concentration which demonstrate countable results (efficacy kinetics).
  2. Apply for a presaturated wipe system: Submit two transcribed assessment reports with original test reports (Method 14.2) as well as an additional assessment report with the simulated-use test for the specified ready-to-use wipe system or specified presaturated wipe systems (Method 14.2).

For more information, please contact:

Verbund für Angewandte Hygiene (VAH) e.V.
c/o Institut für Hygiene und Öffentliche Gesundheit
der Universität Bonn
Sigmund-Freud-Str. 25
D-53127 Bonn
E-Mail: info@vah-online.de
Website: www.vah-online.de
Tel: 0049 (0)228-287 1 4022 oder 1 4911
Fax: 0049 (0)228 287 1 9522