MicroVal Rules and Certification Scheme

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This is version 8 v5 of the MicroVal Rules and Certification Scheme. This document may be subject to changes.

Changes shall be approved by the MicroVal General Committee. The latest version of this document can always be obtained from the MicroVal secretariat.

MICROVAL RULES AND CERTIFICATION SCHEME

VERSION 8 V5, MARCH 2021

0 Summary

The MicroVal Rules and Certification Scheme is a result of the Eureka project “MicroVal” for the validation and approval of alternative methods for the microbiological analysis of food, animal feeding stuffs, beverages and food environmental samples based on the ISO 16140 series, in accordance with Commission Regulation EC No 2073/2005 on microbiological criteria for foodstuffs. MicroVal aims at certifying alternative methods, i.e. methods which perform as well as internationally standardized reference methods. Generally a CEN or ISO standard method is used as a reference; however the method developer may suggest another recognized reference method for review by the MicroVal Technical Committee. This document describes the MicroVal procedures and organization. The MicroVal organization is governed by the MicroVal General Committee and includes the MicroVal Secretariat, the MicroVal Technical Committee and the MicroVal Certification Body.

1 Scope

The MicroVal Certification Scheme is a third party certification scheme for the validation of alternative methods for microbiological analysis of foods, animal feeding stuffs, beverages and food environmental samples.

Certification according to these Rules and Certification Scheme is based on the European Standards

- EN-ISO 16140-2 “Microbiology of food and animal feeding stuffs – Method validation – Part2: Protocol for the validation of alternative (proprietary) methods against a reference method”.

- EN-ISO 16140-6 “Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures”

For alternative test methods where ISO16140-2 or -6 cannot be applied in full during the validation the MicroVal Technical Committee will review these requests and recommend an appropriate validation protocol based on the nature of the proposed method and technical consensus on the best reference methodology available.

NOTE 1 **Microbiological analysis** includes the micro-organism, its components and/or products.

NOTE 2 **Food environmental samples** include process water, air sampling, surface samples, swabs and residues etc. taken from the food handling or production areas in order to monitor the hygiene of the handling environment.

(Alternative) Test methods that are not within the ISO 16140-2 scope can be validated within MicroVal, as long as the following are available:

- a reference method against which the alternative method can be compared.
- experts and expertise in the analyte being tested in the MV TC

- a number of potential applicants that may require such an alternative method validated
- a proper validation protocol (or the opportunity to develop this):
- the consent of the management of the respective Certification Body
- an expert laboratory that can operate the agreed reference method

Or,

- It is a validation on ISO 16140-6

For these methods MVTC will prepare the request for executing the validation, MGC takes the final decision.

2 Normative References

This document incorporates by reference the current revision of the following standards, provisions from other publications. For undated references the latest edition of the publication referred to applies.

EN-ISO 16140-2:2016	*Microbiology of food and animal feed — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*
EN-ISO 16140-6:2019	*Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures*
EN-ISO 9001:2008	*Quality management systems – Requirements*
EN-ISO 9001:2015	*Quality management systems – Requirements*
EN-ISO 17025:2017	*General requirements for the competence of testing and calibration laboratories*
EN-ISO 13485:2003	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN-ISO 13485:2016	*Medical devices – Quality management systems – Requirements for regulatory purposes*
EN-ISO/IEC 17021-1:2015	*Conformity assessment - Requirements for bodies providing audit and certification of management systems*

3 Definitions

For the purposes of this document, the definitions given in EN-ISO 16140-1 and EN-ISO 9001 apply, together with the following.

3.1 Client

The individual or organization who submits an application for certification to the MicroVal Secretariat.

3.2 Product

A product is a test kit with the associated equipment if necessary to conduct the assay.

3.3 Complaint

An inquiry directed to the Secretariat related to the MicroVal certification process for the Client by MicroVal.

3.4 Certification Body

The body that issues a certificate of conformity. Certification of conformity is the action resultant from the MicroVal process at completion, demonstrating that adequate confidence is provided that a duly identified method is in conformity with a validation performed according to a validation protocol approved by the MicroVal Technical Committee by the Microval Certification Body based on the input of the MicroVal Technical Committee.

3.5 MicroVal Organisation

The MicroVal organisation is the whole of the bodies, committees and secretariat that are involved in the whole of the MicroVal certification process and consists of:

- The MicroVal General Committee (MGC),
- The MicroVal Secretariat,
- The MicroVal Certification Body (MCB),
- The MicroVal Technical Committee (MVTC)

4 MicroVal General Committee

The MicroVal General Committee (MGC) is the governing body within the MicroVal Organisation.

4.1 Responsibilities

The MicroVal General Committee:

- approves the elaboration/modification of the MicroVal Rules and the Certification Scheme and forms.
- approves the elaboration/compilation of the of expert laboratories.
- approves the composition and activities of the MicroVal Technical Committee.
- maintains the ability to take action regarding any subject matter in the certification process.
- approves all of the exceptions to the MicroVal Rules and Certification Scheme.
- supervises the activities of the MicroVal Certification Body.
- reviews the appeal of Clients on any matter that is referred directly to the MicroVal General Committee.

4.2 Voting Procedure

The MicroVal General Committee members have an obligation to vote on all questions formally submitted for voting to them. The voting procedure will be as follows:

- A voting document will have a deadline of two weeks and at the most 1 reminder with an extension for one week.
- No reply means approval
- Voting possibilities:
  - ✓ yes
  - ✓ yes with comments
  - ✓ no with reasons for disagreement
  - ✓ abstention with reasons for abstention

- A simple majority of the votes positive (including the no replies) of the total number of members that is entitled to vote means approval.
- If an approval is not achieved, the document will be scheduled for discussion and decision at the next scheduled MicroVal General Committee meeting or a web-conference will be scheduled.

The MicroVal General Committee has a balanced composition constituted by the following members who represent all the interests involved in the process of certification without any single interest predominating.

4.3 Composition of the MicroVal General Committee

The MicroVal General Committee shall consist of no more than 20 people.

Members of the MicroVal General Committee are coming from:

- Public authorities
- Clients
- End users of methods
- Chair of the MicroVal Technical Committee
- MicroVal Expert laboratories
- Certification body
- Other Validation bodies: AOAC and NordVal.
- The MGC strives to have a balanced representation. Admission to the MGC will be judged on a case by case basis.

4.4 Duration of the members' term of office

The members of the MicroVal General Committee and the chairman are appointed for a period of four years. The chairman is elected by the MicroVal General Committee members and is one of them.

The members' term of office is renewable by tacit agreement. Member participation may automatically renew upon agreement of the individual participant. The chairman's term of office is renewable after approval of the MicroVal General Committee.

The MicroVal General Committee members shall approve the application of new members. The appointment of new members is based on peer review. Members sign a confidentiality agreement.

If a MGC member leaves their company, their membership will be decided upon on a case by case basis.

In exceptional circumstances the MGC can decide to vote a MGC member out.

5 The MicroVal Certification Body

The MicroVal Certification Body (MCB) is responsible for:

- Assessing the reports/recommendations of the MicroVal Technical Committee
- Assessing the reports/recommendations of the auditors if any are required under the MicroVal rules and certification scheme
- Taking certification decisions
- Granting the MicroVal certificates

The MicroVal Certification Body shall apply the rules as defined in this document as well as in EN-ISO 16140-2 and -6" and its interpretations as agreed by the MicroVal Technical Committee.

The granting of the certification is the responsibility of the MicroVal Certification Body.

The Certification Body signs the confidentiality agreement.

6 The MicroVal Technical Committee

The MicroVal Technical Committee (MVTC) is the body that is governing the validation studies.

The procedure for the selection of the members is defined in Annex A.

In order to prevent potential conflict of interest during the validation and certification process, the client has the possibility to exclude entirely or restrict the voting rights of one or more of the representatives of other clients acting in the MVTC, if they wish to do so.

Every applicant has the opportunity to join the MicroVal Technical Committee as an observer for his study after signing the confidentiality agreement..

6.1 Responsibilities

The MicroVal Technical Committee is responsible for/decides on:

- The approval of the technical protocol for the validation study conducted in the method comparison study (MCS) and the inter laboratory study (ILS)
- The evaluation of the results of the validation study based on the ISO 16140-2 requirements, the MVTC technical rules and the technical protocol previously approved by the MicroVal Technical Committee
- The certificate renewal as defined in section 13,
- Monitoring of the 2 studies (MCS and ILS),
- Reporting to the MicroVal Certification Body on the results of the 2 studies.
- Once the draft certificate is prepared the MV TC selected expert reviewers cross check on the content.
- Request for consideration of matrix extensions and/or inclusion of data from other studies, including from studies done under schemes other than MicroVal will be evaluated and decided by the MicroVal Technical Committee
- Establish MV TC technical rules that provide clarification for the conduct of studies in accordance with ISO 16140-2- and -6; provided however that in no case shall the requirements specified by the MVTC be more restrictive ISO 16140-2:2016.

6.2 Voting procedure MicroVal Technical Committee.

The MicroVal Technical Committee members have an obligation to vote on all questions formally submitted for voting within the MicroVal Technical Committee.

In addition assigned MV TC experts have an obligation to comment on technical protocol, results and report for both the method comparison study and the interlaboratory study.

The voting procedure will be as follows:

- A voting document will have a deadline of 2 week and at the most 1 reminder with an extension for one week.
- No reply will be regarded as abstention.
- Voting possibilities:
  - ✓ yes
  - ✓ yes with comments
  - ✓ no with reasons for disagreement
  - ✓ abstention with reasons for abstention

- The first vote by email from the individual members of the MicroVal Technical Committee should be regarded as a preliminary vote and if 75% of the members agrees and no major objections indicated, this can be the final vote and the next step in the procedure taken..
- If < 75 % agrees or major objections indicated, then the comments of the members should be sent to all members and these comments should be discussed in the next available MicroVal Technical Committee meeting or by teleconference.
- After the discussion, the members can change their preliminary vote. The members that cannot participate in the MicroVal Technical Committee meeting or teleconference can change their vote by email after receiving the comments of the other members. However their final vote must be known at the time of the MicroVal Technical Committee meeting or teleconference.
- If the final vote (considering the final email votes and the final votes cast at the MicroVal Technical Committee meeting) is not unanimous then a simple majority of the votes (> 50%) determines the outcome.
- Abstentions from final vote are not taken into consideration and at least 50 % of the members should have given their positive or negative vote.
- If an equal number of positive and negative votes exist then the chair of the MicroVal Technical Committee has the deciding vote.

6.3 Composition of the MicroVal Technical Committee

The MicroVal Technical Committee is formed by members who represent all the interests involved in the process of certification The MicroVal Technical Committee should consist of:

- Representatives of end users (at least 2 representatives)
- Representatives of expert laboratories (at least 2 representatives)
- Representatives of clients (at least to 2 representatives)
- Representatives of public authorities (optional)
- Observer organisations (optional) - Observer organizations like expert labs performing studies may participate upon invitation by the MicroVal Secretariat (after singing the confidentiality statement)

The composition of representatives in the MicroVal Technical Committee should be such that no single interest predominates .

The members of the MicroVal Technical Committee will sign a confidentially agreement.

If a MVTC member leaves their company, their membership will be decided upon by the MGC on a case by case basis.

In exceptional circumstances the MGC can decide to vote a MVTC member out.

6.4 Duration of the members' term of office

The members of the MicroVal Technical Committee and the chairman are appointed for a period of four years.

The chairman is elected by the MicroVal General Committee from the members of the MicroVal Technical Committee.

The members' term of office is renewable by tacit agreement. Member participation may automatically renew upon agreement of the individual participant. The chairman's term of office is renewable after approval of the MicroVal General Committee.

The MicroVal Technical Committee members shall approve the application of new members. The appointment is based on peer review.

7 The MicroVal Secretariat

The secretariat performs a general function within the MicroVal organisation and is staffed by NEN.

The secretariat handles all information on the MicroVal validation studies with confidentiality.

The Secretariat is mandated by the MicroVal General Committee to:

- Do the administrative work outlined by the MicroVal General Committee;
- Support the activities of the MicroVal Certification Body and MicroVal Technical Committee;
- Administer the application, validation and certification process;
- Informs the MicroVal Certification Bodies and clients on any changes in the certification process.
- Register suppliers and update the database and maintain the MicroVal website
- Promote and represent MicroVal;
- Coordinate preparation of the certificate by the Expert Lab to be issued by the MicroVal Certification Body
- Establish the fee structure of MicroVal.

8 Expert Laboratory

The Expert Laboratory is responsible for the execution of the full validation study (MCS and ILS) in accordance with the approved technical protocol.

The procedure for the selection of an Expert Laboratory is defined in Annex B.

The Expert Laboratory shall be accredited according to the EN-ISO 17025 requirements for the reference methods in the field of the expertise claimed. The accreditation shall be granted by an organisation that is a full member of ILAC (International Laboratory Accreditation Cooperation). The field of expertise is described as the types of micro-organisms to be tested as well as the techniques used within the validation of the proposed alternative method.

Additionally, the Expert Laboratory should be able to show that it will be fully trained in the use of the alternative method to be validated, and that their staff is considered technically competent to operate the alternative method, before validation work begins.

In order to be able to conduct the inter laboratory study the expert laboratory will make use of collaborative laboratories. These collaborating laboratories are selected by the Expert Laboratory in cooperation with the method developer.

The collaborative laboratories must be representative of the users of the method. The collaborative laboratories do not have to be EN-ISO 17025 accredited. The Expert Laboratory must check whether the laboratory has an adequate quality system in place, not necessarily based on EN-ISO 17025, in order to be able to participate in the validation study.

An Expert Laboratory that is running MicroVal studies shall take part in the MVTC meetings and the MicroVal study review process.

9 Submission of the application

The Client shall send to the MicroVal Secretariat an application form containing the information needed to start the validation process. In addition, if the facility has ISO 13485 and/or 9001 certification, those certificates shall be submitted at the time of application. The flow chart of the certification process is described in annex D.

10 Audit requirements of the Production Facility

The requirements for an audit of the production facility is needed to be met before granting the certificate and upon renewal of the certificate.

The basis for the quality system of the production facility is ISO 9001:2015 and/or ISO13485:2016.

If the facility is certified against ISO 9001:2015 and/or ISO13485:2016 the certificate(s) shall be provided with the MicroVal application form. The certificate(s):

- Shall be issued by a certification body, accredited by an accreditation body which is member of the International Accreditation Forum (IAF);
- Shall be valid (not suspended or even withdrawn).

Besides the certificate(s) the following information must be provided:

- Initial certification or most recent recertification audit reports, and the latest surveillance report including the status of all outstanding nonconformities;
- Information on overdue audits;
- Information on any engagement with regulatory bodies;
- Information on any other concern which may cause the threat of suspension or withdrawal of the certification.

Based on a review of the above information, the MicroVal certification body may request additional clarification to ensure the organisations' continuing ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

If the facility is not certified against ISO 9001:2015 or EN-ISO 13485:2016, a full scope audit must be conducted.

The time needed for the audit depends on the applicable Mandatory Documents issued by the IAF, which can be found at www.iaf.nu.

In the event that an audit is required, the MicroVal Certification Body will select an auditor that complies with the requirements of ISO/IEC 17021-series. The auditor shall be qualified as Lead Auditor for ISO 9001 and/or ISO13485 in accordance with the EN-ISO/IEC 17021-series.

11 Certification decision

The certification decision is taken at the end of the certification process (a flow chart is given in Annex C).

The certification decision is granted based upon:

- A positive recommendation of the MicroVal Technical Committee on the final validation report based on the MCS and ILS results;
- The existence of the required ISO certificates or the positive result of the audit of the production facility.

The template for the certificate is drafted by the Secretariat and approved by the MicroVal General Committee. A standard format for the certificate is held by the secretariat which is approved by the MicroVal General Committee and can be modified based on the outcome of the validation study data.

A draft certificate is made by the Expert Lab and checked for methodological consistency with the final test kit insert by the selected MV TC expert reviewers. This is reviewed and approved by the MicroVal Certification Body.

The MicroVal Certification Body takes the certification decision and sends the certificate to the supplier and an electronic copy of the certificate to the Secretariat for inclusion on the MicroVal website. A copy is sent to the MicroVal Technical Committee for information. A more extensive summary report on the method comparison and inter laboratory study is prepared for interested parties and published on the website.

If the certificate is not granted, the Client can appeal to the MicroVal General Committee.

The certification is given for a period of four years, provided the criteria of the MicroVal Certification Scheme are met.

The Client can demonstrate certification of its product by:

- Information indicated on the kit packaging: this type of information can be conferred by the MicroVal logo that identifies the MicroVal Certification Scheme.
- The logo can be used on the kit insert.
- A copy of the entire certificate can be included in the packaging, but reference to the certificate number is sufficient.
- The logo can be used in advertising provided the scope of certification and the reference method are declared close to the logo.

It is the responsibility of the manufacturer to immediately inform the MicroVal Secretariat of any change in the certification status of the production facility.

12 Complaints

Any complaint regarding the MicroVal certification process or the conduct of the validation studies and/or audit process can be raised in writing to the MicroVal secretariat. The principle steps are as follows:

- The MV Secretariat logs the complaint, confirms receipt to the complainant and brings it forward to the MicroVal General Committee as the responsible party.

The MicroVal General Committee will investigate as required and respond to the complainant via the Secretariat.

- Depending on the outcome of the review of the complaint the MicroVal General Committee can propose corrective actions and in the worst case withdrawal of the MicroVal acceptance of the party involved.

13 Certificate renewal

After the certification is granted, a regular surveillance of the certified method is carried out, depending on the certification/registration held by the Client.

In case of non-renewal of the certification for a method, the certificate and summary report are removed from the website of MicroVal by the Secretariat, a note on the withdrawal is placed on the MicroVal website by the Secretariat and the Client is informed formally in writing of the removal by the Secretariat.

All information not presented in the certificate of conformity or in the list of certified methods, is confidential and can be used only with the agreement of the Client.

13.1 Requirements

Every 4 years, the supplier shall present a complete and up to date documentation of the alternative method to the MicroVal Certification Body.

A member of the MicroVal Technical Committee shall study the documentation and write a report for the MicroVal Technical Committee (MVTC).

The report shall state whether changes have occurred in:

- the alternative method itself
- the reference method (to which the alternative method has been compared) which is determined to have a significant impact of the performance of the reference method in the validation studies.
- methods that have been validated in accordance to ISO 16140:2003

As a conclusion to the report, the reviewer shall state whether any part of the validation study should be redone.

On the basis of this report, the MicroVal Technical Committee can advise to the MicroVal Certification Body:

1. to renew the certification with respect to changes in the method and/or validation requirements,
2. to repeat (a part of) the validation study.

The MicroVal Certification Body will decide upon renewal of the methods certification based on the advice of the MicroVal Technical Committee and the results of the renewal audit of the factory facilities as described in section 10.

The MicroVal General Committee can shorten this period, if there is a specific problem. Based upon the outcome of a certification decision the MicroVal Certification Body shall renew the method certificate for an additional 4 years.

14 Validation of test methods outside the scope of ISO 16140

MicroVal can also provide a service for the validation of test methods that are outside the scope of ISO 16140-2.

For these type of methods the following procedure and requirements applies

1. Upon receiving a request from a test kit manufacturer the secretariat collects the information on:

- availability of a reference method against which the alternative method can be compared.
- availability of experts and expertise in the analyte being tested in the MV TC
- number of potential applicants that may require such an alternative method validated
- availability of a proper validation protocol (or the opportunity to develop this):
- consent of the management of the respective Certification Body
- availability of an expert laboratory that can operate the agreed reference method.

Or,

- if it is a validation on ISO 16140-6

This provides a first indication of the feasibility and the possible acceptance of the proposal.

2. An application is prepared (by the manufacturer with help of secretariat) for discussion and approval by MV TC.

3. The MVTC prepares a proposal for the management of the respective Certification Body and MGC

4. The Certification Body management decides if they can certify on the proposed scope and conditions,

5. The decision of CB is sent to the MGC for either final approval or discussion.

15 Modification in the production of the certified method and/or its kit insert

At any time, the supplier must inform the MicroVal Certification Body and the MicroVal secretariat on any modification occurring in the production of the certified method, the production thereof and/or in its kit insert. These modifications include new software versions.
A Modification Review Form describing the modification must be submitted. The modification must be approved by MicroVal before a supplier/manufacturer may use the MicroVal logo on a test method subject to modification.

Administrative fees to review modifications to test kits are based on the resources required by the MicroVal secretariat and its Reviewers to evaluate the changes (see fee schedule).
Modifications may require a minor or major review, depending on the change to the existing method, the production thereof or the kit insert. The supplier/manufacturer must submit a copy of the revision(s), and other appropriate data.

An exact determination of the level of the modification can only be made by MicroVal after a written explanation, and a completed application and supporting data are received and reviewed by MicroVal. MicroVal TC decides hereupon if a modification is a major review or should be handled as new method.

The MicroVal Certification Body studies all the modifications. Then it can decide:

1. to maintain the current certification
2. to accept the change as a minor change
3. to forward the Modification Review Form to the MVTC to review a major change and come forward with an advise.

Minor review – requires only an MCB-review. The manufacturer/supplier must submit a Modification Review Form with a written explanation of the change(s) including a statement that the modification does not alter the validated performance of the test method.
Examples are:

- Labeling changes.
- Deletion of validated claims or procedures
- Restatements of existing validated claims.
- Add or strengthen an instruction that is intended to enhance the safe use or efficacy of a test kit.
- Additional precaution/warnings or labelling changes that strengthen a warning or precaution and/or
- Changes to manufacturing process, or
- Qualilty Assurance/Quality Control.

Major review – requires submission of a Modification Review Form with appropriate data submission to be reviewed by the MVTC. In some cases the MVTC can advise additional independent testing is necessary. It is always up to the MicroVal TC to define if a modification is indeed major or should better be handled as a new method.

Examples of major reviews are:

- Entirely new procedure.
- Removal of a precaution statement or warning, depending on the importance of the existing precaution.
- Modification to reagents such as changes in formulation, concentration, phase (solid or liquid) or format
- Modification to, and/or changing of detection or measuring equipment/instrumentation and/or
- Addition or deletion of regents and/or measuring instrumentation Matrix extensions.

16 MicroVal fees

As a clarification for the Client, Expert Laboratories, and Members the following fees may include:

- ✓ **Application fee per alternative method**
  This administrative fee is determined for each method and covers the costs of the certification procedure.

- ✓ **Quality audit fee**
  This fee covers the cost of the audit of the factory, including travel costs should an audit be required).

- ✓ **Expert Laboratory fee**
  This fee covers the cost of the validation studies made by the Expert Laboratory (comparative study and interlaboratory study).

- ✓ **Quality surveillance and renewal fees**
  This fee is estimated for each method and covers the cost of the certification body, auditor, and travel costs, as required.

- ✓ **Review of modification to alternative method**
  This fee depends on the importance of the modification (see 10.3)

- ✓ **Rights for the use of the MicroVal certification name (annual renewal fee)**
  This fee, which should be paid every year, covers for each method the general costs linked to the use of the MicroVal name and cost of the general organization.

- ✓ **Expert Laboratory Fee:**
  Upon initial application to become a MicroVal expert lab an entrance fee shall apply. Thereafter an annual participation fee per year shall apply. If the expert lab is inactive for over one year but wishes to remain in the MicroVal system an annual fee shall apply.

MV secretariat keeps the document on the fees up to date.

Annex A
MicroVal Technical Committee membership

The members of MicroVal Technical Committee (MVTC) must read, speak and write English and have a general training in (food) microbiology.

All committee members specifically commit themselves to:

- Regular participation in meetings and tele/videoconferences, and attend at least one face to face meeting per year;
- Confidentiality, for which they will sign the confidentially agreement;
- The promotion of MicroVal certification.

A Committee member through his expertise contributes to the functioning and credibility of MicroVal certification.

The Chairman represents the MVTC for all actions in which its members wish to engage.

The Committee members must:

- have experience in alternative method development and validation;
- ensure that they are able to fill the position and have relevant support for this from their employer;
- give priority to the review of documents submissions to the MVTC members or be authorised by their company to take decisions in the committee within the time limits set;
- provide technical expertise.

The MicroVal Certification Body or the MicroVal General Committee has the right to terminate the participation of a MVTC member if confidentiality has not been observed or the intents of the MicroVal system are mistreated.

Annex B
MicroVal general committee membership

The members of the MicroVal General committee (MGC) must read, speak and write English and have a general knowledge on: certification, the role and importance of alternative test vs reference tests in Europe, US and other relevant regions and the principles of validation studies. In addition specific knowledge might be added on areas of specific interest to MicroVal e.g. marketing.

All committee members specifically commit themselves to:

- Regular participation in meetings (face to face or by web conferencing)
- Confidentiality for which they will sign the confidentiality agreement
- The promotion of MicroVal certification

In addition committee members must:

- Make inputs and decisions for the best interest of MicroVal (not based on individual interests).
- Put forward any specific knowledge they have on subjects discussed/ to be decided on in MGC.
- Ensure that they are able to fill the position and have relevant support for this from their company.

A committee member through its knowledge contributes to the functioning and credibility of MicroVal certification.
The chairman represents MGC for all actions in which members wish to engage.

MicroVal certification body or the MicroVal secretariat has a right to terminate the participation of a MGC member if confidentiality had not been observed or if the intents of the MicroVal system are mistreated.

Annex C
Procedure for the selection of an Expert Laboratory

C.1 Becoming an Expert Laboratory.

To become a MicroVal Expert Laboratory an application form (MicroVal questionnaire for expert and laboratories) must be completed as well as proof of showing experience on performing validation studies within the context of MicroVal. The confidentiality agreement must be signed as well.

The evaluation of the application will be done by the MicroVal Technical Committee that will give a recommendation for approval or disapproval to the MicroVal General Committee. The MicroVal General Committee decides on the suitability of the applicant to become an Expert Laboratory in the area of expertise claimed.

Laboratories that have not performed a MV validation yet have to ensure that technical support is available during the study. The technical support must be specified and agreed upon by the MV TC

The MV secretariat adds the Expert Laboratory to the list of Expert Laboratory on the website indicating expertise area as well the experience in executing MV validation studies.

C.2 Selection of an Expert Laboratory for a validation study

The Expert Laboratory must be selected from the MicroVal Expert Laboratory database, which is held by the MicroVal Secretariat.

This selection is made by the Client, when requesting a MicroVal certification of a method.

The Expert Laboratory qualification is appraised by the MicroVal Certification Body for each separate request for a MicroVal certification of a method. The database shall contain the following information:

- name of organization
- type of organization i.e. commercial lab, government institution, academic lab,
- size of organization
- scope of R&D capabilities, if yes how many persons
- expertise in selected micro-organisms
- R&D area of interest,
- involvement of proficiency testing or ring testing
- accreditation and/or certification of the laboratory, including the scope of accreditation
- field of competence, reference methods used in the laboratory.

A specific contract is signed between the Expert Laboratory and MicroVal Certification Body.

If an Expert Laboratory has not performed a MicroVal validation before, the client should take into account the fact that the validation study might take more time. This is due to the limited expertise as well as additional costs for the technical support that the Expert Laboratory has to guarantee during the execution of the study.

Annex D
Flow chart of the certification process