



**MICROVAL**



European validation and certification organisation

# MicroVal Certification: Validation and Certification of Alternative Microbiological Methods

MicroVal Secretariat, Netty Zegers PhD, Program manager  
21 September 2011. Annual AOAC meeting



## MicroVal:

- a European platform organization for the validation and certification of alternative microbiological methods

**MICROVAL**



# European legislation for food safety testing in food production

- Commission Regulation (EC) 2073/ 2005 on microbiological criteria for foodstuffs of 15<sup>th</sup> Nov 2005, published in OJUE on 22<sup>nd</sup> Dec 2005, stated in Article 5 ‘Specific rules for testing and sampling’:
  - *The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex I and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.*



MICROVAL



# Alternative methods

- Alternative microbiological methods for food safety testing may be used only when they are validated and certified according to EN ISO 16140
- EN ISO 16140 “Microbiology of food and animal feeding stuffs – Protocol for the validation of the alternative methods”
- Alternative methods with a MicroVal certificate fulfill the requirements as stated by EU Commission Regulation.

**MICROVAL**



European validation and certification organisation



## I

*(Acts whose publication is obligatory)*

**COMMISSION REGULATION (EC) No 2073/2005**

**of 15 November 2005**

**on microbiological criteria for foodstuffs**

**(Text with EEA relevance)**

**MICROVAL**



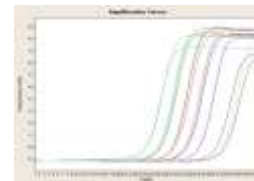
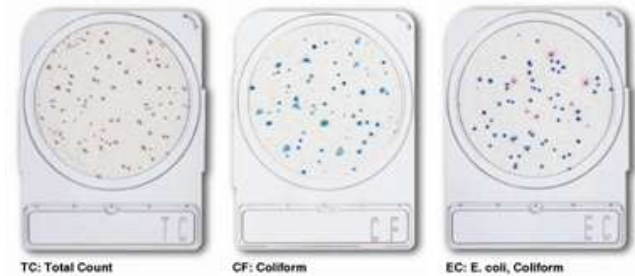
# MicroVal: a European platform organization for the validation and certification of alternative microbiological methods

- MicroVal validation and certification of alternative microbiological methods for food safety testing is based upon EN ISO16140.
- MicroVal is recognized by the EC countries



# Alternative methods (examples)

- Solid culture media
  - chromogenic or fluorogenic substrates
- Immunoenzymatic kits
  - ELISA;
  - Dipsticks/Lateral flow
- DNA-based
  - (real-time)-PCR
  - Hybridization sticks
  - Arrays
- Automated methods



MICROVAL



# MicroVal: European validation and certification

- EU Recognition - MicroVal being recognized as a valid third-party certification body, fulfilling EU regulation
- Combined validations
  - MicroVal / AOAC and MicroVal / NordVal
- Support Food Law Enforcement Practitioners (FLEP)
- Support from food industry (e.g. Nestlé, Unilever)
- 22 MicroVal certificates, 13 validations being performed and several in the pipe line



**MICROVAL**



European validation and certification organisation

# MicroVal: European validation and certification

The MV certification procedure is based on three principles:

1. A **method comparison study** and a **collaborative study** according to EN ISO 16140 have to be performed
2. The organizational quality of the manufacturer where the materials are produced must be in conformity to ISO 9001 / ISO 13485 standards + additional specific requirements
3. A regular verification of the quality of the certified methods, which is made after the certification is granted.



**MICROVAL**



# MicroVal: European validation and certification

MicroVal is a balanced representation of stakeholders and is constituted of

- a common **MicroVal General Committee (MGC)**,
- a common **MicroVal Secretariat**
- group of independent **MicroVal Certification Bodies (MCB)**,
- a European network of sub-contractors:
  - expert and collaborative laboratories, laboratory and method reviewers and technical auditors.

**MICROVAL**



European validation and certification organisation



# MicroVal: European validation and certification

- The MicroVal Certification Bodies (MCB) are headed by an impartial MicroVal General Committee (MGC), which has an international composition and consists of public authorities, manufacturers, users and MicroVal third parties.
- All MicroVal Certification Bodies comply with the EN 45011 requirements.
  - General requirements for bodies operating product certification systems



**MICROVAL**

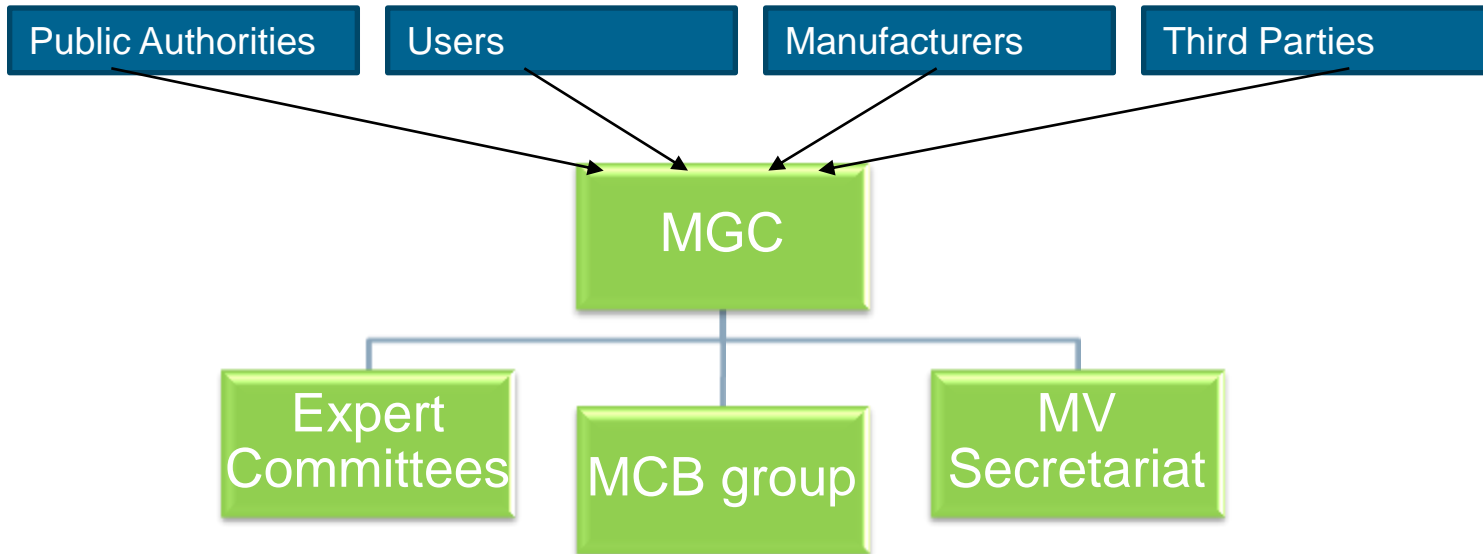


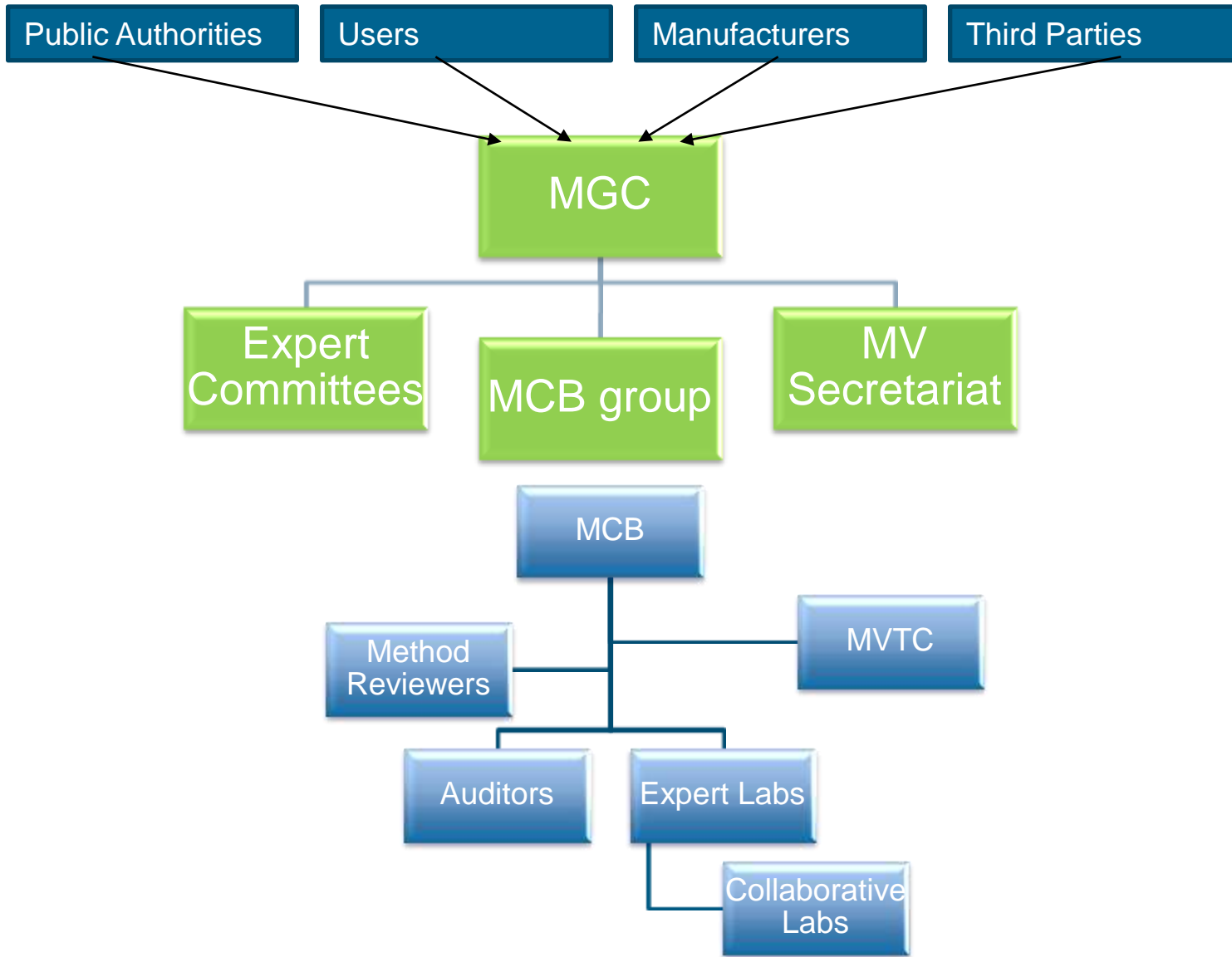
# MicroVal: European validation and certification

- **Expert Laboratories** are independent and must be accredited for EN ISO 17025
- They perform the Method Comparison Study and organize the Interlaboratory Study
- **Collaborative Laboratories** are selected by the Expert Laboratory to participate in the interlaboratory study.
- They must comply with EN ISO 17025, but don't need to be accredited.

MICROVAL

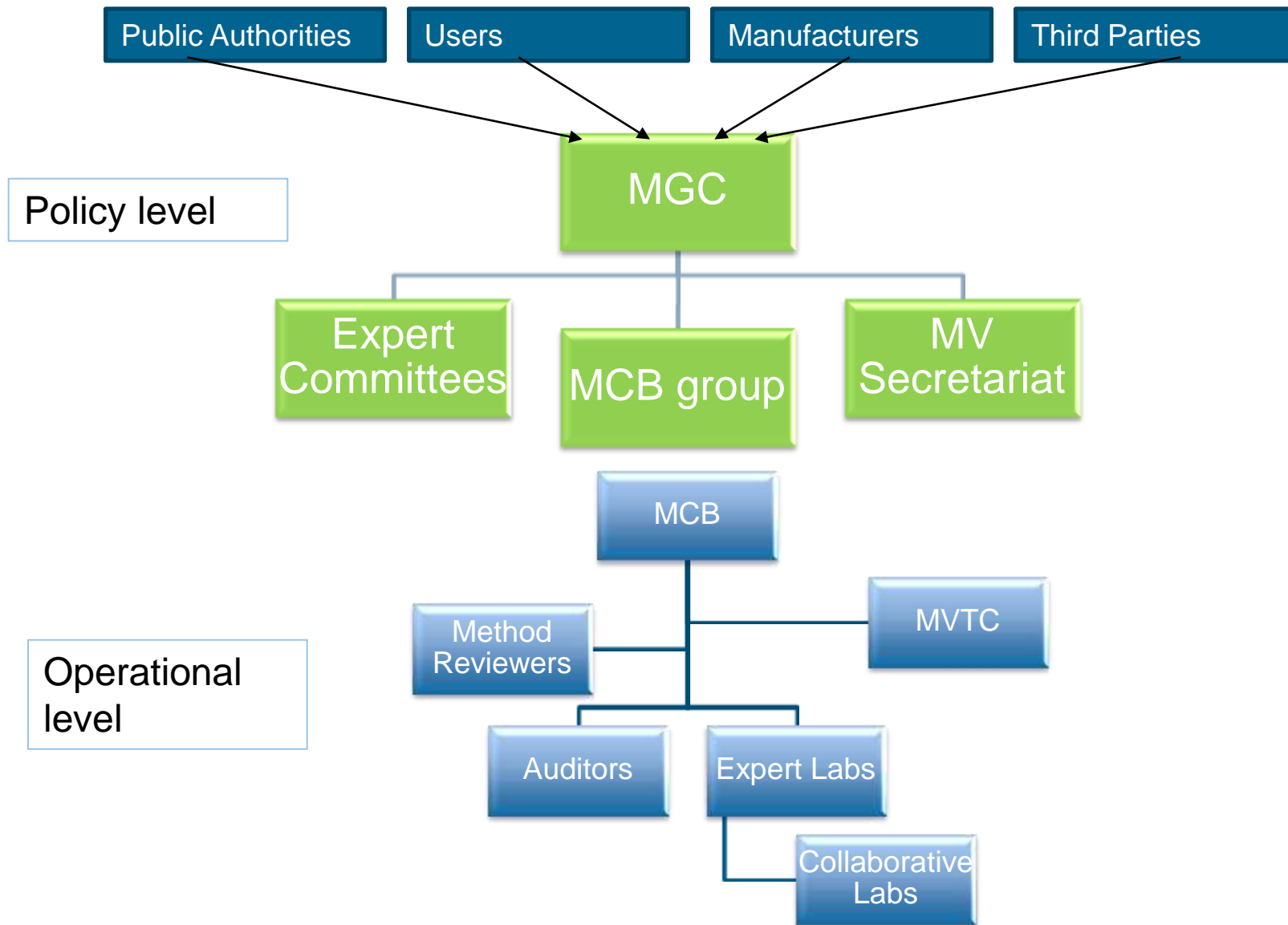






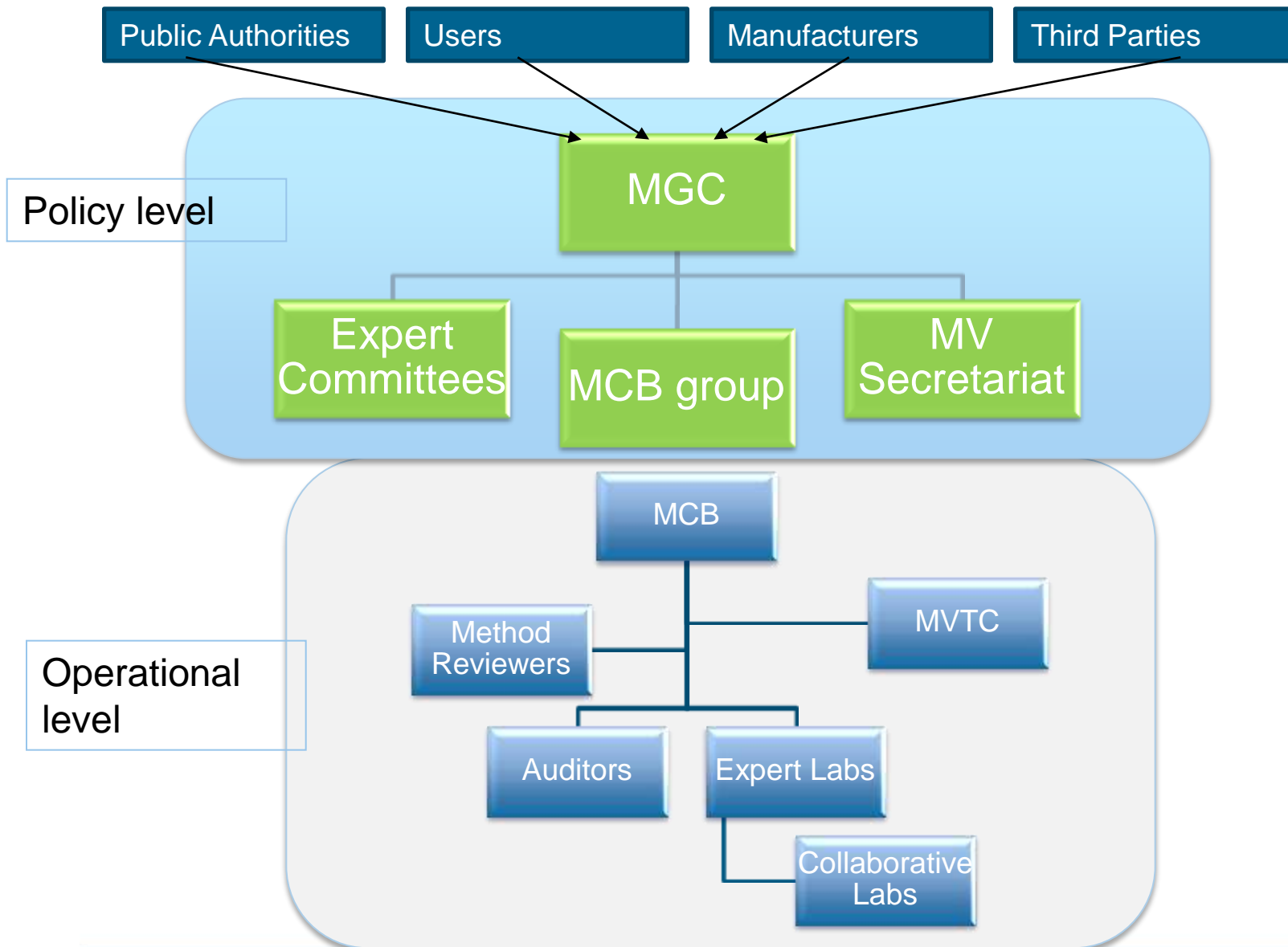
**MICROVAL**

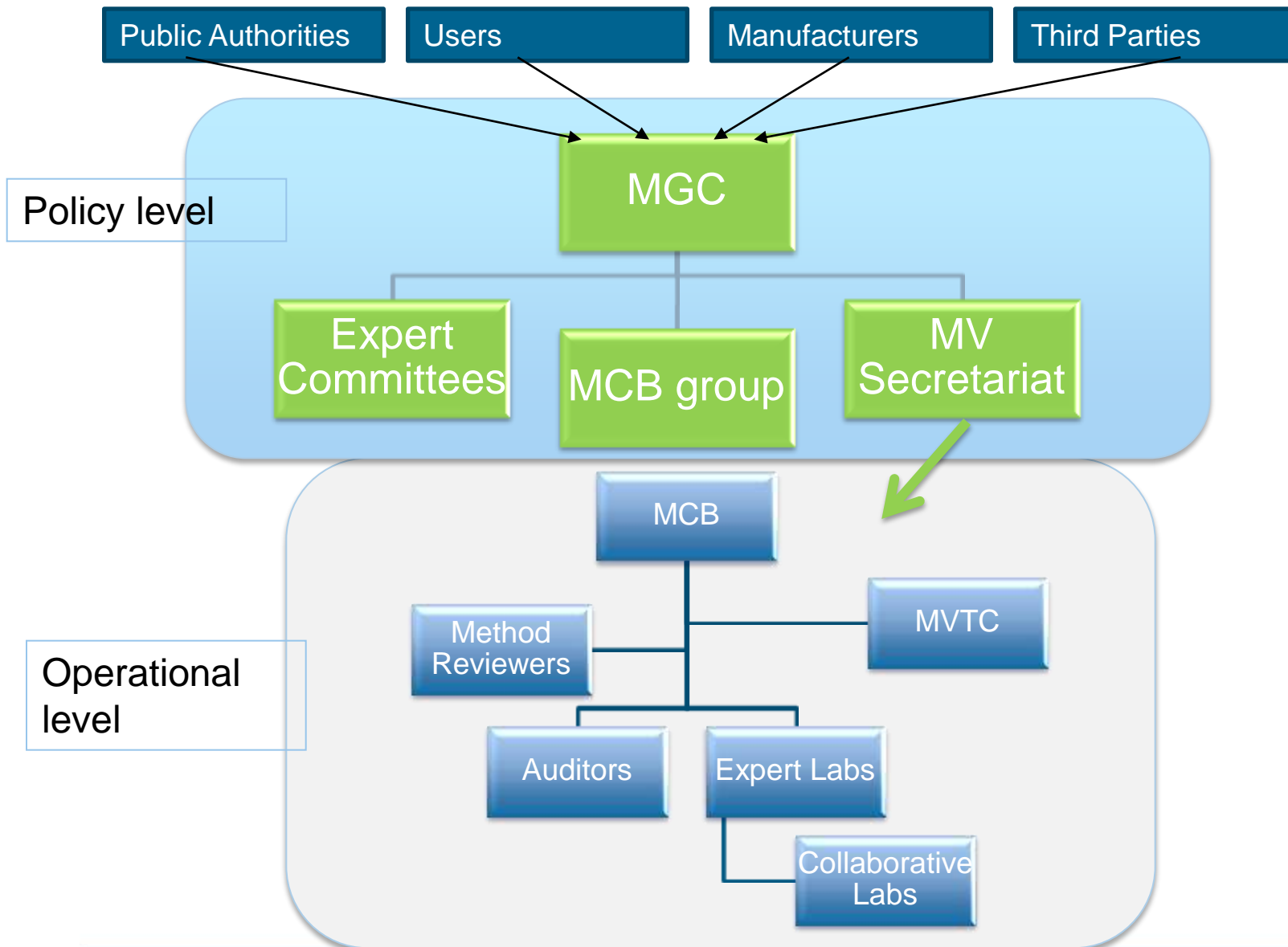


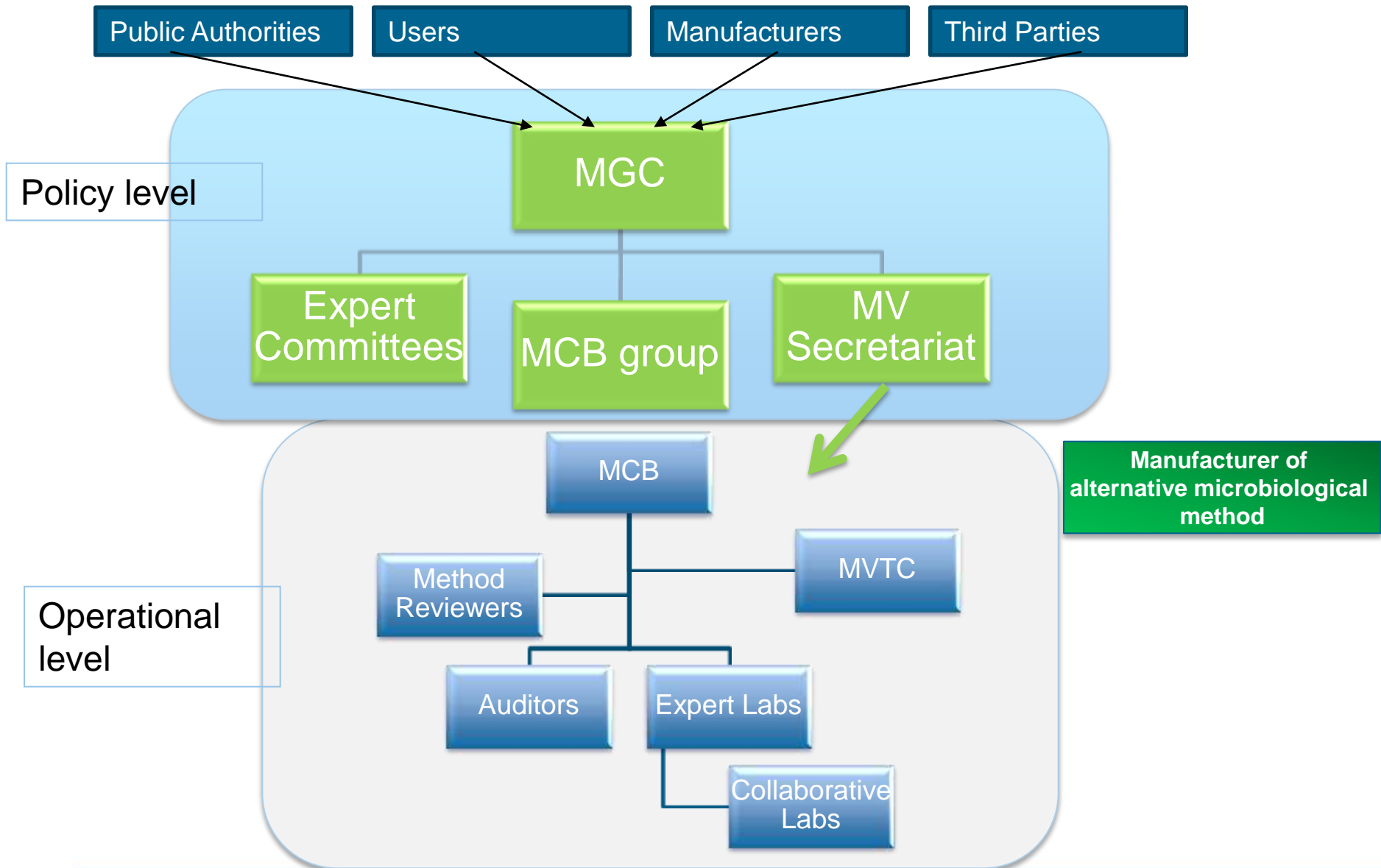


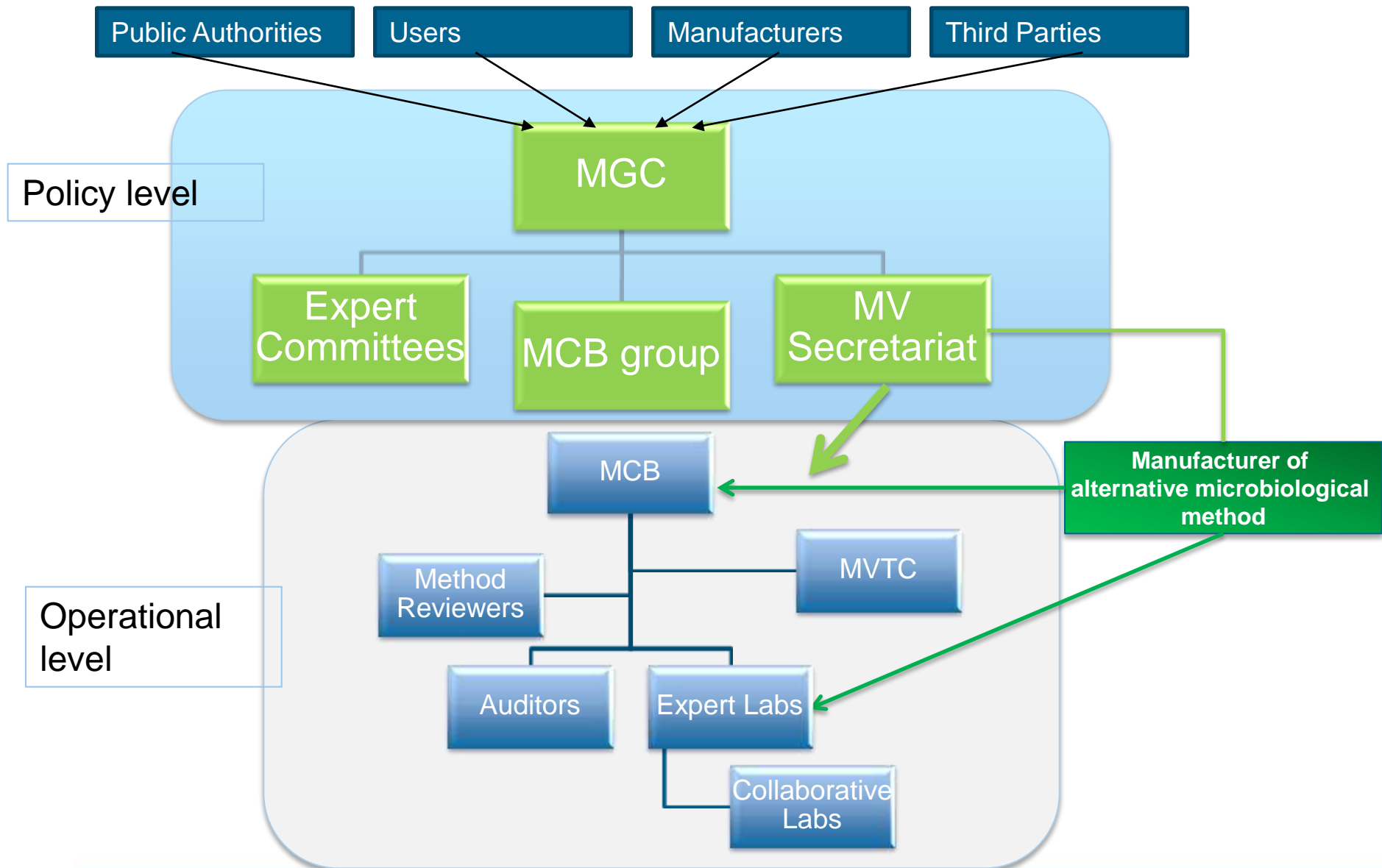
**MICROVAL**





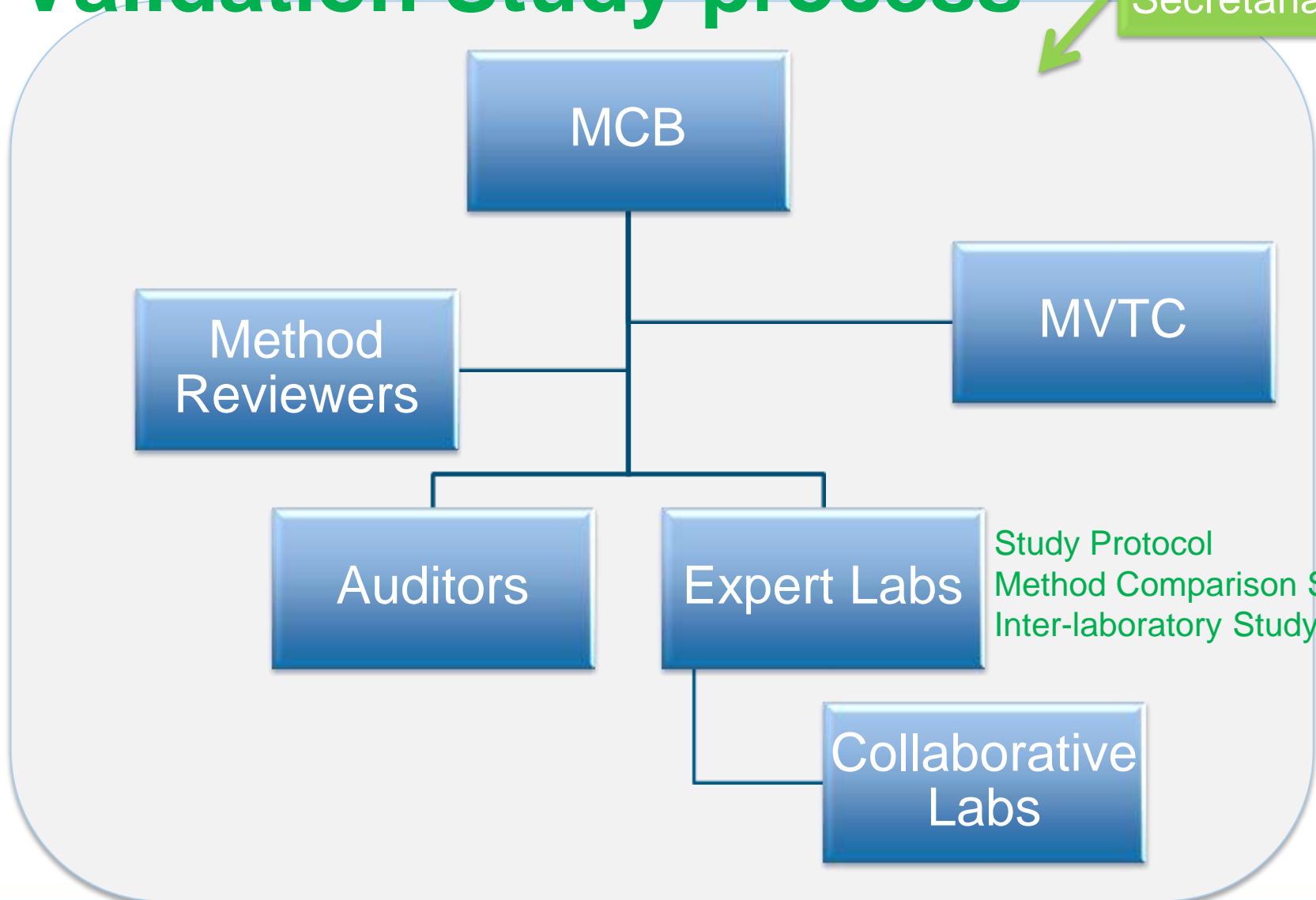






# Validation Study process

MV  
Secretariat

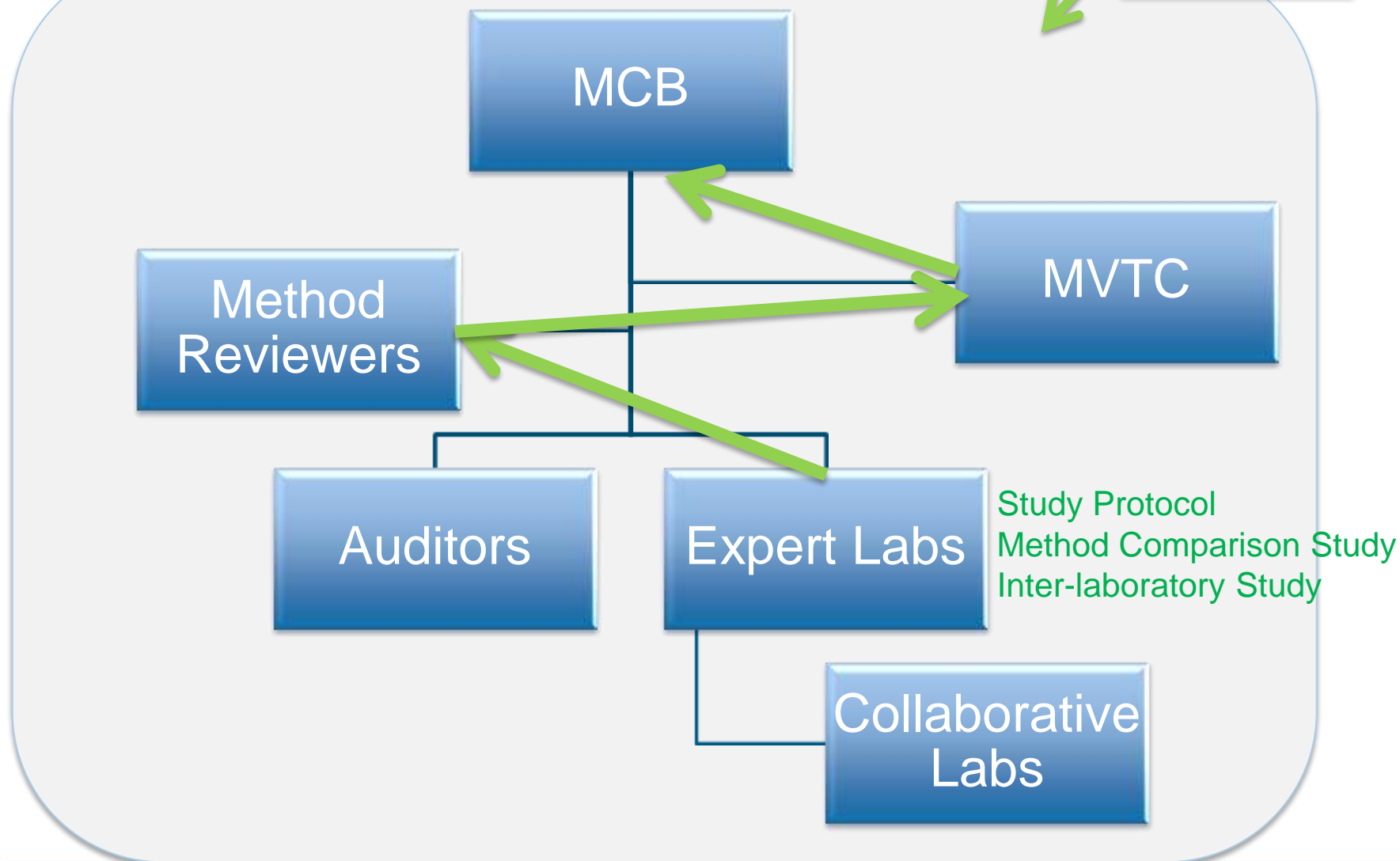


**MICROVAL**



# Validation Study process

MV  
Secretariat



**MICROVAL**



# Becoming certified

- Manufacturer presents request to any MicroVal Certification Body by application form
- The validation studies are performed by a MicroVal Expert Laboratory,
- The audits, if needed, are performed by the MicroVal Certification Body
- The final decision is taken by the MicroVal Certification Body

**MICROVAL**



European validation and certification organisation



# Steps: application, actions for the manufacturer

- Application by manufacturer to MicroVal Secretariat.
  - Secretariat informs MCBs and request quotations to be sent to manufacturer.
- Manufacturer selects MCB.
- Manufacturer selects Expert Lab from the MV Expert Lab list.
- Manufacturer closes contracts with Expert Lab and MCB.



# Steps: Study Protocol

- EL writes Study Protocol (in contact with manufacturer) in accordance with ISO16140 and MicroVal Rules and Scheme.
- MicroVal Method Reviewers (MR), microbiologist and statistician, review Study Protocol and kit inserts, and advice MVTC on approval.
- MVTC takes decision for approval of Study Protocol.
- MicroVal Secretariat receives copies of all documentation and correspondence and is responsible for archiving and guarding process continuation.

**MICROVAL**



# Steps: Method Comparison Study

- EL Performs Method Comparison Study (MCS) following the Study Protocol and writes the MCS report.
- MicroVal MRs review MCS Report and advice MVTC on approval.
- MVTC takes decision for approval of the MCS Report.
- MicroVal Secretariat receives copies of all documentation and correspondence and is responsible for archiving and guarding process continuation.

**MICROVAL**



# Steps: Inter-Laboratory Study

- EL coordinates the Inter-Laboratory Study and prepares the samples and ship them to the Collaborative Laboratories. EL writes ILS report.
- MicroVal MRs review ILS Report and advice MVTC on approval.
- MVTC takes decision for approval of the ILS Report.
- MicroVal Secretariat receives copies of all documentation and correspondence and is responsible for archiving and guarding process continuation.



# Steps: certification

- Upon approval of the Validation Study by the MVTC, the MVTC advises MCB to grant the certificate
- MCB is responsible for the audit requirements.
- MCB takes the final decision for granting the certificate to the manufacturer



# Timelines

- The Validation Study timeline starts with the receipt of the draft Study Protocol.
- 3 weeks
  - Review of Study Protocol by the MRs
  - Answers and adjusting Study Protocol by EL
  - Advice from MR to MVTC
- 1 week
  - Approval by MVTC with or without comments
- 3 weeks
  - Review of comments, adjusting and advice from MR to MVTC
- 1 week for final approval by MVTC

# Timelines

- 10 weeks
  - Performing the MCS and MCS report.
- 3 weeks
  - Review of MCS report by the MRs
  - Answers and adjusting MCS report by EL
  - Advice from MR to MVTC
- 1 week
  - Approval by MVTC with or without comments
- 3 weeks
  - Review of comments, adjusting and advice from MR to MVTC
- 1 week for final approval by MVTC



# Timelines

- 6 weeks
  - Performing the ILS and ILS report.
- 3 weeks
  - Review of ILS report by the MRs
  - Answers and adjusting ILS report by EL
  - Advice from MR to MVTC
- 1 week
  - Approval by MVTC with or without comments
- 3 weeks
  - Review of comments, adjusting and advice from MR to MVTC
- 1 week for final approval by MVTC

Total: 40 weeks

**MICROVAL**



- If not granted the manufacturer can appeal to MicroVal General Committee
- If the method has already been validated and/or certified by an other organisation, specific rules apply in order to consider such results



# Validated Methods

Micro-organism	Reference method
Total Viable Count	ISO 4833
Enterobacteriaceae	ISO 21528-1, ISO 21528-2
Coliforms	ISO 4832
E.coli	ISO 16649-2
Salmonella	ISO 6579
Staphylococcus	ISO 6888-1
Campylobacter	ISO/TS 10272-2
Yeasts and moulds	ISO 21527-1
E. Sakazakii (Cronobacter spp)	ISO/TS 22964
Listeria monocytogenes	ISO 11290-2:1998, ISO 11290-2:1998/A1:2004

**MICROVAL**



European validation and certification organisation

# Why MicroVal

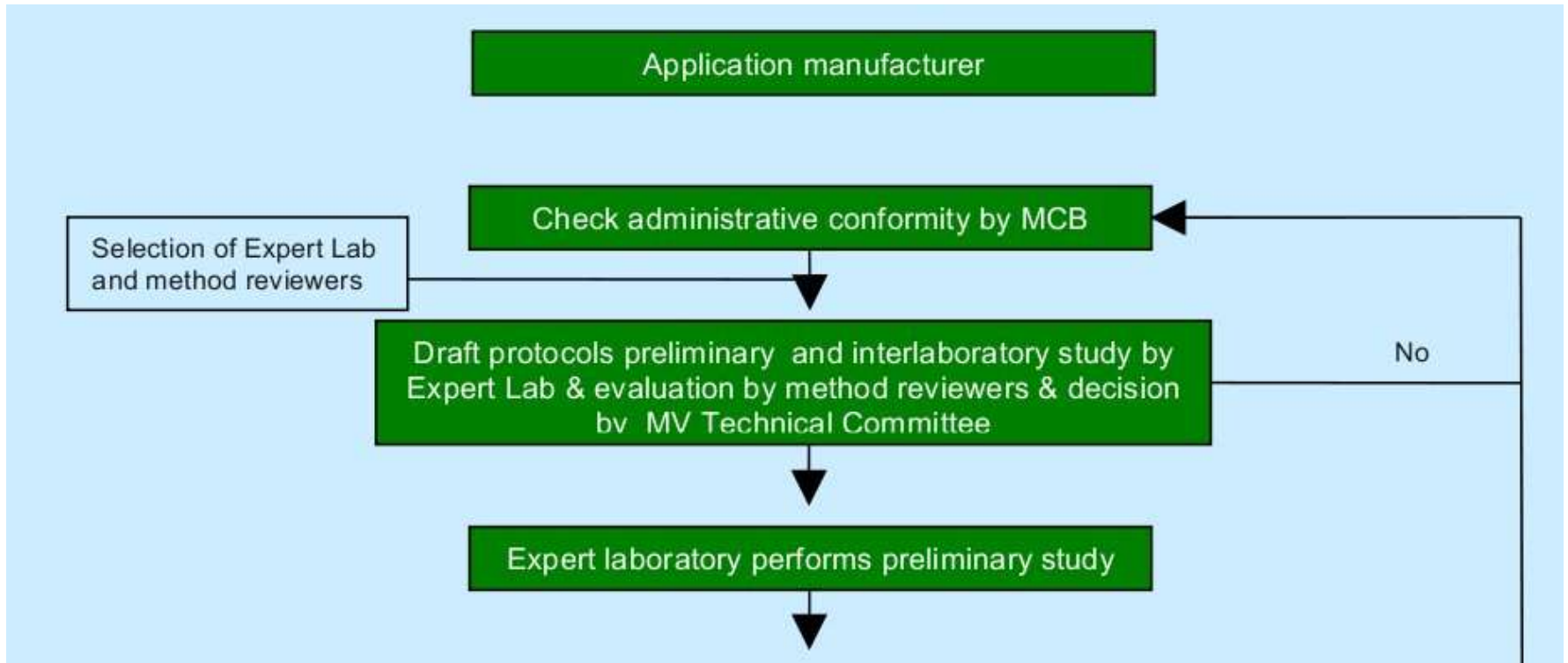
- MicroVal is an open platform for all European Certification Bodies to provide a single system
- aiming at a harmonized interpretation of the EN ISO 16140 for the international market
- working towards a harmonized international market for all test kits
- is headed by one European platform with all European stakeholders involved
- and a neutral MicroVal secretariat



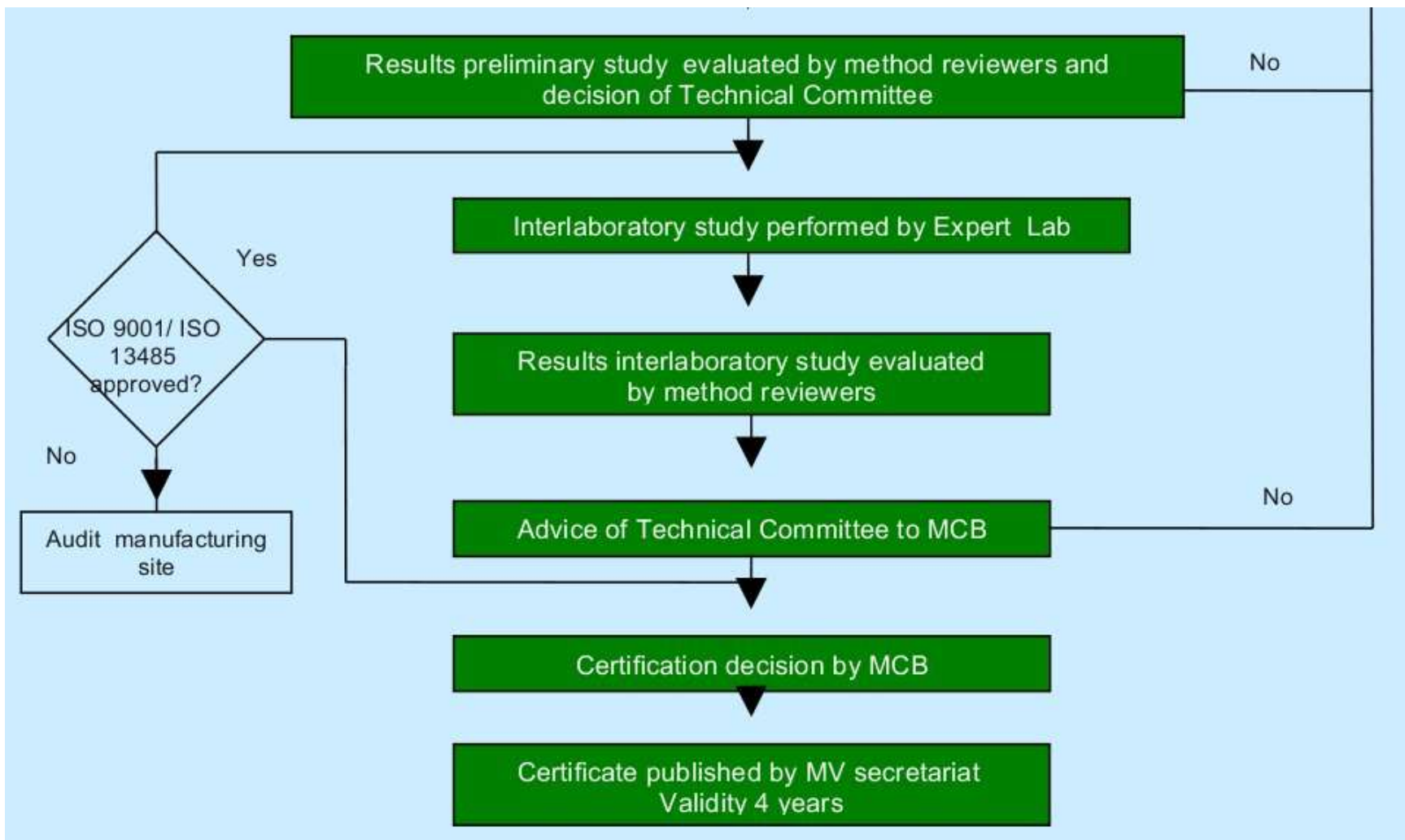
**MICROVAL**



# Workflow Validation 1/2



# Workflow Validation 2/2



MICROVAL



# MicroVal / AOAC combined validation studies

- In 2008 both organisations received requests for combined studies
- November 2008 initial discussion between AOAC-RI and MicroVal
- January 2009 AOAC-RI / MicroVal agreed on a pragmatic approach towards combined validation fulfilling requirements

# AOAC / MicroVal Combined validation studies

- One Method Comparison Study
  - one Expert Laboratory
  - one data set
  - one report
  - reviewed by AOAC GR and MicroVal MRs
  - AOAC-RI PTM certificate
  - saves money and time (=money) for manufacturer
- For MicroVal (ISO16140), in addition, an Inter-laboratory Study is required

# AOAC /MicroVal validations

- 2009:
  - two methods: protocols approved
- 2010:
  - AOAC-RI PTM approved (Greenlight & X-SA);
  - For MV in addition an Inter-lab Study required and started
  - New application
- 2011:
  - Four methods currently approved by both AOAC and MicroVal [X-SA (Hyserve), Greenlight (Luxcel), MMB (Biotest) and Surefood (Congen)]
  - 3 new applications received
  - 2 applications planned

- Do you want your alternative method to be MicroVal validated and certified?
- Interested in a combined AOAC/ MicroVal study?
- Interested in becoming a MicroVal Expert Laboratory?

For more information see our website

[www.microval.org](http://www.microval.org)

Or contact mrs Netty Zegers, [info@microval.org](mailto:info@microval.org)

**MICROVAL**



Phone: +31.15.2690.410

- Thanks for your attention



**MICROVAL**

