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Importance of Laboratory Recognition and Third Party Validated Methods in Food Microbiology Laboratories

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Introduction

To provide food products which are safe and wholesome, all the steps of food production from raw material specification, to manufacturing, handling and distribution must be under control. The microbiological quality of the food along the distribution channel is one of the key point to monitor. The relevance of the microbiological control plan is based on the competency of the laboratory performing the analysis, on the choice of the microbiological criteria to be followed, on the methods used and on the sampling plan.

Information on the microbiological quality of food needs to be recognized across industry partners, including food companies, their local and international customers, contractors, customers associations and regional and local authorities which regulate food safety. Today, the competencies of the microbiological laboratories can be recognized by international systems. In food microbiology there are, in addition to traditional standardized methods, proprietary methods which are internationally validated by third party. Harmonization of international systems is helping both the food manufacturer and the laboratory to choose a relevant plan and relevant methods to control the food before introducing it on the market.

The Laboratory

Laboratories in the food industry can be either an internal laboratory or a contract laboratory. Nowadays, most of the internal laboratories are ISO 9001[1] certified, which demonstrates implementation of a quality management system, including management support and a quality organization, procedures, internal audits and corrective actions system.

Generally corporate laboratories and contract laboratories are willing to also have their technical competencies recognized by a third party. That can be done through an accreditation program, for example, following the ISO/IEC 17025[2] standard. This accreditation will help to get the results accepted by all the interested parties. In addition to the quality management system, technical matters such as the equipment calibration, the results recording, the traceability control, the relevance of the method and the validation data will be reviewed by the auditor. Independent third party validation data significantly strengthens the internal validation. Verification of the performance of the method in the laboratory will be also required. The impartiality of the laboratory will be checked too, that is another critical point to get the results recognized. Today there is an agreement between national accreditation bodies (ILAC[3] Mutual Recognition Agreement) that is facilitating the acceptance of results obtained in accredited laboratories implemented in different countries.

The Methods

When selecting a method for a specific microflora, a laboratory can choose between a reference method and an alternative method.

The Reference Methods

A lot of focus has been put to develop reference methods that are accepted by a large group of stakeholders. Organizations such as the International Standards Organization (ISO), International Dairy Federation (IDF), European Committee for Standardization (CEN) and Nordic Committee of Food Analysis (NMKL) have developed standardized methods, which are often recognized as official methods by local or regional authorities. There are also methods developed by government organization such as the United States Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) which are used as reference methods. There have also been efforts made to develop a more global harmonization of all those reference methods.

The Alternative (Proprietary) Methods

In parallel to the reference methods, alternative methods have been developed to offer more practical, rapid and less expensive tests.

To be sure that the results obtained by those methods will be recognized outside the laboratory, the performance of the methods must be compared with the performance of the reference methods.

Third party validation of the alternative method can be required by regional regulation to get results accepted. For instance in European community, the regulation EC 2073/2005[4] on microbiological criteria specifies that "The use of alternative analytical methods is acceptable, when the methods are validated against the reference method… and certified by a third party in accordance with the protocol set in EN/ISO standard 16140 or other internationally accepted similar protocols."

In the US, regulators reference the Food and Drug Administration Bacteriological Analytical Manual and the United States Department of Agriculture Microbiological Laboratory Guide. In both instances, equivalent alternative testing methodologies are accepted in accordance with internationally recognized organizations, such as AOAC® INTERNATIONAL.

Method Validations and Verifications

The performance of any method (reference or proprietary method) needs to be characterized. The detailed protocol of the method must be fixed. That includes not only the consumables (media, kit, diluent), but also the experimental conditions (e.g. incubation time and temperature, and their tolerance intervals), the equipment, and the categories of food products to be analyzed.

Reference Method Validation

Different performance characteristics are used depending on the type of microbiological methods:

- For the enumeration of microorganisms (quantitative methods): it is generally repeatability, reproducibility, limit of quantification, inclusivity and exclusivity which are determined.
- For the detection of the presence of microorganisms (qualitative methods): it is limit of detection, inclusivity and exclusivity.

Those values are determined by testing different categories of food samples, as well as different types of microorganisms. The method is reviewed periodically to adapt to specific conditions (e.g. challenging food which requires specific preparation) and modified if necessary. The organization which is publishing the method is generally providing the performance characteristics.

Alternative (Proprietary) Method Third Party Validation

In Food Microbiology, the proprietary methods are generally developed to be an alternative to the reference method, that is why the validation schemes are designed to demonstrate that the alternative method is giving results equivalent to a reference method for a given group of products. The comparative validations which are internationally recognized are granted by third party organization: AOAC INTERNATIONAL, AFNOR Certification, MicroVal® and NordVal International.

Methods can be validated based on the results of a comparative study done in one laboratory (e.g. AOAC® *Performance Tested Method*℠ (PTM). The independent expert laboratory will test the performance criteria and compare each of them with the reference method performance. The mean difference between the two methods will be calculated to determine statistical equivalence between the methods.

In order to get more information on the robustness of the method, other validation schemes require a collaborative study as a supplement of the comparative study. This is the case of AOAC® INTERNATIONAL *Official Method of Analysis*℠ (OMA), as well as for methods validated according to ISO 16140-2[5] (AFNOR Certification, MicroVal, NordVal International).

The expert laboratory which is running the comparative study is also coordinating the collaborative study. Other types of laboratories such as plant laboratories, contract laboratories and university laboratories are participating in the collaborative study. Due to the variety of the laboratories involved, that second study provides more information on the possibility to implement the method in different conditions. The reproducibility of the analytical results is very important to get all the stakeholders accepting the conclusion of the analysis.

Additionally, validations obtained in accordance with ISO 16140-2 are reviewed and reconsidered periodically, which is especially important if the reference method has been modified significantly. New comparative data is required to prove that the equivalence of the results between alternative and current reference method is kept.

Generally, the consistency of the alternative method is evaluated by testing different batches during the validation and reviewing the quality system of the kit manufacturer (e.g. AOAC PTM) or by auditing the manufacturing plant periodically (e.g. AFNOR Certification).

Method Verification

Whichever validated method is used, the laboratory implementing a method must check that it performs as expected in the laboratory, with the specific samples to be tested and that the sample is included in the scope of the validation. To test the method, the laboratory needs to get the validated protocols to be used for the different food products which are tested. This information is given in the instructions for use (IFU), in the validation certificates, in the method description or in the standard.

The laboratory will then be able to verify the performance of the method in the laboratory conditions by testing food matrices and by analyzing proficiency testing sample with the validated method. The results of those tests, in addition to the IFU, the certificate and other document describing the validated protocols can be used by the auditor to check if the laboratory is using the kit within the “validated” conditions. This method verification is one of the step required for a laboratory to be accredited.

Conclusion

In the very global market of the food industry, it is important for all the parties of the food sector to trust the results obtained by the laboratory involved in the analysis. The risk to rely on results which are not obtained with recognized methods nor in recognized laboratories is high considering the microbiological criteria are implemented to prevent the circulation of unsafe or spoiled foodstuff. To minimize the risk in releasing noncompliant products or to destroying products that meet the acceptance criteria, the highest level of confidence in the analytical results should be obtained. That means having assurance that the laboratory will choose a relevant and widely recognized method (third party validated method or reference method) and will have all the technical competencies to implement it. This last point can be verified through ISO/IEC 17025 accreditation program which are international recognized.

An accredited laboratory using third party validated methods recognized by official bodies provides assurances that the tests are performed correctly and that the results can be trusted.

References

1. ISO 9001: Quality management systems — Requirements.
2. ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.
3. ILAC: International organization for accreditation bodies.
4. Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.
5. ISO 16140-2: Microbiology of the food chain — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.

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