

Best Practice for Testing Foods when Assessing Compliance with the Microbiological Criteria Specified in Commission Regulation (EC) No 2073/2005

Scope of Factsheet

This factsheet is directed at food business operators requiring foods to be tested for assessing compliance with the microbiological criteria specified in Commission Regulation (EC) No 2073/2005, as amended*.

It focuses on the: (1) laboratory providing the testing service and (2) analytical methods used by the laboratory

1) The Laboratory

There are no specific requirements in the Regulation for laboratories conducting analysis on behalf of food business operators. However, the Food Safety Authority of Ireland (FSAI) strongly recommends that food business operators employ the services of accredited laboratories only. Use of an accredited laboratory gives the food business operator confidence in the standard and quality of service provided.

The Irish National Accreditation Board (INAB) is the national body with responsibility for accreditation of laboratories (private and public) established in Ireland. Accreditation is the formal recognition of a laboratory's competence to conduct testing in compliance with the international standard ISO 17025:2005. This standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. Compliance with this standard requires laboratories to demonstrate competence, impartiality and integrity.

Each accredited laboratory is issued with a certificate of accreditation that lists the analytical tests (including the basis of the method and relevant food matrix) for which the laboratory is accredited. A laboratory's accreditation status and scope of accreditation can be checked on INAB's website at: <http://www.inab.ie/>.

It is important to note that:

- i) A laboratory may be accredited for some but not all of the analytical methods it offers to its clients. In addition, it may be accredited for a method but in a limited range of foods. It is **best practice** that the laboratory analysing samples for food business operators is accredited to conduct the analytical method on the required food matrix. If accreditation of the specific method and matrix is not available, it is best practice to choose a laboratory that is accredited to use the relevant method in other food matrices or a laboratory that has been accredited for a broad range of test methods
- ii) Some laboratories may be accredited under flexible scope which permits the laboratory to extend the range of their tests to include certain analytical techniques or food matrices that may not be explicitly stated on their scope of accreditation. This is on the basis that their competence in the development and validation of these tests has already been evaluated. INAB publishes the renewed schedules of accreditation for each accredited

* Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1)
https://www.fsai.ie/legislation/food_legislation/hygiene_of_foodstuffs/microbiological_criteria.html

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laboratory on its website once per year. For a current list of analytical techniques and food matrices accredited under flexible scope, contact the laboratory directly. INAB will, on request, verify the status and scope of laboratories

- iii) An expiry date is specified on the certificate of accreditation. This is five years from the date of last renewal of accreditation but is subject to successful annual surveillance visits from the accreditation body. Food business operators should seek confirmation from the laboratory that the certificate is valid and that the scope of accreditation is current. This can be verified on request by INAB
- iv) Some commercial providers of microbiological testing services may have their main laboratory operations based outside the Republic of Ireland with branches operating in the Republic of Ireland. While INAB is the national accreditation body for the Republic of Ireland, these laboratory groups may be accredited by other accreditation bodies. Accreditation provided by these accreditation bodies is equivalent if they are signatory to the European Co-Operation for Accreditation (EA) multi-lateral agreement (MLA) for testing, e.g. United Kingdom Accreditation Service (UKAS)

2) The Analytical Methods used by the Laboratory

An analytical reference method is given in the Regulation for each microbiological criterion.

When testing a foodstuff against a criterion, the laboratory can use:

1) The analytical reference method specified in the Regulation:

If the laboratory conducts testing using the analytical reference method specified in the Regulation, **the most recent edition of the method must be used**. Most of the analytical reference methods specified in the Regulation have been developed by ISO (International Organization for Standardization). As these methods are updated regularly, it is important to check that the laboratory is using the most recent edition. The ISO website (www.iso.org) lists the most recent version of their reference methods

2) Alternative methods

Alternative analytical methods may have advantages over the reference method, such as a shorter time-to-result or easier to use. An alternative analytical method that is appropriate for the food matrix under examination may be used; however, it must provide equivalent results to the reference method and must be validated against the most recent edition of the analytical reference method specified in the Regulation. If the alternative method is a proprietary (rapid) method, it must also be certified by a third party. This certification must be undertaken in accordance with the EN/ISO 16140 standard or other internationally accepted similar protocols

Many organisations are involved in the validation and certification of alternative methods for the microbiological analysis of food. Two of these organisations, AFNOR (Association Française de Normalization) and MicroVal, meet the requirements of the Regulation, i.e. they: (i) validate their methods against the most recent version of the analytical reference method specified in the Regulation and (ii) base their certification on the ISO 16140 standard. Please note that the certificate, which is issued for each method, is valid for a specified period of time (only methods with a valid certificate can be used). Lists of validated/certified alternative methods are available on the AFNOR and MicroVal websites.

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AOAC International and NordVal are examples of other organisations involved in the validation and certification of alternative methods. Methods validated and certified by these organisations are only permitted if they meet the requirements of the Regulation, i.e. the alternative method must be validated against the most recent version of the analytical reference method specified in the Regulation and if the alternative method is a proprietary (rapid) method, it must also be certified in accordance with the EN/ISO 16140 standard or other internationally accepted similar protocols.

If a food business operator wishes to use analytical methods other than those validated and certified as described above, the methods must:

- Be validated according to internationally accepted protocols, and
- Authorised by the competent authority

In conclusion, it is the responsibility of the food business operator to ensure (1) the laboratory and (2) the analytical method used by the laboratory meet legal requirements and where possible, follows best practice. To do this, food business operators should:

- Request laboratories to complete the questionnaire presented in Appendix 1
- Interpret the results from the questionnaire using the flow chart provided in Appendix 2

Need more information?

Accredited Laboratories

INAB maintains a directory of accredited laboratories (including their certificates and scope of accreditation) on its website. Please see:

<http://www.inab.ie/Directory-of-Accredited-Bodies/Laboratory-Accreditation/Testing/>

For other accreditation bodies signatory to the EA MLA for testing, please refer to www.european-accreditation.org

Alternative/Rapid Laboratory Methods

Lists of alternative analytical methods for the microbiological analysis of food which are validated and certified according to the requirements of the Regulation are available on:

- **AFNOR:** <http://nf-validation.afnor.org/en/>
(See Certified Methods Food Industry and Certified Methods Water Analysis)
- **MicroVal:** <https://www.nen.nl/MicroVal-validation/Certificates.htm>

Other organisations involved in the validation and certification of alternative methods:

- **NordVal:** <http://www.nmkl.org/index.php/en/nordval>
- **AOAC:** <http://www.aoac.org>
(Search under Performance Methods Tested Program, PTM Validated Methods)

If you have further questions which are not covered by this factsheet, please email the FSAI Advice Line at info@fsai.ie

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Appendix 1

Suggested Questionnaire to be completed by the Food Business Operator and the Laboratory

Please complete this questionnaire for every food matrix/microbiological parameter being examined.

Completion of this questionnaire will help food business operators determine if: i) the laboratory and ii) the analytical method used by the laboratory meet requirements, i.e. legal and best practice requirements. The results from this questionnaire should be interpreted by the food business operator using the flow chart overleaf.

TO BE COMPLETED BY THE FOOD BUSINESS OPERATOR:

Food matrix to be examined:

Microbiological parameter to be examined:

Analytical reference method specified in Annex I of Regulation 2073/2005:

TO BE COMPLETED BY THE LABORATORY:

Laboratory name:

Q1. Does the laboratory use the analytical reference method specified in Annex I of Regulation 2073/2005?

Yes proceed to Q2 **No** proceed to Q3

Q2. Is the most recent version of this method being used?

If yes, please specify the version being used:

Yes proceed to Q7 **No** proceed no further

Q3. Does the laboratory use an alternative method which has been validated against the most recent version of the analytical reference method specified in Annex I of Regulation 2073/2005?

Yes proceed to Q4 **No** proceed no further

Q4. Is the alternative method a proprietary (rapid) method?

Yes *proceed to Q5 **No** proceed to Q7

Q5. Has the proprietary method been certified by AFNOR or MicroVal and is the certificate valid?

Yes proceed to Q7 **No** proceed to Q6

Q6. Has the proprietary (rapid) method been certified by any other organisation, e.g. AOAC, NordVal, in accordance with the protocol set out in ISO 16140 or other internationally accepted similar protocols and is the certificate valid?

Yes #proceed to Q7 **No** proceed no further

Q7. Is the laboratory accredited to conduct this method for the required food matrix in accordance with ISO 17025?

Yes **No**

***Please name the proprietary (rapid) method:**

Please name the certification body:

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Appendix 2

Flow Chart to Interpret Results from Questionnaire

