

# 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<sup>1</sup>.

It focuses on: (1) the laboratory providing the testing service and (2) the analytical methods used by the laboratory. It provides an easy to use table of questions to 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.

## 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. 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 most recent version of the international standard ISO 17025<sup>2</sup>. 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

<sup>1</sup> Available at [www.fsai.ie](http://www.fsai.ie)

<sup>2</sup> ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories. Available to purchase at [www.iso.org](http://www.iso.org)

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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 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.

### 2) The Analytical Methods used by the Laboratory

An analytical reference method is given in the Commission Regulation (EC) No 2073/2005 for each microbiological criterion. Article 5.5 of the Regulation allows for alternative methods to be used but lays down certain requirements if they are used.

When testing a foodstuff against a criterion, the laboratory can use either of the following methods:

#### 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](http://www.iso.org)) lists the most recent version of the analytical reference methods.

Or

#### Alternative methods

Alternative analytical (or test) methods may have advantages over the reference method, such as a shorter time-to-result or easy to use. The use of alternative analytical methods is acceptable **provided** the methods are:

- validated against the specific reference method provided for in Annex I in accordance with the protocol set out in standard EN ISO 16140-2<sup>3</sup>, **and**
- validated for the food category specified in the relevant microbiological criterion set in Annex I, the compliance with which is verified by the FBO, or validated for a broad range of food as referred to in EN ISO 16140-2.

<sup>3</sup> ISO 16140-2 Microbiology of the food chain – Method validation – Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method. Available to purchase at [www.iso.org](http://www.iso.org)

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The alternative analytical/test method must be validated to show that it can provide at least equivalent guarantees of the relative accuracy, specificity, sensitivity and limit of detection compared to the analytical reference method. The alternative test method should be able to detect all target strains and not to have cross-reactions with non-target strains compared to the analytical reference method (i.e. inclusivity/exclusivity testing).

Proprietary methods with a trademark/brand name, which are owned and marketed by a commercial company may be used as alternative analytical methods, **provided** they:

- meet the criterion outlined above for alternative methods **and**
- are certified by an independent certification body.

Proprietary methods are usually rapid methods. Examples include ELISA (enzyme-linked immunosorbent assay) methods which use antibody-based binding to specific target antigens for the detection of foodborne microorganisms, and molecular methods such as PCR (polymerase chain reaction) assays which amplify specific segments of DNA unique to the target microorganism.

The certification of the proprietary method is subject to reassessment through renewal procedures at least every 5 years and must include a summary of, or a reference to, the validation results of the proprietary method and a statement on the quality management of the production process of the method.

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 test methods against the most recent version of the analytical reference method specified in the Regulation and (ii) base their certification on the ISO 16140-2 standard. Please note that the certificate, which is issued for each method, is valid for a specified period of time and only methods with a valid certificate can be used. Lists of validated/certified alternative methods are available on the AFNOR and MicroVal websites.

### Authorisation of alternative test methods using validation protocols other than ISO 16140-2

Analytical methods that are validated or certified using protocols other than EN ISO 16140-2 by organisations such as AOAC International and NordVal are also permitted **where** such methods have been validated in accordance with internationally accepted protocols **and** their use has been authorised by the competent authority.

Use of any alternative test methods that are not validated according to Article 5.5 are not in compliance with the Regulation. Appropriate studies shall be carried out by the FBO to demonstrate the equivalence of alternative test methods to the corresponding reference test method in accordance with the ISO 16140 series<sup>4</sup> or other internationally recognised standards. The results of any validation studies carried out must be submitted to the competent authority for review and approval prior to their use.

### Conclusions

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 complete the table of questions in Appendix 1.

<sup>4</sup> Available to purchase at [www.iso.org](http://www.iso.org)

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## 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](http://www.european-accreditation.org)

### Competent Authorities

Competent authorities verify that food business operators comply with legislation relevant to their food business. Food business operators are required to register with a competent authority before they start operating. Who a food business operator has to register with will depend on the type of business and whether foods of animal origin are handled or processed.

A list of competent authorities responsible for registering and approving food businesses is available here: [https://www.fsai.ie/food\\_businesses/starting\\_business/competent\\_authorities.html](https://www.fsai.ie/food_businesses/starting_business/competent_authorities.html)

### Alternative/Proprietary 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)

Further guidance on food legislation, microbiological sampling and testing, and eLearning on the microbiological criteria in Commission Regulation 2073/2005 is available at [www.fsai.ie](http://www.fsai.ie)

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

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## Appendix 1

Completion of this table of questions 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. Most of the answers to the questions below will be found on the laboratories scope of accreditation available at [www.inab.ie](http://www.inab.ie). If the necessary information is not available, consult the laboratory.

Complete this table for every food matrix/microbiological parameter being examined.

**Food matrix to be examined:**

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**Microbiological parameter to be examined:**

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**Relevant microbiological criteria in Annex I of Regulation 2073/2005, as amended:**

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**Analytical reference method specified in Annex I of Regulation 2073/2005, as amended:**

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**Laboratory name:**

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QUESTION	ANSWER	ACTION
1 Does the laboratory use the analytical reference method specified in Annex I of Regulation 2073/2005, as amended?	<b>Yes</b>	Proceed to Q2
	<b>No</b>	Proceed to Q3
2 Is the most recent version of this method being used? If yes, please specify the version being used.	<b>Yes</b>	Proceed to Q9
	<b>Specify version:</b> <b>No</b>	Not in compliance with Article 5.5, Regulation 2073/2005, as amended.  Approach an alternative laboratory.
3 Does the laboratory use an alternative method validated against the most recent version of the specific reference method provided for in Annex I of the Regulation in accordance with the protocol set out in standard ISO 16140-2 <b>and</b> has it been validated for the relevant food category or validated for a broad range of food as referred to in ISO 16140-2?	<b>Yes</b>	Proceed to Q4
	<b>No</b>	Proceed to Q8

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QUESTION	ANSWER	ACTION
<b>4</b> Is the alternative method a proprietary method?	<b>Yes</b>  <b>Name the proprietary method:</b>	Proceed to Q5
	<b>No</b>	Proceed to Q9
<b>5</b> Has the proprietary method been validated and certified by AFNOR or MicroVal in accordance with the protocol set out in ISO 16140-2 <b>and</b> is the certificate in date?	<b>Yes</b>  <b>Name the certification body and date cert is valid to:</b>	Proceed to Q9
	<b>No</b>	Proceed to Q6
<b>6</b> Has the proprietary method been validated and certified in accordance with other internationally accepted protocols (e.g. AOAC, NordVal) <b>and</b> is the certificate in date?	<b>Yes</b>  <b>Name the certification body and date cert is valid to:</b>	Proceed to Q7
	<b>No</b>	Not in compliance with Article 5.5, Regulation 2073/2005, as amended. Approach an alternative laboratory.
<b>7</b> Is use of the proprietary method certified by this organisation, authorised for use by the competent authority?  If you are unsure about the answer to this question, check with your competent authority.	<b>Yes</b>	Proceed to Q9
	<b>No</b>	Not in compliance with Article 5.5, Regulation 2073/2005, as amended. Approach an alternative laboratory.
<b>8</b> Does the laboratory use an alternative method validated in accordance with internationally accepted protocols other than ISO 16140-2 <b>and</b> is its use authorised by the competent authority?  If you are unsure about the answer to this question, check with your competent authority.	<b>Yes</b>  <b>Specify internationally accepted protocol:</b>	Proceed to Q9
	<b>No</b>	Not in compliance with Article 5.5, Regulation 2073/2005, as amended. Approach an alternative laboratory.

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QUESTION	ANSWER	ACTION
<b>9</b> Is the laboratory accredited to conduct this method for the required food matrix in accordance with the most recent version of ISO 17025?	<b>Yes</b>	<ul style="list-style-type: none"> <li>Request the laboratories certification of accreditation (this includes their schedule of accreditation) or download from <a href="http://www.inab.ie">www.inab.ie</a></li> <li>Seek confirmation from the laboratory that the certificate is valid and that the schedule of accreditation is current (certification body will verify this on request)</li> <li>If satisfied, proceed with this laboratory</li> </ul>
	<b>No</b>	Use an alternative laboratory unless accreditation is rare or difficult to maintain for this method.