

# **Guidance for Irish National Reference Laboratories and Official Laboratories on the Implementation of Regulation (EC) No. 882/2004 for Feed and Food Law, Animal Health and Welfare Rules.**

## **Background**

The Official Control laboratory service in Ireland includes nineteen chemical and microbiological laboratories, eight of which are NRLs, under the auspices of different Competent Authorities. Articles 12 and Article 33 of [Regulation \(EC\) No. 882/2004](#) respectively outline specific requirements for official laboratories and national reference laboratories (NRLs). The requirements are only specified in a general manner and apply to official laboratories and NRLs for chemical and microbiological parameters. In order to ensure the NRLs and official laboratories are meeting the requirements of Regulation (EC) No. 882/2004, this document provides guidance for the laboratories' on compliance with legislation and on how the NRLs and official laboratories should liaise and work together. This guidance also identifies good practices which may in some cases exceed the minimum legal requirements.

The list of Irish NRLs and official laboratories designated under Regulation (EC) No. 882/2004 is available on the FSAI website.

Article 33 of Regulation (EC) No. 882/2004 specifies that “Member States shall arrange for the designation of one or more national reference laboratories for each Community reference laboratory referred to in Article 32”. In Ireland the Department of Agriculture, Food and the Marine and the Department of Health have designated the NRLs for official controls of feed and food law, animal health and animal welfare rules.

Article 12 of Regulation (EC) No. 882/2004 specifies that “The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.” The Department of Agriculture, Food and the Marine, the Department of Health and the Food Safety Authority of Ireland have designated official laboratories for the official controls of feed and food law, animal health and animal welfare rules. Competent Authorities will only designate NRLs and official laboratories that comply with Article 12 (2) and (3) of Regulation (EC) No. 882/2004.

This document is set out in 2 parts:

- Part 1: Requirements/Role of NRLs for chemical and microbiological parameters
- Part 2: Requirements for Official Laboratories

## **Part 1: Requirements/Role of NRLs for chemical and microbiological parameters**

This section includes the legal requirements of Regulation (EC) No.882/2004, guidance on the interpretation of the legal requirements and recommended best practice for NRLs. Overall NRLs should contribute to a high quality and uniformity of analytical results<sup>1</sup>.

1. Operate and be assessed and accredited in accordance with ISO 17025
  - NRLs will be accredited to ISO 17025 for relevant parameters for which the laboratory is the NRL.
  - NRLs will review the scope of accreditation of official laboratories for which it is the NRL and report to the relevant competent authorities.
2. Collaborate with the European Union Reference Laboratory (EURL) in their area of competence and ensure the dissemination to the competent authority and official national laboratories of information that the EURL supplies including:
  - Collaborate with EURL on analytical/testing methods on request.
  - Disseminate information on methodology, EURL workshops
  - Supply of standard materials and negative controls, where practicable.
  - Review the availability of reference materials, identify any gaps and highlight any deficiencies to the relevant EURL.
  - Provide technical advice to the Competent Authorities, through collaboration with the EURLs; make recommendations to the Competent Authorities, where appropriate.
  - In cases where there is more than one NRL for an EURL, NRLs must work closely together so as to ensure efficient coordination between them, with other national laboratories and with the EURL.
  - Where relevant, participate in EURL-led research designed for the development of improved testing procedures.
  - NRLs shall avail of training/networking opportunities offered by the EURL network.
3. Coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples including:
  - Have an overview of the methods of analysis of all official laboratories carrying out official controls within the NRL's area of competence, including performance of methods e.g. by comparative tests.
    - For comparative tests organised by the NRL notify the relevant official laboratory and competent authorities in a timely manner of the performance of the laboratories.
    - Where comparative tests show problems, consider with the official laboratories how to improve methods and eliminate issues and assist official labs to identify solutions to those problems, and notify Competent Authorities.
  - Notify the competent authorities in a timely manner of any deficiencies in official laboratories, identified from the comparative tests, which may affect the outcomes of official control testing.

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<sup>1</sup> Recital 18 of Regulation (EC) No. 882/2004

- Where necessary provide technical assistance to support the activities of official laboratories, by for example:
  - Circulating technical assistance documents prepared by the EURL or NRL
  - Providing advice on methods, and in particular on the application of validated analytical methods that comply with the requirements of Article 11 of Regulation (EC) No.882/2004, and other relevant legislation.
  - Assisting in the training of official laboratory staff.
  - Provide technical assistance to the Competent Authorities in cases of disputes over official results.
  - For microbiological methods, co-ordinating and supporting laboratories involved in the further identification/molecular typing of microbial isolates.
- NRLs shall employ verification techniques to assess the suitability, appropriateness and quality of official control testing carried out in the official laboratories under Article 12, within their area of NRL responsibility and with due regard to the role of INAB. Verification may include, as appropriate, questionnaires, laboratory visits and audits

4. Where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative tests;

- NRLs should have an overview of comparative tests, in which official laboratories are participating within the NRL's area of competence. In particular NRLs should:
  - i. Assess the current level of comparative tests that official laboratories are participating in with a view to assessing gaps; where appropriate organise or recommend comparative tests in which the official laboratories should participate in.
  - ii. Review the results of comparative tests within their area of competence, with due regard to the role of INAB and follow-up as appropriate;
  - iii. Where relevant, prepare summary reports of results of comparative tests organised by the NRL and report these to the relevant official laboratories, and competent authorities.

5. When initiated in accordance with Article 53 of Regulation (EC) No. 882/2004, the NRL will provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans. Where such coordinated control plans are proposed, the NRLs shall review and discuss the coordinated control plan with a view to:

- Driving active surveillance for microbiological parameters.
- Assisting in identifying deficiencies, gaps and overlaps in sampling programmes.
- Providing feedback to the competent authorities.

6. Collaborate and interface with national and international agencies and authorities, as appropriate to:

- Review available data; to proactively identify emergent trends and clusters.
- Participate in international database networks, such as the European Commission Database on Pesticides and Pulse-net database for sharing molecular subtyping "PFGE fingerprinting" of foodborne disease-causing bacteria.

- Disseminate information within agreed/specified timelines.
  - Collaborate with NRLs in other areas, e.g. compare microbial isolates from the feed/food chain with isolates from clinical specimens.
  - In conjunction with competent authorities, provide information to international agencies regarding levels of chemical/microbial contaminants, assist in information collection regarding their area of expertise.
7. NRLs shall periodically verify the suitability, appropriateness and quality of the activities of the NRL, to ensure compliance with Article 33 of Regulation (EC) No. 882/2004.

NRLs are also subject to the internal audit provisions for official controls as specified in Article 4(6) of Regulation (EC) No. 882/2004.

## **Part 2: Requirements for Official Laboratories**

The general rules for official laboratories carrying out chemical or microbiological analysis of samples taken as part of official controls<sup>2</sup> are outlined in Articles 11 and 12 of Regulation (EC) No. 882/2004. These general requirements are supplemented by specific additional legislative requirements for food sampling and testing. Guidance on official sampling and testing has also been prepared and where available this must also be taken into account by official laboratories.

The requirements below are meant to provide a more detailed guidance on the implementation of the requirements in Regulation (EC) No. 882/2004 for official laboratories and recommended best practice for official laboratories. However these requirements must be considered in conjunction with any additional specific requirements for official laboratories that are outlined in specific legislation and guidance documents.

### **Specific requirements for official laboratories under Regulation (EC) No. 882/2004:**

1. Official laboratories must be designated by the Competent Authorities as official laboratories that may carry out the analysis of samples taken during official controls. The Department of Agriculture, Food and the Marine, the Department of Health and FSAI have designated official laboratories.
2. Official laboratories must be accredited to ISO 17025. All official control laboratories may be accredited for the individual tests or group of tests they are using for official control purposes. The scope of accreditation should be appropriate to their operation as an official laboratory. The competent authorities may cancel the designation of official laboratories where they no longer fulfil the accreditation requirements.
3. Methods of analysis for official controls should be in line with the criteria for different testing methods laid down in the European legislation that is relevant to the analysis carried out by the official laboratory including Regulations (EC) No.s 882/2004, 2073/2005 and associated food legislation. The methods should take into account the Commission Guidance document on official controls, under Regulation

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<sup>2</sup> Official control means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules (Regulation (EC) No. 882/2004)

(EC) No. 882/2004, concerning microbiological sampling and testing of foodstuffs or other guidance relevant to the technical area of the official laboratory.

4. Official laboratories shall cooperate with the relevant NRL in the fulfilment of the NRL role of coordinating the activities of official laboratories in their area of competence. Official laboratories for food are obliged under the service contract with FSAI to co-operate with the NRLs in the latter's discharge of their functions under Article 33 of the Regulation. This may include:
  - Providing all information to the NRL, on request, on the methods of analysis used in the official laboratory.
  - Requesting technical assistance from the NRL on methods of analysis within the NRLs area of competence
  - Providing information to the NRL on request on the comparative tests that the official laboratory is participating in.
5. To assist NRLs in their role of monitoring and identifying emergent trends, official laboratories will provide information, samples/specimens, isolates to the NRL, on request.

The list of NRLs and official laboratories designated for official controls under Regulation (EC) No. 882/2004 can be found at the following URL:

[http://www.fsai.ie/enforcement\\_audit/monitoring/national\\_official\\_labs.html](http://www.fsai.ie/enforcement_audit/monitoring/national_official_labs.html)

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