NMKL – NordVal International
email: post@nmkl.org
c/o Institute of Marine Research,
P.O. box 1870 Nordnes, 5817 Bergen, Norway

A Nordic Interpretation of the Control Regulation regarding National Reference Laboratories (NRL) and Official Laboratories (OFL)

February 2021

Contents

1. Introduction

This document has been elaborated by a Nordic project group in NMKL. The document is a revision of the Nordic standard regarding national reference laboratories (NRL Standard of 2009). The scope of the standard was to describe requirements and tasks of national reference laboratories within food and feed based on the Regulation (EC) No 882/2004, and how a Nordic cooperation within these scopes could be enhanced. The NRL Standard of 2009 was elaborated by a working group under the Nordic Council of Ministers for Fisheries, Aquaculture, Agriculture, Food and Forestry.

As the Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, is replaced by a new Control Regulation, NMKL decided to revise the NRL Standard of 2009. The new Control Regulation referred to is the Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. Hereafter referred to as OCR.

The aim of the requirements laid down in the OCR regarding laboratories and their methods of analysis is to ensure reliable and consistent official controls and other official activities across the Union.

2. Scope and field of application

This document is intended to describe and illustrate what is required from national reference laboratories (NRL) and official laboratories (OFL) within food, feed, plant health and animal health. The purpose of this project was to collect articles in the OCR relevant for laboratories, as laboratory matters are not discussed in subsequent articles and includes many references at the expense of being very reader friendly. Further, where relevant interpret the content and discuss how to extend the Nordic cooperation in this sector. Each of the Nordic Countries are small, and within the individual competence area, often the responsible analysts have no national network to contact if there is a need for technical or administrative exchange of opinions. This document is not a binding document but meant to ease the exchange of information between designated NRL, which is intended to strengthen the laboratories' competence. A list of contact persons on reference laboratories within food in the Nordic countries is kept updated at www.nmkl.org for facilitating networking.

In this document, the following verbal forms are used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability

3. Designation of National Reference Laboratories

Each country shall appoint one or more NRL for each designated European Union reference laboratory (EURL). In cases where more than one NRL is appointed for the same area of competence, laboratories shall cooperate, and the roles of the laboratories be clarified. For some EURL workshops and proficiency tests, EURL may limit participation to one laboratory in each country due to capacity issues.

It is possible to designate a laboratory situated in another EU or EFTA country. A Nordic country can for instance appoint a laboratory in another Nordic country as their NRL.

A single laboratory may be designated as a NRL for more than one country, e.g. a Danish NRL could be NRL for all the Nordic countries.

It is also possible to designate a NRL in the cases where there is no corresponding EURL.

The table below shows the responsible body designating NRL in the Nordic countries.

Country	NRL is designated by
Denmark	Danish Veterinary and Food Administration, (the concerned ministry is kept informed)
Finland	Ministry of Agriculture and Forestry
Iceland	Ministry of Industry and Innovation
Norway	Norwegian Food Safety Authority (the concerned ministry is kept informed)
Sweden	The Government of Sweden

The designators forward name and contact information of NRL and any changes thereof to the Commission and to the appropriate EURL and to EU member states. Information about EURL is available at the Commission's webpage https://ec.europa.eu/food/ref-labs_en.

3.1. Organisational requirements of NRL

The bullets below describe the requirements of NRL. The sentences in brackets are comments made by the project group and not quotations from the OCR.

To be appointed as NRL, the laboratory shall according to Article 100 in the regulation:

- be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct when carrying out their tasks as NRL. [The project group acknowledges that NRL for maintaining expertise as well as for financial, practical or other reasons might need to carry out routine analysis and hence will be in the same market as private laboratories designated as OFL. There must be transparency about this practice.]
- have, or have access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;
- possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;
- ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work; [NMKL is established to enable international co-operation and sharing knowledge at Nordic level. Thus, the NRL in the Nordic countries are encouraged to take part in the NMKL network.]
- be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and
- where relevant, be equipped to comply with relevant biosecurity standards.

The wording "or have access to", repeatedly used in the bullets above, have been discussed in the project group. As it is not stated whether the contractually engaged staff or accessed equipment have to be located within the laboratory, it can be interpreted that a designated NRL can contract another laboratory for the tasks of a reference laboratory. The project group concluded that if a contracting laboratory is used for performing NRL tasks, the NRL itself should have profound knowledge in the methods of analysis/diagnosis in the specific competence area.

3.2. Quality requirements of NRL

The NRL shall operate and be accredited in accordance with the standard EN ISO/IEC 17025. The scope of the accreditation shall include those methods of laboratory analysis test or diagnoses used when it operates as an OFL (point (e) of Article 37 (4) and 100 (2)).

The accreditation could comprise groups of methods and might be defined in a flexible manner (Article 37 (5), 100 (2)).

The competent authority may allow temporary derogation (Articles 42 and 100 (2)) from accreditation of the specific method when

- the use of the method is newly required
- changes to a method require a new or extended accreditation
- the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.

The temporary derogation should not exceed a period of one year. It may be renewed once for a further period of one year.

The Commission have power to adopt derogations from the mandatory accreditation of by adopting delegated acts supplementing the OCR (Article 41). The Commissions is currently working on supplementing the Regulation in the areas of plant health, food contact material, food improvement agents and feed additives. Under the prerequisite that the laboratory has a quality assurance in place and the method is validated for relevant method performance criteria, a method within these areas does not necessarily need to be accredited. This is further described in chapter 4.1 of this document.

3.4. Responsibilities and tasks of NRL

The OCR Article 101 describes the tasks of the NRL.

Tasks according OCR, Article 101	**Examples and interpretation by the project group on what this could mean in practise**
Collaborate with the EURL and participate in training courses and in inter-laboratory comparative tests organised by these laboratories.	Participate in workshops and meetings, in proficiency tests (PT) and in method validation studies organised by EURL.
Coordinate the activities of designated OFL with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use.	Give guidance and advise on which methods applicable for use for official samples. If necessary, give practical guidance in the application of the method. Elaborate and validate methods and follow the development in standardisation organisations and other international fora. If appropriate, arrange courses/workshop for the OFL.
Where appropriate, organise inter-laboratory comparative testing or proficiency tests between OFL, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up.	Inform OFL about appropriate national or international PT schemes when relevant. When necessary, organise PT and review the performance of the laboratories. For external organised PTs, NRL shall get summary of the performance of the OFL, reviewing their

Tasks according OCR, Article 101	Examples and interpretation by the project group on what this could mean in practise
	performance. If OFL fails in repetitive or critical PTs, the competent authority shall be notified as it might be necessary to discharge the OFL from the task.
Ensure the dissemination to the competent authorities and OFL of information that the EURL supplies.	Regularly, inform the competent authority and the OFL about EURL resolution and recommendations from workshops and meetings. This can be done for example by regular information letters, seminars and meetings. This information can also be shared within the network of NMKL.
Provide within the scope of their mission scientific and technical assistance to the competent authorities for the implementation of multi-annual control plans (MANCP) and of coordinated control programmes.	Participate in elaboration of governmental control plans, project and assist OFL in analytical technical problem situation.
Where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.	This is new in the OCR and might be relevant within areas where there are few reference substances and where specific reagents are difficult to obtain.
Where necessary, conduct training courses for the staff of OFL.	Assist OFL in analytical technical problem situation and if necessary, arrange training courses. Training courses could be organized and shared within the network of NMKL.
Assist actively the Member State having designated them in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens.	Provide knowledge and laboratory analyses when needed in outbreak situations. Use of established network, such as EURL, NMKL, is essential.

4. Designation of official laboratories, OFL

Official laboratories (OFL) are designated laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities. These laboratories can be public or private laboratories and can also be laboratories located in another EU or EEA country (Article 37).

If the laboratory is located in another EU or EEA country, the laboratory shall already be an OFL of that country, and appropriate arrangements have to be in place under which the competent authorities are enabled to perform the audits and inspections. It is also possible to delegate the performance of such audits and inspections to the competent authorities of the country of the laboratory. See 4.3 below for more information on audits of OFL.

In a Commission Expert Group on OCR, the Commission stated the following in a document for the working group meeting 27 January 2021: While the OCR does not regulate subcontracting, and there are no guidelines on subcontracting, the OCR establishes in Article 37 (1) that OFL are to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities. This would mean that an OFL would only be able to subcontract some of its activities to another OFL.

Lists of designated OFL in the Nordic countries, in cases where such lists exist nationally, will be made available at the NMKL webpage. The Commission is also working to establish a list of designated OFL in the member states.

The designation of an OFL shall be in writing (OCR, Article 37 (3)) and shall include a detailed description of:

- the tasks that the laboratory carries out as an OFL;
- the conditions under which it carries out the tasks, and
- the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.

The table below shows the responsible body for designating OFL in the Nordic countries.

Country	**Official laboratories are designated by**
Denmark	Danish Veterinary and Food Administration
Finland	Finnish Food Authority
Iceland	Food and Veterinary Authority
Norway	Norwegian Food Safety Authority (when appropriate in collaboration with NRL)
Sweden	Relevant competent authority, which can be the Swedish Food Agency, the Municipal Authorities, the Board of Agriculture

For the NRL to fulfil their tasks, the project group is in the opinion that the designators should forward name and contact information of the designated laboratory to NRL.

4.1. Organisational and Quality requirements of OFL

For being appointed as an OFL, the laboratory shall:

- have the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;
- have a sufficient number of suitably qualified, trained and experienced staff;
- be impartial and free from any conflict of interest as regards the exercise of its tasks as an OFL;
- deliver in a timely manner the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities; and

- operate in accordance with the standard EN ISO/IEC 17025 and be accredited by the national accreditation body.

The scope of the accreditation

- shall include those methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses, when it operates as an OFL;
- may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
- may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the OFL when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods.

We recognise that accreditation bodies in Europe are not fully harmonised when it comes to assessing methods for accreditation using flexible scope. The contents and the description of flexible scope may vary between different countries.

In cases where there is no OFL in the EU/EEA for a certain analysis, a laboratory which does not comply with one or more of the requirements can be appointed by the competent authority to perform that analysis (OCR, Article 37 (6)).

Derogations from mandatory accreditation – *Trichinella* methods (OCR, Article 40, (1) point a)

It is not required to have accredited methods for detection of *Trichinella* in meat for laboratories:

- whose sole activity is the detection of *Trichinella* in meat
- using the method described in the Regulation (EC) 2015/1375 and (EU) 2020/1478 (method ISO 18743:2015)
- under supervision* of the competent authorities or of an OFL accredited for the *Trichinella* method.

* By supervision, we interpret that the competent authority (official veterinarians) regularly check that the analysis is carried out correctly and provide guidance if needed. The project group recognised that the frequency of the supervision/or planning of the supervision varies between the countries. Further, that there is no information in the OCR about in the extent of supervision and reporting thereof.

It is required that the laboratory participates regularly and have satisfactory performance in the PT-schemes organised by NRL, and that it has a quality assurance system in place to ensure sound and reliable results.

The non-accredited *Trichinella* laboratories shall be located in the Member States in whose territory the competent authorities which have designated them are located.

Derogations from mandatory accreditation – other methods than *Trichinella* (OCR (52) and Article 40, 1b)

In the OCR under considerations (52) it is noted that in order to ensure the flexibility and proportionality of the approach, in particular for animal health or plant health laboratories, provision should be made for the adoption of derogations aimed at allowing certain laboratories not to be accredited for all the methods they use. That happens in particular where validated methods for detecting particular pests of plants are not available. Moreover, accreditation of a laboratory for all the methods that it should use as an OFL might not be immediately available in cases where new or recently modified methods are to be used, in cases of emerging risks or in emergency situations. Under certain conditions, OFL should therefore be allowed to carry out analyses, tests and diagnoses for the competent authorities before they obtain the relevant accreditation.

Exception from accreditation is given laboratories which only carry out analyses, tests or diagnoses in the context of other official activities, using in prioritised order:

- methods or the performance criteria for those methods described in (Union rules) directives,
- methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted [methods from other international standard developing organisation such as AOAC, IDF, ISO, NMKL also comply] or relevant methods developed or recommended by the EURL and validated in accordance with internationally accepted scientific protocols;
- methods which comply with relevant rules established at national level,
- relevant methods developed or recommended by NRL and validated in accordance with internationally accepted scientific protocols; or relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.

If not being accredited, the laboratories have to carry out the analyses under the supervision of the competent authorities or of the relevant NRL. Further, they need to participate regularly and have satisfactory performance in PT organised by NRL in relation to the methods they use; and have a quality assurance system in place. The regulation does not describe how to carry out supervision, nor does it explain or exemplify the term “other official activities”.

In cases where the methods used require confirmation of the result, the confirmation shall be carried out by an official accredited laboratory.

Any non-accredited OFL have to be located in the Member States in whose territory the competent authorities which have designated them are located.

As mentioned under 3.2 Quality requirements of NRL, the Commission have power to adopt derogations from the mandatory accreditation (Article 41). In the areas of plant health, food contact material, food improvement agents and feed additives, the competent authorities may designate laboratories which are not accredited in relation to all the methods of laboratory analysis, test or diagnosis they use for official controls and other official activities, provided that:

- those laboratories have a quality assurance system in place to ensure that reliable results are obtained from the use of methods of laboratory analysis, test or diagnosis outside the scope of their accreditation; and
- the non-accredited methods used by those laboratories are characterised in accordance with relevant method criteria as stated below in chapter 5.

4.2. Obligations and tasks of OFL

The OCR Article 38 describes the obligation of OFL.

Tasks according OCR, Article 38	**Examples and interpretation by the project group on what this means in practise**
Where the results of an analysis, test or diagnosis carried out on samples taken during official controls or other official activities indicate a risk to human, animal or plant health, or, as regards GMOs and plant protection products, also to the environment, or point to the likelihood of non-compliance, OFL shall inform immediately the competent authorities which designated them for that analysis, test or diagnosis and, where relevant, delegated bodies or natural persons to which tasks have been delegated. However, specific arrangements between the competent authorities, delegated bodies or natural persons to which tasks have been delegated and the OFL may specify that this information is not required to be provided immediately.	Report to the competent authority when finding results exceeding maximum permitted level. How to report should be outlined in the contract between the authority and the laboratories. For some parameters, the NRL should also be notified, e.g. for detection/confirmation of Salmonella spp. (ref. to Salmonella reg,). Furthermore, according to national regulation, the OFL shall also send pathogenic microbial stain to the NRL.
Upon request by the EURL or NRL, OFL shall take part in inter-laboratory comparative tests or proficiency tests that are organised for the analyses, tests or diagnoses they perform as OFL.	Participate in PT-schemes and validation studies arranged by NRL /EURL or international organisations.
OFL shall, upon request of the competent authorities, make available to the public the names of the methods used for analyses, tests or diagnoses performed in the context of official controls and other official activities.	State the methods used for official purposes if requested. As the NRL shall follow up on methods, the NRL also need to know which method the OFL is using. While agreed, the competent authority may have the list of OFL and their methods for official purposes publicly available (in web pages).
OFL shall indicate, at the request of the competent authorities, together with the results, the method used for each analysis, testing or diagnosis, performed in the context of official controls and other official activities.	State the methods used, along with the results, including estimates of measurement uncertainty for quantitative analyses.

4.3. Audits of OFL

According to OCR Article 39, the competent authorities shall organise audits of the OFL on a regular basis and any time they consider that an audit is necessary, unless they find such audits to be redundant considering the accreditation assessment. In some of the Nordic countries the competent authority obliges the OFL to make the accreditation body's surveillance reports available upon request. The project group discussed that it would be welcomed to have a close cooperation with the Nordic accreditation bodies so that OFL could be assessed also according to their requirements given in the OCR.

Organising audits could then be interpreted as the audit can be carried out by the NRL, if contracted by the competent authority, or by the accreditation body if assessed according to the Regulation (EC) 2017/625 in addition to EN ISO 17025. It would be appropriate if the competent authority and the accreditation body could work together, so that the laboratories obligations laid down in the OCR could be assessed when assessing the laboratory according to EN ISO 17025.

The competent authorities shall immediately withdraw the designation of an OFL, either completely or for certain tasks, where the laboratory fails to take appropriate and timely remedial action following the results of an audit. This is when the laboratory no longer complies with the administrative requirements or fulfil the obligations and tasks, or the PT results are not satisfactory.

5. Methods used for sampling, analyses, tests and diagnoses, (OCR, Article 34)

Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities have the following preferences [the texts given in brackets are interpretations]:

1. methods or method performance criteria given in EU regulation
2. available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; [Methods elaborated by standard developing organisations such as ISO (International Organization for Standardization), CEN (European Committee for Standardization), AOAC International, NMKL (Nordic Committee on Food Analysis), IDF (International Dairy Federation) and OIE (World Organisation for Animal Health)]
3. methods which comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or
4. relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols; [Validated methods published in articles]
5. other methods until the validation of an appropriate method in accordance with internationally accepted scientific protocols.

Wherever possible, methods used for laboratory analyses shall be characterised by the criteria, Article 34, Annex III:

- accuracy (trueness and precision),
- applicability (matrix and concentration range),
- limit of detection,
- limit of quantification,
- precision,
- repeatability,
- reproducibility,
- recovery,

- selectivity,
- sensitivity,
- linearity,
- measurement uncertainty,
- other criteria that may be selected as required.

The precision values shall either be obtained from a collaborative study conducted in accordance with an internationally recognised protocol (e.g. ISO 5725 'Accuracy (trueness and precision) of measurement methods and results') or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725 'Accuracy (trueness and precision) of measurement methods and results'). The results from the collaborative study shall be published or freely available.

Note that some method performance characteristics listed above, do not apply for all types of methods. For microbiological methods, alternative methods to reference methods can be applied if validated according to the ISO 16140 series and certified by an independent certification body.

Horizontal analytical methods, i.e. methods applicable to various groups of commodities should be given preference over methods which apply only to individual commodities.

Single laboratory validated methods should be validated in accordance with internationally accepted scientific protocols or guidelines or, where performance criteria for analytical methods have been established, be based on criteria compliance tests.

6. Number of samples, sample size and possible reanalysis

Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity.

In the OCR Article 35, it is described that the operators (the original owner of the samples) have the right to a second expert opinion, at the operator's own expense.

The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.

Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, it should be taken a sufficient quantity to allow for a possible reanalysis. It is not required in the OCR to take several samples (e.g. A, B and C samples), but to sample a sufficient amount.

In case of a dispute situation between the competent authorities and the operators after the document review of a second expert, the operators may request, at their own expense, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another OFL.

The application by the operator for a second expert opinion shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and

plant health, or to animal welfare or, as regards GMOs and plant protection products, also to the environment.

7. Nordic cooperation on NRL activities

Neither the OCR nor the national rules in the Nordic countries give legal obstacles for cooperation on NRL services. In the 2009 version of this document, it was motivated to establish and formalise cooperation on NRL. The rational was that it is resource demanding to keep NRL activities in all competence area, Nordic countries could designate NRL in other countries to help NRL concentrate to not all but fewer NRL areas; specialising the effort.

A NRL that offers other countries NRL laboratory services shall be accredited. In addition, the laboratory should be involved in method development, method validation and if necessary, organise PT. It is not a requirement the NRL is accredited as PT provider. However, it is vital that they follow up the results of OFL.

It is possible to split NRL activities on laboratories. The national body responsible for designating more than one NRL for a EURL shall ensure that such laboratories work closely together, ensuring efficient coordination between them, with other NRL and with the EURL. It is not specified in the regulation if a shared NRL is limited to different matrixes (eg. different food categories) or if it can involve cooperation in arranging PT, performing method validation or on other activities complementing the NRL role.

A country in need for NRL and not having the competence within its country, could look into the list of NRL in the Nordic countries, and contact the NRL of interest directly for terms and agreement. NMKL will keep the list of the NRL updated.

8. Financial aspects

Public laboratories are usually funded through Ministry's annual grants. If the laboratory is not under the same Ministry, it might be necessary to pay for the NRL activity. Further, when an abroad laboratory has been designated as the NRL it is often necessary to pay for the service.

When NRL organises PT schemes and courses for OFL, it is common to take necessary fees.