EUROPEAN HEADS OF FOOD SAFETY AGENCIES

Working Group on Food Safety Laboratories

Interpretation of laboratory aspects of Regulation 2017/625 on official controls and other official activities

HOA HEADS OF FOOD SAFETY AGENCIES

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List of abbreviations/acronyms

CA	Competent Authority
CEN	European Committee for Standardisation
EEA	European Economic Area
EURL	European Union Reference Laboratory
HoA	Head of Agencies
IDF	International Dairy Federation
IUPAC	International Union of Pure and Applied Chemistry
LOD	Limit of Detection
MS	Member State
NAB	National Accreditation Body
NMKL	Nordic Committee on Food Analyses
NRL	National Reference Laboratory
OCR	Official Control Regulation 2017/625
OL	Official Laboratory
PT	Proficiency Test
RL	Reference Laboratory
WG	Working Group

Terminology

In this document, the following verbal forms are used:

“shall” or “must” indicates a legal requirement of Regulation 2017/625;

“should” indicates a recommendation of the Working Group;

“may” or “can” indicates an option proposed by the Working Group

1. Introduction

Following entry into force in April 2017 of Regulation (EU) 2017/625 on official controls (OCR), the EU Heads of Agencies (HoA) Group has established a Steering Group and Working Groups (WGs) on official controls with the purpose of contributing to the implementation of the new OCR and drafting the tertiary legislation thereof. Food safety laboratories have been identified by HoA as one of the initial priority areas for the OCR WGs.

The OCR expands considerably on the laboratory requirements currently in Regulation 882/2004 including the requirements for designated official laboratories (OL) and competent authority (CA) oversight of laboratories they have designated. This follows on from a 2014 European Commission Santé F (formerly the Food and Veterinary Office) overview report on laboratories that identified a number of horizontal issues in Member States' (MSs') laboratories. The OCR incorporates some additional requirements to address these issues.

2. Scope and objectives

The initial objective of the WG on Food Safety Laboratories was to review the relevant obligations of CAs and OLs in the OCR with a view to achieving a common understanding of the new requirements and prepare opinions and proposals to the Steering Group.

In particular the WG considered:

- The coordination between the CA and designated OLs in relation to:
  - Designation process (Article 37)
  - On-going CA oversight of OLs (Various articles)
  - Obligations of OLs (Article 34, 37, 38, 40-42)
  - Audits of OLs (Article 39)
- National Reference Laboratories (NRL) (Articles 100-101 plus relevant aspects of Articles 34-42).

A second objective of the WG was to provide views on the laboratory related Delegated Acts (DAs) and Implementing Acts (IAs) provided for in the OCR. The OCR includes two provisions for tertiary legislation in relation to OLs one of which is mandatory and two empowerments for introduction of tertiary legislation in relation to NRLs. However at the time of completion of this document there are no current plans at European Commission level to introduce this tertiary legislation so the WG has not been active to date in this area.

3. Background

This document is an output from a subgroup of the European HoA OCR Steering Group, which has been specifically reviewing issues related to food safety laboratories.

In order to establish what aspects of the OCR require clarity, specific information was sought from each authority represented on the HoA subgroup in a survey format.

The survey pointed to a number of aspects which could be clarified under each of the relevant articles of the OCR (Articles 34, 37, 38, 39, 40, 41, 42, 100 and 101) and it was agreed to promote the development of discussion papers within the sub group. The following discussion papers were developed:

- Article 34: Methods for sampling, analyses, testing and diagnoses (Section 4)
- Article 37: Template for designation of OLs (Section 5)
- Article 37(2): Designation of an OL located in another MS or a third country (Section 5.3)
- Article 37(4): Requirements for a laboratory to be designated as an OL (Section 5.5)
- Article 37(5), 40, 41 and 42: Accreditation (Section 6)
- Article 39: Audits of OLs (Section 7)
- Article 100 and 101: National Reference Laboratories (Section 8)

This document is a collation of each of the discussion papers in the order their respective Articles would appear in the OCR. In each section, the provision (Article/paragraph) requiring clarity is identified (provided in a grey box in *italics*). An outline of the reason it requires clarity is given (*Subject* sub-heading) and the WG's view on how each provision should be interpreted is stated (*Discussion* sub-heading). For a number of provisions, the WG presents their views and recommendations on how the provisions should be implemented.

The members of the HoA Food Safety Laboratories WG that developed this document can be found in Appendix 3.

4. Methods for sampling, analyses, testing and diagnoses, Article 34

4.1 Introduction

This Article specifies the laboratory methods which must be used for official sampling, analyses, tests and diagnoses. It sets a hierarchy of methods. It also includes criteria where other methods can be used in urgent situations.

4.2 Methods to comply with Article 34(1)

Article 34(1) states *"Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods".*

Subject

Article 34(1) requires compliance with “Union rules” or “performance criteria” which are not defined.

Discussion

“*Union rules establishing methods*” may be understood as the prescription in a legal document of the EU of a certain test method or method protocol which has to be followed exactly.

“*Performance criteria*” are legally set requirements a test method used for official control purposes has to fulfil at the very least. An example of performance criteria may be found in Regulation (EC) 333/2007 laying down the methods of sampling and analysis of certain contaminants in foodstuff. In such cases, the method protocol itself is not prescribed and can be chosen from existing, adapted or newly developed protocols decided by the laboratory. To comply with the legislation, the laboratories have to demonstrate by appropriate validation studies that the method as applied in the laboratory meets specific rules or criteria as laid down in the OCR.

The “*criteria*” listed in Annex III of the OCR are general characteristics that should be taken into consideration when checking for method performance and are not to be confused with the “*performance criteria*” mentioned in Article 34(1) (This means the basic requirement according to Annex III is to check a method’s limit of detection while a corresponding performance criterion could be for example a limit of detection (LOD) ≤ 1.0 µg/kg).

Note that some points in Annex III of the OCR might not apply to all types of methods. In these cases, specific legislation may apply.

4.3 Clarification of terms used in Article 34(2)

Article 34(2)(a) and (b) states *“In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs:*

a) *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;

b) *in the absence of the suitable rules or protocols, as referred to in point (a), 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*

relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols."

Subject

Article 34(2) uses the terms "*internationally recognised rules or protocols*" and "*internationally accepted scientific protocols*". Clarification is needed on the meaning and how to differentiate between these terms.

Discussion

Methods complying with "*internationally recognised rules or protocols*" should be understood as methods, rules or protocols approved and issued by international standardisation bodies (e.g. ISO, CEN and other bodies relevant for the specific areas). This includes protocols on certain analytical issues (e.g. methods standardised by the WGs under ISO TC 34 or CEN TC 275) as well as standards on general statistical principles to be applied in method validation.

As for the term "*internationally accepted scientific protocols*", the WG assumes that this specifically refers to protocols on validation. It should be understood as guidance on validation issues published by international scientific associations or societies representing expert knowledge within a scientific discipline (e.g. IUPAC, EURACHEM).

In addition, agreements reached within the network of European Reference Laboratories (EURLs) and NRLs reflects expert knowledge and should in the context of Article 34 be understood as "*internationally accepted*". This includes any Guidance documents of the EURLs that were discussed and agreed upon in the EURL/NRL network.

4.4 Hierarchy of methods given in Article 34(2)

Subject

The most suitable sequence of methods provided in Article 34(2) is not fully clear. Is there a hierarchy between the options given within Article 34(2)(a) and within Article 34(2)(b), respectively?

Discussion

According to Article 34(1) and 34(2), methods are to be applied in this order, according to the suitability for laboratories' needs. Laboratories should carefully check methods in terms of scope of application, working range and conformity with criteria, in order to comply with Article 34, as shown in this example:

A laboratory wants to analyse for a certain residue. A CEN method for this residue is available, but validated for a different commodity. In this case, the laboratory is not

obliged to apply the CEN method despite its high ranking in the hierarchy. If there is no EURL or NRL method available, the laboratory may either try to adapt the CEN method or set up an in-house method. In both cases full validation is required to show fitness for purpose and, if applicable, conformity with EU performance criteria.

1.	Article 34(1)	methods complying with Union rules establishing those methods or the performance criteria set by EU legislation
2.	Article 34(2)(a)	methods complying with relevant internationally recognised rules or protocols including those accepted by CEN or relevant methods developed or recommended by the EURL and validated in accordance with internationally accepted scientific protocols.
3.	Article 34(2)(b)	methods which comply with relevant rules established at national level or relevant validated methods developed or recommended by NRLs and validated in accordance with internationally accepted scientific protocols
4.	Article 34(2)(b)	relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols
5	Article 34(3)	Other methods (i.e. without complete validation), only if *urgently needed.*

The two alternatives in Article 34(2)(a) are to be treated as equal options, i.e. a validated EURL method may be chosen despite a CEN method being available. This decision may be based on practical considerations (e.g. workflow or instrumentation needed).

The requirement of validation "*in accordance with internationally accepted scientific protocols*" may in the case of methods developed by EURLs and NRLs be fulfilled either by ring-trial validation or by in-house validation.

Where there is uncertainty, the laboratory should consult the NRL on which methods to choose.

4.5 Method development by NRLs, Article 34(2)(b)

Subject

Article 34(2)(b) proposes that methods developed by NRLs may be used; however, method development is not listed under the NRL tasks listed in Article 101.

Discussion

Although not listed in Article 101, the continuous development and improvement of methods (which may also include optimisation of existing methods or the extension of

scope) can be seen as an additional task of the NRLs. Therefore, this task which is included in Article 34(2)(b) can be understood as meaning, in situations where no other option is available, NRLs may be expected to provide methods that they have developed. Consequently, in these situations NRLs should be granted sufficient capacity (which includes equipment, staff and time) to build up adequate knowledge in this field of work. NRLs should collaborate with the relevant EURL with an aim to improve methods.

4.6 Recommendation of methods by EURLs and NRLs, Article 34(2)(a)&(b)

Subject

In Article 34(2)(a)&(b) it is foreseen that EURLs or NRLs may recommend methods for official control. It is unclear how they should do this in practice and to what extent an EURL or NRL is obliged to check a method before recommending it for use in other laboratories.

Discussion

Reference laboratories (RLs) recommending methods for official controls on the basis of Article 34(2)(a)&(b) should give preference to methods tested in their own facilities or at the least, to methods based on techniques the RLs have gained experience with. When recommending methods taken from the scientific literature, the RLs are expected to do preliminary checks on the performance of the methods. Validation of these methods must be completed by the laboratories applying them. RLs are well advised to act in close cooperation with their network to gather available experience and to avoid recommending methods contrary with the technical conditions and instrumentation available in the laboratories.

4.7 Modifications to methods, Article 34(2)

Subject

From a practical point of view, laboratories need to be granted some room for technical improvement of methods while still complying with the OCR.

Discussion

Laboratories applying standardised methods with modifications that reflect technical progress may be in compliance with Article 34, provided the basic characteristics of the method are kept. For example, this can apply to the use of a technically related, but more specific detection system than originally specified in the standard. In any case the laboratory has to verify by appropriate validation that the performance parameters of the method are still met.

4.8 Urgent need of analyses, tests or diagnoses, Article 34(3)

Article 34(3) states *"Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols".*

Subject

Article 34(3) refers to situations where analyses, tests or diagnoses are "*urgently needed*". It is not specified further as to which situations this applies.

Discussion

An urgent need of laboratory analyses, tests or diagnoses may occur when immediate action is required, e.g. to protect consumers' health or consumers' interests or under the cases mentioned in Article 42(1)(c)[1]. Only in these cases is a laboratory allowed to deviate from the requirements of Article 34(1) & 34(2) and this should be specified in the designation agreement between the CA and the OL (section 5.3). Methods used without complete validation should be supported by expert knowledge and by basic tests on robustness and performance. In these situations, there should be close cooperation between the laboratory and the CA. Laboratories are expected to inform the CA about temporal lack of a fully validated method.

4.9 Summary

Article 34 strongly emphasises a harmonised use of methods for official control within the EU. Thus, methods defined by EU rules or performance criteria; internationally standardised methods or those developed by EURLs are given priority over options established at national level. Appropriate method validation is a basic requirement to comply with the provisions of this article.

5. Designation of official laboratories, Article 37

5.1 Introduction

Article 37 of the OCR requires CAs to designate OLs to carry out analyses, tests and diagnoses on samples taken during official controls and other official activities. The designation must be in writing and cover the areas specified in the OCR. This is a more prescriptive requirement for laboratory designation than in Regulation 882/2004.

[1] *"in cases where 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"*

Article 37 (2) of the OCR specifies requirements a MS must meet when designating an OL from another MS. The performance of audits by the CA and the designation of an OL by the CA of the MS on whose territory it is located are two of the conditions mentioned in this Article.

Article 37(4) of the OCR refers to the requirements a laboratory should meet to be designated as an OL by the CA, the CA should refer to these requirements when choosing which laboratory(s) to designate as official laboratories. This paragraph of the article refers to expertise, equipment, staff, operational capacity and the standard of the laboratory. The main points of Article 37(4) are addressed by ISO/IEC 17025. This section highlights how ISO/IEC 17025 can be used as guidance on the interpretation of the requirements of this Article.

Article 37(6) of the OCR refers to the requirements which may not be complied with in circumstances where no OL is available which has the expertise, equipment, infrastructure or staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses.

This Section discusses the designation requirements of Article 37 and suggests how they can be interpreted and complied with.

5.2 Designation of official laboratories, Article 37

Article 37 states *"The competent authorities shall designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities, in the Member State in whose territory those competent authorities operate or in another Member State or a third country that is a Contracting Party to the Agreement on the European Economic Area".*

Subject

Article 37(1) requires the CA(s) to designate OLs, but does not specify who this CA is.

Discussion

Article 3 defines CA widely, as either, the central CA of a MS responsible for the organisation of official controls and other official activities; any other authority to which that responsibility has been conferred; or where appropriate, the corresponding authorities of a third country.

It is recommended that the CA(s) that designates OLs in a MS is a central CA or a CA with central responsibility for organisation of official controls within a specific sector in the scope of the OCR.

The intent of the OCR is enhanced oversight and more detailed arrangements between the CA and the OLs. Therefore, it is important that the written designation under Article 37 is clear which body oversees OL's compliance with the requirements

of Articles 34-42, especially where this oversight function is not exerted by the designating CA. For example, the NRL may supervise certain derogations from accreditation instead of the CA. A table containing the CA's obligations related to OLs laid down in the OCR is included in Appendix 1.

It is recommended that where there is an NRL designated in the area of responsibility of the OL that their expertise may be sought by the CA to advise on technical aspects of designation and in relation to oversight of OLs.

5.3 Designation of an official laboratory located in another Member State or third country that is a Contracting Party to the Agreement on the European Economic Area, Article 37(2)

Article 37(2) states *"Competent authorities may designate as an official laboratory a laboratory located in another Member State or third country that is a Contracting Party to the Agreement on the European Economic Area, subject to compliance with the following conditions:*

- ***a)*** *appropriate arrangements are in place under which the competent authorities are enabled to perform the audits and inspections referred to in Article 39(1) or delegate the performance of such audits and inspections to the competent authorities of the Member State or third country that is a Contracting Party to the Agreement on the European Economic Area where the laboratory is located; and*
- ***b)*** *that laboratory is already designated as an official laboratory by the competent authorities of the Member State on whose territory it is located*

Subject

For some MSs, it is necessary to use OLs from other MSs as they may not have sufficient analytical capacity in their MS to analyse all the samples taken during official controls and other official activities. The designation of an OL from another MS is therefore essential for certain MSs to ensure the fulfilment of their National Control Plans.

The requirement to use an OL designated as an OL by the CA of the MS on whose territory it is located significantly restricts the number of laboratories that MSs can use.

Discussion

Article 37(2)(a) specifies that arrangements must be in place in which the CA are enabled to perform the audits and inspections referred to in Article 39(1) on laboratories designated as OLs in other MSs or third countries that are contracting parties to the EEA. These arrangements related to audits and inspections are covered in Section 7.

Article 37(2)(b) specifies that CAs may designate as an OL a laboratory in another MS or third country that is a contracting party to the EEA, where the OL is already designated as an OL by the CA of the MS or third country where the laboratory is

located. The designation of an OL in another MS is a common practice in some MSs. An example is where a MS does not have sufficient analytical capacity in their own MS to analyse all of the samples taken during official controls and other official activities. To facilitate these practices, communication between the CAs from the different MSs in relation to the OLs they have designated and the OL's capacity to analyse samples from a CA in another MS is therefore important. This is in recognition that some MSs' designated OLs are publically funded government laboratories that, may not accept external samples.

The designation of a laboratory in another MS or third country should be:

- A formal written designation (See Section 5 relating to Article 37(3))
- Subject to official communication of the designation by the CA in the designating MS. This could ideally be an internet publication and could include a list of OLs and their capacity to analyse samples from other MSs.
- Available from a central contact point in each MS - this could be the central contact point for the Multi-Annual National Control Plan.
- Notified to the CA in the MS or third country in which the laboratory is located to facilitate communication between the CAs in both MSs on any matters relating to the laboratory designation.

Agreements should be promoted between MSs i.e. recognition between MSs where there is a need for a MS to use an OL designated in another MS.

Where it is necessary for a MS to use an OL in another MS or a third country the following options should be considered (in descending order of preference):

1. Use an OL in another MS or third country designated by the MS in which it is located
2. When the OL is not a designated OL in the other MS or third country, a request should be sent to the other MS or third country to designate the laboratory as an OL
3. To use subcontracting via a designated OL in the MS. It is recommended that subcontracting is only used for analysis, tests or diagnoses performed on small sample numbers or for infrequent testing

5.4 Written designation

Article 37(3) states *"The designation of an official laboratory shall be in writing and shall include a detailed description of:*

a) the tasks that the laboratory carries out as an official laboratory;
b) the conditions under which it carries out the tasks referred to in point (a); and
c) *the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities".*

Subject

Article 37(3) does not specify the procedure for the designation of an OL other than it is the responsibility of the CA and that the designation should be in writing.

Discussion

The designation of an OL could be done through administrative procedure, in national law and/or in service level agreements. MSs' CAs can determine the procedure for designation but there should be a formal process.

For instance in some MSs there is a legal framework that OLs must comply with, which may include conditions such as; the obligation of the laboratory to become and remain an approved or designated OL, to be accredited to ISO/IEC 17025, to follow the instructions of the CA and the NRLs, to comply with the obligation to notify the CA of non-compliant analytical results, to report results in a particular official format (i.e. a template for official result certificates) and the right for the CA to carry out an audit or inspection at any time during the duration of the approval or designation.

While it is not specified in the OCR it is recommended that each MS publish a list of the OLs they have designated. The list should be published on a central website and contain a link to the MSs' multi-annual national control plan (MANCP) that is already done by a number of MSs. Ideally this list should indicate if OLs will accept official control samples from other MSs to facilitate a MS's compliance with obligations in the OCR relating to the use of OLs in other MSs.

A proposed template for the written designation, which covers the elements of Article 37 discussed below, is included in Appendix 2.

Subject

Article 37(3)(a) does not define the "*tasks*" a laboratory carries out as an OL.

Discussion

The "*tasks*" are not defined in Article 37(3)(a) but it is recommended that all the testing and related functions the laboratory carries out when it is acting as an OL are specified in writing with details such as:

- Whether the tasks are for official controls and/or other official activities
- The analyses/tests/diagnoses and matrices for which the laboratory is designated as an OL
- Any additional tasks agreed between the laboratory and CA such as official control sampling or reporting statements of conformity as referred to in Section 7.8.6 of ISO/IEC 17025

The written designation should provide sufficient detail to ensure clarity between the CA and OL on the OLs tasks, in particular where the laboratory also carries out other non-official control analysis/tests/diagnosis such as on a private or commercial basis.

Subject

Article 37(3)(b) does not define the "*conditions*" under which a laboratory carries out the tasks referred to in point (a).

Discussion

The conditions could be understood as all of the requirements and obligations of OLs in Article 34-42. It is recommended that the written designation includes a general statement that the laboratory operates in accordance with the requirements of the OCR. For the purpose of clarity it is recommended to also specify:

- The methods the laboratory is required to use to ensure compliance with Article 34 including any specific methods (see Section 4 dealing with Article 34)
- Expertise, equipment, staff, infrastructure etc. the laboratory should provide (see Section 5 dealing with Article 37(4))
- Scope of accreditation - Article 37(5) requires the OL's scope of accreditation to include the methods used by the laboratory when acting as an OL, subject to a number of derogations. The CA or NRL or in the case of *Trichinella* laboratories an OL, must supervise these derogations. Therefore, it is recommended to set out in writing the specific conditions including:
    - the requirement for the laboratory to be ISO/IEC 17025 accredited for all methods of analyses/test/diagnosis used by the laboratory when operating as an OL; or
    - state the derogation from accreditation and the additional conditions associated with the derogation
    - where the laboratory is availing of permanent derogations from accreditation[2] under Article 40 (1)(a) and (b), i.e. laboratories whose sole activity is detection of *Trichinella* in meat or laboratories only carrying out other official activities
- Where the laboratory is availing of temporary derogations under Article 42 additional conditions should be specified, such as:
    - the specific circumstances in which a temporary derogation may be sought[3]
    - the procedures between the CA and OL where the OL needs to avail of the derogation
    - how the CA or, where relevant the NRL, will supervise the testing carried out by the OL while availing of the temporary derogation
    - the time limit for this derogation[4]

[2] Article 41 empowers the Commission to adopt other additional derogations from mandatory accreditation
[3] Article 42(1) when use of method newly required by Union rules; when changes to method in use require a new accreditation or an extension of the scope of the accreditation or in cases where 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.
[4] Shall not exceed one year but may be renewed once for a further period of 1 year (Article 42)

    - Arrangements to ensure results indicating a risk or non-compliance are reported by the OL to the CA immediately. The written designation should set out clearly what constitutes a risk and non-compliance, to whom in the CA this information should be reported to and by what means (Article 38(1))
- Requirement for the OL to cooperate with the NRL in their respective area of competence, where an NRL has been designated
- Requirement for the OL to, on request, participate in EURL or NRL inter-laboratory comparative or PTs (Article 38(2))
- Any other national, EU or international legislation, standards or guidelines relevant to the designation that the OL must comply with

Subject

Article 37(3)(b) does not define the "*arrangements*" necessary to ensure efficient and effective coordination and collaboration between the laboratory and the CA.

Discussion

It is recommended to include a schedule for liaison, coordination, auditing and reporting between OLs, CAs and other bodies to whom specific OL functions have been assigned, such as the NRL. This could include a schedule for meetings, any reports to be provided by the OL to the CA, such as reports of PT results, updates to accreditation, and audit outcomes. It is also useful to include a regular review period of the written designation to facilitate any updating necessary.

Other obligations recommended for inclusion in the written designation:

- The circumstances under which the OL designation may be withdrawn or modified (Article 39 (2))
- A requirement to provide additional information on an OL's methods used for analysis, tests or diagnoses that may have been developed based on Union rules or international standards, where there is ambiguity about the method and its compliance with Article 34, i.e. in-house method
- A requirement to make the names of methods used for official control and/or other official activity available to public (Article 38), on the request of the CA
- The turnaround time for delivery of results (Article 37(4)(d))
- The arrangements to ensure the CA and, where relevant, the NRL are informed in a timely manner of underperformance in any PT relevant for official testing.
- Any conditions relating to the subcontracting of tests, analysis or diagnoses, where relevant. ISO/IEC 17025 recognises that externally provided laboratory activities can occur and provides requirements for this. However, the OCR does not mention whether subcontracting by an OL is permitted. If for any reason an OL is unable to carry out an analysis or test, it may be necessary to sub-contract

to another laboratory in an EU MS or country in the EEA which is accredited to ISO/IEC 17025 and is suitably qualified to carry out the sub-contracted tasks. The laboratory may also be designated as an OL by the CA of the MS in which it is located. It is recommended that where subcontracting is required, additional criteria should be included in the written designation such as:

- Subcontracting by an OL should be done in line with the procedures for using externally provided products and services as part of the laboratory's quality management system[5]. This should include a provision that subcontracted laboratories are accredited to ISO/IEC 17025 for the subcontracted analysis/test/diagnosis except under exceptional circumstances which should be in line with the derogations from accreditation permitted for OLs.
- Subcontracting should only be used for occasional or infrequent testing. If this testing is a regular requirement it is recommended to designate the subcontracted laboratory as an OL.
- The OL that is subcontracting should be responsible for ensuring that the subcontracted laboratory also complies with the requirements of the OCR. The OL should have oversight of the subcontracted laboratory including, where necessary, auditing the laboratory on a risk basis. See Section 5.3 regarding the use of laboratories in other MSs or third countries that are contracting parties to the EEA.

5.5 Requirements laid down in Article 37(4)

Article 37(4)(a) states *"The competent authorities may only designate as an official laboratory a laboratory which:*

a) *has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;"*

Subject

Article 37(4) specifies that OLs are required to have "*expertise, equipment and infrastructure*" for them to carry out analyses, tests or diagnoses on samples.

Discussion

Article 37(4)(a) is self-explanatory and is covered by paragraphs 5 and 6 of ISO/IEC 17025. An OL should be able to carry out the tests which it has been requested to do. Therefore if a laboratory has ISO/IEC 17025 accreditation, it would satisfy this requirement of Article 37(4).

Article 37(4)(b) states *"The competent authorities may only designate as an official laboratory a laboratory which:*

[5] Section 6.6 ISO/IEC 17025:2017

b) *has a sufficient number of suitably qualified, trained and experienced staff;"*

Subject

It is not specified what is required for "*suitably qualified, trained and experienced staff*".

Discussion

This criteria is addressed in ISO/IEC 17025. Therefore, if a laboratory is accredited to this standard, these aspects will be addressed.

- Sufficient number of staff – i.e. enough staff to ensure the smooth operation of the laboratory and for it to manage and perform its duties.
- Suitably qualified staff – i.e. personnel in the laboratory have the competence to perform the activities for which they are responsible.
- Suitably trained staff – OL shall be accredited for the methods used in accordance with ISO/IEC 17025. This is awarded on the basis that the laboratory has suitably qualified staff undertaking the analyses for official controls. ISO/IEC 17025 requires that a laboratory has procedures in place to fulfil competence requirements, training, performance, appointment, supervision and management of laboratory staff. There should be documented records of the above criteria for all laboratory staff and for the work that they are undertaking to ensure that appropriately trained staff are undertaking the duties assigned to them.
- Experienced staff should have satisfied the criteria for suitably trained staff as covered in the accreditation/certification processes. Staff should be authorised to perform specific activities including:
    - Development, modification, verification and validation of results,
    - Analysis and interpretation of results,
    - Reporting, review and authorisation of results.

OLs that are derogated from mandatory accreditation (e.g. for *Trichinella* testing), where possible should follow the specific provisions of ISO/IEC 17025 as listed above to ensure compliance with Article 37(4).

Article 37(4)(c) states *"The competent authorities may only designate as an official laboratory a laboratory which:*

c) *ensures that the tasks conferred upon it as set out in paragraph 1 are performed impartially and which is free from any conflict of interest as regards the exercise of its tasks as an official laboratory;"*

Subject

It is not specified how an OL would address the requirement to perform tasks impartially.

Discussion

ISO/IEC 17025 addresses impartiality and states that laboratories shall not allow commercial, financial and other pressures to compromise impartiality. This should always be addressed in audits organised or performed by either the CA, NRL or National Accreditation Body (NAB).

If a commercial laboratory is designated as an OL, CAs should seek additional assurances regarding conflict of interest and impartiality. The laboratory should be able to demonstrate that measures are in place to avoid and address any conflicts that may occur, involving staff or the operation of the laboratory.

Article 37(4)(d) states *"The competent authorities may only designate as an official laboratory a laboratory which:*

d) *can 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"*

Subject

It is not specified what is meant by "*in a timely manner*".

Discussion

This timing should be agreed between the CA and the OL and is dependent on the type and nature of the official controls being performed. Where necessary or possible, this should be agreed in advance of the samples being sent to the laboratory and details of the requirements for delivering results on official control samples should be included in the designation document.

Article 37(4)(e) states *"The competent authorities may only designate as an official laboratory a laboratory which:*

e) *operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008."*

Subject

All OLs must be accredited in accordance with ISO/IEC 17025.

Discussion

All OLs shall have ISO/IEC 17025 accreditation in order to meet the designation criteria for an OL. The main criteria in Article 37(4) are satisfied if the laboratory is accredited to this standard for the methods used for official controls. This is already a requirement under Regulation 882/2004 and should therefore not be an issue for any existing OLs.

5.6 Where no official laboratory designated in the Union or in a third country that is a Contracting Party to the Agreement on the European Economic Area is available, Article 37(6)

Article 37(6) states *"Where no official laboratory designated in the Union or in a third country that is a Contracting Party to the Agreement on the European Economic Area in accordance with paragraph 1 has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which does not comply with one or more of the requirements set out in paragraphs 3 and 4 to carry out those analyses, tests and diagnoses."*

Subject

The recommendation in Article 37(6) for a CA to check every OL in every MS will be very challenging and difficult in practice. It is not clear how a CA will check all MSs for an OL which has the "*expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses*"?

Discussion

As a first option, the CA should designate an OL located in their MS or in another MS. This Article allows for another laboratory "*To perform new or particularly uncommon laboratory analyses, tests or diagnoses"* even if it does not comply with the requirements set out in paragraphs 3 and 4 of Article 37 to carry out those analyses, tests and diagnoses.

The absence of expertise, staff or impartiality could compromise the results of official control testing and should only be accepted in exceptional cases. As good practice, the laboratory could consult with an NRL in a related area, where available, or an NRL in another MS in relation to the methods of laboratory analysis, test or diagnoses.

To aid with the implementation of this Article it would be useful if the European Commission set up a Focal Point network to deal specifically with laboratory related issues. Each MS would nominate a central Focal Point and it would be responsible for disseminating relevant information and coordinating responses to requests for information in its MS.

5.7 Summary

The CA and OL should ensure that the written designation document between them is sufficiently detailed and clear to facilitate compliance with the requirements of the OCR and ensure that results obtained through official control testing are legally robust. The requirements of Article 37(4) can be achieved by OLs if they have ISO/IEC 17025 accreditation for the methods used in official controls. Therefore, CAs should be able to interpret that the requirements of this Article are met if the laboratory is accredited

to ISO/IEC 17025 for the methods they use. If the laboratory is also testing commercial samples the CA should pay special attention in these cases to ensure the laboratory is impartial.

It is commonplace for MSs' CAs to use laboratories in other MSs or third countries that are contracting parties to the EEA for their official testing. In particular, in smaller MSs it may not be feasible for the available OLs to fulfil all official testing requirements. The European Commission and EURLs can facilitate compliance with this article by ensuring information is easily available on official control laboratory testing available in all MSs and third countries that are contracting parties to the EEA.

To comply with Article 37(6), where no OL has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the CA should request an NRL in a related area or the NRL in another MS. As a recommendation, it would be useful if a central European organisation set up a Focal Point Network that would deal with laboratory related technical issues.

6. Accreditation, Articles 37(5), 40, 41 and 42

6.1 Introduction

Regulation 882/2004 required OLs to be ISO/IEC 17025 accredited but was not specific on the scope of accreditation. The OCR addresses this by providing more detail on the accreditation requirements and includes conditions under which a laboratory can be derogated from accreditation. This Section discusses the accreditation requirements of the OCR and suggests how they can be interpreted.

6.2 Accreditation requirements of Article 37

Article 37(4)(e) states *"The competent authorities may only designate as an official laboratory a laboratory which:*

1) *operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008".*

In addition, Article 37(5) states *"The scope of the accreditation of an official laboratory as referred to in point (e) of paragraph 4:*

a) 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 official laboratory;
b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
c) 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 official laboratory 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."

Subject

Article 37(5) requires that the scope of accreditation includes those methods required to be used by the laboratory when it operates as an OL. This is considerably more prescriptive than Regulation 882/2004.

Discussion

While "*methods*" are referred to, the intent appears to be that laboratory results reported as official controls shall all be accredited unless specifically derogated from accreditation under Article 40, 41 and 42.

Reporting results as accredited is an important component of demonstrating that official results used as part of official controls are robust and reliable. However, it is noted that achieving and maintaining the scope of accreditation required under the OCR may pose challenges and some provisions have been included in the OCR to address this:

- Flexible Scope (Article 37(5)(c))

The OCR allows that accreditation may be granted through flexible scope accreditation. Flexible scope has the potential to allow laboratories to expand their scope of accreditation more quickly in response to official testing needs. It is recommended that the CAs work with their NABs to ensure that flexible scope is available to OLs and NRLs where necessary.

- Derogation from accreditation (Articles 40, 41 and 42)

Derogations from accreditation are provided in Articles 40, 41 and 42. In all cases the CA should be involved in the decision to avail of derogations from accreditation. It is recommended that where there is an NRL designated in the area of responsibility of the OL, that their scientific expertise is sought to advise on derogations from accreditation and that they have a role in the oversight of these derogations.

Types of derogation:

1) Permanent derogation for certain OLs (Article 40)
   This only applies to:
   - *Trichinella* testing laboratories (Article 40(1)(a)) do not require accreditation for any methods used for detection of *Trichinella* in meat. *Trichinella* detection must be carried out under the supervision of the CA or a designated and accredited OL for *Trichinella*. The laboratory must comply with the specific aspects of Article 40(1)(a).

- Laboratories only carrying out analyses/tests/diagnosis as other official activities[6] (Article 40(1)(b)) do not require accreditation for any methods used for other official activities, however, the testing must be done under the supervision of the CA or NRL and comply with the specific aspects of Article 40(1)(b).

2) Permanent derogation from the requirement to have all methods accredited for certain OLs as derogated by the Commission (Article 41)

   The Commission has the power to adopt legislation that allows CAs to derogate certain methods from the requirement to be accredited. The laboratory itself would still have to be accredited. It is expected that this derogation will be limited to plant health and certain animal health methods. This derogation will not be available unless the Commission adopts delegated legislation under this empowerment. No legislation permitting permanent derogations has been introduced to date (May 2019),

3) Temporary derogations from mandatory accreditation (Article 42)

   This derogation only applies to existing accredited OLs. It is likely that this derogation may need to be used occasionally due to the circumstances outlined in Article 42(1). This derogation is time-bound to one year but can be renewed once for another year (i.e. 2 years maximum). Therefore, CAs and OLs will need to ensure they have a means of tracking the time period associated with the use of this derogation.

   In order for temporary derogations to be effective, the CA must be in a position to act quickly to authorise temporary derogations.

   The use of derogations puts an additional responsibility on the CAs and/or NRLs to supervise and oversee the laboratory in these situations. The process for agreeing and overseeing use of derogations should be documented in the written OL designation document to aid compliance with the OCR.

   A CA can only grant a temporary derogation for an OL in its own MS. This will be challenging to comply with for CAs that have designated OLs in other MS. The OL in the other MS cannot be used for official control testing for the relevant test until it is accredited, unless the CA in the MS where the OL is located grants it a derogation and oversees its use. It is recommended that CAs from MSs that are affected by the abovementioned issue seek agreement on the provision of derogations with the CA of the relevant MS in advance of a laboratory being used.

[6] Article 2(2) defines other official activities as "*activities, other than official controls, which are performed by the competent authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated …including activities aimed at verifying the presence of animal diseases or pests of plants, preventing or containing the spread of such animal diseases or pests of plants, eradicating those animal diseases or pests of plants, granting authorisations or approvals, and issuing official certificates or official attestations".*

6.3 Summary

OLs must be accredited for all official testing unless specifically exempt under the derogations provided, which includes permanent and temporary derogations. Achieving and maintaining accreditation for all testing may be challenging especially for laboratories providing a wide range of analyses, tests or diagnoses in a variety of matrices. Laboratories should consider options such as flexible scope accreditation to facilitate compliance with this requirement.

Use of derogations from accreditation requires oversight by CAs and where relevant NRLs. There should be clear lines of responsibility and communication established between the CA or NRL and OL in these cases. The provision of derogations for OLs designated in other MSs may pose additional challenges for CAs.

7. Audits of official laboratories, Article 39

7.1 Introduction

Article 39 obliges CAs to organise audits of the OLs they have designated. The condition in which the designation of an OL is withdrawn by the CA is also established. This Article does not identify who should carry out audits and is not explicit on what is meant by some of the terminology used, i.e. underperformance. This section aims to elaborate on who can be involved in audits of OLs and give clarity on certain terminology used.

7.2 Audits of official laboratories by the Competent Authority, Article 39(1)

Article 39(1) states *"The competent authorities shall organise audits of the official laboratories they have designated in accordance with Article 37(1) 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 referred to in point (e) of Article 37(4)".*

Subject

Article 39(1) does not specify who is responsible for carrying out audits of OLs and who may be involved in the audit process.

Discussion

Article 39(1) indicates that the CA is responsible for the organisation of the audits, but does not stipulate that they must perform the audits. It may be possible to involve other CA(s), the NAB, delegated bodies and NRLs in the auditing process.

Although the task of auditing OLs is not mentioned as one of the tasks of a NRL (Article 101), experts of the NRL may be included in an audit team as a technical expert. Otherwise, depending on the scope of the audits, the CA may nominate the NRL as

the primary body responsible for organising and conducting the audit. This role is implied for the NRL.

For the NAB, in general, accreditation with ISO/IEC 17025 is a prerequisite for an OL (Article 37(4)(e), with exceptions being mentioned in Article 40). Therefore, almost all OLs will be already audited by their NAB on a regular basis. Moreover, Article 39(1) states that the CA might "*find such audits to be redundant considering the accreditation assessment*" by the NAB. On this basis, an assessment of the audit report generated by the NAB may be used in the audit system of a CA, and might in certain cases be sufficient to meet the requirements of Article 39. However, it should be considered that these audits by the NAB mainly concern the requirements of ISO/IEC 17025 and not the specific requirements, tasks and obligations mentioned in Articles 34, 37 and 38 of the OCR. Therefore additional audits and audit criteria need to be considered. As a solution, the NAB could be asked by the CA to include additional criteria in their audit system. The feasibility of adding these additional audit criteria to the audits carried out by the NAB will depend on the NABs capacity to do so, costs associated with the additional audit criteria, but also the specialised area in which the laboratory operates.

To avoid duplication of audits, as a minimum the CA should oblige the OL to make available the annual NAB surveillance reports upon request.

Subject

It is not clear what is meant by "*On a regular basis*" and on what criteria "*considered necessary*" should be based?

Discussion

The CA may decide what frequency is needed. The frequency should be risk based and should consider factors such as the accreditation status of the laboratory, whether the laboratory is availing of a temporary derogation from accreditation for methods, results of previous audits by the CA and/or NAB, volume of sub-contracting, results of PTs, signals of non-compliance (e.g. underperformance in PTs, complaints, unusual/unexpected trends in results or other signals of lack of confidence in the laboratory), volume of commercial activities, etc. It is not desirable to give a general definition for what is meant by "on a *regular basis*" in Article 39(1). The frequency that a CA organises audits of OLs will depend on several factors such as the laboratories specialised area and the type of laboratory.

Subject

It is not clear under what circumstances the CA may "*find such audits to be redundant considering the accreditation assessment referred to in point (e) of Article 37(4)".*

Discussion

The CA can decide, based on the audits performed by the NAB, and/or based on other criteria as mentioned in discussions on Article 39(1), that an audit organised by the CA is unnecessary. For audits of OLs, the criteria set out in ISO/IEC 17025 are a priority; however, without including additional audit criteria it may not be sufficient to fulfil the audit requirements of the OCR. Therefore, the decision to find CA audits redundant should be risk based and consider factors such as whether a laboratory also operates as a commercial laboratory, where there may be a higher risk or conflicts of interest or partiality.

As an example of good practice:

1. Audits and inspections of the OL could be performed according to the situation:
    a. Before the approval of a laboratory, the central CA may choose to perform an audit of the laboratory
    b. During the ISO/IEC 17025 audits, the CA may accompany the accreditation body on their audits with an aim to check additional audit criteria not covered in ISO/IEC 17025
    c. Audits are also possible as part of the annual control plan
    d. In case of suspicion or finding of non-conformity (complaints, findings during an audit, etc.)
2. The audits frequency could be planned according to the following criteria:
    a. The volume and range of analyses performed as an OL and whether private or commercial samples are also tested by the laboratory
    b. Any findings of non-compliances with the instructions of/requirements of the CA (complaints, etc.)
    c. The results of previous audits or inspections
    d. The frequency of previous audits
3. The audits and inspections are performed by the CA (accompanied by experts from the NRL, if required), the NRL (accompanied by expert from the CA, if required) or the NAB (accompanied by expert from the NRL or CA, if required).

In addition, the CA could implement an (multi-) annual audit plan in which the audits are described and planned based on a risk assessment. A risk based matrix to decide on audit frequency could also be developed.

7.3 Withdrawal of an official laboratories designation, Article 39(2)

Article 39(2) states *"The competent authorities shall immediately withdraw the designation of an official laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit provided for in paragraph 1 which disclose any of the following:*

a) it no longer complies with the conditions provided for in Article 37(4) and (5);
b) it does not comply with the obligations provided for in Article 38;
c) *it is underperforming at inter-laboratory comparative tests referred to in Article 38(2)".*

Subject

It is not clear from Article 39(2) what is meant by "*underperformance*"?

Discussion

"*Underperformance*" is not defined specifically in ISO/IEC 17043 (*Conformity assessment – General requirements for proficiency testing*). Instead, ISO/IEC 17043 classifies results of comparative tests, which are typically indicated in terms of z-scores, as "satisfactory", "questionable" (a warning signal) or "unsatisfactory" (an action signal).

As Article 39(2)(c) refers to "*tests*" in the plural form, this implies that the history of a laboratories PT results should be considered. Thus, "*underperformance*" may be understood as a repetition (more than one isolated event) of questionable or unsatisfactory results in comparative tests in a certain area of competence that calls for intervention by the CA. Instances of repeated unsatisfactory results may be discovered as part of an audit and require intervention where the laboratory fails to take appropriate and timely remedial action.

It is recommended that the CA carries out, on a case-by-case basis, an assessment of the appropriateness of the laboratories investigation following the incidence of "*underperformance*" and implemented corrective measures taking into consideration the analyte (measurand), technique and commodity. The NRL coordinating the comparative tests which produced the results in question should provide the CA with technical assistance in such cases.

In order to fulfil the responsibilities mentioned in this Article the designating CA should have a strong link with bodies that carry out audits on its behalf or on who's audit information it relies e.g. another CA, the NRL or the NAB. This stresses the need for a robust audit plan and coordination of the CA.

The CA that designates the OL should be notified at least annually:

1. By the NRL of the outcome of the comparative studies they organise or carry out in the event of underperformance of an OL in an inter-laboratory comparative test. The CA should be notified when the comparative study is completed.
2. By the auditing body with the obligation to perform audits on OLs in the event of a finding of underperformance in an inter-laboratory comparative test observed during an audit. A notification should be sent to the CA immediately after the audit is completed.

There are other circumstances were it would be justified for a CA to withdraw the designation of an OL. For example, if an OL is found to be non-compliant with Article 37(4), Article 37(5) or Article 38 on the basis of information gathered via questionnaires. Similarly, a withdrawal of an OL's designation would be justified if there is underperformance or a repeated unjustified lack of participation in a PT organised by the NRL which has been notified to the CA by the NRL.

7.4 Summary

Article 39 obliges CAs to organise audits of OLs which they have designated in accordance with Article 37. This article does not specify who should perform the audits of OLs. Therefore, it can be understood that the CA can delegate or involve other bodies in the audits of OLs, such as the NAB or the NRL. To avoid duplication of audits, it is recommended that audits carried out by the NAB relating to accreditation include additional criteria to determine an OLs compliance with the requirements of the OCR, or otherwise a member of the NRL or CA could accompany the NAB on audits to cover the additional OL requirements of the OCR. In these situations consideration should be given to any additional audit costs that may arise. As a minimum, it is recommended that the OL makes the NAB annual surveillance reports available to the CA on request

The frequency of audits and whether audits may be deemed redundant considering the accreditation assessment by the NAB, should be a risk based decision and depend on a number of factors such as, performance in PTs, complaints, unusual/unexpected trends in results, etc. The withdrawal of an OL's designation shall occur were an OL fails to take timely remedial action following repeated questionable or unsatisfactory results in a comparative test or where it fails to comply with the criteria laid down in Articles 37(4), 37(5) or 38.

8. National Reference Laboratories (NRLs), Article 100-101

8.1 Introduction

In this section, some laboratory obligations of an NRL are discussed and how these obligations can be met.

8.2 Designation of National Reference Laboratories, Article 100(3)

Article 100(3)(a) states *"National reference laboratories shall:*

a) *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 as regards the exercise of their tasks as national reference laboratories;*"

Subject

In this section it is considered how an NRL that operates also as an OL could fulfil its obligation to be impartial and free from conflict with regards to its role as an NRL over its OL operations.

Discussion

It is often the case that an NRL also acts as an OL for the area of analysis over which it has responsibility. This duality could be necessary for highly specialised analytical

methods or where resources are limited, as would be the case in small MSs. However, this is not considered to constitute a conflict of interest so long as the laboratory can demonstrate to have put in place systems and procedures to demonstrate its impartiality when operating as both an OL and NRL.

Article 100(3)(d) states *"National reference laboratories shall:*

d) *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;"*

Subject

In this section it is considered how an NRL can ensure their staff meets the requirements laid down in this paragraph.

Discussion

To meet this obligation, NRLs should encourage their staff to be involved in or at least follow the work of international standards organisations such as ISO, CEN, IDF, NMKL, etc. as a means of ensuring that staff remain up to date with scientific and policy developments. The EURL-NRL network is an ideal way to encourage the sharing of information in this area.

Article 100(3)(e) states *"National reference laboratories shall:*

e) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations;"

Subject

The meaning of "*emergency situation*" is not specified further so it is unclear what requirements the NRLs must meet.

Discussion

"*Emergency situation*" has a similar meaning as the situation described in Article 34(3). ("*Where laboratory analyses, tests or diagnoses are urgently needed*…"). Therefore, the terms "*emergency situation*" may similarly be understood as a compelling need to take immediate action to protect consumers' health or consumers interests or in case of an emerging risk.

To perform well in such situations, an NRL should have the capacity (equipment, staff, time) and knowledge to fulfil the complete list of tasks in Article 101(1). Tasks that might otherwise be treated as optional such as Article 101(1)(c), (f), (g) could be of particular importance in an "emergency situation" to achieve an adequate and uniform level of analytical performance among the laboratories involved.

Consequently, "*necessary equipment*" (or access to) for emergency situations would mean that an NRL is in a position to fulfil the complete list of tasks in Article 101(1) regardless of its regular work schedule.

Additionally, NRLs should be capable to develop or examine test methods (see Article 34), as it could be assumed that in case of an emerging risk there may be no standardised methods available.

Article 100(3)(f) states *"National reference laboratories shall:*

f) *where relevant, be equipped to comply with relevant biosecurity standards".*

Subject

In this section it is considered in what circumstances an NRL would need to be equipped to comply with relevant biosecurity standards.

Discussion

The Working Group considers that this requirement is also addressed in Article 100(3)(b) ("*staff*") and Article 100(3)(c) ("*infrastructure*"). However, there is a role for the EURL in providing the NRLs with guidance on the "*biosecurity standards*" which relate particularly to their area, or if these do not exist, general standards such as CWA 15793 (CEN workshop agreement CWA 15793 Laboratory biorisk management).

8.3 Responsibilities and tasks of National Reference Laboratories, Article 101

Article 101(1)(c) states "*National reference laboratories shall, in their area of competence:*

c) where appropriate, organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;"

Subject

Article 101(1)(c) does not mention PTs available from commercial providers and requirements for PTs to be accredited.

Discussion

Although there is no specific requirement for PTs to be accredited in the OCR, it is recommended that where feasible they are accredited to ISO 17043:2010.

It is also not stated whether proficiency testing, which is a NRL-EURL task, can be subcontracted to commercial providers. Where commercial PT providers are used it is recommended that accreditation to ISO 17043:2010 is a prerequisite.

Article 101(1)(f) states *"National reference laboratories shall, in their area of competence:*

f) 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;"

Subject

In this section it is considered in what circumstances ("*where relevant"*) an NRL would have to validate the reagents and lots of reagents and how this responsibility relates to the obligation of an EURL to verify the quality of reagents in accordance with Article 92(2)(j). An opinion is presented on how the task would be better delivered jointly by the EURL-NRL tandem.

Discussion

The validation of reagents and lots of reagents is a responsibility unique to NRLs as it is absent from the list of EURL responsibilities. The closest task of the EURL relates to the verification of the quality of reagents and this is only concerned with the diagnosis of foodborne, zoonotic, animal and plant diseases. There seems to be an inconsistency between EURL and NRL tasks in this regard. The EURL is "*verifying quality of reagents*" while the NRL is "*validating reagents*". Clarification is required on the difference between these activities, as it is considered that the threshold for validation is higher than for verification.

The EURL, contrary to the NRL, has *responsibility for "coordinating or performing tests for the verification of the quality of reagents and lots of reagents",* and as validation of reagents and lots of reagents would necessitate a level of co-ordination, this is an additional reason for considering that the EURL should carry out this task. A guidance document from EURLs setting out in more detail how this responsibility should be exercised by NRLs would be welcomed.

8.4 Summary

The provisions of Articles 100 and 101 on NRLs are relatively self-explanatory. However, some guidance is given on how to interpret certain requirements and responsibilities of NRLs. In particular, the responsibility of the NRL to validate reagents needs clarification. This question has been raised with the Commission by the Working Group.

In relation to the designation of an NRL by the CA, it is recommended that the CA has a stand-alone written designation for NRLs that is similar to the written designation that is required for an OL. In cases where an NRL is situated outside the designating MS, there is no requirement in the OCR for this laboratory to have been designated as an NRL or OL by the MS where the laboratory is situated.

For clarification, it was concluded by the Working Group that a NRL can act as an OL at the same time without causing a conflict of interest.

9. Concluding remarks

The OCR which entered into force in April 2017 expands considerably on the laboratory requirements currently in Regulation 882/2004. This follows on from a 2014 European Commission Santé F overview report on laboratories that identified a number of horizontal issues in MSs' laboratories. The OCR incorporates some additional requirements to address these issues.

The primary objective of this Heads of Agencies WG on Food Safety Laboratories was to review the relevant obligations of the CAs and OLs in the OCR with a view to achieving a common understanding and prepare opinions on the new requirements. This document considered five main areas including: methods for sampling, analyses, testing and diagnoses; designation of official laboratories; accreditation; audits of OLs; and NRLs. These areas were considered in detail by the WG members who were representative of a range of EU MSs, CAs, OLs and NRLs.

In summary some of the key points the working group noted are:

- The OCR strongly emphasises a harmonised use of methods for official sampling, analyses, tests and diagnoses. Thus, methods defined by EU rules or performance criteria; internationally standardised methods or those developed by EURLs are given priority over options established at national level. Appropriate method validation is a basic requirement to comply with the provisions of this article.
- The OCR specifies that the CA must have a written designation with the OLs they designate. A written designation document should provide sufficient detail to facilitate and ensure clarity on an OLs obligations under the OCR and ensure that results obtained through official control testing are legally robust. Many of the requirements of designated OLs set out in the Regulation are also contained in ISO/IEC 17025 and an OL's accreditation to this standard will demonstrate compliance with a number but not all of the requirements of the OCR.
- It is commonplace for MSs' CAs to use laboratories in other MSs or third countries that are contracting parties to the EEA to fulfil their official testing requirements. The European Commission and EURL can facilitate the CAs, in fulfilling the obligations relating to OLs when such laboratories are designated, by ensuring information relevant to this Regulation is accessible on official control laboratory testing available in other MSs and third countries that are contracting parties to the EEA.
- Reporting results as accredited is an important component of demonstrating that official results used as part of official controls are robust and reliable. The mandatory accreditation of official control testing, unless specifically exempt under one of the derogations provided, will be a challenge for some areas, particularly for laboratories with a wide range of analyses, tests or diagnoses

for a variety of matrices. Laboratories should consider options such as flexible scope accreditation to facilitate compliance with this requirement. The use of derogations from accreditation will require clear lines of responsibility and communication between the CA or NRL and the OL in these cases.

- The CA has a responsibility under the OCR to organise audits of designated OLs unless they are deemed redundant due to ISO 17025 audits. As it does not specify who should perform the CA audits, it is understood that NABs or NRLs can be delegated or involved in the task of auditing OLs. To minimise duplication of audits, it is recommended that CAs and NABs consider whether audits performed by the NAB related to accreditation can include additional criteria to determine an OLs compliance with the full requirements of the OCR. The frequency of audits and whether they may be deemed redundant considering the accreditation assessment by the NAB should be a risk based decision and depend on a number of factors.
- With respect to NRLs the responsibilities and tasks are clear. However, certain provisions such as the responsibility of NRLs to validate reagents and lots of reagents will present challenges to NRLs, will not be necessary in many cases and require clarification. For the designation of an NRL by the CA, it is recommended that the CA has a stand-alone written designation for NRLs, similar to the written designation between CAs and OLs.

In conclusion, the OCR is more prescriptive than Regulation 882/2004 and has increased obligations for CAs, NRLs and OLs. This document provides interpretation and recommendations on laboratory related aspects of the OCR to support CAs, NRLs and OLs in their compliance with the OCR. It also identifies some points which require clarification.

Appendix 1 - CA obligations/functions in relation to designated official laboratories, Articles 37-42

Reg. 2017/625 reference	Summary of legislative requirements
Article 37(1)	CAs shall designate OLs with a detailed written designation
Article 38(1)	CA that designated the OL must be informed by the OL where results indicate a risk or point to likelihood of non-compliance
Article 39(1)	CA shall audit the OLs they have designated
Article 39(2)	CAs shall immediately withdraw designation of OLs where the OL fails to take appropriate and timely remedial action following results of a CA audit that disclose non-compliance
Article 40(1)(a)	CA may designate an official *Trichinella* laboratory that does not fulfil accreditation requirements provided *Trichinella* testing is carried out under the supervision of the CA or an official accredited *Trichinella* laboratory
Article 40(1)(b)	CA may designate a laboratory that does not fulfil accreditation requirements which only carries out other official activities provided they carry out analysis/tests/diagnosis under supervision of CA or NRL
Article 42	CA may temporarily designate an existing OL located in the same MS for use of a method it is not accredited for subject to certain conditions and under the supervision of the CA or NRL for that method

Appendix 2 - Template for written designation of official laboratories

List of information to include in the written Designation for Official Laboratories under Article 37 of Regulation 2017/625 - for detailed explanation refer to Section 5.4

1. Name & contact point of central CA designating the OL.
2. Name & contact point of designated OL.
3. A statement that the lab will operate in conformity with the requirements of OLs in the OCR.
4. Information required in writing under Article 37(3) of the OCR (i.e. "*tasks*", "*conditions*" and "*arrangements*" for efficient and effective coordination and collaboration between the OL and the CA):
    - List of the testing & related functions the laboratory carries out when it is acting as an OL, whether these are for official controls or other official activities.
    - Any permanent derogation from accreditation and the basis for this derogation laid down in the OCR.
    - Any conditions relating to availing of temporary derogations from accreditation and arrangements between the OL, CA and NRL to supervise such derogations, where relevant.
    - The reporting arrangements between the laboratory and CA(s) where testing results indicate a potential risk or likelihood of non-compliance.
    - Any conditions relating to subcontracting to other laboratories, where relevant.
    - A schedule for liaison, coordination and reporting between the OL, CAs and other bodies to whom specific tasks related to OLs have been assigned such as the NRL. This should include a schedule for meetings/formal liaison and any reports to be provided such as PT results, changes to accreditation, audit outcomes.
    - Where relevant, any other national, EU or international legislation, standards or guidelines relevant to the designation that must be complied with including methods to comply with Article 34.
5. Statement that OL designation is subject to review and may be subject to withdrawal under certain conditions where there is non-compliance with legislative and other agreed requirements.

Appendix 3 - Members of the HoA Food Safety Laboratories Working Group

Ms. Gail Carroll (Chair), Enforcement Policy Manager. The Food Safety Authority of Ireland, The Exchange, George's Dock, IFSC, Dublin 1, Ireland.

Dr. James Choiseul, Head of Agricultural Laboratories, Department of Agriculture, Food & the Marine, Backweston Campus, Celbridge, Co. Kildare, Ireland.

Ms. Fabienne Clabots, Coordinateur contrôle analytique, Le Gouvernement du Grand-Duché de Luxembourg, 7A rue Thomas Edison, L-1445 Strassen, Luxembourg.

Dr. Yasmine Ghafir, Head of Unit External Laboratories, General Direction of Laboratories, Belgian Federal Agency for the Safety of the Food Chain, Boulevard du Jardin Botanique 55, 1000 Brussels, Belgium.

Drs. H.N. (Henk) de Groot, Divisie manager Laboratoria Nederlandse Voedsel- en Warenautoriteit Catharijnesingel 59, 3511 GG Utrecht, Netherlands.

Dr. Montserrat Gutierrez, Head of Veterinary Public Health Regulatory Laboratory, Department of Agriculture, Food & the Marine, Backweston Campus, Celbridge, Co. Kildare, Ireland.

Dr. Rudolf Hackenberg, Head of Unit, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Unit 504 P.O.B 11 02 60, 10832 Berlin, Germany.

Dr. Joseph Hannon (Secretariat), Technical Executive Officer, Food Science and Standards, The Food Safety Authority of Ireland, The Exchange, George's Dock, IFSC, Dublin 1, Ireland.

Ms. Chelvi Leonard, Senior Advisor, Surveillance, Methods & Laboratory Policy Team, Science, Evidence & Research Division, Food Standards Agency, Clive House, 70 Petty France, London, SW1H 9EX, United Kingdom.

Prof. Pia Mäkelä, Director of Department, Professor, Laboratory services, Finnish Food Safety Authority, Evira, Mustialankatu 3, FI-00790 Helsinki, Finland.

Dr. Ondrej Mikes, Head of the Laboratories Unit – Control, Laboratories and Certification Department, Kvetna 15, 603 00 Brno, Czech Republic.

Dr. Ingveig Olberg, Senior Advisor, Mattilsynet - Norwegian Food Safety Authority, Felles postmottak, Postboks 383, 2381 Brumunddal, Norway.

Ms. Inga Ørntoft, Head of Laboratory, Ministry of Environment and Food of Denmark, Danish Veterinary and Food Administration, Stationsparken 31-33, 2600 Glostrup, Denmark.