Overview of findings in relation to laboratories in Member States arising from audits carried out by the Food and Veterinary Office

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OBJECTIVE

- to present a concise analysis of the main findings and conclusions in FVO reports in relation to the performance of laboratories in EU Member States,
- with a view to identifying **horizontal issues** which could usefully be addressed by Member States or by the European Commission services

Scope

- The overview report is not intended to present an exhaustive account of all findings in relation to laboratories in FVO reports

- It does not cover European Union Reference Laboratories (EURLs) but does consider some issues in relation to National Reference Laboratories (NRLs).

Conclusions - Designation(1)

Although laboratories are an important part of Member States' control systems, some competent authorities designating official control laboratories relied solely on the laboratory's accreditation status and took no other steps to ensure that designated laboratories met, and continued to meet, all of the designation criteria in Article 12 of Regulation (EC) No 882/2004.

Conclusions - designation (2)

Not all competent authorities communicated their 'customer requirements' (such as if particular methods have to be used or validated according to specific requirements) to designated laboratories or national accreditation bodies.

Conclusions – Accreditation (1)

Laboratories face significant challenges in maintaining their accreditation and ensuring that they possessed accredited methods for all analyses undertaken:

- In some MS a large number of laboratories were carrying out similar analyses;
- Conversely, examples were seen where the **consolidation and centralisation of laboratory services** offered not only cost savings but an increased reliability of results, through the centralisation of expertise

Conclusions – Accreditation (2)

- In certain sectors, the development and validation of analytical methods for all of the possible analyses required to be undertaken, and their inclusion in the scope of accreditation, presented a considerable challenge for laboratories
- National Accreditation Bodies differ with regard to the scope of the accreditation (flexible scope accreditation vs. traditional fixed scope accreditation

Conclusions – NRLs

In a small number of cases:

- NRLs have not been designated in some Member States for certain areas; or
- NRLs have been designated which do not have the necessary resources and/or expertise to carry out the functions required.

The degree to which NRLs carry out the duties laid down in Article 33(2) of Regulation (EC) No. 882/2004 varies considerably between sectors.

Conclusions – Private samples

- Where non-compliant results arise in private samples, the competent authority is not necessarily informed of these results.
- With some specific exceptions, there is no EU-level requirement for such notification
- In at least one MS laboratories are legally obliged to notify the competent authority of non-compliant results from analyses of private samples

Conclusions – Wider role of labs

- FVO auditors have noted that laboratories, in particular NRLs, can undertake a much more significant role in the development of Member States control systems rather than just carrying out analyses.

- Examples were seen of laboratories operating effectively when they were involved in the process of developing sampling programmes, including new analytes and commodities.

Follow-up actions taken or planned:
Accreditation

- The legislative proposal for the recast of Regulation (EC) No 882/2004 (currently in discussion) makes more explicit the requirement for all laboratory methods used for official controls to be included in the scope of accreditation

- The *General guidelines for the cooperation between the European Co-operation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities* maps out opportunities to address the issue of accreditation scope

Follow-up actions taken or planned: Private samples

The legislative proposal for the recast of Regulation (EC) No 882/2004 (currently in discussion) provides under 'Obligations of official laboratory' that "*official laboratories shall immediately inform the competent authorities where the results of an analysis, test or diagnosis carried out on samples indicate non-compliance or point to the likelihood of non-compliance by an operator*".

Follow-up actions taken or planned:
For Member States

Member States were invited to:

- Consider the issue of competent authority oversight in relation to designation of official control laboratories; and
- Consider whether national measures should be taken to ensure that non-compliant results arising from samples other than official samples are notified to the relevant CA, pending the adoption of such a requirement at EU level.