REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

"Includes requirements for official control laboratories and designation and duties of reference laboratories"

(13) The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.

(14) Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.

(15) The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.

(16) The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

(17) Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria based performance standards and use methods of analysis that have as far as possible been validated. Such laboratories should in particular have equipment that enables the correct determination of standards such as maximum residue levels fixed by Community law.

(18) The designation of Community and national reference laboratories should contribute to a high quality and uniformity of analytical results. This objective can be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.

(19) The activities of reference laboratories should cover all the areas of feed and food law and animal health, in particular those areas where there is a need for precise analytical and diagnostic results.

(20) For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European Standards (EN Standards) appropriate for the purpose of this Regulation. These EN Standards relate in particular to the operation and assessment of testing laboratories and to the operation and accreditation of control bodies. International standards have also been drawn up by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These standards might, in certain well defined cases, be appropriate for the purposes of this Regulation, taking into account that performance criteria are laid down in feed and food law in order to ensure flexibility and cost effectiveness.

(21) Provision should be made for delegating competence for performing specific control tasks from the competent authority to a control body, and for the conditions under which such delegation can take place.

(e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;

(f) interviews with feed and food business operators and with their staff;

(g) the reading of values recorded by feed or food business measuring instruments;

(h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;

(i) any other activity required to ensure that the objectives of this Regulation are met.

CHAPTER III : SAMPLING AND ANALYSIS

Article 11

Methods of sampling and analysis

1. Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,

(a) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for standardisation (CEN) has accepted or those agreed in national legislation; or,

(b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.

2. Where paragraph 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

3. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.

4. The following implementing measures may be taken in accordance with the procedure referred to in Article 62(3):

(a) methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute;

(b) performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of the methods referred to in (a); and

(c) rules on the interpretation of results.

5. The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.

6. In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.

7. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

Article 12

Official laboratories

1. The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.

2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European Standards:

(a) EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories";

(b) EN 45002 on "General criteria for the assessment of testing laboratories";

(c) EN 45003 on "Calibration and testing laboratory accreditation system-General requirements for operation and recognition",

taking into account criteria for different testing methods laid down in Community feed and food law.

3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4. The competent authority may cancel the designation referred to in paragraph 1 when the conditions referred to in paragraph 2 are no longer fulfilled.

CHAPTER IV: CRISIS MANAGEMENT

Article 13

Contingency plans for feed and food

1. For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

TITLE III

REFERENCE LABORATORIES

Article 32

Community reference laboratories

1. The Community reference laboratories for feed and food referred to in Annex VII shall be responsible for:

(a) providing national reference laboratories with details of analytical methods, including reference methods;

(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

(f) collaborating with laboratories responsible for analysing feed and food in third countries.

2. The Community reference laboratories in the animal health sector shall be responsible for:

(a) coordinating the methods employed in the Member States for diagnosing diseases;

(b) assisting actively in the diagnosis of disease outbreaks in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(c) facilitating the initial or further training of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Community;

(d) collaborating, as regards methods of diagnosing animal diseases falling within their competence, with the competent laboratories in third countries where those diseases are prevalent:

(e) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

3. Article 12(2) and (3) shall apply to Community reference laboratories.

4. Community reference laboratories shall fulfil the following requirements. They must:

(a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence;

(b) possess the equipment and products needed to carry out the tasks assigned to them;

(c) have an appropriate administrative infrastructure;

(d) ensure that their staff respect the confidential nature of certain subjects, results or communications;

(e) have sufficient knowledge of international standards and practices;

(f) have available, if appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

(g) take account of research activities at national and Community level;

(h) have trained personnel available for emergency situations occurring within the Community.

5. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII in accordance with the procedure referred to in Article 62(3). In accordance with the same procedure, Annex VII may be updated.

6. Additional responsibilities and tasks for Community reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).

7. Community reference laboratories may be granted a Community financial contribution in accordance with Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1].

8. Community reference laboratories may be subject to Community controls to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements or tasks for which they have been designated, necessary measures may be taken in accordance with the procedure referred to in Article 62(3).

9. Paragraphs 1 to 7 shall apply without prejudice to more specific rules, and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 806/2003.

Article 33

National reference laboratories

1. Member States shall arrange for the designation of one or more national reference laboratories for each Community reference laboratory referred to in Article 32. A Member State may designate a laboratory situated in another Member State or European Free Trade Association (EFTA) Member and a single laboratory may be the national reference laboratory for more than one Member State.

2. These national reference laboratories shall:

(a) collaborate with the Community reference laboratory in their area of competence;

(b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;

(c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

(d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;

(e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;

(f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

3. Article 12(2) and (3) shall apply to national reference laboratories.

4. Member States shall communicate the name and address of each national reference laboratory to the Commission, the relevant Community reference laboratory and other Member States.

5. Member States that have more than one national reference laboratory for a Community reference laboratory must ensure that these laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the Community reference laboratory.

6. Additional responsibilities and tasks for national reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).

7. Paragraphs 1 to 5 shall apply without prejudice to more specific rules and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

3. Community reference laboratory for the monitoring of marine biotoxins

Ministerio de Sanidad y Consumo, Vigo, Spain.

4. Community reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs

The laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, United Kingdom.

5. Community reference laboratories for residues

(a) For the residues listed in Annex I, Group A 1, 2 , 3, 4, Group B 2 (d) and Group B 3 (d) to Council Directive 96/23/EC

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