



Directorate-General for
Health & Consumers

Die Rolle der EU-Kommission bei der Etablierung von Methoden

Frans Verstraete

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OUTLINE PRESENTATION

Limitations to my presentation

Objectives of feed and food safety legislation

Official Feed and Food Control Regulation

Elaboration of analytical requirements

- **Feed**
- **Food in particular contaminants**
- **EURL/NRL**
- **CEN**

Challenges to enforcement

Conclusive remarks

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Limitations

Commission is active on (legal) provisions as regards sampling and methods of analysis on many aspects of feed and food (safety) legislation

Presentation will focus on aspects within my responsibility

Objectives of feed and food safety legislation → requirements for analysis

- * providing a high level of animal and public health safety
 - * ensure free movement of compliant feed and food within the EU
- requires sensitive methods of analysis correctly applied across the EU in order to generate reliable and comparable analytical results



OFFICIAL FEED AND FOOD CONTROL LEGISLATION – 882/2004

**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**

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OFFICIAL FEED AND FOOD CONTROL LEGISLATION – 882/2004

Article 11 – Methods of sampling and analysis

1. Sampling and analysis methods used in the context of official controls shall comply with relevant Union rules or,
(a) if no such rules exist, with internationally recognised rules or protocols, e.g. those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation;

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OFFICIAL FEED AND FOOD CONTROL LEGISLATION – 882/2004

Article 11 – Methods of sampling and analysis

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

2. Where the above does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol (e.g. IUPAC Harmonised Guidelines).

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OFFICIAL FEED AND FOOD CONTROL LEGISLATION – 882/2004

Article 11 – Methods of sampling and analysis

3. Wherever possible, methods of analysis shall be characterised by the following criteria

- accuracy; applicability (matrix and concentration range); limit of detection; limit of determination; precision; repeatability; reproducibility; recovery; selectivity; sensitivity; linearity; measurement uncertainty; other criteria that may be selected as required.

- Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

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Article 11 – Methods of sampling and analysis

4. The following measures may be taken by the Commission:

- (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.

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OFFICIAL FEED AND FOOD CONTROL LEGISLATION – 882/2004

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 ISO/IEC 17011 on 'General requirements for accreditation bodies accrediting conformity assessment bodies'
- taking into account criteria for different testing methods laid down in Union feed and food law.

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

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OFFICIAL FEED AND FOOD CONTROL LEGISLATION – 882/2004

REVIEW –points under consideration (not exhaustive)

- Clarification of cascade of methods (CEN, methods validated by EURL/NRL)
- derogations to cascade
- general requirements for official laboratories / scope of accreditation
- temporary designation of official laboratories (new method, important changes to method, emergency situations or risks but conditions).

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Elaboration of methods of analysis

Methods of analysis in feed

- Establishment of many Union methods of analysis since 1970's
- Specific Expert Committee (CEMA) more than 100 plenary meetings // in addition several working groups
- Intensive activity stopped some 10 years ago.
- Advantages / Disadvantages of the approach

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Elaboration of methods of analysis

Methods of analysis feed

- 18 Directives (several times amended) compiled into one Regulation → Regulation (EC) 152/2009 laying down the methods of sampling and analysis for official control of feed
- Methods of analysis newly established at EU level only in very specific cases as regards safety of feed and food
 - **Dioxins, dioxin-like PCBs and non-dioxin like PCBs (criteria)**
 - **Constituents of animal origin**
- Standardisation of methods is largely entrusted to CEN (see later)
- new "screening" of existing measures envisaged.

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Elaboration of methods of analysis

Methods of analysis contaminants food

Performance criteria based approach.

- Advantage: does not avoid making use of technological progress and newest technologies and laboratories can use the analytical method most appropriate for their facilities
- includes parameters such as detection limit, repeatability, coefficient of variation, reproducibility recovery for various levels

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Elaboration of methods of analysis

Methods of analysis contaminants food

Performance criteria based approach + interpretation of analytical results

- Nitrates – Regulation (EC) No 1882/2006
- Mycotoxins – Regulation (EC) No 401/2006 (as amended)
- Lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons – Regulation (EC) 333/2007 (as amended)
- Dioxins, dioxin-like PCBs and non-dioxin-like PCBs – Regulation (EU) 252/2012

Envisaged: Performance criteria for multi-methods and screening techniques for the analysis of mycotoxins

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Elaboration of methods of analysis

Methods of analysis contaminants food

* Monitoring recommendations: in some cases guidance provided on methods of analysis to be used (e.g. *Alternaria* toxins)

* Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation, with particular reference to Union legislation concerning

- contaminants in food
- undesirable substances in feed

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Elaboration of methods of analysis

Veterinary drug residues → Decision 2002/657/EC

- * Concept of routine methods and reference methods superseded by criteria approach, in which performance criteria and procedures for the validation of screening and confirmatory methods are established
- * common criteria for the interpretation of test results
- * minimum required performance limits (MRPL) for certain prohibited substances

Pesticide residues

Guidance document on « Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed (SANCO/12495/2011)

Describes the method validation and analytical quality control requirements – interpretation of results for enforcement purposes

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EURL/NRL – an important network

- * A network gradually established since late 1970s
- * Aim of the network: ensure high quality, uniform testing within the EU and support Commission's activities in relation to risk management
- * Important contribution to:
 - the achievement of the objectives pursued by EU legislation
 - the improvement of food and feed safety in the EU
- * Embedded in (public) institutions with high level, long-standing expertise
- * International reputation

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EURL/NRL network - OBJECTIVES

- * Priority risks/hazards/diseases covered by the EURL network
- * Efficient, well structured and organised EURL network
- * Highly performing EURLs
- * Optimum use of financial resources
- * Continuous improvement of the network/EURLs
- * International reputation of the network/EURLs



EURL- Reg. 882/2004 Article 32 - Tasks

The EURL shall be responsible for

- Providing NRLs with details of analytical methods, including reference methods
- Co-ordinating application by NRLs of the methods, in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols
- Co-ordinating practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field



EURL- Reg. 882/2004 Article 32 - Tasks

The EURL shall be responsible for (cont'd)

- Conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries
- Providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analysis
- Collaborating with laboratories responsible for analysing feed and food in third countries

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EURL- Reg. 882/2004 Article 32 – Requirements

The EURL shall

- Have suitably qualified staff with adequate training in analytical techniques
- Possess the equipment and products needed to carry out the tasks assigned to them
- Have an appropriate administrative infrastructure
- Ensure that their staff respect the confidential nature of certain subjects, results or communications

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CRL- Reg. 882/2004 Article 32 – Requirements

The EURL shall (cont'd)

- Have sufficient knowledge of international standards and practices
- Have available an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents
- Take account of research activities at national and Union level
- Have trained personnel available for emergency situations occurring within the Union

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NRL- Reg. 882/2004 Article 33

- * Member States designate one or more reference laboratories (NRLs) for each EURL (may be a laboratory in another Member State or EFTA Member, one lab can be NRL for more than one Member State).
- * In case Member States designate more than one NRL for one EURL, they must ensure that these laboratories work closely together to ensure efficient co-ordination between them, with other national laboratories and with the EURL.

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NRL- Reg. 882/2004 Article 33

These NRLs shall

- Collaborate with the EURL
- Co-ordinate for their area of competence the activities of official laboratories
- Organise where appropriate comparative tests between the official national laboratories and ensure follow-up of such comparative testing
- Ensure the dissemination to the competent authority and official national laboratories of information that the EURL supplies

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NRL- Reg. 882/2004 Article 33

These NRLs shall (cont'd)

- Provide scientific and technical assistance to the competent authority for the implementation of co-ordinated control plans
- (Be responsible for carrying out other specific duties provided for following the comitology procedure)

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EURL-NRL network

Wide range of topics in the feed and food sector covered

- ***Milk and milk products, zoonoses, marine biotoxins, viral and bacteriological contamination of bivalve molluscs, Listeria monocytogenes, Staphylococci, Escherichia, Campylobacter, parasites, antimicrobial resistance, residues of veterinary medicines and contaminants in food of animal origin, animal protein, TSE, feed additives, GMO's, Food contact materials, pesticide residues, heavy metals, mycotoxins, PAH, dioxins and PCBs***

EURLs for animal health and live animals

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CEN

Commission addresses mandates for standardisation to CEN to provide standards of methods of analysis and sampling within a certain time period

Mandates concluded (to be concluded) in the field of feed and food safety

- **M 315 (2001): feed (CEN TC 327)**
- **M 381 (2006): food hygiene**
- **M 382 (2006): feed (CEN TC 327)**
- **M 383 (2006): mycotoxins in food (CEN TC 275)**
- **M 422 (2009): heavy metals in food (CEN TC 275)**
- **M 463 (2010): food contaminants (CEN TC 275)**
- **M (2012): feed (CEN TC 327)**
- **M (2012): mycotoxins in food (CEN TC 275)**

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Challenges Effective Enforcement

* Development of adequate sampling procedures: representative and feasible – heterogeneity – large size batches – estimation of sampling uncertainty

* Methods of analysis + measurement uncertainty

- **Screening**
- **Confirmatory**

* Screening approach (not only analysis but also sampling): sampling and analysis – very low rate of false negatives – acceptable rate of false positives

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Challenges Effective Enforcement

Control strategy: screening + confirmatory

- **In some cases: explicitly foreseen in legislation (criteria, rules, certification)**
- **In many other cases done in practice**

For ensuring the reliability of the results of the screening /confirmatory methods: certified reference materials of major importance

Challenge: Availability of certified reference materials for a wide range of contaminants (analytes) in a wide range of feed and food matrices at the levels of interest: a large need !

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Conclusive remarks

Role of the Commission

- * Establishment methods of analysis
- * Ensure a good functioning of the EURL/NRL network
- * Standardisation of methods of analysis → entrusted to CEN via mandates
- * Ensure research is undertaken (and funded) to elaborate / improve (new) methods of analysis
- * Funding elaboration of methods / validation of methods (CEN – EURL)
- * Interaction activities research – EURL - CEN -> ensure cooperation links / avoid overlapping
- * ...