



Directorate-General for Health & Consumers

EU policy on contaminants in food and feed: An indispensable need for reliable measurements, testing and reference materials

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Outline of this presentation

- General objectives and principles of food legislation (General Food Law)
- Framework legislation for contaminants in food and feed
- Framework legislation for official control
 - Sampling and analysis
 - Reference laboratories
 - Standardisation
- Enforcement legislation contaminants
- Challenges for enforcement



EU-FRAMEWORK LEGISLATION FEED AND FOOD SAFETY

Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002

laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

“The General Food Law (GFL)”



General Food Law

General objectives and principles

- The principles and the objectives of the general food law apply to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals: **“farm to fork” approach**
- The objectives of a **high level of protection of human health** and the protection of consumers' interests and of, where appropriate, the protection of animal health and welfare, plant health and the environment shall be pursued by food legislation



General Food Law

General objectives and principles

- Food legislation shall aim to achieve the **free movement** in the Community of feed and food manufactured or marketed according to the general principles and requirements of food law
(!) *Importance reliable measurements and testing*
- When **international standards** exist or their completion is imminent, they shall be taken into consideration in the development of food law, except where such standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law



General Food Law

General objectives and principles

- In order to achieve the general objective of a high level of protection of human health, **EU feed/food legislation shall be based on *risk analysis*** (process consisting of three interconnected components: risk assessment-risk management-risk communication) except where this is not appropriate to the circumstances or the nature of the measure
- Risk assessment shall be based on the ***available scientific evidence*** and undertaken in an **independent, objective and transparent manner**



General Food Law

General objectives and principles

- The **risk management shall take into account the results of risk assessment, other factors legitimate** to the matter under consideration and the precautionary principle where appropriate
(!) enforcement – reliable measurement and testing
- The **precautionary principle:** where, following an assessment of available information, the **possibility of harmful effects** on health has been identified but **scientific uncertainty** persists, **provisional risk management measures** necessary to ensure the high level of health protection chosen in the EU may be adopted, **pending further scientific information for a more comprehensive risk assessment**



General Food Law

General objectives and principles

- An **open and transparent public consultation** must be ensured, directly or through representative bodies, during the preparation, evaluation and revision of food legislation, except where the urgency of the matter does not allow it
- **Food shall not be placed on the market if it is unsafe**
- **Traceability**



Council Regulation (EEC) 315/93

■ Regulatory framework :

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

(this Regulation does not apply to contaminants which are the subject of more specific Community rules, such as pesticide residues, veterinary drug residues, ...)



Regulation (EEC) 315/93

Provisions

■ General provision:

- food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market

■ Good practice:

- contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)



Regulation (EEC) 315/93

Provisions

- When necessary for protecting public health maximum levels shall be established for specific contaminants --> Procedure for setting maximum levels. This can also include a reference to the sampling and analysis methods to be used.
- Obligatory consultation of the European Food Safety Authority (EFSA) Panel on contaminants in the food chain before provisions having effect upon public health shall be adopted.



Contaminants regulated / to be regulated under 315/93

- **Nitrates**
- **Mycotoxins:** aflatoxins, ochratoxin A, patulin, **Fusarium-toxins** (zearalenone, fumonisins, **trichothecenes:** Deoxynivalenol, *T-2 and HT-2 toxin*), *ergot alkaloids, ...*
- **Heavy metals:** lead, cadmium, mercury, (*inorganic*) arsenic, methylmercury...
- **Other environmental contaminants:** dioxins, dioxin-like PCBs, PAH, *non-dioxin-like PCBs, BFRs, PFOS, tributyltin (TBT), iodine,...*
- **Processing/industrial contaminants:** 3-MCPD, inorganic tin, PAH, acrylamide, furan, ethylcarbamate
- **Inherent plant toxins:** *pyrrolizidine alkaloids, tropane alkaloids, hydrocyanic acid, solanine ...*



Contaminants feed Directive 2002/32/EC

- Regulatory framework for contaminants/undesirable substances in feed:
 - Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed

(this Directive does not apply to veterinary matters relating to public and animal health regulated by other Community rules)



Contaminants feed Directive 2002/32/EC

- General provision:
 - Products intended for animal feed may enter for use into the Community, be marketed and used in the Community only if they are sound, genuine and of merchantable quality and therefore do not represent any danger to human health, animal health or to the environment or do adversely affect livestock production.
 - Maximum levels and action levels can be set for contaminants in all products intended for animal feed



Contaminants feed

Directive 2002/32/EC

- Obligatory consultation of the European Food Safety Authority (EFSA) Panel on contaminants in the food chain before provisions having effect upon public health or animal health or the environment
- Mixing of products intended for animal feed not complying with maximum level with other products intended for animal feeding for dilution purposes is prohibited
- Detoxification is allowed also by chemical treatment



Directive 2002/32/EC Annex undesirable substances

■ Ions and elements

- arsenic, lead, fluorine, mercury, nitrites, cadmium

■ mycotoxins

- aflatoxin B1, rye ergot

■ organic contaminants

- dioxins, dioxin-like PCBs, organochlorine pesticides (aldrin, dieldrin, camphechlor, chlordane, DDT, endosulfan, endrin, heptachlor, HCB, HCH (alpha, beta and gamma isomers))



Directive 2002/32/EC Annex undesirable substances

■ inherent plant toxins

- hydrocyanic acid, free gossypol, theobromine, volatile mustard oil, vinyloxazolidine thione, ...

■ botanical impurities

- (*Lolium temulentum*, *Lolium remotum*) Datura stramonium, Castor oil plant, *Crotalaria* spp, (*apricots*, *bitter almond*,) unhusked beech mast, (*camelina*), mustard (Indian, Sareptian, Chinese, black, Ethiopian), (*Mowrah*, *Bassia*, *Madhuca*), purghera, croton



Regulation on official feed and food controls

- 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



Regulation (EC) 882/2004

Sampling and analysis (Art 11)

- Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or
 - if none exist, internationally recognised rules or protocols, for example those that the European Committee for standardisation (CEN) has accepted or those agreed in national legislation
 - if none exist, other methods fit for the intended purpose or developed in accordance with scientific protocols



Regulation (EC) 882/2004

Sampling and analysis (Art 11)

- In case the above mentioned does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol



Regulation (EC) 882/2004

Sampling and analysis (Art 11- Annex III)

- Wherever possible, methods of analysis shall be characterised by the following appropriate criteria:
 - accuracy,
 - applicability (matrix and concentration range)
 - limit of detection
 - limit of determination
 - precision
 - repeatability
 - reproducibility



Regulation (EC) 882/2004

Sampling and analysis (Art 11- Annex III)

- Characterisation by appropriate criteria (cont'd):
 - recovery
 - selectivity
 - sensitivity
 - linearity
 - measurement uncertainty
 - ...
- precision values (from collaborative trial conducted in accordance with e.g. ISO 5725 or IUPAC International Harmonised Protocol)



Regulation (EC) 882/2004

Sampling and analysis (Art 11- Annex III)

- Where performance criteria for analytical methods are established, they must be based on criteria compliance tests
- repeatability and reproducibility values must be expressed in an internationally recognised form (e.g. 95 % confidence intervals)
- methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities

Regulation (EC) 882/2004

Sampling and analysis Art 11

- The Commission may lay down
 - methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute
 - the performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of such methods
 - rules on the interpretation of the results



Regulation (EC) 882/2004

Accreditation requirement

- **Laboratories (Article 12)**
 - Competent authority shall designate laboratories that may carry out the analysis of samples taken during official control
 - Competent authorities may only designate laboratories that operate and are assessed and accredited following EN ISO/IEC/17025 on "General requirements for the competence of testing and calibration laboratories"
 - The accreditation and assessment of laboratories relate to individual tests or groups of tests



Regulation (EC) 882/2004

EU-RL- NRL

- Article 32 : European Union reference laboratories (EU-RL)
- Article 33 : National reference laboratories (NRL)



Regulation (EC) 882/2004

Article 32 – Tasks EU-RL

- The EU-RL 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



Regulation (EC) 882/2004

Article 32 – Tasks EU-RL

- The EU-RL 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



Regulation (EC) 882/2004

Article 33 –NRL

- Member States designate one or more reference laboratories (NRLs) for each European Union reference laboratory (may be a laboratory in another Member State or EFTA Member, one lab can be NRL for more than one Member State).
- NRLs must be accredited
- In case Member States designated more than one NRL for one EU-RL, they must ensure that these laboratories work closely together to ensure efficient co-ordination between them, with other national laboratories and with the European Union reference laboratory.
- Additional responsibilities and tasks for NRLs may be determined following the comitology procedure.



Regulation (EC) 882/2004

Article 33 –Tasks NRL

- These NRLs shall
 - Collaborate with EU-RL
 - 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 EU-RL supplies



Regulation (EC) 882/2004

Article 33 –Tasks NRL

- 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



Standardisation of methods

- Standardised methods of analysis are of importance to guarantee the safety of feed and food and to ensure the free circulation of feed and food within the EU
- DG Health and Consumers intends to establish methods of analysis only in very specific cases as regards safety of feed and food.
- Standardisation of methods is largely entrusted to CEN
- Technical Committees (TC) within CEN of direct relevance for contaminants: TC 327 Feed and TC 275 Food
- Commission addresses mandates for standardisation to CEN to provide standards of methods of analysis and sampling within a certain time period



Regulatory limits contaminants – enforcement - Sampling

- Adequate sampling procedures are of crucial importance for estimating lot average levels in case contaminants are heterogeneously distributed throughout a lot (as is the case in particular for mycotoxins) and is therefore in these cases an essential component in the development of any maximum level
- In EU and international legislation, maximum levels for contaminants are in most cases combined with sampling provisions (and requirements for the methods of analysis)



Regulatory limits contaminants – enforcement - Sampling

- Through sampling procedure, an accurate estimate of the true level of contaminant in a batch is pursued
- exporter's risk/producer's risk against importer's risk/consumer's risk: EU policy is that a sampling procedure must be practicable and must minimise the consumer's risk without rendering trade impossible



Regulatory limits contaminants – enforcement - Methods of analysis - 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



Regulatory limits contaminants – enforcement - Methods of analysis - Food

- Regulation (EC) 401/2006 of 23 February 2006 – mycotoxins
- Regulation (EC) 1882/2006 of 19 December 2006 – nitrates
- Regulation (EC) 1883/2006 of 19 December 2006 – dioxins and dioxin-like PCBs
- Regulation (EC) 333/2007 of 28 March 2007 - lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene



Regulatory limits contaminants – enforcement - Methods of analysis - Feed

- Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed
- Methods of analysis for composition, feed additives, constituents of animal origin, undesirable substances (gossypol and dioxins and PCBs)



Regulatory limits contaminants enforcement – reporting of analytical results

- Corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported
- Analytical result to be reported as $x \pm U$ whereby x is the analytical result and U the expanded measurement uncertainty
- Expanded measurement uncertainty, using a coverage factor of 2 , which gives a confidence interval of approx. 95 %
- For contaminants in food of animal origin, alternatively the approach by establishing the decision limit $CC\alpha$ (according to Commission Decision 657/2002/EC) can be used
- Detailed report on relationship analytical results, measurement uncertainty and recovery:
http://ec.europa.eu/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf



Regulatory limits contaminants enforcement – reporting of analytical results

- A consignment is considered as non-compliant if analytical result, corrected for recovery exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty



Effective enforcement contaminants

Need for a joint effort

- Legislation
- EU-RL / NRL network
- CEN

AND

- Availability of certified reference materials

→ **Reliable measurements and testing**
→ **Effective enforcement**



EU-RL/CEN/ suppliers of certified reference materials

- EU-RL, CEN and suppliers of certified reference materials share both the same objectives: to guarantee the safety of feed and food and to ensure the free circulation of feed and food within the EU, through reliable and comparable analysis across the EU.
- Activities of EU-RL, CEN and suppliers of certified reference materials complementary
- Cooperation needed – exchange of information



Challenges for Enforcement

- Development of adequate sampling procedures: representative and feasible – heterogeneity – large size batches – estimation of sampling uncertainty
- Methods of analysis + measurement uncertainty
 - Confirmatory
 - Screening
- Screening approach (not only analysis but also sampling): sampling and analysis – very low rate of false negatives – acceptable rate of false positives
- **Availability of certified reference materials for a wide range of contaminants in a wide range of feed and food matrices at the levels of interest: a large need !!!**