Setting regulatory limits at EU level with focus on contaminants

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GENERAL FOOD LAW

Regulation (EC) 178/2002 of the European Parliament and of the Concil

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

GENERAL FOOD LAW OBJECTIVES

- General food law applies to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals
- Food law shall pursue one or more general 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

GENERAL FOOD LAW OBJECTIVES

- Food law 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
- 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 RISK ANALYSIS

- In order to achieve the general objective of a high level of protection of human health, the GFL lays down that EU food legislation shall be based on *risk analysis* except where this is not appropriate to the circumstances or the nature of the measure (e.g. labelling)
- Risk assessment shall be based on the *available scientific evidence* and undertaken in an independent, objective and transparent manner

GENERAL FOOD LAW RISK ANALYSIS

- 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

GENERAL FOOD LAW
The precautionary principle

- The precautionary principle provides that 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
The precautionary principle

- Measures adopted on the basis of the precautionary principle must be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration
- Such measures must be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment

Setting regulatory limits Decision-making in the EU

- Procedure
  - **Discussion on measures to be taken with experts of the Member States in the Expert Committee "Contaminants/Undesirable substances" (Working party of the Standing Committee on the Food Chain and Animal Health)**
  - **internal consultation of draft measure within Commission services (legal service)**
  - **submission of draft measure concerning contaminants to the regulatory committee: Standing Committee on the Food Chain and Animal Health**

Setting regulatory limits Decision-making in the EU

- notification of draft measure to WTO
- Committee expresses an opinion
- Commission adopts the measure in case of favorable opinion (qualified majority)
- Council adopts the measure in case of unfavorable opinion

Contaminants food
Council Regulation 315/93

- Regulatory framework for contaminants in food:
  Council Regulation (EEC) N) 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 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 315/93 Provisions

- When necessary for protecting public health maximum levels shall 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.

Regulation 315/93 Provisions

- safeguard clause: as consequence of new information or reassessment of existing information --> suspicion of constituting a health risk although complying EU legislation
- internal market: no restriction on placing on the market for foods complying with EU legislation for reasons relating to their contaminant content
- competent Standing Committee: Standing Committee on the Food Chain and Animal Health

Setting regulatory limits for contaminants – food

- Scientific risk assessment: assessment of the risks related to the presence of a contaminant in foodstuffs for human health / establishment of a tolerable intake --> is the basis for the measures to be taken
- exposure assessment: human exposure (average and 95 percentile) assessed against tolerable intake. Particular attention to vulnerable groups of population, high level consumers, ...

Setting regulatory limits for contaminants – food

- Determination of foods/food groups significantly contributing to the exposure
- Occurrence data of the contaminant in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake

Instruments to reduce/prevent presence

- EC-Measures to reduce the contaminant level in food are determined on a case by case basis (dependent of the nature of the contaminant), are divergent and can be a combination of several approaches into one strategy.
- Prevention of major importance
- Instruments: maximum levels, action levels, target levels, source-directed measures, code of practices, encouraging GAP, GMP, …
- maximum levels for contaminants are always combined with sampling provisions and requirements for the methods of analysis

Setting regulatory limits for contaminants – food sampling

- Adequate sampling procedure is of crucial importance for estimating lot average levels in case contaminants are heterogeneously distributed throughout a lot (as is the case for aflatoxins, ochratoxin A,…) and is therefore in these cases an essential component in the development of any maximum level
- 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

Setting regulatory limits for contaminants – food methods of analysis

- 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**

Community legislation in application of 315/93

- **Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.**
  - Maximum level does apply to edible part
  - For dried, diluted,processed or compound foodstuffs: concentration/dilution factor, relative proportion (exception aflatoxins)
  - Maximum level do also apply to products used as food ingredient
  - prohibition of mixing contaminated with non contaminated consignments and prohibition of detoxification by chemical treatment (mycotoxins)

Contaminants regulated / to be regulated under 315/93

- **Nitrates**
- Mycotoxins: **aflatoxins**, **ochratoxin A**, **patulin**, *Fusarium-toxins (zearalenone, fumonisins, Deoxynivalenol, T-2 and HT-2 toxin), ...*
- Heavy metals: **lead, cadmium, mercury**, *arsenic*,...
- Other industrial and environmental contaminants: **3-MCPD**, **dioxins**, **tin**, **PAH**, *PCBs*, *acrylamide, TBT, PBDE, PFOS, furan*...
- Plant toxins: ...

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 environement
- Mixing of products intended for animal feed not complying with maximum level with other products inteded for animal feeding for dilmution purposes is prohibited

Contaminants feed Directive 2002/32/EC

- safeguard clause: as consequence of new information or reassessment of existing information --> suspicion of constituting a animal or human health risk although complying EU legislation
- internal market: no restriction on placing on the market for feeds complying with EU legislation for reasons relating to their contaminant content
- competent Standing Committee: Standing Committee on the Food Chain and Animal Health

Setting regulatory limits for contaminants – feed

- Scientific risk assessment: assessment of the risks related to the presence of a contaminant in feed for animal and human health / establishment of a toxic exposure level for different animal species // carry over into food of animal origin --> is the basis for the measures to be taken
- Toxic exposure assessment: identification of most sensitive animal species // carry over into food of animal origin …

Setting regulatory limits for contaminants – food

- Determination of the feed materials which are important sources of contamination
- Occurrence data of the contaminant in the various feed materials/feeds
- Setting a maximum levels for feed materials and feeds taking into account the factors mentioned above (sensitivity animals, feed materials source of contamination, …) and considering what is reasonably achievable.

Setting limits using occurrence data

- Problems encountered considering occurrence data
  - **QA- data ?**
  - **Reliability ?**
  - **Measurement uncertainty ?**
  - **Corrected for recovery ?**
  - **Representative sampling ?**
  - **Targeted or at random sampling?**
  - **Sampling uncertainty ?**
  - **…**

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 on official feed and food controls

- Applicable from 1 January 2006
- 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 on official feed and food controls

- 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 on official feed and food controls

- 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 on official feed and food controls

- 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: 1994 or IUPAC International Harmonised Protocol)

Regulation on official feed and food controls

- 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 on official feed and food controls

- 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 on official feed and food controls

- Analysis of samples taken during official controls are carried out by laboratories designated for that purpose by the competent authority
- However only laboratories that operate and are assessed and accredited in accordance with following European standards may be designated:

Regulation on official feed and food controls

- ISO/IEC/17025 on “General requirements for the competence of testing and calibration laboratories”
- EN 45002 on “General criteria for the assessment of testing laboratories”
- 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

Hygiene Regulation

- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L139, 30.4.2004)
- Applicable from1 January 2006
- Legal basis for setting microbiological criteria for foodstuffs and associate sampling and analysis methods (Art 4)

contaminants - interpretation of analytical results

- SCOOP-Task 9.1 – Working document in support of uniform interpretation of legislative standards (March 2002)
  - http://europa.eu.int/comm/food/fs/scoop/9.1_fr_en.pdf
- Issues
  - **Different treatment of measurement uncertainty in evaluating compliance with a legislative standard**
  - **Different use of recoveryu correction when calculating and reporting an analytical result.**
  - **The number of significant figures**

contaminants - interpretation of analytical results

- Detailed report on relationship analytical results, measurement uncertainty and recovery and the provisions in EU Food and Feed legislation : http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf
- Particular reference to contaminants in food and undesirable substances in feed

contaminants - interpretation of analytical results

- Provisions on harmonised interpretation of analytical results has been introduced in legislation on contaminants food-feed
- Measurement uncertainty: principle of “beyond reasonable doubt” : expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approx. 95 %
- Analytical result to be corrected for recovery for checking compliance

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 +/- 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 dioxins, alternatively the approach by establishing the decision limit CCα (according to Commission Decision 657/2002/EC) can be used (see later)

Contol regulatory limits Screening methods

- Specific reference thereto to the monitoring for the presence of dioxins in feed and food
  - **can be performed by a strategy involving a screening method in order to select those samples with levels of dioxins and dioxin-like PCBs that are less than 30-40 % below or exceed the level of interest. The concentration of dioxins in these samples with significant levels needs to be determined/confirmed by a confirmatory method**

Commission Decision 2002/657/EC

- Commission Decision of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results --- food of animal origin
- Definition of a screening method
  - **means methods that are used to detect the presence of a substance or class of substances at the level of interest . These methods have the capability for a high sample throughput and are used to sift large numbers of samples for potential non-compliant results. They are specifically designed to avoid false compliant results (definition applies also to control dioxins**

Commission Decision 2002/657/EC

- Screening method (cont'd)
  - **requirement: only those analytical techniques , for which can be demonstrated in a documented traceable manner that they are validated and have a false compliant rate of < 5 % (beta error) (for the control on dioxins: false negative rate < 1% !) at the level of interest shall be used for screening purposes . In case of a suspected non-compliant result, this result shall be confirmed by a confirmatory method**

Commission Decision 2002/657/EC

- Confirmatory method
  - **definition: means methods that provide full or complementary information enabling the substance to be unequivocally identified and if necessary quantified at the level of interest**

Commission Decision 2002/657/EC - interpretation

- Minimum required performance limit (MRPL)
  - **means content of an analyte in a sample, which at least has to be detected and confirmed. It is intended to harmonize the analytical performance of methods for substances for which no permitted limit has been established (e.g. chloramphenicol, MPA, nitrofuran,metabolites, malachite green)**

*** Commission Decision 2005/34/EC of 11/01/2005 - harmonised approach for control**

Commission Decision 2002/657/EC-interpretation

- Analytical recovery to be applied (during validation and application of the method) – this rule do not apply to qualitative methods.
- Alpha error means the probability that the tested sample is compliant, even though a non-compliant measurement has been obtained (false non-compliant decision)
- Decision limit (CCα) means the limit at and above which it can be concluded with an error probability of α that a sample is non-compliant.

Commission Decision 2002/657/EC-interpretation

The result of an analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded

*** In cases of substances for which a permitted limit has been established: CCα is the concentation above which it can be decided with a statistical certainty of 1 – α that the permitted limit has been truly exceeded**

- **In cases of substances for which no permitted limit has been established: CCα is the lowest concentation level at which a method can discriminate with a statistical certainty of 1 – α that the analyte is present**
- **(α = 1 % for prohibited substances, 5 % for all other substances)**

Commission Decision 2002/657/EC-interpretation

- Beta error means the probability that the tested sample is truly non-compliant, even though a compliant measurement has been obtained (false compliant result).
- Detection capability (CCβ) means the smallest content of the substance that may be detected, identified and/or quantified with an error probability of β

Commission Decision 2002/657/EC-interpretation

- In cases of substances for which no permitted limit has been established: CC β is the lowest concentation at which a method is able to detect truly contaminated samples with a statistical certainty of 1 - β
- In cases of substances for which a permitted limit has been established: CCβ is the concentation at which a method is able to detect permitted limit concentrations with a statistical certainty of 1 - β
- (β = 5 %)

The future

- Further harmonisation of controls and interpretation of results
- Further harmonisation of actions to be taken in case of non-compliance
- Sampling uncertainty ?
- …