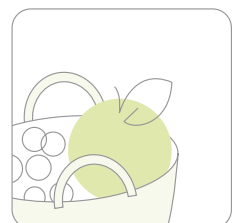
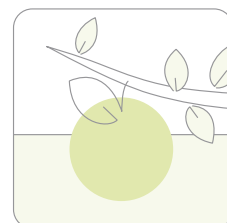
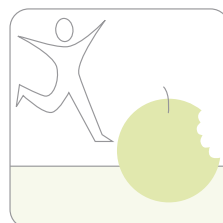
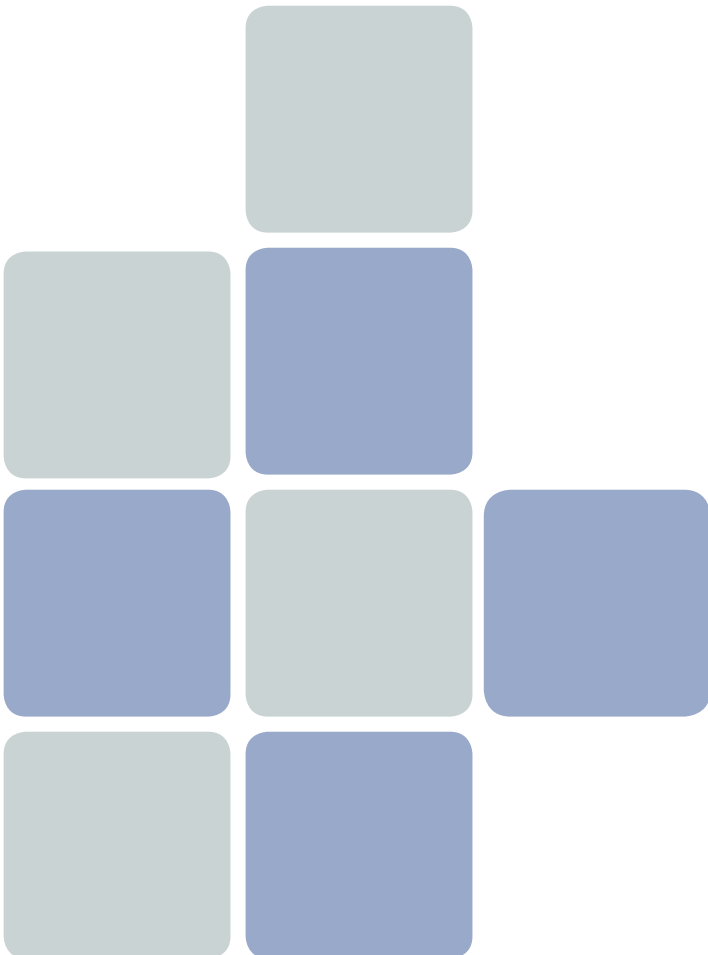


GUIDANCE DOCUMENT

on official controls, under
Regulation (EC) No 882/2004, concerning
microbiological sampling and testing of foodstuffs.





COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13 November 2006

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PURPOSE OF THIS DOCUMENT

This document is mainly directed at competent authorities carrying out official controls and aims to give guidance on official sampling, requirements of official laboratories, analysis methods to be used for official samples and microbiological criteria applied to official samples.

NOTE

This document is an evolving document and will be updated to take account of experiences and information from competent authorities.

1. INTRODUCTION

Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare¹ was adopted on 29 April 2004. It is directed at competent authorities and lays down the principles to be respected for ensuring that official controls are objective and efficient.

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs² was adopted on 15 November 2005 and is directed at food business operators. When Regulation (EC) 2073/2005 was prepared there was a wish from the Member States to make guidelines for competent authorities to explain how microbiological criteria can be applied to official controls.

This document aims to assist competent authorities in understanding, particularly, Regulation (EC) No 882/2004 in relation to performing official controls in a uniform way by checking the compliance of food with microbiological requirements. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

For this purpose the document provides guidance on official sampling, requirements of official laboratories, analysis methods to be used for official samples and interpretation of microbiological analysis results.

This document aims to provide guidance on official controls and explaining the link between Regulation (EC) No 882/2004 and Regulation (EC) No 2073/2005. In addition, this document assists competent authorities to understand better the link between Regulation (EC) No 882/2004 and Regulation (EC) No 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 safety³ in particularly on the interpretation of microbiological analyses results, when no Community criteria have been set down.

Regulation (EC) No 882/2004 applies horizontally to all food law, feed law, animal health, animal welfare and plant health. Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents⁴, Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents⁵ and their implementing provisions (the zoonosis monitoring and control provisions) are a part of those and are therefore fully subject to Regulation (EC) No 882/2004. It is not the purpose of this guidance document to

¹ OJ L 191, 28.5.2004, p. 1.

² OJ L 338, 22.12.2005, p. 1.

³ OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

⁴ OJ L 325, 12.12.2003, p. 31.

⁵ OJ L 325, 12.12.2003, p. 1. Regulation as amended by Regulation (EC) No 1003/2005 (OJ L 170, 1.7.2005, p. 12).

address the link between the zoonosis monitoring and control provisions and Regulation (EC) No 882/2004.

For the purpose of this guidance document the definitions laid down in the relevant Community legislation, and set out in Annex I to this document, shall apply.

2. BASIC LEGISLATION

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at:

- (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment;

and

- (b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

For a complete understanding of the different aspects of official controls concerning microbiological sampling and testing of foodstuffs included in Regulation (EC) No 882/2004 it is essential to be familiar with the following parts of Community legislation:

- Regulation (EC) No 2073/2005
- Regulation (EC) No 178/2002
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁶
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁷
- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption⁸
- Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004⁹.

In addition, several guidance documents in the field of food hygiene have been published on the DG SANCO website.

⁶ OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

⁷ OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

⁸ OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

⁹ OJ L 338, 22.12.2005, p. 83.

3. **REGULATION (EC) No 2073/2005 AND OFFICIAL CONTROLS**

Regulation (EC) No 2073/2005 sets down obligations for food business operators, who must ensure that foodstuffs are in compliance with the microbiological criteria of this Regulation. Although these microbiological criteria are mainly intended to be used by food business operators in the context of their good hygiene practice and HACCP procedures, the criteria apply also to samples taken for official controls to verify that the criteria laid down for food are met. However, sampling and testing is only part of the process of ensuring compliance with the Regulation.

As regards official controls it is important to note that the **food safety criteria** set down in Regulation (EC) No 2073/2005 also apply to intra-Community trade and to imported products from third countries, whereas **process hygiene criteria** apply only during the production process.

Article 14 of Regulation (EC) No 178/2002 provides that unsafe food products must not be placed on the market. Further, according to Regulation (EC) No 882/2004 the competent authorities shall verify the operators' compliance with Community legislation. Accordingly, the competent authority is authorized to stop the marketing of unsafe products even if no Community criteria are set.

4. **THE ROLE OF THE COMPETENT AUTHORITIES AND THE OFFICIAL LABORATORIES**

The competent authority in each Member State should in their overall strategy for controlling microbiological contamination base their official controls on risk taking into account the results of the checks carried out by the food business operator under HACCP-based control programmes whether or not integrated in quality assurance programmes as laid down in Regulation (EC) No 882/2004. The labelling requirements set down in Articles 6 and 8 of Regulation (EC) No 2073/2005 in relation to *Salmonella* criteria for minced meat, meat preparations and meat products intended to be eaten cooked, should also be checked in this context to ensure that sufficient information is provided to show that the meat requires thorough cooking before consumption.

Official sampling and testing is only part of the verification process. Compliance can be verified in a number of ways including audits, inspections, monitoring, surveillance, sampling and testing. The auditing of HACCP plans as well as good hygienic practices will include an assessment of the verification of the adequacy of the food businesses' sampling and testing schemes, checking test result reports and assessing the adequacy of corrective and preventive actions.

The majority of sampling and testing to demonstrate compliance with Regulation (EC) No 2073/2005 will be carried out by food business operators within their food safety management systems.

Official sampling can be carried out for a range of reasons, e.g. monitoring, surveying and checking the compliance with the legislation. In order to benefit from

sampling and testing of foodstuffs the sampling must be well-planned taking into account also the intended purpose of the sampling.

The competent authority should inspect and assess all the systems in place, including the sampling regime and any testing results, and may then wish to carry out its own testing if it has concerns about the food business operator's approach. In many cases, where the inspection and assessment is satisfactory, there will generally be no need for the competent authority to carry out additional testing.

Official laboratories in the field of food microbiology together with competent authorities form an important structure within the EU to ensure the safety of foods.

Failure to meet any microbiological criteria as set out in Regulation (EC) No 2073/2005 could result in a number of responses by the food business operator including withdrawal/recall of the product. It should always lead to an investigation of the process and procedures by the food business operator to identify the reason for failure and action to ensure compliance in the future.

5. SAMPLING

5.1. Relevant Community rules

Article 11 of Chapter III of Regulation (EC) No 882/2004

“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.”

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

Article 5(2) of Regulation (EC) No 2073/2005 refers to ISO 18593 as a reference sampling method for sampling of processing areas and equipment.

Point 3.1 of Chapter 3 of Annex I to Regulation (EC) No 2073/2005 refers to relevant standards of ISO and the guidelines of the Codex Alimentarius, which shall be used as reference methods in the absence of more specific rules on sampling and preparation of test samples.

Point 3.2 of Chapter 3 of Annex I to Regulation (EC) No 2073/2005 gives rules for bacteriological sampling in slaughterhouses and at premises producing minced meat and meat preparations.

Internationally recognised standards and guides for sampling

Codex Alimentarius: General guidelines on sampling, CAC/GL 50-2004

ISO/DIS 7218: Microbiology of food and animal feeding stuffs – General rules for microbiological examinations.

ISO 17604: Microbiology of food and animal feeding stuffs - Carcass sampling for microbiological analysis.

ISO 18593: Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs.

NMKL (Nordic Committee on Food Analysis) Procedure No. 12: Guide on Sampling for Analysis of Foods. www.nmkl.org

The most recent edition of the standards and guides shall be used.

5.2. **Sampling strategy**

A sampling strategy means a planned procedure for selecting samples from a population and for conducting the sampling to obtain the information needed. Terminology for selecting samples from a population is under development in EUROSTAT/Food Safety statistics. The importance of having a common glossary is a basic need to be able to compare data among countries and among different control areas. One of the key issues is to identify which strategy has been used to select the units of the target population that will be subject to controls: businesses, animals, foodstuffs, etc. This determines how the results can be interpreted and if the information from different systems and countries is comparable or not. From the analysis of the information already provided to the European Commission, it appears that there are three possible sampling strategies (objective, selective, suspect) that are currently used.

The competent authority should establish a sampling strategy taking into account the sampling procedures proposed by EUROSTAT¹⁰. The following definitions for these three identified sampling strategies in the context of control and monitoring activities have been proposed by EUROSTAT:

Objective sampling

A planned strategy based on the selection of a random sample, which is statistically representative of the population to be analysed. Each unit, within the framework population, has a specified probability of being selected. This strategy provides data from which statistical inference can be implemented. That means that the results inferred are comparable.

This approach could be applied to a convenient selection of food retailers for hygiene controls, where the retailers are grouped according to predefined characteristics or to a stratified regional selection of food producers for HACCP controls. It would give results that could be extended to all the population and breakdown by region. The

¹⁰ ESTAT/D6/ES/104 Rev. 1, under revision.

way the sampling procedure is established should be in line with the objectives of the analysis.

Example: Sampling of fresh meat at retail level for detection of *Salmonella* to determine the prevalence in fresh meat at a specific point of the food chain, or other monitoring schemes or surveys on the prevalence of food-borne pathogens in certain food categories.

Selective sampling

A planned strategy where the selection of the sample is from previously defined “high-risk” population groups. Samples are normally selected to either illustrate or document unsatisfactory conditions or suspected adulteration of a product. The sampling is deliberately biased and is directed at the particular products or manufacturers. The sampling procedure can be random or not. The specification of the “high-risk” population comes from either scientific studies or previous analysis and information of other regions or countries. The comparability of the results lies on both the definition of the population to be analysed and the way the samples have been drawn. If the sample is drawn randomly to be representative of the population analysed, the results can be applied to the whole of this population.

Example: Sampling of high-risk products, for instance vacuum-packed cold-smoked fish product supporting the growth of *Listeria monocytogenes* during its shelf-life for detection and/or enumeration of *L. monocytogenes* to determine the rate of contamination and/or the level of contamination.

Suspect sampling

A selection of samples, where the units are selected based on the judgement and experience regarding the population, lot, or sampling frame. The samples obtained from this procedure are not randomly extracted.

Example: Sampling carried out as a part of a food-borne outbreak investigation or where an inspection indicates there may be a food safety problem or where a HACCP plan review results in concerns regarding potential food safety problems.

5.3. Aim of sampling

Sampling may be carried out for a number of reasons including:

- to verify the compliance with the criteria laid down in Regulation (EC) No 2073/2005,
- to verify the microbiological safety of food for which no microbiological criteria are laid down at Community level,
- to obtain general information on the microbiological status of certain products placed on the market,
- to observe carefully one or more food businesses verifying their food safety management systems,

- to check the compliance of individual batches,
- to investigate suspected food-borne outbreaks, complaints *etc.*
- to identify and obtain information on new or emerging microbiological hazards, generating data for risk profiles and risk assessments.

For each of these, different sampling regimes may be required.

5.3.1. *Monitoring and surveillance*

Knowledge of the current situation and trends regarding the occurrence and spread of pathogens in the food chain has an important contribution to make in managing food safety. Acquiring this knowledge involves the gathering of information under the terms of monitoring and surveillance.

Monitoring and surveillance are defined in Article 2 of Regulation (EC) No 882/2004 as follows:

“Monitoring means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed and food law, animal health and animal welfare rules”

“Surveillance means a careful observation of one or more feed or food businesses, feed or food business operators or their activities”

When controlling microbiological hazards in food monitoring and surveillance can be considered to include the following specific features:

- **monitoring** is the performance of routine microbiological analysis aimed at detecting microbiological contamination of foodstuffs from which useful prevalence data may emerge.
- **surveillance** is the performance of routine microbiological analysis aimed at detecting microbiological contamination of foodstuffs for the purpose of applying appropriate control measures. Such control measures are normally determined in advance by the competent authority. One of the main objectives of surveillance is to follow-up unsatisfactory results with an investigation and possible enforcement action.

For monitoring and surveillance programmes and depending on the aim of such programmes, the competent authority should choose the sampling procedures and sampling plans according to the micro-organism or its toxin and the type of foodstuff concerned.

In order to obtain relevant data on the occurrence of food-borne hazards in the food chain it is recommended that competent authorities direct their sampling and testing activities to well-planned monitoring and surveillance programmes. It is recommended that where single random samples are taken at retail level, such sampling should be done in the context of a monitoring and surveillance programme.

5.3.2. *Assessment of food safety management plans*

When assessing a food business operator's food safety management plan based on HACCP, GHP and GMP the competent authority might find it necessary to take additional samples for official control if it has concerns about the food safety management systems. The extent of such official sampling is dependent on the food business operator's analyses results and the competent authority's assessment of a food business operator's food safety management plans. However, the focus of the activities of the competent authority should be on both the assessment of the activities of the food business operator, and on requesting them to correct their food safety management plans to ensure that the food business operator remedies weaknesses in their food safety control.

5.3.3. *Import control*

The information about the food business operator's food safety management systems available to import control officers is often limited. However, in case of food of animal origin only approved establishments are allowed for import to EU. Documentary checks to verify such approvals and sampling of the individual batches are the main control tools for import control. In such cases the sampling plans set out in Regulation (EC) No 2073/2005 shall be respected as a minimum and the competent authority can establish its own sampling plans based on the risks associated with particular products, establishments and countries of origin.

5.3.4. *Food-borne outbreaks*

In case of food-borne outbreaks the investigations should reveal suspect batches and should identify the establishment in which the product was manufactured/processed. In such cases the competent authority assesses the situation and can decide to take samples for microbiological analysis. The competent authority should choose the necessary sampling procedures according to the situation and should also take account of the operator's records from the food safety management systems. The sampling plan may include environmental samples and samples of different raw materials, products and batches. Account could also be taken of measures taken by food business operators to prevent, reduce or eliminate the risk in concern according to Article 19 of Regulation (EC) No 178/2002.

5.4. **Sampling plan**

Sampling plans and microbiological limits should be chosen according to the severity of the health hazard and the expected conditions in which the foodstuff will be handled and consumed.

Two- and three-class attribute sampling plans are the most commonly used plans for microbiological examination. Two- and three-class sampling plans are used in Regulation (EC) No 2073/2005 as follows.

- In a two-class sampling plan, the samples analysed are divided into two categories: *satisfactory and unsatisfactory*, based on one limit value 'm=M'.

- In a three-class sampling plan, the samples examined are divided into three categories: *satisfactory*, *acceptable* and *unsatisfactory*. A three-class sampling plan is used if it is acceptable that some samples exceed the lower limit (m), as long as a risk contamination level (M) is not exceeded.

In the context of official sampling the sampling plans described in Regulation (EC) No 2073/2005 should be used, as a minimum, when the acceptability of a food batch or a process is assessed.

For any sampling plan there is probability of accepting a batch which may be unacceptable. The following example¹¹ illustrates the uncertainty linked with a two-class sampling plan provided that the pathogen concerned (e.g. *Salmonella*) is homogeneously distributed in the batch (which is unlikely in a number of solid foods). The probability of accepting a batch that contains a proportion of *Salmonella* positive units, when 5 sample units (n=5) are tested and no *Salmonella* positive sample unit is permitted (c=0), is as follows:

- There is a 90 % chance of accepting a batch containing 2 % *Salmonella* positive units.
- There is a 77 % chance of accepting a batch containing 5 % *Salmonella* positive units.
- There is a 59 % chance of accepting a batch containing 10 % *Salmonella* positive units.
- There is a 17 % chance of accepting a batch containing 30 % *Salmonella* positive units.
- There is a 3 % chance of accepting a batch containing 50 % *Salmonella* positive units.

When fewer sample units than 5 are tested the probability of accepting a defective batch increases and *vice versa* when a higher number of sample units are tested the probability of identifying defective batches increases.

In the context of monitoring and surveillance programmes single random samples may be a choice as referred to in point 5.3.1.

¹¹ International Commission on Microbiological Specifications for foods (ICMSF). Microorganisms in foods. 2nd ed. 2. Sampling for microbiological analysis: principles and specific applications. University of Toronto Press 1986.

5.5. Sampling frequency

Regulation (EC) No 2073/2005 sets down a fixed weekly sampling frequency for the food business operators for certain products, such as carcasses, minced meat, meat preparations and mechanically separated meat. In other cases the food business operators have to decide the sampling frequency on a case-by-case basis taking into account the risk related to their products. If necessary, detailed guidelines for sampling frequencies for specific food sectors may be included in the guides to good hygiene practice referred to in Article 7 of Regulation (EC) No 852/2004.

As regards official controls no fixed sampling and testing frequency has been set down in the Community legislation. The need for official sampling and testing should be assessed, when the competent authorities are planning their sampling strategy and aim of sampling in the context of their multi-annual national control plans according to Article 41 of Regulation (EC) No 882/2004.

5.6. Sampling information

Guidance for sampling information that should accompany the sample is included in NMKL Procedure No. 12: Guide on Sampling for Analysis of Foods.

5.7. Transport of samples, storage and starting of the analysis

Standardized procedures for the transport of samples to the laboratory, the storage and the starting of the analysis are presented in ISO/DIS 7218: Microbiology of food and animal feeding stuffs – General rules for microbiological examinations.

ISO/DIS 7218 does not set a maximum limit for the time of transportation of products not stable at ambient temperature. However, given the potential for change in the levels of the target organisms, it is recommended that this type of sample should arrive at the laboratory within 36 hours after sampling. According to the above-mentioned ISO/DIS document the microbiological analysis should be started as soon as possible after receipt at laboratory, preferably within 24 hours. It is recommended that analysis is started, as a rule, within 48 hours of taking the sample, unless the testing protocol specifically states otherwise.

For highly perishable fresh, refrigerated products the following additional guidance is given:

- During transport and storage freezing temperatures must be avoided.
- Pre-packed food should be stored at or below the storage temperature given on the label.
- In case of examination at a later stage, e.g. for checking compliance of a pre-packed food at the use by date the samples should be stored at the laboratory under the recommended conditions given on the label.

6. REQUIREMENTS FOR OFFICIAL LABORATORIES

6.1. Relevant Community rules

Article 12(1) to Regulation (EC) 882/2004

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

Article 12(2) to Regulation (EC) 882/2004

“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”

Article 18 to Commission Regulation 2076/2005 states with regard to accreditation of laboratories:

“By way of derogation from Article 12(2) of Regulation (EC) No 882/2004, the competent authority may designate a laboratory not accredited, provided that the laboratory:

- (a) demonstrates that it has initiated and is pursuing the necessary accreditation procedures in accordance with Regulation (EC) No 882/2004;*
- (b) provides the competent authority with satisfactory guarantees that quality control schemes for the analyses it conducts for the purpose of official controls are in place by 1 January 2006.”*

6.2. Designation of official laboratories

According to the derogation given in Commission Regulation (EC) No 2076/2005 the competent authority may appoint a laboratory for executing official controls, which does not have an accreditation yet as laid down in Regulation (EC) No 882/2004. However, the laboratory must have started the accreditation process and must have a quality control scheme in place for the tests and analyses it is conducting. In the field of feed and food hygiene there was a need to have this derogation particularly for small laboratories carrying out official tests for *Trichinella* and for laboratories testing feed samples.

The derogation applies until 31 December 2009 after which all laboratories carrying out official controls must be accredited according to the standard EN ISO 17025.

The competent authority must designate an official laboratory or laboratories to facilitate its official controls in relation to detection and enumeration of the micro-organisms and their toxins and metabolites. All official control laboratories should be accredited for the individual tests or groups of tests they are using for official control purposes when the derogation period ends.

In the case of new microbiological criteria and/or new reference methods, a transitional period may need to be considered and agreed at the Community level on a case-by-case basis for official laboratories to be accredited for these new analyses.

6.3. Storage of isolated pathogenic micro-organisms

Presence/absence testing and enumeration of target micro-organisms during microbiological analysis yield bacterial isolates. Bacterial isolates of pathogenic micro-organisms should be maintained and preserved for reference purposes according to general microbiological procedures. Where possible and needed the isolates should be sent to appropriate reference laboratories for typing and identification. In outbreak situations typing and identification may be an immediate requirement. The isolated pathogenic strains should be kept at the laboratory at least until deemed necessary by the competent authority.

7. METHODS OF ANALYSIS

7.1. Relevant Community rules

Article 11(1) of Chapter III to Regulation (EC) No 882/2004

”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.”

7.2. Methods for official controls

7.2.1. CEN and ISO standards

In the absence of analytical methods under EU law, methods standardised by CEN and/or ISO, when available, should be used for testing samples of official controls and their use is highly recommended for intra-Community trade and import from third countries. While CEN or ISO methods are not available for all hazards included in Regulation (EC) No 2073/2005, the use of other reference methods given in this Regulation are highly recommended.

7.2.2. *Other methods*

Other methods, e.g. methods of the International Dairy Federation (IDF) and methods of the Nordic Committee on Food Analyses (NMKL), can be used if agreed in the national legislation. However, if other methods are used they should provide at least equivalent results compared to the reference method. As regards the validation of microbiological methods, the procedure in EN ISO 16140, including an intra-laboratory and an inter-laboratory study (collaborative study) is highly recommended.

If a method has been used for detection of a pathogen, where the technique is not based on the isolation of the pathogen, it is recommended that the result is confirmed by a traditional culture method.

The isolation of a pathogen by any method should always prompt an investigation, though it may not always lead to formal enforcement action.

In some cases - especially acute situations related to food-borne diseases – the competent authority may have to perform analysis on parameters where no standardized method has been developed. In order to ensure valid data for the actual purpose, methods developed for such situations should preferably be characterized for their performance by the following characteristics:

Qualitative methods

Limit of detection

Inclusivity & exclusivity

Sensitivity

Specificity

Quantitative methods

Limit of quantification

Inclusivity & exclusivity

Linearity

These characteristics are defined in Standard EN ISO 16140, which also provides experimental protocols and calculations for them (the most recent edition must be used).

The characteristics mentioned above should be established through a single laboratory validation procedure performed on pure strains (for inclusivity/exclusivity) or on samples of the relevant matrices preferably naturally contaminated, or spiked with the agent concerned in relevant concentrations.

The number of characteristics and the level of the criteria for acceptance may vary due to the actual situation (seriousness, need for immediate investigation and possibility of choosing other methods).

8. INTERPRETATION OF MICROBIOLOGICAL ANALYTICAL RESULTS

8.1. Relevant Community rules

Microbiological criteria set down in Community legislation

Annex I to Regulation (EC) No 2073/2005

sets down limits for specific microbes, their toxins and metabolites in specific food categories at specific points of the food chain.

Absence of Community criteria

Article 14 of Regulation (EC) No 178/2002

- “1. Food shall not be placed on the market if is unsafe.*
- 2. Food shall be deemed to be unsafe if it is considered to be:*
 - (a) injurious to health;*
 - (b) unfit for human consumption.*
- 3. In determining whether food is unsafe, regard shall be had:*
 - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and*
 - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.”*

Community rules for special guarantees for salmonella

Article 8 of Regulation (EC) No 853/2004

“1. Food business operators intending to place the following food of animal origin on the market in Sweden and Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:

(a) meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;

(b) meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM;

and

(c) eggs.”

Article 5 of Commission Regulation (EC) No 1688/2005

“Microbiological methods for the examination of the samples

1. Microbiological testing for salmonella of the samples taken in accordance with Articles 1 to 4 shall be carried out in accordance with the most recent edition of:

(a) standard EN/ISO 6579; or

(b) method No 71 described by the Nordic Committee on food Analysis (NMKL) (method No 71).

Where the results of the microbiological testing are contested between Member States, the most recent edition of EN/ISO 6579 shall be regarded as the reference method.

2. However, for samples of meat from bovine and porcine animals and of meat from poultry, the following analytical methods, which shall be validated by the use of meat samples in the validation studies, may be used for the microbiological testing for salmonella:

methods that have been validated against the most recent editions of EN/ISO 6579 or of method No 71 and if a proprietary method, certified by a third party in accordance with the protocol set out in standard EN/ISO 16140 or other internationally accepted protocols.”

8.2. Measurement uncertainty

At Community level, no implementing measures have been established on how measurement uncertainty (MU) should be taken into account when microbiological analyses results of foodstuffs are interpreted.

MU linked to microbiological analyses is one of the factors affecting the test result. How the MU should be taken into account when interpreting the test results against the statutory limit is a complex issue. This is particularly the case in microbiological analyses, as the calculation of the MU is not as developed in this sector as in the chemical side and as the MUs in microbiological analyses tend to be high, quite often of the order of 0.5-1.0 log units.

According to the strategy for setting microbiological criteria for foodstuffs in Community legislation¹² the general policy is that food business operators should always regard all test results above the limits as unacceptable regardless of the MU involved, whereas in the official controls the MU could be taken into account in order to be sure beyond reasonable doubt that the batch in question does not comply with the criterion.

8.2.1. Qualitative analyses and MU

Currently, there is no agreed way at international level on how to express MU of qualitative determinations. Therefore, there is no guidance on how to take into account the MU in the context of qualitative microbiological results at Community level.

8.2.2. Quantitative analyses and MU

ISO/TS 19036: Microbiology of food and animal feeding stuffs – Guide on estimation of measurement uncertainty for quantitative determinations (the most recent edition must be used). This ISO Technical specification provides guidance on the estimation and expression of MU attached to results of quantitative food microbiology. MU is based on a standard deviation of reproducibility of the final result of the measurement process in this ISO Technical specification.

In the context of official controls it is recommended the following principles are taken into account until more specified rules for the quantitative analysis have been established at Community level:

- As regards food-borne pathogens the highest acceptable result including MU should still be low enough to ensure a high level of human health protection. Particularly, in the context of enforcement actions the highest acceptable result must be considered carefully on a case-by-case basis. In Regulation (EC) No 2073/2005, only one quantitative limit is fixed for a pathogen as a food safety criterion, ie *Listeria monocytogenes* (100 cfu/g).
- Indicators are used to determine the acceptable functioning of a production process. Therefore, the rules for interpretation of results of these indicators

¹² http://europa.eu.int/comm/food/food/biosafety/salmonella/microbio_en.htm

related to process hygiene criteria in Regulation (EC) No 2073/2005 need not be as strict as in the context of food safety criteria.

Each accredited laboratory must calculate the MU in relation to each quantitative microbiological determination and if requested by the competent authority to attach it in the test report.

8.3. Microbiological criteria set down in Community legislation

The wish for total harmonisation of microbiological criteria is clearly expressed by the legislator in Regulation (EC) No 852/2005, which entered into force 1 January 2006. Article 17(3) provides that “*pending the setting of criteria referred to in Article 4(3)(a), Member States may maintain any national rules establishing such criteria that they had adopted in accordance with Directive 93/43/EEC.*” These criteria have been set in Regulation (EC) No 2073/2005. Microbiological criteria set down in Regulation (EC) No 2073/2005 must be followed within the Community.

The main objectives of Regulation (EC) No 2073/2005 are to harmonise microbiological criteria within the EU thus enhancing the safety of food as well as elaborating fair rules for food businesses and thus facilitating international trade.

Within the Community **food has to be in compliance with these criteria**. On one hand the food business operators are responsible for ensuring that their products fulfil the criteria set down in this Regulation. On the other hand competent authorities may, for various reasons, take samples to ensure that those criteria are met. It must be emphasised that the point of the food chain specified for each criterion is also applicable to limits of results of official controls.

Regulation (EC) No 2073/2005 contains two types of microbiological criteria: food safety criteria and process hygiene criteria.

Food safety criteria define the acceptability of the batch and they apply only to products placed on the market. When food safety criteria are not fulfilled the product/batch has to be withdrawn or recalled from the market. Food safety criteria apply both to food placed on the Community market and to food imported into the Community.

Member States shall immediately notify the Commission under the rapid alert system for food and feed (RASFF) when the microbiological test result indicates that a Community food safety criterion is exceeded.

Process hygiene criteria indicate the acceptable functioning of the process and they apply during the production process or at the end of it. When process hygiene criteria are not met, the actions to be taken are usually focused on the improvement of production hygiene and/or the selection of the raw material. As a consequence of the definition of the process hygiene criterion, it is neither possible to apply these criteria to products on the intra-Community trade nor to products imported from third countries.

Exceeding of Community process hygiene criteria is not a subject for notification under the rapid alert system.

8.4. Special guarantees for *Salmonella*

Special guarantees for salmonella have been granted to Finland and Sweden for consignments of certain meat and eggs. Consignments of meat and minced meat of bovine and porcine animals and of domestic fowl, turkeys, guinea fowl, ducks and geese must be sampled according to a specific sampling plan in the dispatching establishment and subjected to a salmonella test with negative results before dispatching to Finland and Sweden.

8.5. Absence of Community criteria

In the absence of Community microbiological criteria the evaluation of the food can be done in accordance with Article 14 of Regulation (EC) No 178/2002, which provides that unsafe food products must not be placed on the market. The competent authority can restrict the marketing of a product, on the basis of a case-by-case risk assessment, if there is an indication that the batch is unsafe, e.g. suspected to cause or to have caused human illnesses. On the basis of isolating a pathogen from a batch which has not been sampled in accordance with the sampling plans indicated in point 5.4. e.g. a single sample, the competent authority may take appropriate enforcement action. However, enforcement actions taken by the competent authority should be proportionate and based on scientific proof of the pathogenicity of the organisms present or the health risk associated with the normal conditions of use of the food by the consumer or the food is unfit for human consumption.

8.6. Future Community microbiological criteria

Discussion on the possibility of introducing some new Community microbiological criteria based on some national criteria has been started. Developing new criteria will be based on the principles set down in “Strategy for setting microbiological criteria for foodstuffs in Community legislation” according to which criteria must be relevant and effective in relation to human health protection. The latest scientific advice will be taken into consideration when new criteria are developed.

9. SAMPLES FOR A SUPPLEMENTARY OPINION

9.1. Relevant Community rules and internationally recognised standards

Article 11(5) and (6) of Regulation (EC) No 882/2004

- “5. The competent authorities shall establish adequate procedures in order to guarantee the right of 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.”

Codex Alimentarius: Principles for the establishment and application of microbiological criteria for foods, CAC/GL 21 - 1997

- “4.3 The number and size of analytical units per lot tested should be as stated in the sampling plan and should not be modified. However, a lot should not be subjected to repeated testing in order to bring the lot into compliance.”

9.2. Sampling and analysis

The competent authority must establish a procedure, which ensures that during the official sampling the food business operator or his representative is always aware of his right to obtain samples for a supplementary expert opinion. This right of the food business operator should always be respected. The decision taken by the food business operator should be recorded in the sampling report.

The competent authority should inform the food business operator about the limitations of supplementary sampling for microbiological analysis. For microbiological analysis the results obtained from samples for a supplementary opinion may be of limited value as the distribution of micro-organisms within a food is often not homogenous. No two samples of the food will be the same and it is not uncommon that the results of samples for official controls and for supplementary opinion will differ. Also, bacteria may not survive or may even multiply during storage of the sample again affecting the results of samples for a supplementary opinion.

The right of the food business operator to have samples submitted for a supplementary opinion may be restricted only if the food is highly perishable or there is insufficient substrate.

There is no definition for a '*highly perishable food*' in Community legislation, but Article 3(1) of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs¹³ stipulates the following on the labelling of foodstuffs:

“(5) the date of minimum durability, or in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the ‘use by’ date.”

Furthermore, Article 10(1) states as follows:

“1. In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the ‘use by’ date.”

¹³ OJ L 109, 6.5.2000, p. 29.

ANNEX I

Definitions

The definitions laid down in the relevant Community legislation should be noted:

“Official control” means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules.

(Article 2(1) of Regulation (EC) No 882/2004)

“Competent authority” means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country.

(Article 2(4) of Regulation (EC) No 882/2004)

“Food business operator” means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

(Article 3(3) of Regulation (EC) No 178/2002)

“Batch” means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period.

(Article 2(e) of Regulation (EC) No 2073/2005)

“Food safety criterion” means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market.

(Article 2(c) of Regulation (EC) No 2073/2005)

“Process hygiene criterion” is a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law. (Article 2(d) of Regulation (EC) No 2073/2005)

“Compliance with microbiological criteria” means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority.

(Article 2(1) of Regulation (EC) No 2073/2005)

“Sample” means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it.

(Article 2(j) of Regulation (EC) No 2073/2005)

“Representative sample” means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample.

(Article 2(k) of Regulation (EC) No 2073/2005)

“Food law” means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food and also of feed produced for, or fed to, food producing animals.

(Article 3(1) of Regulation (EC) No 178/2002)

“Risk” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

(Article 3(9) of Regulation (EC) No 178/2002)

“Risk assessment” means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

(Article 3(11) of Regulation (EC) No 178/2002)

“Monitoring” means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed and food law, animal health and animal welfare rules.

(Article 2(8) of Regulation (EC) No 882/2004)

“Surveillance” means a careful observation of one or more feed or food businesses, feed or food business operators or their activities.

(Article 2(9) of Regulation (EC) No 882/2004)

In addition, the following Codex definitions apply:

“Sampling plan” means a planned procedure which enables one to choose, or draw separate samples from a lot, in order to get the information needed, such as a decision on compliance status of the lot. A sampling plan is a scheme defining the number of items to collect and the number of non-confirming items required in a sample to evaluate the compliance status of a lot. (CAC/GL 50-2004)

“Two-class attribute plan” provides a simple means of inspection where the sampling plan is defined by two values, n and c . The value of n defines the sample size in terms of the number of sample items; and the value c denotes the maximum number of nonconforming items permitted in the sample. When undertaking a microbiological assessment, a maximum concentration of micro-organisms permitted in any item is denoted by m ; any item contaminated at a concentration greater than m is considered to be nonconforming. (CAC/GL 50-2004)

“Three-class attribute plan” is defined by the values n , c , m and M ; and are applied to situations where a quality of the product can be divided into three attribute classes depending upon the concentration of micro-organisms within the sample:

- unacceptable quality, with a concentration of micro-organisms above the value M (which must not be exceeded by any items in the sample)

- satisfactory quality, where the concentration must not exceed the value m .
- acceptable quality. Marginal items have a concentration which exceeds m , but which is less than M (such concentrations are undesirable but some can be accepted, the maximum number acceptable being denoted by c). (CAC/GL 50-2004)

ANNEX II

List of international standards and guides referred to in the guidelines

Codex Alimentarius: General guidelines on sampling, CAC/GL 50-2004.

ISO/DIS 7218: Microbiology of food and animal feeding stuffs – General requirements and guidance for microbiological examinations.

EN ISO 16140: Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods.

ISO 17604: Microbiology of food and animal feeding stuffs – Carcass sampling for microbiological analysis.

ISO 18593: Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs.

ISO/TS 19036: Microbiology of food and animal feeding stuffs – Guide on estimation of measurement uncertainty for quantitative determinations

NMKL (Nordic Committee on Food Analysis) Procedure No. 12 – Guide on Sampling for Analysis of Foods. www.nmkl.org

OBS. The most recent edition of the standards and guides shall be used.