EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D2 - Biological risks

Brussels 8.3.2005
SANCO/ 1252/2001 Rev. 11

DISCUSSION PAPER

On strategy for setting microbiological criteria for foodstuffs in Community legislation

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION

ABBREVIATIONS

ALOP	The appropriate level of protection
CAC	Codex Alimentarius Commission
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EN/ISO standard	Standard of the European Committee for Standardization and of the International Organization for Standardization
EU	The European Union
FSO	Food safety objective
HACCP	Hazard analysis critical control point
ISO	International Organisation for Standardization
MU	Measurement uncertainty
PO	Performance objective
PC	Performance criterion
SCOOP	Scientific co-operation
SCVPH	Scientific Committee on Veterinary Measures relating to Public Health
SCF	Scientific Committee on Food
VTEC	Verotoxigenic *Escherichia coli*
WTO's SPS agreement	The agreement on the application of sanitary and phytosanitary measures of the World Trade Organisation

TABLE OF CONTENTS

Summary

This paper describes the Community strategy to set and revise microbiological criteria for foodstuffs in Community legislation. The strategy includes the principles for development and application of the criteria, and proposals for measures to be taken. The strategy covers the foodstuffs and the food chain in a similar way to the proposed new Community food hygiene legislation.

Microbiological criteria give guidance on the acceptability of foodstuffs and their manufacturing processes. Microbiological testing alone cannot guarantee the safety of a foodstuff tested, but these criteria provide objectives and reference points to assist food businesses and competent authorities in their activities to manage and monitor the safety of foodstuffs respectively.

The criteria to be laid down in the Community legislation must be relevant for consumer health protection and their application should be practicable. The criteria will be developed in accordance with internationally recognised principles, such as those of Codex Alimentarius. Whenever possible, the criteria will be based on formal risk assessments. However, pending the conclusions arising from such risk assessments, the available risk profiles and current scientific information may be utilised. A consultation of the European Food Safety Authority (EFSA) is essential when new criteria are set or when the existing criteria are revised.

A criterion should consist of the following components: the micro-organisms of concern, the analytical method, sampling plan, limits, the foodstuff in question, the points of the food chain where the criterion applies and the actions to be taken when the criterion is not met. Sampling plans and limits should reflect the severity of the health hazard. Only the reference methods will be laid down in the legislation, and preference must be given to horizontal methods developed by international standardisation organisations. Such methods should be used when compliance with regulatory requirements is monitored. Sampling frequencies would generally not be established in Community legislation.

It is preferable that food businesses use the microbiological criteria in the context of their food safety management systems based on HACCP principles. The food businesses should be able to ensure that foodstuffs meet the criteria and that manufacturing processes function in such a way that the criteria are met. It is acknowledged that flexibility concerning the analyses and sampling methods is needed in the testing linked to food businesses' own controls.

While awaiting the results from formal risk assessments, it is necessary to revise the current criteria in Community legislation. These measures to be taken will be open to review, and revised, if appropriate, in order to take into account progress in science, technology and methodology as well as the outputs from risk assessments. Criteria set for end-products are proposed for the most important micro-organisms of

demonstrable concern. In addition the proposed measures include criteria able to indicate hygiene in manufacturing processes. The proposed measures are based on the current criteria and on the scientific opinions issued by the EU's Scientific Committees and by EFSA (since 2003).

1. Introduction

A strategy to set and revise the microbiological criteria for foodstuffs in Community legislation is presented in this paper. The criteria will be prescribed on the basis of Regulation 852/2004[1] on the hygiene of foodstuffs applicable from 1.1.2006. The strategy includes:

- definitions of microbiological criteria to be used in Community legislation,
- principles on the development and application of the criteria, and
- proposals for measures to be taken.

Microbiological criteria give guidance on the acceptability of foodstuffs and their manufacturing processes. However, the application of microbiological criteria has certain limitations. Due to reasons related to sampling, methodology and uneven distribution of micro-organisms, microbiological testing alone can never guarantee the safety of a foodstuff tested. Therefore the safety of foodstuffs is principally ensured by a structured preventive approach, such as good product and process design and the application of good hygiene practice and the Hazard Analysis Critical Control Point (HACCP) principles.

While the Community legislation on food hygiene and on control of zoonoses has been revised, there is also a need to revise the microbiological criteria in current Community legislation. Regulation 853/2004[2] laying down specific hygiene rules for food of animal origin and Regulation 2160/2003[3] on the control of salmonella and other foodborne zoonoses already include some provisions on criteria for microorganisms, parasites and marine biotoxins.

2. Current legislation

The Community legislation in force before 1 January 2006 includes numerous microbiological criteria for foodstuffs. These criteria are laid down in the following Directives and Decisions:

- Council Directive 80/777/EEC[4] of 15July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters,
- Council Directive 89/437/EEC[5] of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products,
- Council Directive 91/492/EEC[6] of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs,

1 OJ L 226, 25.6.2004, p. 3.
2 OJ L 226, 25.6.2004, p. 22.
3 OJ L 325, 12.12.2003, p. 1.
4 OJ L 47, 20.2.1981, p. 43
5 OJ L 212, 22.7.1989, p. 87
6 OJ L 268, 24.9.1991, p. 1

- Council Directive 91/493/EEC[7] of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products,
- Council Directive 92/46/EEC[8] of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products,
- Commission Decision 93/51/EEC[9] of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish,
- Council Directive 94/65/EC[10] of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations, and
- Commission Decision 2001/471/EC[11] laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat.

The criteria in force until 1 January 2006 are summarised in Annex I. These criteria are applicable at the site of food production as well as in import control and intra-Community trade, but not at retail level, with the exception of the criteria set for natural mineral waters. A number of other Directives include enabling provisions, which provide the possibility to set microbiological criteria in accordance with the comitology procedure.

Many Member States have additional microbiological criteria for various foodstuffs in their national legislation. A summary of these criteria is presented in the report of SCOOP: Microbiological criteria, collaboration of scientific and methodological information with a view to the assessment of microbiological risk for certain foodstuffs (Reports on tasks for scientific co-operation, 1998). The main findings and conclusions of this report are still valid and they are presented in Annex II.

National microbiological criteria adopted according to the procedure laid down in Directive 93/43[12] on the hygiene of foodstuffs and which do not constitute a barrier to trade may be maintained after 1 January 2006 (Regulation 852/2004 Article 17.3). Other national criteria will cease to be applicable to operators as of 1 January 2006. In order to continue the harmonisation of microbiological criteria in the EU the Commission collects information about present national criteria in 2005. In particular, data of the stage where the criterion applies, status of the criterion and scientific evidence are asked.

---

7 OJ L 189, 9.7.1992, p. 47.
8 OJ L 41, 18.2.1993, p. 50.
9 OJ L 129, 27.5.1993, p. 28.
10 OJ L 127, 29.4.1998, p. 34
11 OJ L 165, 21.6.2001, p. 48
12 OJ L 208, 5.9.1995, p. 20

3. Opinion of the Scientific Committee

In the context of the recast of Community hygiene legislation a question concerning microbiological criteria was addressed to the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH). As regards foodstuffs of animal origin, the Committee was asked to evaluate the need for using microbiological testing against criteria and the appropriateness of the criteria layed down in current EU provisions as well as to make recommendations for change where appropriate.

The Committee gave its opinion on the evaluation of microbiological criteria for food products of animal origin for human consumption on 23 September 1999. The Committee concluded that the current criteria were not based on risk assessment or on internationally approved principles. In addition the criteria were numerous, varied and laid down in different formats. The Committee recommended that microbiological criteria should be relevant and effective in relation to consumer health protection. The criteria should also take into account regional differences in the prevalence of pathogens and changes in food animal production practice. If the criteria are revised, they should be harmonised and the existing problems regarding emerging foodborne pathogens should be considered using a horizontal approach. The Committee proposed as interim measures revised criteria, which they indicated would need to be further reviewed in the light of risk assessments, when available. The principles of Codex Alimentarius and the recommendations from the Scientific Committees of the EU should be followed if the current microbiological criteria are to be revised or new criteria set. The conclusions of the report and the interim criteria are presented in Annex III.

The SCVPH also issued an opinion on *Listeria monocytogenes* in 1999, an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* in 2001, an opinion on Norwalk-like viruses (noroviruses) in 2002, an opinion on verotoxigenic *E. coli* (VTEC) in 2003, an opinion on staphylococcal enterotoxins in 2003 and an opinion on *Salmonella* in 2003. Additionally, the Scientific Committee on Food (SCF) adopted an opinion on *L. monocytogenes* in 2000 as well as a risk profile on microbiological contamination of fruit and vegetables eaten raw in 2000 and an opinion on gelatine in 2002. The European Food Safety Authority's (EFSA) Scientific Panel on Biological Hazards (BIOHAZ Panel) issued an opinion on the microbiological risks in baby formulae and follow-on formulae in 2004. Several new questions concerning appropriateness of setting certain microbiological criteria for foodstuffs have been recently addressed to the EFSA.

4. Development of criteria

Codex Alimentarius issued a guideline "Principles for the establishment and application of microbiological criteria for foods CAC/GL 21-1997" in 1997. The SCF and the SCVPH gave recommendations on principles for the development of microbiological criteria for foodstuffs in 1996 and 1997, respectively. According to the definition of Codex Alimentarius "a microbiological criterion for food defines the acceptability of a product or a food lot, based on the absence or presence, or number

of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot". The definition given by the SCF and the SCVPH is similar except that it refers additionally to the acceptability of a process.

The main principles in these three documents are identical. They agree among other things on the following principles:

- Microbiological criteria should be established and applied only where there is a definite need and where their application is practical.
- A mandatory microbiological criterion shall only apply to those products and/or points of the food chain where no other more effective tools are available, and where it is expected to improve the degree of protection offered to the consumer.
- The microorganisms included in a criterion should be widely accepted as relevant - as pathogens or as indicator organisms - to the particular food and technology.

5. Appropriate Level of Protection and Food Safety Objectives

The appropriate level of protection (ALOP) is defined in the WTO's SPS[13] agreement, as follows: "the level of protection deemed appropriate by the Member (country) establishing sanitary or phytosanitaty measures to protect human, animal or plant life or health within its territory".

The principles of microbiological risk management are currently being discussed at the international forums. The new concepts of "a food safety objective (FSO)", "a performance objective (PO)" and "performance criterion (PC)" have been introduced by Codex Alimentarius Commission[14] as tools to be used in risk management of microbiological hazards in foodstuffs. However, the application of these concepts is still under development.

The following definitions have been accepted for these new concepts:

- FSO: the maximum frequency and/or concentration of a [microbiological] hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)
- PO: the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable
- PC: the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

In the context of microbiological risk management the ALOP is a reflection of a particular country's expressed public health goals for a microbiological hazard associated with a food. An ALOP can be implicit or explicit. An explicit description of ALOP may be in terms of a probability of an adverse public health consequence or an incidence of disease.

---

13 The agreement on the application of sanitary and phytosanitary measures of the World Trade Organization

14 Codex Alimentarius Commission, 14th Procedural Manual

The concept of FSO has been introduced because of the difficulties of relating control measures directly to an ALOP. While ALOP is an expression of a public health risk, an FSO expresses the level of hazard in relation to that risk. As the FSO applies to the time of consumption, it will need to be used in conjunction with performance or other criteria to establish the level of control needed to other parts of the food chain. In most cases the acceptable levels of hazard at the earlier stages of the food chain differ from the FSO. The performance criteria are by definition the required outcomes of control measures at a step or combination of steps to contribute to assuring the safety of food.

It is probable that in the future FSOs will also be used as a basis for Community legislation. This opportunity is foreseen in the recast of Community hygiene legislation where targets and criteria could be set to facilitate the implementation of Regulation 852/2004 on the hygiene of foodstuffs.

6. Foodborne pathogens of most concern

The SCVPH identified in its opinion on foodborne zoonoses of 12 April 2000 the following zoonotic agents as public health priorities in Europe: *Salmonella* sp., *Campylobacter* sp., verotoxigenic *Escherichia coli* (VTEC), *Listeria monocytogenes,* and parasites such as *Cryptosporidium* sp., *Echinococcus granulosus/multilocularis* and *Trichinella spiralis*. The SCVPH's opinion on microbiological criteria mentioned in particular *Salmonella*, *Campylobacter,* verotoxigenic *E. coli* and *L. monocytogenes,* together with other foodborne pathogens, as existing problems that need urgent consideration.

According to the Community report on zoonoses[15], salmonellosis and campylobacteriosis were the most frequently reported zoonotic diseases in humans in the EU during the year 2003. In the 7th and 8th reports from the World Health Organisation Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe in 1993-1998 and in 1999-2000 respectively, the majority of outbreaks where causative agents were reported were caused by *Salmonella* serotypes. Other frequently reported causative agents included *Staphylococcus aureus*, *Clostridium perfringens*, *Bacillus cereus* and foodborne viruses. In particular, viruses have been increasingly found to be responsible for foodborne outbreaks, as analytical methods have improved. Although *Campylobacter* is infrequently associated with outbreaks, it is nevertheless an important agent in sporadic cases of foodborne disease.

7. A Community strategy

In the framework of the recasts of Community food hygiene and zoonoses legislation there is a need for a comprehensive strategy concerning setting and implementation of microbiological criteria. This strategy must cover the foodstuffs and the production and distribution chain (including retail trade) in a similar way to the proposed new hygiene legislation. The food hygiene legislation exempts from the scope only the

[15] Report on Trends and Sources of Zoonotic Agents in Animals, Feedingstuffs, Food and Man in the European Union and in Norway in 2003.

direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments. The strategy should also recognise the limited role of microbiological criteria within a legislative framework that focuses on the control of hazards within food business operations. The following principles form the basis for a Community strategy on microbiological criteria:

7.1. Definition of criteria

The definition of the Codex Alimentarius for a microbiological criterion can be adapted as a Community definition with an extension to cover also the acceptability of processes as proposed by the SCF and the SCVPH.

- *Microbiological criterion for foodstuffs* would thus mean a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence or presence, or number of micro-organisms (including parasites), and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.
  The two different kinds of criteria would be defined as follows:
  1. *A food safety criterion* would mean a criterion defining the acceptability of a product or a batch of foodstuff applicable to products ready to be placed on the market or which are already in the market.
  2. *A process hygiene criterion* would mean a criterion indicating the acceptable functioning of the production process. 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.

A criterion consists of the following components:
- a statement of the micro-organisms or their toxins/metabolites of concern and the reason for that concern;
- the analytical methods including, when available, the analytical tolerance;
- the plan defining the number of field samples to be taken and the size of the analytical unit;
- the microbiological limits considered appropriate to the food at the specified point(s) of the food chain;
- the number of analytical units that should conform to these limits.

The criterion should also state
- the foodstuff to which the criterion applies;
- the points of the food chain where the criterion applies; and
- the actions to be taken when the criterion is not met.

The microbiological criteria in Community legislation can be used in different ways depending on the site of application and the actions to be taken in case of non-compliance:

Criteria set for processes (process hygiene criteria) are applicable only to the food businesses manufacturing, preparing or producing the foodstuff in question. These criteria are set for a product at a specified stage of the process and they do not apply to products already placed on the market. These kinds of criteria are usually used in the monitoring of manufacturing and preparation processes. They are for example able to indicate whether good hygiene practices are being followed and may assist in understanding whether the HACCP procedures are functioning properly.

Criteria set for end-products (food safety criteria) may apply to the products ready to be placed on the market or which are already at the retail stage. These criteria are applicable both to the sale and delivery to final consumers as well as to retail trade operators. Food safety criteria are also applicable at the point of entry on the territory of the EU when imported from third countries.

Food safety criteria would be mandatory in nature and process hygiene criteria would take more the form of a guideline. A non-compliance with mandatory type of criteria would lead to rejection, sorting, reprocessing or withdrawal from the market of the product/batch in question. A non-compliance with the guideline type of criteria would usually only lead to corrective actions in processing or handling of the foodstuffs and the food business operator would mainly decide on the actions to be taken. The measures required would depend on the risk involved, the point of the food chain and the product in question.

The site of application and the actions to be taken in case of non-compliance will always be described in the criterion itself when it is laid down in the legislation.

The definitions given in Regulation 178/2002[16] laying down the general principles and requirements of food law are applicable when the microbiological criteria are to be laid down. This regulation contains the following definitions for foodstuffs and retail:

- *'Food'* (or foodstuffs) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation and treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.
- '*Retail*' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

7.2. Establishment of Community criteria

The principal objective of Regulation 852/2004 on the hygiene of foodstuffs is to ensure a high level of consumer protection with regard to food safety. The introduction of microbiological criteria relevant to public health will contribute to this objective. The application of the criteria should enhance food safety and at the same time be feasible in practice. The intention is not to create unnecessary burdens and testing for the food businesses. Consequently, thorough consideration should be given to the necessity and applicability of each criterion.

[16] OJ L 31, 1.2.2002, p. 1.

The microbiological criteria to be included in Community legislation are to be developed in accordance with internationally recognised principles, such as the principles adopted by Codex Alimentarius, and the recommendations presented by the EU's Scientific Committees. These main principles are described in Chapter 4.

A consultation of the EFSA is essential when new criteria are set or when the existing criteria are revised. The criteria should, whenever possible, be based on formal risk assessment. The EFSA will have an important role in promoting and co-ordinating risk assessments and their methodologies as well as in interpretation and consideration of risk assessments conducted by the Member States, other countries or international organisations.

So far few formal risk assessments have been finalised and the quantitative microbiological risk assessment is still under development. Therefore, the EFSA should encourage the Member States and scientific bodies in the EU to conduct collaborative microbiological risk assessments as well as studies to provide information for risk assessments.

Pending the conclusions arising from risk assessments, one can take into account the risk profiles available for certain microbiological agents or a given agent/food commodity combination. Risk profiles provide for a description of a food safety problem and its context, and are developed to identify those elements of a hazard or risk that are relevant to risk management decisions. Risk profiles can enable a quick application of risk management measures, which may include the establishment of microbiological criteria. The measures would be temporary but reasonable and efficient because they are based on an initial evaluation of the food safety issue within the framework of public health, scientific data and the availability of management options. These measures may be amended, completed or even repealed in the light of the conclusions of the actual risk assessment.

7.3. Sampling plans, analytical methods and limits

When a microbiological criterion is laid down in Community legislation it should contain an analytical reference method, including the limit of detection and the analytical tolerance, if available, an appropriate sampling plan and the microbiological limit.

Sampling plans and microbiological limits should be chosen according to the severity of the health hazard and the expected conditions in which the foodstuff shall be handled and consumed. The described sampling plans should always be used, as a minimum, when the acceptability of a food batch or a process is assessed. However, a strict adherence to sampling plans is not always necessary in routine testing linked to food businesses' own controls. In particular, the number of sample units may be reduced when the food business has a well functioning HACCP system. Nevertheless, it has to be borne in mind that a single satisfactory sample does not guarantee that the hygienic status of the batch sampled is satisfactory as well. It follows that the use of single sample analysis is limited as a HACCP verification tool because failure to detect a pathogen does not imply that the process is microbiologically safe. Similarly,

when competent authorities are taking samples from foodstuffs at retail level for monitoring purposes, it is also possible to use single samples as a part of the overall approach to official control. If the product is then found unsatisfactory, more samples can be taken to clarify the situation along with the other appropriate measures deemed necessary by the competent authority.

The analytical methods should preferably be internationally recognised. Only the reference methods should be laid down in the legislation and preference should be given to horizontal methods developed by international standardisation organisations. The use of alternative methods would then be authorised if they offer equivalent results to those obtained by the reference method and if they are validated in accordance with internationally recognised rules, such as those laid down in EN/ISO standard 16140. In addition analytical methods other than those mentioned above may be used in food businesses' own controls if the methods are demonstrated to offer equivalent guarantees, if the methods are validated in an appropriate way.

Measurement uncertainty (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. General policy in recent discussions seems to be that food business operators should always regard all test results above the limits 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.

The analytical tolerance will be used in order to take into account the variability in the results caused only by the analytical method. However, it is good to keep in mind that the sampling is often a greater source of differences in test results. As regards the microbiological limits, unsubstantiated differences will be avoided when new limits are set or the old limits revised.

Generally, the food business operators may choose to use sampling and testing procedures other than those described in the legislation. This relates to the choice of analytical and sampling methods, the site of sampling, the microbiological limits, the number of sample units taken and even to the group of organisms to be tested. This is possible as far as the procedures offer equivalent guarantees to the methods set in the legislation. The food business should be able to demonstrate this equivalency when requested by the competent authority. But adherence to the methods, sampling plans and limits laid down in legislation would usually be necessary where a formal assessment under the statutory provisions is needed.

In some cases it is useful to include samples taken from the production environment in the sampling procedure. This applies, particularly to situations where the environment is known to form an important source of contamination, such as *Listeria monocytogenes*, *Enterobacter sakazaki* and salmonella contamination in some food processing plants.

The Commission's intention is generally not to establish sampling frequencies in Community legislation. This is because the main focus of the Community approach will be the management of food safety risks by each food business operator through the implementation of HACCP-based principles. The frequency and value of microbiological sampling will need to be judged on a case by case basis in that context. On a day-to-day basis, this is the responsibility of food business operators. However, in some areas, where the microbiological risks involved are regarded to be high, community sampling frequencies may be established in order to ensure uniform implementation of the controls.

The analysis of samples taken for official controls must be carried out by laboratories designated for that purpose by the competent authority. According to Regulation 882/2004[17] on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules the laboratories must be accredited in accordance with the European standard EN ISO/IEC 17025[18]. It is equally important that the results of the analyses made by the food businesses are reliable. Therefore the laboratories used for these analyses should also fulfil adequate quality assurance standards and preferably be accredited, as well.

7.4. The responsibility of food businesses

The microbiological criteria to be complied with by food business operators in the new hygiene legislation will be laid down on the basis of Regulation 852/2004 on the hygiene of foodstuffs, which describes the obligations of food businesses in relation to food hygiene. One of the basic obligations is that food businesses shall implement permanent procedures based on the HACCP principles in order to ensure the safety of their products. The food business operators also have to comply with the microbiological criteria and take measures to meet the target set to achieve the objectives of the Regulation.

The Community approach to the operation of microbiological criteria must be established in the context of the food safety management system based on HACCP principles. A major advantage of the HACCP based approach is the focus on prevention and systematic, effective process controls, rather than mainly relying on end product testing. With such an approach, microbiological criteria in legislation or in published literature may provide a reference point and an objective to assist food business operators in evaluating their HACCP data.

Food business operators should view microbiological criteria laid down in Community legislation in this way. The operators may decide, in the context of their HACCP procedures or their other own controls, how they are going to ensure that the criteria in the legislation are met and to what extent testing against the criteria is needed. The idea is that the food businesses should be able to demonstrate to the satisfaction of the competent authorities that their products, when properly handled and stored during distribution, retail and by consumers, meet the food safety criteria throughout the shelf-life. To this end the food businesses may need to conduct studies

[17] OJ L 191, 28.5.2004, p. 1.

[18] EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'

to investigate the compliance during the shelf-life. The businesses should also ensure that manufacturing processes function in such a way that the criteria are met. The food businesses must be ready to respond appropriately in case of non-compliance, for example by following the predetermined actions set by the criteria.

It is possible that the food businesses choose to use more stringent criteria in their own controls. On the other hand microbiological testing might not be necessary at all for some food businesses, if they are able to ensure, by applying some other control measures, that the criteria are met. However, the main responsibility for testing against criteria would rest with the food businesses.

Traditional microbiological methods are usually too slow to be used in the monitoring of the critical points in HACCP systems. However, such analyses are useful for the verification of the correct implementation of HACCP based systems as well as in validation of food hygiene measures. Methods based on physiochemical parameters often meet the need to provide rapid results and therefore such methods may be used in the control of critical control points.

In addition to comparing the results against the criteria, it is preferable that food businesses also follow and assess the trends in the results over a longer period of time. This would allow them to react before the processes are already out of control and the limits exceeded. The trends can be followed, for example, by displaying the test results graphically on control charts.

7.5. The role of competent authorities

As a part of the official controls of foodstuffs the competent authorities must verify the compliance with the microbiological criteria laid down in Community legislation. For this purpose the authorities have at their disposal several control methods and techniques, such as sampling and analysis, monitoring, surveillance, audits and inspection. These methods include, for example, assessments of the HACCP and other control systems operated by the food businesses and examinations of documentation kept by the food business operators. In this context the authorities may check the results from microbiological testing and the actions taken in case of unsatisfactory results. The competent authorities may also take samples by themselves for microbiological analyses. This sampling may include samples from the producer's samples from the market as well as samples from the Border Inspection Point of imported products.

The Community legislation on food hygiene also provides Community controls. Commission experts carry out on a regular basis general audits and specific inspections in the Member States in co-operation with the competent authorities. The main purposes of these controls are to verify that the official control activities in the Member States are in line with Community legislation and to investigate important or emerging problems in the Member States.

7.6. Setting the criteria in Community legislation

While acknowledging that the results from formal risk assessments are needed for the formulation of microbiological criteria, it is nevertheless necessary to revise the current criteria in Community legislation. These measures to be taken will be open to review, and revised if appropriate, in order to take into account progress in science, technology and methodology as well as the possible outputs from risk assessments including their uncertainties.

The intention is that the proposed Commission Regulation laying down these revised criteria would be submitted for adoption mid 2005 after the adoption of the Regulation on the hygiene of foodstuffs with due consideration for the industry's need for time to operate the new requirements by 1 January 2006. The objective of this Commission Regulation is that foodstuffs should not contain micro-organisms or their toxins in quantities that present a risk to human health. Setting microbiological criteria is one available risk management option to meet this objective together with other control measures. This Commission Regulation will be updated regularly in order to achieve in a medium term (about 4-4 years) a complete harmonisation of the microbiological criteria used in the EU.

A harmonised approach is proposed as follows:

a) Criteria for ready-to-eat foods and certain other categories of food:

Ready-to-eat foods are regarded as being of potentially higher risk, because these foods are not usually subject to treatments that would destroy pathogens before consumption. Ready-to-eat food means all types of food intended for consumption without further bactericidal or viricidal heat treatment or processing with an equivalent effect.

These criteria would be set for pathogenic micro-organisms that are common causes of foodborne diseases in humans and/or are able to cause severe foodborne diseases in humans.

Criteria would be only set for those categories of ready-to-eat foods where the risk in question is relevant and where application of the criteria is expected to improve protection of consumers. The sampling plans and frequencies used for different categories of ready-to-eat foods could vary according to the risk involved.

In addition, if a special risk is known to relate to a particular food category, which cannot be regarded as ready-to-eat, and if this risk is considered important in terms of consumer safety, specific criteria could be set concerning the micro-organisms and the food category in question.

b) Criteria for processes (process hygiene criteria):

Current Community legislation includes criteria which can be interpreted as being criteria set for processes in that they are used to indicate hygiene during the manufacturing process. It is still deemed necessary to prescribe these kinds of criteria in Community legislation in order to ensure the same hygiene level is being applied in

establishments throughout the Community and to promote the safety of the foodstuffs produced. A question can nevertheless be posed whether these criteria could in the future be set in the national or Community guides to good practice and guides to the application of HACCP referred to in the recast of food hygiene legislation. Food businesses are best placed to know the most suitable process criteria to indicate good hygiene in processes used in their operations.

The Commission intends to propose revised criteria for indicating the hygiene of the manufacturing process based on criteria in force and on the opinion of the SCVPH (Annex III). The Commission will also reflect on the setting of additional process hygiene criteria for certain products, such as poultry meat and products of plant origin.

c) Evaluation of the need for microbiological criteria for pathogenic micro-organisms in raw foodstuffs:

The Commission is taking a comprehensive approach to decrease the number of infectious foodborne diseases in humans. The new zoonoses legislation already foresees the setting of targets for the reduction of zoonoses and zoonotic agents in animal populations. In this context it is necessary to evaluate the need for microbiological criteria for the most important foodborne pathogens in those foodstuffs, which are usually subject to further bactericidal treatment before consumption but which are potential sources for cross-contamination during the distribution, storage and handling. Such foodstuffs may include e.g. fresh meat, fresh poultry meat, certain raw fishery products and raw vegetables. The pathogens involved would include *Salmonella*, *Campylobacter, L. monocytogenes,* VTEC and *Vibrios*. Regulation 2160/2003 on the control of salmonella and other food-borne zoonotic agents already contains a criterion for salmonella in broiler meat.

d) Consultations of the EFSA and the Scientific Committee and panels:

The existing and forthcoming opinions from the Scientific Committees on microbiological risks related to foodstuffs will be taken into account when Community criteria are established. Furthermore the EFSA will be consulted as regards questions which are not yet covered by the existing opinions.

Under the recently revised legislation on the monitoring of zoonoses[19], EFSA has been entrusted to produce the yearly Community report on trends and sources of zoonoses along the food chain, which was produced since 1995 by the Community Reference Laboratory for epidemiology of zoonoses in Berlin. EFSA will also provide technical and scientific assistance to the Commission in the monitoring of zoonoses; EFSA will produce its first report on data 2004 by the end of 2005. The data collection should support risk assessment activities, like exposure to zoonotic agents, or characterisation of risks.

The data collected in humans through the Communicable Disease Network[20] and European Centre for Disease Prevention and Control (ECDC) will therefore be of

[19] Directive 2003/99/EC, OJ L 325, 12.12.2003, p. 31

[20] Decision 2119/98/EC, OJ L, 20.10.1998, p. 76

utmost importance when considering animals or foods as sources to diseases in humans and the impact of pathogenic micro-organisms and their toxins.

8. References

The Scientific Committee on Veterinary Measures relating to Public Health:

- Recommendation on the principles for the development of microbiological criteria for animal products and products of animal origin intended for human consumption, September 1997
- Opinion on *Listeria monocytogenes*, 23 September 1999
- Opinion on The evaluation of microbiological criteria for food products of animal origin for human consumption, 23 September 1999
- Opinion on revision of meat inspection procedures, 24 February 2000
- Opinion on food-borne zoonoses, 12 April 2000
- Opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* (in raw and undercooked sea food), 20-21 June 2001
- Opinion on Norwalk-like viruses, 30-31 January 2002
- Opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs, 21-22 January 2003
- Opinion on staphylococcal enterotoxins in milk products, 26-27 March 2003
- Opinion on salmonellae in foodstuffs, 14-15 April 2003

The Scientific Committee on Food:

- Recommendation on the principles for the development of microbiological criteria for foodstuffs covered by the hygiene of foodstuffs directive 93/43/EEC
- Recommendation on the principles for the development of risk assessment of microbiological hazards under Directive 93/43/EEC concerning the hygiene of foodstuffs, September 1997
- Opinion in respect of *Listeria monocytogenes*, 22 June 2000
- Opinion on specifications for gelatine in terms of consumer health, 27 February 2002
- Report on the risk profile on the microbiological contamination of fruits and vegetables eaten raw, 24 April 2002

The Scientific Panel on Biological Hazards of the European Food Safety Authority:

- Opinion on the microbiological risks in baby formulae and follow-on formulae

Codex Alimentarius:

- Principles for the development and application of microbiological criteria for foods. CAC/GL 21 -1997
- Recommended international code of hygiene practice for foods for infants and children. CAC/RPC 21-1979 (amended 1981)
- Codex Alimentarius Commission, 14th Procedural Manual

SCOOP:

Reports on tasks for scientific co-operation, Microbiological criteria: Collation of scientific and methodological information with a view to the assessment of microbiological risk for certain foodstuffs, Report of experts participating in Task 2.1,

European Commission, EUR 17638, Office for Official Publications of the European Communities, Luxembourg, 1998.

ICMSF (1986). International Commission on Microbiological Specifications for Foods (ICMSF) Microorganisms in Foods, 2. Sampling for microbiological analysis. Principles and specific applications, 2nd Edition, Blackwell Science, Oxford.

European Commission: Report on Trends and Sources of Zoonotic Agents in Animals, Feedingstuffs, Food and Man in the European Union and in Norway in 2003.

WHO surveillance programme for control of foodborne infections and intoxications in Europe: 7th report 1993-1998.

WHO surveillance programme for control of foodborne infections and intoxications in Europe: 8th report 1999-2000.

ANNEX I

MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS IN COMMUNITY LEGISLATION IN FORCE (in force until 1 January 2006)

Food category	Microorganisms	Limit	Sampling plan				Additional information
			N	c	m	M	
Carcasses of cattle, sheep, goat and horse (Decision 2001/471/EC)	Aerobic colony count		5-10		3,5 log cfu/cm^2	5,0 log cfu/cm^2	Daily log mean
	Enterobacteriaceae (E.coli)		5-10		1,5 log cfu/cm^2	2,5 log cfu/cm^2	Daily log mean
Carcasses of pig (Decision 2001/471/EC)	Aerobic colony count		5-10		4,0 log cfu/cm^2	5,0 log cfu/cm^2	Daily log mean
	Enterobacteriaceae (E.coli)		5-10		2,0 log cfu/cm^2	3,0 log cfu/cm^2	Daily log mean
Minced meat (Directive 94/65/EEC)	Aerobic mesophilic bacteria		5	2	5x10^5 /g	5x10^6 /g	
	E. coli		5	2	50 /g	500 /g	
	Salmonella	Absence in 10 g	5	0			
	S. aureus		5	2	100 /g	1000 /g	
Meat preparations (Directive 94/65/EEC)	*E. coli*		5	2	500 /g	5000 /g	
	S. aureus		5	1	500 /g	5000 /g	
	Salmonella	Absence in 1 g	5	0			
Raw cow's milk intended for processing (Directive 92/46/EEC)	Plate count at 30°C	10^5 cfu/ml					
	S. aureus		5	2	500 cfu/ml	2000 cfu/ml	Milk for manufacturing of raw products

Raw goat's, sheep's and buffalo's milk	Plate count at 30°C	5x 10^5 cfu/ml					Milk intended for manufacture of products made from raw milk
	Plate count at 30°C	1.5x10^6 cfu/ml					Milk intended for manufacture of heat treated milk based products
Raw cow's milk intended for direct human consumption (Directive 92/46/EEC)	*Salmonella*	Absence in 25 g	5	0			
	S. aureus		5	2	100 /ml	500 /ml	
	Plate count at 30°C	5x10^4 cfu/ml					
	Pathogenic microorganisms and their toxins	Not in quantities to affect human health					
Pasteurised drinking milk (Directive 92/46/EEC)	Pathogenic microorganisms	Absent in 25 g	5	0			
	Coliforms		5	1	0 cfu/ml	5 cfu/ml	
	Plate count at 21°C		5	1	5x10^4cfu/g	5x10^5 cfu/g	After incubation at 6°C for 5 days
UHT milk and strerilized milk (Dir. 92/46/EEC)	Plate count at 30°C	10 cfu/0,1 ml					After incubation at 30°C for 15 days
Cheeses made from raw milk and from thermized milk (Directive 92/46/EEC)	*Listeria monocytogenes*	Absence in 1 g (hard cheeses) or in 25 g (other)	5	0			
	Salmonella	Absence in 1 g	5	0			
	S. aureus, guideline[21]		5	2	1000 cfu/g	10000 cfu/g	
	E. coli, guideline[2]		5	2	10^4 cfu/g	10^5 cfu/g	

[21] Mandatory if pathogenic or enterotoxinogenic strains found

Soft cheese (made from heat-treated milk) (Directive 92/46/EEC)	*Listeria monocytogenes*	Absence in 25 g	5	0			
	Salmonella	Absence in 1 g	*5*	*0*			
	S. aureus, guideline[2]		5	2	100 cfu/g	1000 cfu/g	
	E. coli, guideline[2]		5	2	100 cfu/g	1000 cfu/g	
	Coliforms, guideline		5	2	10^4 cfu/g	10^5 cfu/g	
Fresh cheese (Directive 92/46/EEC)	*Listeria monocytogenes*	Absence in 25 g	5	0			
	Salmonella	Absence in 1 g	5	0			
	S. aureus, guideline		5	2	10 cfu/g	100 cfu/g	
Other cheeses than those mentioned in 5.5-5.7 (Directive 92/46/EEC)	*Listeria monocytogenes*	Absence in 1 g (hard cheeses) or in 25 g (other)	5	0			
	Salmonella	Absence in 1 g	5	0			
Butter (Directive 92/46/EEC)	*Listeria monocytogenes*	Absence in 1 g	5	0			
	Salmonella	Absence in 1 g	5	0			
	Coliforms, guideline		5	2	0 cfu/g	10 cfu/g	
Powdered milk and milk based products (Directive 92/46/EEC)	*Salmonella*	Absence in 1 g	5	0			
	Listeria monocytogenes	Absence in 1 g	5	0			
	S. aureus, guideline		5	2	10 cfu/g	100 cfu/g	Powdered milk
	Coliforms, guideline		5	2	0 cfu/g	10 cfu/g	Powdered milk-based products
Frozen milk-based products (Directive 92/46/EEC)	*Salmonella*	Absence in 1 g	5	0			
	Listeria monocytogenes	Absence in 1 g	5	0			
	S. aureus, guideline		5	2	10 cfu/g	100 cfu/g	
	Coliforms, guideline		5	2	10 cfu/g	100 cfu/g	
	Plate count, guideline		5	2	10^5 cfu/g	$5x10^5$ cfu/g	
Liquid milk-based products (Directive 92/46/EEC)	*Salmonella*	Absence in 1 g	5	0			
	Listeria monocytogenes	Absence in 1 g	5	0			
	Coliforms		5	2	0 cfu/g	5 cfu/g	

	Plate count		5	2	$5x10^4$ cfu/g	10^5 cfu/g	Heat-treated and unfermented products
Live bivalve molluscs (Directive 91/492/EEC)	*Salmonella*	Absence in 25 g					
	Faecal coliforms, or	<300 / 100g < 6000 / 100 g < 60000/ 100g					Production area A Production area B Production area C
	E. coli	<230 / 100g <4600 / 100 g					Production area A Production area B
Cooked crustaceans and molluscan shellfish (Decision 93/51/EEC)	*Salmonella*	Absence in 25 g	5	0			
	S. aureus		5	2	100 cfu/g	1000 cfu/g	
	Any pathogen	Quantities to affect human health					
	Thermotolerant coliforms or		5	2	10 cfu/g	100 cfu/g	
Cooked crustaceans and molluscan shellfish (Decision 93/51/EEC)	*E. coli*, guideline		5	1	10 cfu/g	100 cfu/g	
	Mesophilic aerobic bacteria, guideline		5	2	10^4 cfu/g	10^5 cfu/g	Whole products
			5	2	$5x10^4$ fu/g	$5x10^5$ cfu/g	Shelled and shucked
			5	2	10^5 cfu/g	10^6 cfu/g	Crabmeat
Egg products (Directive 89/437/EEC)	*Salmonella*	Absence in 25 g					
	Aerobic mesophilic bacteria	10^5 cfu/g or ml					
	Enterobacteriaceae	100 cfu/g or ml					
	S. aureus	Absent in 1 g					
Natural mineral waters (Directive 80/777/EEC)	Total colony count	20 cfu/ml					At source, incubated at 20-22°C for 72 hours
		5 cfu/ml					At source, incubated at 37°C for 24 hours
		100 cfu/ml					After bottling, incubated at 20-22°C for 72 hours

Natural mineral waters		20 cfu/ml					After bottling, incubated at 37°C for 24 hours
	E.coli, other coliforms, feacal streptocci	Absence in 250 ml					At source and during marketing
	Sporulated sulphite-reducing anaerobes	Absence in 50 ml					At source and during marketing
	Pseudomonas aeruginosa	Absence in 250 ml					At source and during marketing

ANNEX II

SUMMARY OF THE REPORT OF EXPERTS PARTICIPATING SCIENTIFIC CO-OPERATION IN TASK 2.1

"MICROBIOLOGICAL CRITERIA; COLLATION OF SCIENTIFIC AND METHODOLOGICAL INFORMATION WITH A VIEW TO THE ASSESSMENT OF MICROBIOLOGICAL RISK FOR CERTAIN FOODSTUFFS"
1998

The report is the result of the work undertaken within task n° SCOOP/MICR/2.1 established under Directive 95/5/EEC on the assistance to the Commission and Co-operation by the Member States in the Scientific Examination of Questions relating to Food. The task focused on microbiological criteria and collection of scientific and methodological information with a view to assessing the microbiological risk for certain foodstuffs.

The **main findings and conclusions** are the following:

1. the "systems" of microbiological criteria used in participating countries vary greatly and primarily depend on:

   - the number and types of commodities concerned;
   - the selection of micro-organisms of interest (pathogens or indicators);
   - the method(s) chosen for their detection and enumeration;
   - the approach to sampling and sampling plans;
   - legal status.

   Simplification and harmonization may contribute to a reduction in the differences perceived among Member States. However, due to the complexity of the present situation, this would be better achieved through reaching an interim agreement on a general approach to the establishment and use of microbiological criteria. Due consideration would need to be given to their relationship with other approaches to the microbiological safety and quality of foods such as the preventive approach based on the principles of HACCP and the development of guides to Good Hygienic Practice. These will have longer term implications for microbiological standards in EC food hygiene legislation.

2. In recent years, the collection of data and reports on foodborne illness in Europe has made considerable progress as reflected by the amount and variety of data collected in the task. All these data confirm the importance of foodborne diseases in Europe and it has been estimated that each year 130 million Europeans (15% of the total population of the WHO European region) are affected by episodes of foodborne diseases ranging from mild gastrointestinal affections to severe gastro-enteritis.

However, some of this information, collected for a surveillance purpose and useful to identify trends, has some limitations that may constitute an obstacle to its direct use for microbiological food safety assessment and subsequent managerial decisions such as the establishment of microbiological criteria for some foods. More specific information has still to be gained through targetted studies.

3. Ensuring product safety by end product testing has a number of inherent weaknesses not least the statistical problems associated with selecting samples for analysis. The greater the number of units analysed the greater is the likelihood of detecting unacceptable samples. Therefore, any selection of samples should be based on properly devised and implemented sampling plans although these have a number of inherent weaknesses and are not ideal for use as a standalone verification tool.

   Where microbiological analysis is used for the verification of HACCP-based systems it should be based on properly devised and implemented sampling plans. If available, additional methods other than microbiological analysis should be used as verification tools.

   The usefulness of sampling plans might be improved if EU countries could agree on consistent statistically sound microbiological sampling and testing protocols.

   Taking a single sample might have some benefits in food inspection such as detecting gross defects. However, it should not be considered as an integral part of critical control point (CCP) monitoring or a hazard analysis verification procedure since poor sensitivity could lead to a false sense of product security. Nevertheless, single sample analysis might be an option for small-scale food businesses which have limited resources and where the operation is of low risk in terms of public health.

   Microbiological analysis based on properly devised and implemented sampling plans might still have an important role to play where the operation does not have a fully implemented HACCP- based system or where information, including details of application of the HACCP plan, are otherwise unavailable e.g. non-EU goods at port of entry

   When applying microbiological criteria, specific consideration should be given to the methods used for the detection and enumeration of microorganisms. Special emphasis should be put on the development, validation and application of new rapid methods.

4. The need for the development of a formal approach to microbiological risk assessment based upon science has been recognized and is emphasized in this report.

   The task has considered some of the basic information needs to enable authorities to undertake risk assessment of microbial hazards and set down the basic steps of a formal risk assessment. This has been done primarily for the purpose of

identifying the information needs for more accurate assessments to be undertaken and to aid identifying areas of future work for SCOOP task(s) activities.

5. Recognizing that the Scientific Committee for Foods (SCF) has developed guidelines for the establishment and use of microbiological criteria for foods and is preparing a framework document on risk assessment, **areas of future work** have been identified as follows:

   - Continue collecting information on the progress of discussion in participating member states with regard to the work done in the Codex Committee on Food Hygiene on microbiological criteria to inform the discussion on the establishment and use of such criteria in the SCF.

   - Notwithstanding the use of the SCF document on risk assessment to design an appropriate system of data collection in Europe, take immediately several steps to develop rapidly a better and more comprehensive approach to the assessment of food safety. To obtain the necessary information, there is a need to continue collecting specific information to aid in determining risk factors by way, in particular, of an extention of surveillance data analysis, collecting and collating information on sentinel and population studies and case-control studies, collating information on the development and use of predictive models.

   - Finally, there is a need to provide information and data to inform the discussion in the SCF on the different elements that have to be considered in a formal risk assessment process, according to the framework and guideline document to be developed by this committee. Initially, information should be gained on where such data exist, on how they have been collected and on how they have been used. The ultimate goal would be the identification of focused research needs and the collection of existing or improved data in line with the requirements of the implementation of a formal risk assessment process. The related activities might constitute, due to the foreseeable need for time resources, the objective and focus of a new SCOOP task.

ANNEX III

OPINION OF THE SCIENTIFIC COMMITTEE ON VETERINARY MEASURES RELATING TO PUBLIC HEALTH on the evaluation of microbiological criteria for food products of animal origin for human consumption:

THE CONCLUSIONS, RECOMMENDATIONS AND THE PROPOSED INTERIM MICROBIOLOGICAL CRITERIA

Conclusions:

(1) The microbiological criteria listed in the current 'Vertical Directives' were developed between 5 and 10 years ago and have not been formally reviewed since their production.

(2) The current microbiological criteria were not established on the basis of a formal risk assessment.

(3) Most of the current microbiological criteria are not based on Codex Alimentarius principles.

(4) Many of the microbiological criteria do not appear to be meaningful in terms of consumer health protection, for example, aerobic plate counts and coliform counts in certain foods.

(5) The current Directives give very little guidance on corrective actions to be taken when criteria are not met. Any revision or setting of new microbiological criteria should follow the principles 4 laid down by Codex Alimentarius and the EU.

(6) Little information is available on the results of microbiological testing of end products in current Vertical Directives and how useful the current microbiological criteria have been in hazard or risk control.

(7) At present, EU provisions do not take into account the difference in prevalence or concentration of pathogens in different regions and different production sites.

(8) Microbiological testing of end products can never assure the safety of a food even when large numbers of samples (e.g. n=60) without positives are tested.

(9) Since protection of public health is the main objective of setting microbiological criteria, unsubstantiated differences in the microbiological criteria for final product of different foods should be avoided unless they can be justified in terms of differences in risk.

(10) The criteria considered in this report are those applicable at the site of food production. They may have some relevance to criteria at the retail end of the food chain if deemed necessary in future legislation.

Recommendations:

(1) Microbiological criteria should be relevant and effective in relation to consumer health protection. The Committee proposes as interim measures the criteria in Appendix 2, awaiting formal risk assessment.

(2) Formal risk assessment should be used to support risk management decisions including the need for setting a microbiological criterion for a food. However, in some situations a formal risk assessment will not be realistic in the near future and in these circumstances, other approaches (e.g. consideration of epidemiological data, decision trees) must be used.

(3) The existing problems in the food chain regarding *Salmonell*a, *Campylobacte*r, *EHEC* including *E.coli O157*, *L. monocytogenes* and other foodborne pathogens need urgent consideration and should be considered in a structured manner [using a horizontal approach] with a view to assessing the possibilities for decreasing their incidence in humans.

(4) If revised or additional criteria are to be introduced they must be harmonised and uniform. They should also take into account regional differences in the prevalence of pathogens and changes in food animal production practice.

(5) Criteria must be set with consistent sample sizes, wherever possible (e.g. 25 g for specific pathogens such as *Salmonella* spp. in specified products). Methods must be specific, sensitive and based on those standardised or validated by appropriate organisations (e.g. ISO/CEN).

(6) The possibility of defining common health related criteria must be investigated for food products belonging to the same broad category and for certain pathogens. A clear distinction must be made between mandatory criteria in EU legislation and guidelines, which should be advisory only.

The interim criteria proposed by the SCVPH:

Food category	**Criteria in current Community legislation**	**Interim criteria proposed in the opinion of the SCVPH**	**Other opinions or comments from the SCVPH**
Minced meat (Directive 94/65/EEC)	Aerobic mesophilic bacteria	Guideline	Assumption made that the products are intended for cooking; consider use in relation to *E.coli* O157
	E. coli	Guideline	
	Salmonella	Standard, consider sample size 25g	
	S. aureus	Deletion	
Meat preparations (Directive 94/65/EEC)	*E. coli*	Guideline	Assumption made that the products are intended for cooking; consider use in relation to *E.coli* O157
	S. aureus	Guideline (uncontrolled fermentation)	
	Salmonella	Standard, consider sample size 25g	
Raw cow's milk intended for direct human consumption (Dir. 92/46/EEC)	*Salmonella*	Standard	Consider milk from other animal species. Consider other pathogens (*E.coli* O157, *Campylobacter*)
	S. aureus	Deletion	
	Aerobic plate count	Deletion, *E.coli* as a guideline	
Pasteurised drinking milk (Dir. 92/46/EEC)	Pathogenic micro-organisms	Deletion of *Salmonella* and *Listeria* criteria are proposed	Consider milk from other animal species. Consider other pathogens *(E.coli* O157, *Campylobacter)*
	Coliforms	Replace with *Enterobacteriacae* as a standard	
	Aerobic plate count	Guideline	
UHT milk and strerilized milk (Dir. 92/46/EEC)	Aerobic plate count	Deletion	
Cheeses made from raw milk and from thermized milk (Dir. 92/46/EEC)	*Listeria monocytogenes*	Retain (not concerning hard cheese)	
	Salmonella	Retain (not concerning hard cheese)	

Cheeses made from raw milk and from thermized milk (Dir. 92/46/EEC)	*S. aureus,* guideline	Standard for hard cheeses, guideline for other	
	E. coli guideline	Standard for hard cheeses, guideline for other	
Soft cheese (made from heat-treated milk) (Dir.92/46/EEC)	*Listeria monocytogenes*	Standard	
	Salmonella	Deletion	
	S. aureus, guideline	Standard	
	E. coli, guideline	Deletion	
	Coliforms, guideline	Replace with *Enterobacteriacae*	
Fresh cheese (Dir. 92/46/EEC)	*Listeria monocytogenes*	Standard for cheeses made from raw/thermised milk	
	Salmonella	Standard for cheeses made from raw/thermised milk	
	S. aureus, guideline	Deletion in cheese produced by fermentation	
Other cheeses than those mentioned above (Directive 92/46/EEC)	*Listeria monocytogenes*	Deletion	
	Salmonella	Deletion	
Butter (Dir. 92/46/EEC)	*Listeria monocytogenes*	Deletion	
	Salmonella	Deletion	
	Coliforms, guideline	Deletion	
Powdered milk (Dir. 92/46/EEC)	*Salmonella*	Standard	
	Listeria monocytogenes	Deletion	
	S. aureus, guideline	Deletion	
Frozen milk-based products (Dir. 92/46/EEC)	*Salmonella*	Deletion	
	Listeria monocytogenes	Deletion	
	S. aureus, guideline	None	
	Coliforms, guideline	Replace with *Enterobacteriacae*	
	Aerobic plate count, guideline	Deletion	

Liquid milk-based products and powdered milk-based products (Dir. 92/46/EEC)	*Salmonella*	Standard only for products made from raw/thermised milk	
	Listeria monocytogenes	Standard only for products made from raw/thermised milk	
	Coliforms, guideline	Replace with *Enterobacteriacae*	
	Aerobic plate count (for liquid heat-treated unfermented milk based products)	Guideline	
Live bivalve molluscs (Directive 91/492/EEC)	*Salmonella*	Standard	Main hazard is viruses; criteria should be linked to management and intended use
	Faecal coliforms or	Deletion	
	E. coli	Guideline, consider sampling plan	
Cooked crustaceans and molluscan shellfish (Decision 93/51/EEC)	*Salmonella*	Deletion	
	S. aureus	Guideline	
	Any pathogen		
	Termotolerant coliforms, guideline, or	Deletion	
	E. coli guideline	Guideline	
	Mesophilic aerobic bacteria, guideline	Guideline for whole products and crabmeat; deletion for peeled or shelled products	
8. Egg products (Directive 89/437/EEC)	*Salmonella*	Standard, consider sampling plan	
	Aerobic mesophilic bacteria	Guideline, consider sampling plan	
	Enterobacteriaceae	Guideline, consider sampling plan	
	S. aureus	Deletion	