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SCIENTIFIC COMMITTEE ON VETERINARY MEASURES

RELATING TO PUBLIC HEALTH

on

**The evaluation of microbiological criteria for food products of animal
origin for human consumption**

23 September 1999

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1. TERMS OF REFERENCE

To provide a scientific opinion from 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

2. MANDATE

Microbiological criteria in current Community legislation concerning food of animal origin are numerous, varied and laid down in different formats. In the context of the recast of veterinary legislation with regard to the production, marketing and importation of products of animal origin intended for human consumption the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) is asked:

- to evaluate the need for using microbiological testing against criteria;
- to evaluate with regard to this need, the appropriateness of the components of the microbiological criteria as laid down in current EU provisions; and
- to make recommendations for change where appropriate.

3. DEFINITIONS

Microbiological criterion - a microbiological criterion for foodstuffs defines the acceptability of a process, product or food lot based on the absence or presence, or number of microorganisms and/or quantity of their toxins/metabolites, per unit(s) of mass, volume or area.

Microbiological criteria currently within EU Directives can be divided under the headings:

Microbiological standards - criteria included in legislation or regulations where failure to comply with them can result in rejection of the food.

Microbiological guidelines - criteria included in legislation or regulations which are intended to guide the manufacturer and help to ensure good hygienic practice.

4. INTRODUCTION

4.1. The interpretation of laboratory results in food microbiology is often the most difficult and complex aspect of the whole examination process. Interpretation can be largely meaningless unless there is agreement as to what results are achievable or desirable.

4.2. Several international organizations are concerned with the establishment and application of microbiological criteria for foods: these include i.a. the World Health Organization, the Codex Alimentarius Commission, the European

Union (EU) and the International Commission on Microbiological Specifications for Foods (ICMSF). The purpose of establishing microbiological criteria is to protect the health of the consumer by providing safe, sound and wholesome products, and to meet the requirements of fair practices in trade. The mere existence of criteria cannot protect consumer health *per se*; of greater importance is the use of Good Hygienic Practice (GHP) and Hazard Analysis Critical Control Point (HACCP) systems to ensure that undesirable microorganisms are eliminated or minimized to an extent that they cannot cause harm to human health.

- 4.3. Microbiological criteria may be applied at various points in the food chain. They may be used during production and/or to assess the finished product. They may also be used when examining food sampled at the retail level or foodstuffs at port of entry from third countries. Comparing the results of microbiological testing against microbiological criteria can give important information to both food producers and food inspection services on the acceptability of foodstuffs.
- 4.4. The focus of this report is on current EU Directives where microbiological criteria apply at the point of production. In the report we consider these EU criteria in the context of Codex and EU principles for the establishment of microbiological criteria as well as risk assessment and risk management, which will increasingly be used to underpin food hygiene issues within the EU.
- 4.5. In view of time constraints the report does not attempt to consider the whole area of microbiological criteria for products of animal origin and should therefore be seen as a contribution towards the revision and standardization of current criteria. Future consideration of criteria following Codex and EU principles are expected to relate to specific microorganisms and food groups using a more horizontal approach. An example of an initiative in this area is the opinion of the SCVPH on *Listeria monocytogenes* in ready-to-eat food of 23 September 1999.

5. RISK ASSESSMENT, RISK MANAGEMENT AND MICROBIOLOGICAL CRITERIA

- 5.1. Principles for the development of risk assessment of microbiological hazards have been developed by Codex Alimentarius and the EU Scientific Committee for Food (Anon 1997a; 1998a). Formal microbiological risk assessment is a relatively new activity and it is likely to be increasingly used to support a risk management decision. Principles and guidelines for the management of microbiological hazards for foods in international trade are being developed by Codex (Anon 1998b).
- 5.2. Risk management decisions may include the setting of Food Safety Objectives (FSOs) and microbiological criteria for foodstuffs (Anon 1998b). Although still to be agreed internationally, a provisional definition of a microbiological (food safety) objective has been provided in the Codex Committee on Food Hygiene risk management paper currently at step 3 of the Codex process (Anon 1998b). This states that “A *microbiological (food safety) objective is a*

statement of the frequency or concentration of a microbiological hazard in a food appropriate for consumer protection”.

- 5.3. FSOs may in some cases be expressed as microbiological levels (the concentration or prevalence) of pathogens in relevant products.
- 5.4. FSOs can be used by the industry to establish performance criteria, necessary to meet the FSO for a particular hazard in a product.
- 5.5. FSOs can be used by authorities to establish microbiological criteria that should be met in order to comply with the FSO for a particular hazard in a product.
- 5.6. When an FSO has not been established, establishing microbiological criteria should involve, wherever possible, some form of risk assessment. It will not always be possible, or necessary, to adhere to the complete Codex Alimentarius or EU assessment format. Limits are often related to the level of tolerable risk (risk assessment does not provide this parameter), and epidemiological data can be used to determine whether the establishment of a criterion is necessary in the absence of a risk estimate with its attendant uncertainties.
- 5.7. The use of microbiological criteria as risk management tools should only be applied where they can be shown to be effective, i.e. meaningful in terms of consumer protection. Even if the process of testing and rejecting a food does not directly achieve the goal of protecting human health, the act of rejection, or application of other control options, could raise the level of awareness by food producers. This may in turn lead to a lowering of the prevalence of specific pathogens in the food chain.
- 5.8. Microbiological criteria can be used to assess whether the prevalence of a pathogen in specific foods is increasing/decreasing relative to a target level. The use of microbiological criteria to monitor such changes should be considered at national, regional or community level.
- 5.9. The determination of safe, realistic and achievable hazard and risk levels depends not only upon the hazard and risk situation, but also upon a number of socio-economic and technological factors. According to these factors the best management options could be:
 - control at the source;
 - action plans in the production level;
 - introduction of general hygiene measures (e.g. GHP);
 - introduction of specific production control measures (e.g. HACCP);
 - microbiological criteria in relevant parts of the production chain;
 - mandatory microbiological criteria in the final product;

- consumer education; or
- a combination of these.

6. COMPONENTS OF MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS

- 6.1. Codex Alimentarius has published principles for the development of microbiological criteria (Anon 1997b). EU principles and guidelines for animal products and products of animal origin intended for human consumption have also been published (Anon 1997c). According to these principles a microbiological criterion consists of:
- a statement of the microorganisms of concern and/or their toxins/metabolites and the reason for that concern in the product;
 - a plan defining the number of field samples to be taken, the size and characteristics of the sample and analytical unit;
 - the methods for their detection and/or quantification;
 - microbiological limits considered appropriate to the food at the specified point(s) of the food chain; and
 - the number of analytical units that should confirm to these limits.
- 6.2. It therefore follows that food samples should be taken and transported in an appropriate way to Official Control Laboratories for testing. There should be recognition of the need for microbiological testing to be undertaken using appropriate, validated methodology which is both sensitive and specific.
- 6.3. The principles indicate that a microbiological criterion should also state:
- the food(s) to which the criterion applies;
 - the point(s) in the food chain where the criterion applies; and
 - the actions to be taken when the criterion is not met.
- 6.4. Priority for the development of mandatory microbiological criteria should be given to those microorganisms, their toxins or metabolites in foods where a risk assessment has established a hazard and corresponding risk to the consumer (Anon 1997b,c). Wherever possible, the setting of such criteria should take into account as much scientific data and information as possible.
- 6.5. A microbiological criterion should be established and applied only where there is a definite need for it and where it can be shown to be effective and practical. Such need is, for example, demonstrated by epidemiological evidence that the food under consideration may represent a public health hazard and that a criterion is meaningful for the protection of the consumer, or by the results of a risk assessment. It should be technically attainable by

applying good manufacturing practice and be realistic in terms of achievability (Anon 1997b,c).

6.6. To fulfil the purposes of microbiological criteria, the principles¹ document states that consideration should be given to:

- evidence of risk to health;
- the microbiological status of the raw material(s);
- the effect of processing on the microbiological status of the food;
- the likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage and use;
- the categories of consumers concerned; and
- the cost/benefit of applying such a criterion.

7. MICROORGANISMS TO BE CONSIDERED

7.1. When assessing microbiological hazards associated with a specific food all foodborne or potentially foodborne microorganisms should be considered including bacteria, viruses, yeasts, moulds, algae and parasites including helminths. Hazards associated with toxins/metabolites produced by these organisms or other intrinsic properties (e.g. antibiotic resistance) should also be considered as part of any assessment.

7.2. The microorganisms included in a criterion must be relevant to a particular food and situation (e.g. raw material, end of production, at consumption). If criteria are to be set for indicator microorganisms, their purpose (e.g. to detect unsatisfactory hygiene, indicate possible health hazard) must be clearly stated.

8. SAMPLING PLANS FOR MICROORGANISMS IN FOODS

8.1. Central to the assessment of the role of microbiological criteria are the concepts of probability and sampling involved in the definition of a sampling plan. A sampling plan includes the sampling procedure and the decision criteria to be applied to a food lot, based on examination of a prescribed number of analytical sample units by defined methods. Sampling plans should be administratively and economically feasible (Anon 1997b,c). A sampling plan may define the probability of detecting a microorganism (or group of microorganisms) in a foodstuff or that a specified concentration of microorganisms is not exceeded. The main advantage of using sampling plans

¹ Principles for the development of microbiological criteria for animal products and products of animal origin intended for human consumption (Opinion of the Scientific Committee for Food endorsed by the Scientific Veterinary Committee - Public Health Section), (Anon, 1997c)

is that they are statistically based and provide a uniform basis for acceptance of a lot against defined criteria.

- 8.2. A statistically based sampling plan is the particular choice of sampling procedures and the decision criteria to be applied to a lot, based on examination of a prescribed number of sample units by defined methods. There are two widely accepted types of sampling plans, the two class plan (e.g. $n = 5, 10, 15, 20$ or more, and c usually = 0) and the three class plan (e.g. $n = 5, c = 2, m = 10^3, M = 10^4$) as defined by the ICMSF (1986) where:

n = the number of sample units examined from a lot;

m = the microbiological limit which in a 2-class plan separates good quality from defective quality and in a 3-class plan separates good quality from marginally acceptable quality;

M = the microbiological limit which in a 3-class plan separates marginally acceptable quality from defective quality;

c = the maximum allowable number of defective sample units (2-class plan) or marginally acceptable sample units (3-class plan).

- 8.3. The 2-class plan is used essentially for pathogens and/or where a presence/absence test is to be performed, whereas a 3-class plan is frequently used to examine for hygiene indicators where enumeration of microbes in a unit-volume or mass is possible.

- 8.4. It must be recognised that no practical sampling plan can ensure absence of the target microorganism and that the concentration of microorganisms measured may be exceeded in a part of the food lot that was not sampled. Furthermore, confidence in the results of testing will depend on the number of sample units tested, whether or not there is a homogeneous distribution of pathogens in the lot, whether the sampling is performed randomly and whether the methodology used for testing is both sensitive and specific. For example, testing five randomly taken samples and finding none of them positive gives 95% confidence that the food lot is less than 50% contaminated. Testing 30 randomly taken samples and finding none of them positive indicates that the food lot is less than 10% contaminated. Examining 300 randomly taken samples with none of them positive means that the food lot is < 1 % contaminated (all at a 95% confidence level) (ICMSF 1986), assuming 100% sensitivity and specificity.

- 8.5. Whilst foodstuffs with a high rate of contamination can be detected with this approach, where the prevalence of a microorganism is very low (<5% samples) the number of samples needed to detect contaminated batches is very high and is often impractical for testing. It is important to emphasise that no sampling plan can assure the absence of a pathogen from a foodstuff.

8.6. According to the principles² document on microbiological criteria (Anon 1997c), sampling plans should take into account a number of factors:

- The severity of the hazard and an assessment of the risk;
- The susceptibility of the target group of consumers (very young or old, immunocompromised etc.);
- The heterogeneity of distribution of microorganisms (or the randomness of sampling); and
- The statistical probability of detecting unacceptable food lots or rejecting acceptable food lots.

Sampling plans, taking these factors into account, have been developed by the ICMSF (ICMSF 1986).

9. LABORATORY METHODS

9.1. The methods used for detection or enumeration of microorganisms form an integral part of a microbiological criterion (Anon 1997b,c). Preference should be given to sensitive reference methods developed under the aegis of a European or internationally recognized standards institute (e.g. CEN, ISO) which have already been validated for the commodity concerned.

9.2. In recent years there have been significant advances in the development of new methods for the detection and separation of microorganisms in foods. Molecular (e.g. PCR) and immunological (e.g. ELISA, immunobeads) approaches offer some advantages (which have to be weighed against certain disadvantages) over conventional culture methods, particularly speed, but they have yet to be used routinely for examining samples taken for surveillance or enforcement.

10. PURPOSE OF MICROBIOLOGICAL CRITERIA

10.1. When microbiological criteria are used at a food production site to supplement the verification of the HACCP system they can be effective to deliver the required level of safety. In this situation the identified agents of concern to public health can be determined directly, if methods allow this. For example, if raw minced meat should not contain *Salmonella* in more than 20% of the product units, a sampling plan can be established to test conformity to this requirement.

10.2. If the hazard cannot be determined directly because the level is too low (e.g. *Clostridium botulinum* in canned meat, *Salmonella* in pasteurised milk), tests

² Principles for the development of microbiological criteria for animal products and products of animal origin intended for human consumption (Anon 1997c).

for indicator microorganisms can sometimes be used (e.g. *Enterobacteriaceae* or coliforms in milk).

- 10.3. Consignments with unknown “hygienic history” or origin represent increased variations in consumer risk necessitating more stringent risk management procedures to achieve the same level of consumer protection.
- 10.4. Microbiological criteria can also be developed to set targets or "acceptable levels" to be met by the industry.

11. LIMITATIONS OF USING MICROBIOLOGICAL TESTING

11.1. Management of safety and quality of food materials by the use of microbiological criteria requires that samples taken from the material under investigation are examined in a laboratory and the results interpreted by a microbiologist who will decide whether the material is acceptable or unacceptable with regard to the criterion. This approach has a number of inherent limitations.

- Sampling problems. A major drawback is the variability inherent in drawing samples for analysis because of the uneven distribution of microorganisms in most foods. It is possible to draw up sampling plans with defined probabilities of detection such as those devised by the ICMSF (1986). Even under perfect test conditions, “unacceptable” batches of material can falsely appear to be “acceptable”, depending on such factors as the proportion of “defective” units actually present in the batch and the number of samples analyzed. This problem is particularly important in relation to the very low prevalence in many foods of important pathogens such as *Salmonella* spp., *Campylobacter* spp. and *Escherichia coli* O157. Laboratory analysis costs are high and sampling and microbiological analysis are destructive.
- Variation in results: Biological (variability) and methodological (uncertainty) variation can result in different outcomes of repeated sampling, even for a simple test such as a mesophilic aerobic plate count. Methods validation and laboratory accreditation are important in determining reliability of results, as are the sensitivity and specificity of any methods used.
- Delay in obtaining results: Delay may be considerable with conventional microbiological methods. Rapid test methods also have shortcomings. They tend to be very specific and often have minimum detection limits above the levels commonly found in food.
- Location of testing separated from the workplace: Reliance on microbiological criteria means that, in effect, the operation may be dependent on a scientist at a laboratory remote from the site of the food operation. This can lead to an attitude among production and management staff that only a section of the work force, primarily technical personnel, are directly responsible for product safety.

- Poor sensitivity in monitoring trends: The traditional sampling plans relating to microbiological criteria lack sensitivity in monitoring pathogens with a low prevalence in a food and the effect of interventions aimed at lowering the prevalence of pathogens.
 - Lack of review: Because EU microbiological criteria are currently not considered within the context of formal risk analysis, little information is available on what impact they have had on food safety and how useful they have been to food manufacturers and enforcement officers.
- 11.2. Significant differences in the prevalence of certain foodborne pathogens, notably *Salmonella* spp., can be found between different regions. Therefore, microbiological criteria in general and more specifically sampling plans should not always be considered applicable. The results from testing could, in some situations, reflect relevant and significant regional differences.

12. THE HACCP APPROACH

- 12.1. All Member States are now promoting the use of Hazard Analysis and Critical Control Points (HACCP). This is in keeping with developments in EU food hygiene legislation, both general and product specific. HACCP aims to prevent health-related problems rather than picking them up after they have occurred.

The principles of HACCP are a systematic way of analysing the potential hazard(s) in an food processing operation. The points in the operation at which control can be applied are identified. These are the critical control points (CCPs) which are essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The critical limits at CCPs define what is acceptable and what is not. CCPs must be monitored and reviewed periodically.

The advantages of HACCP are:

- Control is proactive in that remedial action can be taken before problems occur;
- Control is by features that are easy to monitor such as:
 - time;
 - temperature; and
 - observation.
- Control is fast enough for prompt remedial action to be taken if necessary;
- Control is less expensive in comparison to chemical and microbiological end-product testing;
- Those persons directly involved with the food control the operation;

- Other more meaningful measurements can be taken for each batch of product because control is focused at the critical points in the operation; and
 - HACCP can be used to preclude significant hazards whenever possible.
- 12.2. Whenever possible, rapid monitoring tests should be chosen in HACCP systems to eliminate reliance on sampling and on microbiological criteria. Microbiological criteria may, however, play a supplementary role in the verification of HACCP programs; that is, testing outside the scope of routine monitoring. This might serve to provide support that the HACCP program is valid and is being correctly applied but it does not provide a standalone verification tool for HACCP systems. Even though a food manufacturer may achieve a reduction in contamination of food batches to a very low level, the results of microbiological testing could result in a false safety interpretation in a verification procedure. However, it is recognized that there can exist situations where microbiological testing is the only practical option available (Anon 1998c).

13. EUROPEAN UNION LEGISLATION

- 13.1. The main emphasis of Directive 93/43/EEC on the Hygiene of Foodstuffs is on preventing the microbiological contamination of food and the growth of harmful or undesirable microorganisms. Responsibility is placed on food businesses for ensuring that food is processed, transported, stored and sold in a satisfactory condition. It requires food business operations to identify any steps in their activities which are critical to food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed (Article 3.2).
- 13.2. Microbiological standards of an extensive nature have existed for many years in the legislation of most Member States. Unfortunately, there is little published information on how many samples and types of food are examined, the number meeting the required microbiological standards and the action taken by enforcement officers or food manufacturers. Furthermore, little information is available on how useful the microbiological criteria in the current Vertical Directives have been in relation to hazard or risk control.
- 13.3. Council Directive 93/5/EEC on the assistance to the Commission and Co-operation by the Member States in the Scientific Examination of Questions relating to Food was adopted in February 1993. The Directive identified the need to examine questions relating to the protection of public health, to promote safe food and to ensure the smooth operation of the internal market.
- 13.4. A Scientific Co-operation (SCOOP) Task Group established under Directive 93/5/EEC focused its activities on the collation of scientific and methodological information with a view to the assessment of microbiological risks for certain foodstuffs. In addition, the Task Group was asked to consider the scientific basis for legislation relating to microbiological criteria, which may be developed under Article 4 of Directive 93/43/EEC on the Hygiene of Foodstuffs. The report from the Task Group

(SCOOP/MICR/2.1) was published in 1998 (Anon 1998c), and the principal findings and conclusions are summarized in Appendix 1.

- 13.5. Food safety and hygienic practice throughout the EU is increasingly being controlled by a multitude of Directives, the most significant being the so-called “Vertical Directives”, dealing with products of animal origin only, e.g. fresh meat, poultry, milk, fish, eggs, which apply at manufacture, storage and during transport. The so-called “Horizontal Directives”, provide the safety measures for all foodstuffs not covered by the Vertical Directive and when all foods enter the retail market. In theory, EU-based microbiological standards within the Vertical Directives would provide common criteria against which the safety of food could be measured consistently. Directives that include microbiological criteria are:
 - Egg Products Directive (89/437/EEC);
 - Live Bivalve Molluscs Directive (91/492/EEC);
 - Fishery Products Directive (91/493/EEC) and the Commission Decision on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish (93/51/EEC);
 - Milk and Milk based Products Directive (92/46/EEC); and
 - Minced Meat and Meat Preparation Directive (94/65/EEC).
- 13.6. Microbiological criteria in current legislation are used to assess absence of pathogens in foods, to demonstrate the application of GHP and to guide manufacturers in ensuring GHP. In almost all cases the microbiological criteria in these Directives apply to end products at the point of production. In a few cases they apply to raw materials (e.g. milk intended for processing) or finished products sold direct to the consumer (e.g. raw milk for drinking, raw fish). For some, e.g. those for cooked crustaceans and molluscan shellfish and for milk and milk-based products the Directives contain a mixture of criteria. The EU criteria apply to both trade between Member States and to imports from Third countries.
- 13.7. Other Vertical Directives have provision for microbiological criteria to be added in the future. Where standards have been set in Directives there is scope for them to be revised or added to. The EU may also lay down suitable laboratory methods to conform to these standards.
- 13.8. Details of the specific microbiological criteria in the Vertical Directives are given in Appendix 2. The Directives have been transposed into the legislation of Member States who are then responsible for their implementation and enforcement.
- 13.9. Microbiological criteria have also been included in several recent EU provisions for various foods imported from Third countries.

14. PROBLEMS WITH THE CURRENT EU MICROBIOLOGICAL CRITERIA

- 14.1. Traditionally, microbiological examination has played an important role in assuring the microbiological safety and quality of foods. The emphasis of several Vertical Directives on testing end products against microbiological criteria reflects this situation. There are, however, a number of problems:
- The criteria listed in the Directives were developed 5-10 years ago and have not been formally reviewed since their publication.
 - There is a wide diversity and complexity in some of the microbiological criteria selected. For example the current Directives include:
 - (a) Criteria for *Staphylococcus aureus*, which range from absence in 1g to a microbiological limit (M) of 15,000 per g.
 - (b) Criteria for *Salmonella* spp. which range from absence in 1g to absence in 25g.
 - (c) Broadly or narrowly defined criteria for taxonomically related groups of bacteria in the family *Enterobacteriaceae* – *Escherichia coli*, faecal coliforms, thermotolerant coliforms and coliforms.
 - Only the Egg Products Directive prescribes the methods to be used in the laboratory, but unlike all of the other Vertical Directives it does not include a sampling plan.
 - Implementation of the current EU criteria takes no account of differences in the prevalence of pathogens in foods in different regions.
 - The criteria apply at the point of production and do not cover the retail level, except in a few cases where products are sold direct to the consumer (e.g. raw milk, fish).
- 14.2. A number of microorganisms have become more prominent as causes of infectious intestinal disease in humans in Europe in the 5-10 years since the current EU criteria were established. These include *Campylobacter* spp., enterohaemorrhagic *E.coli*, particularly serogroup O157, and small round structured viruses (SRSV). In some Directives (e.g. milk products) general statements cover the need for absence of such organisms in certain products. However, these are not specific criteria and if criteria for “new pathogens” are established they should be based on the principles of formal risk assessment.
- 14.3. If revised or additional standards are to be introduced into Community legislation it is essential that a greater degree of co-ordination and uniformity than hitherto be applied to the microbiological criteria set.

15. SETTING MICROBIOLOGICAL CRITERIA BASED ON DECISION TREES AND ICMSF SAMPLING PLANS

- 15.1. Microbiological criteria may differ widely in nature or stringency, depending on the purpose and the point of application in the food chain. However, wherever and for whatever purpose they are intended to be used, they should be established with a certain logic and consistency in approach. Whilst such an approach should ideally be based on risk assessment and risk management principles it is recognised that quantitative risk assessment according to the Codex and EU approaches will not necessarily be feasible in the short term. For this reason we have included an alternative risk-based approach to the setting of microbiological criteria based on some elements already used by the ICMSF. This is based on the use of two decision trees, one for pathogens and the other for hygiene indicators. Where the output of these trees indicates a need for criteria these are linked to the ICMSF sampling plans which are based on categories of hazard and likelihood of occurrence (Appendix 3, Table A3.1, ICMSF 1986).
- 15.2. The ICMSF approach to developing sampling plans has distinguished four categories of hazards based upon the relative degree of severity to human health (Table A3.1, ICMSF 1986). It should be realised that the categorisation was based on the best epidemiological data available at the time of publication and may need to be revised as a result of new risk assessment procedures. The other factor to be considered is the likelihood of occurrence of the hazard (i.e. risk), taking account of the anticipated conditions of use.
- 15.3. The ICMSF developed 2-class sampling plans in which "n" indicates the number of sample units to be tested and "c" the number of defective sample units, which can be accepted. These sampling plans were described by ICMSF (1986). The plans direct more of the available resources for analysis towards those situations where there is a high level of concern.
- 15.4. Three class sampling plans were developed for tests for indicator microorganisms (e.g. aerobic mesophiles, *Enterobacteriaceae*, coliforms, *E.coli* etc). The same categories of conditions were used (reduction, no change and increase of risk), and in all cases the number of samples was 5 (n=5). The values for c were: case 4 (reduction) c=3; case 5 (no change) c=2; case 6 (increase) c=1.
- 15.5. The microorganisms, information and factors to consider in the establishment of microbiological criteria for foods, as have been mentioned in sections 6, 7 and 8 and have been summarised in the two decision trees (Appendix 3, Figures A3.1 and A3.2). Figure A3.1 is a decision tree for pathogens and Figure A3.2 for indicator organisms. The use of these trees is one approach to the establishment or review of criteria in the absence of formal risk assessment. The decision trees cover all situations, sampling at the production site, at a border between countries or at a point in the distribution chain.
- 15.6. As has been mentioned, a criterion may change depending on the point where it has to be applied and the purpose or expected use of the product. The EU

document on the establishment of microbiological criteria (Anon 1997c) does not specify in which situation a particular sampling scheme should be used. In order to provide such plans, those published by the ICMSF (1986) are recommended in the absence of EU or Codex sampling plans.

- 15.7. A few examples of the use of the decision trees are provided in Appendix 3. These examples are based on existing EU microbiological criteria to illustrate the approach for pathogens and indicators with different foodstuffs
- 15.8. It should be emphasised that the use of the decision trees (Figures A3.1 and A.3.2) provide an example of a practical approach to formulating sampling plans. They do not replace the need for criteria to be based on risk assessment, which should take into account as much scientific data and information as possible. The decision trees were not used exclusively when we considered the existing EU microbiological criteria presented in section 16 of this report.

16. PROPOSED REVISIONS TO THE CURRENT EU MICROBIOLOGICAL CRITERIA

- 16.1. The microbiological criteria in EU legislation have been examined with regard to their current status and appropriateness in terms of protecting public health. Comments on each criterion are summarised in Appendix 2, Table A2.1. The Committee examined the criteria with a view to whether they should be standards or guidelines and whether they should be retained, modified or deleted. It was the view of the Committee that guidelines incorporated into the current Directives were not intended for the protection of public health. It should also be noted that the tables include additional comments relating to the criteria in the Directives.
- 16.2. The Committee did not consider sampling plans or specific limits for pathogens and indicator microorganisms. This was considered to be more appropriate for expert committees who have experience of the food commodities concerned.
- 16.3. It should be noted that the Committee did not specifically examine analytical methods and corrective actions in relation to the criteria although these should be given due consideration in any revisions.
- 16.4. The changes suggested in Appendix 2, Table A2.1 do not eliminate all inconsistencies in the current EU Directives, but may ensure a more consistent approach. The specific comments made in this table have been elaborated to: a) separate mandatory (e.g. pathogens) from guideline (e.g. indicator) criteria, b) limit the number of criteria which are not relevant to consumer protection and, c) achieve better uniformity. This has resulted in some suggestions for deletion of criteria for pathogens in specific food groups. These changes are proposed because consumer protection is not achieved for these food groups through the application of microbiological criteria. However, this should not be interpreted as indicating that pathogens in these products are acceptable.

- 16.5. The Committee considers it likely that future considerations of criteria will focus on a horizontal approach relating specific pathogens and relevant food groups. Considerations with regard to *L. monocytogenes* in ready-to-eat food has been carried out and is the subject of a separate opinion³.

³ Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on *Listeria monocytogenes* adopted on 23 September 1999.

17. 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 principles⁴ 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.

⁴ Principles for the development of microbiological criteria for animal products and products of animal origin intended for human consumption (Anon 1997c).

18. 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 *Salmonella*, *Campylobacter*, *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.

Extracts from the main conclusions of the Scientific Co-operation (SCOOP) Task 2.1 - Microbiological criteria: Collation of scientific and methodological information with a view to the assessment of microbiological risk for certain foodstuffs (Anon 1998c)

PARTIAL SUMMARY

This report is the result of the work undertaken with task No. SCOOP/MICR/2.1 established under Directive 93/5/EEC on the assistance to the Commission and Cooperation 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 “system” of microbiological criteria used in participating countries vary greatly and primarily depend on:
 - the number and types of commodities concerned;
 - the selection of microorganisms 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 harmonisation 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 Hygiene Practice. These will have longer term implications for microbiological standards in EU 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 targeted 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.

When 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 for 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 procedures 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.

Appendix 2

Table A2.1. List of EU microbiological criteria for foods of animal origin together with the Committees comments. It should be noted that the criteria only apply at the production site. The column "Limits" only applies to the absence of the microorganism. As regards "*Listeria monocytogenes*" reference is made to the opinion of the SCVPH on *Listeria monocytogenes* of 23.09.1999. The sampling plan components (n, m, M and c) are described in section 8.2 of this paper.

MINCED MEAT and MEAT PREPARATIONS (DIRECTIVE 94/65/EEC)

	Microorganisms	Limits ⁵	Sampling plan				COMMENTS OF THE COMMITTEE	
			n	c	m	M		
Minced meat							Criteria for the following products depend on use (i.e. raw or cooked). Assumption has been made that product is intended for cooking. Need to consider use in relation to <i>E.coli</i> O157. Clarification needed for components of criteria (S ⁶ and M)	
	1	Aerobic mesophile bacteria	5	2	5 x 10 ⁵ / g	5 x 10 ⁶ / g	Guideline only	
	2	<i>Escherichia coli</i>	5	2	50 / g	500 / g	Guideline only	
	3	<i>Salmonella</i> spp..	Absence in 10 g	5	0			Retain standard. Consider sample size 25g.
	4	<i>Staphylococcus aureus</i>		5	2	100 / g	5000 / g	Deletion proposed

⁵ General comment: applies only to absence

⁶ Microbic limit value S (Cf. Council Directive 94/65/EEC of 14 December laying down the requirements for the production and placing on the market of minced meat and meat preparations (OJ N° L 368, 31.12.1994, p. 10)

Meat preparations	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
5	<i>Escherichia coli</i>		5	2	500 / g	5000 / g	Criteria for the following products depend on use (i.e. raw or cooked). Assumption has been made that product is intended for cooking. Need to consider use in relation to <i>E.coli</i> O157. Clarification needed for components of criteria (S and M)
							Guideline only
6	<i>Staphylococcus aureus</i>		5	1	500 / g	5000 / g	Guideline only (uncontrolled fermentation)
7	<i>Salmonella</i> spp.	Absence in 1 g	5	0			Retain standard. Consider sample size 25 g.

EGG PRODUCTS (DIRECTIVE 89/437/EEC)

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
8	<i>Salmonella</i> spp.	Absence in 25 g or ml					Retain standard. Consider appropriate sampling plans (depending on use) (minimum n=5)
9	Aerobic mesophile bacteria					10 ⁵ in 1 g or ml	Guideline only, consider sampling plans e.g. n=5, c=2
10	<i>Enterobacteriaceae</i>					10 ² in 1 g or ml	Guideline only, consider sampling plans
11	<i>Staphylococcus aureus</i>	Absence in 1 g or ml					Deletion proposed

DAIRY PRODUCTS (DIRECTIVE 92/46/EEC)

Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
		n	c	m	M	
						Consider milk of other animal species. Consider other pathogens (<i>E.coli</i> 0157, <i>Campylobacter</i>)

Raw Cow's drinking milk⁷

12	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Retain standard
13	<i>Staphylococcus aureus</i>		5	2	100 / g	500 / g	Deletion proposed ⁸
14	Aerobic microorganisms 30°C	5 x 10 ⁴					Deletion proposed. Replace with <i>E.coli</i> as a guideline

⁷ The Committee recognizes that there is an inherent risk from the consumption of raw milk

⁸ The majority of the Committee was in favour of proposing deletion of the standard for *Staphylococcus aureus*. However, the Committee unanimously recommended that other pathogens be considered. This should also involve the consideration of milk of other animal species.

Pasteurised drinking milk

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
15	<i>Listeria monocytogenes</i>	Absence in 25 g	5	0			Deletion proposed
16	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Deletion proposed
17	Coliforms 30°C		5	1	0 / g or ml	5 / g or ml	Deletion proposed. Replace with <i>Enterobacteriaceae</i> as a standard. In the opinion of the Committee this is the preferred option but note long history of using coliforms as an indicator although poorly defined.
18	Aerobic microorganisms 21°C		5	1	5 x 10 ⁴ / g	5 x 10 ⁵ / g	Guideline only

Sterilised and UHT drinking milk

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
19	Aerobic microorganisms 30°C	10 per 0.1 ml					Deletion proposed

Hard cheese made from heat-treated milk

(ndlr : "heat-treated" means "at least pasteurised")

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
20	<i>Listeria monocytogenes</i>	Absence in 1 g					Deletion proposed
21	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Deletion proposed

Hard cheese made from raw or thermised milk

22	<i>Listeria monocytogenes</i>	Absence in 1 g					Deletion proposed
23	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Deletion proposed
24	<i>Staphylococcus aureus</i>		5	2	1000 / g	10 000 / g	Retain standard
25	<i>Escherichia coli</i>		5	2	10 000 / g	100 000 / g	Retain standard

Fresh cheese

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
26	<i>Listeria monocytogenes</i>	Absence in 25 g	5	0			Retain if made with raw/thermised milk
27	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Retain if made with raw/thermised milk
28	<i>Staphylococcus aureus</i>		5	2	10 / g	100 / g	Deletion proposed in cheese produced by fermentation ⁹

Cheese other than hard or fresh made from heat-treated milk (ndlr : "heat-treated" means "at least pasteurised")

29	<i>Listeria monocytogenes</i>	Absence in 25 g	5*	0			Retain standard
30	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Deletion proposed
31	<i>Staphylococcus aureus</i>		5	2	100 / g	1000 / g	Retain standard
32	<i>Escherichia coli</i>		5	2	100 / g	1000 / g	Deletion proposed
33	Coliforms 30°C		5	2	10 000 / g	100 000 / g	Deletion proposed. Replace with <i>Enterobacteriaceae</i> . In the opinion of the Committee this is the preferred option but note long history of using coliforms as an indicator although poorly defined.

* : 25 g obtained by taking 5 aliquots of 5 g from the same sample, at different points

⁹ The majority of the Committee was in favour of proposing deletion of the standard for *Staphylococcus aureus*. However, the Committee unanimously recommended that other pathogens be considered.

Cheese other than hard or fresh made from raw or thermised milk

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
34	<i>Listeria monocytogenes</i>	absence in 25 g	5*	0			Retain standard
35	<i>Salmonella</i> spp.	absence in 25 g	5	0			Retain standard
36	<i>Staphylococcus aureus</i>		5	2	1000 / g	10 000 / g	Retain guideline
37	<i>Escherichia coli</i>		5	2	10 000 / g	100 000 / g	Retain guideline (M and m too high?)

* : 25 g obtained by taking 5 aliquots of 5 g from the same sample, at different points

Pasteurised butter

38	<i>Listeria monocytogenes</i>	Absence in 1 g					Deletion proposed
39	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Deletion proposed
40	Coliforms 30°C		5	2	0	10/g	Deletion proposed

Milk powder

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
41	<i>Salmonella</i> spp.	Absence in 25 g	10	0			Retain standard
42	<i>Listeria monocytogenes</i>	Absence in 1 g					Deletion proposed
43	<i>Staphylococcus aureus</i>		5	2	10 / g	100 / g	Deletion proposed
44	Coliforms 30°C		5	0	0	10 / g	Deletion proposed. Replace with <i>Enterobacteriaceae</i> . In the opinion of the Committee this is the preferred option but note long history of using coliforms as an indicator although poorly defined

Liquid dairy products

45	<i>Listeria monocytogenes</i>	Absence in 1 g	5	0			Retain standard for products made with raw/thermised milk
46	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Retain standard for products made with raw/thermised milk
47	Coliforms 30°C		5	2	0	5 / g	Deletion proposed. Replace with <i>Enterobacteriaceae</i> . In the opinion of the Committee this is the preferred option but note long history of using coliforms as an indicator although poorly defined.
48	Aerobic microorganisms 21°C		5	2	50 000 / g	100 000 / g	Guideline only

Frozen dairy products including ice cream

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
49	<i>Listeria monocytogenes</i>	Absence in 1 g					Deletion proposed
50	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Deletion proposed
51	Coliforms 30°C		5	2	10	100/g	Deletion proposed. Replace with <i>Enterobacteriaceae</i> . In the opinion of the Committee this is the preferred option but note long history of using coliforms as an indicator although poorly defined
52	Plate count 30°C		5	2	100 000	500 000/g	Deletion proposed

Other milk products

53	<i>Listeria monocytogenes</i>	Absence in 1 g	5	0			Retain standard for products made with raw/thermised milk
54	<i>Salmonella</i> spp.	Absence in 25 g	5	0			Retain standard for products made with raw/thermised milk

LIVE BIVALVE PRODUCTS (DIRECTIVE 91/492/EEC)

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
55	<i>Salmonella</i> spp.	Absence in 25 g or ml					Main hazard is viruses (e.g. SRSV). Criteria should be linked to management and intended use (raw or cooked). Algal biotoxins ASP, DSP, and PSP were not considered. Retain standard. Consider appropriate sampling plan.
56	Faecal coliforms	< 300 per 100 g flesh					Deletion proposed
57	<i>Escherichia coli</i>	< 230 per 100 g flesh					Guideline only

COOKED SHELLFISH AND MOLLUSCS (DECISION 93/51/EEC)

	Microorganisms	Limits	Sampling plan				COMMENTS OF THE COMMITTEE
			n	c	m	M	
58	<i>Salmonella</i> spp.	Absence in 25 g or ml	5				Deletion proposed
59	<i>Staphylococcus aureus</i>		5	2	100	1000	Guideline only
60	Thermotolerant coliforms 44°C		5	2	10	100	Deletion proposed
61	<i>Escherichia coli</i>		5	1	10	100	Guideline only
62	Aerobic mesophile bacteria, 30°C		5	2	10 000	100 000	Whole product. Retain guideline
63	Aerobic mesophile bacteria, 30°C		5	2	50 000	500 000	Peeled or shelled products except crab flesh. Deletion proposed
64	Aerobic mesophile bacteria, 30°C		5	1	100 000	1 000 000	Crab flesh. Retain guideline

Decision tree approach to setting microbiological criteria using the ICMSF system

Table A3.1. Plan stringency (Case) in relation to degree of health hazard and conditions of use.

Figure A3.1. Establishment of microbiological criteria for pathogens.

Figure A3.2. Establishment of microbiological criteria (indicators).

Examples of using the decision trees to evaluate microbiological criteria.

Table A3.1 Plan stringency (Case) in relation to degree of health hazard and conditions of use (Adapted for ICMSF 1986)

Type of Hazard	Conditions in which food is expected to be handled and consumed after sampling in the usual course of events.		
	Reduce Degree of Concern	Cause No Change in Concern	May Increase Concern
Health hazard low, indirect (indicator)	Case 4 n = 5, c = 3	Case 5 n = 5, c = 2	Case 6 n = 5, c = 1
Health hazard moderate, direct, limited spread	Case 7 n = 5, c = 2	Case 8 n = 5, c = 1	Case 9 n = 10, c = 1
Health hazard moderate, direct, potentially extensive spread	Case 10 n = 5, c = 0	Case 11 n = 10, c = 0	Case 12 n = 20, c = 0
Health hazard Severe, direct	Case 13 n = 15, c = 0	Case 14 n = 30, c = 0	Case 15 n = 60, c = 0

n = the number of sample units tested

c = the number of defective sample units which can be accepted

Examples of using the decision trees to evaluate EU criteria

CRITERIA FOR MINCED MEAT TO BE USED AT THE PRODUCTION SITE (94/65/EEC)

A) *Salmonella*

Decision tree for pathogens (Figure A3.1)

Question 1: "Is the criterion to be applied at the food production site?" has to be answered with YES in this case. This leads to:

Question 3: "Are GHP and HACCP expected to be applied and verified?". Assuming that Good Hygienic Practices are, but HACCP is not yet applied the answer would be NO. If the answer is YES, the next question would apply.

Question 4: "Is criterion to be used for official control?". The answer would be YES.

Question 5: "Is there evidence of a risk to health for this food?" *Salmonella* in minced meat, either in the form of undercooked hamburgers or in the form of "Dutch minced meat balls" etc. have been implicated in food poisoning; thus the answer is YES.

Question 6: "Will the application of a criterion benefit public health?" The answer should be YES, because the criterion should prevent heavily contaminated batches of minced meat from reaching the consumer which could lead to more cases of illness than when only low contamination is present.

Question 7: "Potential for unacceptable multiplication during storage, distribution, preparation or use?" Assuming that the temperature is kept below 7°C and that the time between preparation and consumption is very short, the answer should be NO. This means that ICMSF case 11 should be applied. *Salmonella* is usually a moderate health hazard and there is a potential for extensive spread in the kitchen as well as by infected persons. The ICMSF foresees that in case 11, ten samples have to be examined and that no sample should be positive. If the answer is YES to this question, a potential for unacceptable multiplication does exist, then the next question has to be answered.

Question 8: "Potential for acceptable reduction during storage, distribution, preparation or use?" The answer would be NO if the minced meat is insufficiently cooked before consumption. In this situation, case 12 would apply. That means *Salmonella* should be absent in 20 samples. If the answer is YES, then we still need to know whether the killing is sufficient and can be relied upon.

Question 9: "Killing of pathogens of concern before consumption assured?" If the answer is YES, then there is no need to establish a criterion. If the answer is NO, then case 10 would apply. This means examination of 5 samples for *Salmonella*.

The EU criterion includes this sampling scheme, i.e. $n=5$ and $c=0$ (i.e. case 10), but specifies a sample unit size of 10g. The Committee suggests retaining the sampling scheme but prefers a sample unit size of 25g for the analysis of *Salmonella*.

B) *Staphylococcus aureus*

Decision tree for indicators (Figure A3.2)

Staphylococcus aureus is apparently regarded in the EU Directive as a hygiene indicator. The microorganism would need to multiply in a food to reach levels of 10^5 - 10^6 in order to produce sufficient enterotoxin to make people ill. Since minced meat is a perishable product which has to be kept refrigerated to prevent rapid spoilage, the chance that *S. aureus* will reach high numbers without evidence of spoilage is highly unlikely. Staphylococci are not normal intestinal bacteria and they are more prevalent on the hides and skin of animals. Their presence in high numbers in minced meat may indicate insufficient hygiene during slaughter or manufacture of minced meat. Inadequate hygiene may lead to unacceptable levels of foodborne pathogens; thus staphylococci should remain at low levels. In this case, the decision tree for indicators should be used.

Question 1: "Is the criterion to be applied at the food production site?" This has to be answered with YES.

Questions 3, 4, 5 and 6 have to be answered in the same manner as was done for *Salmonella*.

Question 7: "Potential for unacceptable multiplication during storage, distribution, preparation and use?" has to be answered with NO in the situation mentioned above. Thus, case 5 has to be applied, this means $n=5$ and $c=2$. If the answer is YES, then question 8 has to be answered.

Question 8: "Potential for acceptable reduction during storage, distribution, preparation or use? If the answer is NO, because the reduction does not take place or cannot be relied upon, then case 6 applies, i.e. $n=5$ and $c=1$. If the answer is YES, question 9 has to be answered.

Question 9: "Killing of pathogens of concern before consumption assured?" If the answer is NO, then case 4 has to be applied, i.e. $n=5$ and $c=3$. If the killing is rendering the food safe, no criterion needs to be established.

The EU document specifies $n=5$ and $c=2$ (i.e. case 5). The limits are $m=10^2$ and $M=5 \times 10^3$. The Committee proposes the deletion of this criterion.

CRITERIA FOR EGG PRODUCTS TO BE USED AT TREATMENT-ESTABLISHMENTS (89/437/EEC)

A) Salmonella

Decision tree for pathogens (Figure A3.1)

Question 1: "Is the criterion to be applied at the food production site?" has to be answered with YES in this case. This leads to:

Question 3: "Are GHP and HACCP expected to be applied and verified?". Assuming that Good Hygienic Practices and HACCP are to be applied and verified the answer would be YES, and question 4 would follow.

Question 4: "Is criterion to be used for official control?" The answer would be YES.

Question 5: "Is there evidence of a risk to health for this food?" *Salmonella* in egg-products has been implicated in food poisoning, particularly where egg products have been used in salad dressings, tiramisu, or other foods which are ready- to-eat, therefore the answer is YES.

Question 6: "Will application of a criterion benefit public health?" The answer should be NO. The HACCP monitoring data should indicate whether the process is under control. Normally the level of *Salmonella* present would be too low to detect with end-product testing. If the process were out of control HACCP monitoring data and the results of tests for *Enterobacteriaceae* should show this.

NB. If there would be a benefit in examining egg-products for *Salmonella*, than the following would apply.

Question 7: "Potential for unacceptable multiplication during storage, distribution, preparation or use?" would be answered with NO in the case of a frozen or dried egg product. This means that case 11 has to be applied, because *Salmonella* is usually a moderate health hazard and there is a potential for extensive spread by infected persons. In case 11 the ICMSF foresees that ten samples have to be examined and that no sample should be positive. If the answer were YES, there is a potential for unacceptable multiplication, for instance in a reconstituted powdered egg-product, then the next question has to be answered.

Question 8: "Potential for acceptable reduction during storage, distribution, preparation or use?" would be answered with NO in products mentioned above, i.e. salad dressings or tiramisu, and case 12 would apply. If another use is foreseen that would kill *Salmonella* then question 9 should be answered with YES that means no criterion should be established.

Question 9: "Killing of pathogens of concern before consumption assured?" If the answer is NO than case 10 would apply. If the answer is YES then no criterion should be established.

The EU criterion specifies absence of *Salmonella* in 25g or ml but with no sampling plan. The Committee recommends that the standard is retained but that sampling depends on the use of the product with a minimum of $n = 5$.

The Committee recommends that the sampling plan should depend on the use of the product.

B) Enterobacteriaceae

Decision tree for indicators (Figure A3.2)

This group of microorganisms is used as an indicator of whether sufficient heat treatment and/or adequate hygiene has been applied during production. Thus the decision tree for indicators (Figure A3.2) should be applied.

Question 1: "Is the criterion to be applied at the food production site?" This has to be answered with YES.

Question 3: "Are GHP and HACCP expected to be applied and verified?" This will, for the sake of this example, be answered with YES.

Question 4: "Is criterion to be used for official control?" This has to be answered with YES.

Question 5: "Is there evidence of risk to health for this food?" This has to be answered with YES, particularly when egg products are used in salad dressings, tiramisu, or other foods which are ready-to-eat, thus no killing step occurs before consumption.

Question 6: "Will application of a criterion benefit public health?" This has to be answered with YES. Unhygienic food, which might indicate a risk of *Salmonella* contamination, can be prevented from reaching the consumer.

Question 7: "Potential for unacceptable increase during storage, distribution, preparation or use?" This would be answered with NO in the case of a frozen or dried egg product (If there is concern about multiplication during thawing or reconstitution, the answer would be YES).

Question 8: "Potential for acceptable reduction of concern during storage, distribution, preparation or use?" would be answered with NO in relation to the products mentioned above, i.e. salad dressings or tiramisu. Case 6 would apply. If another use is foreseen that would kill sufficient pathogens of concern, then the next question, question 9, should be answered with YES, which means that no criterion should be established. If killing of pathogens of concern before consumption is not assured, the answer would be NO and case 4 would apply.

The EU document does not foresee a sampling plan, the criterion be a guideline only and only mentioning that $M=10^2$ per gram or ml. The Committee recommends that the sampling plans should depend on the use of the product.

C) Aerobic mesophile bacteria

Decision tree for indicators (Figure A3.2)

Question 1: "Is the criterion to be applied at the food production site?" This has to be answered with YES.

Question 3: "Are GHP and HACCP expected to be applied and verified?" This will, for the sake of this example, be answered with YES.

Question 4: "Is criterion to be used for official control?" This has to be answered with NO. Tests for this group of microorganisms do not normally indicate hygiene or safety concerns. Industries may have trade agreements or internal objectives, which they may want to check against a criterion.

The Committee recommends that a criterion for aerobic mesophile bacteria should be used as a guideline only.

D) Staphylococcus aureus

Decision tree for indicators (Figure A3.2)

Question 1: "Is the criterion to be applied at the food production site?" This has to be answered with YES.

Question 3: "Are GHP and HACCP expected to be applied and verified?" This will, for the sake of this example, be answered with YES.

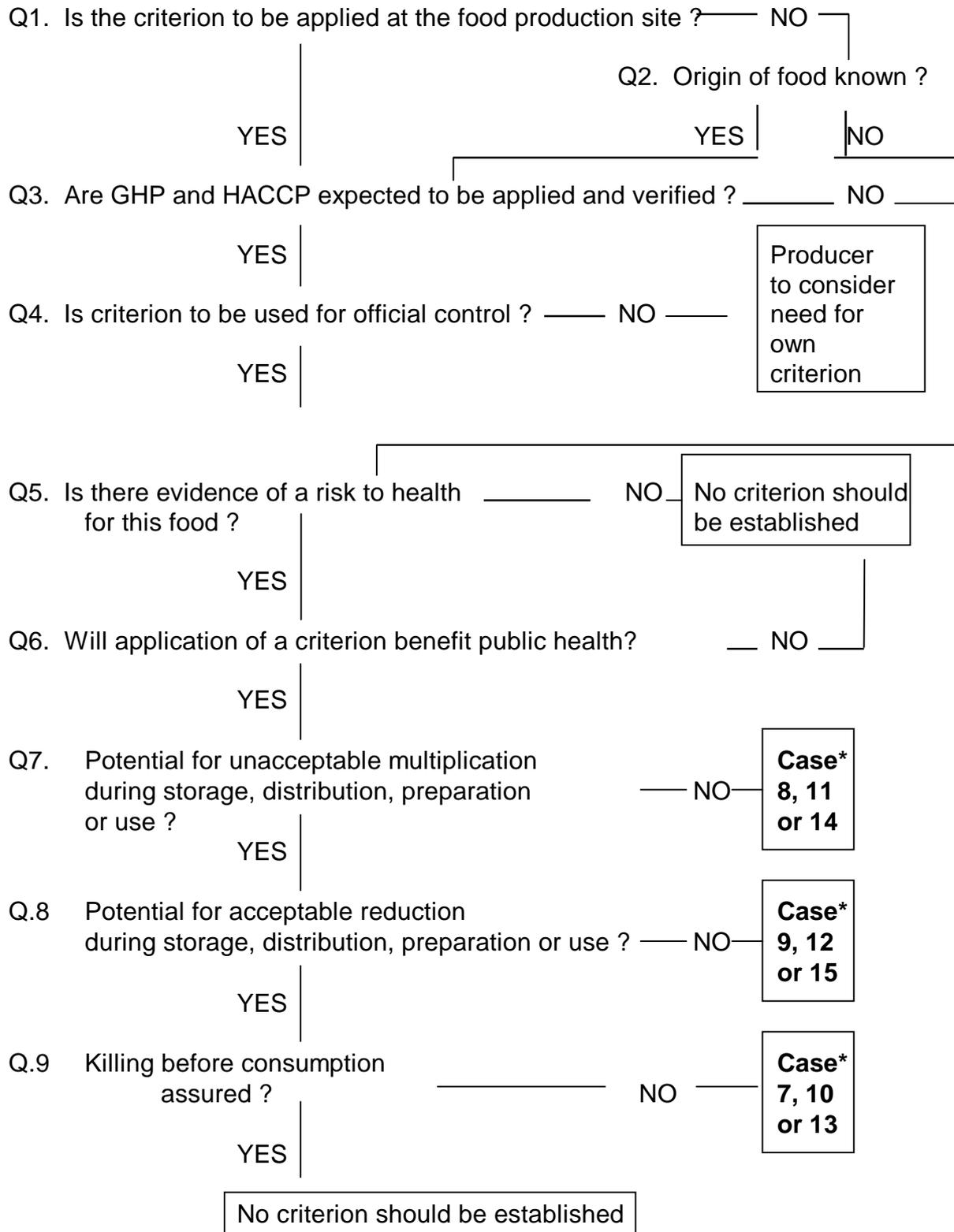
Question 4: "Is criterion to be used for official control?" This has to be answered with YES. Industries will not use a criterion for *S. aureus* because it is neither a hygiene indicator in this type of establishment, nor a hazard according to the HACCP principles applied to production of this product.

Question 5: "Is there evidence of a risk to health for this food?" This has to be answered with NO with regard to *S. aureus*, consequently no criterion should be established.

The Committee recommends that this criterion be deleted.

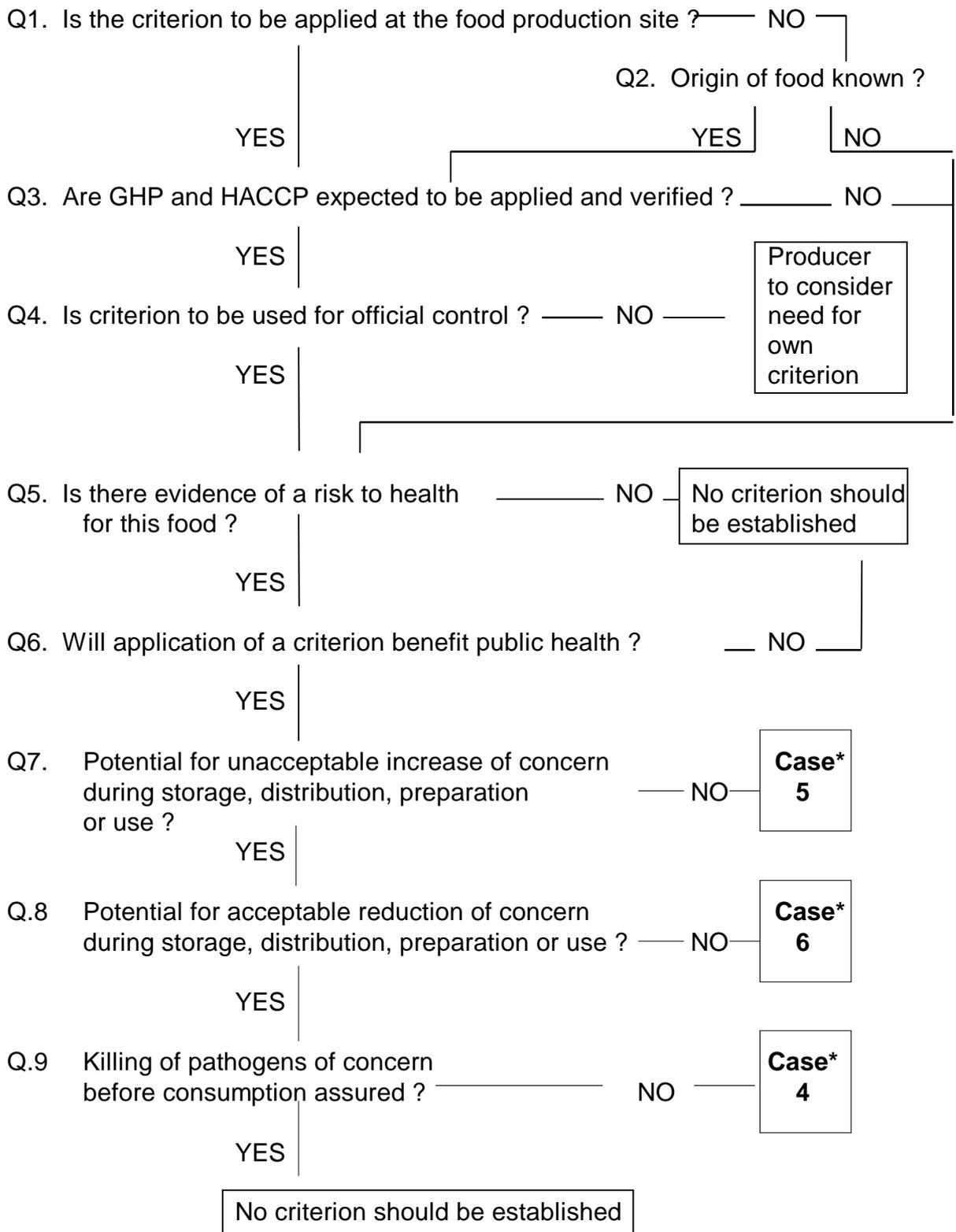
The purpose of giving these examples is only to show how the decision trees automatically lead to sampling plans which take into account, how the product is going to be used, whether there is a reduction, an increase, or no change in the likelihood of occurrence and what the severity of hazard could be.

Figure A3.1 Establishment of Microbiological Criteria for Pathogens



NB. The number of samples or sample size may need to be increased when the food is specifically intended for highly susceptible individuals. * See ICMSF(1986)

Figure A3.2 Establishment of Microbiological Criteria for Indicators



NB. The number of samples or sample size may need to be increased when the food is specifically intended for highly susceptible individuals. * See ICMSF (1986)

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