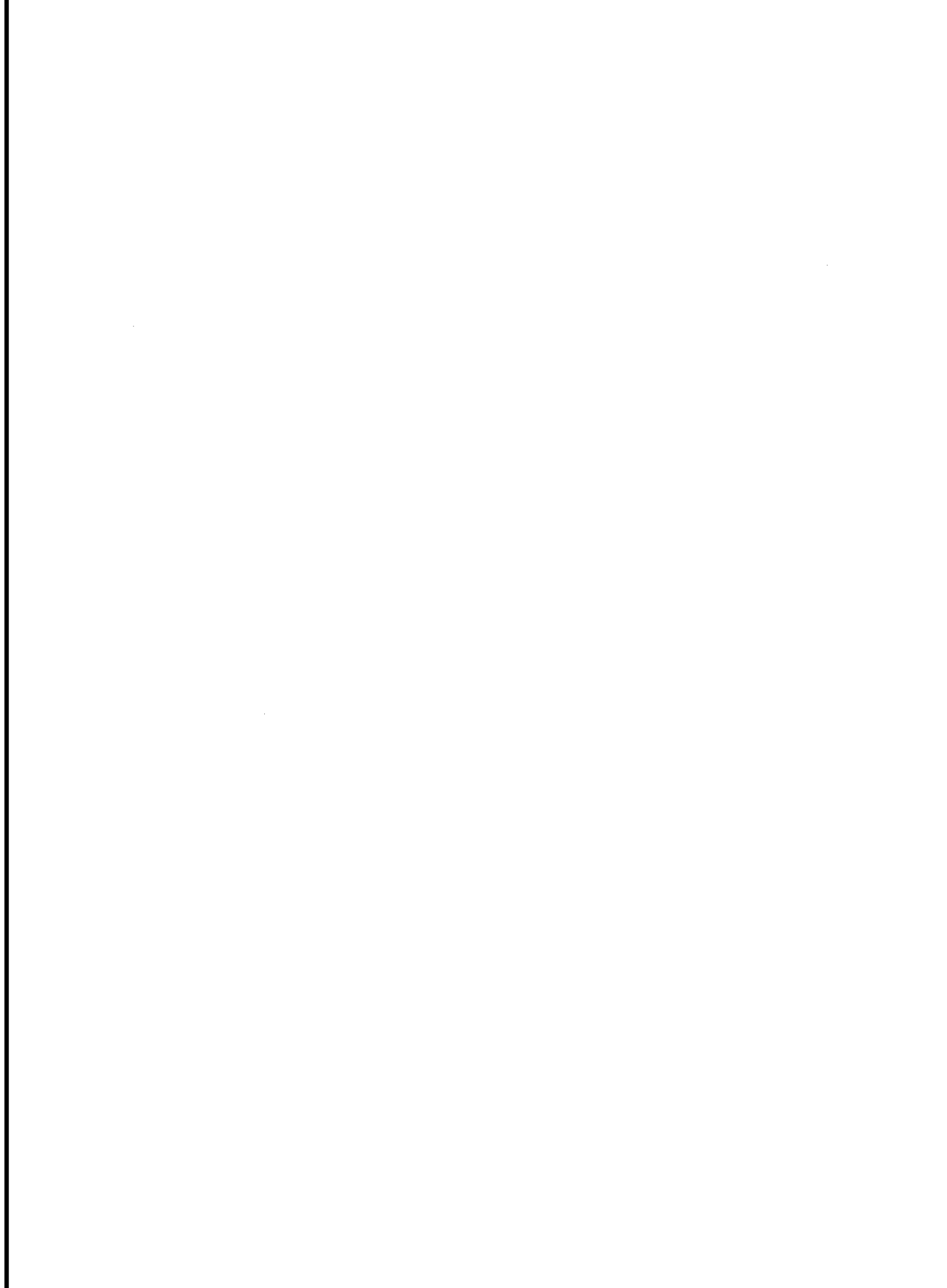


**PRINCIPLES FOR THE DEVELOPMENT OF RISK  
ASSESSMENT OF MICROBIOLOGICAL HAZARDS  
UNDER DIRECTIVE 93/43/EEC CONCERNING  
THE HYGIENE OF FOODSTUFFS**

**PRINCIPLES FOR THE DEVELOPMENT OF  
MICROBIOLOGICAL CRITERIA FOR ANIMAL  
PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN  
INTENDED FOR HUMAN CONSUMPTION**



**EUROPEAN  
COMMISSION**



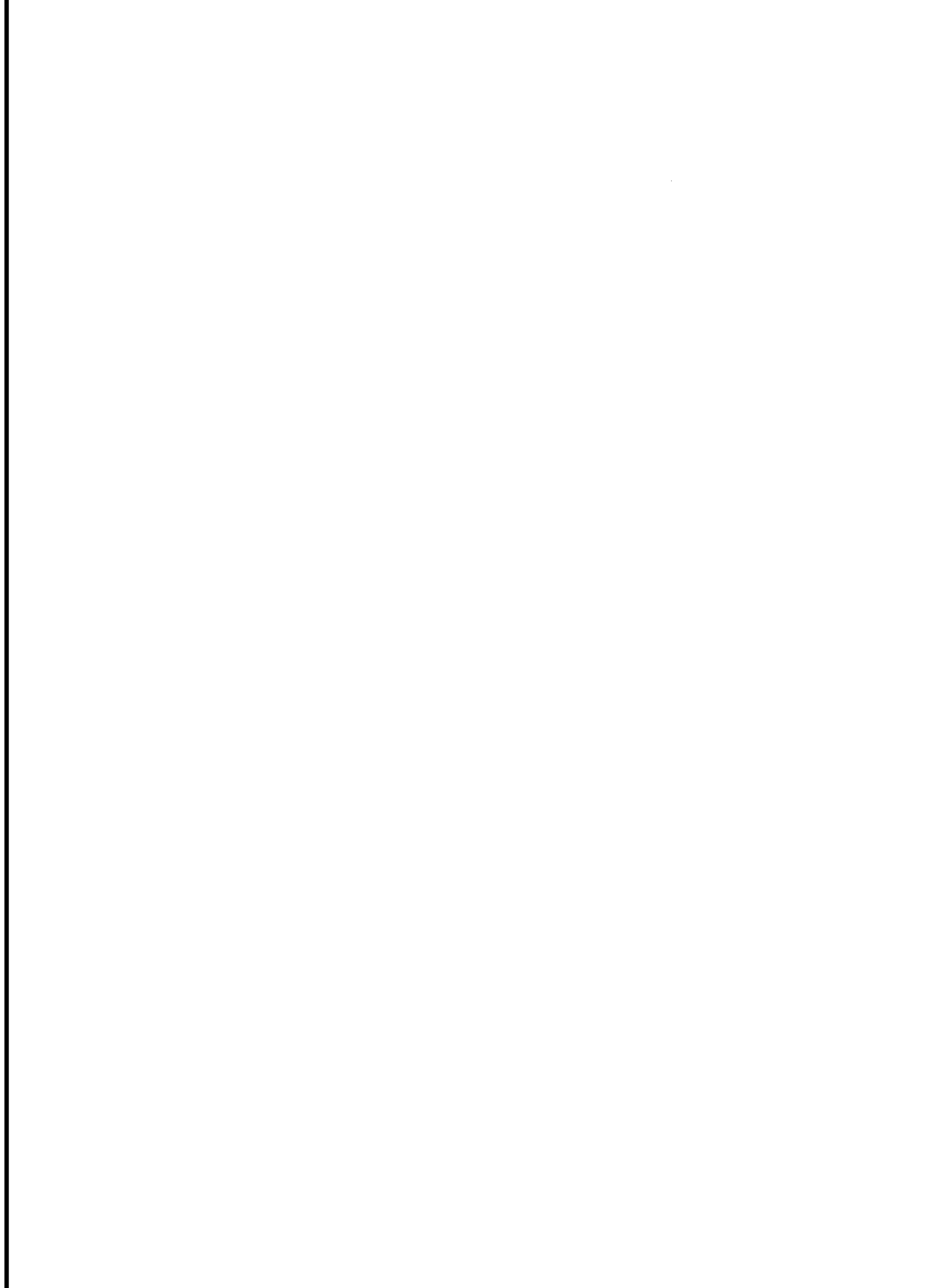
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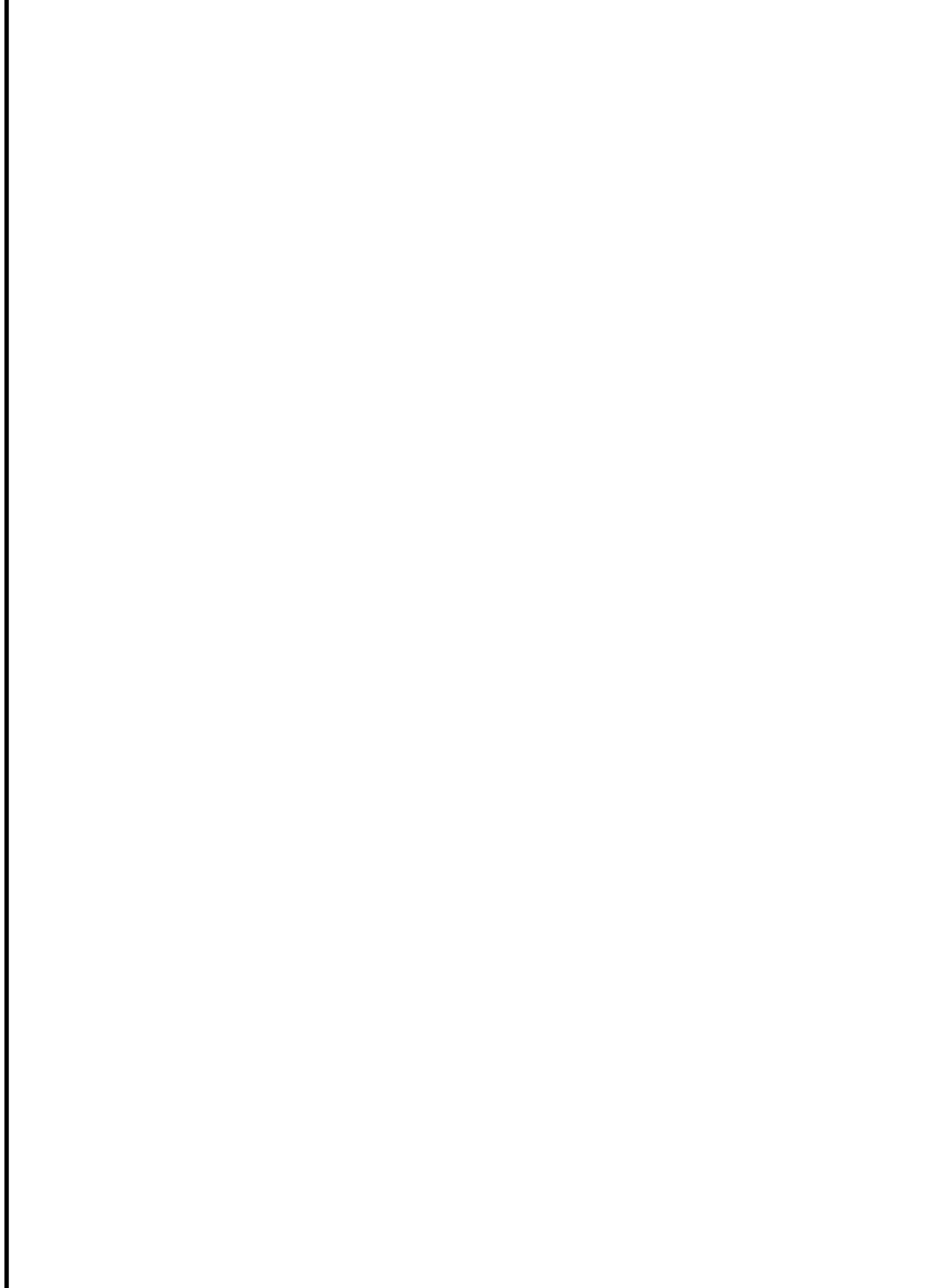
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September 1997



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## FOREWORD

Community legislation concerning consumer protection against foodborne diseases was first established to respond to the needs of the Internal Market. The achievement of this objective has led to the adoption of a high number of directives establishing or allowing the establishment by comitology procedures of microbiological criteria for foodstuffs, animal products and products of animal origin intended for human consumption.

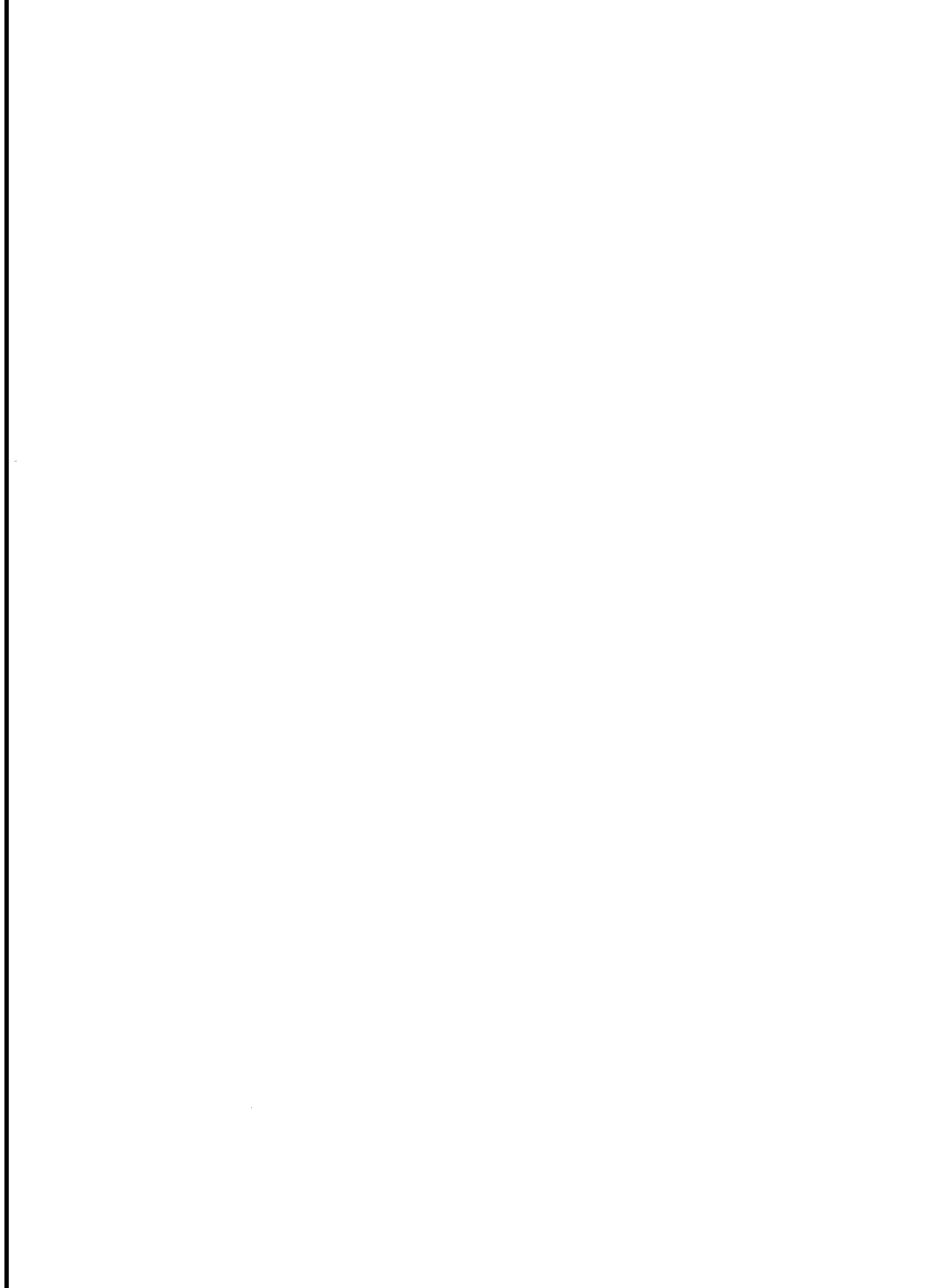
The Sanitary and Phytosanitary Agreement included in the Marrakech Agreements, to which the Community is a contracting party, provides that sanitary standards must be based on risk assessment.

The Commission has undertaken to revise all the legislation concerning food hygiene with a view to its simplification and clarification and also to base it more specifically on risk assessment. In order to achieve these objectives and in parallel to the work carried out at international level in the Codex Alimentarius, the Commission has asked the Scientific Committee for Food to establish the principles for the development of microbiological criteria for foodstuffs, animal products and products of animal origin intended for human consumption as well as the principles for the development of risk assessment for microbiological hazards in accordance with the Food Hygiene Directive (93/43/EEC).

Following this request from the Commission, the Scientific Committee for Food has adopted two documents which represent useful tools for the development of food hygiene based on scientifically sound data and procedures.

Moreover, the obligation to apply procedures for the management of food safety based on the principles of the Hazard Analysis Critical Control Point (HACCP) is gradually being introduced for the various sectors of the food industry. These procedures require an evaluation of microbiological risks and the setting of critical limits. The industry will find in this publication useful guidelines for the establishment of their HACCP programmes.

The importance of the two documents fully justifies their publication by the Commission to ensure their widest possible distribution.





**PRINCIPLES FOR THE DEVELOPMENT OF RISK ASSESSMENT OF  
MICROBIOLOGICAL HAZARDS UNDER THE HYGIENE OF FOODSTUFFS  
DIRECTIVE 93/43/EEC**

**RECOMMENDATION OF THE SCIENTIFIC COMMITTEE FOR FOOD**

**1. BACKGROUND**

**1.1** Under Article 4 of the Hygiene of Foodstuffs Directive 93/43/EEC (1), without prejudice to more specific Community rules, the Commission, assisted by the Standing Committee for Foodstuffs, after consultation with the Scientific Committee for Foodstuffs, may adopt microbiological criteria and temperature criteria for certain classes of foodstuffs.

This document has been produced by the Scientific Committee for Food.

**1.2** Under the Sanitary and Phytosanitary (SPS) Agreement reached within the Uruguay round of the multi-lateral trade negotiations under the General Agreement on Tariffs and Trade (GATT), food regulations outside of those contained in internationally recognised food standards may be required to be justified in relation to, amongst other issues, the level of health protection provided by the measure in question. (O.J. Nr L336 of 23 December 1994, Annex 1A P.41 Art. 3.)

**1.3** Risk assessment for foodborne microbiological hazards is a new activity and there have been different approaches to its methodology. Due to its importance in the international context, the process should be undertaken in a transparent and comparable way by different risk assessors and there is a need for a common understanding of its basic elements. For harmonisation and transparency, risk assessments should be developed according to a structured and universally accepted framework. However, within this framework, some flexibility should be recognised in relation to the detail of application and use of tools which may vary depending on the purpose of the risk assessment.

**1.4** These principles identify the essential elements of a risk assessment framework for foodborne microbiological hazards, incorporating the standard risk assessment paradigm (the <<4 steps paradigm>>) agreed upon at the WHO/FAO consultation on risk assessment (2), which constitutes the basis of the Codex discussions on risk assessment (ALINORM 97/13A APPENDIX IV).

In addition they provide an outline of the diverse elements and factors that may be considered at each stage and an outline of the possible sources of information and techniques that may be used. These are not offered as formal guidance as they are not exhaustive, nor will all of them be relevant in every assessment.

**1.5** In the following sections, the essential elements of a risk assessment framework are presented in frames and printed in bold letters. Text which is not in bold type refers to explanatory notes or identifies areas where some flexibility in details of application is recognised.

## **2. DEFINITIONS**

The definitions below originate from the Codex Alimentarius Commission (3)

**HAZARD:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**RISK:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**RISK ANALYSIS:** A process consisting of three components: risk assessment, risk management and risk communication.

**RISK ASSESSMENT:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation.

**HAZARD IDENTIFICATION:** The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

**HAZARD CHARACTERISATION:** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

**DOSE-RESPONSE ASSESSMENT:** The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

**EXPOSURE ASSESSMENT:** The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

**RISK CHARACTERISATION:** The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.

**RISK MANAGEMENT:** The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

**RISK COMMUNICATION:** The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

### **3. MICROBIOLOGICAL RISK ASSESSMENT IN THE CONTEXT OF RISK ANALYSIS**

**3.1** *Risk analysis* is a structured and multidisciplinary approach to identifying and, where necessary, reducing risk.

A broad consensus recognises that the process of risk analysis consists of three essential components (Figure 1):

- risk assessment,
- risk management,
- risk communication.

**3.2** *Risk assessment* is the scientific evaluation of known or potential adverse health effects resulting from human exposure to (foodborne) hazards.

The purpose of risk assessment is documentation and analysis of scientific evidence to measure risk and identify factors that influence it, for use by risk managers.

The outcome of the risk assessment is called the **risk estimate**.

**3.3** *Risk management* is the process of weighing policy alternatives to accept, minimise or reduce assessed risks and to select and implement appropriate options.

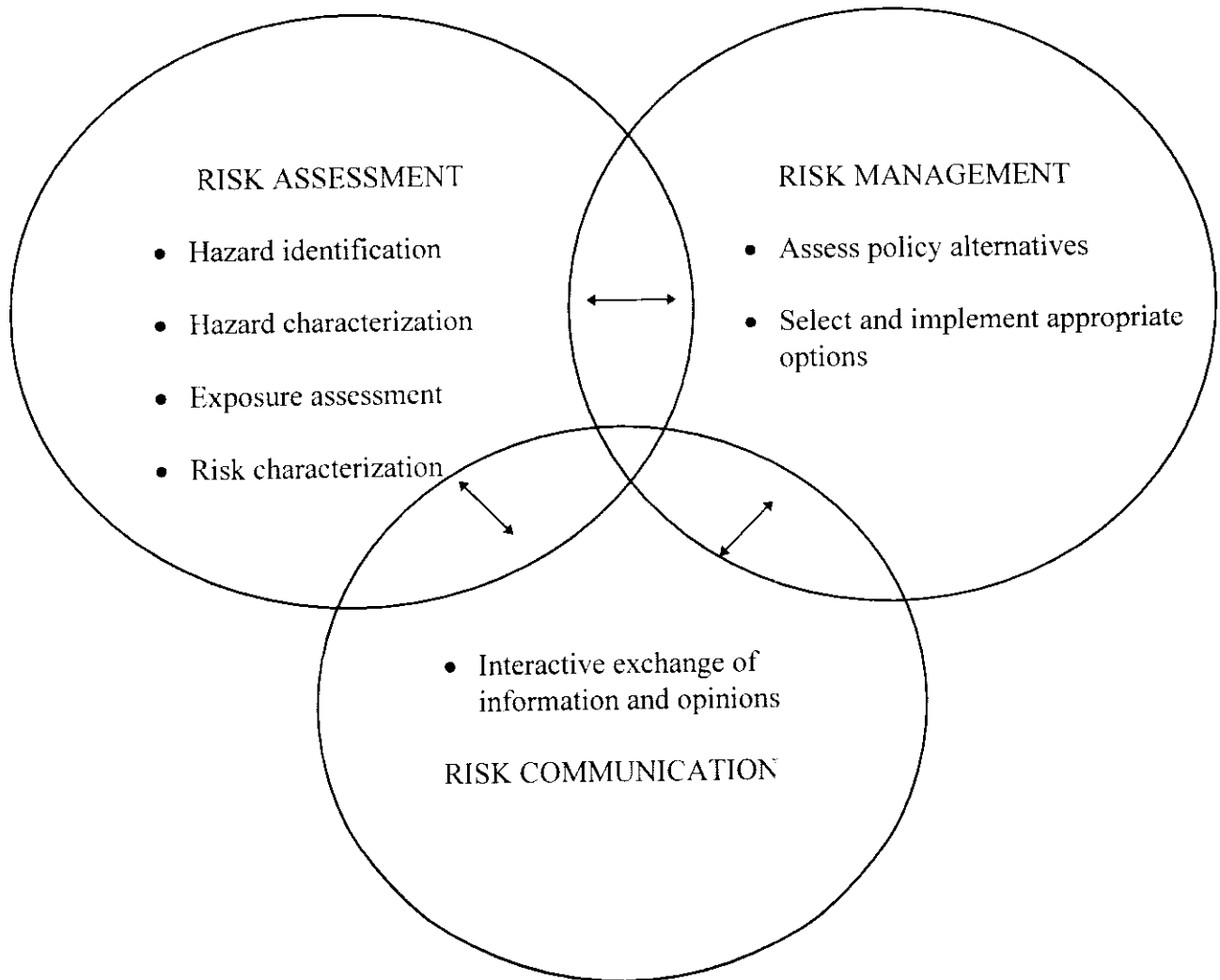
The purpose of risk management is to identify acceptable risk levels, develop and implement control options within the framework of public health policy. A cost-benefit analysis of options would also support risk management.

**3.4** *Risk communication* is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties.

In particular, communicating foodborne risk to the public involves an informational exchange between risk managers, those concerned with production and the consumers about risk, potential control options and the cost of control options. Risk communicators also interface with those involved through educational programmes to enhance the effectiveness of selected management strategies.

**3.5** This document deals only with risk assessment.

**Figure 1 : Risk Analysis Framework (modified from Lammerding, A., 1996) (4)**



#### **4. RISK ASSESSMENT FOR MICROBIOLOGICAL HAZARDS IN FOODS - GENERAL PRINCIPLES**

##### **4.1 Risk assessment for microbiological hazards must be soundly based on science.**

For the purpose of this document, the term microbiological hazard includes hazards caused by bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, their toxins and metabolites. All available scientific data relevant to the risk assessment should be considered. These data are likely to come from different sources. For example, data may include clinical and epidemiological studies such as disease symptoms, severity and dose-response data; microbiological studies including the physiology, biochemistry and ecology of microorganisms and the biochemistry and stability of their toxins; sources and prevalence of microorganisms and their toxins in foods and the effect of processing and food handling operations on them; data on food production and consumption patterns. Where scientific data are limited, otherwise incomplete or conflicting, informed judgements may be made on the basis of the best information available.

##### **4.2 There must be a functional separation between Risk Assessment and Risk Management.**

Risk assessment of microbiological hazards is a scientific process aimed at identifying and characterising a microbiological hazard and estimating the risk of that hazard to a population. Risk management is a separate process aimed at identifying options for action(s) needed to manage that risk and has a policy function. However, certain interactive elements are essential for a systematic Risk Analysis process. For example, these may include the ranking of hazards in the risk assessment process and risk management policy issues. Where risk management issues may affect the decision-making process used in risk assessment, the implications of this must be made clear in the final report.

##### **4.3 A structured approach must be used when conducting a Risk Assessment of Microbiological Hazards.**

This structured approach must include four components: Hazard Identification, Hazard Characterisation, Exposure Assessment and Risk Characterisation. The sequence of use of these may vary depending on the purpose of the risk assessment.

**4.4 A Risk Assessment of Microbiological Hazards must clearly state both the purpose of the assessment and the form of the risk estimate that will be the output.**

The objective might be to estimate the risk associated with a microbiological hazard in the total food supply to a population or the risks associated with a number of microbiological hazards associated with a specific food commodity. The output might take the form of an estimate of the annual occurrence of illness or an estimate of the annual rate of illness per 100,000 population or an estimate of the rate of illness per eating occurrence.

**4.5 Risk Assessment must be transparent.**

This requires that the assessment is documented in full and that a complete and formal record is made of the assessment. The formal record must include any constraints imposed by costs, resources or time and an evaluation of the possible effect of these on the quality of the risk estimate. Any assumptions or judgements made during the assessment, and which may have affected the outcome of the estimate, should also be described and the rationale explained and fully documented in the record. Where appropriate, the record should include an evaluation of the impact of the resource constraint(s) on the risk assessment. The formal record, including a summary must be made available, on request, to independent parties so that other risk assessors can evaluate the assessment and repeat it if deemed necessary.

**4.6 The risk estimate must contain a detailed description of uncertainty and where this arose during the risk assessment process.**

To ensure transparency in the decision making process it is essential that there is a clear understanding of any limitations in the data or models used in the risk assessment and how these limitations influenced the risk estimate. Such limitations should be recorded in the report.

**4.7 Data must be of sufficient quality and precision such that uncertainty in the risk estimate is minimised as far as possible.**

It is important that the best available information and expertise is applied to a risk assessment in order to reduce uncertainty and increase reliability of the risk estimate. Quantitative information should be used to the extent possible, but where this is not available good qualitative information should be used.

**4.8 Where appropriate, a Risk Assessment of Microbiological Hazards must consider the fate of the hazard(s) in food(s) and the disease process following infection.**

The dynamics of microbial growth, survival and death should be explicitly considered. Where applicable the dynamics of microbial toxin formation and destruction should also be considered together with distribution of the agent, in appropriate foodstuffs. The interactions between humans and the agent (including possible sequelae) following consumption and the potential for horizontal or vertical spread of the agent are part of the assessment.

**4.9 Risk estimates, where possible, must be re-evaluated over time against human health data and when new data become available.**

For microbiological agents human health data relating to the results of exposure to a microbiological agent may be available. This may provide the opportunity to compare a risk estimate of such an agent with the actual occurrence of human disease, thereby providing a gauge as to the reliability of a risk estimate. If there is a significant discrepancy between the risk estimates and the human data there must be a re- evaluation of the risk assessment.



## 5. RECOMMENDED SCHEME FOR RISK ASSESSMENT OF FOODBORNE MICROBIOLOGICAL HAZARDS

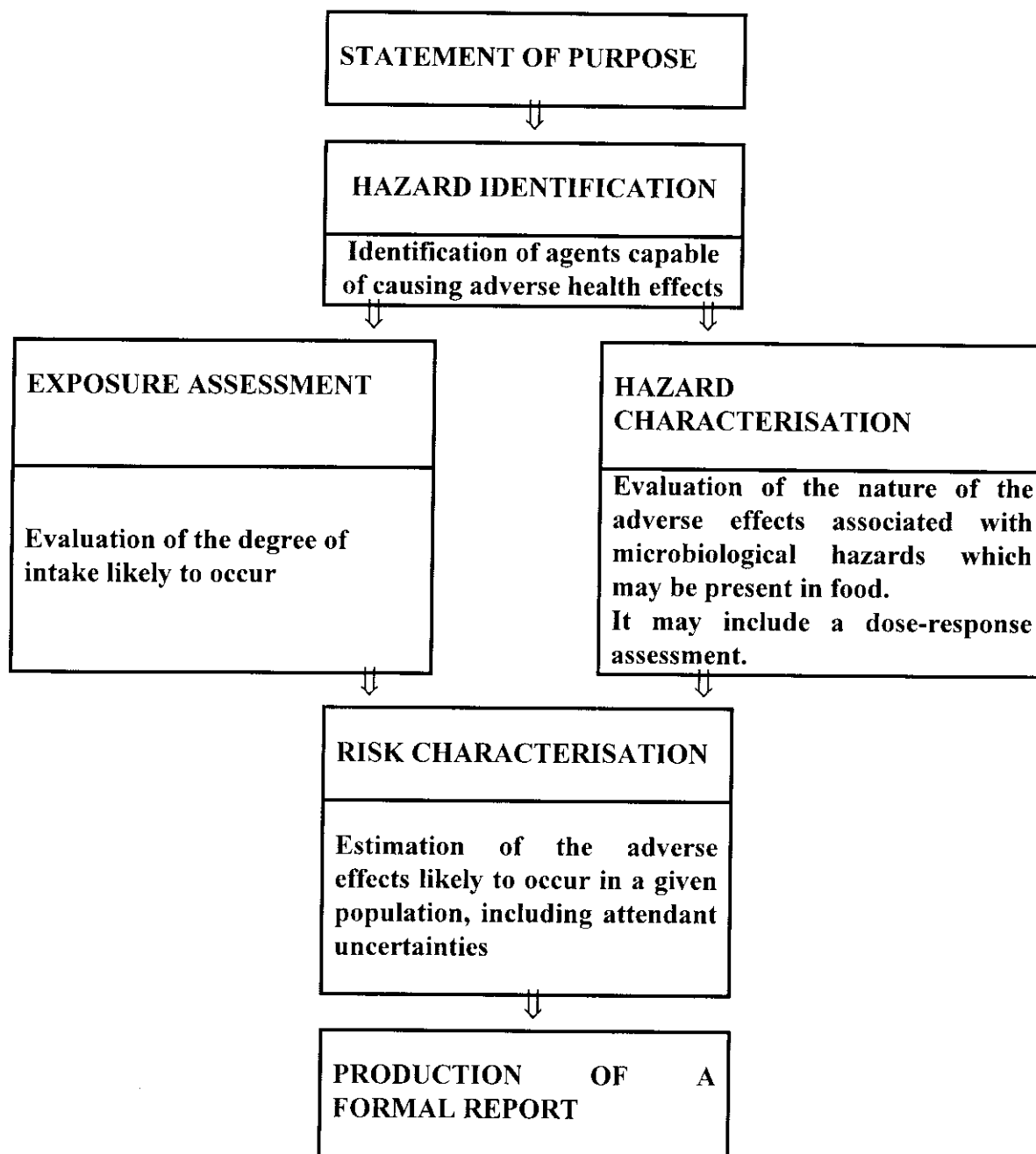
*Risk assessment* is a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment, and (iv) risk characterisation.

Based on this definition, the following scheme is recommended (Figure 2):

- Statement of purpose of risk assessment
- Hazard identification
- Hazard characterisation (including a dose-response assessment)
- Exposure assessment
- Risk characterisation
- Production of a formal report

The following sections will consider in turn the elements of this recommended scheme.

**Figure 2: Risk Assessment Scheme for Foodborne Microbiological Hazards**



Noterman, S., Mead, G.C. and Jouve, J.L. (1996) (5)

The recommended scheme for risk assessment for foodborne microbiological hazards provides a working agenda. However, the stages listed may not necessarily be considered in sequence but rather in an orderly manner, as suggested in Figure 2.

These stages are the same for microbiological or chemical risk assessment. However, the emphasis among such stages and the elements to be considered at each stage is likely to differ. For example, the hazard identification phase needs less investigation for already known foodborne pathogenic bacteria than for new chemicals. Alternatively, carrier state and potential secondary spread are not factors to be considered when assessing chemical risks but are important when considering microbiological risk assessment.

Risk assessment is the science of understanding hazards, how likely they are to occur and the consequences if they do occur. Therefore, the product of risk assessment, i.e. the <<risk estimate>>, is a statement that links the probability that exposure to a pathogenic agent will occur and that such exposure will affect the host. For microbiological risk assessment of foodborne pathogens, this may often be coupled to a consideration of severity (or magnitude) of the adverse effects.

The scope, detail and complexity of a given risk assessment may vary depending on factors such as the availability of time, availability of data, resources, perceived seriousness of the hazard or the outcome and possible consequences of any decision. Risk assessment should be comprehensive but remain feasible given the available time and resources.

## **5.1 STATEMENT OF PURPOSE**

**5.1.1 - The specific purpose of the risk assessment should be clearly stated. The output form and possible output alternatives should be defined.**

**5.1.2** This stage refers to problem formulation. During this stage, the cause of concern, the goals, breadth and focus of the risk assessment should be defined. The statement may also include data requirements, as they may vary depending on the focus and the use of the risk assessment and the questions relating to uncertainties that need resolving.

**5.1.3** Entry into a risk assessment process for foodborne microbiological hazards may be triggered in different ways, for example, by:

- emerging and re-emerging pathogens
- public concern
- the need to establish or to evaluate control options, for example microbiological criteria, etc.

**5.1.4** Depending on its purpose, a microbiological risk assessment process may be focused on either the agent, the food vehicle or the treatment/process (the latter may cover, for a given product, all the stages of the food chain, one segment of specialised activity, e.g. production or processing or wholesale/retail activities, a multistep process or a single treatment, e.g. different pasteurisation temperatures). Such a focus may in turn influence the information and data requirements.

As an example, if the focus is on the agent, there is a need to collect data which identify if foodborne transmission plays an important role in the aetiology of disease and which foods are implicated. If the focus is on food, data are necessary to determine which pathogens have been, or potentially could be, associated with the product. Where the focus is on the treatment/process, there is a need to understand the possible food handling practices and consumers' preferences and habits to identify their possible consequences and determine how likely are these consequences in specific situations.

**5.1.5** The output might, for example, take the form of an estimate of:

- annual occurrence of illness,
- annual rate of illness per 100,000 population,
- rate of human illness per eating occurrence,

which facilitate in particular the comparison with human health data.

## **5.2 HAZARD IDENTIFICATION**

**5.2.1 Hazard identification is the identification of biological, chemical and physical agents which are capable of causing adverse health affects and may be present in a particular food or group of foods.**

**The purpose of hazard identification is to identify the microorganism or microbial toxin of concern and to evaluate whether the microorganism or the toxin is a potential hazard when present in food.**

**5.2.2** The key to hazard identification is the availability of public health data and a preliminary estimate of the amount, frequencies and sources of the microorganism.

**5.2.3** The necessary information can be obtained from scientific literature, from data bases such as those maintained in governmental agencies and in the food industry and through expert advice.

**5.2.4** Areas of relevant information may include, among others:

- clinical studies
- epidemiological studies and surveillance
- laboratory animal studies
- investigation of the characteristics and properties of microorganisms (e.g. genotype, phenotype and behaviour)
- interaction between microorganisms and their environment through the food chain from primary production up to and including consumption
- information on analogous microorganisms, situations or contexts.

**5.2.5** For many established foodborne pathogens, hazards are already well documented and the formal requirements for information and data are minimal. However, there is a perceived need for better identification of newly emerging (or re-emerging) foodborne pathogens and to develop for that purpose targeted medical studies, epidemiological monitoring (e.g. sentinel or case/control studies) and microbiological techniques (e.g. improved detection and identification techniques, differentiation of strains).

### **5.3 EXPOSURE ASSESSMENT**

**5.3.1 Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposure from other sources if relevant.**

**The ultimate goal of exposure assessment is to evaluate the level of microorganisms or microbial toxins in the food at the time of consumption. This may include an assessment of actual or anticipated human exposure.**

**For foodborne microbiological hazards, exposure assessment might be based on the possible extent of food contamination by a particular hazard and on consumption patterns and habits (i.e. "dietary information").**

**5.3.2** Assessing the potential extent of food contamination involves consideration of the frequency or likelihood of contamination of foods by the pathogenic agent and its prevalence and/or level in those foods over time, up to the time of consumption.

In addition to the characteristics of the pathogenic agent information of interest may include:

- the microbial ecology of the food
- the initial contamination of the raw materials
- the effect of the production, processing, handling, distribution steps and preparation by the final consumer on the microbial agent (i.e. the impact of each step on the level of the pathogenic agent of concern)
- the variability in processes involved and the level of process control
- the level of sanitation
- the potential for (re) contamination (e.g. cross contamination from other foods; recontamination after a killing treatment)
- the methods or conditions of packaging, distribution and storage of the food (e.g. temperature of storage, relative humidity of the environment, gaseous composition of the atmosphere)
- the characteristics of the food that may influence the potential for growth of the pathogen (and/or toxin production) in the food under various conditions, including abuse (e.g. pH, moisture content or water activity, nutrient content, presence of antimicrobial substances, competitive flora).

- 5.3.3** To gain this information several techniques may be used as for example:
- data collection on prevalence and distribution of microorganisms in food(s) including foods involved in outbreaks
  - storage testing
  - challenge testing
  - historical performance data of a food process or laboratory studies of such performance (e.g. 'D' values of survivors to a heat treatment)
  - mathematical modelling to predict the growth, death or survival of microorganisms in response to environmental conditions and the likely number of microorganisms present in food at the time of consumption.
  - examination of foods involved in outbreaks.

Such exposure assessment includes various levels of uncertainty. This uncertainty can be estimated using various techniques, e.g. event tree analysis, fault tree analysis, HAZOP (Hazard Analysis and Operability Study) and probabilistic scenario analysis (PSA) (6,7).

**5.3.4** Information on consumption patterns and habits ("dietary information") may include:

- socio-economic and cultural background, ethnicity
- consumer preferences and behaviour as they influence the choice and the amount of the food intake (e.g. frequent consumption of high risk foods)
- average serving size and distribution of sizes
- amount of food consumed over a year considering seasonality and regional differences
- food preparation practices (e.g. cooking habits and/or cooking time, temperature used, extent of home storage and conditions, including abuse)
- demographics and size of exposed population(s) (e.g. age distribution, susceptible groups)

## **5.4 HAZARD CHARACTERISATION**

**5.4.1 Hazard characterisation is the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical and physical agents that may be present in food. A dose-response assessment should be performed if data is obtainable.**

**The purpose of hazard characterisation is to provide an estimate of the nature, severity and duration of the adverse effects associated with harmful agents in food. Factors important to consider relate to the microorganisms, the dynamics of infection and the sensitivity of the host.**

**5.4.2** Factors relating to the microorganisms may include the following:

- microbial replication
  - e.g. self replication, generation time
- virulence factors
  - e.g. synthesis of various toxins; presence of attachment factors on the cell surface, antigenic properties, ability to circumvent host's immune response
- dynamic evolution of virulence of microorganisms depending on their interaction with environment and host,
- microbial variability in response to environmental factors or natural mutation that may result in changes in pathogenicity
  - e.g. . altered biochemical activity
  - . genetic changes
- antigenic variation
- DNA transfer leading to transfer of characteristics such as antibiotic resistance
- tolerance to adverse conditions
- transmissibility that may allow spread



**5.4.3** Factors relating to dynamics of infection may include:

- rate of infection
- latency (delayed onset of clinical infection following exposure)
- disease pattern
  - . infection(asymptomatic) vs clinical disease
  - . disease acute, chronic, persistent, latent
  - . incubation period
  - . severity and duration of episode(s)
  - . possible diseases outcome (e.g. recovery, mortality, chronic sequelae)
  - . persistence of the microorganism in certain individuals leading to continued excretion and risk of spread

**5.4.4** Factors relating to the host may include:

- genetic factors that may influence the immune response e.g. Human Leucocyte Antigen (HLA) type
- immune status of sub-population ( e.g. infants, the elderly, pregnant women, immuno compromised individuals) as well as previously exposed or unexposed populations
- breakdown of physiological barriers leading to increased susceptibility (e.g. concomitant infections, consumption of antibiotics, antacids, excessive level of iron in the blood, reduced liver/kidney function)
- diet and social behaviour ( e.g. nutrition deficiencies, poor hygiene, stress)

**5.4.5** Specific to risk assessment of foodborne microbiological hazards, consideration should also be given to the interaction between the food matrix, the microorganism and the host which may influence the survival of the agent through the hostile environment of the stomach. Related factors may include:

- increase of stomach pH (e.g. age, use of antacids)
- decreased residence time ( e.g. initial rapid transit of liquids in empty stomach)
- increased acid tolerance ( e.g. pre-exposure of bacteria to moderately acid conditions, entrapment of bacteria in lipid droplets, highly buffered foods)

**5.4.6** Not all factors listed above will be important for all foodborne microbiological hazards, depending on the purpose of the risk assessment.

**5.4.7** A key aspect of hazard characterisation is establishing a **dose-response relationship**.

Dose-response assessment is the process of obtaining quantitative information on the probability of human illness following exposure to a hazard; it is a translation of exposure into harm.

**5.4.8** In general, dose-response assessment is carried out for the population (or sub population) exposed to the hazard but it should be taken into account that the dose-response relationship depends on the sensitivity of the exposed group and that there exists a large variation in the human population.

**5.4.9** Information on which to base quantitative dose-response estimates is difficult to obtain, due to e.g. the variability in virulence and pathogenicity of microorganisms, the variation in attack rates, the large variation in host susceptibility, the type of food vehicle which modulate the ability of bacteria to infect and otherwise affect the host.

Data sources, where available could possibly include results of:

- foodborne disease analysis
- population characteristic surveys
- animal trials
- human volunteer studies

**5.4.10** Mathematical models have been developed (beta-Poisson distribution, exponential distribution) to provide assistance in developing dose-response relationship, in particular at low levels. It is recognised that the development of such mathematical models may facilitate this approach, but the assumptions on which they are based, their usefulness and limitations still need to be carefully considered. Since minimum infective dose (MID) may vary widely from person to person, this concept may not be appropriate for risk assessment in a population.

## **5.5 RISK CHARACTERISATION**

**5.5.1 Risk characterisation is the quantitative and/or qualitative estimation including attendant uncertainties of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.**

**Bringing together the information of the previous stages, it provides an estimate, qualitative or quantitative, of risk to a given population or sub-population.**

**The degree of confidence of the final estimation of risk will depend on the factors considered and their uncertainty identified in all the previous stages.**

**5.5.2** Risk characterisation is the last step in risk assessment from which a risk management strategy can be formulated.

**5.5.3** Risk characterisation has been defined as the integration of the Hazard Identification, Hazard Characterisation and Exposure Assessment determinations previously described into qualitative or quantitative estimates of the likelihood of the adverse effects occurring in a given population, including a description of the uncertainties and variability.

**5.5.4** These estimates can be assessed by comparison with independent epidemiological data that relate hazards to disease prevalence.

Risk Characterisation brings together all of the qualitative or quantitative information of the previous steps to provide a soundly based estimate of risk for a given population or subpopulation. The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk.

**5.5.5** The degree of confidence in the final estimation of risk will depend on the variability, uncertainty and assumptions identified in all previous steps. Uncertainty is associated with the data themselves and with the choice of model. Data uncertainties include those that might arise in the evaluation and extrapolation of information obtained from epidemiological, microbiological and laboratory animal studies. Uncertainties arise whenever attempts are made to use data concerning the occurrence of certain phenomena obtained under one set of conditions to make estimations or predictions about phenomena likely to occur under other sets of conditions for which data are not available. Biological variation includes the differences in virulence that exist in microbiological populations and variability in susceptibility within the human population and particular subpopulations. It is important to demonstrate the influence of the estimates and assumptions used in risk assessment; for quantitative risk assessment this can be done using sensitivity and uncertainty analyses.

## **5.6 PRODUCE A FORMAL REPORT**

**5.6.1** The risk assessment should be fully and systematically documented. To ensure transparency, the final report should indicate in particular any constraints and assumptions relative to the risk assessment. The report should be made available to independent parties on request.

**5.6.2** The specific format should indicate all the elements of a scientific report.

## **6. CONCLUSIONS AND RECOMMENDATIONS**

The field of risk assessment of foodborne microbial hazards is a dynamic developing scientific discipline. The principles and guidance for risk assessment presented in this document are recommended for use by the European Commission and EU Member States and may form the basis for refinement of the risk assessment procedure.

Experiences gained from such usage as well as scientific experiences, e.g. from ongoing Scientific Co-operation projects, will need to be taken into account in an update of this document as well as global experiences assembled within the Codex Alimentarius.

The Scientific Committee for Food recommends to revisit this document in five years time in order to refine and focus the scientific procedures for qualitative and quantitative microbial risk assessment to be applied in the European Union.

## 7. REFERENCES

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- 2 FAO/WHO (Food and Agriculture Organisation/World Health Organisation) (1995) - *Application of Risk Analysis to Food Standard Issues*. Report of a joint FAO/WHO expert consultation, WHO/FNU/FOS/95.3., Geneva
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- 7 Roberts, T., Jensen, H. and Unnevehr, L. -Ed.- *Tracking Foodborne Pathogens from Farm to Table: Data Needs to Evaluate Control Options*. US Department of Agriculture, Economic Research Service, Food and Consumer Economics Division, Miscellaneous Publication n° 1532.

**PRINCIPLES FOR THE DEVELOPMENT OF MICROBIOLOGICAL  
CRITERIA FOR ANIMAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN  
INTENDED FOR HUMAN CONSUMPTION**

**RECOMMENDATION OF THE SCIENTIFIC COMMITTEE FOR FOOD AND  
THE SCIENTIFIC VETERINARY COMMITTEE (PUBLIC HEALTH SECTION)**

**1     BACKGROUND**

**1.1**     This document has been produced by the Scientific Committee for Food and endorsed by the Scientific Veterinary Committee (Public Health Section). It recommends to the Commission the scientific principles which should be taken into account when developing microbiological criteria for foodstuffs.

**1.2**     This document describes the broad scientific framework within which consideration of the development of microbiological criteria should take place. It recommends that a microbiological criterion should be based on scientific analysis and advice together with an assessment of the risk appropriate to the foodstuff and its use (1, 2).

**1.3**     The analysis of risk from biological agents and in particular microbiological agents is very much a developing area and as such it is recommended that further consideration is given to this within the framework of the Scientific Committees, taking into account the work being undertaken by the Scientific Co-operation task on Microbiological Risk Assessment according to Directive 93/5/EEC (3).

**1.4**     The scientific principles recommended in this document can be applied generally to the development of all microbiological criteria for foodstuffs, animal products and products of animal origin. However they are specifically recommended to the Commission for application to those foodstuffs and parts of the food chain covered by the Hygiene of Foodstuffs Directive 93/43/EEC. These principles are not designed or intended to be used for investigative work.

**1.5**     Article 4 of the Hygiene of Foodstuffs Directive 93/43/EEC (4) states that without prejudice to more specific Community rules, microbiological criteria and temperature control criteria for certain classes of foodstuffs may be adopted within the framework of the Standing Committee for Foodstuffs after consultation with the Scientific Committee for Food, following the procedure in Article 14.

1.6 Fundamental to the application of this Directive is the utilisation of the principles of the Hazard Analysis Critical Control Point System (HACCP). The safety of foods is principally assured through control at the source, the use of Guides to Good Hygiene Practice and the application of HACCP principles during production, processing, handling, distribution, storage and sale.

1.7 The analysis of foods for compliance with mandatory microbiological criteria must be undertaken in an official laboratory in compliance with the Official Control of Foodstuffs Directive (5) and The Additional Measures Concerning the Official Control of Foodstuffs Directive (6).

## 2. DEFINITION OF A MICROBIOLOGICAL CRITERION FOR FOODSTUFFS

**A microbiological criterion for foodstuffs defines 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.**

## 3. COMPONENTS OF MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS

### 3.1 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;
- the methods for their detection and/or quantification;
- a plan defining the number of field samples to be taken, the size and characteristics of the sample and analytical unit;
- 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.

### 3.2 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,
- the actions to be taken when the criterion is not met.



#### **4. RECOMMENDATIONS ON THE DEVELOPMENT AND APPLICATION OF MANDATORY MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS**

**4.1** The emphasis in the Hygiene of Foodstuffs Directive is placed on the use of preventive actions and the utilisation of the principles of HACCP to assure the microbiological safety of food at the point of consumption. This reduces the justification for a reliance on microbiological testing of foods for this purpose.

**4.2** The development of mandatory microbiological criteria should be limited to those products and/or points of the food chain where their use is effective and the degree of protection offered to the consumer can be considered to be improved by using this type of tool.

**4.3** Where consideration has been given to the above and the need for a mandatory microbiological criterion has been identified, its development should take into account as much scientific data and information as possible relating to a risk assessment. The resulting criterion should be product-type specific and only applied at the point of the food chain stated.

**4.4** Priority for the development of mandatory microbiological criteria should be given to those micro-organisms, their toxins or metabolites in foods where a risk assessment has established a hazard to the consumer.

**4.5** Microbiological testing may be used by control officials and/or food businesses operators to determine the microbiological safety and wholesomeness of raw materials, ingredients, products and food lots, particularly those of unknown or uncertain origin. Testing can also be used to establish whether good hygienic practices have been applied and provide information on the efficacy of a business's food safety management system.

**4.6** In these cases, mandatory microbiological criteria may be applied to define the acceptability of raw materials, ingredients, products, food lots and processes by control officials and/or food business operators based on an evaluation of the risk to the consumer.

**4.7** Depending on the results of an evaluation of the risk to the consumer the official control actions may be sorting, reprocessing, rejection or destruction of product and/or further investigation. The actions to be taken by control officials, where a microbiological limit stated in the criteria has been exceeded, should be appropriate for the safety and proportionate to the risk to the consumer.

**4.8** Microbiological criteria used for contractual purposes by food businesses, to assess the acceptability of raw materials, ingredients, intermediate or finished products as part of their own safety management system, should not be confused with legal requirements for official control purposes.

## **5. FACTORS TO CONSIDER WHEN ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA**

**5.1** The hygiene and safety of foodstuffs to which Directive 93/43/EEC on the Hygiene of Foodstuffs applies should be ensured through the application of the requirements of this Directive relating to good hygienic practices and the development and implementation of the principles of HACCP contained in Article 3.

**5.2** 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.

**5.3** To fulfil the purposes of microbiological criteria, 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.

**5.4** The number and size of analytical units per product or food lot tested should be stated in the sampling plan and should not be modified. A product or food lot should not be subjected to repeat testing in order to establish compliance with a microbiological criterion.

**5.5** The microbiological tests applied, the limits and the point in the food chain assessed should be appropriate, practical and provide as much information as possible about the safety of the food at the point of consumption.

## **6. MICROBIOLOGICAL ASPECTS OF CRITERIA**

### **6.1 Microorganisms and toxins of importance in a particular food**

**6.1.1** For the purpose of this document microorganisms and toxins include:

- bacteria, viruses, yeasts, moulds and algae,
- parasitic protozoa,<sup>a</sup>
- their toxins/metabolites.

**6.1.2** The microorganisms included in a criterion should be widely accepted as relevant as pathogens or as indicator organisms to the particular food and food business operation.

**6.1.3** The mere finding, with a presence or absence test of certain organisms known to cause foodborne illness, may not necessarily indicate a hazard. The relevance of their presence should relate to the results of the risk assessment.

**6.1.4** Where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to indicator organisms. If a test for an indicator organism is applied there should be a clear statement as to whether the test is used to indicate an unsatisfactory hygiene practice or the possible presence of a health hazard.

### **6.2 Microbiological methods**

**6.2.1** Preference should be given to reference methods developed under the aegis of an European Standards Institute which have already been validated for the commodity concerned. When this is not possible, only methods for which the reliability (accuracy, reproducibility, inter- and intra-laboratory variation) has been statistically established in comparative or collaborative studies in several laboratories should be used in the microbiological criterion.

**6.2.2** Methods used to determine the suitability for consumption of highly perishable foods or foods with a short shelf-life should be chosen such that the results of microbiological examinations are available before the foods are consumed or exceed their shelf-life.

**6.2.3** The microbiological methods specified should be reasonable with regard to complexity, availability, ease of interpretation, time required and costs.

**6.2.4** Methods which are applicable to various groups of commodities should be given preference over methods which apply only to individual commodities.

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<sup>a</sup> Helminths may be considered in specifications when appropriate

## **6.3 Microbiological limits**

**6.3.1** Limits used in criteria should be based on microbiological data appropriate to the food and should be applicable to a variety of similar products. They should therefore be based on data gathered over as wide a range of situations as possible and where good hygienic practices are in operation.

**6.3.2** In the establishment of microbiological limits, changes in the microflora which could result from likely storage and distribution practices should be taken into account. For the development of mandatory microbiological criteria within the terms of Directive 93/43/EEC, when appropriate, the conditions under which the foodstuff is expected to be handled and consumed should be taken into account.

**6.3.3** Numerical limits should also take account of the likelihood of uneven distribution of microorganisms in the foodstuff and the inherent variability of the analytical procedure.

**6.3.4** It should be borne in mind that no feasible sampling plan can ensure complete absence of a particular organism in a product or food lot.

## **7. SAMPLING PLANS, METHODS AND HANDLING**

**7.1** A sampling plan is the particular choice of a sampling procedure and the decision criteria to be applied to a lot, based on examination of a prescribed number of analytical sample units by defined methods. Sampling plans should be administratively and economically feasible.

In particular, sampling plans should take into account:

- consideration of the severity of the hazard and an assessment of the risk,
- the heterogeneity of distribution of microorganisms,
- the statistical probability of detecting unacceptable food lots or rejecting acceptable food lots.

For many applications 2- or 3-class attribute plans may prove useful (7).

**7.2** The sampling method should be defined in the sampling plan. The time between taking the field samples and analysis should be as short as possible. During transport to the laboratory the conditions (e.g. temperature) should be appropriate to the foodstuff, so that the results reflect - within the limitations given by the sampling plan - the microbiological conditions of the lot or food product.

## **8. REPORTING.**

**8.1** The test report shall give the information needed for complete identification of the sample, the sampling plan, the test methods, the results and their interpretation.

## **9. REFERENCES**

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