

Opinion On Principles For The Development Of Risk Assessment Of Microbiological Hazards Under The Hygiene Of Foodstuffs Directive 93/43/Eec (Expressed On 13 June 1997)

1 Terms of reference

To prepare for the Commission guidance on the principles to be considered when assessing the potential risks caused by micro-organisms and their toxins in foodstuffs and the scientific basis for risk assessment for the development of hygiene requirements for certain classes of foodstuffs under Article 4 of the Hygiene of Foodstuffs Directive 93/43/EEC.

2 Background

2.1 Under Article 4 of the Hygiene of Foodstuffs Directive (93/43/EEC) 1993 without prejudice to more specific Community rules, the Commission, assisted by the Standing Committee for Foodstuffs, after consultation with the SCF, may adopt microbiological criteria and temperature criteria for certain classes of foodstuffs.

In order to advise the Commission in this area the Scientific Committee for Foods has given its opinion on the "Principles for the Development of Microbiological Criteria for foodstuffs as covered by the Hygiene of Foodstuffs Directive 93/43/EEC". (2)

2.2 Under the Sanitary and Phytosanitary (SPS) Agreement reached within the Uruguay round of the multi-lateral trade negotiations under the General Agreement on Tarriff 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. (J.O. L336 of 23 December 1994, Annexe 1A P.41 Art. 3.)

2.3. 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.

2.4. These guidelines 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, (3) and 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 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.

2.5. In the following sections, the essential elements of a risk assessment framework are presented into 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.

3 Definitions

(Origin Codex Alimentarius Commission) (4)

- **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.

4 Microbiological Risk Assessment in the Context of Risk Analysis

4.1. 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

4.2. 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**

4.3. 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.

4.4. 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.

4.5. This paper deals with risk assessment. Risk management and risk communication should be dealt with in future documents.

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

RISK ASSESSMENT

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

RISK MANAGEMENT

- Assess policy alternatives
- Select and implement appropriate options
- Interactive exchange of information and opinions

RISK COMMUNICATION

5. Risk Assessment for Microbiological Hazards in Foods - General Principles

5.1. 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.

5.2. 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.

5.3. 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.

5.4. 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.

5.5. 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 report. 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.

5.6. 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.

5.7. 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.

5.8. 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.

* It should explicitly consider the dynamics of microbial growth, survival and death. 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.

5.9. Risk estimates, where possible, must be re-evaluated over time against human health data, and when new data becomes 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.

6 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

STATEMENT OF PURPOSE



HAZARD IDENTIFICATION

Identification of agents capable of causing adverse health effects



**EXPOSURE
ASSESSMENT**



HAZARD CHARACTERISATION

Evaluation of the degree of intake likely to occur

Evaluation of the nature of the adverse effects associated with microbiological hazards which may be present in food.

It may include a dose-response assessment.



RISK CHARACTERISATION

Estimation of the adverse effects likely to occur in a given population, including attendant uncertainties



PRODUCTION OF A FORMAL REPORT

Jouve, J.L.(1996)

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.

6.1 Statement of purpose

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

6.1.2 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.

6.1.3 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.

6.1.4. 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 identifies 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.

6.1.5. 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.

6.2 HAZARD IDENTIFICATION

6.2.1 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.

6.2.2 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.

6.2.3 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 experts advice.

6.2.4 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

6.2.5 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)

6.3 EXPOSURE ASSESSMENT

6.3.1 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")

6.3.2 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).

6.3.3 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).

6.3.4 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)

6.4 HAZARD CHARACTERISATION

6.4.1 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.

6.4.2 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

6.4.3 Factors relating to dynamics of infection may include:

- -rate of infection
- -latency (delayed onset of clinical infection following exposure)
- -disease pattern
- infection(asymptomatic) v's 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

6.4.4 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)

6.4.5 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)

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

6.4.7. 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.

6.4.8 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.

6.4.9. Information on which to base quantitative dose-response estimates is difficult to obtain, due to e.g. for instance, 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

6.4.10. 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.

6.5 Risk Characterisation

6.5.1 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.

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

6.5.3 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.

6.5.4 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.

6.5.5 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.

6.6 PRODUCE A FORMAL REPORT

6.6.1 The risk assessment should be fully and systematically documented. To ensure the 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.

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

7 CONCLUSIONS AND RECOMMENDATIONS

The field of risk assessment of food borne 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, EU Member Countries 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 system.

The SCF recommends to revisit this document in 5 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.

8 References

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