

ILSI Europe
Report Series

FOOD SAFETY MANAGEMENT TOOLS

2ND EDITION



REPORT

Commissioned by the ILSI Europe Risk Analysis in Food
Microbiology Task Force

About ILSI / ILSI Europe

Founded in 1978, the International Life Sciences Institute (ILSI) is a nonprofit, worldwide foundation that seeks to improve the well-being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. ILSI is recognised around the world for the quality of the research it supports, the global conferences and workshops it sponsors, the educational projects it initiates, and the publications it produces. ILSI is affiliated with the World Health Organization (WHO) as a non-governmental organisation and has special consultative status with the Food and Agricultural Organization (FAO) of the United Nations. By bringing together scientists from academia, government, industry, and the public sector, ILSI fosters a balanced approach to solving health and environmental problems of common global concern. Headquartered in Washington, DC, ILSI accomplishes this work through its worldwide network of branches, the ILSI Health and Environmental Sciences Institute (HESI) and its Research Foundation. Branches currently operate within Argentina, Brazil, Europe, India, Japan, Korea, Mexico, North Africa & Gulf Region, North America, North Andean, South Africa, South Andean, Southeast Asia Region, as well as a Focal Point in China.

ILSI Europe was established in 1986 to identify and evaluate scientific issues related to the above topics through symposia, workshops, expert groups, and resulting publications. The aim is to advance the understanding and resolution of scientific issues in these areas. ILSI Europe is funded primarily by its industry members.

This publication is made possible by support of the ILSI Europe Task Force on Risk Analysis in Food Microbiology, which is under the umbrella of the Board of Directors of ILSI Europe. ILSI policy mandates that the ILSI and ILSI branch Boards of Directors must be composed of at least 50% public sector scientists; the remaining directors represent ILSI's member companies. Listed hereunder are the ILSI Europe Board of Directors and the ILSI Europe Task Force on Risk Analysis in Food Microbiology industry members.

ILSI Europe Board of Directors

Non-industry members

Prof. A. Boobis, Imperial College of London (UK)
Prof. P. Calder, University of Southampton (UK)
Prof. G. Eisenbrand, University of Kaiserslautern (DE)
Prof. A. Grynberg, Université Paris Sud – INRA (FR)
Prof. M. Kovac, Ministry of Agriculture (SK)
Prof. em. G. Pascal, National Institute for Agricultural Research – INRA (FR)
Prof. G. Rechkemmer, Max Rubner-Institut – Federal Research Institute of Nutrition and Food (DE)
Dr. J. Schlundt, National Food Institute (DK)
Prof. V. Tutelyan, National Nutrition Institute (RU)
Prof. G. Varela-Moreiras, University San Pablo-CEU of Madrid (ES)

Industry members

Mr. C. Davis, Kraft Foods Europe (CH)
Mr. R. Fletcher, Kellogg Europe (IE)
Dr. M. Knowles, Coca-Cola Europe (BE)
Dr. G. Kozianowski, Südzucker/BENEOL Group (DE)
Dr. G. Meijer, Unilever (NL)
Prof. J. O'Brien, Nestlé (CH)
Prof. C. Shortt, McNeil Nutritionals (UK)
Dr. J. Stowell, Danisco (UK)
Dr. G. Thompson, Danone (FR)
Dr. P. Weber, DSM (CH)

ILSI Europe Risk Analysis in Food Microbiology Task Force industry members

Barilla G. & R. Fratelli
Danone
H J Heinz
Kraft Foods Europe
Mars
McDonald's Europe
Nestlé
Unilever



FOOD SAFETY MANAGEMENT TOOLS

2ND EDITION

By Steve Crossley and Yasmine Motarjemi

This second edition report is an update, prepared by Steve J. Crossley and Yasmine Motarjemi, based on the first edition (published in 1998) written by Jean Louis Jouve, Mike Stringer and Anthony Bird-Parker

**REPORT OF AN ILSI EUROPE EXPERT GROUP
COMMISSIONED BY THE ILSI EUROPE RISK ANALYSIS IN FOOD MICROBIOLOGY TASK FORCE**

AUGUST 2011

© 2011 ILSI Europe

This publication may be reproduced for non-commercial use as is, and in its entirety, without further permission from ILSI Europe. Partial reproduction and commercial use are prohibited without ILSI Europe's prior written permission.

"A Global Partnership for a Safer, Healthier World.®", the International Life Sciences Institute (ILSI) logo image of the microscope over the globe, the word mark "International Life Sciences Institute", as well as the acronym "ILSI" are registered trademarks of the International Life Sciences Institute and licensed for use by ILSI Europe. The use of trade names and commercial sources in this document is for purposes of identification only and does not imply endorsement by ILSI Europe. The opinions expressed herein and the conclusions of this publication are those of the authors and do not necessarily represent the views of ILSI Europe nor those of its member companies.

For more information about ILSI Europe, please contact

ILSI Europe a.i.s.b.l.
Avenue E. Mounier 83, Box 6
B-1200 Brussels
Belgium
Phone: (+32) 2 771 00 14
Fax: (+32) 2 762 00 44
E-mail: info@ilsieurope.be
www.ilsieurope.be

Printed in Belgium

D/2011/10.996/27

ISBN 9789078637301

CONTENTS

FOREWORD	4
1. INTRODUCTION TO FOODBORNE ILLNESS AND FOOD SAFETY POLICY	5
1.1 Foodborne illness	5
1.2 Factors that affect the epidemiology of foodborne illness	5
1.2.1 Changes in microbial features	6
1.2.2 Changes in food production and trade	6
1.2.3 Changes in lifestyle and consumer requirements	6
1.2.4 Changes in susceptible populations	6
1.3 Evolution in food safety policies	7
2. FOOD SAFETY MANAGEMENT IN THE FOOD INDUSTRY	8
2.1 A managed programme	8
2.2 Programme development	8
2.2.1 Management responsibility and commitment	8
2.2.2 Preliminary food safety review	8
2.2.3 Food safety policy	9
2.2.4 Planning	9
2.2.5 Validation	9
2.2.6 Implementation and operation	11
2.2.7 Assessment of performance: verification and audit	11
2.2.8 Adjustment, improvement and review	11
3. FOOD SAFETY PROGRAMME: USE OF TOOLS	12
3.1 An integrated approach	12
3.2 Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP)	13
3.3 HACCP	13
3.4 Models for management systems	14
3.4.1 Food safety management systems	14
3.4.2 Quality management systems	15
3.4.3 Environmental management systems	15
3.4.4 Total Quality Management (TQM)	15
3.5 Risk analysis	16
3.5.1 Risk assessment	16
3.5.2 Risk management	17
3.5.3 Risk communication	18
3.6 Objectives for implementation	18
3.7 Other tools	19
4. SUMMARY AND CONCLUSIONS	21
5. DEFINITIONS AND GLOSSARY	22
6. REFERENCES	24
7. WEBSITES OF INTEREST	26

Scientific editors: Stephen J. Crossley, Food Standards Australia New Zealand (AU),
Yasmine Motarjemi (CH)

Scientific Reviewer: Roger Stephan, University of Zurich (CH)

Report Series Editor: Kevin Yates (UK)

Coordinator: Pratima Rao Jasti, ILSI Europe (BE)

FOREWORD

Throughout the world, the food supply chain, including food manufacturing, distribution and retailing, has become a highly complex business. Raw materials are sourced on a global scale, an ever-increasing number of processing technologies are used, and vast arrays of products are available to consumers. Such complexity necessitates the development of comprehensive control procedures to ensure the production of safe and high quality food. In addition, consumer expectations are changing, with a desire for convenient, “less-processed” and fresher food with more natural characteristics. Against this backdrop of change, the total food chain has to ensure that the highest standards of safety are maintained.

At all stages of the food supply chain, from production of raw materials to manufacture, distribution and sale, both through retail and catering outlets, consideration must be given to the safety issues associated with the specific products, processes and methods of handling. Food safety issues also arise during the storage, handling and preparation of food by consumers in the home.

This report provides an overview of tools currently available for the management of food safety. It does not describe the tools in detail, as the information is available in other texts (Lammerding, 2007, Stringer, 2004 & 2005, Schothorst, 2004 and Gorris *et al.* 2000). It should be of use to all those in the food supply chain where product safety is a potential issue: primary producers, food and food ingredient manufacturers and processors, food distributors, food handlers, food retailers and the food service sector. Irrespective of size and complexity, all these food businesses should have an appropriate programme for ensuring that the food it supplies is safe.

Background to the development of this report

The first edition of this report was written by Jean-Louis Jouve, Mike Stringer and Anthony Baird-Parker. It has been widely distributed, translated into Russian, and used for various purposes. When it was published in 1998, many of the views it expressed were prospective in nature. Since then, regulation and standardisation has evolved considerably and continues to do so.

In this second edition, recent advances have been taken into account, and the original text has been updated as necessary. The primary focus remains on microbiological food safety management; however, the general principles presented are also applicable to the management of chemical food safety.

1. INTRODUCTION TO FOODBORNE ILLNESS AND FOOD SAFETY POLICY

1.1 Foodborne illness

Despite the progress in medicine, food science and the technology of food production, illness caused by foodborne pathogens continues to present a major problem to health and is of economic significance. Estimates of the incidence of foodborne illnesses vary greatly, due mainly to large differences in the sources of data and in surveillance systems. Nevertheless, there is agreement that foodborne illness is one of the principal causes of human morbidity. In industrialised countries, the percentage of people suffering from foodborne diseases each year has been estimated to be up to 30% (WHO, 2003; WHO, 2006). For example, it has been estimated that each year foodborne illness causes approximately 2,366,000 cases, 21,138 hospitalisations and 718 deaths in England and Wales (Adak *et al.*, 2002). In 2005 it was reported that there were 17.2 million cases of gastroenteritis in Australia each year, of which 5.4 million (32%) were estimated to originate from contaminated food. The most common pathogens responsible for foodborne gastroenteritis were pathogenic *Escherichia coli*, Norovirus, *Campylobacter* and non-typhoidal *Salmonella* (Australian Government, 2005). Recently, Scallan *et al.* (2011) published data on foodborne illness obtained from active and passive surveillance and other sources in the United States.. They reported that each year 31 major pathogens caused 9.4 million episodes of foodborne illness, 55,961 hospitalisations and 1,351 deaths.

It can be assumed that the burden of foodborne illness is of the same order of magnitude in most industrialised countries. It should also be taken into account that only a small proportion of these cases are ever brought to the attention of health authorities.

Even when the incidence rate is low, the public health impact of foodborne illnesses can be high, due to the severe consequences these diseases have for certain segments of the population (e.g., young children, elderly people, pregnant women or immuno-compromised people) and the high mortality rate of certain diseases (e.g., listeriosis or botulism). It has also to be appreciated that even less severe episodes of foodborne gastroenteritis may lead to chronic and often severe sequelae including rheumatoid conditions, nutritional and malabsorption problems, haemolytic-uraemic syndrome (Verotoxin producing *E. coli*) or Guillain-Barré syndrome (*Campylobacter*).

Estimates have been made of the economic consequence of foodborne illness, where costs are incurred by individuals who become ill (including sequelae), by their employers, their families, health-care agencies and the food companies and businesses involved. Beyond productivity losses, additional costs may be incurred by industry or in some cases by governments. These costs relate to disease eradication, litigation, product recalls, market impact and the impact on value of firms (OECD, 2003). For instance, in England, the Food Standards Agency (FSA, 2000) calculated the overall annual cost of infectious intestinal diseases at GB £742.8 million (US \$1137.5 million). Similarly the total cost of foodborne illness in Australia is estimated at AUS \$1,249 million per annum (Australian government 2006).

1.2 Factors that affect the epidemiology of foodborne illness

A number of changes justify concern about the incidence of foodborne illness. These include, in particular, microbial adaptation, changes in food production and trade, changes in lifestyle and consumers expectations, and changes in susceptible populations (WHO, 2000).

1.2.1 Changes in microbial features

Most of the new or emerging pathogens (e.g., *E. coli* O157:H7, *Campylobacter jejuni*) have an animal reservoir and may enter the food chain at an early stage. Changes in microbial populations associated with changes in food production and distribution can foster the ability of pathogens to survive in adverse environmental conditions.

1.2.2 Changes in food production and trade

Modern intensive animal husbandry practice, intensive farming and associated practice (e.g., recycling waste products) were introduced to maximise production. Many can also increase the opportunity for infection and colonisation of farm animals, and allow the rapid spread of human and animal pathogens.

Advances in processing, preservation, packaging and storage technologies have enabled the food industry to supply a greater variety of foods. Increasingly, the advances in processing technologies have been made to develop products with minimal process-induced changes in sensory or nutritional characteristics. It is expected that these technologies will play an increasing role in the future. However, they may also introduce a number of limitations in terms of pathogen inactivation and reduction, or process control. The use of these alternative technologies may have consequences on the microbial population (e.g., selection and spread of resistant strains of pathogens) further along the food chain, beyond the immediate effects (IFT, 2002). All developments in processing technology have to be fully evaluated to ensure the design of safe commercial processes.

The increasing globalisation of the food trade has also affected the epidemiology of foodborne diseases, as the increased use of raw materials and products sourced from a wider range of countries facilitates the geographic spread of diseases associated with particular contaminants.

1.2.3 Changes in lifestyle and consumer requirements

Food products innovation is largely being driven by lifestyle and consumer requirements. Examples of those requirements include the increased demand for accurate, understandable nutritional information, and the increasing emergence of functional foods making nutritional or health claims. There is also a significant worldwide trend to increased consumption of food outside the home (e.g., in restaurants and fast food outlets). When unhygienic food preparation occurs in these establishments, it may lead to foodborne illnesses that affect large numbers of people. (It should also be noted that unhygienic food preparation also occurs in the home and is not regulated.)

A major increase in international travel for business or vacation purposes means that more people are potentially being exposed to pathogens that are either uncommon in their own countries, or are present with a low prevalence.

In developed countries, demand is increasing for convenience foods that are produced with minimum preparation and processing. The production of these foods challenges the industry to use less harsh processing and production regimes, meaning that these foods require great care in their distribution, storage and preparation prior to final consumption. In addition, in some countries consumer resistance to the use of added preservatives has resulted in alternative preservation methods being used that may be less efficacious.

1.2.4 Changes in susceptible populations

Young children are more likely than adults to develop illness from foodborne pathogens. Elderly people are particularly susceptible and in many countries the aged population is increasing. People with weakened immune systems may become infected with foodborne pathogens at lower infectious doses and are more likely to experience morbidity and/or mortality, in particular from opportunistic pathogens.

1.3 Evolution in food safety policies

Facing the changing context in which food is produced and traded, important changes in food safety policies and food regulatory measures have taken place at both international and national levels.

The Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO) put emphasis on the role of the Codex Alimentarius Commission (the “Codex”) as representing the international consensus with respect to food standards. Codex is an inter-governmental programme for standards setting, with the objective of promoting food safety and fair practice in trade. Codex has now developed a number of basic texts on food hygiene (Codex Alimentarius, 2003) and a large body of standards and other texts. These documents serve as reference documents. Many governments have adopted Codex standards into their national regulations. For example, in the USA, the regulation on Pathogen Reduction incorporates the implementation of the Hazard Analysis Critical Control Point (HACCP) system, the use of Sanitation Standard Operating Procedures and of Microbiological Performance Criteria and Standards from the Codex (USDA, 1996). In Europe, the redraft of EU regulations related to food safety establishes that food operators should comply with identified food hygiene requirements and put in place, implement and maintain permanent procedures based on the HACCP principles (Regulation numbers 178/2002, 852/2004 and 853/2004).

Moreover, the SPS Agreement has established the tenet that “Members shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risk to human, animal or plant life or health”. This led to the progressive emergence of a risk-based approach to food safety. It has fostered the development of formal methodologies for risk assessment, whereby risk analysis has now become a core paradigm in modern food safety governance. In this regard, FAO and WHO have played a leading role in commissioning risk assessments and in elaborating and promoting related methodology and guidelines (FAO/WHO, 2006a). Codex, FAO and WHO actively advocate a risk analysis approach to managing food safety.

2. FOOD SAFETY MANAGEMENT IN THE FOOD INDUSTRY

2.1 *A managed programme*

Safety is of paramount importance to all companies and organisations involved in the production, sale and handling of food. Modern trading conditions and legislation require food businesses to demonstrate their commitment to food safety through an appropriate management programme. Such a programme should take account of the role of businesses in the food chain, whether they are primary producers, manufacturers, retailers or caterers. This programme will ensure that a company elevates commitment to the safety of its product to the highest level.

The food safety programme should focus on where improvements are necessary and can properly be applied to organisational, technical and communication issues. All company employees, from senior management to food handlers, should be aware of the significance of food safety and the damage that can be caused both to the company and to its customers and consumers should the programme break down. The programme should identify the key tools available and their application to all stages of production, distribution and sale.

2.2 *Programme development*

The programme can be developed through a series of specific activities. These activities are considered in the following sections.

2.2.1 *Management responsibility and commitment*

Senior company management, in all sectors of the food industry from farm to delivery to the consumer, has the ultimate responsibility for ensuring that the highest standards of food production and handling (this includes areas of primary producers; food and food ingredient manufacturers and processors; food distributors; food handlers; food retailers; and the food service sector) are achieved with respect to food safety. Total commitment to this aim is crucial to the successful implementation of a food programme.

2.2.2 *Preliminary food safety review*

A preliminary food safety review aims at establishing the current business position with regard to food safety and to determine the needs and opportunities for improvement. The review would include the following:

- The identification of relevant food safety issues.
- The production, processing, distribution and consumption conditions, and their potential impact on food safety, in all operating conditions.
- The current safety procedures and practical level of control.
- The information gained from investigations of past problems.
- An inventory of constraints, in particular legal and regulatory requirements for control (e.g., performance objectives, microbiological criteria), other professional or contractual requirements (e.g., codes, guidance documents, requirements for certification), as well as market constraints (economic issues and costs, e.g., of raw materials).
- An assessment of performance against expressed internal or external criteria.
- An overview of opportunities, e.g., product development, process innovation, new markets.
- Current management control practices for chemical and physical hazards.

Note: Aiming at continuous improvement, the development of a food safety programme is flexible and iterative. Where a food safety programme already exists, this examination would follow performance assessment and serves as a starting point for revision and improvement of the programme.

2.2.3 Food safety policy

The food safety policy is a statement by senior management, which outlines the general approach to ensure the safe production and handling of food. The company should make sure that the food safety policy:

- is appropriate to the nature and activity of the business,
- provides a commitment to continuous improvement,
- complies with legislation, and
- is fully communicated, understood and supported by all employees.

2.2.4 Planning

Senior management should ensure a logical and structured approach to both organisational and product/process-related activities.

Organisational planning should include the preparation of a detailed food safety programme. This should clearly define assignment of responsibility, resources, requirements and lines of communication to gain the full commitment from all personnel to the food safety programme. This process, through assessment and audit, should seek continuous improvement.

Product and process planning should result in the definition of clear and unambiguous standards for products and practices. All such requirements should be based on a full consideration of constraints, opportunities and other factors as identified in the preliminary food safety review. Food safety requirements include the definition of product and process characteristics as well as the characteristics and level of control necessary.

Techniques for product and process planning vary, but typically require a thorough understanding of all stages of the production cycle from raw material production and acquisition through to finished goods and their use. This will include a detailed knowledge of product-process interaction, product and process specifications, monitoring and verification procedures and methods for dealing with non-conformance.

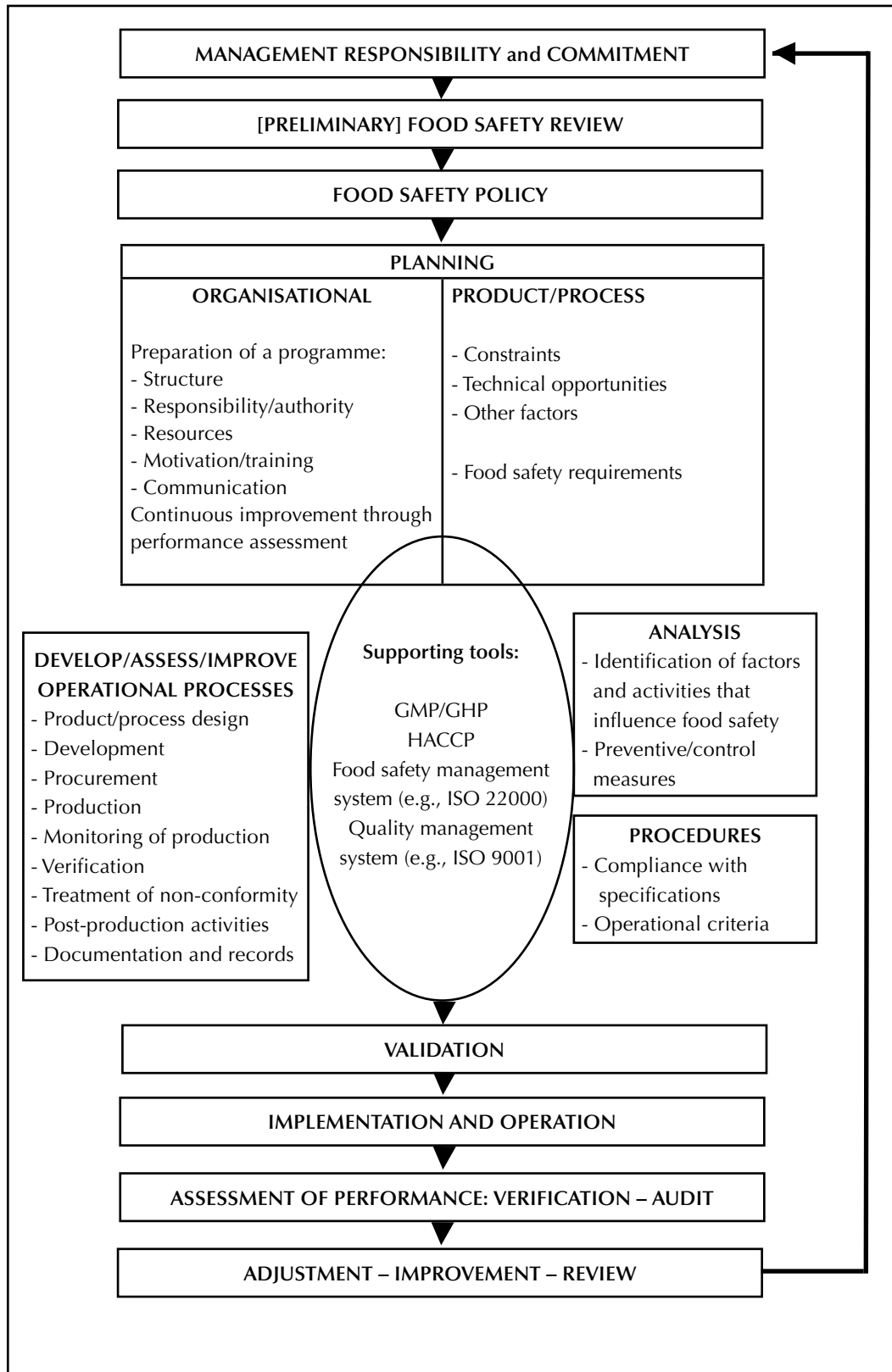
With this knowledge, a detailed analysis can be undertaken to identify factors that may affect food safety. Appropriate control measures can then be identified and implemented. It is essential to fully document this analysis, which will describe the procedures to ensure compliance with food safety requirements and the operational criteria necessary for product and process control.

To achieve this analysis, a number of specific tools have been developed, some of which have been widely used in the food industry, e.g., HACCP (see Section 3).

2.2.5 Validation

Validation is a process intended to ensure that all decisions are sound, based on robust supporting scientific evidence and technical inputs, and result in implementation plans and activities that are effective in ensuring that the appropriate level of protection against identified food safety risks will be achieved. Typically, validation encompasses a critical assessment of the evidence supporting the analysis of hazards and risks to food safety and decisions based on that evidence, including a company's food safety requirements and controls. As far as possible, a thorough validation should be undertaken before the food safety programme is finalised and implemented.

Figure 1: Development of a microbiological food safety programme



2.2.6 Implementation and operation

Effective implementation of planned arrangements requires adequate apportioning of human, technical (facilities, equipment) and financial resources, and development of appropriate support mechanisms. Establishment and maintenance of operational control, together with the development of operating procedures and appropriate documentation, is crucial to ensuring that food safety performance is consistent with the organisation's policy and requirements. Implementation has also to include procedures to respond to accidents or emergency situations.

2.2.7 Assessment of performance: verification and audit

Senior management should ensure that there is a process of regular assessment of performance of the food safety programme. This will include gathering information, verification and audit of operational activities to ensure that they conform to the planned arrangements, that all food safety requirements are being met, and to identify any weaknesses.

Verification is included as part of a company's food safety programme (e.g., within the HACCP plan). It is part of the internal process of performance assessment and responsibilities are attributed to staff members. Verification includes planned activities, e.g., internal audits and data review, necessary to demonstrate that the food safety programme is working effectively.

Third-party audits are assessment activities carried out by entities that are not part of the company's structure. The auditing process is intended to check for adherence to specified and documented procedures and requirements (e.g., regulations or standards) at one point in time. Third party audits provide a useful mechanism by which supplier–customer trust is built up through conformity evaluation. The results of audits, reports or certificates, can also serve as support for communication. To ensure the quality of their service, auditing entities should operate in accordance with specific requirements, as laid down in International Standards (e.g., EN 45012 or EN 45011) or in specific documents (e.g., EFSIS – the European Food Safety Inspection Service – service protocol, or requirements for accreditation authorities and auditors laid down in the IFS standard itself, see Section 3.4). Such an assessment is the specific aim of validation activities.

2.2.8 Adjustment, improvement and review

The analysis and assessment process is likely to identify issues for adjustment, modification and improvement. These should be undertaken and appropriate follow-up carried out. There should be an ongoing review process designed to ensure that changes in the food safety context, in production conditions and in the regulatory requirements are taken into account to further enhance the assurance of food safety.

3. FOOD SAFETY PROGRAMME: USE OF TOOLS

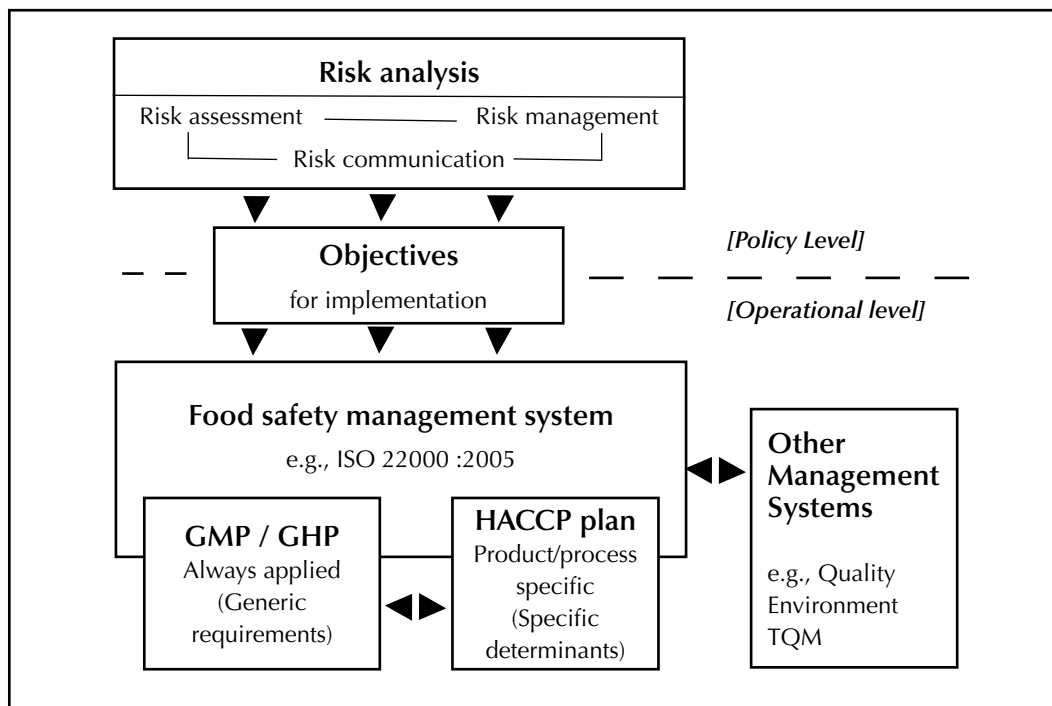
The practical success of the food safety programme will depend on the proper use of appropriate methods and tools. These will include Good Hygiene Practice (GHP), Good Manufacturing Practice (GMP) and HACCP (Hazard Analysis Critical Control Points). Other tools of more general application are standardised models for management systems and the Total Quality Management (TQM) approach. Increasingly risk assessment, developed in the framework of risk analysis, emerges as a means to link operational performance and regulatory or business requirements to the health and safety of consumers.

Section 3 describes the application of these tools in the context of a food safety programme.

3.1 An integrated approach

Figure 2 illustrates the interrelationship among the commonly used food safety tools.

Figure 2: Food safety tools – An integrated approach for microbiological hazards in food.



An essential foundation of any activity involving food manufacture, handling and catering is a thorough understanding of the appropriate requirements of GHP and GMP associated with the particular product or commodity. Adherence to these good practices is the absolute minimum requirement in any food business.

HACCP is now widely adopted as an essential approach to the systematic identification, evaluation and control of hazards associated with the production, manufacture, distribution and use of food products. It provides a mechanism to define preventive measures for hazard control. Although GMP and GHP address the generic requirements for manufacturing safe food, the benefit of HACCP is that it addresses specific hazards unique to particular products and processes.

Food businesses are increasingly concerned to achieve and demonstrate sound food safety performance. Consequently, they develop management systems, which address key aspects of food safety control and assurance. Where such a system exists, GMP/GHP and HACCP are integral parts of the overall system. Models for the development of food safety management systems include International Standards (ISO 22000) and other standards such as the BRC standard-food or the IFS model (see Section 3.4). Food safety management systems can be integrated with other management systems, quality management and environmental management in particular. There are many forms for such systems; perhaps the most widely used are based on the ISO 9001:2000 standard for quality management and on the ISO 14000 series for environmental management. They are components of a longer-term strategy to manage industrial risks.

Risk analysis, as carried out by governments, encompasses three components which are risk assessment, risk management and risk communication. The approach is key to understanding the factors that determine the impact of food chain activities on human health, as well as determining and communicating the most appropriate measures for mitigating risk. Risk mitigation strategies used by governments include public information campaigns, mandatory standards and codes of practice. The application of risk analysis is now central to public decision making on food safety. This includes determination of objectives intended to guide the performance of food operators along the food chain.

3.2 Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP)

GMP covers the fundamental principles, procedures and means needed to design an environment suitable for the production of food of acceptable quality. GHP describes the basic hygienic measures which establishments should adopt and which are the prerequisite(s) of other approaches, HACCP in particular. GMP/GHP requirements have been developed by governments, the Codex Committee on Food Hygiene (Codex Alimentarius, 2003) and the food industry, often in collaboration with other groups and food inspection and control authorities.

GMP codes and the hygiene requirements they contain (GHP) are the relevant boundary conditions for the hygienic manufacture of foods. They should always be applied and documented. The Codex General Principles of Food Hygiene (Codex Alimentarius, 2003) makes provisions for the following measures of a general nature:

- The hygienic design and construction of food manufacturing premises
- The hygienic design, construction and proper use and maintenance of equipment
- Cleaning and disinfection procedures (including pest control)
- General hygienic and safety practices in food processing including:
 - the quality of raw foods,
 - the hygienic operation of each process step, and
 - the hygiene of personnel and their training in the hygiene and safety of food.

3.3 HACCP

HACCP provides a structured approach to the assurance of the safety of specific products and their associated processes. In essence, it involves:

- Identification and evaluation of hazards of concern, such as pathogenic agents or chemical contaminants and the conditions leading to their presence and proliferation
- Identification of the specific requirements for their control
- Mechanisms to measure and judge continuously the efficacy of the HACCP system

The methodology for using HACCP involves, in its simplest form, involves the systematic application of seven principles (Codex Alimentarius, 2003):

- Conduct a hazard analysis.
- Determine Critical Control Points (CCPs).
- Establish critical limits.
- Establish a system to monitor control of CCPs.
- Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control.
- Establish verification procedures to confirm that the HACCP system is working effectively.
- Establish documentation concerning all procedures and records appropriate to these principles and their application.

Regulations in the European Union, and the legislation of a number of countries, require the implementation of a HACCP-based system in businesses associated with food production. Irrespective of the size of a food business, HACCP should be an essential component of the food safety management system.

Full compliance with GMPs/GHPs, including procedures for sanitation, is an essential precondition to the introduction of HACCP into a food production or processing plant. The combination of GMP/GHP and HACCP is beneficial in that its effective application allows the HACCP plan to focus on the critical determinants of safety.

For steps in the food production process that have not been recognised as critical control points, the application of GMP/GHP provides assurance that control is nevertheless being applied. Hazard analysis within the HACCP programme might also provide information to improve current GMP/GHP for specific products or processes.

The evolution of food safety policies and recent experiences in applying HACCP put strong emphasis on the need for validating the elements of the HACCP plan. Validation should in principle be conducted before implementation of the plan. Basically, validation should include a critical assessment of 1) the supporting scientific and technical evidence used to prepare the HACCP plan, and 2) the resulting decisions related to hazard analysis, control measures, critical limits, monitoring, corrective actions and verification procedures (ILSI Europe, 1999; 2004b). In the contemporary context of legal accountability and responsibility, validation is of utmost importance in food safety and should be emphasised in programme development. Validation may also be needed if the verification procedures indicate a problem in meeting the specification of final products, or if a change in the process or product is introduced.

3.4 Models for management systems

3.4.1 Food safety management systems

In light of the evolution of the agro-food industrial sector and taking into account the increased perception of the importance of food safety requirements, a number of models have been developed to standardise approaches to food safety management. Standardised models include the International Standard ISO 22000:2005 and several other standards, such as the BRC standard-food or the IFS model.

The International Standard ISO 22000:2005 is presented as a means to harmonise the requirements for food safety management in food and food-related business on a global level. It applies therefore to all types of organisations in the food chain, from (for example) food producers through to distribution and retail outlets. Specifically, the ISO 22000:2005 standard specifies a number of requirements for operating a food safety management system. It also integrates Good Practices (GMP and GHP) as prerequisites,

but without expressing specific requirements in this regard, and incorporates the use of the Hazard Analysis Critical Control Point (HACCP) system to facilitate its implementation. This standard has been developed as an auditable standard. The ISO 22000 standard may be applied in its own right. Nevertheless, its format is aligned with ISO 9001:2000 (quality management) and ISO 14001:2004 (environmental management) to enhance compatibility and foster complementarities.

Other standards have been developed by groups of retailers, with the aim of providing a common reference for their suppliers. These standards can also be used by the manufacturing industry for its own suppliers. For example, the BRC standard-food has been developed in the United Kingdom as a “technical standard for companies supplying retailer-branded food products” by the British Retail Consortium. Additionally, the International Food Standard (IFS) originated in Germany at the initiative of the HDE (*Hauptverband des Deutschen Einzelhandels*) and is rapidly gaining international favour. In essence, these standards express requirements related to the effective and documented implementation of a management system. They require companies to demonstrate that appropriate HACCP systems have been developed and specify a number of detailed requirements related to the site and factory environment, products, processes and personnel. The requirements are expressed in the form of criteria that can be used for auditing, accreditation and rating of suppliers.

An essential feature of all these standards is that they provide recognised, consensual and systematic reference for third party audits, carried out by, or on behalf of, entities outside the company structure.

3.4.2 Quality management systems

Quality systems cover organisational structure, responsibilities, procedures, processes and the resources needed to implement comprehensive quality management. They apply to, and interact with, all phases of a product cycle. They are intended to cover all quality elements.

A quality system is designed to ensure that all factors affecting the quality of a product will be under control. Such control enables the reduction, elimination and, most importantly, prevention of quality deficiencies. It is intended to perform two basic functions, quality control and quality assurance. Quality control covers the operational techniques and activities that eliminate causes of unsatisfactory performance and also covers the monitoring of processes. Quality assurance provides internal and external confidence that a company or an operational process will fulfil the requirements for quality.

The ISO 9001:2008 standard specifies agreed requirements for quality management systems and serves as a basis for third party audit (EN 45012). This standard and the guidelines on its application to the food and drink industry (ISO 15161) provide organisations with a methodology to initiate, improve or maintain quality management systems.

Food safety management can be developed on its own, e.g., through the ISO 22000 model. However, it should be appreciated that, because all aspects of quality are covered by a quality management system, it is important that food safety management should be aligned with other food safety systems and tools. Their integration will result in a management system which is more effective and consistent than applying either one alone.

3.4.3 Environmental management systems

Organisations may consider the ISO 14000 series of standards to develop, implement or enhance their environmental management system. The requirements of this series of standards can be aligned with the requirements for food safety and/or quality management systems.

3.4.4 Total Quality Management (TQM)

TQM represents the “cultural” approach of an organisation. It is centred on quality and based on the participation of all members of the organisation and the concept of continuous improvement. It aims at long-term success through customer satisfaction, benefits to the members of the organisation and benefits to society in general.

A total systems approach to food production, which embraces quality, productivity, food safety and environmental aspects, is provided by a combination of HACCP, food safety management systems, quality management systems, environmental management systems, TQM and business excellence. Collectively, these tools provide a comprehensive, consistent and proactive approach to manage the main industrial risks encompassing food safety, quality, environment, occupational safety (risk of workplace injury) and security (risk of being subjected to criminal activities during production).

3.5 Risk analysis

Increasingly, government authorities at national and international levels are basing their decisions regarding food safety on the principles of risk analysis. Risk analysis is a deliberate, structured and formal approach to understand and, where necessary, reduce risk. Risk analysis consists of three components: risk assessment, risk management and risk communication.

3.5.1 Risk assessment

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 (Codex Alimentarius 2010). Risk assessment would usually follow a statement of purpose, or problem formulation. It is a scientific approach to estimating a risk and to understanding the factors that influence it.

- (i) **Hazard identification** is 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. The key to hazard identification is the availability of public health data and a preliminary estimate of the sources, frequency and amount of the agent or agents under consideration.
- (ii) **Hazard characterisation** is the qualitative and/or quantitative evaluation of the nature of adverse health effects associated with biological, chemical and physical agents, which may be present in food. For biological agents, factors to be considered are the physiology and the pathogenicity and virulence of the microorganism, the dynamics of infection and susceptibility of the host. When data are obtainable, a dose-response assessment should be performed. A dose-response assessment determines the relationship between the magnitude of exposure (dose) to a biological, chemical or physical agent and the severity and/or frequency of adverse health effects (response).
- (iii) **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. Exposure assessment involves consideration of two important factors. The first is the frequency or likelihood of contamination of foods by the agent under consideration and its prevalence and concentration in those foods over time, up to the moment of consumption. The second is the pattern of consumption of the food in question (i.e., “dietary” information).
- (iv) **Risk characterisation** is 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, exposure assessment and hazard characterisation. It provides an estimate, qualitative and/or quantitative, of the risk. The degree of confidence in the final estimation of risk depends on the variability, uncertainty and assumptions identified in the previous steps.

Microbiological Risk Assessment

The risk assessment of microbiological hazards in food is usually referred to as a microbiological risk assessment (MRA). The methodology for conducting MRAs has made significant advances over a short time span. The Codex Alimentarius Commission has promoted the use of MRA and developed a framework, guidelines and principles for MRA (Codex Alimentarius, 2003). In response, FAO and WHO played a leading role in the conduct of several risk assessments and developed methodological guidelines (FAO/WHO, 2006a). Nationally, various countries have developed MRAs suited to various pathogens, products or processing systems.

The present trend is to favour the use of a formal structure for MRA (the “four steps paradigm” as set forth by Codex), and to promote the use of quantitative probabilistic risk assessments. These offer the added value of combining a formal representation of the risk generating system (through a risk model), incorporation of variability and inference of probability of adverse outcomes. However, it should be appreciated that a range of different approaches exist, from narrative through structured qualitative or deterministic quantitative to probabilistic assessments. The process can be flexible and the approach taken consistent with the scope, resources available, type of problem and specific information needed. For instance, governmental MRAs would seek to characterise population health impacts preferably using probabilistic food chain MRAs. Outside of public health measures, e.g., for the industry, MRA may be product and process specific and used to characterise risk as a measure of exposure against a threshold level of concern. Regardless the type chosen, MRA should be scientifically valid and fit for its overall purpose, guiding decisions on food safety and facilitating the development of targeted and effective food safety risk management strategies.

Risk assessment is now recognised as a decision-support tool in food safety management. It is a particularly useful tool in enabling the risk manager to consider and compare risk management options and to select control measures. Recently there has been a particular focus on the use of MRA to establish and/or implement quantitative risk-based microbiological objectives. Together with other tools, such as epidemiology-based tools and economic analysis, MRA can provide a sound scientific foundation for risk-based management approaches (FAO/WHO, 2006b).

3.5.2 Risk management

Risk management is the process, distinct from risk assessment, of assessing policy alternatives in consultation with all interested parties and, if needed, selecting and implementing appropriate prevention and control options, including regulatory measures. Risk management combines scientific inputs (e.g., the results of risk assessment) and other relevant factors (e.g., economics, politics, social preferences, technical feasibility) to arrive at a decision regarding what to do about a particular risk, if anything. Risk management can be applied to biological, chemical and physical hazards in food capable of causing adverse health effects.

Microbiological Risk Management

Risk management of microbiological hazards in food are usually referred to as microbiological risk management (MRM). MRM aims to ensure that the food available is safe and to improve the level of consumer protection. During the past ten years, FAO, WHO and the Codex Alimentarius have advocated the development of a generic MRM framework (Codex Alimentarius, 2006). The framework includes four basic steps: preliminary risk management activities, including the development of a risk profile; identification and selection of MRM options; implementation of MRM options; and monitoring and review of MRM options. The MRM framework is a structured, systematic and on-going process that uses the results of MRA and other relevant evaluations to develop effective MRM options for implementation at appropriate steps along the food chain.

In recent years, a number of individual countries have made significant progress in working through this framework, recognising the added value of a “risk-based” approach as a means of enhancing the ability of food safety management to meet its goals. Basically, a risk-based approach takes into account the consequences to public health of the adverse effects associated with foodborne pathogens, as a function of the probability and severity of those adverse effects. In addition to the traditional approaches to hazard control, a risk-based approach encourages a formulation of control measures according to the knowledge of risks to life and health, and allows control measures to be explained or evaluated in the same terms (FAO/WHO, 2006b). Risk-based management actions are aimed at achieving a level of health protection which can be expressed through a variety of quantitative expressions or objectives.

3.5.3 Risk communication

Risk communication is the interactive exchange of information and opinions throughout the risk analysis process. It concerns risk, risk-related factors and risk perceptions, and involves risk assessors, risk managers, consumers, industry, the academic community and other interested parties. It should include the explanation of risk assessment findings and the basis for risk management decisions. Risk communication is a socio-deliberative process, aiming at promoting dialogue, mutual understanding and negotiation. It is applicable to biological, chemical and physical hazards in food. It is universally recognised that effective communication is critical to the entire risk management process, and essential for engendering trust in risk management decisions. In spite of a number of studies and publications and several commendable initiatives in a number of countries, risk communication is still frequently underutilised.

3.6 Objectives for implementation

As described in the section above, risk analysis is primarily the prerogative of government authorities. However, the process can be difficult as governments frequently do not have access to all the data, particularly those considered commercially sensitive, e.g., melamine levels in infant formula. With regard to microbiological food safety, the formal approach to risk analysis is increasingly playing an important role in the determination of the level of consumer protection that a government considers necessary and achievable. This can be expressed in the form of public health goals or, in the context of the SPS agreement, as the “Appropriate Level Of Protection” (ALOP). Public health goals are set to inspire action to improve the public health status and reduce the disease burden. The setting of such goals requires consideration of the current health status or disease burden, and of the feasibility of the goals, in terms of how to achieve the goals and how to measure the degree of achievement (FAO/WHO, 2006b). In the context of the SPS agreement, the ALOP is an expression of the level of protection in relation to food safety that is currently achieved in a country either for in-country use (i.e., in manufacturing within the country) or for imports. In addition, exported food should meet the food safety standards that have been established by the importing country to meet their own ALOP. The ALOP may be general or specific, and expressed in different forms, e.g., in terms of risk (expression of the probability of the adverse effects of concern) or in terms of the number of cases of a disease per 100,000 population.

For practical implementation in specific sectors of the food chain, it is the responsibility of government authorities to translate the expected level of protection into quantitative objectives for practical implementation. These incorporate a risk-based approach and establish an explicit link to public health (a level of risk or risk reduction). They inform food operators concerned about the level of performance that should be achieved, thus allowing them to make decisions on the most appropriate control measures and their implementation. Codex’s risk-based objectives encompass Food Safety Objectives, Performance Objectives and Performance Criteria (Codex Alimentarius, 2010).

A **Food Safety Objective (FSO)** is the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP.

A **Performance Objective (PO)** is the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to the appropriate level of protection or to an FSO or ALOP, as applicable.

A **Performance Criterion (PC)** is the effect on the frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

FSO is a useful concept that allows risk managers to describe the overall stringency of a food safety system, considering the food chain as an integrated whole, including consideration of how consumers handle products. Nevertheless, PO and PC may find wider utility as risk-based targets, because they can be used at different points in the food chain where control and verification are possible, something that is not the case for FSO (FAO/WHO, 2006b).

Risk-based objectives, as defined by government authorities, are not designed to be actively and systematically controlled and verified in every case they are used. Rather, they should be used to derive appropriate operational standards, which can be controlled and verified, e.g., product and process criteria, such as critical limits in the HACCP system, or microbiological criteria (ILSI Europe, 2004; Stringer, 2005). Government objectives are the minimum objectives on which food operators base their own approach, as illustrated in Figure 3. The government's objectives may be adopted as such in the form of a company's food safety requirements, including performance criteria, product criteria and process criteria, as appropriate.

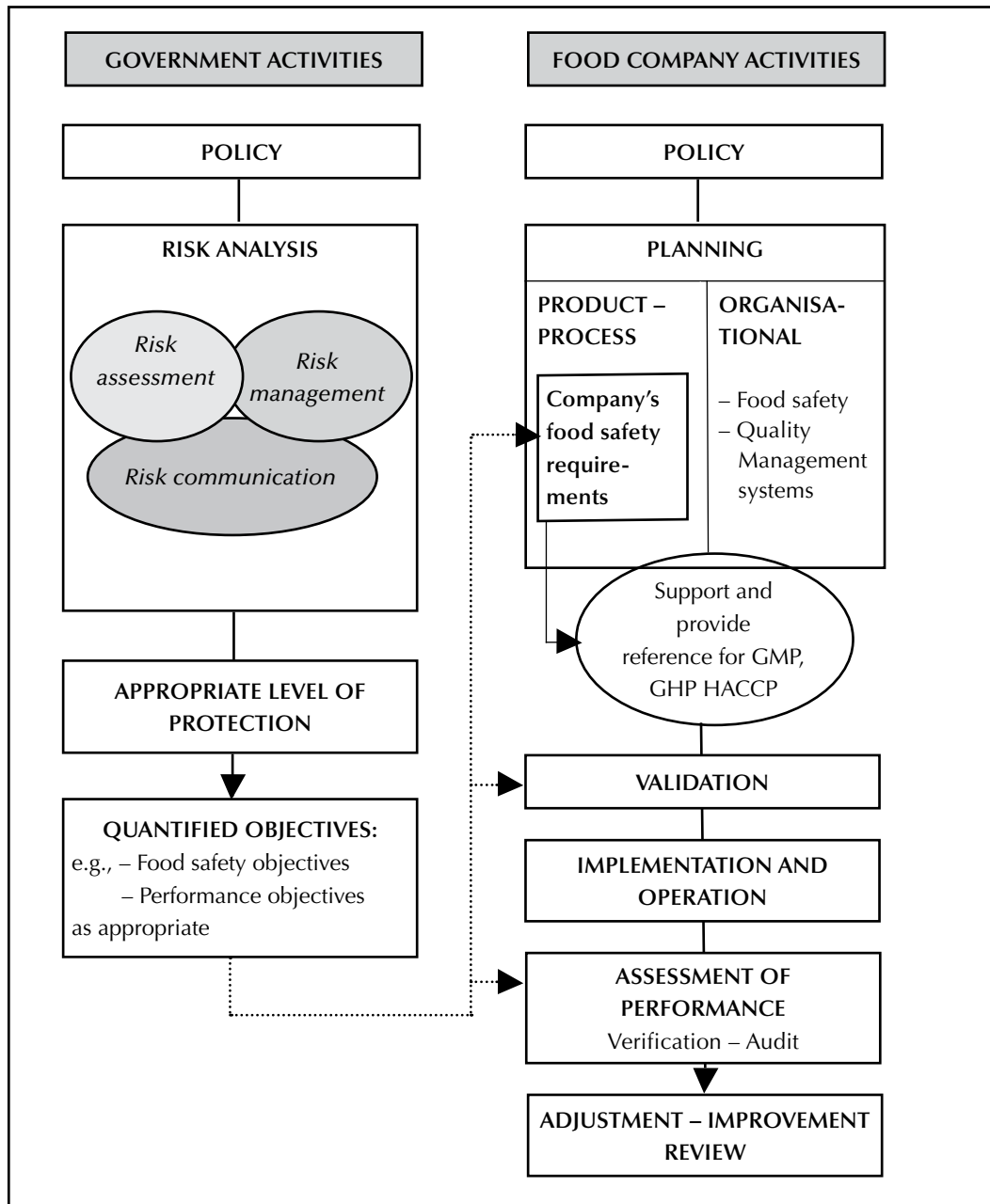
Alternatively, depending on commercial factors, a company may wish to establish more demanding food safety requirements. Food safety requirements provide input to the food safety programme. They direct product and process planning, design and implementation of GMP, GHP, HACCP, food safety and quality management systems with the aim of fulfilling the food safety requirements.

3.7 Other tools

Other tools of a more specialised nature may have application in areas of food safety management. These include in particular

- Other Safety and Quality assurance tools:
 - Hazard analysis and operability studies (HAZOP)
 - Cause-and-effect diagram (fishbone or Ishikawa diagram)
 - Event tree analysis
 - Fault tree analysis
 - Failure mode and effect analysis (FMEA)
- Predictive microbiology tools:
 - Predictive mathematical modelling (process modelling, microbial growth, death or survival, etc.), such as:
 - The Pathogen Modelling Programme (<http://ars.usda.gov>), which is a tool for estimating the effects of multiple variables on the growth or survival of foodborne pathogens
 - The ComBase initiative, which includes a database on microbial response to food environments supplemented by a number of predictive models (<http://www.combase.cc>)
- Decision analysis tools:
 - These include commercial computer software programmes aimed at performing risk analysis, Monte Carlo simulation, sensitivity analysis, creating decision trees and influence diagrams, fitting data to distributions and solving optimisation problems.

Figure 3: Interaction between the government's and a company's food safety activities with respect to microbiological hazards in food



4. SUMMARY AND CONCLUSIONS

Several tools for the management of food safety, which together form an integrated approach, are described in this report. The primary focus remains on microbiological food safety management, but the general principles are also applicable to the management of chemical food safety.

The basis for the general hygienic requirements for any operation is Good Manufacturing Practice (GMP), including Good Hygienic Practice (GHP). The product- and process-specific requirements are established by applying the HACCP system. Other tools described encompass the use of a food safety management system based on recognised standards and use of a quality system as a means of effectively managing total product quality. It should be recognised that the control procedures established in an HACCP plan fit well into such management systems and can be readily incorporated. Total Quality Management (TQM) embraces quality, productivity, safety and environment. It can be thought of as a means of generating greater commitment from all members of an organisation in order to achieve these aims, and will provide added confidence that products will conform to safety needs.

This document also considers the interrelationship between risk analysis (i.e., risk assessment, risk management and risk communication) as carried out by regulatory authorities and the food safety management programmes of companies involved in the production, sale and handling of food. This then leads to the expression of an appropriate level of protection and definition of appropriate objectives to ensure safe food, which should then be used by companies to establish their own requirements.

5. DEFINITIONS AND GLOSSARY

Internationally agreed definitions of food safety related terms, of HACCP-related terms and of risk analysis terms related to food safety can be found in the following Codex documents:

- Codex Alimentarius Commission, Procedural Manual, (Codex Alimentarius, 2010).
- Guidelines for the application of the HACCP system.
- Principles for the application of microbiological criteria for foods.
- Principles and guidelines for the conduct of microbiological risk assessment.

All documents are available on-line on the Codex website: <http://www.codexalimentarius.com>. The terms used in the field of quality management (marked as * below) are defined in the International Standard ISO 8402.

The following terms have been extracted from those documents.

Appropriate level of protection (ALOP) – The SPS Agreement defines the appropriate level of sanitary or phytosanitary protection as the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. This concept is also referred to as the acceptable level of risk.

Dose-response assessment – The determination of the relationship between the magnitude of exposure (dose) to a biological, chemical or physical agent and the severity or frequency of associated adverse health effects (response).

Exposure assessment – The qualitative and quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources, if relevant.

Food safety objective – The maximum frequency or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

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

Hazard characterisation – The qualitative and 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.

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

Quality (*) – The totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs.

Quality assurance (*) – All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.

Quality control (*) – The operational techniques and activities used to fulfil requirements for quality.

Quality management (*) – All activities of the overall management function that determine the quality policy, objectives and responsibilities, and that implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

Quality system (*) – The organisational structure, procedures, processes and resources needed to implement quality management.

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.

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 communication – The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk management – The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of the consumers and for the promotion of fair trade practices, and if needed, selecting and implementing appropriate prevention and control options, including regulatory measures.

Safety policy – The overall intentions and direction of an organisation with regard to safety as formally expressed by top management (by analogy with quality policy(*)).

SPS – Agreement on the Application of Sanitary and Phytosanitary Measures.

Total quality management – An organisation's management approach centred on quality, based on the participation of all its members and aimed at long-term success through customer satisfaction and benefits to the members of the organisation and to society.

6. REFERENCES

- Adak, G.K., Long, S.M. and O'Brien, S.J. (2002). Intestinal infections: trends in indigenous foodborne diseases and deaths, England and Wales, 1992 to 2000. *Gut*, **51**, 832-841.
- Australian Government (2005). Foodborne illness in Australia; annual incidence circa 2000. Australian Government Department of Health and Ageing. ISBN 0 642 82576 9.
Available at: [http://www.ozfoodnet.org.au/internet/ozfoodnet/publishing.nsf/Content/7BDEF9F8EC3835D9CA257165001AB31D/\\$File/foodborne_report.pdf](http://www.ozfoodnet.org.au/internet/ozfoodnet/publishing.nsf/Content/7BDEF9F8EC3835D9CA257165001AB31D/$File/foodborne_report.pdf)
- Australian Government (2006). The annual cost of foodborne illness in Australia. Australian Government Department of Health and Ageing.
Available at: <http://www.ozfoodnet.org.au/internet/ozfoodnet/publishing.nsf/Content/annual-cost-foodborne-illness.htm>
- Codex Alimentarius (2003). *Food Hygiene Basic Texts*. 3rd Edition.
- Recommended international code of practice: general principles of food hygiene. CAC/RCP 1-1969, Rev. 3 (1997), amended 1999.
 - Hazard Analysis and Critical Control Points (HACCP) system and guidelines for its application. Annex to CAC/RCP 1-1969, Rev. 3. 1997.
 - Principles for the establishment and application of microbiological criteria for foods. CAC/GL 21, 1997.
 - Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL 30, 1999.
- Codex Alimentarius (2006). Draft principles and guidelines for the conduct of microbiological risk management. ALINORM 07/30/13, Appendix IV, Food and Agriculture Organization, Rome.
- Codex Alimentarius (2010). Codex Alimentarius Commission. Procedural manual, 19th edition. World Health Organization and Food and Agriculture Organization of the United Nations. Rome, 2010. ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_19e.pdf
- FAO/WHO (2006a). Risk assessments, pathogen-commodity combinations:
- *Salmonella* in eggs and broiler chickens
 - *Listeria monocytogenes* in ready-to-eat foods
 - *Vibrio* spp. in seafoods
 - *Campylobacter* spp. in broiler chickens
 - *Enterobacter sakazakii* and other microorganisms in powdered infant formulas
- Food and Agriculture Organization, Rome. Electronic Edition:
www.fao.org/ag/agn/jemra/riskassessment_en.stm
- FAO/WHO (2006b). The use of microbiological risk assessment outputs to develop practical risk management strategies: metrics to improve food safety. A Report of a Joint FAO/WHO Expert Consultation (Kiel, Germany, 3-7 April 2006). Food and Agriculture Organization, Rome.
- FAO (2003). Electronic Edition: ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2003e.pdf
- FSA (2000). A report on the study of infectious intestinal disease in England. Food Standards Agency, HMSO, London.
- Gorris, L.G.M., Jouve, J-L., and Stringer, M.F. (2000, Editors). Microbiological risk assessment. *International Journal of Food Microbiology* **58**(3):141-246.

- IFT (2002). Expert report on emerging microbiological food safety issues: implications for control in the 21st century. Institute of Food Technologists.
Available at www.ift.org
- ILSI Europe (1999). Validation and verification of HACCP. *ILSI Europe Report Series*, ILSI Europe, Brussels.
- ILSI Europe (2004a). Food safety objectives – role in microbiological food safety management. *ILSI Europe Report Series*, ILSI Europe, Brussels.
- ILSI Europe (2004b). A simplified guide to understanding and applying the Hazard Analysis Critical Control Point concept. *ILSI Europe Concise Monograph Series*, ILSI Europe, Brussels.
- Jouve, J.L., Stringer, M.E. and Baird-Parker, A.C. (1998). Food safety management tools. *Food Science and Technology Today*, **13**(2): 82-91.
- Lammerding, A. (2007). Using microbiological risk assessment (MRA) in food safety management. *ILSI Europe Report Series* 2007:1-36.
- OECD (2003). The economic costs of foodborne diseases. OECD, Directorate for Food, Agriculture and Fisheries – AGR/CA/APM(2003)12.
- Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M-A, Roy, S.L., Jones, J.L. and Griffin, P.M. (2011). Foodborne illness acquired in the United States – major pathogens. *Emerging Infectious Diseases* **17**(1): 7-15. <http://www.cdc.gov/EID/content/17/1/7.htm>
- Stringer, M. (2004). Food safety objectives – role in microbiological food safety management. *ILSI Europe Report Series* 2004:1-36.
- Stringer, M. (2005a). Impact of food safety objectives – role in microbiological food safety management. Summary report of an ILSI Europe Workshop, *Food Control* **16**(9), 775-794.
- Stringer, M. (2005b). Food safety objectives – role in microbiological food safety management. *Food Control* **16**(9): 775-830.
- USDA (1996). Pathogen reduction; Hazard Analysis and Critical Control Point (HACCP) systems; final rule. United States Department of Agriculture, 25 July 2011. (9 CFR Part 304, *et al.*, 1996).
<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf>
- van Schothorst, M.A. (2004). Simple guide to understanding and applying the Hazard Analysis Critical Control Point concept -Third Edition. *ILSI Europe Concise Monograph Series* 2004 :1-23
- WHO (2000). Foodborne diseases, a focus on health education, World Health Organization, Geneva.
- WHO (2003). The present state of foodborne disease in OECD countries. World Health Organization, Geneva.
- WHO (2006). Food safety and foodborne illness. Fact sheet n° 237, web page, <http://www.who.int/mediacentre/factsheets/fs237/en/print.html>

7. WEBSITES OF INTEREST

Codex Alimentarius: <http://www.codexalimentarius.com>

Nutrition and consumer protection at FAO: <http://www.fao.org/ag/agn>

Food safety at WHO: <http://www.who.int>

European Food Safety Authority: <http://www.efsa.europa.eu>

Global Food Safety Initiative: <http://www.mygfsi.com/>

UMFDA-University of Maryland Clearinghouse: <http://www.foodriskclearinghouse.umd.edu>

Completed risk assessments:

- Risk assessment completed by FAO/WHO:
http://www.fao.org/ag/agn/jemra/riskassessment_en.stm
- Inventory of quantitative microbiological risk assessments studies in Europe:
<http://www.cost920.com/00020.html>
- Risk assessments for all hazards and commodities:
http://www.foodriskclearinghouse.umd.edu/risk_assessment.cfm

International Portal on Food Safety, Animal and Plant Health: <http://www.ipfsaph.org>

SPS measures at the World Trade Organization: http://www.wto.org/english/tratop_e/sps_e/sps_e.htm

Other ILSI Europe Publications

Concise Monographs

- Alcohol – Health Issues Related to Alcohol Consumption
- A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point Concept
- Calcium in Nutrition
- Carbohydrates: Nutritional and Health Aspects
- Caries Preventive Strategies
- Concepts of Functional Foods
- Dietary Fibre
- Food Allergy
- Food Biotechnology – An Introduction
- Functional Foods – From Science to Health and Claims
- Genetic Modification Technology and Food – Consumer Health and Safety
- Healthy Lifestyles – Nutrition and Physical Activity
- Microwave Ovens
- Nutrition and Genetics – Mapping Individual Health
- Nutrition and Immunity in Man
- Nutritional and Health Aspects of Sugars – Evaluation of New Findings
- Nutritional Epidemiology, Possibilities and Limitations
- Oral and Dental Health - Prevention of Dental Caries, Erosion, Gingivitis and Periodontitis
- Oxidants, Antioxidants, and Disease Prevention
- Principles of Risk Assessment of Food and Drinking Water Related to Human Health
- The Acceptable Daily Intake – A Tool for Ensuring Food Safety
- Threshold of Toxicological Concern (TTC)
- Type 2 Diabetes – Prevention and Management

Reports

- Addition of Nutrients to Food: Nutritional and Safety Considerations
- An Evaluation of the Budget Method for Screening Food Additive Intake
- Animal-Borne Viruses of Relevance to the Food Industry
- Antioxidants: Scientific Basis, Regulatory Aspects and Industry Perspectives
- Applicability of the ADI to Infants and Children
- Application of the Margin of Exposure Approach to Compounds in Food which are both Genotoxic and Carcinogenic
- Approach to the Control of Enterohaemorrhagic *Escherichia coli* (EHEC)
- Assessing and Controlling Industrial Impacts on the Aquatic Environment with Reference to Food processing
- Assessing Health Risks from Environmental Exposure to Chemicals: The Example of Drinking Water
- Beyond PASSCLAIM – Guidance to Substantiate Health Claims on Foods
- *Campylobacters* as Zoonotic Pathogens: A Food Production Perspective
- Considering Water Quality for Use in the Food Industry
- Consumer Understanding of Health Claims
- Detection Methods for Novel Foods Derived from Genetically Modified Organisms
- Emerging Technologies for Efficacy Demonstration
- Evaluation of Agronomic Practices for Mitigation of Natural Toxins
- Evaluation of the Risks Posed in Europe by Unintended Mixing of Food Crops and Food Crops Developed for Non-Food Uses
- Exposure from Food Contact Materials
- Foodborne Protozoan Parasites
- Foodborne Viruses: An Emerging Problem
- Food Consumption and Packaging Usage Factors
- Food Safety Management Tools

- Food Safety Objectives – Role in Microbiological Food Safety Management
- Functional Foods in Europe – International Developments in Science and Health Claims
- Functional Foods – Scientific and Global Perspectives
- Guidance for the Safety Assessment of Botanicals and Botanical Preparations for Use in Food and Food Supplements
- Impact of Microbial Distributions on Food Safety
- Markers of Oxidative Damage and Antioxidant Protection: Current status and relevance to disease
- 3-MCPD Esters in Food Products
- Method Development in Relation to Regulatory Requirements for the Detection of GMOs in the Food Chain
- Micronutrient Landscape of Europe: Comparison of Intakes and Methodologies with Particular Regard to Higher Consumption
- *Mycobacterium avium* subsp. *paratuberculosis* (MAP) and the Food Chain
- Nutrition in Children and Adolescents in Europe: What is the Scientific Basis?
- Overview of the Health Issues Related to Alcohol Consumption
- Overweight and Obesity in European Children and Adolescents: Causes and consequences – prevention and treatment
- Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications
- Packaging Materials: 2. Polystyrene for Food Packaging Applications
- Packaging Materials: 3. Polypropylene as a Packaging Material for Foods and Beverages
- Packaging Materials: 4. Polyethylene for Food Packaging Applications
- Packaging Materials: 5. Polyvinyl Chloride (PVC) for Food Packaging Applications
- Packaging Materials: 6. Paper and Board for Food Packaging Applications
- Packaging Materials: 7. Metal Packaging for Foodstuffs
- Recontamination as a Source of Pathogens in Processed Foods – A Literature Review
- Recycling of Plastics for Food Contact Use
- Safety Assessment of Viable Genetically Modified Microorganisms Used in Food
- Safety Considerations of DNA in Foods
- *Salmonella* Typhimurium definitive type (DT) 104: A multi-resistant *Salmonella*
- Significance of Excursions of Intake above the Acceptable Daily Intake (ADI)
- The Safety Assessment of Novel Foods
- The Safety Assessment of Novel Foods and Concepts to Determine their Safety in use
- Threshold of Toxicological Concern for Chemical Substances Present in the Diet
- Transmissible Spongiform Encephalopathy as a Zoonotic Disease
- Trichothecenes with a Special Focus on DON
- Using Microbiological Risk Assessment (MRA) in Food Safety Management
- Validation and Verification of HACCP
- Water Use of Oil Crops: Current Water Use and Future Outlooks

To order

ILSI Europe a.i.s.b.l.
Avenue E. Mounier, 83, Box 6
B-1200 Brussels, Belgium
Phone: (+32) 2 771 00 14 • Fax: (+32) 2 762 00 44
E-mail: publications@ilsieurope.be

ILSI Europe's Concise Monographs and Report Series can be downloaded from: www.ilsieurope.eu

ISBN 9789078637301



9 789078 637301