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FOOD SAFETY MANAGEMENT TOOLS

REPORT

Prepared under the responsibility of
ILSI Europe Risk Analysis in
Microbiology Task Force

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by J.L. Jouve, M.F. Stringer and A.C. Baird-Parker

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PREPARED UNDER THE RESPONSIBILITY OF ILSI EUROPE RISK ANALYSIS IN MICROBIOLOGY TASK FORCE

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Report on Food Safety Management Tools

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FOREWORD

Throughout the world, food manufacturing, distribution and retailing is becoming a highly complex business. Raw materials are sourced on a global scale, an ever-increasing number of processing technologies are used, and a vast array of products are available to the consumer. 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 convenience, "less-processed" and fresher, more natural characteristics. Against this backcloth of change, the total food chain has to ensure that the highest standards of safety are maintained.

At all stages of the food chain, from acquisition of raw materials, to manufacture, distribution and sale, whether it be through retail or catering outlets, consideration must be given to the safety issues associated with the specific products, processes and methods of handling.

This report considers the tools currently available for food safety management and outlines a framework for their interaction and use. It does not describe the tools in detail, since this information is available in other texts.

The report should be of use to all those in the food chain who are involved in food-handling processes or operations where product safety is a potential issue. Irrespective of size and complexity, all food businesses must have an appropriate food safety management programme. Although the primary focus of this report is on microbiological issues, the general principles addressed by the report are equally applicable to the management of chemical and physical contaminants.

INTRODUCTION

Food safety is a major concern facing the food industry today. Much publicity is given to issues associated with microbiological and chemical contamination.

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 of both health and economic significance. In 1990, an average of 120 cases of foodborne illness per 100,000 population were reported from 11 European countries, and more recent estimates, based on a "sentinel" study indicate that in some European countries there are at least 30,000 cases of acute gastroenteritis per 100,000 population yearly (Notermans and van der Giessen 1993), much of which is thought to be foodborne. It is clear that only a small proportion of cases of foodborne illness are brought to the attention of food inspection, control and health agencies.

In addition, we have seen in recent years the emergence of bacterial pathogens which may cause serious illness in susceptible individuals, e.g., *Listeria monocytogenes* and verocytotoxigenic *Escherichia coli*, such as O157:H7.

Estimates have been made of the economic consequence of foodborne illness, where costs are incurred by individuals who become ill and by their employers and by families, health care agencies and the food companies and businesses involved. For instance, in England and Wales in 1991, some 23,000 cases of salmonellosis were estimated to have resulted in an overall cost of £40 million to £50 million (Sockett 1991).

Changes in food production

Significant changes are taking place in animal husbandry and in large-scale food production and distribution methods. The increased use of raw materials and products sourced from a wider range of countries has increased the potential for the geographic spread of diseases associated with particular contaminants. Many new processing techniques have been introduced which, alone or in combination, offer distinct product quality advantages, e.g., milder thermal processing, microwave heating, ohmic heating and high-pressure processing techniques. All of these developments in processing technology have to be fully evaluated to ensure the design of a safe commercial process.

Changes in consumer requirements

Demand is increasing for convenience foods requiring minimum preparation for consumption. In addition, consumers are seeking foods which are more "fresh" and with enhanced natural flavours, which inevitably challenge the industry to use less harsh processing and production regimes. Although there is little evidence that such trends have led to increased foodborne illness, it must be appreciated that these foods require great care in their production, distribution, storage and preparation prior to final consumption.

Socioeconomic changes

There is a significant worldwide trend to increased consumption of food outside the home. Also, a major increase in the frequency of international travel for business and vacation purposes means that more people are potentially being exposed to new microbiological hazards. Population changes are taking place: the young and the aged have always been of particular concern with regard to foodborne illness, and in a number of countries the aged population is increasing.

It is most important that new risks and hazards be identified and appropriate action taken to safeguard the production and sale of safe food. Socioeconomic changes and the scientific and technical advances in food production and distribution procedures have resulted in the marketing of a range of minimally processed refrigerated foods requiring great care throughout the chain to the point of final consumption.

All sectors of the food chain will need to increase their vigilance and frequently review the operation of their food safety programmes.

FOOD SAFETY STRATEGY

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 both organisational and technical 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 and their application to all stages of production, distribution and sale.

Programme elements

The programme can be applied through a series of specific activities as illustrated in Figure 1. These activities are considered in the following sections.

- *Management responsibility and commitment*

  Senior company management has the ultimate responsibility for ensuring that the highest standards of food production and handling are achieved with respect to food safety. Total commitment to this aim is crucial to the successful implementation of a food programme.

- *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:

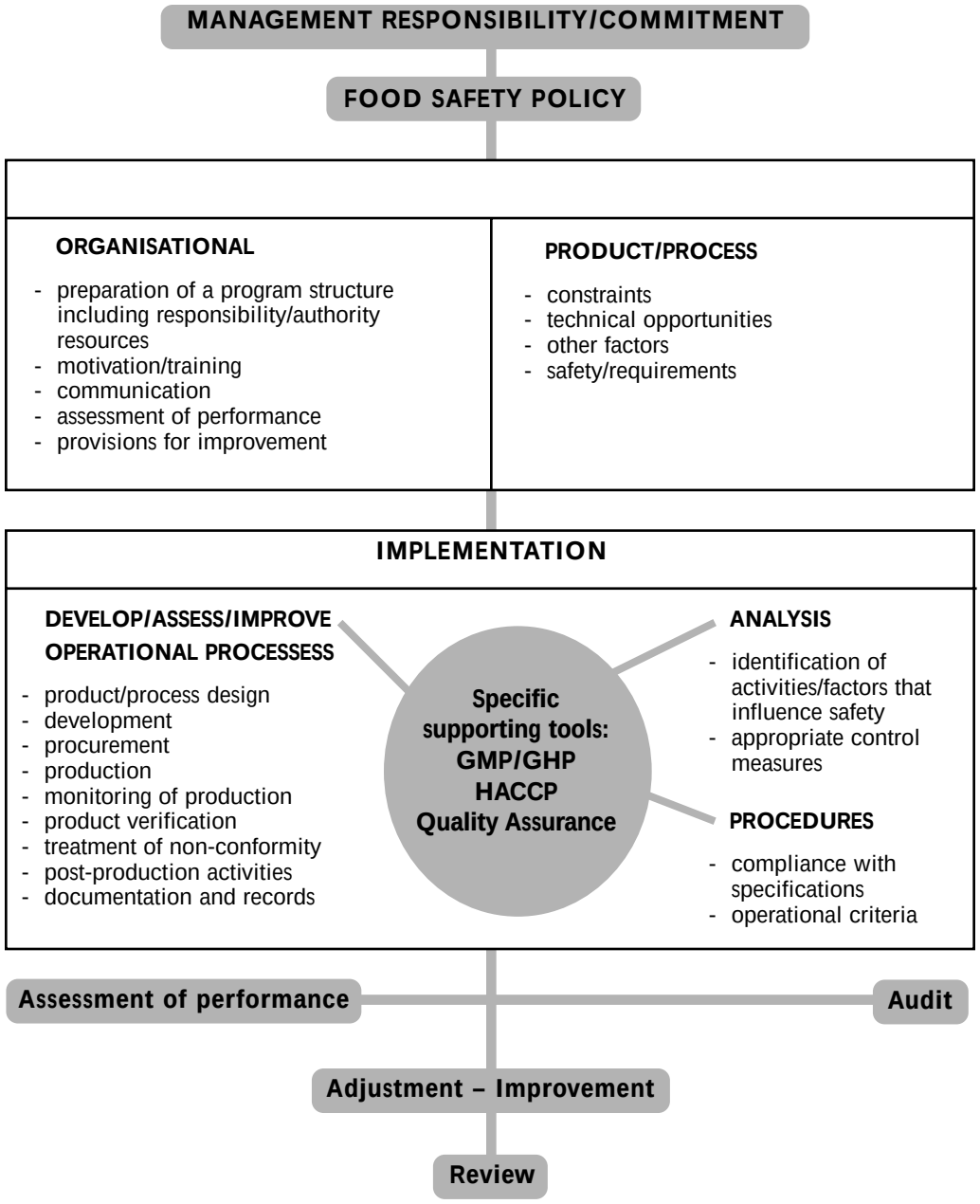
  – is appropriate to the nature and activity of the business,
  – provides a commitment to continuous improvement,
  – complies with legislation, and
  – is fully communicated, understood and supported by all employees.

- *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.

Figure 1: Food safety programme



– Product and process planning should result in the definition of clear and unambiguous food safety requirements. All such requirements should be based on a full consideration of constraints, opportunities and other factors where relevant. Constraints may include regulatory and commercial requirements. Opportunities may include product development, process innovation and new markets. Other factors may include economic issues and costs, e.g., of raw materials.

- *Implementation*

The first requirement is a thorough understanding of all stages of the production cycle from raw material production and acquisition through 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 which may affect 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.

- *Assessment of performance and audit*

Senior management should ensure that there is a process of regular assessment of performance of the food safety programme. This will include audit of individual stages and identification of any weaknesses. In this way it can be assessed whether the **food safety requirements** are being met and whether the programme is truly effective.

- *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. This is an ongoing review process designed to ensure compliance with changing regulations and to further enhance the assurance of food safety.

FOOD SAFETY PROGRAMME: USE OF TOOLS

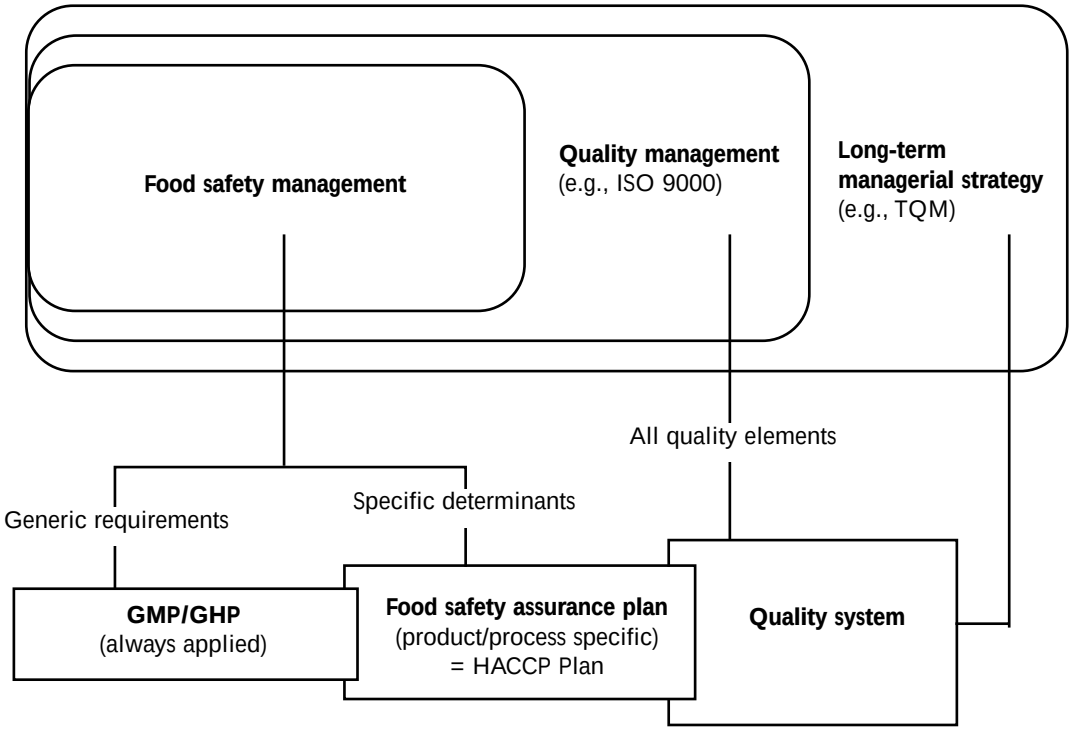
The practical success of the food safety programme will be dependent on the proper use of appropriate methods and tools. These will include Good Hygiene Practice (GHP), Good Manufacturing Practice (GMP) and HACCP (the Hazard Analysis Critical Control Point) specifically targeted to food safety. Other tools of more general application are quality assurance methods and systems such as the ISO 9000 series of standards (ISO 1994) and the Total Quality Management (TQM) approach.

This report does not contain detailed information on the characteristics of these tools, since that can be found in numerous other texts (Anon 1993a, 1993b, 1995, 1989; Mortimore and Wallace 1994; Jablonski 1991; Webb and Marsden 1995; Codex Alimentairius Commission 1995). It does, however, describe the application and integration of these tools in a food safety programme.

An integrated approach

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

Figure 2: Food safety tools: an integrated approach



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 and control of hazards associated with the 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 determinants unique to a particular product and process.

Most food businesses have a quality system which addresses all aspects of quality control and assurance. There are many forms of such systems; perhaps the most widely used is that based on the ISO 9000 series of standards. Where such a system exists, HACCP is an integral part of the overall standard.

From Figure 2 it can be appreciated that food safety management is an integral part of overall quality management activity and a key component of the longer-term managerial strategy to enhance the safety and quality of products.

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 meet and which are the prerequisite(s) to other approaches, in particular HACCP. GMP/GHP requirements have been developed by governments, the Codex Alimentarius Committee on Food Hygiene (FAO/WHO) and the food industry, often in collaboration with other groups and food inspection and control authorities.

General GHP/requirements usually cover the following:

- the hygienic design and construction of food manufacturing premises,
- the hygienic design, construction and proper use of machinery,
- cleaning and disinfection procedures (including pest control), and
- general hygienic and safety practices in food processing including:
  - the microbial 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.

GMP codes and the hygiene requirements they contain are the relevant boundary conditions for the hygienic manufacture of foods. They should always be applied and documented.

HACCP

HACCP provides a structured approach to the assurance of the safety of specific products and their associated processes. It involves:

- identification of hazards of concern, such as pathogenic agents and the conditions leading to their presence and proliferation,
- identification of the specific requirements for their control, and
- mechanisms to measure/judge continuously the efficacy of the HACCP system.

Increasingly, national and international legislation requires the implementation of HACCP in businesses associated with food production (Anon 1993b, 1995). Irrespective of the size of a food business, HACCP should be an essential component of the food safety programme. HACCP should, however, be as comprehensive as the range of products manufactured or handled and their associated risks necessitate.

The combination of GMP/GHP and HACCP is beneficial in that the effective application of GMP/GHP allows the HACCP plan to focus on the critical determinants of safety.

For steps in the food production process which 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.

Quality 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.

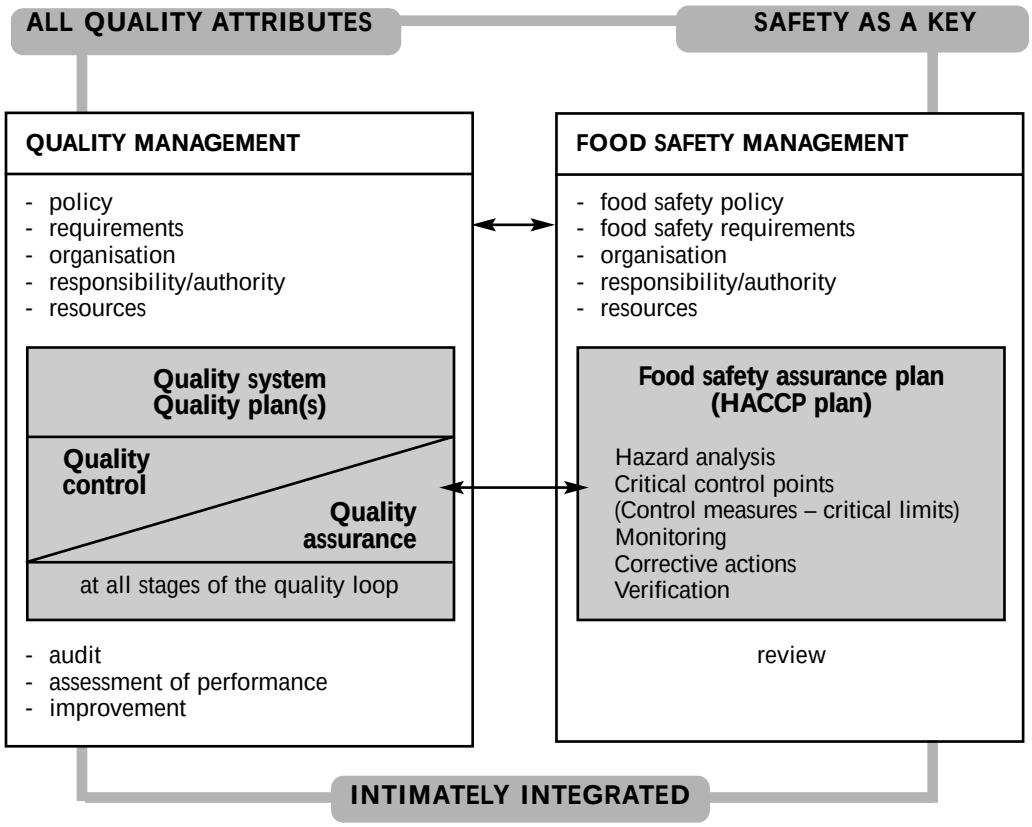
A quality system is designed to ensure that all factors affecting the quality of a product will be under control, such control being oriented towards the reduction, elimination and, most importantly, prevention of quality deficiencies. It is intended to perform two basic functions, quality control and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

Because all aspects of quality are covered by this means, it is important to introduce food safety considerations most efficiently into a quality system.

Figure 3 illustrates the intimate relationship between HACCP and the overall quality management system. Within the framework of a quality system, HACCP provides an approach to a food safety assurance plan which sets out the specific practices, resources and sequence of activities relevant to a particular product's safety.

The implementation of GMP/GHP and the utilisation of a specific food safety assurance plan based on HACCP, embraced within a comprehensive quality management system, will provide an effective food safety management programme.

Figure 3: Food safety and quality management



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 organization 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 combination of HACCP, quality systems, TQM and business excellence provides a total systems approach to food production, which embraces quality, productivity and food safety.

TQM and quality systems provide the philosophy, culture and discipline necessary to commit every member of an organisation to the achievement of all managerial objectives related to quality. Within this framework, the inclusion of HACCP as the key specific safety assurance plan provides the necessary confidence that products will conform to safety needs and that no unsafe or unsuitable product will leave the production site.

Collectively, these tools provide a comprehensive and proactive approach to further reduce the risk of food safety problems.

Risk analysis

Increasingly, government bodies at national and international levels are addressing food safety risk analysis associated with biological hazards. Risk analysis is a deliberate, structured and formalised approach to understanding and, where necessary, reducing risk. It is generally recognised that risk analysis consists of three components: risk assessment, risk management and risk communication.

Risk assessment is a scientific approach to estimating a risk and to understanding the factors that influence it. Starting with a statement of purpose or problem formulation, the process includes four elements: hazard identification, exposure assessment, hazard characterisation and risk characterisation.

Hazard identification consists of the identification of biological agents (microorganisms and toxins) and/or, depending on purpose, chemical and physical agents capable of causing adverse health effects 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(s) under consideration.

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 (i) the frequency or likelihood of contamination of foods by the pathogenic agent and its prevalence/level in those foods over time, up to the moment of consumption, and (ii) consumption patterns and habits (i.e., "dietary" information).

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 refer to the physiology and the pathogenicity/virulence of the microorganism, to the dynamics of infection and to the host susceptibility. 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 and physical agent and the severity and/or frequency of adverse health effects (response).

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.

Risk management is the process of weighing policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. Although it is recognised that certain interactive elements are necessary for a systematic risk analysis process, there must be a functional separation between risk assessment and risk management to ensure both the scientific integrity of risk assessment and the transparency of the decision-making management process.

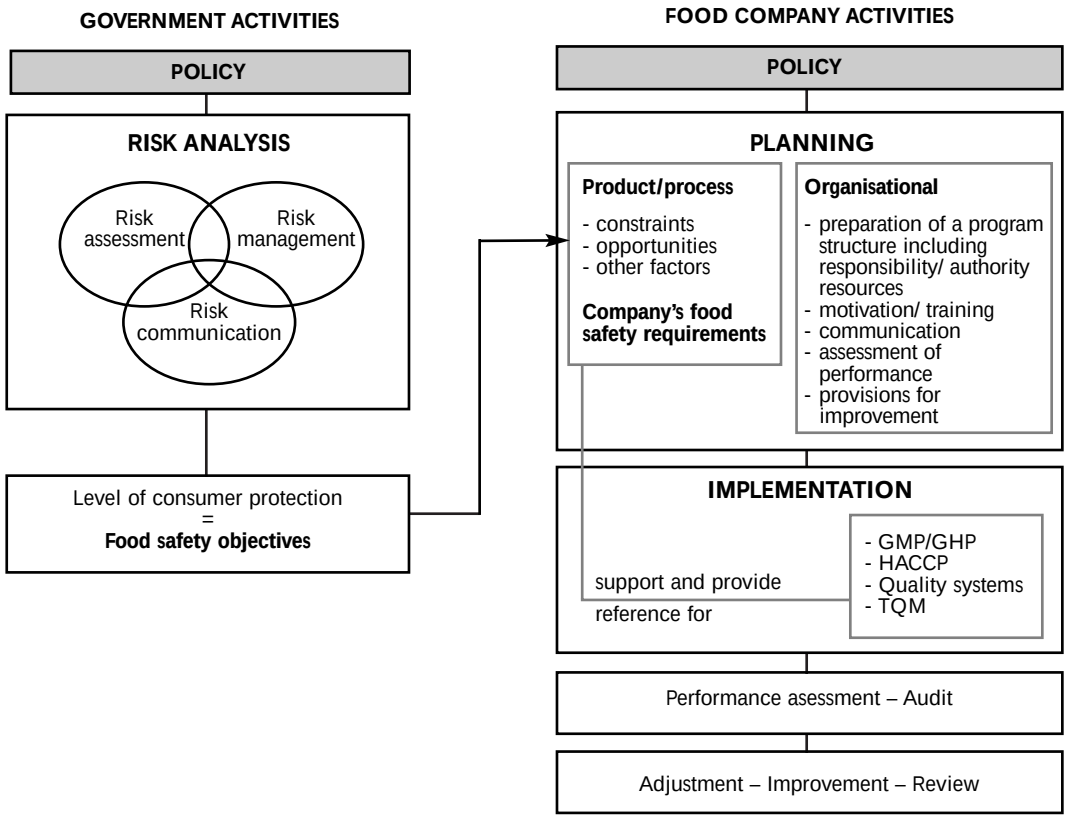
Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

Risk analysis is primarily the prerogative of government bodies that have access to all necessary data and research findings. Although it is recognised that with regard to food microbiology the formalised approach to risk analysis is in its infancy, it is likely that in the near future this approach will play a more important role in the determination of the level of consumer protection that a government considers necessary and achievable. For practical implementation in specific sectors of the food chain, it is the responsibility of governmental authorities to translate the expected level of protection into food safety objectives. Such objectives delineate the specific target(s) that any food operator concerned should endeavour to achieve through appropriate interventions.

Food safety objectives are a statement of the maximum level of a microbiological hazard in a food considered acceptable for human consumption. Whenever possible, food safety objectives should be quantitative and verifiable.

Food safety objectives as defined by governmental authorities represent the minimum target on which food operators base their own approach, as illustrated in Figure 4. The government's **food safety objectives** may be adopted as such in the form of a company's **food safety requirements**. 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 and quality assurance systems with the aim of fulfilling the **food safety requirements**.

Figure 4: Interaction between the government's and a company's food safety activities



Other tools

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

- 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 mathematical modelling (process modelling, microbial growth, death or survival, etc.), and
- probabilistic safety assessment (PSA).

Expert guidance should be sought on the use of these techniques, particularly those based on statistical concepts. Increasing numbers of software-based food safety packages are commercially available. Further information on these tools can be found in Mortimore and Wallace (1994), Montgomery (1996) and Whiting (1995).

SUMMARY AND CONCLUSIONS

Several tools for use in an integrated approach to the management of food safety are described in this report. They comprise the use of elements of Good Manufacturing Practice (GMP) that are specifically concerned with the general design and operation of hygienic premises and equipment and with the hygiene of personnel and their training, GMP requirements associated with hygiene (often referred to as Good Hygiene Practice [GHP] requirements) form the basis for the operation of a hygienic food operation. The product safety requirements for the manufacture of a specific foodstuff, and the design and operation of the associated plant such that production of a safe food is assured, can be established only by applying HACCP, the second of the tools described herein. The importance of applying HACCP within a GMP framework is emphasised, recognising the importance of both GMP / GHP and HACCP in assuring product safety. The third tool described is the use of a quality management system such as the ISO 9000 series as a means of effectively managing total product quality, recognising that the control procedures established in a HACCP plan fit well into such a management system and can be readily incorporated into it. The fourth and final tool described, Total Quality Management (TQM), embraces quality, productivity and safety. It can be thought of as a means of generating greater commitment from all members of an organisation to achieve these aims, and will provide added confidence that products will conform to safety needs.

The document also considers the interrelationship between risk analysis (i.e., risk assessment, risk management and risk communication) and HACCP. The former is a governmental activity leading to the establishment of **food safety objectives**, which can be used by a company to establish its own **food safety requirements**.

GLOSSARY

Dose-response assessment – The determination of the relationship between the magnitude of exposure (dose) to a biological, chemical 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

Food safety objective – A government-defined target considered necessary to protect the health of consumers (this may apply to raw materials, a process or finished products)

Food safety requirement – A company-defined target considered necessary to comply with a food safety objective

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

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

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 characterisation and exposure assessment

Risk communication – The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties

Risk management – The process of weighing policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate 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

Total quality management – An organization'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

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