
Food Safety Plan of Catalonia 2007-2010



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Preface

In our immediate environment, the administration's intervention in food safety issues has traditionally taken the structure of a multiple system of bodies in which, very often, each organisation attempts to respond to the problems of one particular sector. This frequently generates shortcomings where there is a need for transversal cooperation. However, social demand for greater efficiency and effectiveness from action taken by public authorities obliges these to advance towards consolidating a model in which all competent administrations share a global approach to safety in the food chain as part of a strategy which places the emphasis on synergy and complementarity. It is also important to involve all stakeholders in the food chain, particularly the general public.

The responsibilities of operators involved at different stages in the food chain are clearly defined. In the framework now provided, and without prejudice to these responsibilities, the role of the public administration cannot be limited to that of a management body that merely performs its duties of assessing, managing and communicating existing problems efficiently; it must also mobilise resources and foster actions amongst all those involved, based on principles of coordination and cooperation. Without this new relational focus, it will be very difficult to truly ensure that the public enjoys high a standard of food safety.

To meet these needs, certain countries, such as Belgium and Canada, have adopted systems based on a single body, which is responsible for all action aimed at promoting and guaranteeing food safety. Nonetheless, the general tendency is to work towards an integrated intervention model in which all the competent authorities act in a coordinated way, a system based on shared objectives and explicit commitments. This model increases the coherence of the system whilst not interfering with the other roles played by the organisations involved, and is simpler to adopt since it can be adapted to the initial situation. This enables a clear separation to be made between the functions of risk assessment and risk management, thereby enhancing both objectivity and transparency.

Working towards an integrated intervention model requires certain instruments that can serve as a reference framework. The Food Safety Plan of Catalonia, one of the most important of these instruments, is designed to guide joint action by public authorities towards achieving specific, shared results in cooperation with all sectors involved. The Plan, whose goals are to achieve specific results and constant improvement, is an instrument that enshrines the commitment to efficient, effective action and results evaluation in a common culture.

The Plan was drawn up with the participation of all public administrations in Catalonia with responsibilities for food safety. These administrations are called upon to form a public network for integral food safety that will promote a relational model based on the fundamental idea that different stakeholders should participate and share responsibilities for finding and applying solutions to meet new challenges in today's society. That is why it was considered essential that the plan should include contributions made by all professionals and organisations that form part of the food chain.

The Food Safety Plan of Catalonia, then, launches a new stage, one aimed at promoting the principles of goal-based planning, transversal coordination and quality of service, as well as all the elements that make up the food hazard assessment process. The full deployment of risk assessment and communication, along with more efficient risk management, will enable us to achieve higher levels of food safety, something that will not only help to minimise risks to the public, but also to enhance Catalonia's reputation, furthering our country's projection as a reference in agri-food production.

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Introduction

Health crises relating to food described in the late-20th and early-21st century make clear not only the complexity of food production processes, but also the need to take an integral approach to food safety, an approach which embraces the entire production chain from the earliest stages to final consumption, with one basic priority: to protect the health of the population. Certain crises, such as, for example, those caused by bovine spongiform encephalopathy or by dioxins, have shown the importance of the primary sector to food safety, as certain types of contamination can originate at this early stage in the food chain.

All stages and processes in the food chain must be completed according to correct practices, ensuring that hazards are controlled and eliminated or reduced to acceptable levels. Economic operators must be aware of their responsibilities and the need to comply with all applicable rules and regulations. For their part, it is the duty of the competent authorities to promote the implementation of good practices and to ensure compliance with current regulations.

In the developed countries, the concept of food safety has acquired a complex, broad-ranging sense that goes beyond safety and has begun to include other issues that are linked directly or indirectly to it. The legitimate expectations of citizens and society in general as regards food and the food production chain go beyond mere demands for guarantees of safety, and growing concern is being noted in other spheres such as ethics, sustainability, the link between nutrition and health, socio-economic effects and quality, amongst others.

The relation between food and health is not limited only to the chemical, biological and physical safety of foodstuffs, but also involves ingesting essential nutrients in a balanced way. Scientific data shows that an adequate, varied diet is an essential condition for good health and general wellbeing. Consumers are showing growing concern about the nutritional value of foodstuffs and we are seeing rising demand for information about such issues. In view of the effects this information can have on decisions regarding consumption, therefore, we need to seriously consider everything to do with information about nutrition and food composition that is made available to consumers. This is a particularly important issue when it comes to preventing adverse reactions to food and in the case of pathologies associated with nutritional imbalances, where lack of correct information may be an important risk factor. We need to strengthen measures aimed at guaranteeing the right to make a conscious decision based on reliable information.

We can see, then, that food safety is a broad-ranging and complex issue, one which needs to be approached through strategic planning informed by recognised principles and methodologies such as risk analysis, ensuring the quality of services, the involvement of all parties concerned and the coordination of action. By putting such principles into effect, we can strengthen and improve the development of assessment, management and communication instruments as regards both health risks and other related issues.

It is in this context, then, that we must see the Food Safety Plan of Catalonia, which is designed to be a regulatory instrument and to provide a framework of reference for all public action regarding food safety carried out by the Generalitat Administration and local authorities in Catalonia.

The Food Safety Agency of Catalonia (ACSA), was established under Law 20/2002, of July 5, on Food Safety. ACSA is an autonomous body with responsibilities for risk assessment and communication, as well as coordinating and planning risk management. The Agency's mission includes drawing up and monitoring the Food Safety Plan, and the aforementioned law establishes the principal characteristics and content that this plan must contain. The Plan, enacted for a four-year period, establishes both the guidelines and the activities and programmes required to achieve its objectives. According to Law 20/2002, the Food Safety Plan of Catalonia must take into account:

- a) The objectives and levels to be achieved as regards health control of foodstuffs and areas related directly or indirectly to food safety: animal health, nutrition and welfare, plant health, zoosanitary and phytosanitary products and environmental pollution.
- b) All the services, programmes and actions to be developed.
- c) Mechanisms for evaluating the application and monitoring of the Plan.

It is also established that the procedure for drawing up the Food Safety Plan shall guarantee the participation of administrations, institutions, scientific societies and professionals concerned with food safety, as well as civil society. The Plan must be approved by the Government at the proposal of the Catalan Food Safety Agency, and submitted to the Catalan Parliament.

For this first edition of the Food Safety Plan of Catalonia a whole series of contextual elements and guidelines have been taken into account, and these are gathered together in Chapter One and Chapter Two of this document. Chapter Three is devoted to the methodology employed for drawing up and designing the Plan, which is based on the principles of goal-based planning. This is a methodology entirely appropriate to the needs of the Food Safety Plan of Catalonia, as it allows us to establish the actions required to achieve certain objectives. The methodology is based on a logical thought process in which the first consideration is "what we wish to achieve", after which the actions required to do this can be established, taking into account all the circumstantial factors and issues that may affect this, such as, for example, the peculiarities of the initial situation. The method also includes an assessment system. These elements ensure that the methodology conforms fully to the requirements of Law 20/2002, of July 5, as regards the conditions the Plan must meet.

Chapter Four contains the text of the Food Safety Plan of Catalonia. The first section defines the Plan's mission, purposes, objectives and strategic orientation. Its mission and purposes, defined as general guidelines to be followed, are to be achieved through objectives and interventions described in Sections Two and Three, grouped into two different blocks: firstly, objectives and interventions concerned with risk analysis and, secondly, those relating to cooperation, efficiency and coordination of food safety actions, key considerations for the full achievement of the goals regarding assessment, management and communication that constitute the central objectives of the Plan.

The block relating to risk analysis is structured into four sections: risk assessment; management of risks to health; management of issues relating to food safety; and communication about food safety.

For its part, the block devoted to cooperation, efficiency and coordination is structured into two sections: quality, efficiency and coordination of public administrations intervening in food safety; and cooperation and coordination with participants in the food chain.

Given the importance, singularity and complexity of the subject, it was considered necessary to devote a specific section to constant improvements to quality, efficiency and coordination of action by public administrations.

Official control is one of the main axes in risk management. Official control is a fundamental and crucial element that must be planned in accordance with to new European regulations governing the issue. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004, on “official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare”, establishes that multi-annual official control plans shall be promoted, embracing “all sectors and all stages of the feed and food chain”. The Food Safety Plan must provide for the official control objectives and interventions necessary to comply with requirements deriving from the application of these regulations.

The problems, objectives, interventions and assessment systems described in the Food Safety Plan were selected with the participation of public administration units responsible for carrying out activities or programmed intervention, scientific organisations, professional associations and consumers. This made it necessary to employ work systems enabling us to gather contributions from all parties related in some way to the food chain, such as the relevant departments and agencies from both the Autonomous Government of Catalonia and local authorities, as well as business associations, consumer groups, universities and other scientific bodies.

The interventions established under the Plan should be understood as lines of action that must find their executive projection in specific action programmes, which are to be defined, designed and implemented by the public administrations responsible. As provided for by Law 20/2002, of July 5, on Food Safety, an annual report is to be drawn up, analysing food safety management results and the food safety situation in Catalonia. This report must periodically summarise specific actions carried out in compliance with the interventions provided for under the Plan, making this a key element for ensuring that the official bodies responsible develop and carry out such interventions as specified.

The Plan details the commitments undertaken by the competent public administrations as regards the actions to be developed in order to achieve the objectives established. These objectives can only be fully achieved if the other participants in the food chain comply with their obligations and responsibilities, described in current regulations. The Plan establishes lines of action to be implemented by the administrations responsible for promoting and verifying compliance with these obligations.

The greatest efforts were made at all times to ensure the quality and rigour of content, taking into account the starting situation, the existing problems and the risks that needed to be managed. Since we start from a situation in which the different competent authorities and responsible units have carried out planning and execution of actions in areas in which they exercise powers, interventions that have been under way for some years are also included. These ongoing interventions constitute in themselves a solid block of measures that, under the framework of the Food Safety Plan, should evolve according to the principles of constant improvement, coordination, quality and efficiency.

The Plan design incorporates the value added provided by strategic planning, an integrated vision and a transversal approach to the entire food chain and the risk analysis process, the development of increased cooperation, coordination and efficiency in actions concerning food safety, as well as the impulse of constant improvement. Moreover, provision has also been made for certain new actions and improvements to increase the overall efficiency and cohesion of the system. These include, particularly, considerable strengthening of risk assessment and communication.

Efforts were also required to unify concepts, as the terminology used has different meanings or definitions according to the source consulted. The most important terms and their mean-

ing within the context of the Plan are listed in the Glossary section, whose aim is to make the contents of this document easier to read and understand precisely.

Furthermore, conditioning factors outside the control of planning bodies were also taken into account. These include regulations and decisions concerning risk management in force in the European Union and in the Spanish State, as well as the possible appearance of new problems requiring resolution. The Plan should be seen as providing a solid base for intervention, but it also needs to be remembered that unexpected circumstances may require new objectives and intervention measures to be included in it, or may make it necessary to change, modify or amend the Plan. In order to make provision for such a circumstance, permanent systems have been put into place to gather information about emerging problems and legal changes, amongst other things, as have procedures to ensure that an appropriate response is made in each case.

The process goal-based planning through which the Plan was drawn up is a methodology resulting from a logical sequence that is internationally recognised and whose effectiveness has been demonstrated. Although there are certain shortcomings and difficulties in applying it, the process leads the administrations with responsibilities in the field of food safety to become more strongly committed and to improve their coordination. The Food Safety Plan of Catalonia gives sector-based actions the quality of forming part of a whole and of belonging to an inter-departmental and inter-administrative project. The Plan also enables assessment of results, as well as encouraging debate, participation and consensus amongst all those involved in food safety issues, fostering and providing an enriching framework for learning. The Food Safety Plan, together with the annual report on analyses of food safety management and situation, is designed both to raise the profile of food safety policy in Catalonia, integrating measures, and to provide a tool to promote improvement in management of available resources.

In short, the Food Safety Plan of Catalonia is aimed at providing the population with the highest levels of food safety possible at all times. However, we should remember that the Plan forms part of a process of constant improvement in which the results of its application and scientific advances will enable us to formulate new objectives and interventions designed to achieve ever higher standards of food safety as the Plan is implemented and updated over the years.

The background of the slide features a stylized, light-colored illustration of wheat stalks on the left side, set against a solid orange background. The wheat stalks are depicted with long, thin leaves and several heads of grain, rendered in a minimalist, line-art style.

I

Food Safety Plan of Catalonia: background

Foodborne diseases continue to pose an important public health problem, both in the countries in our immediate environment and in the rest of the world. The closing two decades of the 20th century and the opening years of the 21st have been characterised by the emergence of new problems concerning food, placing the issue of food safety at the centre of attention for national governments, international organisations and society in general.

Today, despite the improvements achieved, there is more than ever a need to guarantee high standards of food safety and to regain and maintain public confidence concerning the safety of the food we eat. The public authorities are responsible for adopting policies that are appropriate to meeting these objectives.

The Food Safety Plan of Catalonia, which is designed to provide a regulatory instrument and frame of reference for such policies, is deployed in a highly specific context from the historic, social, economic and technological development standpoints. The Plan is, moreover, based on a series of principles and guidelines, outlined in Chapter II.

There follows a description of some of the main contextual elements that were taken into account in drafting and implementing the Food Safety Plan of Catalonia.

1 Brief historic perspective. Food safety and technical and production development

A historical review of food safety enables us to conclude that, at a very early stage, the root of problems lay in the difficulty of acquiring food in sufficient quantities, lack of hygiene, unbalanced diet and ignorance about the aetiology and transmission of disease.

The main problem that humankind has faced as regards food –and a problem that continues to exist in many countries– is the shortage of food.

The main problem that humankind has faced as regards food and which is, indeed, a problem that still continues to exist in many countries, is the lack of food in sufficient quantities. Nonetheless, technological developments in agricultural and industrial processes and advances in scientific knowledge have enabled this problem to be resolved, at least to a large extent, in the developed countries. At the same time, many water- and food-borne diseases, which once caused high levels of morbidity and mortality amongst European populations, have been brought under control. However, this fact cannot be allowed to detract from the importance of current problems and public concerns, nor should it lead to any reduction in the constant search for improvement that society demands. However this may be, the great advances in food safety achieved by the developed world should be very much taken into account when evaluating the real magnitude of the problems we face in this regard today.

Examples of the main foodborne diseases described over the course of history

Taking a historical perspective of food safety, we can mention certain foodborne diseases that have now, fortunately, been overcome, but which in their day caused serious suffering and loss to humankind, largely due to lack of knowledge at the time. There follow a number of examples.

Many foodborne diseases described over the course of history were caused by ignorance.

- Botulism, which is caused by an anaerobic bacterium, *Clostridium botulinum*, and is present, above all, in preserves which have not been properly sterilised, in sausages and in smoked fish. Poisoning by this bacillus, which can cause death, did not come under control until such a time as preventive methods and systems were developed.
- Ergotism, also known as ergot poisoning, an illness well known in the Middle Ages which is caused by the contamination of cereals by a parasitic fungus, *Claviceps purpurea*. Ergotism, which causes vasoconstriction in the extremities, leading to gangrene and often

death, is another example of the consequences of ignorance about the causes of disease in by-gone times.

- Scurvy, a condition resulting from deficiency of ascorbic acid (vitamin C) and whose symptoms are anaemia, general extreme weakness, muscular and joint pain and bleeding from the gums and under the skin, and affected all those unable to eat fruit and vegetables, sailors for example, until its causes were discovered. Scurvy, like pellagra, a disorder whose symptoms include red skin lesions, diarrhoea and mental confusion and is caused by dietary lack of niacin (vitamin B₃) or tryptophan, is linked to nutritional problems, and not to foodborne hazards. Nonetheless, these conditions illustrate the complex nature of the food factor as the origin of illnesses over the course of history, stressing the importance of taking nutrition into account when discussing the relation between food and health.
- Typhoid fever and cholera, acute intestinal bacterial infections that lead to watery diarrhoea, vomiting, rapid dehydration, acidosis and circulatory collapse, are pathologies that clearly illustrate the historic importance of serious water- and foodborne illnesses.
- Saturnism, or lead poisoning, is caused by using recipients made from materials containing lead. Also known as plumbism, this is an example of a condition produced by a chemical hazard described as far back in history as Roman times.

Food safety problems were complex and serious long before modern agri-food production techniques were introduced.

We can see, then, that food safety problems were complex and grave long before modern agri-food production techniques were introduced. Although most of the historic food safety problems have now been overcome in our part of the world, new challenges face us to which we need to find appropriate responses.

In recent years, attention has focused particularly on problems caused by emerging pathogens such as prions and verotoxigenic *E. coli*, dioxins and other environmental contaminants, pesticides, veterinary medicines and additives when used wrongly.

Despite the improvements achieved, such new problems make it necessary to continue working to ensure that the public enjoys the highest possible level of food safety.

The historic development of techniques designed to improve food safety

Since humans discovered fire, heat treatment has been one of the principal ways in which we protect ourselves against the hazards that food may harbour.

Throughout history, humankind has constantly sought to develop techniques aimed at improving the safety of food products. Ever since humans discovered fire, heat treatment has been one of the principal ways in which we have protected ourselves against the hazards that food may harbour. Heating food makes it easier to digest, destroys pathogenic germs and for a time blocks the mechanisms that lead to food deterioration.

Salting, drying and smoking are other effective methods that have been used to conserve food since prehistoric times.

The use of salt, a highly effective technique for conserving food against microbiological contamination, has encouraged the custom of salting food to such an extent that this habit now constitutes a health problem for people in the West, as excess salt can cause pathologies associated with arterial hypertension. This is an example which illustrates the need for care when using food production and conservation techniques, whether recently introduced or used since time immemorial.

We cannot forget, in this brief reference to the history of food safety, the contribution made by Pasteur in the field of microbiology, particularly as regards the link between germs and disease, fermentation and the mechanisms that cause microbial contamination of food. The contribution of Nicolas Appert and “appertisation” or sterilisation as a way of conserving food were also crucial to the development of the food industry. Another outstanding devel-

opment was the widespread introduction of cooling technologies which, together with sterilisation and pasteurisation, represented a great step forward in food safety.

Despite improvements and advances, solutions have still to be found for many food safety problems.

Despite the fact that the fight against food hazard can, from a historical perspective, be considered successful, and although we have ever more knowledge and techniques available to ensure high levels of food safety, technological evolution has led to the emergence of fraud and other problems that have contributed to the present negative perception of technification and industrialisation that is widespread amongst the general public in Europe.

The bovine spongiform encephalopathy crisis, linked to the use of animal protein in feed, is an illustrative example of this recent phenomenon.

Although we can safely affirm that we have never before enjoyed such access to food and such high levels of food safety in Europe, nor so many resources and efforts aimed at ensuring food safety, the population does not always share this perception. Moreover, there still remain many problems that have still to be resolved, obliging us to continue working to ensure higher safety levels and the best possible information in order to regain public confidence.

Food safety and technical and production development

Agriculture and the food industry in Europe have long been obliged to develop largely with a view to increasing productivity, since for many years the main problem, particularly up to the 1960s, was to provide the population with sufficient food.

Risks are involved in both intensive production and more ecological systems. These risks, often shared by both, must be managed appropriately.

This production effort was accompanied by important reductions in food risks. However, there exists a general perception that quite the opposite has occurred. Both agriculture and industry have devoted enormous efforts not only to increasing production, but also to improving safety. Animal and plant preventive measures and plans have reduced and in some cases partially eradicated diseases that traditionally presented serious public health problems, such as tuberculosis, brucellosis and ergotism, amongst others.

However, consumers do not always perceive this evolution in such a positive way, and have maintained an idealised vision of traditional agriculture and livestock farming, forgetting how hard these activities are, their low productivity and the associated food hazards. There exists, in the collective imagination of urban societies, a direct link between natural food and healthy food, a perception that does not always respond to reality. Threats of natural origin can also be important, on occasions even greater than those associated with industrialisation. The collective consciousness needs to understand the fact that all foodstuffs and all production systems entail risks requiring correct, appropriate management, and we need to give up all our preconceived ideas about inherent or *a priori* safety.

We need to find a place for ecological production systems alongside intensive production. Their co-existence is both possible and desirable.

We should also remember that all technological innovation may entail risk. However, rejecting technological advances for this reason could cause enormous damage and deprive society of important benefits. The solution is not, therefore, to reject new production systems out of hand, but to seek a balance between improvements in production techniques and necessary acceptance of risks, as long as these can be handled by appropriate management measures.

The idea of a return to traditional production methods is, to a large extent, utopian, as it would be practically impossible to meet the needs of the population today in this way, and huge ecological adjustments would be required, as much larger areas of land would be needed for agriculture and livestock farming. Our objective should therefore be a food production chain that employs modern methods, meets productivity requirements and guarantees food safety and quality whilst also being ecologically, economically, ethically and socially sustain-

The public should have a greater awareness and understanding of the production methods used today in order to increase their confidence and to remove the link that is often made between intensive production and loss of quality and safety.

able. We also need to find a place for ecological production systems as a valid formula that meets the wishes of certain consumers and should not be seen in opposition to intensive production. Consumers and society in general will decide on how these two production models will evolve in the future, and the role they will play. In the meantime, their co-existence is both possible and desirable.

Whatever choice citizens finally make, both ecological and intensive systems must be subject to the necessary food safety measures in accordance with the hazards linked to each process, and which are often, in fact, shared by both.

The public should be better informed and made more aware of the food chain, from primary production to delivery to the final consumer. This would increase general understanding and acceptance of the production methods used today. It is important to promote fair appreciation of the benefits generated by modern methods, though without forgetting the risks entailed by them, and to discourage all references to an idealised vision of traditional production systems. Public understanding of these issues should be promoted in order to increase confidence and to show how erroneous the link that is often made between intensive production and loss of quality and safety can be.

Information and transparency are key factors in achieving this goal, and all food chain stakeholders should devote efforts and activities of all kinds to this. Such activities could well include introducing an open-door policy at food chain companies and making available to members of the public all information that might be of interest to them.

2 Food safety levels in Catalonia compared to other regions

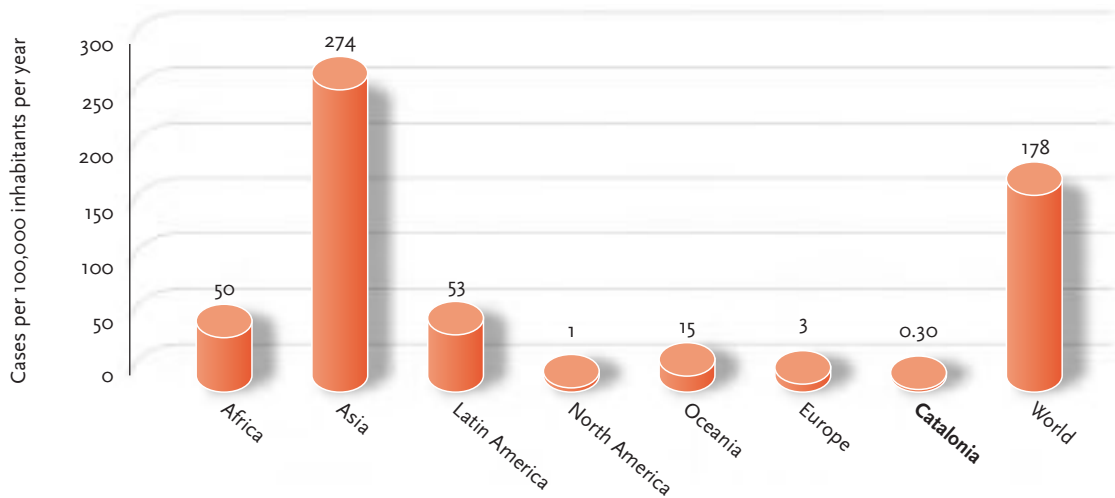
In order to put the subject of food safety in Catalonia into context, it is necessary to compare our situation to that in other European Union regions and third countries. There are serious methodological difficulties in making such a comparison, however, as it is by no means easy to estimate the overall level of food safety in a particular territory.

Particularly dramatic is the situation described by the World Health Organisation, which estimates that 2.1 million people are killed every year by food- and waterborne diarrhoeal diseases in the developing countries

One possible indicator might be the number of existing foodborne diseases. With regard to this parameter, particularly dramatic is the situation described by the World Health Organisation in its report *WHO Global Strategy for Food Safety*, which estimates that 2.1 million people are killed every year by food- and waterborne diarrhoeal diseases in the less developed countries. Due to the food safety measures that operate our part of the world and to the effectiveness of our health care systems, such figures may seem far-fetched to us, but the truth is that they graphically reveal differing levels of health and safety in different countries according to their degree of development.

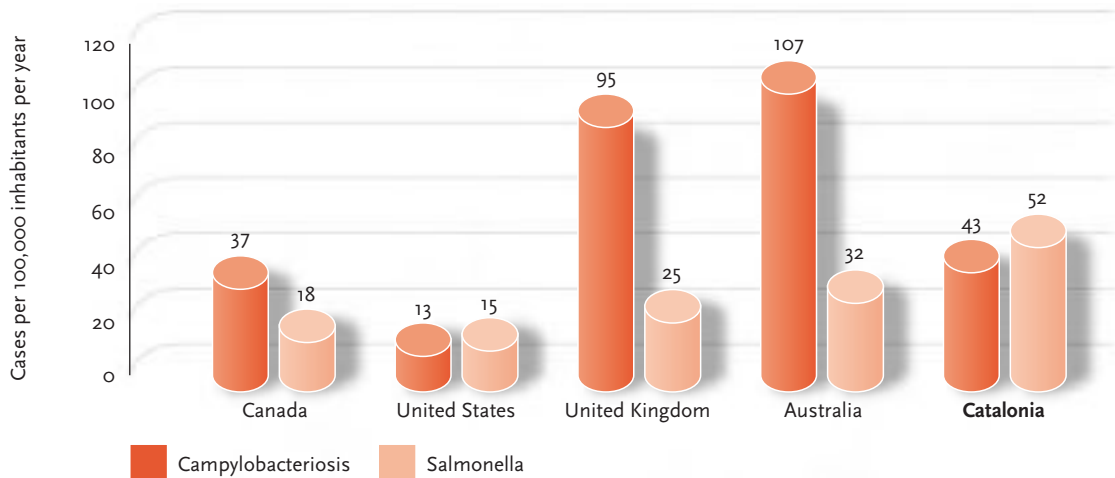
Official data gathering systems do not normally include many foodborne diseases that occur in the domestic environment or cause less serious symptoms. Moreover, notification systems vary greatly as regards the criteria they use and the efficiency of procedures, making it difficult to process information comparatively. Nonetheless, the graphs below include data on the incidence of certain foodborne diseases declared in a number of countries. Although, for the reasons given above, it is not possible to guarantee that the data is really comparable, these figures nonetheless provide an interesting and useful portrait of the situation.

Incidence of typhoid fever by world region, according to different sources



Source: *Bulletin of the WHO* (May 2004). *Butlletí Epidemiològic de Catalunya* (October 2003).

Incidence of salmonella and campylobacteriosis in Catalonia and certain OECD countries, according to different sources



Source: WHO Department of Food Safety. "The present state of foodborne disease in OECD countries. 2003". *Butlletí Epidemiològic de Catalunya* (August 2003).

The lack of a system enabling us to carry out comparative studies between territories makes it all the more necessary to redouble efforts to design better, more standardised assessment systems to ascertain food safety levels. Such systems should be based, without doubt, on studies of multiple data which go much further than mere evaluation of cases of foodborne diseases. Initiatives launched by the World Health Organisation, such as the Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe, and the European Centre for Disease Prevention and Control, established under Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004, may prove most useful for this purpose.

Food safety plans and their assessment systems should also make an important contribution to steps towards the standardisation of data-gathering. This will require standardisation of international parameters for indicators, something that may be achieved in the future.

3 The concept of food safety. Related issues

Before moving on to discuss food safety problems and to describe the interventions necessary to prevent or resolve them, we need to determine the field of action to which efforts should be addressed. This entails defining the concept of food safety and its limits as established with a view to drawing up the Food Safety Plan of Catalonia.

There is no one, single, unique definition of food safety. According to the definition adopted at the World Food Summit in 1996, food safety means “access to sufficient quantities of safe and nutritious food”.

In the context of countries and periods where problems exist for providing the population with food, the concept is closely linked to the idea of guaranteeing access to sufficient sources of food. It logically follows, then, that we should use more precise terms such as “food safety” when making specific reference to issues relating to health risks.

In the developed countries at present, the concept of food safety principally concerns guaranteeing the safety of food, without going into questions regarding guarantees of supply, as this problem has, to a large extent, been resolved. For this reason, the Plan does not include issues related to food availability within the concept of food safety.

Nonetheless, the concept of food safety has acquired a broad, complex sense in the developed countries, one which goes beyond the concept of safety itself to include conditions also relating to public perception, confidence and expectations. It is not possible to speak of a high level of food safety unless a correspondingly high level of public confidence is achieved.

However, confidence is a complex concept, one which is influenced by a large number of interrelated factors. The public has the legitimate expectation not only of being kept safe from real risks, but also of feeling safe and far removed from the need for permanent suspicion. We are clearly faced by demands which go beyond the need to protect health against foodborne illness to embrace the additional expectation that food will also be nutritional and good for the health. Besides these guarantees of wholesomeness and healthiness, moreover, people in western societies also demand that the food chain should be ethically, ecologically and economically sustainable.

Furthermore, consideration of economic aspects should not be forgotten within an overall concept of food safety. Applying preventive and management measures places an additional burden on companies, as such measures require financing. This state of affairs can even distort business competitiveness if at least equal conditions are not guaranteed amongst the different operators in the same market. Along with health protection, this is one of the main reasons for the provision of mechanisms in the European Union and the global market to establish and maintain conditions that are, at least, comparable.

Regarding the economic factor, it is also true that food crises can have disastrous effects on market development and the viability of certain sectors. On occasions, such crises may not even have started in the sector that suffers the consequences. Due to this close interrelation, then, the food chain must be seen as a structure in which each stage can be greatly affected and influenced by conditions that have their origins in others, and as concerning both health and economic aspects.

All stakeholders in the food chain must commit themselves to sharing responsibilities that go beyond their own particular sphere of activity, since the consequences of their actions, as regards health, economic and social issues, are not limited solely to their area of activity. In this light, food safety can be seen as a common good, one requiring real, effective participation and cooperation amongst all players in the interests of all.

It is not possible to speak of a high level of food safety unless a corresponding high level of public confidence can be achieved.

Apart from guarantees of safety, Western societies also demand that the food chain should be ethically, ecologically and economically sustainable.

All stakeholders in the food chain must commit themselves to shared responsibilities that go beyond their own particular sphere of activity.

Food safety, then, is related to production costs, competitiveness, fair trading and the viability of the sectors involved, for people in modern societies expect and demand guarantees with respect to all these factors.

Animal health crises often have serious effects on consumption and public confidence, even in cases where there is no risk to human health.

Animal health crises, such as foot and mouth and swine fever outbreaks, during which the public witnesses scenes of mass slaughtering in the media, serve only to reinforce the negative image that part of the population holds with regard to intensive primary production. Such situations do not help to improve consumer confidence in food of animal origin, and at times they can generate effects on consumption similar to those caused by zoonotic diseases, despite not posing any threat to human health. Moreover, we also need to take into account the possibilities of non-zoonotic diseases spreading from one species to another, a growing concern if we remember experiences in recent years concerning spongiform encephalopathy, avian influenza, etc. Animal health, animal welfare and communication policies in this field, are, then, strategic elements in attempts to regain consumer confidence.

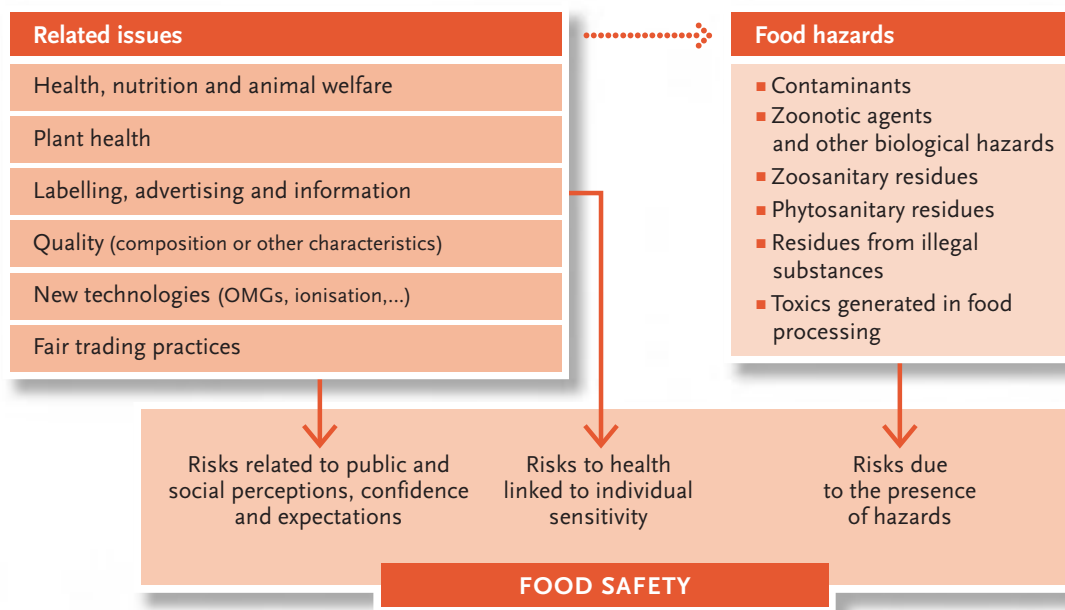
We therefore need to take a global, integral approach to this issue, bearing in mind many concerns that go beyond epidemiological statistics, scientific estimates of health risks and public health concerns. This complexity clearly shows the need to draw up studies and decision-making procedures that enable all factors involved to be integrated in a balanced way, and to take steps to make it easier for society to understand the decisions that are taken.

Another issue linked to food safety is the correspondence between information and advertising about food and its real characteristics. Given the influence this may have over consumer decisions, the information provided to the consumer about the quality, composition or functional and nutritional properties of food must be completely reliable. There is an important link between this issue and certain health problems, such as, for example, allergies and intolerance to certain ingredients, as well as nutritional disorders. Moreover, we also need to bear in mind issues such as the right not to consume ingredients and components due to religious, ethical or other reasons. This right cannot be guaranteed if products do not correspond to the information provided on labels or advertising or as required under current legislation.

Given the influence that they may have over consumer decisions affecting health, the information provided to the consumer about the quality, composition and functional and nutritional properties of food must be completely reliable.

Taking into account all the above considerations and issues, it is clear that there is a need to define the concept of on food safety within the context of the Plan in order to determine its sphere of action. Our response to this need takes into account the stipulations laid down in Law 20/2002, of July 5, in which food safety is defined in terms of guaranteeing consumers the safety of foodstuffs with regard to any biological, physical and chemical hazards they may contain. Although this is the priority area of concern, however, the law also refers to aspects that are related either directly or indirectly to such issues as, for example, health, nutrition and animal welfare, plant health and environmental pollution. Besides those issues to which the Law expressly alludes, a global, integral concept of food safety should also include other concerns that citizens today link to the idea of food safety. These include food quality, new technologies, new ingredients and new foods. The Food Safety Plan of Catalonia must, therefore, take into account all these considerations, which we will hereafter refer to as “issues relating to food safety”, where there exists a direct or indirect link to public health or to ideas, confidence and expectations regarding the food production chain.

The concept of food safety and related issues



4 Foodborne hazards

The central concern of food safety, defined as the guarantee that foodstuffs should cause no harm to consumers when prepared and/or consumed according to the use for which they are produced, is that food should present no hazards whatsoever. To ensure the absence of hazards, or to reduce any hazards to levels that do not constitute a risk, is the principal purpose of any food safety system.

Food hazards are defined as “any biological, chemical or physical agent present in food or feedstuffs, or any biological, chemical or physical condition of food or feedstuffs that may cause an effect harmful to health”. Human responses to diseases or the agents that cause them, including so-called adverse reactions, depend on a series of variables and on many interrelations between these. For this reason, their effects on health may be serious for one person yet slight or non-existence for others.

There are a whole series of factors, such as misuse of chemical products in agriculture, environmental pollution, the use of banned additives and the intrinsic characteristics of micro-biological agents, amongst others, that contribute to the emergence of hazards in the food chain or make them difficult to mitigate.

In recent years we have observed a clear increase in public awareness and concern about the effects that food hazards may have on the health. Consumers express more and more misgivings about additives, chemical waste from products used in agriculture and veterinary care and, generally speaking, biological, chemical and physical contamination and practices used in handling and processing food throughout the food chain that may lead to the introduction or increased presence of food hazards.

Although there will be a certain degree of co-existence between the two, current debates about food safety and hazards point to a future scenario in which efforts will focus on spe-

cific food safety objectives (FSOs), rather than taking a more traditional focus based on a detailed description of the measures that need to be adopted in order to achieve this goal. A food safety objective is defined as the maximum frequency and/or concentration of a hazard in a food at the moment of consumption which ensures or contributes to attaining a suitable level of protection. To meet these food safety objectives, performance objectives (POs) are established. POs are defined as the maximum frequency and/or concentration of a hazard in a food at a given stage in the food chain prior to the moment of consumption, which ensures or contributes to attaining acceptable levels of protection or safety.

The European Commission has recognised the advantage of such a system. However, the definition of an FSO or a PO must be based on solid scientific advice. Establishing such objectives requires time and careful thought and reflection about risk management. For this reason, they have still not been introduced on a Community-wide basis as yet, although procedures have been put in place that will allow the Commission to do so in the future.

As our scientific knowledge develops, new hazards of which we are at present unaware may be revealed.

Food hazards can be classified into three broad categories: physical, chemical and biological. A more detailed classification, along with additional information about the hazards associated with the food chain, can be found in Annex I of this document. The physical hazards (for example, stones in cereals or pulses, pieces of bone in meat) are the easiest to explain. However, the effects of chemical and biological hazards on human health are more difficult to understand due to the complexity of the interactions between agents and human physiology. This complexity is even greater in the case of chronic exposure to chemical hazards.

It is difficult to draw up an exhaustive list of all existing or potential hazards. The future evolution of scientific knowledge may reveal new hazards of which we are at present unaware. Moreover, changes in production processes or consumer habits may lead to the appearance of new hazards or increase the importance of existing ones, whilst the incidence of others may decrease or disappear. The environment in which the Food Safety Plan of Catalonia is to be deployed must be understood as a dynamic one requiring constant adaptation according to changing circumstances and problems at any given moment, not only in terms of the variable dynamic that characterises the hazards to be faced, but also the way in which they are assessed, managed and communicated.

5 The food chain. Overall figures for Catalonia

We can define the food chain as the series of phases or stages necessary for the production of food and feedstuffs, from primary production to the moment of consumption.

The objective of the Food Safety Plan of Catalonia is to guide coordinated intervention by the competent public administrations at the different stages and in the different sectors and activities that form the food chain, consistent with the “from the farm to the table” principle. It is necessary, therefore, to analyse the concept of the food chain and to identify the stages, sectors and activities it embraces, as this comprises both the context and the area in which action under the Plan is to be carried out.

We can define the food chain as the series of phases or stages necessary for the production of food and feedstuffs, from primary production to the moment of consumption, including the production and sale of any raw material, product and service necessary for their production, processing and/or distribution and sale.

According to the Plan, the phases or stages that form the food chain are as follows:

- I Primary stage
- II Processing and distribution stage
- III Retail stage
- IV Consumption stage

We define food chain products as a general term that includes the animals and/or materials used and/or generated by any activity in food and feed production and the distribution chain, including agricultural products, live animals, means of production such as phytosanitary and zoosanitary products and fertilisers, materials that come into contact with food, food and drink products, feedstuffs and any other material or substance used.

Despite this simplified structural summary, the food chain is hugely complex internally, and is also characterised by the large number of interrelations which need to be taken into account under the framework of the Food Safety Plan.

Firstly, we should point out that all activities in the food chain, and particularly those involved at the primary stage, must be carried out under suitable environmental conditions in order to minimise any chemical or biological contamination of food chain products. For this reason, the Food Safety Plan must also take into account certain environmental issues.

Moreover, food chain products follow a flow that is neither always linear nor always one-way. Certain activities included at a given stage generate raw materials necessary for other activities at that and other stages. For example, agricultural activities generate raw materials that are used not only at the retail and/or processing stage for human consumption, but also at the primary stage in the production of feed for use in livestock farming. Again, certain activities forming part of the processing stage generate by-products that are used as raw materials at the primary stage.

In the case of a regional territory, as is the case of Catalonia, we also need to take into account issues relating to the entrance and exit of food chain products that can be made either from primary stage products or others from the processing and distribution stages.

We also need to take into account matters relating to waste disposal. Such issues are transversal in nature, since waste is present at all stages in the food chain.

These are just a few examples to illustrate the complex nature of the food chain and the close interrelations between the different stages, which sometimes generate a structure resembling more a network than a chain. These are issues that must be taken very much into account in any overall, strategic food safety planning.

Structure of the food chain. Stages, sectors and activities

In order to develop the Plan, we need to remember that the food chain structure is made up of the aforementioned phases or stages, each of them integrated into a series of sectors and activities. Although any theoretical structure proposed may be open to debate and to change and improvement in the future, it is convenient here to use as a reference model the ordered structure of the food production chain which corresponds to the classifications and information management systems that exist at present.

Within each of the phases or stages in the food chain we can describe different sectors that are defined according to the types of products or services they generate. Moreover, different activities or groups of activities take place within each sector. The food chain is structured, then, into stages, sectors and activity groups which must be defined in order to create a

schematic diagram or map of the food chain that will enable us to refer more specifically to interventions established under the Plan.

We can define the sector as each of the parts into which the different phases in the food chain can be divided, and which groups together the activities related to a particular product or class of products. We define activities as the actions carried out with regard to food chain products. Examples include agricultural and livestock farming production, food handling and processing, storage and distribution, as well as other, more specific activities linked to certain types of product (abattoirs, meat cutting plants, fish exchanges, use classification centres, etc).

In accordance with this model, there follows a definition of the stages, sectors and activities which form the food chain, and which are the subject of interventions under the Plan.

1 Primary stage

The broad, varied sectors and activities that form part of the primary stage can be grouped as follows:

- Raw materials and production means
- Agricultural produce, animal produce and produce from fisheries, hunting and wild vegetables and plants.

Raw materials and means of production

This group includes a huge and varied range of activities and sectors, from obtaining plant and mineral raw materials to producing and distributing different types of processed products that are used at different stages of the food chain. It includes raw materials and products of biological origin such as wood, cork and other vegetable products, and products of mineral origin, including salt, calcium carbonate and other minerals and chemicals used to produce ingredients, additives, and other chemical substances used to produce food, feed, phytosanitary and zoosanitary products and fertilisers.

This primary stage in the food chain is characterised by a high degree of complexity, due not only to the huge variety of raw materials and products involved, but also to the fact that each of these is, in turn, subject to varied and complicated production, processing and distribution processes. On many occasions, moreover, these processes are not exclusively related to the food chain, but are also used to supply other sectors of activity. This diversity and non-specific nature explains why, traditionally, production means were not considered part of the food chain. Nonetheless, they should be the subject of particular attention in order to detect and manage the risks associated to these processes, particularly if we bear in mind that they have been at the origin of several of the most important food crises in recent years.

Although, traditionally, production means were not considered part of the food chain, they should be the subject of particular attention.

Primary stage in the food chain. Raw materials and production processes

Sectors	Activities
<ul style="list-style-type: none"> ■ Chemical products obtained from natural resources (examples: salt, calcium carbonate, iron, sulphur, etc) 	<ul style="list-style-type: none"> ■ Operation of natural resources
<ul style="list-style-type: none"> ■ Water for irrigation and supply 	<ul style="list-style-type: none"> ■ Food handling
<ul style="list-style-type: none"> ■ Biological products obtained from natural resources (wood, cork and other materials of wild plant origin) 	<ul style="list-style-type: none"> ■ Storage and distribution
<ul style="list-style-type: none"> ■ Feedstuffs 	<ul style="list-style-type: none"> ■ Importation
<ul style="list-style-type: none"> ■ Veterinary medicines 	<ul style="list-style-type: none"> ■ Retail trade
<ul style="list-style-type: none"> ■ Pesticides 	
<ul style="list-style-type: none"> ■ Plants and seeds 	
<ul style="list-style-type: none"> ■ Animal semen, ova, embryos 	
<ul style="list-style-type: none"> ■ Biological and chemical fertilisers 	
<ul style="list-style-type: none"> ■ Additives and technological adjuvants for animal feeding 	
<ul style="list-style-type: none"> ■ Materials for contact with feed and feed ingredients 	

Agricultural produce, animal produce and management of fishing, hunting and wild plant resources

These groups include sectors and activities engaged in producing biological raw materials for the processing and/or distribution stage in food or feedstuff production.

Primary stage in the food chain. Agricultural produce, animal produce and operation of fishing, hunting and wild plant resources

Sectors	Activities
<ul style="list-style-type: none"> ■ Milk (cows, sheep, goats) 	<ul style="list-style-type: none"> ■ Farms and harvesting in farming areas
<ul style="list-style-type: none"> ■ Saltwater and freshwater fish products (fish, shellfish, molluscs, other marine invertebrates, frogs legs) 	<ul style="list-style-type: none"> ■ Storage and distribution
<ul style="list-style-type: none"> ■ Eggs (hens, other birds) 	<ul style="list-style-type: none"> ■ Importation
<ul style="list-style-type: none"> ■ Honey 	
<ul style="list-style-type: none"> ■ Types of meat production (beef, lamb, goat, pork, horse, poultry, rabbit, farm game, wild game) 	
<ul style="list-style-type: none"> ■ Oil (olives, oil seeds) 	
<ul style="list-style-type: none"> ■ Vegetables, mushrooms and fruit (green vegetables, fungi, fruit and dried fruit) 	
<ul style="list-style-type: none"> ■ Tubers 	
<ul style="list-style-type: none"> ■ Pulses 	
<ul style="list-style-type: none"> ■ Cereals 	
<ul style="list-style-type: none"> ■ Spices 	
<ul style="list-style-type: none"> ■ Food stimulants (cacao, coffee and infusions) 	
<ul style="list-style-type: none"> ■ Natural sweeteners (sugar beet, honey) 	

II *Processing and distribution stage*

This stage embraces the distribution of products from the primary stage, with or without prior processing, and which can be more or less complex according to the particular case.

Processing and distribution stage

Sectors	Activities
■ Milk and dairy products	■ Food processing or handling
■ Fish, shellfish, molluscs and fish products	■ Storage and distribution
■ Eggs and egg products	■ Importation
■ Meat and meat products (cattle, poultry, farm game, rabbits, wild game)	■ Specific activities in certain sectors:
■ Oils and edible fats	● Milk collection centres, ships, exchanges, waste-water treatment stations, shellfish farms, aquaculture facilities in the fish and fish products industry
■ Vegetables, mushrooms, fruits and vegetable products	● Collection and packaging centres in the egg and egg products sector
■ Tubers and products	● Abattoirs and cutting plants in the meat and meat products sector
■ Pulses	● Catering services
■ Flour and products	
■ Cereals	
■ Spices and condiments	
■ Food stimulants and products	
■ Natural sweeteners and products	
■ Alcoholic beverages	
■ Water and ice	
■ Soft drinks	
■ Ice-cream	
■ Catering services	
■ Prepared or precooked dishes	
■ Non-dairy desserts, breakfast products, potato chips and appetizers, intermediate food preparations for industrial use	
■ Dietary products and foodstuffs prepared to specific formulae (baby food and milk, diet food, food for special medical uses)	
■ Additives, aromas and technological adjuvants	
■ Chemical products used in the food industry.	
■ Materials and objects in contact with food	
■ Polyvalents (includes bottling and packing companies, storage companies, distributors and retailers for more than one food type, markets, supermarkets and similar)	

III *Retail and restaurant trade*

This stage includes all activities providing retail sales and services directly to the final consumer, including restaurants, bars and cafeterias.

IV Consumption stage

This stage includes transport, storage, handling, production and/or consumption by final consumers in the domestic sector.

Other sectors and activities linked to the food chain

We also need to take into account certain groups of activities in the food chain which cannot be exclusively included in previous sections, as they are linked to all sections. In any case, these are components that need to be seen from an integral, overall vision of the food chain.

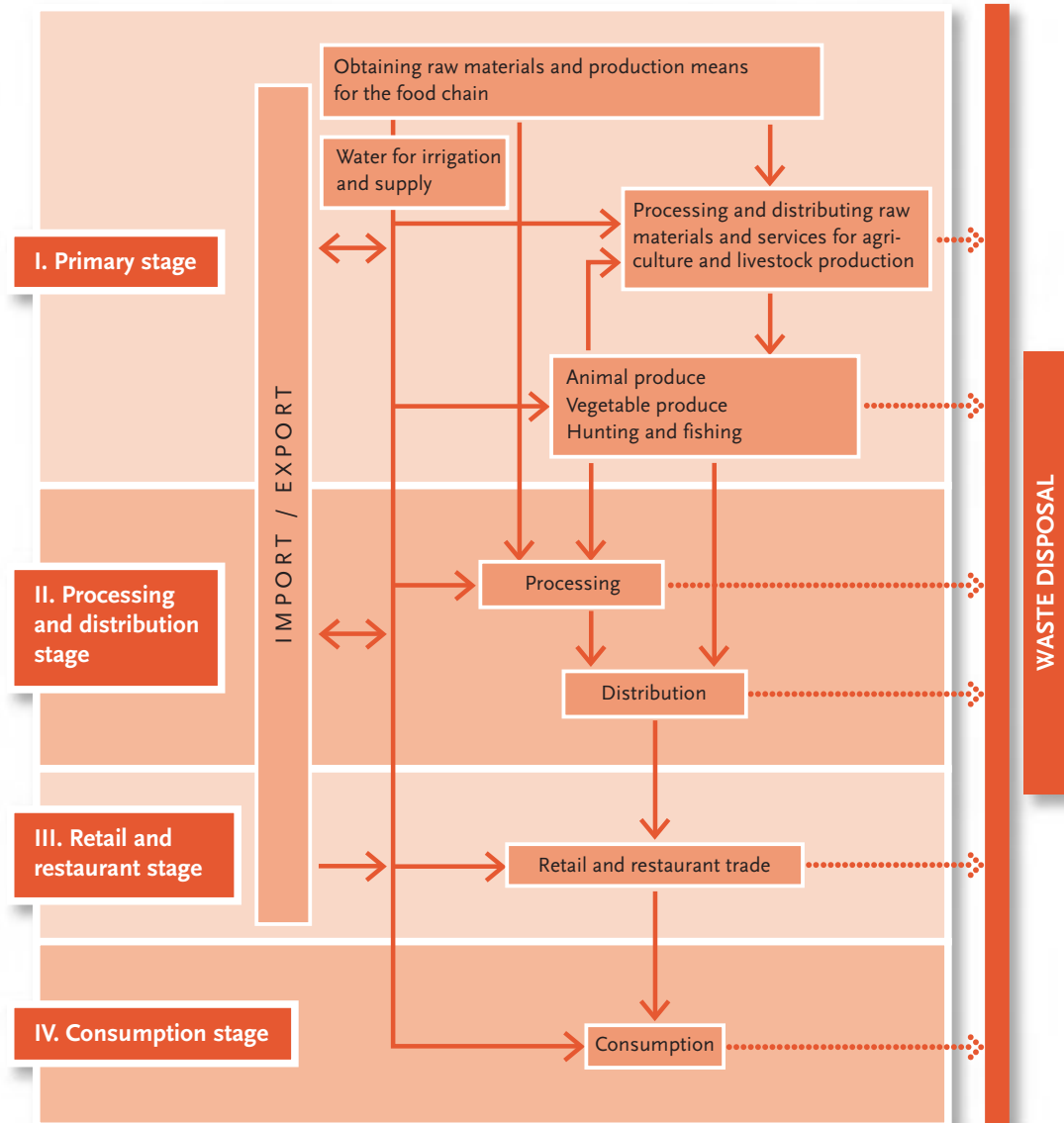
- **Food chain company service providers.** This section includes activities provided by certain specific services and which may, on occasion, be addressed to different food chain stages and activity groups, so that they cannot be specifically classified under any particular stage or activity. This group includes activities and companies that provide services in the following fields:
 - Treatments to eradicate pests
 - Advice and self-control in food hygiene, animal health and plant health
 - Training
 - Analysis laboratories
 - Waste collection and management
- **Activities with environmental effects on the food chain.** All issues relating to the environment are very closely linked to these questions due to their effects on food chain products, particularly on products from farming, livestock, hunting, fishing and fish farming activities. For this reason, the Food Safety Plan should also provide for interventions aimed at reducing pollutant emissions and surveillance of the presence in the environment of contaminants that could enter the food chain, such as, for example dioxins or heavy metals, as well as certain biological agents.

Specific hazard assessment and management activities should be particularly intensive in areas that have traditionally not been the object of clear action from the point of view of food safety.

If we consider the complexity of the food chain we have just described, we can see that there is a clear need to describe in detail all areas which affect food safety. Similarly, we need to determine the risks linked to each and the factors entailed in developing appropriate risk management measures. The specific activities concerning risk assessment and management should be particularly intense in areas which have traditionally not been the object of clear action from the point of view of food safety.

The different sections of the Plan should be identified and the risks associated with each stage, sector and group of activities evaluated, whilst the possibilities for intervention in each should also be determined. This is particularly important as regards risk assessment, which should help to increase existing knowledge and to guide efforts towards reducing any weak points that may exist as regards safety.

The food chain



Overall figures on the food chain in Catalonia

Having seen the overall structure of the food chain, which will serve as a reference point for the Food Safety Plan, we now need to consider some overall facts and figures about the sectors and activities which go to form the food production chain in Catalonia. There follows some general information that should be taken into account as contextual data surrounding the Plan. More detailed figures are available on the websites of IDESCAT (Statistical Institute of Catalonia), the Ministry of Agriculture, Food and Rural Action and the Health Ministry.

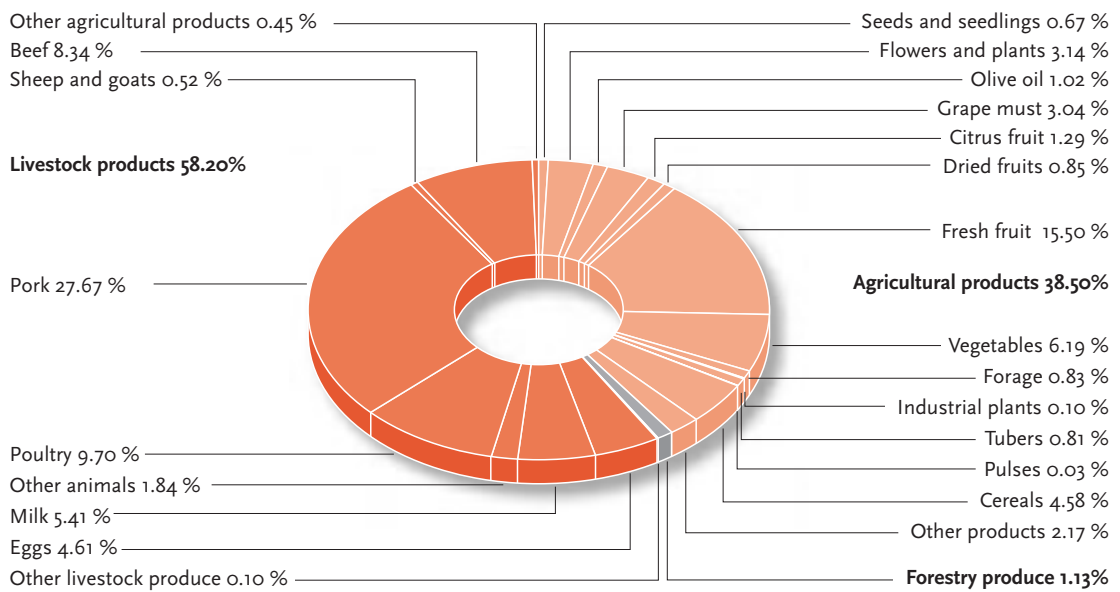
Primary stage

Although agrarian activities account for only a small proportion of the Catalan economy overall, a large proportion of Catalan territory is made up of rural areas. Agricultural and livestock farming production accounts for around 1-2% of Catalan GDP. The economic value of final

agrarian production (FAP) is made up of around 55-65% final livestock production and 35-40% vegetable produce.

The production area with the greatest economic value is pork meat, which represents around 30% of FAP production, followed by the fruit industry, which accounts for 15%, and poultry, approximately 10%. Beef production is also important, accounting for around 8% of FAP, whilst milk accounts for a further 5%. Other products, such as wine (3-4%) and olive oil (1-2%) are important particularly in certain *comarques*, or counties. The oil and wine sectors –which are also high quality areas– continue to present considerable growth potential.

Distribution of final agrarian production



Source: Summary of Catalan Agricultural Production. 2003. Ministry of Agriculture, Food and Rural Action. Autonomous Government of Catalonia.

An outstanding characteristic of the agricultural sector in Catalonia is its close links to primary and secondary processing agri-food industry activity.

The population employed in agriculture accounts for approximately 2% of the total occupied population. Although the sector's importance is low in general terms, this is the activity group which employs most people in several inland and Pyrenean mountain *comarques*. This importance in terms of population increases if we also add people working in the food and drink industry, who account for 3-4% of the total occupied population.

An outstanding characteristic of the agricultural sector in Catalonia is its close links to primary and secondary processing agri-industrial activity. Growing demand from the urban population –a population which is itself constantly rising– has led to the development of considerable agri-industrial activity. This concerns, first and foremost, the supply of foodstuffs to the population of Catalonia (42% of sales), but also the distribution of quality produce to the rest of Spain (46%). In recent years, moreover, exports have also risen, chiefly to European Union countries (7-8%), although these figures do not fully balance imports of products from these countries, nor raw materials imported by the intensive livestock farming sector.

The leading exports are meat, oil and fat, drinks and alcohol, three sectors where there also exists considerable agri-industrial development. The largest imports are raw materials used to produce feedstuffs, demonstrating the dependence of the Catalan livestock farming sector on imported production means.

Based on statistics describing the structure of farming businesses in Catalonia, we can generate a number of important indicators to illustrate the state of the Catalan countryside and its development over time.

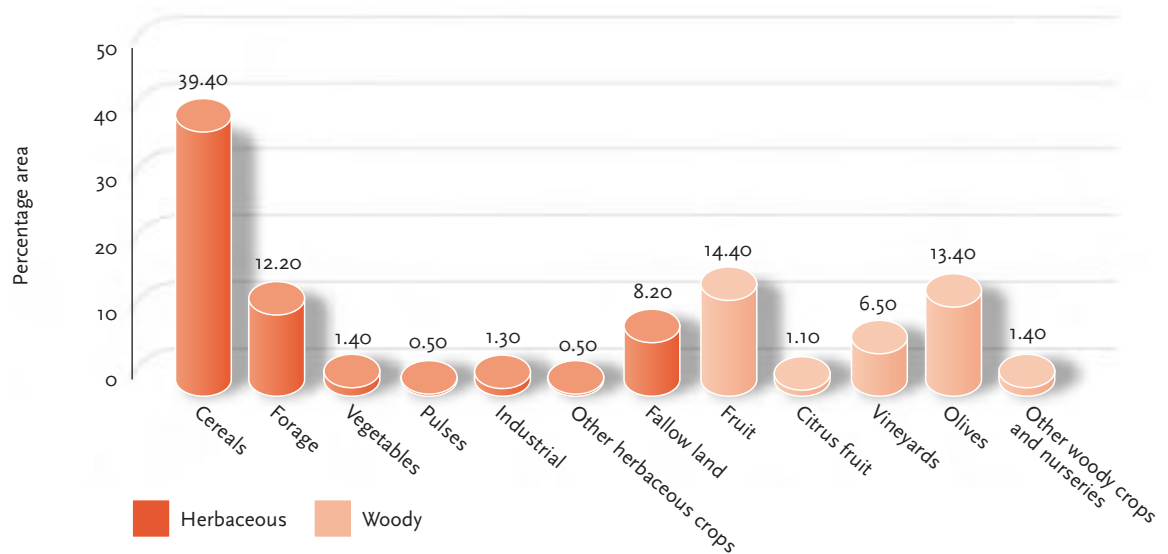
The number of farming businesses in Catalonia has fallen gradually, year after year, whilst the average size of farms has risen sharply, from 12.5 hectares in 1989 to 19 hectares in 2003. This increase in size has also enabled Catalan farms to become more competitive. However, despite the improvement in the age structure seen in recent years, the population engaged in agrarian activities continues to suffer a serious ageing process.

Agriculture

Nearly 30% of Catalan land is given over to crop farming. Of this, some 30% is occupied by irrigation farming, whilst the remaining 70% is dry farming land. By crop group, cereals are those that occupy the largest area, accounting for 37-40% of the total, distributed over practically the entire territory and situated for the most part in the Catalan Central Depression, as well as covering part of the Mediterranean area devoted to dry farming.

The area occupied by forage crops accounts for 12% of the total. As regards woody crops, these are largely made up of typically Mediterranean products: fruit (14-15%), olives (13%) and grapes (7%), spread over the entire territory with the exception of the Pyrenean area.

Farming areas in Catalonia



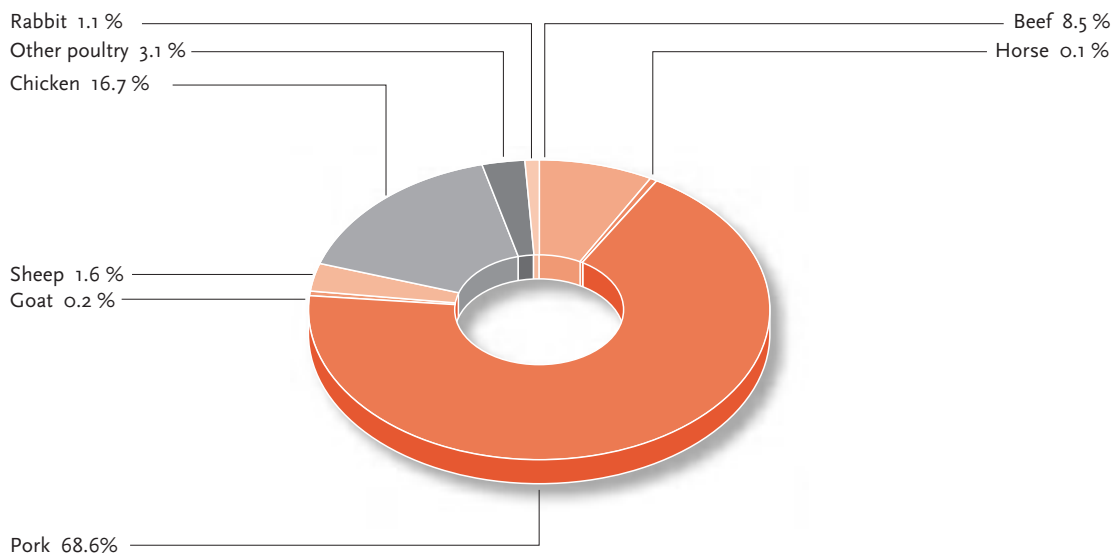
Source: Summary of Catalan Agricultural Production. 2003. Ministry of Agriculture, Food and Rural Action. Autonomous Government of Catalonia.

Livestock farming

Livestock farming accounts for around 60% of total farming production. Intensive farming (pig, beef-finishing, chickens and eggs) is a particularly important activity here, enabling many small farms to increase their financial turnover considerably. Pork accounts for 30% of final agrarian production (FAP). Catalan poultry farming occupies an important place in both the Spanish and even the European context, as the second most important region in the Community for chicken production. Dairy farming is concentrated particularly in firmly-established farming areas and in certain Pyrenean valleys. Regarding cattle, beef finishing is an important industry in Mediterranean dry farming areas, whilst beef farming activities are largely concentrated in the Pyrenean counties of Catalonia.

Slaughter of food-producing animals	
Species	Number
Beef	602,049
Horse	7,284
Pork	14,282,677
Sheep	211,549
Goat	26,092
Chicken	162,771,474
Rabbit	14,085,398

Meat production



Source: Ministry of Health. Directorate-General for Public Health. 2004.

Fisheries, aquaculture and hunting activities

Fishing and aquaculture occupy a modest place in the overall primary production figures for Catalonia, accounting for less than 1% of this production. Hunting accounts for an even smaller proportion of primary production, and can be considered negligible within the overall figures we are considering here.

The total fish catch in 2004 was around 33,000 tonnes, whilst fish farming production reached 4,200 tonnes, representing 12-13% of total fishing and aquaculture production in Catalonia for the year.

Sales and catches of fish in Catalonia 2002 and 2003		
Group	2002 (t)	2003 (t)
Cartilaginous fish	98	111
Shellfish	1,745	1,744
Invertebrates	4	11
Molluscs: bivalves	137	178
Molluscs: cephalopods	2,623	1,935
Molluscs: gastropods	372	280
Osseous fish: white	11,122	10,168
Osseous fish: oily	20,703	19,146
Total	36,804	33,572

Source: Summary of Catalan Agricultural Production. 2003. Ministry of Agriculture, Food and Rural Action. Autonomous Government of Catalonia.

Agricultural and livestock farming productivity has gradually increased thanks to modernisation, the introduction of new farming methods and improved combinations of agriculture and livestock farming.

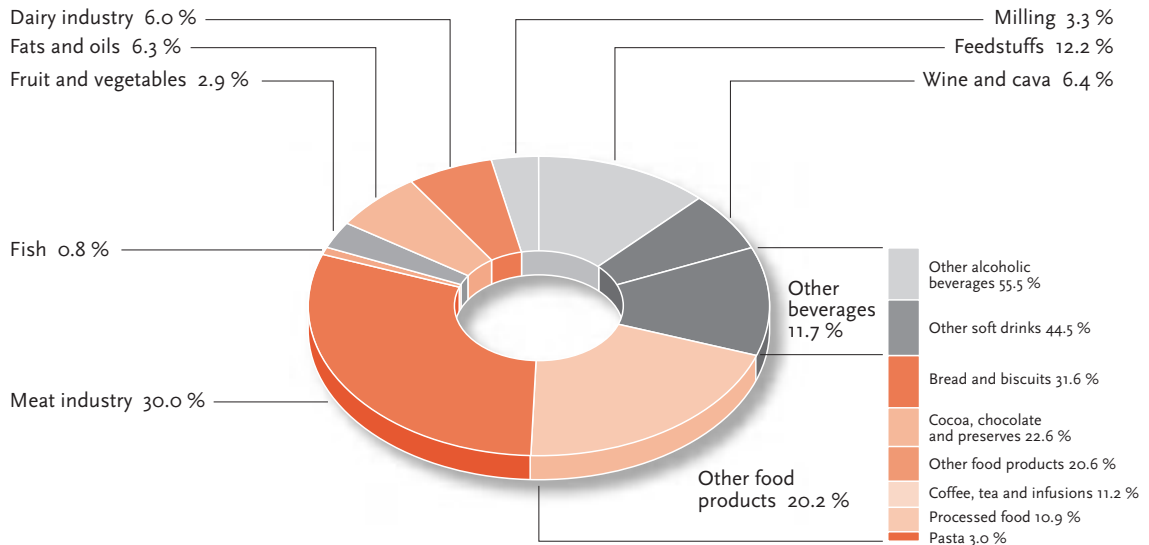
Agricultural and livestock farming production in Catalonia combines diversification of products (final agrarian production includes both typical products of European continental agriculture and Mediterranean products) and is strongly intensive in nature, with a clear predominance of intensive livestock farming and irrigation agriculture. Productivity has also gradually increased thanks to modernisation, genetic improvement to breeds, the increased use of machinery in production processes, the extension of irrigation farming and the introduction of new farming methods, as well as improved combinations of agriculture and livestock farming. Moreover, the number of so-called protected denominations of origin (*denominacions d'origen protegides*, DOP) and protected geographic indications (*indicacions geogràfiques protegides*, IGP) has also increased, and many more private brands and marks guaranteeing product quality and increasing value added have also been established.

Farming product processing and retail stage

The agri-food industry accounts for approximately 4% of total Catalan GDP, double its contribution at the primary stage (1-2%). Regarding employment, moreover, the Catalan agri-food industry also accounts for approximately 3-4% of the occupied population.

The agri-food industry occupies second place amongst all Catalan industrial sectors with regard to gross value added (GVA) production, surpassed only by the chemical industry, whilst it holds first place in terms of sales volume, followed by the chemical industry and such important sectors as textiles, metallurgy and car manufacture.

The Catalan agri-food industry, by sector



Source: Summary of Catalan Agricultural Production. 2003. Ministry of Agriculture, Food and Rural Action. Autonomous Government of Catalonia.

In terms of income from activities, the primary processing industry accounts for 67% of total income in the food and drink industry. By sector, the most important is meat, which accounts for around 30-40% of total income in the primary food processing industry. In terms of employment, meat processing also accounts for more than half the total jobs in the primary agri-food processing industry. These figures demonstrate that the agri-food industry has developed largely in the agrarian sector in which local production is highest: livestock farming.

Production of dairy products, oils and fats and wine and cava each accounts for around 6-9% of total income. The fruit and vegetable processing and preserving industries make up approximately 2-3% of the total, whilst fish processing and preserving accounts for around 1%.

In the meat industry, the pork subsector accounts for 52% of total turnover. Although small businesses predominate in this sector in terms of number, it is medium-sized enterprises that account for the highest proportion of turnover.

There is a tendency for the food processing chain to become longer.

Regarding activities, there is a tendency for the processing chain to become ever longer. The industries that account for the largest business volume are those that carry out more than one activity. These are followed in importance by processing industries, meat cutting plants and, finally, abattoirs.

The Catalan meat processing industry is concentrated to a large extent in Barcelona province, which accounts for 41% of turnover. The *comarca* or county with the most meat processing companies is Osona (which accounts for 17% of the total in Catalonia). Barcelona province is followed in importance by Girona (35%), where La Garrotxa county accounts for 8% of total turnover in the industry in Catalonia. Next, Lleida province represents 18-19% of turnover, with La Segarra the leading county (7%). Finally, Tarragona province accounts for 6% of total turnover in the sector.

Enterprises in the fruit and vegetable sector are generally small in size: companies with fewer than 9 workers make up 40% of the total, mostly concentrated in the counties in Lleida province, which accounts for approximately 34% of turnover, followed by Barcelona, with 30%, and Tarragona, with 25%, whilst Girona accounts for the remaining 10%.

Agricultural and livestock farming production is highly integrated with the agri-food industry, the former supplying half the raw materials employed by the latter. All the different sectors that go to form the agri-food industry are highly active in Catalonia, particularly the meat industry, which processes not only a large proportion of Catalan agricultural produce, but also much from other autonomous communities in Spain. Moreover, the agri-food industry also helps to keep the population in the territory stable, since facilities are usually located in rural areas, providing additional employment opportunities to those provided by farmers.

The fact that Catalonia is a small country, with a largely urban demographic base (67% of the population is concentrated in 7.54% of the territory), combined with proximity to large, dynamic centres of consumption, has greatly facilitated the extension of this industry, as it provides practically half the natural market for the Catalan agri-industry.

Nonetheless, the number of industrial facilities in rural areas represents only a small proportion of industry in Catalonia as a whole. The reason for this must be sought in the country's great communication networks, which determines the distribution and location of Catalan industry, for the most part far from rural areas.

Retail trade and food consumption stages

Within the retail trade sector, which accounts for around 11% of gross value added (GVA) in Catalonia, the food and drink industry represents 12-14%, with meat and meat products leading the way, followed in order of importance by fish products, bread, preserves, cakes and pastries, milk and dairy products, fruit and vegetables and beverages of various types. The hotel trade is another important sector here, accounting for nearly 7% of total GVA in Catalonia, including an important food preparation and service component.

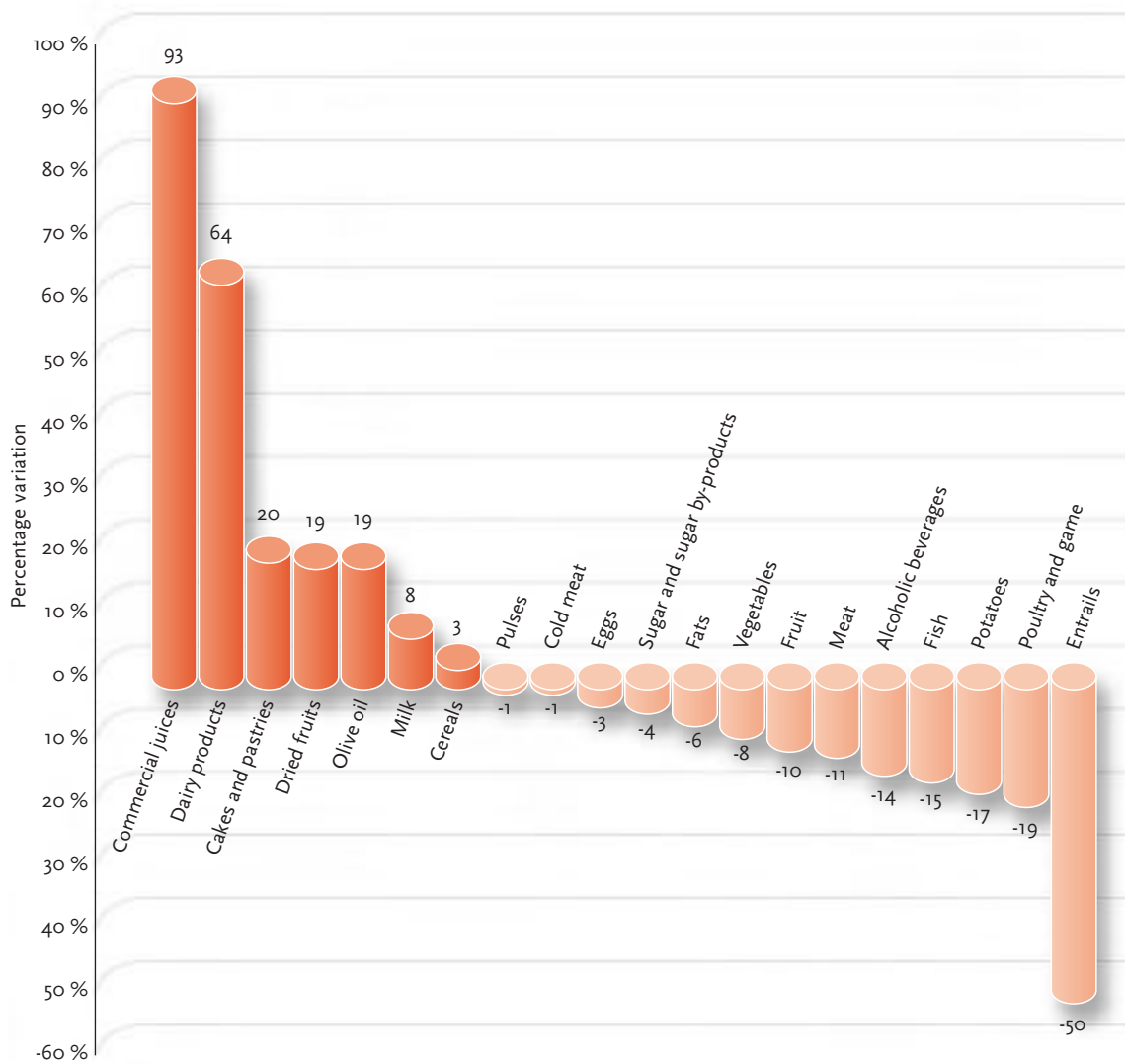
Families consume food, basically, in two main settings: the home, and mass catering facilities outside the home. Some 73% of food consumption takes place in the home, whilst restaurants account for the remaining 27%. There has been a tendency for domestic food consumption to fall in recent years, whilst consumption outside the home has risen.

Catalonia's food culture is based on the Mediterranean diet, a very health nutritional model associated with lower rates of chronic and degenerative illnesses. The nutritional and non-nutritional ingredients of the Mediterranean diet are found in combinations and synergies generated by different foodstuffs: olive oil, cereals, bread and bakery products, pulses, fruit and vegetable, dairy products (milk, cheese), dried fruits, wine, fish and meat (in small quantities) and seasoning.

Recent food surveys in Catalonia show changing consumption habits in the country over the 1992-2003 period for an age group ranging from 10 to 75 years. According to these facts and figures, there has been a decrease in the consumption of fruit and vegetables, pulses and fish, accompanied by an increase in the consumption of dairy products, commercial juices and cakes, indicating growing numbers of people abandoning the Mediterranean diet model. On the brighter side from the nutritional point of view, there has also been an increase in the consumption of cereals, olive oil and dried fruits.

The domestic sector accounts for 73% of food consumption, whilst mass catering facilities account for the remaining 27%. There has been a tendency for domestic food consumption to fall in recent years, whilst consumption outside the home has risen.

Trends in food consumption in Catalonia, 1992-2003



Source: *Assessment of the Nutritional State of the Catalan Population, 2002-2003*. Directorate-General for Public Health. Ministry of Health.

Food consumption in Catalonia

Structure of food spending in Catalonia, and total food consumption in Catalan homes, 2003		
Product	Food spending in million euros	Total food consumption in million kg
■ Eggs	101	60
■ Meat and processed meat products	1,934	340
■ Fish products	1,210	172
■ Milk and dairy products	963	684
■ Bread, biscuits, cakes and pastries	873	324
■ Cocoa and chocolate	88	16
■ Coffee and other infusions	83	11
■ Rice, pasta and dried pulses	104	71
■ Sugar	21	22
■ Oils and fats	177	85
■ Fresh fruit and vegetables	663	432
■ Processed fruit and vegetables	173	91
■ Potatoes	121	201
■ Dried fruits	132	23
■ Precooked dishes	296	74
■ Wines and cavas	148	91
■ Beer	94	87
■ Other alcoholic beverages	65	8
■ Soft drinks (including juices)	353	859
■ Others	101	55
■ Total	7,699	—

Source: Summary of Catalan Agricultural Production. 2003. Directorate-General for Public Health. Ministry of Health.

6 The supra-territorial dimension of food safety

The present structure of markets, both domestic and international, is such that solely national or territorial responsibilities no longer exist. Nowadays, all competent territorial authorities are answerable as regards foodstuffs produced within their territory, not only to the citizens in the territory itself, but also to the entire citizenry of the European Union and in third countries.

The competent authorities are responsible not only before citizens in their own territories, but also before people at the place of destination of foodstuffs produced within their respective territories.

In the international context, sanitary and phytosanitary measures are harmonised according to regulations, directives and guidelines drawn up by such competent international bodies such as the World Health Organisation (WHO), the United Nations Food and Agriculture Organisation (FAO), the Mixed FAO/WHO Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), and the World Trade Organisation (WTO) Sanitary and Phytosanitary Measures Agreement (SPS Agreement). The purpose of these measures, which are based on scientific risk assessments, is not to be excessively restrictive, but to guarantee adequate protection.

According to commitments made by the European Union to the WTO, food safety measures established within the European Union and concerning international trade must be based on

international regulations or, if not, must be scientifically justifiable. Where scientific data is insufficient, it is possible to adopt provisional measures in accordance with the information available.

The process of drafting and monitoring the Food Safety Plan of Catalonia must be influenced by the reports and recommendations of the afore-mentioned international bodies with regard to issues concerning Catalonia.

Here, too, it should be pointed out that one of the basic principles enshrined in the White Paper on Food Safety is that foodstuffs produced in the European Union –and, therefore, in Catalonia– for the international market must conform to the same high food safety standards that are applied to internal trade.

The Food Safety Plan will help to enhance Catalonia's international standing as a food producer and as a tourist destination which guarantees the highest standards of food safety.

For this reason, the Food Safety Plan takes on a dimension that goes beyond the territory of Catalonia and the need to guarantee high levels of food safety for the Catalan population, since the implementation of the plan entails ensuring that this guarantee also includes foodstuffs produced for export to other territories, as well as for consumption by the many citizens from other countries who visit Catalonia every year as tourists.

From this standpoint, then, the Food Safety Plan should help to enhance Catalonia's international standing as a food producer and tourist destination where the highest standards of safety as regards food and drink products are guaranteed.

To this end, it is necessary to establish channels of communication with the tourism and hotel industries, as well as with the local and regional authorities involved, in order to provide appropriate communication channels and mechanisms for action.

Similarly, it will be necessary to establish contacts and ensure coordination with producers and distributors active in international markets in order to find lines of action that can ensure the safety and enhance the prestige of Catalan food products abroad, implementing all necessary safety guarantees.

Moreover, the tendency for trade to become ever more global means that many problems that originate in other territories may have repercussions in Catalonia. This is a factor which could limit the extent to which the food safety targets established under the Plan are actually achieved. However, it is possible to implement measures that can help to provide higher safety guarantees. Crucial factors in achieving this objective will be to ensure that food alert and information exchange systems operate correctly, and to implement appropriate controls at destination.

II

Food Safety Plan of Catalonia: guidelines



The objective of implementing the Food Safety Plan is to guarantee, in the sphere of food safety, the maximum possible levels of protection as regards public health and interests and to restore and maintain public confidence. All of this can be achieved through an integrated and coordinated policy that enables synergies to be generated through coordinated actions carried out in collaboration with the different stakeholders in the food production chain.

The strategic orientation behind the Plan is based on a set of principles and concepts known as guidelines. The outstanding criteria amongst these are the objectives of food safety policy in Catalonia and Europe and an integral vision of the food production chain and all issues relating to risk analysis processes, questions that are analysed in greater detail below.

1 Objectives of food safety policy in Catalonia and Europe

Food safety policy in Catalonia is obliged to follow the principles and actions established under European food safety policy. The European Commission's *White Paper on Food Safety*, and Regulation (EC) No. 178/2002 (OJ L 31 of 1.2.2002) of the European Parliament and of the Council, of 28 January 2002, establish the principles and actions that should guide food safety policy in Europe over the coming years. The legislative and organisational reforms proposed in these documents focus on an approach to food safety that is integrated with the production cycle, defining the responsibilities of all stakeholders at each different stage. The essential goals of food safety policy in the European Union are to:

- Guarantee a high level of protection for human, plant and animal health at all stages in the food production chain.
- Make food safety a priority. This global concept includes consumer health and all other factors or questions that may be reasonably linked to it.
- Guarantee that processes in the food production chain are carried out in such a way that hazards are controlled and eliminated or reduced to acceptable levels.
- Re-establish the confidence of consumers in health safety.

Law 20/2002 of July 5 on food safety (DOGC No. 3679 of 17.7.2002) has the objective of guaranteeing the maximum degree of protection regarding the health and interests of food consumers, taking into account all stages of production, processing and distribution of food and feedstuffs. Article 3 of this law establishes in detail the principle objective of food safety policy in Catalonia, basically to guarantee consumers that they are safe from all hazards that foodstuffs may contain. To this end, it is necessary to:

- Assess and manage the exposure of the population to the risks associated with food consumption by identifying and characterising any possible hazards.
- Guarantee, at all stages in the food production chain, from primary production to final distribution, that the necessary control mechanisms will intervene in a normal, periodic and programmed fashion.
- Increase training in issues concerning food safety, and promote hygienic conduct and behaviour when handling food.
- Provide adequate human and material resources for inspection, official controls and analytic research into biological, physical and chemical hazards which may affect food at any stage in the food production chain.

The principle objective of food safety policy in Catalonia is to guarantee food safety to the consumer.

- Encourage and guarantee the introduction and supervision of self-control systems by food companies.
- Promote education and information for consumers over the nature and risks of food products.
- Promote the participation of institutions in processes to guarantee food safety.

Collecting and analysing information, providing scientific advice and communicating information to consumers are essential elements in food safety policies.

Collecting and analysing information, providing scientific advice and communicating information to consumers are essential elements in food safety policies. The Resolution of the European Parliament on the European White Paper provided for the establishment of a European food agency that should be independent, representative, under the control of the Administration and citizens and responsible for determining and communicating risks in matters of food safety. This body, set up under Regulation (EC) No. 178/2002, is the European Food Safety Authority (EFSA). The work of the EFSA should be coordinated with that of food safety agencies in Member States and with any working groups that are established.

The European Food Safety Authority carries out six main functions. These are to:

- Issue independent scientific reports on food safety, animal health and welfare, and developments concerning plants, genetically modified organisms and nutrition.
- Issue reports on food questions of technical content with a view to establishing political and legislative measures concerning the food production chain.
- Compile and analyse data on any potential risk or exposure to foodborne illnesses.
- Identify and notify emerging risks as early as possible.
- Assist the Commission in the event of an emergency and issue scientific directives in crisis cells set up *ad hoc*.
- Maintain a permanent dialogue with the public and inform about potential and emerging risks.

An appropriate food safety policy requires coordination with scientific institutions so that reliable networks for risk surveillance assessment can be set up.

In Catalonia, the function of risk assessment and communication falls to the Catalan Food Safety Agency (CFSa), while at national level the Spanish Food Safety and Nutrition Agency (AESAN) is the main authority in this sphere. Food safety policy in Catalonia must take into account the reports and recommendations of the European Food Safety Authority and other proposals, reports and legislation published in the European Union, as well as the standards established by the FAO and WHO Codex Alimentarius Food Code and the World Trade Organisation (WTO).

2 Integral vision of food safety. The principle of food safety “from farm to table”

One of the main principles laid down in Regulation (EC) No. 178/2002 is a global and integrated approach to food safety. Food safety policies should cover the entire food production chain, from the primary phases of production to the final consumer’s table, based on the principle known as “from farm to table”.

Food crises have alerted the public to the importance of the primary sector to food safety, and the fact that some risks from biological, chemical or physical contamination may originate at the initial stages in the food production chain. The production, rearing and cultivation of primary products and the products and services necessary to carry out these activities must be undertaken in accordance with correct practices so that hazards are controlled, eliminated or reduced to an acceptable level, following the same principles that are to be applied to the entire food production chain.

Food safety policies should cover the entire food production chain, from the primary phases of production to the final consumer's table.

Commercial operators at the different stages in the food production chain must be made aware of their role and responsibility in preventing food hazards from entering the food production chain, guaranteeing health, animal welfare, product traceability and respect for the environment through compliance with the applicable legislation and also through the application of codes of good practice.

Certain factors should also be taken into consideration, such as: the heterogeneous nature of the chain's structure, in which business small in both size and resources co-exist alongside large facilities with high production levels that distribute their products over a wide territorial area; the increasing complexity and technical nature of trade and distribution; the globalisation of trade in foodstuffs, increasing the possibility of hazards from other geographical regions entering the food production chain; and food company staff training needs.

With regard to the consumption phase, the issues we should bear in mind include: the existence of particularly vulnerable groups like children, the elderly, pregnant women or people suffering from different illnesses; the need for better training and information to be able to exercise a free right to choose; the need to apply food safety measures in handling, storage and cooking processes that are carried out in the home; changes in life styles such as the increase in numbers of people who eat outside the home and rising consumption of pre-cooked meals; the increasing trend towards diversity as a consequence of the integration into our society of people and habits from outside the Mediterranean culture; and the tourism phenomenon and industry, for which food and food safety represent a strategic factor.

The objective and interventions provided for under the Plan should respond to an integrated, exhaustive concept that takes into consideration all aspects of the food production chain, understood as one continuous sequence from primary production to consumption, including the environment in which activities take place and the raw materials and means of production involved, as each one of these elements may have a decisive influence on the safety of foodstuffs made available to the public.

3 Scientific advice and the participation of stakeholders in the food production chain

Food safety policies must be based on well-grounded scientific advice that obeys the principles of excellence, transparency and independence.

Food safety policies must be based on well-grounded scientific advice that obeys the principles of excellence, transparency and independence. The Plan should be supported by reliable scientific advice, both at the draft stage and at the subsequent stages of deployment, execution, monitoring and evaluation. The collaboration of scientists and experts in the various fields affecting the Plan has therefore to be obtained as part of a multidisciplinary approach.

Even the most complete system cannot work without the collaboration and commitment of all stakeholders. For this reason, economic operators, from the agricultural and livestock farming sectors to the food and drink industry, as well as distributors and retailers must also be involved, providing their opinions and cooperation.

Efforts should be made to involve all stakeholders in order to overcome the deficiencies in the traditional approach, one characterised by excessive rigidity, compartmentalisation and sector-based interests.

The opinions and experience of local and regional agencies in the public Administration in exercising official control, health protection, regulation or intervention activities in the market is crucial in the design, execution and monitoring of a Plan that will be the fruit of a vision covering the food production chain as a whole, as well as all other areas related to it.

This global, integrated approach should tend towards a more coherent, effective and dynamic food safety policy aimed at resolving the deficiencies that derive from a traditional focus characterized by excessive rigidity, compartmentalisation and sector-based interests.

Efforts should be made to promote the joint participation of all stakeholders, to enable them to contribute effectively. Mechanisms should be set up to establish permanent contacts

between stakeholders in the food production chain (operators and consumers), institutions and scientific environments. These contacts should be made more dynamic through the establishment of common bases of information and systems to promote a permanent relationship, generating synergies and cooperation with the shared goal of achieving the highest possible levels of food safety.

4 The risk analysis procedure

Food safety policies should be based on a procedure known as risk analysis. To analyse the meaning and use of this procedure, the concepts of hazard and risk should be defined as a first step.

A hazard is defined as any biological, chemical or physical agent present in a food or feed-stuffs, or any biological, chemical or physical condition of a food or feedstuffs that may cause harm to health.

Risk is the probability of a harmful effect on health as a consequence of the presence of one or more hazards in food.

Risk analysis is a process made up of three interrelated phases: risk assessment, management and communication.

Risk assessment is aimed at assessing the likelihood of exposure to food hazards and its effects on health.

Risk assessment is a series of actions aimed at qualitatively and quantitatively identifying and evaluating hazards, and at evaluating and characterising the risk to the health of the population resulting from exposure to a chemical, biological or physical agent in food. Originally an English expression, "Risk Assessment" has been translated in different ways. Although the expression most widely used in our context is "risk assessment", terms such as "risk determination" and "risk evaluation" have also been used to refer to the same concept.

Risk assessment in Catalonia should be based on the scientific data available and should be carried out in an independent, objective and transparent manner and in accordance with principles of coordination and complementary with the Spanish Food Safety and Nutrition Agency (AESAN), the European Food Safety Authority (EFSA) and other international bodies.

Risk management focuses on minimising the risk to health by selecting and applying appropriate measures for prevention and control.

Risk management encompasses all actions directed at preventing or minimising a risk to health by selecting and applying the most appropriate prevention and control measures, including legislative initiatives.

Risk management should take into account the results of risk assessment and, in particular, the directives of the Catalan Food Safety Agency (ACSA), the Spanish Food Safety and Nutrition Agency (AESAN) and the European Food Safety Authority (EFSA).

What is involved here is a process of identifying, selecting and implementing measures which enable risks to be reduced, measures that should be implemented according to an eminently scientific approach. However, risk management policy is not concerned with health issues only; management demands legislative action and political decisions based not only on scientific elements but also on a wider evaluation of the needs and desires of our society.

This requires a delicate balance aimed at guaranteeing protection for the public through effective management measures that are also compatible with the operational and economic needs of the business sector. Moreover, risk management has important implications for official controls, acting as a key element in guaranteeing compliance with the management measures laid down by law.

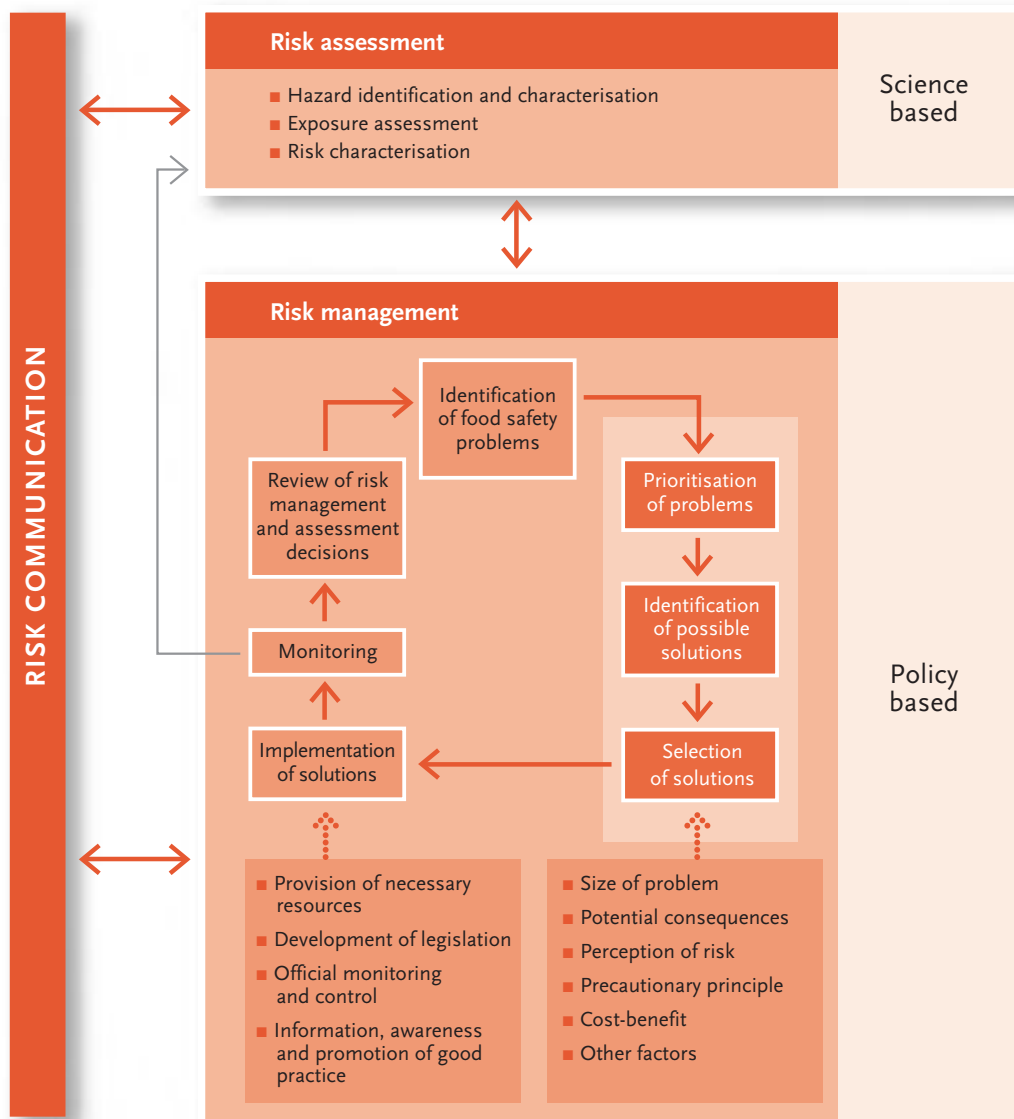
Risk communication consists of the interactive exchange of information and opinions between all stakeholders involved in food safety, integrating in a transparent and interrelated way all processes and decisions concerning risk assessment and management.

Risk communication consists of interactive exchange of information and opinions related to hazards and risks between the people charged with assessment and management, consumers, industry representatives, the academic community and other stakeholders. Public opinion must also be taken into account regarding all aspects of food safety, and a framework established for debate involving experts, scientists, authorities and the public.

A communication policy should be designed to embrace all aspects of risk assessment and management in a appropriate, transparent and interrelated way, enabling society to understand the decisions taken in matters of risk management and the factors that must be taken into account globally. Risk communication should foster a calm, objective perception of the risk assessment and management process that leaves no room for doubt about the principle of guaranteeing the protection of health above other factors that must also be taken into consideration. Likewise, we should focus on advance planning, especially for communicating risks, taking into account particularly the most vulnerable groups (pregnant women, children, the elderly and people with specific illnesses).

The Food Safety Plan should provide for the necessary interventions at the different stages involved in the process of risk analysis, particularly regarding risk management and communication.

The risk analysis process and its interactions



5 Risk assessment. A procedure based on scientific evidence

The aim of risk assessment is to ascertain exposure to food hazards and its potential adverse effects on health. This phase of risk analysis brings into play the scientific knowledge on which the management and communication stages should be based.

The risk assessment stage involves four stages:

- **Hazard identification.** The identification of known or potential agents associated with a particular agent in food that may have adverse effects on health if consumed.
- **Hazard characterisation.** The qualitative and/or quantitative evaluation of the adverse effects associated with biological, chemical or physical agents which may be present in

The process of risk assessment has a largely scientific nature and is based on studies undertaken by internationally recognised organisms.

food, the exposure levels that may cause adverse effects and the population groups that may be affected.

- **Exposure assessment.** The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.
- **Risk characterisation.** Consists of a qualitative and/or quantitative estimate, including concomitant uncertainties, of the probability that a harmful, known or potential effect will be produced, and of the severity of its effects on the health of a specific population group, based on identification of the hazard, its characterisation and evaluation of exposure.

The risk assessment process is largely scientific in nature and is based on studies undertaken by internationally recognised organisms. The Food Safety Plan should be focused particularly on developing and improving data collection systems in this area. Continuous collection of data of interest to food safety must be kept up, most particularly as regards available studies on risk assessment in this field. Similarly, this information should be made available to all the stakeholders in the food production chain to whom it may be of interest, especially administrative bodies, so that suitable risk management and communication measures can be drawn up in Catalonia.

The Plan should provide for research and monitoring programmes, relevant contacts with official European agencies and institutions, laboratories, universities, scientific institutions, professional associations and food and drink industry sectors. Monitoring and assessment are important tools for adopting an anticipatory and predictive approach that permits the early identification of problems, their minimisation and enables us to prevent or palliate crises and their impact.

6 Data gathering and analysis as elements of risk analysis

Monitoring is necessary to evaluate the magnitude of problems, to understand trends, to identify priorities, to set management policies and to evaluate results.

The collection and analysis of information are essential elements in food safety policy, both in matters of assessment and in risk management and communication. Monitoring food-borne diseases and hazard and exposure levels is necessary in order estimate the magnitude of food safety problems, to discover trends, to identify priorities, to set management policies and to evaluate the results of the strategies and management measures applied.

In the risk analysis process, use is made of information from many different sources, such as systems of epidemiological and analytical monitoring, results from research into outbreaks of illnesses, studies of exposure patterns, and information on the characteristics of those affected and the effects on their health.

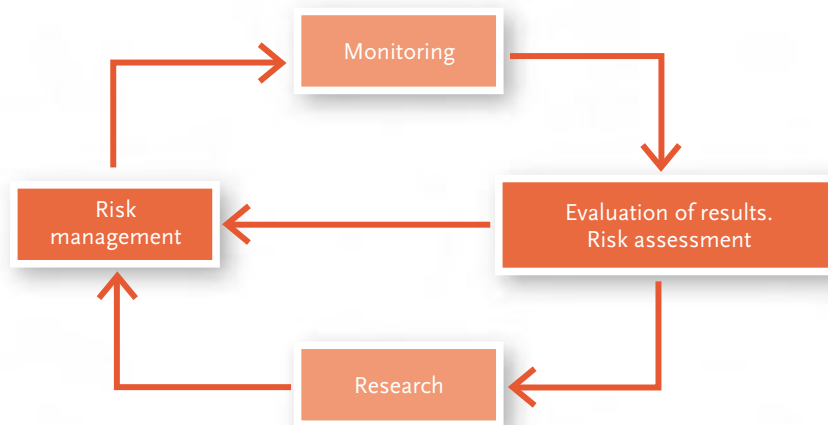
The sources of information available are many and varied. Those particularly worth noting here include data obtained from controls carried out on the food production chain and from disease and micro-organism monitoring networks and notifications, epidemiological research, results from laboratory analyses of data obtained from monitoring and control procedures, zoonosis and residue monitoring plans, and monitoring systems for contaminants in the environment and research activities, among others.

It is all the more difficult to integrate this data because, through routine monitoring, many institutions gather and update information on a constant basis.

Monitoring may also be carried out which is aimed at gathering more complete data on certain diseases or agents through specific actions or studies.

Research into outbreaks also represents an important source of data. In most outbreaks, difficulties exist in gathering all the information necessary because, on many occasions, either the food responsible cannot be traced, or it is not possible to isolate the pathogen. It can even occur that those affected cannot remember the relevant facts. However, in certain cases it is possible to gather valuable information for the risk analysis process. Improvements can be introduced in this area by applying additional resources and carrying out specific studies to facilitate the collection of useful information.

Cycle of risk analysis based on monitoring



Source: Global Surveillance of Foodborne Disease: Report on a consultation to the WHO. Geneva, Switzerland, November 26-29 2001.

The ideal situation would be the integration of data relative to human, animal and plant diseases, hazards and other useful data from each stage in the food production chain.

The ideal situation would be the integration of data relative to human, animal and plant diseases and hazards, and also other useful data from each stages in the process, from primary production to consumption. This would imply the constant collection of validated information from the different stages in the food production chain. Such integrated collection and study of data requires a coordinated structure and mechanisms to ensure systematic, integrated collection, analysis and interpretation of the data proceeding from all parties that generate and store information. For greater consistency and coherence, data should be integrated and interpreted by a specialised, multidisciplinary unit.

Data analysis should enable the evolution of known risks and the detection of new ones to be studied so that food safety policy and measures can be better defined and established and more closely adapted to existing problems.

Interrelations between surveillance / epidemiological studies and the risk analysis process for microbiological hazards.

Information on foodborne disease	Risk assessment				Risk management			Risk communication
	HI	CH	EA	RC	OA	I	MR	
Incidence of cases	●	●	●	●	●	●	●	●
Incidence attributable to food	●	●	●	●	●	●	●	●
Severity of disease	●	●	●	●	●	●	●	●
Information about outbreaks	●	●	●	●	●	●	●	●
Geographic distribution	●	●	●	●	●	●	●	●
Trends of diseases	●	●	●	●	●	●	●	●
Identification of population at higher risk	●	●	●	●	●	●	●	●
Identification of pathogens and associated foodstuffs	●	●	●	●	●	●	●	●
Identification of risk factors	●	●	●	●	●	●	●	●
Results of measures implemented	●	●	●	●	●	●	●	●
Data on changes in pathogens	●	●	●	●	●	●	●	●

HI: hazard identification
 CH: hazard characterisation
 EA: exposure assessment
 RC: risk characterisation
 OA: option assessment
 I: implementation
 MR: monitoring and review.

Interrelation:
 ● very high
 ● high
 ● medium
 ● low

Source: J. Rocourt, G. Moy, K. Vierk and J. Schlundt. Department of Health Safety of the WHO, Geneva. The present state of foodborne disease in OECD countries.

The Food Safety Plan of Catalonia should provide for the development and improvement of data collection and analysis systems, their standardisation and their greater integration and coordination. An updated system for data management needs to be provided in order to effectively carry out the activities of risk assessment, management and communication. Here, efforts should be made to coordinate the data collection systems of different organisations and institutions involved in food safety, such as the Spanish Food Safety and Nutrition Agency (AESAN), the World Health Organisation (WHO) and competent bodies in the European Union.

Within the framework of the Food Safety Plan, objectives and actions should be set out so that specific research can be carried out into exposure to given hazards, as well as surveys to understand the habits, opinions and perception of the citizens of Catalonia, so that future management and communication objectives, interventions and actions can be established.

Systems of risk alert and coordinated management in the European Union providing relevant sources of information

- **RAPEX** (Rapid Exchange of Information System): system for the rapid exchange of information on risks from non-food products (toys, etc).
- **RASFF** (Rapid Alert System for Food and Feed): alert system for notifying risks to human health from foodstuffs and feedstuffs. Corresponds to the SCIRI (Coordinated Rapid Exchange of Information System) in Spain
- **EWRS** (Early Warning and Response System): warning and response system to alert public health authorities and the European Commission about outbreaks of transmissible diseases.
- **EUROPHYT** (European Network of Plant Health Information): system for the rapid exchange of information about plant health issues (organisms harmful to plant or plant products that do not comply with EU legislation).
- **SHIFT** (System to Assist with Health Controls of Imports of Items of Veterinary Concern at Frontier Inspection from Third Countries): system to provide assistance with veterinary issues at border health of imports from third countries.
- **ADNS** (Animal Disease Notification System): system for notifying and recording the focal points of contagious animal diseases.
- **BICHAT** (New Rapid Alert System on Biological and Chemical Attacks and Threats): rapid alert system monitoring potential chemical and biological attacks and threats.
- **ANIMO**: system for the exchange of information that cannot be considered a warning system as its objective is to gather information on the movements of certain live animals and products between the Member States.

This is an area where there is wide margin for improvement. The correct use and management of information can help to speed up the detection of potential problems, enabling crisis management measures to be taken earlier and scientific research into problems to be launched. An anticipatory and preventive role is required, therefore, in order to permit the early identification of risks and to prevent crises or reduce their impact.

In order to formulate the objectives to be achieved appropriately, moreover, scientific knowledge about the peculiarities of Catalonia should also be improved. For this purpose, and without detriment to the collection of information with reference to national, EU and international forums, specific information on Catalonia should be collected concerning such issues as:

- Most frequent hazards and exposure levels.
- Problems and needs as perceived by the public.
- Diet and nutrition patterns, as a basis for assessing how well adapted to circumstances are the toxicological safety levels established for different groups of chemical hazards.
- Specific problems and needs that can be observed from a scientific point of view.
- Specific problems and needs as observed by economic operators or other stakeholders in the food production chain.
- *Ad hoc* research in cases where specific problems are detected.

7 The precautionary principle. The concepts of prevention and precaution

The precautionary principle takes its place in the area of risk management within the general framework of risk analysis. This principle is applicable to many human activities and is acquiring great relevance in many areas such as the environment, as well as food safety.

The precautionary principle is applied in cases in which the possibility is foreseen that harmful effects on health will be caused although it is not possible to determine the risk to a sufficient degree of certainty.

When, after making an evaluation of the information available, the possibility is foreseen that a given phenomenon, process or product may cause harmful effects to health and it is not possible to determine the risk to a sufficient degree of certainty, and even though scientific doubt may exist, provisional risk management measures can be adopted to guarantee high levels of health protection whilst additional scientific information is awaited that will enable more exhaustive risk assessment to be carried out.

Measures deriving from recourse to the precautionary principle depend on a political decision made in accordance with the risk considered acceptable by the society that must run such a risk. The form such action will take needs to be determined, perhaps through the establishment of a research programme or through legislative or control measures, amongst other possible courses of action. In any event, however, the choice cannot be an arbitrary one.

The precautionary principle is applied in the event of a suspected or potential hazard about which little is known scientifically. The difficulty lies in deciding on the temporary measures to be applied once the social and economic consequences have been taken into account. This is an extremely complex question, one which requires the participation of different stakeholders such as scientists, politicians, professionals, business and the general public. This complexity is due to the fact that each different stakeholder brings different perceptions and logical processes to bear on the issue at hand.

While new scientific data is awaited, the precautionary measures to be adopted, the procedure for adopting them and the respective terms of reference should be established.

The precautionary principle has been recognised in various international agreements, and is included in the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). However, the precautionary principle should never be applied as a pretext for protectionist measures.

A distinction should be made between the precautionary principle as applied to little known risks in a situation of scientific uncertainty and the preventive measures applied to minimise known risks.

There is often great confusion between the significance of applying preventive measures and the application of the precautionary principle. Furthermore, the notions of risk and scientific uncertainty should not be confused. Prevention means applying measures to deal with risks that are already known. When a risk has been scientifically evaluated, data must be available on the dose and its effects, the associated risks and the cost-benefit relationship. Based on this knowledge, a series of preventive measures is established. This area covers most of the legally established conditions on food safety.

The objective of the precautionary principle is to protect the consumer against a risk considered potential but which has not yet been completely evaluated. Certain conditions must be ensured when the principle is to be applied:

- The risk should first be assessed objectively and the degree of scientific uncertainty identified.
- There should be complete transparency regarding the entire process and the participation of all stakeholders.

- The measures should be proportional to the risk, and neither discriminatory nor arbitrary. They should be acceptable according to a cost-efficiency analysis and to an analysis of the advantages and drawbacks of action or inaction, and they should be temporary and subject to review as new scientific knowledge becomes available.

Similarly, confusion between the precautionary principle and zero risk should be avoided. The precautionary principle should provide a guide for public authorities in times of scientific controversy, but should not be allowed to paralyse or block progress.

8 Legislation as a component in risk management

Regulation (EC) No. 178/2002 of the European Parliament and of the Council establishes the general principles and requirements of food safety legislation, as well as laying down procedures on food safety. The requirements and principles brought together in this Regulation have provided the basis for the far-reaching changes undertaken by the European Union concerning food laws.

Principles and objectives of food legislation contained in the *White Paper on Food Safety* and in (EC) Regulation No. 178/2002

- Guarantee a high level of protection for human life and health.
- Ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, and in its scientific basis.
- Achieve a global, integral vision of the food production chain from primary production to final consumer.
- Base measures to be applied on the risk analysis process.
- Determine risk in an objective, independent, transparent way in accordance with scientific information and data.
- Apply the precautionary principle where scientific uncertainty persists in accordance with uniform standards that prevent these principles from being used to create barriers to the free movement of goods.
- Establish suitable measures for managing emergencies.
- Take into account other relevant factors, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.
- Ensure the free circulation of safe foodstuffs in the internal market, protecting public health and welfare and social and economic interests.
- Clearly define the functions of all food production chain stakeholders: feed producers, farmers, other operators, authorities in the Member States and European Union institutions.
- Consider food business operators as those best placed to ensure that the food they supply is safe.
- Ensure scientific and technical support that provides a highly qualified, independent and efficient basis for food law.
- Guarantee the competitiveness of European industry and enhance export standards.
- Guarantee coherence, harmonisation, rationality, clarity and ease in bringing in legislation.
- Ensure the non-discriminatory application of legislation.
- Guarantee an exhaustive, integrated approach to food safety.
- Guarantee traceability as a system to allow the recall of specific products, inform the consumer and agents entrusted with control and avoid additional problems in the event of an alert or food crisis.
- Improve the rapid alert system established under Council Directive 92/59/EEC, of 29 June 1992, to include feedstuffs.

Establishing legislation is one of the key elements in risk management within the context of the democratic states. Effective food safety policy requires effective legislation to manage risks and to establish official control systems to supervise and guarantee their application. All these elements should be brought together appropriately in texts with a legally binding status so that action by operators and authorities intervening in the food production chain are given the necessary consistency and legal security. For these reasons, attention should focus on legal instruments available to make the necessary improvements that will result in greater effectiveness, efficiency and security.

The establishment of binding legislation is a key element of risk management in democratic systems.

Unlike legislation governing food safety conditions with regard to food and drink production, and official control programmes and directives, which are the product of European legislation, the legal framework necessary to carry out interventions such as inspections, authorisation or the application of precautionary measures and sanctions by the competent authorities requires the development of a solid national, regional and local legal basis that enables these functions to be carried out by all the public bodies and officials involved. In view of this, one of the objectives of the Food Safety Plan should be that of providing a suitable legal framework to ensure that these functions can be fulfilled through the implementation of legislation and the improvement and adaptation to present needs of applicable legislation in the area of food safety.

We need a simple, stable, effective and controllable legal basis, without which it will be impossible to efficiently and effectively carry out planned intervention in food safety.

Food standards in the local, regional, national, European and international spheres

From a global perspective, current legislation governing food consists of different legal texts at local, autonomous, national, community and extra-community level, and has reached a high level of complexity.

The approval of legislation implies a political decision and paves the way for judgements based not only on scientific knowledge concerning risks, but also on a broader appreciation of the desires and needs of society as a whole.

The Codex Alimentarius Commission, with headquarters in Rome, was established in 1963, at a time when the United Nations Organisation for Food and Agriculture (FAO) had decided that it was necessary to contribute to the protection of consumer health by drawing up regulations to provide guidelines for the international agri-food industry. The objective of these regulations is to guide and promote the formulation and establishment of definitions and criteria applicable to foodstuffs, to contribute to harmonisation and to facilitate international exchanges. The Codex Alimentarius includes, among other things, provisions regarding food hygiene, residues, contaminants, labelling, presentation and methods of analysis. Although the Codex Alimentarius Commission's most important work is in the sphere of food safety, it also addresses other important issues affecting the international food trade.

Moreover, the World Trade Organisation (WTO) devotes a chapter of its legislation specifically to food safety and public health in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). After prior evaluation of the health situation in third countries, moreover, the European Commission has also established agreements with certain third countries under which, in accordance with the SPS Agreement, food safety measures and controls are accepted as equivalent.

Mention should also be made here of the World Organisation for Animal Health (OIE) based in Paris, a reference body in matters of animal health.

At European level, the basic legislation established is approved jointly by the Council and the Parliament, and is developed by legislation approved by the Council and Commission under the powers granted to them.

The approval of legislation implies a political decision and paves the way for judgements based not only on scientific knowledge of risks, but also on a broader appreciation of the desires and needs of society as a whole.

Legislation at national, autonomous and local level should establish the legal framework for exercising official controls and other measures empowering the public authorities to intervene.

The Commission monitors the correct transposition of EU law to national jurisprudence and its correct application and execution by the authorities in the Member States. The control function corresponds to the Food and Veterinary Office (FVO), which reports on results and formulates recommendations that are essential elements for the possible adoption of safeguarding measures or for starting sanctions procedures against Member States.

EU food law thereby becomes compulsory and binding, by implication establishing measures for risk assessment and management and a strategic approach to food safety problems.

At national, autonomous and local level, a series of different food laws exists. These laws should be coherent with each other and with food safety legislation as applied throughout the European Union as a whole. Moreover, besides incorporating the health conditions established by EU institutions, these food laws provide the necessary legal framework for exercising official controls and other intervention measures, under both civil and criminal law, an aspect regulated by the competent regional authority, this being an internal question for individual Member States and the regional bodies or autonomous communities that constitute them.

Need to simplify and modernise EU legislation

New challenges highlight the on-going need to modernise, simplify and improve current legislation.

Thanks to the implementation of EU legislation, a series of objectives has been achieved, unifying the market, harmonising national provisions, adopting measures within the framework of the Common Agricultural Policy (CAP) and protecting consumers and public health. This confluence of objectives has given rise, at times, to a certain inconsistency, to divergences and shortcomings that have worsened due to historic reasons over the past thirty years. Legislation has evolved slowly and includes provisions that were approved in a dispersed manner in response to the needs of the internal market and to a combination of scientific, social, political and economic influences that sometimes gives rise to a lack of overall consistency. This dispersion has led to the existence of a series of different systems governing hygiene according to whether substances are animal or vegetable in origin, or to the sub-sector concerned.

Similarly, certain sectors were left outside the scope of the first general regulations governing hygiene, as is the case with the production of food of vegetable origin by agri-businesses.

This situation can only be justified due to historic reasons. Inconsistencies, gaps that have been generated and food crises have highlighted the need to modernise and simplify legislation as well as to constantly improve it. The legislation passed by the European Union and the objectives and actions provided for under the Plan should aim to correct these shortcomings.

The European Commission's White Paper on Food Safety called for a review of legislation, and progress has been achieved in this field in recent years. A new phase is now imminent in which more general and horizontal legislation will be applied and detailed measures implemented, and vertical legislation will be developed only when necessary. Moreover, in order to avoid problems that may arise from late or incorrect transposition, it is considered preferable to publish legislation to be applied directly rather than directives, and preference is also given to the adoption of simplified procedures for adapting laws to scientific and technical progress.

Plans also exist to introduce a general legal obligation to guarantee the safety of food products in such a way that operators are obliged to guarantee that they only trade in wholesome

products fit for human consumption, and that these products are free from any risk to consumer health. This provision, already incorporated into internal law in some Member States, is closely related to the principle of due diligence, which obliges operators to go beyond strict compliance with the law and to apply any measures necessary to guarantee the safety of their products.

In order to improve and simplify EU law, a large body of food law has been repealed, and a range of laws published in the following areas:

New European Union legal framework on food safety

- Regulation (EC) No. 178/2002 of the European Parliament and of the Council, of January 28, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, of 1.2.2002).
- Regulation (EC) No. 852/2004 of the European Parliament and of the Council, of April 29 2004, on the hygiene of foodstuffs (OJ L 226, of 25.6.2004).
- Regulation (EC) No. 853/2004 of the European Parliament and of the Council, of April 29 2004, laying down specific hygiene rules for food of animal origin (OJ L 226, of 25.6.2004).
- Regulation (EC) No. 882/2004 of the European Parliament and of the Council, of April 29 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 191, of 28.5.2004).
- Regulation (EC) No. 854/2004 of the European Parliament and of the Council, of April 29 2004, laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 226, of 25.6.2004).
- Regulation (EC) No. 183/2005 of the European Parliament and of the Council, of January 12 2005, laying down requirements for feed hygiene (OJ L 35, of 8.2.2005).

There is a need to incorporate the principles of food safety into legislation governing the primary phase of the food production chain.

Modification of EU legislation and its subsequent review will undoubtedly affect the Food Safety Plan of Catalonia, particularly as regards the activities it provides for and some of the objectives it establishes. This fact should be taken into account at the draft stage, as scientific, legal, economic and commercial reasons exist which require action called for under the Plan to be adapted to these legal texts.

The legal development referred to affects all stages in the food production chain, but most particularly primary production and the production of goods and services necessary at this stage in the chain, as is the case, for example, of feedstuffs. There is a need to incorporate the principles of food safety into legislation governing the primary phase of the food production chain. The existence of controls on feedstuffs equivalent to those carried out on food for humans, the publication of positive and negative lists of ingredients, additives and other components that may be incorporated, labelling, traceability and the inclusion of feedstuffs in the rapid alert system used for food for human consumption laid down in the White Paper; these are all good examples of risk management provisions that it has been considered necessary to include.

Specific Community legislation

Food safety policy is governed overall by a principle of sustainable development of a general and transversal nature. Nonetheless, specific EU legislation exists in certain areas, amongst which we can mention in particular the following:

- Food additives
- Flavourings
- Foodstuffs heated with ionising radiation
- Novel foods and novel ingredients
- Animal nutrition
- Feed hygiene and feedstuff production
- Zootechnical requirements in animal breeding
- By-products and residues of animal origin
- Transmissible spongiform encephalopathies
- Control of salmonella and other zoonotic agents
- Residues and contaminants
- Plant health
- Labelling
- Genetically modified organisms
- Food packaging and containers
- Drinking water
- Animal health
- Waste management
- Atmospheric pollution, quality of water and protection of nature and biodiversity
- Animal identification and beef traceability

EC legislation also aims to prevent any unnecessary suffering that might be caused to food-producing animals.

Health regulations governing feedstuffs focus on production, labelling, use of additives and restrictions on the use of certain substances, such as, for example, dioxins, by establishing maximum limits. Such regulations also concern the use of materials and specific products, authorisation of feedstuff production plants and control and self-control measures, as well as the introduction of a rapid warning system.

Review of current provisions also aims to tighten up health legislation governing by-products of animal origin not fit for human consumption. Depending on the potential risk that exists, rigorous measures should be applied to govern the identification, transport, storage and handling of such products.

Taking the view that animals are sensitive creatures, moreover, EC legislation also aims to prevent any unnecessary suffering by animals in three key areas: breeding, transport and slaughter.

On the subject of labelling, a balance needs to be struck that guarantees consumers are provided with useful information whilst avoiding needlessly detailed and possibly confusing data.

The health of plants used in human food and feedstuffs is as important as the health and welfare of animals. A harmonised surveillance and control system is therefore needed. In this area, the three main elements of competence are: the correct use of veterinary products; control over their presence in food; and protection against micro-organisms harmful to plants.

Food contamination also presents a threat to food safety. Such contamination may come from different sources, such as environmental pollution, the food production chain or materials coming into contact with food. In this field, a wide range of legislative measures has been implemented with a view to protecting food. One general provision regulates the presence of

contaminants in human food by establishing maximum content levels for them. Moreover, specific legislation exists on radioactive contamination. At first, measures were adopted to prohibit and limit the use of certain chemical products. However, due to the appearance of dangerous new elements such as endocrine disruptors and persistent organic contaminants, a new strategy has been put into place, based on the precautionary principle, sustainable development and the harmonisation of existing legislation.

Formulas need to be found to allow all stakeholders in the food production chain access to current legislation and to ensure that this is easy to consult and to understand.

On the question of labelling, a balance needs to be struck that guarantees consumers access to all useful information, including information about production methods, but which avoids being needlessly detailed, which may lead to confusion.

Genetically modified organisms (GMOs), defined as organisms whose genetic material has been artificially modified, must not pose any threat to the environment or to the public. In order to guarantee this, dispositions on the subject include a rigorous system of evaluation, authorisation, labelling and traceability governing both GMOs and GMO derivatives.

EC legislation also refers to the preparation of foodstuffs and to the composition of certain types of food. Provisions exist to govern food destined for such uses as, for example, foodstuffs for people suffering from metabolic problems, for breastfeeding mothers and small children, as well as for special medical uses such as enteric feeding.

There also exist legislation on foodstuffs known as food complements, which are characteristically presented in pre-dosed form. These food complements at present include vitamins and minerals.

This new approach and the above-mentioned European legislation should be very much borne in mind in drafting, implementing and executing the Food Safety Plan of Catalonia, and in the Plan's future development. We should also take into account possible future changes by prioritising the objectives and interventions that are least likely to change, given their scientific justification.

Official control systems must demonstrate their rigour and transparency to the public.

Furthermore, efforts need to be made so that the legislation is easily accessible to all those who may be involved or interested. In this sense, we should not only provide easy access to current legislation by business and the general public, but should also seek ways of making legislative texts easier to consult and understand.

Improvements to food safety depend not only on the suitability (adaptation and simplification) of legislation, but also on how it is applied and the authorities' ability to ensure that it is obeyed. Adequate planning and harmonisation measures should be established for official control systems, including the corrective measures to be applied in each case. Within systems of official control, procedures and standardisation processes should make clear to the public their necessary rigour and transparency. These are key elements in ensuring food safety and also in restoring and maintaining consumer confidence.

9 The distribution of responsibilities. Self-control by operators as a key element in food safety

In Spain, food law has regulated the production and distribution of food since well before the country's entry into the European Union. Compliance with current legislation has always been an obligation for businesses and subject to the control of the competent public authorities. Businesses or activities that meet legally established conditions obtain authorisation to operate and remain so authorised. Despite this, in practice, public administrations in Latin countries have traditionally shouldered considerable responsibility due to their role in controlling and certifying, which they are called upon to exercise with particularly frequency and intensity in certain sectors such as foodstuffs of animal origin.

Despite the existence of a degree of confusion in this respect, those responsible for safety in general, and compliance with current legislation in particular, have always been food business operators.

This role of the public authorities in Latin countries, which is strongly criticised by sectors in Anglo-Saxon countries, may lead operators to underestimate their responsibilities and to play a passive role in risk analysis, considering that they have complied sufficiently with requirements, either by satisfying certain bureaucratic formalities or by successfully passing periodic controls carried out by the competent authorities. In this aspect, the traditional Latin philosophy in matters of food safety, according to which the food business operators have played a secondary role and the competent administrations have played a leading role as guarantors of safety, certainly presents considerable shortcomings.

This situation began to change with entry into the European Union and the legislative changes that the adoption of EU legislation led to in the 1990s. That said, European legislation, in many cases with its origins in the 1960s, did little to remedy many of the deficiencies outlined here. The publication of Council Directive 93/43/EEC, of 14 June 1993, on the hygiene of foodstuffs, led to a sea change in notions regarding operators' responsibility and the role of the competent authority.

Directive 93/43/EEC clearly establishes, with no doubt whatsoever, that commercial operators are those responsible for the hygiene and safety of foodstuffs brought to the market. Certain general obligations have been conserved in the style of the traditional system with regard to facilities, materials and staff hygiene, but the concept of self-control is introduced and specific reference made to the principles of the hazard analysis and the critical control point (HACCP) system. Another peculiarity that should be highlighted here was the Directive's horizontal nature, as its scope covered all food sectors, in general and without exclusion. However, this regulation left primary production out of its scope and so was not applicable to agricultural and livestock farming. Because of this, a key element in introducing a global, integrated vision according to the principle of "from farm to table" was lost, though this was later rectified by new legislation.

For all the above reasons, the new Regulation (EC) No. 852/2004, on the hygiene of foodstuffs, now includes primary production within its scope of application, for its objective is to guarantee the hygiene of food products throughout the food production chain, from primary production to sale to the final consumer. Food hygiene is defined as meaning the measures and conditions necessary to control hazards and to ensure that foodstuffs are fit for human consumption, taking into account their intended use. Another feature of Regulation 852/2004 is its reference to the creation and application of good practice guides as a way of improving product safety.

The Regulation offers operators greater flexibility as to how they establish their methods of production and facilities and the technologies that they wish to use. Against this, however, they also become wholly responsible for the safety of their products.

As established in the Commission's White Paper on Food Safety, Regulation (EC) No. 178/2002 and Law 20/2002, of July 5, responsibility for the safety of products lies largely with the food and feedstuff business operators, while the competent authorities are called on to supervise the exercise of this responsibility and to ensure compliance through appropriate monitoring and control systems. The Commission's control services should evaluate, by means of audits and inspections, the capacity of the competent authorities to apply these systems.

Consumer protection should be ensured through the active association of four elements:

- Operators should be obliged to introduce effective systems of self-control and supervision, guaranteeing that products conform to food safety legislation.
- The authorities should draw up coordinated control programmes that cover the food production chain in its entirety.
- Systems to supervise official control measures, based on audits, should be introduced.
- The Commission should monitor the actions of the competent authorities throughout the food production chain.

Law 20/2002, on food safety, unequivocally defines a distribution of responsibilities in which responsibility for food safety lies with the food business operators. The authorities should ensure compliance with this obligation by introducing monitoring and control systems.

Consumers also have some responsibility in exercising their freedom to choose and with regard to ensuring safety in the final phases in the food production chain as regards transport, conservation and the correct application of freezing, cooking, consumption processes and any others that may take place in the home.

The public authorities are responsible for establishing the conditions that must be complied with and for ensuring compliance with them. There is a certain perception that shortcomings, even a degree of laxity, exist in controls, and for this reason, it is important to ensure greater transparency and participation in procedures and the criteria applied under official control policies, and in results and sanctions procedures and all other types of measure adopted.

It is evident that many different stakeholders come together within the food production chain, forming a complex interrelationship. Economic operators, consumers and public administrations are essential players in the chain, and their interrelations are so complex as to make it essential to foster a culture of joint or collective responsibility. Food safety can only be effectively guaranteed through such an approach, as the consequences of any food incident affect the entire food production chain. The principles of self-control in accordance with the HACCP, the use of good practice guides, traceability and the development of mechanisms to ensure transparency are all crucial to achieving this objective.

The hazard analysis and critical control point (HACCP) system

The hazard analysis and critical control point (HACCP) system was used for the first time in the United States chemical industry as a way of ensuring safety in processing operations in the 1960s. In 1972, the Pillsbury Corporation adapted this method to the food industry, applying it in the processing of foodstuffs destined for the NASA space programme.

Subsequently the Food and Drug Administration (FDA) made adoption of the HACCP compulsory in the canning industry. Nowadays, the system is recognised and recommended by the Codex Alimentarius for control over food safety.

Since 1990, European food law has made reference to the principles of the HACCP system within the self-control systems of businesses. The method allows for identification and analysis of the hazards associated with the different stages in the production processes, defining the measures necessary for their control and ensuring that such measures are effectively put into practice.

The HACCP system allows for the identification of hazards, defining the measures necessary to control them and ensuring that these measures are effectively put into practice.

The HACCP system is based on the following steps:

- Detect any hazard that must be avoided, eliminated or reduced to acceptable levels.
- Identify the critical control points in the stage or stages at which control is essential.
- Establish critical limits in the critical control points beyond which intervention becomes necessary.
- Establish and apply effective monitoring procedures at the critical control points.
- Establish corrective measures when monitoring indicates that a critical point is not being controlled.
- Establish verification procedures to confirm that the HACCP system is working correctly.
- Establish a suitable documentation system to cover all procedures and records.

In order to apply the system, it is necessary to establish prior requirements, known as pre-requisites. These are based on standardised procedures concerning staff training and hygiene, cleaning, disinfection and the control of infections, among other things.

The HACCP system is a method with a scientific, rational, integral, organised, systematic and effective basis. Designed to control food hazards that are currently known to us, its principles are applicable to the entire food production chain, even primary production. It is compatible, if need be, with quality guarantee systems such as the ISO standards, into which it can be integrated. It allows for the application criteria for prioritisation and flexibility. Unlike systems based on an examination of the final product, HACCP facilitates a preventive and anticipatory approach, making it more effective and economical. Finally, moreover, it allows for more efficient official control by providing complete information that is not limited to a specific point in time. This is an attribute that facilitates, through auditing techniques, global study of the guarantee system introduced by a business.

The effective application of the HACCP system requires commitment by the directors of businesses and their staff, as well as a multidisciplinary focus.

Nonetheless, some criticisms of the system have been raised, such as the difficulty for small businesses to apply it, its complexity and the discouraging influence it can have on workers due to the voluminous records they are often obliged to keep. The HACCP system requires commitment by the directors and staff of businesses, as well as a multidisciplinary approach.

Given that the HACCP system's validity is considered indisputable, suitable formulas should be sought to facilitate its introduction by all types of businesses and activities, including those in the primary sector, and to find suitable methods to motivate staff and facilitate recording of the required data.

Economic agents in the food sector should apply the principles of the HACCP system as laid down in the Codex Alimentarius, but they should do this with a sufficiently flexible approach that takes into account the different circumstances that may be found in practice. Nonetheless, food product hygiene regulations do not, in principle, make adoption of the HACCP system in the primary sector a requirement; rather, they call for its principles to be applied through good practice guides and the recording of certain operations crucial to food safety at that stage. The HACCP system might be fully incorporated if and when experience shows that it can be practically applied in primary production.

Guides to Good Hygiene Practice (GHP guides)

Guides to Good Hygiene Practice (GHP guides) are tools that can be applied voluntarily in order to ensure compliance with hygiene requirements and as a way of meeting obligatory self-control measures that operators throughout the food production chain are required to introduce.

These guides allow operators to base their responsibility on recognised procedures, themselves the result of studies that take into account all aspects of safety. Their approval by pub-

lic authorities provides official recognition for such guides, enabling them to be used in official control processes.

Good practice guides provide an effective tool for the application of HACCP principles in a way adapted to the peculiarities of the primary phase in the food production chain.

Good practice guides should provide for the introduction of practical elements for applying self-control systems based on HACCP principles, adapted to the peculiarities of each sector and the procedures, technologies or products in question. They can be applied throughout the food production chain and constitute an effective tool in themselves. They are particularly useful at primary production stages, and facilitate the adoption of principles related to minimising the use of fertilizers and biocides as well as the use of scarce resources such as land and water within the global concept of sustainability. Additionally, they also provide an appropriate basis for the possible future introduction of the HACCP system.

The essence of good hygiene practices are control measures and procedures that minimise the possible appearance of hazards.

The authorities should encourage economic stakeholders to draw up GHP guides. EU Member States should study these guides to ensure that they can be feasibly adopted. Such guides should be drawn up in line with principles of the Codex Alimentarius and after consultations with all stakeholders. National guides considered acceptable should be submitted to the Commission, which will enter them in a register. Provision is also made for the possibility of drawing up uniform Community guides when appropriate. Economic agents in the food sector will be free to follow either national or Community guides, as they consider most appropriate.

10 Traceability

One of the essential principles established in the White Paper on Food Safety, Regulation (EC) No. 178/2002, and Law 20/2002, of July 5, is the importance of traceability or tracking, which allows products to be monitored over all the stages of the food production chain, including the production of feed, primary food production, processing, preparation for distribution, storage, transport and retail sale.

Traceability should allow for products to be monitored over the entire food production chain so that it is possible to recall a product from the market and to undertake research or to apply other appropriate measures in cases where product safety has been compromised.

Traceability is defined as the ability to trace and follow a food, feed, food producing animal or substance intended to be or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

The idea of traceability is based a concept that goes beyond activities which are the responsibility of each different operator. To ensure that the system is fully effective, complete involvement is required at all stages in the food production chain. A break at any point may invalidate the whole system.

Apart from being a legal requirement, traceability is in itself a need in the management of any production or distribution activity. When any type of issue arises, whether with regard to health, a customer's complaint or a problem in production, the operator can identify the origin, ingredients, processes involved and/or destination of the product in such a way that it becomes possible to investigate the causes, to rectify the problem and/or to quickly and efficiently recall the product, if necessary.

Moreover, traceability facilitates action by the authorities responsible for food safety as regards research and management of alerts and crises. Traceability is a basic instrument that enables products to be identified and tracked, and even to be recalled if necessary. Effectiveness in this area can minimise social alarms and the harm that such alarms frequently cause to the sectors affected.

A traceability system should define and develop the elements described below, without prejudice to any specific legislation that may exist in given areas such as, for example, genetically modified organisms (GMOs), beef, fish products and eggs.

Definition of batch size. The product units that will make up a traceable lot or batch must be established. The criteria for batching products may vary, and depend on the activity and on current legislation. Composition may, for example, be individual, by single unit, as is the case with animals of the bovine species (a legal requirement). Alternatively, the criteria used may be time period (weekly, daily, time of production) or the place and date of capture in the case of hunting or fishing products, and so on.

The degree of precision to which products are grouped determines the size of the batch. Excepting cases for which specific legislation exists, this should be defined by the business itself. In doing so, a balance should be sought between the cost and complexity of the system and an operationally acceptable level of efficiency.

System for identifying batch size. Each traceability batch or group of product units should be identified permanently and unequivocally. There are several methods for identifying batches, from simple labels to more sophisticated systems using bar codes or radiofrequency identification devices (microchips).

Definition of the area of traceability or tracking. The tracking area should be defined both as regards input and output, and must include the processes applied in the activities under the control of each different operator.

Upstream traceability should make it possible to obtain relevant information about a product from an intermediate or final product: the processes it has been submitted to, the raw materials used and their origin. It is important to ascertain the name and address of suppliers as well as data on incoming products and their identification, number of units, reception date and use-by date. Information about all raw materials and means of production used must be included, including materials not finally contained in the final product but that are part of the production process (technological adjuvants, materials that come into contact with products, etc).

The traceability of the process should make it possible to link company input and output products, as well as the results of self-control measures they are subject to. Any splitting, changing or mixing of batches or groups should be taken into account, as well as the number of points at which it is necessary to set up records or links. Records must be kept and identification made of the products obtained as a result of the operations carried out and of their relationship with final products or initial materials, and all this information should be included into the self-control system used.

Downstream traceability should provide information about where a given product has been placed on the market. This information must include the name and address of customers, the products distributed, with identification of the batch or batches supplied and the date they were dispatched by the company.

Traceability should be ensured over the entire food production chain, from the initial stages to the retail phase. However, direct supply to the final consumer is exempt from this obligation. The responsibility of each firm for traceability ends when a prior or subsequent stage can be identified with regard to a specific product brought onto the market. Bringing all this data together as supplied by each of the operators intervening in the chain should enable complete tracking to be carried out and a full history of the product to be built up.

A documentary recording and filing system should be set up to allow the rapid compilation of information in the event of an incident. A document describing the system should be avail-

able, stating the criteria for product batching, the scope of the traceability system, the procedures for data collection and other characteristics of the system.

Information should also be recorded and the relevant documentation kept on file regarding the products themselves (raw materials, intermediary products and final products) and their distribution and marketing, taking into account both suppliers and final users or customers.

Finally, a periodic review needs to be carried out to check that the traceability system works properly. There are different formulae for such verification. One of the most useful is the simulation of an alert in which a product is taken at random and the tracking procedure is carried out on the processes followed, the raw materials involved and the suppliers of these.

A traceability system should enable fast, precise and effective action to be taken. All steps in the food production chain should guarantee the traceability of products so that the system can respond to expectations regarding its usefulness and effectiveness in the event of a food alert and/or crisis. Traceability is a key instrument in food safety, one that should enable research into a product's history to ascertain and identify the causes behind a given incident and those responsible for them. Furthermore, it should allow all the products implicated in an incident to be traced and withdrawn from the market, and should make it possible to provide consumers with useful information in the event of an alert or crisis.

Moreover, ascertaining the origins and researching into the causes of a given problem or incident should make it possible to establish monitoring and prevention measures for similar or related processes. Traceability, then, is not only a key element in providing a fast and effective response to specific problems, but is also a basic tool in the procedure to be followed in research aimed at preventing similar problems from arising in the future.

However, one must bear in mind that the unequivocal traceability of foodstuffs and their ingredients is a complex question in which the peculiarities of each sector and product must be taken into account. We should also remember the enormously varied nature of legislative requirements for traceability, which depend on the sector in question and the circumstances affecting it. A clear example of this is meat from cattle, where the levels demanded are very high as a consequence of the bovine spongiform encephalopathy crisis.

We should, therefore, consider traceability as an essential element in matters of food safety and one that must be included in the objectives and interventions provided for under the Food Safety Plan.

11 Official control as a component of risk management

Official control is an intervention measure undertaken by the competent authorities to verify, by way of examinations or the study of objective tests, compliance with current legislation.

Official control consists of any form of control undertaken by the competent authority to verify, by means of examination and study of objective tests, compliance with current legislation and regulations. This key element forms an integral part of the Food Safety Plan.

Official control should be brought to bear at all the stages in the food production chain, and this therefore also includes primary production, along with the services and products necessary to make feedstuffs, which should be the subject to special attention. The chain for eliminating and processing by-products and residues of animal origin, animal welfare, animal health (particularly zoonosis), the pharmacological treatment of animals, and the identification and traceability of animals and products should also be subject to official control measures.

Regulations governing official control

Regulation (EC) No. 882/2004 of the European Parliament and of the Council, of 29 April 2004, lays down the principles and legislation governing official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Official controls consist of different activities, such as inspections to check hygiene conditions at food and feedstuff businesses, interviews with managers and staff at firms and other measures aimed at verifying compliance with legislation on feedstuffs and foodstuffs.

The above-mentioned Regulation introduces a new approach to control, based on a single integrated process. The control cycle under these new regulations is composed of the following principal steps:

- a) The Commission will draw up general guidelines to foster a harmonised approach to controls in such a way that all legislation, all production sectors and all stages in human and animal food production chains are covered. The Commission will also indicate the principal results indicators that it will apply to assess and audit national control plans.
- b) The competent authorities in the Member States will draw up and execute a national Plan for an integrated, multi-annual control system, which must include description of the structure and organisation of the systems of official control.
- c) The Commission will regularly carry out general audits of the control activities of each Member State, which may include selective regional controls.
- d) The Commission will draw up a general report on the functioning of the national control systems.
- e) The Member States will present annually updated reports on the initial plan, including the corresponding adaptations with regard any new laws introduced, structural modifications and operational changes.

Advantages and drawbacks to the new approach

The new approach, based on multi-annual official control programmes, should provide higher levels of guarantees, harmonisation and transparency.

This new approach will have a series of advantages for those responsible for planning and implementing official controls, as they will be provided with clear references on the objectives to be achieved at Community level and about the assessment and auditing criteria applied by the European Commission. This will foster the increased harmonisation of official control systems, guaranteeing that all important requirements laid down by law will be regularly verified and ensuring that no important gaps are left within the control process.

Moreover, this new approach is more transparent and easier for consumers to understand. The publication of reports on the overall functioning of control plans and audit results will provide a clearer picture of how EU health safety legislation is applied and what the authorities are doing in this area.

However, this new approach also imposes limits on the planning freedom that regions and States enjoy, and these will have to devote additional efforts to complying with European standards as well as meeting the priorities that they have set themselves in accordance with the specific problems they face in their own territories. Moreover, considerable efforts will also be required to adapt the procedures of official control bodies so that they comply with the new requirements laid down in the Regulation.

Improved coordination and quality of official controls

One of the general principles in food safety holds that all stages in the food production chain must be subject to official control. The Food Safety Plan of Catalonia should provide for

objectives and actions to ensure compliance with this principle and to establish a framework to coordinate and improve the quality of controls carried out by the different public administration bodies responsible. To this end, the following issues should be decided, in cooperation with stakeholders:

- Priorities concerning different hazards
- General operational criteria
- Efficient management and cooperation systems between the bodies or administrations involved
- Effective procedures
- Indicators to evaluate performance efficiency and results

Through the Food and Veterinary Office (FVO), the European Commission provides for a programme of audits and inspections to assess the performance of authorities responsible for introducing and managing official control systems. For this reason, it is necessary to provide mechanisms to coordinate possible visits by FVO inspectors to Catalonia.

In this overview of official controls in a national and European context, we should also make reference to the demands for official controls made by third countries. One illustrative example is the standard hygiene control programme (SHCP), which facilities authorised to export to the USA are obliged to comply with. This example highlights the importance of establishing an effective and adequate official control system that meets the demands of third countries, as well as making clear the importance of official controls to the international projection of food companies.

12 Food alert and food crisis management

A differentiation must be made here between a “crisis”, which has economic and social effects, and an “alert”, which should be understood to indicate a hazard requiring appropriate management measures, and which is in itself crucial for preventing a crisis from occurring.

Alerts - situations where, before a severe and imminent hazard, management measures need to be urgently applied –should be differentiated from crises– in which important social and economic effects are caused, irrespectively of whether or not there exists an immediate, serious risk to health.

Some authors define food crises in the old sense of the Greek word: more than a transitory problem, they are a true transition to a different state. The announcement of an uncontrolled food hazard causes indignation and concern. After the crisis phase, a new situation comes about, and things are never the same again.

Moreover, the repetitive nature of certain crises has an amplifying effect, so that each new crisis further increases the mistrust consumers show towards the food system.

It may be useful here to look at the origin of food crises in recent years. It is curious to see that certain crises have come about even though there was no immediate food risk, as is the case of avian influenza, while certain other important risks have caused little impact on public opinion and have been resolved by legally established systems based on food alerts and withdrawing the product in question, or by other appropriate measures.

On the other hand, some food alerts and crises are more directly linked to the strengthening and improvement of monitoring systems, making it possible to detect risks that not long ago would have gone unnoticed, rather than to the appearance of health problems in humans.

Food crises cause numerous players (businesses, administrations, experts, politicians) to intervene, often in a disorganised way. When a crisis situation affecting food safety is declared, we need to compile and analyse the relevant information and procure the best scientific advice possible, as well as coordinating the organisations that will participate in man-

When a crisis situation in food safety is declared, the relevant information should be compiled and analysed and the best scientific advice available sought. It is also necessary to coordinate the bodies involved in managing the situation and to take the lead in communication activities.

aging the situation and taking the lead in communication activities. All this requires prior crisis management planning.

As noted in the food safety report drawn up by Capp Gilbert and adopted by the French Economic and Social Council, “in cases of crisis, politicians may be tempted to adopt measures addressed at rapidly covering the situation and any possible responsibilities, scientists may become fascinated by the fame that their speciality can win for itself thanks to a brilliant performance, economic players may fall into the temptation of trying to avoid measures with damaging economic effects on their interests, and the news media may be tempted by audience expectations.”

The response to a crisis should follow procedures that are clear, proportional to the risk and transparent, thus avoiding disproportionate economic and social consequences with respect to the real risk to public health. To this end, a mechanism should be established that allows problems to be tackled from a multifactor approach, one proportional to the real risk, in order to ensure effective, efficient management.

Crisis reaction quality and speed depends on preparation. Predefined procedures should exist to ensure appropriate management of crises.

Management of these problems should be undertaken through a system in which all the players in the food production chain take part, including scientists and the experts in each different area.

The starting point must be that responsibility belongs, in the first instance, to the economic operator who placed the product on the market, though public authorities may also bear some responsibilities regarding control over the application of current legislation.

The quality and speed of the reaction to a crisis depends on preparation. To avoid improvisation, predefined procedures for evaluation, control and intervention must be in place.

Principle rules for crisis management

- General interest and consumer health must be the priority.
- An overall study of the problem should be quickly completed, taking into account both safety aspects and social and economic concerns.
- It is necessary to establish coordination and decision-making bodies on which all groups affected are represented to ensure that appropriate management and communication decisions are taken.
- A truly multidisciplinary vision should be applied in decision making.
- The measures applied should be proportionate to the severity of the crisis.
- Predefined management procedures should be readied.
- Speed in releasing information and deploying management mechanisms should be ensured.
- There must be good coordination between the administrations involved in order to cover the whole territory and all stages in the food production chain affected.
- Appropriate traceability systems must exist in order to identify the origin and destination of products.
- Transparency must be guaranteed in public information, aimed at explaining the situation and preventing its effects without causing undue concern. This communication should be preceded by communication and education work in periods of calm. Consideration should be given to the order and the way in which information is provided to the public. The role of the media is decisive to the success of crisis information procedures. If information is processed and handled in an excessively urgent manner, this give rise to undesired effects. A communication policy should be established with the media beforehand.
- Care in the broadest sense should be provided for those affected, including not only those directly concerned, but also all those who may feel affected in some way; psychological effects or the mere perception of being affected are in themselves a form of affection.

Analysis is required after each crisis in order to understand at what points a more effective intervention would be possible to improve the way future crises are managed.

An analysis should be carried out after each crisis to investigate the causes, the evolution of events, the factors involved and its consequences, for the purpose of determining at what points there could have been more effective intervention so as to ensure better management of future crises.

Regulation (EC) No. 882/2004 of the European Parliament and of the Council, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare, establishes that the Member States should draw up operating contingency plans for alert management. These plans should include measures to be applied without delay if it is discovered that any feedstuff or food product implies a serious risk to people or animals, whether directly or through the environment. These plans should specify the administrative authorities to be engaged, their powers and responsibilities and also the channels and procedures for sharing information between the relevant parties. Moreover, the Member States are called on to revise these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience.

When necessary, directives can be issued to harmonise these contingency plans and ensure that they are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No. 178/2002. These directives will also indicate the role that stakeholders should play in establishing and operating contingency plans.

In this context, the Food Safety Plan of Catalonia should provide for action aimed at developing food crisis and alert management mechanisms in both a territorial and inter-territorial way, including the necessary coordination with the relevant national or international organisations. These should include health care services and epidemiological monitoring to detect any effects on human health.

13 Risk communication

Risk communication is an essential element for ensuring that consumers and operators are informed, for maintaining confidence and for reducing the possibility that unfounded social alarms may arise.

Risk communication is essential to ensure that consumers are provided with accurate, adequate information, that confidence is maintained and that the possibility of unfounded social alarm about food safety arising is minimised. Scientific opinions should be published and the measures to be applied should be quickly and widely communicated so that consumers and other stakeholders in the food production chain are provided with useful, accessible information that is easy to understand.

Purposes of risk communication

- Promote awareness and understanding of the specific issues under consideration during the risk analysis process.
- Promote consistency and transparency in arriving at and implementing risk management decisions.
- Contribute to the development and delivery of effective information and education programmes when they are selected as risk management options.
- Foster public trust and confidence in the safety of the food supply.
- Promote the appropriate involvement of all stakeholders in the risk communication process; and exchange information on the knowledge, attitudes, values, practices and perceptions.

Source: "The application of risk communication to food standards and safety matters" (Report of a Joint FAO/WHO Expert Consultation. Rome, 2-6 February 1998).

Risk communication is a necessary tool not only in crisis situations and during alerts and emergencies, but also, even, at times when everything is "normal", as a way of minimising the disproportion between real risks and those perceived by the public.

The right of consumers to information must be guaranteed. Consumers must have access to objective data on questions of food safety and this information should be both accessible and useful for resolving problems. Consumer involvement in assessing and implementing measures should be promoted.

All information about directives and controls should be placed at the disposal of the public. Measures should be implemented to make the information provided to consumers easier to understand and to raise awareness of the public's rights and duties, as well as to promote risk prevention.

Risk communication should not be merely the passive transmission of information, but rather an interactive process that should generate dialogue and a response from all stakeholders.

Risk communication should not be merely the passive transmission of information, but rather an interactive process that should generate dialogue and a response from all stakeholders. Risk communication consists of an exchange of information between stakeholders regarding the nature of risks and the measures required to control them. The public authorities have a basic responsibility for promoting risk communication as well as managing risks to public health. To this end, the policies implemented should seek to establish systems which enable risks to be assessed and transparent decisions to manage them made public by providing consumers with full information about scientific reports, management measures and controls carried out. Such a policy is essential in order to satisfy the objective of restoring and maintaining public confidence in the food production chain and its safety.

Principles of risk communication

- Analyse the audience to understand their motivations and opinions, and keep channels of communication open with them.
- Involve experts and scientists in explaining concepts, bases of evaluation and risk management, uncertainties and the justification for management decisions.
- Involve experts in communicating the risk, since experts in risk assessment and management do not always have the necessary means or skills for maintaining effective communications with the different audiences and participating interlocutors.
- Set up sources of information that have a high degree of credibility with the public.
- Share responsibility. The authorities, the media, business, etc, all play different roles in discharging the shared responsibility to communicate risk in a way founded on scientific bases.
- Report the facts and uncertainties and the risk levels considered acceptable that zero risk is often unattainable.
- Guarantee transparency.
- Put the risk in perspective, taking into account its benefits and, when appropriate, its severity compared to other known risks.

Source: "The application of risk communication to food standards and safety matters" (Report of a Joint FAO/WHO Expert Consultation. Rome, 2-6 February 1998).

Constant monitoring of all food safety issues is necessary, as is communication amongst all stakeholders. The Catalan Food Safety Agency should be both a catalyst and a reference point in this area with regard to all those involved in communication, such as consumers, the public administrations implicated, the food industry, the agricultural and livestock farming sector and national and EU bodies and agencies. We must be prepared to generate rapid responses, to establish the relevant preliminary contacts and to offer stakeholders, especially consumers, information, orientation and advice in matters of food safety.

It is necessary, then, to set up channels to inform and consult the public, operators and other stakeholders involved in all aspects of food safety, as well to promote communication and exchanges amongst the public, operators, scientists and the administrations involved.

Quality of crisis management depends, to a large extent, on the capacity for communicating the information available even when this is incomplete. One of the most important elements here is the action taken during periods of normality or calm.

A constant communication effort, embracing risk assessment and management in an integrated, interrelated way, is necessary during periods of calm.

Elements of effective risk communication

The nature of the risk

- Characteristics and importance of the hazard
- Magnitude and severity of the risk
- Urgency of the situation
- Whether the risk is becoming greater or smaller (trends)
- Probability and distribution of exposure
- The amount of exposure that constitutes a significant risk
- Nature and size of the population at risk
- Population groups at greatest risk

Uncertainties in risk evaluation

- The methods used in assessing the risk
- The assumptions on which estimates are based
- Weaknesses of, or inaccuracies in, the available data
- The effect of changes in the estimates on risk management decisions

Risk-benefit relationship

- The relation and balance between the risks assumed and the benefits obtained

Risk management

- The actions taken to manage the risk
- The actions individuals may take to reduce personal risk
- The justification for choosing a specific risk management option
- The benefits and effectiveness of the measures applied
- The cost of managing the risk, and who pays for it
- The risks that remain after a risk management option is implemented

Source: "The application of risk communication to food standards and safety matters" (Report of a Joint FAO/WHO Expert Consultation. Rome, 2-6 February 1998).

A permanent system and communication effort is required at times of calm to assess risks and the management measures taken. In the event of a crisis, information must be provided about any issues that may arise and the risk management measures to be carried out.

It is important to keep permanent communication channels open with all stakeholders: farmers, transporters, industrialists, retailers, consumers, the media, etc. A framework should be created to ensure adequate information, confidence, transparency, and a realistic, scientific focus on problems.

The role of the media

The media have on occasions been accused of inducing exaggerated concern during food crises. According to a report published by the American Council on Science and Health in 2004, alarmist views over issues related to food safety are, unfortunately, found frequently in the media, as bad news has greater media impact than good, and these alarms are often used to make political and economic gains. We should remember that this situation is nothing more than the result of the confluence of opposing but legitimate interests that require appropriate management. The American Council on Science and Health has selected the factors that most frequently contribute to episodes of alarm.

The media can have an important amplifying effect on risk perception, but cannot be considered as solely responsible for the problem, as this is the result of fulfilling their mission to inform.

Usual elements that contribute to alarmism

- Ignoring the basic toxicological principle that "the dose makes the poison", and causing alarm over the mere presence of potentially toxic substances, without considering whether they are there in sufficient amounts to produce adverse effects on health.
- Misunderstanding or misinterpreting a statistical correlation to mean that a causal connection is present between an observed condition and a risk to health.
- Assuming that if large doses of a substance given to animals cause cancer or other illnesses, then even trace amounts of that substance in food will cause the same result in humans.
- Presenting only one side of a health-related issue.
- Failing to acknowledge that there can be risks associated with not using a product because of exaggerated fears.

Source: Kava, R.; Stimola, A.; Weiser, R. & Mills, L. "The Top Ten Unfounded Health Scares of 2004", American Council on Science and Health, 13 December 2004. New York: American Council on Science and Health, 2004.

The media can generate an important amplifying effect in the perception of risk, but cannot be considered solely responsible for the problem, as this is the result of performing their mission keep the public informed.

Even though it is true that the way in which the media handles a problem can exaggerate or attenuate a crisis, it is also true that the information they provide is largely what they have obtained from political, professional and scientific spheres. Moreover, the lack of experts in agricultural and food matters in the new media may influence the form and background of the message transmitted. Links should therefore be maintained with the media in order to provide full information of the necessary quality so that they can fulfil their mission in an appropriate way at all times.

Dialogue is necessary between the media, the public authorities, the scientific community, commercial operators in the food production chain and consumers for the purpose of constructing the bases of a collective food safety culture.

Similarly, this communication with the media should serve to jointly analyse their considerable responsibility in the field of food safety. The new media play an especially important role with regard to information made available to consumers, owing to the enormous influence that they can have on consumer opinions, trust and attitudes, as well as on the quality of the information made available to the public.

We need to ensure, therefore, that the information provided is true and scientifically based, encouraging and enabling consumers to form an objective opinion based on reliable information. Public attitudes should be proportional to the real situation, and artificial exaggerations of problems avoided; these factors do not contribute to solving the problems and that at times can even make them worse.

Dialogue is necessary between the new media, the public authorities, the scientific community, commercial operators in the food production chain and consumers for the purpose of building the bases for a collective culture in matters of health safety, a culture grounded in transparency and scientific rigour. If dialogue and an effective information policy are established in times of calm, this will later help all stakeholders to overcome food crises in a more objective, mature way.

The role of certain groups in risk communication and perception

Risk communication should begin at primary school, for which reason measures should be provided for it within the education environment. The education system must be mobilised to help to establish a solid health safety culture. Basic knowledge about agriculture, food production, food risks and dietary risks must be adequately integrated into the education system.

Certain groups, such as educators, health workers, scientists, politicians, consumers and professionals in the food production chain, must be implicated and mobilised for the purpose of creating a solid, shared food safety culture.

Similarly, we should not forget the role of health workers, particularly doctors, bearing in mind the authority they exercise in forming the population's opinions.

Their proximity to the public makes health and education professionals, together with workers in the retail and restaurant trades, crucial for implementing a strategy aimed at providing the public with objective information about food safety. Steps should be taken, therefore, to ensure that such professionals receive a high level of training in this subject, given their pedagogical effects.

Another of the groups towards which information and training efforts must be addressed are professionals engaged in the agri-food sector. Consumer confidence can only be reinforced through well-informed awareness that the whole process that foodstuffs go through, from primary production to the retail or restaurant trade, is under the responsibility of professionals trained in and committed to food safety. Training for staff and professionals in the food industry should focus intensively on food safety. Amongst those working in the food sector, the commitment of businessmen and executives is crucial to achieving these objectives.

The scientific community should be made fully aware of the importance and potential consequences of the information that it provides to the media. Scientific information made available should obey principles of prudence and form part of a global system of communication that is both coherent and credible to the public.

Only adequate communication, involving all the different stakeholders and based on a principle of transparency, can ensure rational, measured management of health hazards and a high level of public confidence based on objective information.

With the objective of creating a shared culture and achieving a greater degree of trust and confidence amongst the public, public administrations and economic operators, the active participation of consumers through their associations is also necessary. Consumers should participate actively in communication and decision-making processes, whilst at the same time it is necessary to correct the mistaken idea that guaranteeing food safety is a task that falls exclusively under the responsibility of the public authorities. In a shared, mature food safety culture, each and every stakeholder should be aware of and committed to the role they are responsible for playing.

Only adequate communication and participation, based on a principle of transparency, between the different agents involved can ensure rational, measured management of health hazards and a high level of public confidence grounded in objective information. Mechanisms should be established to facilitate joint decision-making with regard to management and communication processes.

Communication should be understood in an interactive way, and each and every stakeholder should simultaneously receive and emit information.

The role of labelling and advertising as elements in risk communication

Labelling and advertising should provide consumers with appropriate information so that they can exercise their right to choose, assisted by knowledge of all the pertinent facts.

Efforts must be made to ensure that the information required by law to be stated on labelling is provided in an appropriate way and is easy to understand. Information about composition, storage and use are decisive when it comes to making a choice. Composition may also be a decisive safety element for consumers who, for ethical or health reasons, are obliged or wish to avoid certain ingredients. Special attention should be paid to misleading promotional messages or labelling that may lead to health risks.

The necessary steps should be taken to ensure that labelling and other methods of providing information not only comply with requirements established by current legislation, but are

also truly valid systems for providing information about food safety. The appropriate contacts should therefore be made with operators in order to jointly find a way to take the fullest advantage of this channel.

Operators should fully bear their responsibility for communicating risk, an area in which labelling and other means of public communication can be very useful.

Progress is also required towards devoting a section on labels to food safety warnings or recommendations. Good examples of this idea would be advice about storing fresh foodstuffs at the correct temperature when they may contain microbiological hazards, about consuming certain products with moderation and about not consuming foodstuffs beyond a certain time after opening.

Operators should fully bear their responsibility for communicating risk, an area in which labelling and other means of communicating with the public can be very useful. They should understand that this issue entails not only a responsibility to consumers, but also a factor for their own legal protection. The evolution of society towards a more Anglo-Saxon model with regard to responsibility for safety may lead in the future to a demand for businesses to be made liable if they fail to warn consumers about the hazards of a given food, whether due to nutritional problems (cardiovascular diseases, diabetes, obesity) or to the presence of food-borne pathogens in it. Commercial operators should provide consumers with all the information they need in order to make a free, informed choice and to ensure that they can make safe use of the product supplied.

Labelling should also be seen as an element forming part of the environment surrounding the consumer's right to information about such sensitive issues as the use of new techniques, including, for example ionization or genetically modified foodstuffs. Apart from food safety, which should be guaranteed, the consumer should also be able to exercise their right to information about the nature of the product they are consuming.

Both labelling and advertising on occasion include messages about the effects of treatment and the prevention of diseases, something that may lead consumers to make choices that are unbalanced in the dietary sense. We find here another aspect of the relationship between labelling and advertising and health which should be taken into account in actions to be taken and for which we should take as our guide current European legislation governing functional and nutritional descriptions.

The consumer should be empowered to make a free choice in accordance with objective and understandable information.

Labelling should provide the consumer with full information about all the ingredients and the nutritional value of foodstuffs, as well as functional indications –for example, any effects on normal bodily functions, nutritional information concerning the absence or presence of nutrients or nutritional value compared to other products or references.

Safeguards should be established to ensure that the information provided is adequate for the purpose of restoring and maintaining consumer confidence.

In any case, the consumer should be empowered to make a free choice based on objective and understandable information. Labelling is a key element in achieving this objective, but so is other information and educational measures that may be carried out by public administrations, consumer associations or other public or private organisations.

The role of monitoring facilities in perceptions of risk

Both in risk communication and in crisis management, there is an amplifying factor to take into account. When new measures are put into practice to improve monitoring or even when a more advanced technology becomes available, the increased research intensity normally leads to a rise in the number of hazards and cases identified. Although the risk continues to be the same or is even reduced, such developments can be perceived by public opinion as a breakdown in the system of protection rather than an improvement in the system, as the

Improved monitoring and technological progress help to increase our knowledge and understanding of existing hazards. Rather than assuring the public that levels of food safety guarantees are rising, this may lead to a greater perception of risk amongst the public.

effectiveness or sensitivity of detection rises. Educational and communication measures are required to ensure that the public at large understands this question.

An illustrative example of the aforementioned phenomenon is the transmissible encephalopathy spongiform crisis. As soon as systematic tests were put into place and many more cases were detected, public perception was of an increase in the number of cases instead of an increase in safety levels, which was what, in fact, was happening.

The communication strategies established should, therefore, be aimed at preventing improvements in hazard monitoring technology from actually adding to rather than decreasing public perceptions of risk.

The perception of risk in the context of risk communication

Ideas and issues concerning risk perception are directly linked to risk communication and consumer confidence in the food safety system. Each different group, even each different individual, have their own perceptions of risk, and these do not always coincide with the real risk. Social perceptions of risk should therefore be taken into account in communications strategies, in order to ensure their success. We should start from the assumption that, in food matters, the public is probably much less inclined to tolerate risk than in other aspects of life.

In food matters, the public is probably much less inclined to tolerate risk than in other aspects of life.

The truth is that, even though food risks are the cause of an infinitely lower number of diseases and deaths than smoking or road accidents, there is a lower acceptance of risk, or a higher perception of risk, when it comes to food. The reasons for this differing perception need to be analysed.

Moreover, we should point out that risk perceptions are very different in crises than during periods of “calm”. During a crisis, health and hygiene safety become much more important. In consequence, immediate, short-term responses are provided. In the medium and long term, effects may take the shape of negative associations with the products concerned and perceptions of hazards that do not normally extend beyond the suspect product itself. However, the stakeholders implicated –producers, the administration, etc– can be subject to more general suspicion or doubt.

In a situation of “calm”, that is to say, the absence of specific food alerts, negative perceptions and mistrust remain at a fairly low level. Opinions about foodstuffs and the resulting behaviour patterns towards them take food safety considerations little into account and are guided more by other factors, such as smell, nutritional value, etc. Nonetheless, certain negative associations towards particular products and stages in the food production chain continue to exist. Many different factors interact in perceptions, mutually reinforcing or balancing each other out, and these factors are not limited exclusively to food hazard issues. Moreover, these factors are not constant; rather, they vary over time according to events, crises and experience.

Considering how rarely public food risks occur, and their low level of severity when they do occur, particularly if we compare them to other sources of risk, it is paradoxical that such a high perception of risk should exist among the population. This exaggerated perception of the real food risk, which appears above all in times of crisis and diminishes somewhat during the periods of calm between them, is probably caused by the difficulty of accurately assessing the magnitude of problems, by the suspicion that something potentially serious looms on the mid- and long-term horizon, and by the rather inappropriate communication policies of public administrations, the sectors involved and the media.

The lack of absolute certainty and the need to assume a small risk –zero risk is unattainable– have both helped to create a feeling of insecurity that is not proportional to the real risk. The categorical messages of some political representatives, set against more qualified communications from scientists during food crises, has helped to create confusion, increasing consumers' feeling that they are being confronted by rather cloudy, opaque issues in which many vested interests are concealed together.

Scientific knowledge is often incomplete, as it is built up gradually and is always subject to review. Moreover, scientists are not always in full agreement. Western societies find this fact difficult to accept, as they are more receptive to unequivocal, categorical messages without too many nuances.

We need to evolve towards a mature, well-informed society that understands food safety as a right, that is aware of the existing risks and that trusts the preventive and precautionary measures provided for because it participates in risk evaluation and in planning risk management.

This dynamic needs to be broken, and to this end all stakeholders should provide messages that are clear and free from contradiction, both in form and in meaning, providing valid, comparable information that can help to generate and nurture a culture of food safety. We need to evolve towards a mature, well-informed society that understands food safety to be a right, that is aware of the existing risks and that has confidence in the preventive and precautionary measures provided, because society itself participates in assessing and planning them.

Society's reactions should be rational and not influenced by unfounded fears and mistrust. Nonetheless, needless to say, all stakeholders must make the greatest efforts aimed at attaining the highest possible levels of food safety.

In our region, the high levels of food safety that exist means that risks are more related to nutrition than to biological, chemical or physical hazards from foodstuffs. Cardiovascular diseases, obesity and its consequences are good examples. Although popular perceptions are becoming more mature and the reality of the situation is accepted by a large part of the public, we still need to give study and thought to the causes behind this exaggerated perception of biological and, above all, chemical risks linked to foodstuffs that persists in the collective imagination.

At times we try to persuade the public to analyse food risks rationally, from the point of view of the experts, a view based on the possibility that an undesirable situation may arise and on an estimate of the severity of its consequences.

Unlike scientific assessment, which is based on concepts of a cost-benefit type, individual perceptions focus on security and the search for zero risk.

The experts consider risk assessment and management as objective, rational processes in which the probability that the hazard will materialise is evaluated and decisions taken based on the evidence available. Public reaction does not normally follow this approach and is more complex and less objective, because many factors exist to influence perceptions. People perceive things through an individualistic, intuitive nature in which subjective emotions and perceptions are most important. Perceptions are frequently generated by anecdotal evidence resulting from prior experience, and are not always based on concepts of probability, but rather take into account many different and not necessarily reliable sources of information. Moreover, individual perceptions focus on safety and the search for zero risk, unlike scientific evaluation, which is based on concepts of the cost-benefit type.

The public forms its perceptions based on other factors that we go on describe below, and which should be taken into account in any process of communication.

Factors related to risk perception	
■	Knowledge or familiarity with the risk, and understanding of its causes. Lack of information normally leads to an increase in the perceived risk. New risks are more difficult to accept than those that are already known.
■	Whether it is avoidable or not. If a hazard is invisible, the feeling the one cannot use one's own resources to control the hazard, and whether or not exposure to it is voluntary. Smoking and driving are considered controllable, since our perception is that we can choose whether or not to engage in such activities. The perception of control is zero in the case of food hazards.
■	Uncertainty, or the non-existence of scientific agreement and a lack of categorical statements. The existence of a large number of nuances or questions yet to be definitively clarified. For much of the public, the idea that everything is susceptible to review and that affirmations can only be made in accordance with current knowledge is usually difficult to accept, and helps to generate a greater perception of risk.
■	The existence of advantages and disadvantages linked to the risk. Certain risks can be accepted if one is aware of some benefit to be gained. The motor car is a good example of a risk that is accepted due to the benefits associated with it.
■	Whether its origin is deliberate or unintentional, and whether some third party obtains benefits from it, factors that aggravate negative perceptions, since the situation is considered especially unfair.
■	Natural or human origin, since risks of natural origin are accepted more readily than those caused by human action.
■	Risk to the infant population
■	The severity of the consequences and the concentration of effects. A plane accident or a terrorist attack concentrate a greater number of victims at a single point in time, something that leads to a greater perception of risk than is the case with car accidents, although the total number affected each year is much higher. In food issues, there is a higher perception of risk when there is a widespread effect (spongiform encephalopathy, dioxins) than when hazards are more restricted (food poisoning in collective eating areas).
■	The area covered by the disease. The larger the area, the greater the uncertainty and the higher the perception of risk. Hence the perception of high risk from chemical contaminants and residues with potential long-term toxic effects even though their effect on health has not been demonstrated by epidemiological data.
■	The severity of the effects.
■	Powerlessness when a disease is considered incurable. Hence the strong perception of risk from any agent linked directly or indirectly to cancer.
■	Geographical proximity. Undesirable events have less impact when they are perceived as distant. However, the globalisation of information and the food trade are elements that are causing the influence of this factor in perceptions of risk to change.

Perception is conditioned by the cultural models that human beings use to interpret everything around them.

Experts consider that perception is conditioned by the cultural models that humans use to interpret everything around them. Familiarity with a risk may lead to it being accepted or ignored, as may the fact that it is controllable or that it is possible to take personal steps to limit or avoid it. Risks that are not familiar, that conflict with our values or that do not seem to be controllable are less easily accepted. Genetically modified organisms are a good case in question, because they depart from the collective ideal of natural agriculture, do not depend on our will and are manmade, not controllable by the individual, suspected of being created in the interests of big business and government and, above all, arouse doubts about scientific impartiality. All this, despite the fact that no diseases caused by these agents have been reported. Against this, the alarm over salmonella is lower in spite of the many cases of the disease reported. The explanation for this phenomenon, in theory paradoxical, is linked to questions regarding familiarity with the hazard, its natural origin and the perceived existence of effective measures to counteract it.

The bovine spongiform encephalopathy crisis is another classic example of this phenomenon, as it brings together many of the negative attributes attached to the perception of risk: a hazard that appeared recently, is not visible, cannot be controlled by the individual, in which there is a lack of knowledge and understanding, uncertainty and differing scientific opinions, randomness, a long incubation period, the death of those affected and ignorance about the number of people who might potentially be affected.

This contrasts with the very different perception of the risk of food poisoning, which is a hazard understood traditionally, partially controllable by the individual, in which there is understanding of the phenomenon, scientific certainty, a short incubation period, low or zero mortality rate and for which means are available to cure the illness.

The principle of transparency in risk communication

The principle of transparency should govern all actions aimed at assessing and managing food safety in accordance with the public's right to be correctly informed about the collective health problems implied by a risk.

Transparency implies not only rapid and easy access to results from studies, management programmes and recommendations in matters of food safety. It also requires that the processes, criteria and decisions applied in formulating such initiatives should be as freely accessible as possible. The general population must have access to all the information that can enable them to understand the decisions taken. However, these principles should be made compatible with those of confidentiality and legislation governing data protection.

Transparency implies not only fast, easy access to the results of studies and management programmes; the public also needs access to information about processes, decisions and criteria.

In this respect, reference must be made to Article 7 of Law 20/2002, which establishes that, without prejudice to current legislation on access to official documents, where there are reasonable grounds for suspecting that a food or feedstuff may represent a health risk to people, the competent authorities, depending on the nature, severity and magnitude of the risk, should adopt appropriate measures to inform consumers about the nature of the risk linked to the food. To this end, information must be given, as far as possible, about the food or feedstuff involved, the risk it may present and the measures adopted to prevent, reduce or eliminate this risk. Food production chain operators are required to inform the authorities about any risk they may detect and to cooperate by providing all necessary information. This is an example of legally-required management and transparency measures, as well as one showing the strong interrelation between all the components in risk analysis, as this is a measure in which elements of risk management and communication come together simultaneously.

We can see, then, that the principle of transparency is a crucial element in risk communication and in restoring and maintaining consumer confidence.

III Methodology used to develop the Food Safety Plan of Catalonia: goal-based planning



The Food Safety Plan of Catalonia was drawn up by applying a methodology based on the principles of goal-based planning. This planning system is well adapted to the need to use a tried-and-test, effective and scientifically consistent method enabling us to determine measures to be carried out in order to meet the objectives established according to a logical thought sequence resulting from the identification and prioritisation of existing issues. This system also provides us with an assessment procedure which enables goals to be studied in the results obtained from applying the Plan and the degree to which its objectives are achieved.

The method of planning by goals, which was also used to draw up the Health Plan of Catalonia from the very outset, then, meets the planning requirements established in Article 14.4 of Law 20/2002, of July 5, on food safety, which expressly states that the Plan must include the objectives and the levels to be achieved, the services to be provided, the programmes and actions to be carried out and the assessment mechanisms for monitoring the Plan.

The main objective of food safety policy in Catalonia is to guarantee that no harm will be caused to consumers by food.

Avedis Donavedian is a leading expert in this field. Donavedian transplanted into the health field the strategy of goal-based planning applied by Robert McNamara in private business and administration in North America. Two outstanding personalities in health promotion and disease prevention are Raynald Pinauld (Department of Community Health at the University of Montreal) as a theorist, and J.M. McGinnis (Department of Health, United States) as a practitioner. Pinauld and McGinnis proposed and applied Donavedian's planning principles in the field of community health. Pinauld published the book *Planification de la Santé* in 1986, whilst McGinnis directed the United States' first health plan, published in the mid 1980s.

These two authors established the bases for planning health policies by the public administration. In their view, the process for preparing a plan is based on a logical sequence which, with a mission in mind, must include, firstly, strategic planning, setting out the aims to be achieved, and, secondly, tactical planning based on specific long term objectives (5-10 years). These long term objectives are achieved through short term operational goals (4-5 years). This methodology also provides for the application of systems to evaluate performance in terms of objectives achieved.

Stages involved in goal-based planning for the Food Safety Plan of Catalonia

Goal-based planning must be based on a thorough study of the environment in which plans are to be implemented and the organisations which will implement and execute plans. Both studies of this environment and internal analyses are necessary.

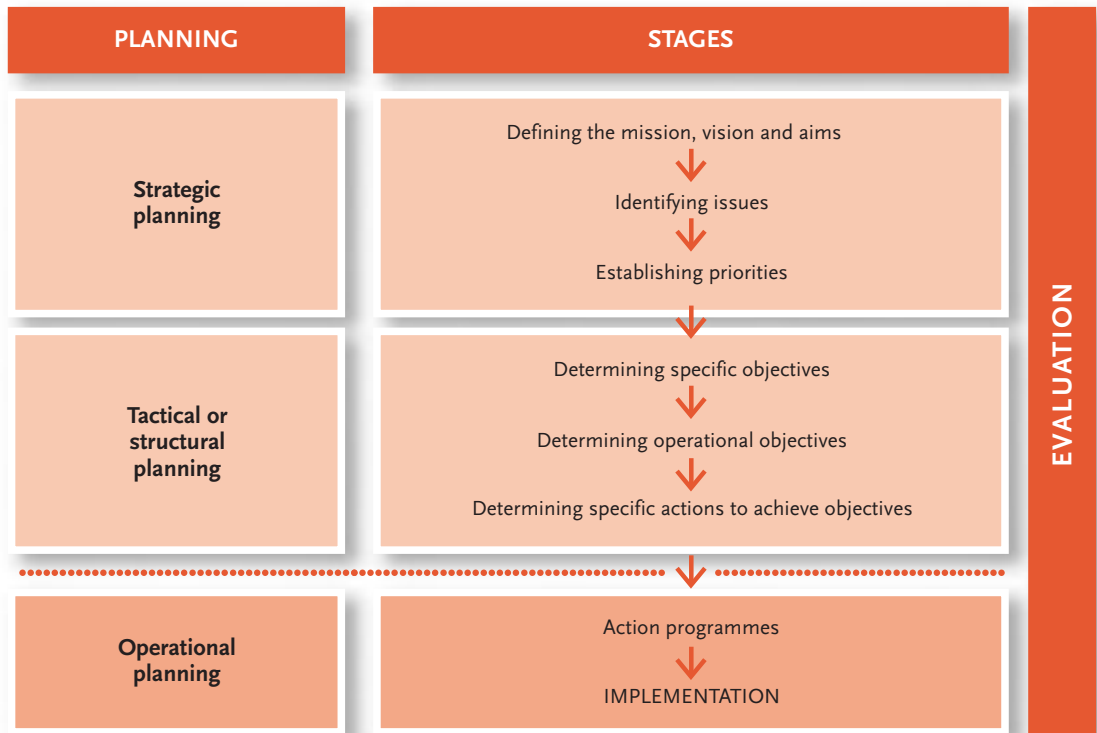
Study of the environment. This is aimed at ascertaining the external circumstances and factors which define the real situation in the environment in which the plan is to be applied. The factors studied include threats, unfavourable situations, opportunities and environmental factors that might provide advantages or benefits.

Internal analysis. This is aimed at ascertaining the peculiar characteristics of the organisation or organisations which will deploy and apply strategic planning. The factors studied include weak points or unfavourable factors and strong points or factors which could enable an efficient response to existing challenges to be made.

The overall results from these internal and external analyses are known as the SWOT analysis (strengths, weaknesses, threats, opportunities). This SWOT analysis serves as the basis for subsequent strategic, tactical and operational planning.

As we can see in the diagram below, the planning sequence can be broken down into different stages corresponding to different types of planning: strategic, tactical and operational.

Planning stages



These three levels of planning are closely interrelated. There are areas in which they intersect, so that strategic planning also includes defining the general structure and factors that will guide tactical planning to identify specific and operational objectives, as well as defining action plans to be implemented. The Food Safety Plan of Catalonia describes the strategic and tactical stages of this methodological sequence, whilst most of the tactical planning and everything concerning operational planning is left to the bodies or units responsible for implementation. More detailed definitions of specific and operational objectives are reserved for risk managers where appropriate, so such objectives can be adapted to the characteristics of each stage of the food production chain and to each area of action. In the operational phase, drawing up and applying action programmes is left entirely in the hands of risk managers.

The planning stages involved in the Plan are described below.

- 1. Defining the mission, vision and aims.** The mission, understood as the final objective, the *raison d'être*, the overall goal or target, must be fully specified and defined through description of its purposes. We may define these purposes as the different elements into which the mission can be divided, or as the objectives or final goals that shape the mission itself. The vision is defined as a representation of the ideal situation that we hope to achieve in the future.
- 2. Identifying concerns.** This consists of ascertaining the concerns that exist in the field of food safety and which require action to prevent, attenuate, correct or resolve them.

3. **Establishing priorities.** This procedure enables us to identify issues or concerns which must be considered in the first place, according to a series of criteria establishing the severity of these issues, our understanding of them, the availability of measures to resolve them and the real possibility of applying such measures.
4. **Determining specific long term objectives (8 years).** Specific objectives should be defined for each different area included in the Plan. These objectives will be set out in a clear, precise, quantifiable manner, with the corresponding indicators, performance criteria and time scale, aimed at contributing to or achieving some part of the purposes behind the Plan. The specific objectives of the Food Safety Plan of Catalonia are divided into the following groups:
 - **Health objectives:** these focus on the state or health situation of the population with regard to a particular issue. These objectives are normally evaluated in terms of morbidity.
 - **Objectives to attenuate risks:** these refer to health risk factors, whose presence should be reduced. In the field of food safety, this normally entails attenuating such risks at the different stages in the food production chain, and decreasing the extent to which people are exposed to them.
 - **Food safety communication objectives:** these are aimed at promoting exchanges of information and, especially, at improving the public's perception of food safety.
 - **Objectives concerning guarantees over food safety issues:** these focus on issues that do not involve an immediate risk or health concern, but which are directly or indirectly related and are important within the general context of food safety. They refer to issues that may affect the confidence and expectations of consumers and of society in general.
5. **Establishing mid term operational objectives (4 years).** Operational objectives are directly linked to measures aimed at achieving specific objectives, and compliance with them is mandatory for bodies responsible for creating the desired operational situation.
6. **Determining measures to achieve objectives.** By "intervention", we understand the activities to be carried out in order to achieve operational objectives laid down and, in short, to resolve, prevent or attenuate the emergence of a particular issue. Defining, planning and applying the activities required to achieve operational objectives, as well as providing the resources to be mobilised to this purpose, are tasks for which bodies responsible for implementing interventions are also responsible.
7. **Establishing evaluation systems** for specific and operational objectives.

According to the logical sequence set out here, a series of interventions must be developed in order to achieve certain operational objectives. This, in turn, will enable us to meet specific objectives required to achieve the purposes defined under the overall mission.

In order to apply this methodological sequence in the field of food safety, we need to formulate a global, integrated concept, according to which the process of identifying issues and subsequently setting out objectives and interventions should embrace the entire food production chain, from primary production to final consumption, including all the sectors and activities involved.

Types of food safety issues

Food safety issues may be classified into three large groups: those concerning food safety itself, those concerning other related issues and those to do with food safety communication.

It is only possible to set out realistic health objectives when the food route is the crucial element.

Regarding concerns related with food safety itself, we should bear in mind that in many cases full epidemiological data is available concerning the direct, demonstrable effects on health of particular hazards in human beings, and that the morbidity/mortality related to many identified hazards is unknown. It would be especially useful to have data on the relative risk and the risk attributable to each hazard associated with food. This would allow us to ascertain the relation between the incidence in both exposed persons and non-exposed persons, as well as the proportion and the number of cases of an illness which can be traced to a particular foodborne hazard. Although several epidemiological studies have attempted to answer this question, there is not enough information at present with regard to this question. This state of affairs is even more evident as regards chemical hazards, to such an extent that risk evaluation must be based on toxicity studies in experimental animals.

Percentages of foodborne transmission according to pathogens			
Pathogen	Percentage	Pathogen	Percentage
Bacteria		Parasites	
<i>Bacillus cereus</i>	100 %	<i>Cryptosporidium parvum</i>	5-10 %
<i>Brucella</i>	50 %	<i>Giardia</i>	10 %
<i>Campylobacter</i>	80 %	<i>Toxoplasma gondii</i>	50 %
<i>Clostridium perfringens</i>	94-100 %	<i>Trichinella spiralis</i>	100 %
<i>E. coli</i> (verotoxigenic)	63-85 %	Viruses	
<i>Listeria monocytogenes</i>	99 %	Noroviruses	10-40 %
<i>Salmonella typhi</i>	80 %	Rotaviruses	1-2,5 %
Other salmonellas	91-95 %	Hepatitis A virus	5 %
<i>Shigella spp.</i>	8-20 %		
<i>Staphylococcus aureus</i>	96-100 %		
Toxicogenic <i>Vibrio cholerae</i>	90 %		
<i>Yersinia enterocolitica</i>	90 %		

Source: J. Rocourt, G. Moy, K. Vierk and J. Schlundt. The present state of foodborne disease in OECD countries. WHO Department of Food Safety, Geneva 2003.

It is more realistic to confront concerns through risk attenuation objectives, which are normally associated to activities or interventions aimed at decreasing exposure to the hazard in question.

In the area of biological hazards, it is possible at times to determine the incidence or prevalence of the illness or health concern and to propose health objectives, although objectives to attenuate risk must also be established. We must also bear in mind that many health concerns caused by hazards related to food, including those of a biological type, are not exclusively foodborne, since other factors and other routes of contact with the pathogenic agent often also intervene. For this reason, it is only possible to formulate realistic health objectives when the food route is the determinant, or crucial element, as is the case, for example, with food poisoning.

With regard to most food related hazards, it is either not possible to demonstrate a full, direct correlation with the effects on the health of the population, or factors may intervene which are outside the realm of food safety. For this reason, it is more realistic to tackle concerns through risk attenuation objectives, which are usually linked to activities or interventions designed to reduce exposure to the hazard in question. This approach forms part of an eminently preventative strategy whose purpose is to minimise public exposure to food related hazards, independently of whether or not health issues have been described in the population. It is for this reason that risk attenuation objectives predominate when health objectives are set out in the Food Safety Plan of Catalonia.

Turning now to the second group of issues, regarding guarantees concerning food safety issues, we should point out that, in most cases, no direct correlation exists between these and public health protection. However, these are issues that are closely related to the food production chain and to the general idea of food safety, understood as a global concept going beyond the mere safety of foodstuffs.

Although the objectives related directly to public health must be considered as the priority, we should also remember that other issues and factors are also of great importance, as they have far-reaching effects on the prestige of the food production chain and foodstuffs produced in Catalonia, with evident repercussions on confidence amongst consumers and in international markets. These are highly sensitive issues, since present public concerns go far beyond the question of whether or not a food entails a risk to their health. It is for this reason that we must also take into account certain questions that have ethical, social and economical components and repercussions, and which have an effect on public confidence. Due attention must be given to such issues in accordance with a global and integrated concept of food safety.

Moreover, linked to the two groups described here, there also exist concerns about food safety communication in which issues can arise due to the lack of interactive exchanges of information and opinions amongst all stakeholders, and to a lack of public understanding, perception and trust.

Determining priorities

A concern is a deviation from a desired situation, whilst a requirement refers to what must be done to prevent, control or resolve such a concern.

In order to define objectives, it is necessary, firstly, to understand concerns and requirements. To this end, a distinction should be drawn between a concern and a requirement. A concern is a deviation or the possibility of a deviation from a desired situation. It may be caused by a public health problem by the prevalence of a hazard, by the perception that the public has of such a hazard, or by a lack of guarantees regarding any of these issues. On the other hand, a requirement refers to what needs to be done to prevent, control or resolve such a concern.

A requirement is born when a difference is reported between the situation considered to be optimal and the actual situation observed, a difference we wish to attenuate. But it also is possible that a requirement may arise from the desire to maintain a situation considered acceptable or optimum in order to avoid the emergence or worsening of a concern. Many of the objectives in the field of food safety are related to this second form of requirement, since we take quite a high level of food safety as our starting position.

Concerns and requirements, can be studied based on information sources built up from epidemiological data, the opinions of professionals and scientists, data obtained from surveillance programmes, and other sources depending to the needs felt or expressed by the general public.

Studies of concerns and requirements and evaluation studies all rely on relatively similar data collection methods. Briefly stated, this is a dynamic process in which evaluation helps to identify concerns and requirements. We should remember this fact, since the evaluation process will run parallel to the process of identifying concerns and requirements in future revised versions of the Food Safety Plan of Catalonia.

Determining priorities forms part of strategic planning. The methodology for selecting and prioritising concerns used must form part of a systematic structure and should make it possible to weight and take into account a full series of relevant factors. Amongst the different methodologies described in the scientific literature, the most outstanding include those based on weighting criteria. We should mention two such methodologies in particular here: that proposed by Hanlon, and the Bloom criteria weighting methodology. Annex II describes a proposed methodology for the prioritisation of criteria based on these two methods and adapted to the Food Safety Plan, along with examples of the results that can be obtained for certain groups of food safety concerns.

In any case, determining priorities does not necessarily mean that resources have to be dedicated exclusively to those concerns identified as priorities, since there exist determining con-

The determination of priorities does not necessarily mean that resources have to be dedicated exclusively to concerns identified as priorities.

ditions, such as current legislation, which require measures to be applied independently of the results of prioritisation. Similarly, lack of complete solutions should not prevent action from being taken to attenuate a concern identified as a priority by studies.

However this may be, the proposed prioritisation system should serve as a reference element for risk managers when drawing up and applying programmes for intervention. The Food Safety Plan of Catalonia is structured according to different areas and lines of action. Within each line of action there are programmes which often address concerns of different types simultaneously. For example, many official surveillance and control programmes which include different types of hazards to be studied should be modified over the years according to circumstances and the situation at any given time. The strategic prioritisation obtained by applying the method described should provide risk managers with a guide to giving programmes a coherent strategic orientation within the framework of the Food Safety Plan, as regards both risk management and assessment and risk communication.

Determining objectives

There should be one or more indicators for the correct formulation of each objective, and for the corresponding starting levels and expected target level within a particular timeframe.

Objectives must be laid down only if they can be assessed, that is to say, only objectives for which valid indicators are available should be established. In order to appropriately define each different objective, one or more indicators are required, along with information about the initial situation and the target level within a certain timeframe. It is also important to establish a single methodology for obtaining data, so that these are comparable, both over time and, if possible, with other fields or regions.

Establishing objectives that can be assessed quantitatively and within a particular timeframe encourages commitment to achieve such goals. Furthermore, the objective must be feasible, in order to avoid large discrepancies between the target result and the result actually obtained, since it makes no sense to establish objectives which are not reasonably achievable.

To establish the level to be achieved, or target level, we must bear in mind the opinion of the experts regarding the expected development of each concern as well as the data available on its past evolution and legally required levels, where such have been established.

The target level must also be established in a realistic manner so that it is feasible to reach it within the time frame set. For this reason, in cases where the prospects for attenuating a concern do not seem favourable, the objective established may be that of reversing or containing the unfavourable trend observed in recent years. In cases of low or zero incidence, the objective should be to maintain the situation of the past few years and to keep existing low levels stable.

At times there exists a methodological problem for setting out certain target levels due to lack of available information regarding the most suitable indicators and the corresponding initial levels and target levels.

When faced by such a methodological difficulty, it is necessary to provide for actions aimed specifically at resolving them through research and by collecting the necessary data about starting levels, target levels and the most suitable indicators, with a view to improving the way these objectives are formulated in the future.

This methodological difficulty arises in formulating most of the objectives under this first Food Safety Plan of Catalonia, since the Plan is based on a generic formulation of objectives which will be described in greater detail at a later time. One of the objectives of the plan is to provide strategic guidance for intervention over food safety, leaving managers considerable freedom of action. This is why many of the objectives under this first Plan are stated generally, and are linked to generic indicators and to performance criteria in the shape of guidelines to be further developed and defined in greater detail as they enter into operation. More

Many of the objectives of this first Plan are stated generally and are associated with generic indicators which will have to be deployed and defined in more detail.

specific monitoring and assessment studies will need to be developed once the Plan is operative, taking into account data and information obtained from the operational intervention programmes launched by risk managers. The report presenting an analysis of food safety management and the food safety situation in Catalonia should gather together information about specific action carried out as part of interventions provided for under the Plan, making it a key element in monitoring the way in which the official bodies responsible deploy and apply the Plan.

Defining interventions

Interventions are defined as actions launched throughout the food production chain in order to achieve operational and specific objectives.

We define interventions as actions launched throughout the food production chain in order to achieve the operational and specific objectives set out under the Plan. The public administrations involved in the food production chain are responsible for these actions, without prejudice to those applied by operators in accordance with current legislation and the principles of responsibility and due diligence.

Operational objectives must be linked to effective, efficient, feasible and accepted interventions.

One element which gives rise to a certain degree of complexity in developing and applying the Plan is to be found in the interventions it provides for and the need to adapt these to existing operational requirements, structures and programmes.

For many years, institutions responsible for food safety, both in the European Union and at national, autonomous region and local level, have studied the available information, detecting needs and planning and implementing interventions. This process, as already indicated, is often reflected in regulations, whether in the form of recommendations to the European Union or as mandatory legislation.

Although the process followed in establishing and designing them differs, the Plan should provide for maintaining and constantly improving the several surveillance and control programmes that have already been launched in Catalonia.

The existence and heterogeneity of intervention programmes, with their different origins, are elements that increase complexity and which must be taken into account. Reference should be made in the Plan to the peculiarities of the objectives and scope embraced by such programmes, often for historical, operational and structural reasons. For instance, a particular programme may include activities concerning different fields of action provided for under the Plan, and may include both actions complying with general hygiene or food safety regulations and others concerning surveillance and control of particular, specific hazards, and this not only for operational reasons, but also due to the close links that exist between them.

The actions required for a particular intervention may be performed through different programmes designed according to operational or structural requirements or to the need for efficiency in employing available means. To these elements we must also add the fact that responsibility for certain areas of action may be shared by more than one body or entity, so that different departments of the Generalitat and of local administrations may be involved simultaneously.

Furthermore, in most cases, analytical surveillance provisions are complemented by official control measures, including actions aimed at correcting any irregularities detected, so that surveillance and control activities often form part of the same programme.

This complexity must be borne in mind because, although the Plan establishes a series of operational objectives and interventions which are formulated according to a particular scheme and a logical sequence according to the requirements detected in particular areas,

Interventions under the Plan are formulated more as lines of action, giving the bodies responsible for carrying them out a wide margin of manoeuvre to implement them in the form of programmes.

in practice these actions must be carried out through programmes which respond to historical circumstances and to structural and operational requirements.

The Plan should be adapted to the peculiarities of the starting situation and of the bodies responsible for putting it into effect. Therefore, the interventions necessary to achieve operational objectives must be defined so that the actions to be implemented are clearly specified. As far as possible, the way in which these actions are to be carried out and those responsible for this should also be clearly stated. In order to respond to this need, interventions under the Plan are formulated more as lines of action than as specific interventions, giving the bodies responsible for carrying them out a wide margin of manoeuvre and allowing interventions to take the form of programmes or specific actions, taking into account the circumstances underlying each particular case.

Selection of interventions

We can distinguish in the planning framework priorities for actions addressing concerns which will be the object of preventative or corrective intervention. These priorities are found throughout the Plan. For their part, research priorities addressing concerns for which increased knowledge of causes and possible solutions is required are to be found in the chapter on risk assessment.

The interventions were selected according to different criteria which will allow us to establish prioritisation when necessary. Prioritisation consists of rationally ordering the requirements and interventions that provide a response to concerns, assigning available resources as appropriately as possible.

To select and prioritise interventions, a method of weighting criteria may be used, similar to that described above in the section on determining priorities. Here, we must take into account criteria of effectiveness, efficiency, feasibility and acceptability. It is, therefore, important to consider the capacity of the intervention to prevent or correct the concern, the cost-efficiency ratio involved, availability within the actual context, legal security, the current legal situation and also other factors which might be related, including the opinions of scientists, professional organisations and consumers, the bodies responsible for carrying out interventions and experts in the field, since acceptability is an important factor in achieving objectives. All these elements should be taken into account by bodies responsible for implementing interventions under the framework of the Food Safety Plan of Catalonia.

Legal constraints

There exists a certain overlap between planning carried out nationally and in the European Union and under the Food Safety Plan of Catalonia.

In the area of food it is normal to encounter legally established constraints at national or EU level. In drawing up the Plan, consideration was given to such factors as the severity of concerns, social perception and consequences for related issues, amongst other considerations. Since these are legally established issues, there is a legal imperative which has to be borne in mind when deciding the objectives and interventions to be included in the Plan. This consideration particularly affects the selection of interventions. There exists, therefore, a certain overlap between planning carried out nationally and in the European Union and under the Food Safety Plan of Catalonia. Current legislation is, in this case, decisive in determining the choice of objectives and interventions, placing restraints on planning but also providing a reference point for selecting interventions.

Results evaluation

Evaluation is a fundamental element in the Plan. Its importance is that it enables us to ascertain the extent to which previously established objectives have been achieved, a crucial element as this provides guidance for setting out new objectives in the future, enabling us to see trends followed with regard to different concerns, as well as gauging the effectiveness of measures applied.

It is important that the evaluation be performed quantitatively and within a particular timeframe. The written formulation of the objective should define as far as possible the indicator by which its evolution is to be measured.

It is important that the evaluation be performed quantitatively and within a particular timeframe. Indeed, the written formulation of the objective should define as far as possible the indicator by which its evolution is to be measured.

The formulation of an objective and its evaluation are closely linked, since the indicator and the target level must be included in the description of the objective. For this reason, the guidelines provided for formulating objectives should also be used to evaluate interventions.

Furthermore, we should remember that, in many cases, evaluation also requires specific activity, since it is necessary on occasion to carry out surveys, analyses, studies and research work specifically forming part of the evaluation process. As already stated, this circumstance is of particular importance in this first draft of the Plan, since in many fields there is a lack of complete and reliable information.

The Plan and its evaluation system must be designed to enable us to analyse their development and to make comparisons with other fields or periods of time for which data is available. To this end, consideration should be given to the difficulty of ensuring that data remains comparable. Efforts will be required to systematise or standardise information gathering and evaluation systems in order to maximise comparability.

To provide for results evaluation, a system equivalent to that contained in the Health Plan for Catalonia will be applied, and the results will be classified according to the following categories:

- Completely achieved (CA): the indicator level shows expected changes in the required direction to levels equal or superior to the target level.
- Partially achieved (PA): the indicator level shows expected changes in the required direction to at least 50% of the target level.
- Not achieved (NA): the indicator level shows expected changes in the required direction of less than 50% of the target level, or that change has occurred in an unexpected direction.

Where objectives are not achieved or in cases where evaluation is not possible, the reasons will have to be investigated in order to improve future editions of the Food Safety Plan.

IV Food Safety Plan of Catalonia 2007-2010



IV

1 Aims, strategic orientation and scope of intervention

Strategic planning should be based on thorough studies of the starting situation. Amongst the techniques most commonly used is SWOT (strengths, weaknesses, opportunities and threats) analysis. These four factors provide a framework which an organisation can use to conduct a structured analysis of its potential and limitations, as well as its interactions with its environment. The main objective of this crucial analysis is to provide useful information for establishing strategies and targets.

Various sessions, organised according to the SWOT method, enabled an internal analysis to be carried out, identifying the strengths and weaknesses of the public intervention system for food safety in Catalonia, and an external analysis to identifying existing opportunities and threats. The results obtained from these studies is detailed below.

Internal analysis

Weaknesses

- Compartmentalisation of functions and a lack of cross-coordination
- Disproportionate measures applied. These vary in intensity depending on the phase and sector of the food production chain concerned, and not always on the risk associated
- Lack of sufficient development in the evaluation of problems from a scientific, multilateral and multidisciplinary perspective
- Lack of development in risk communication
- Lack of coordination and collaboration with those participating in the food production chain to achieve common objectives
- Historic inertia and resistance to change
- Lack of transparency and exchange of information
- Existence of a certain lack of definition in the sharing of competencies between and within the same organisations
- Lack of planning and standardisation of procedures
- Underuse of IT resources
- Existence of changing situations in managing organisations
- Financial difficulties due to the high cost of interventions

Threats

- Subordination to European and State decisions and law
- Persistence of risk of traditional hazards
- Persistence of food poisoning as the main problem difficult to control
- Appearance of emerging hazards
- Rapid development in demand for services in step with the progress of scientific knowledge
- Public discredit and distrust
- Lack of tradition of food safety in the primary phases of the food production chain
- Financial and technical difficulties in the various sectors for the full implementation of general conditions in food safety (training, traceability, in-house controls, etc.)
- Changes in public habits and the perception concerning food
- Complexity and breadth of what society understands as food safety
- Globalisation of problems together with local impact of actions
- Strong financial interests relating to the food production chain which could generate distortions

- Lack of knowledge and awareness about food safety on the part of a large number of food production chain operators
- Lack of visibility in the media and public opinion of positive outcomes, whilst unfavourable results are given wide coverage
- Conflicting interests between media and certain organisations over risk communication policies

External analysis

Strengths

- Organisations with considerable technical and operational experience
- Availability of a team with good qualifications and experience
- Multidisciplinary. Availability of specialists in a large variety of disciplines and fields
- Deployment throughout Catalonia
- The most important interventions on questions of risk management are already mainly implemented, although they must be improved
- Existence of a large number of responsible administrations, with presence in all the stages of the food production chain, making possible the execution of actions in a shared, coordinated way, generating synergies
- Considerable executive capacity deriving from attribution of competent authority and from the regulatory framework
- Capacity to influence and initiate within the regulatory framework.
- Influence over questions with financial repercussions

Opportunities

- Compartmentalisation - dynamic and complex circumstances stimulating constant adaptation and improvement
- Technological development facilitates improvement in efficiency and productivity
- Food safety is an advantage in terms of projection abroad for the economy, tourism and business
- Society values and demands services which guarantee the safety of foods
- There is a strong public demand for information on food safety
- Society understands food safety as an integrated whole that goes beyond the mere harmlessness of foods
- Considerable interest from the production sectors in collaborating with the administrations and consumer representatives with the aim of satisfying public demand
- Increase in value given by and interest from politicians
- Commercial operators understand food safety as a responsibility and they are also aware of the possible financial repercussions
- Epidemiological and analytical surveillance data indicate that the current level of food safety is high, although it could be improved

From this analysis of the situation we may define the mission, vision and aims of the Food Safety Plan of Catalonia.

MISSION of the Food Safety Plan of Catalonia

- To maintain a high level of food safety in Catalonia, acting as an indicator and reference framework to define, in cooperation with all the participants in the food production chain, including consumers, objectives and interventions to be performed by the Catalan public administrations, as well as monitoring and evaluation systems.

This mission breaks down into the following aims:

AIMS of the Food Safety Plan of Catalonia

1. Prevent food-related illnesses, as well as reducing their incidence and prevalence to the most reasonably possible minimum.
2. Prevent and reduce to reasonably possible or acceptable levels exposure of the public to foodborne diseases.
3. Increase and maintain a high level of trust in the Catalan food safety system by both the citizens of Catalonia and those of other countries.
4. Maintain a high level of protection of public interest in the fields and questions relating to food safety, such as: health, nutrition and animal welfare; plant health; and quality of the products from the food production chain.
5. Maintain a high standard of fair trading principles where food safety is concerned.

This vision can be defined as an idealised summary of what we would like to obtain in the future, and it includes the most important principles and values. It can be defined as follows:

VISION of the Food Safety Plan of Catalonia

- A food production chain where health hazards and other related problems are eliminated or reduced to acceptable levels via efficient systems established through participation and consensus, implemented in a coordinated and complementary manner by the participants at each of its stages, from primary production to consumption; at the same time the competent administrations coordinate to verify efficiently the accomplishment of expected standards and ensure they are met; and in which a sensitive and well-informed public has full trust due to the credibility merited by the evaluation systems and management implemented.

Strategic orientation

The Food Safety Plan of Catalonia should serve as a global and systematic method for understanding problems and responding to them from a broad perspective throughout the food production chain, without the administrative nature of the different bodies involved acting as a barrier.

Fundamental elements of strategic orientation
1. Offer a general framework for the identification of problems and needs.
2. Orient the concerted action of public administrations toward certain shared results.
3. Offer an organised, coherent and integrated set of activities and services.
4. Facilitate the work in a transversal and inter-sectoral manner.
5. Make explicit the commitment of the public administrations responsible for food safety.
6. Improve management and service to the public on the basis of principles of sustainability, quality and efficiency.
7. Promote collaboration and cooperation amongst all stakeholders in the food production chain.
8. Evaluate results to move toward continuous improvement.

To achieve the mission and the aims formulated in the framework of this strategic orientation, we must first define the objectives and interventions as well as the monitoring and evaluation systems, following the logical structure described below:

The Plan is structured into two large blocks containing definitions of the objectives to be achieved and the interventions to be performed. The first block refers to the risk analysis process and includes aspects relating to risk evaluation, management and communication, both health risks and other questions relating to food safety. The second block refers to everything related to improving efficiency, cooperation and coordination amongst all stakeholders in the food production chain.

A section aimed at risk evaluation is planned for the first block. To ensure that management and communication objectives can be fully achieved, it is necessary to count on suitable risk evaluation which should enable their identification and characterisation, as well as to determine the most suitable management alternatives.

Next, suitable management of health risks deriving from foodborne hazards must be planned, with management aimed fundamentally at minimising public exposure to these agents. This proposal requires guarantees of meeting general food safety conditions by food production chain operators as a basic wide ranging measure to prevent and/or minimize risks. The relevant administrations must ensure they are met. Using this as a base, more specific management actions must also be applied to each of the stages in the food production chain for the hazards considered as a priority.

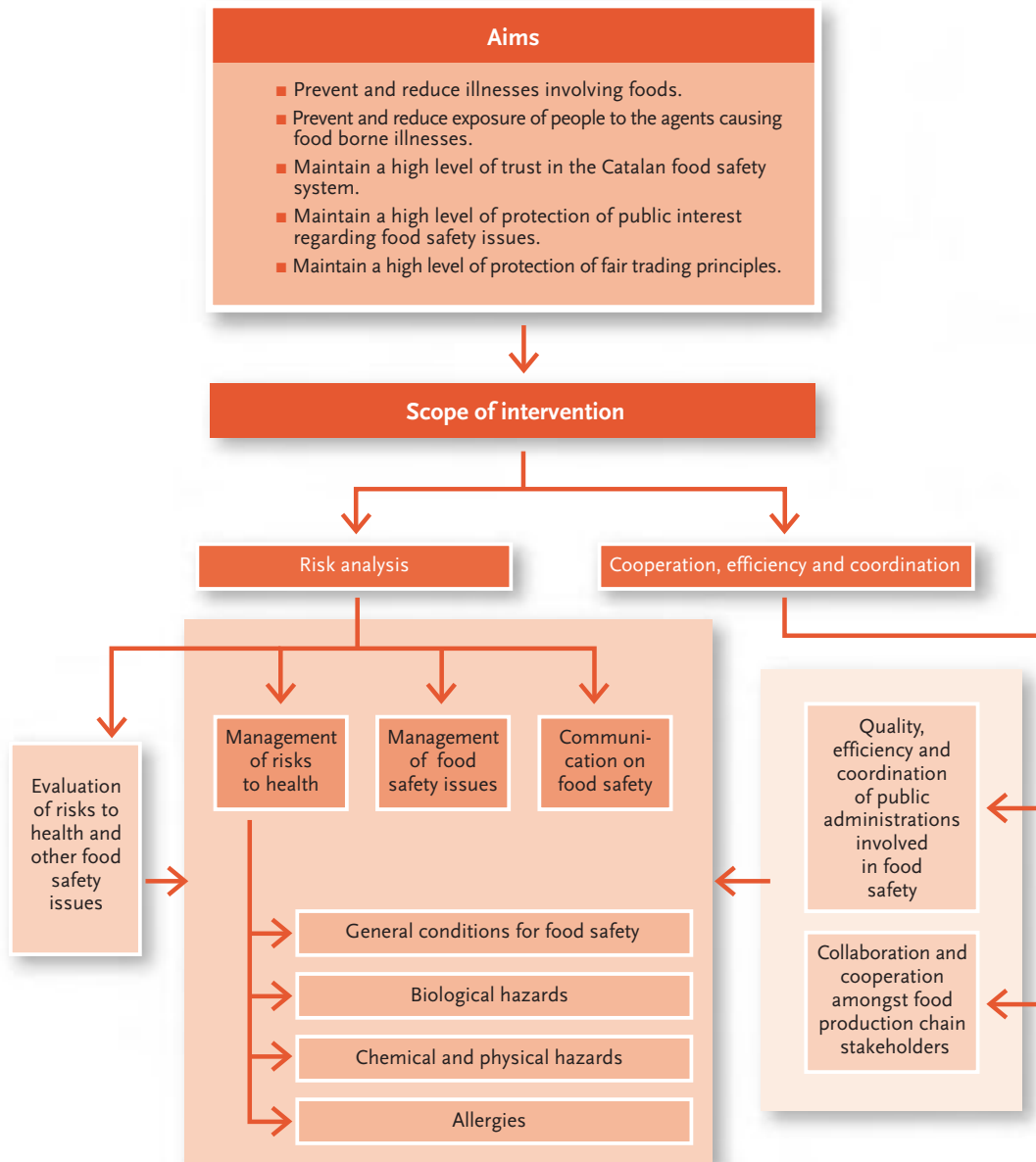
It is also necessary to define management objectives and actions in the field of the so-called "issues relating to food safety". We should plan a strategy aimed at minimizing problems existing in all those areas which could impact directly or indirectly on the harmlessness of foods or on public trust in the food production chain and its safety. Also, we should bear in mind that these are related but independent questions, so the objectives and interventions raised must be compatible with the specific planning which exists for each issue, and should not be a distorting element.

Finally, within the risk analysis procedure, we must develop a communication strategy aimed at increasing the exchange of information and opinions as well as the improvement of public information in all aspects relating to food safety, so leading to an increase in public trust.

Specific objectives and interventions must be planned in the field of cooperation, efficiency and coordination amongst all food production chain stakeholders so that the abovementioned risk analysis objectives and interventions may be suitably achieved. **We must guarantee a high degree of quality, efficiency and coordination amongst the public administrations involved in food safety and, at the same time, maintain the optimum level possi-**

ble of cooperation and coordination with the other food production chain stakeholders, including consumers and the scientific community. These elements can be qualified as coadjutants or instruments required to achieve the central objectives of the Plan. If we take into consideration their typology, they could even be included in the group of operational objectives. Nonetheless, due to their size and importance, as well as to avoid excessive complexity in the Plan document, it was decided to dedicate them their own sections and to set them out as specific objectives.

Aims and scope of intervention under the Food Safety Plan of Catalonia



IV

1.1

Structure and contents of the Plan

The sequence described determines the strategic orientation to be followed. As a consequence, the Food Safety Plan is structured into a series of fields identified below, with definitions for each of them of the objectives to be achieved and the actions to be taken.

A. Objectives and interventions for risk analysis

1. Evaluation of risks, which includes the determination both of health risks and of risks or problems relating to food safety issues.
2. Management of risks to health, which includes the application of general hygiene measures together with specific risk management actions, with the following structure:
 - 2.1 General food safety conditions
 - 2.2 Biological risks
 - 2.3 Chemical and physical risks
 - 2.4 Allergies
3. Management of questions relating to food safety, which includes everything with no direct repercussion on the harmlessness of foods but which could have an indirect influence on public perception and trust in the safety of the food production chain.
4. Communication concerning food safety.

B. Objectives and interventions for cooperation, efficiency and coordination

1. Quality, efficiency and coordination of the public administrations involved in food safety.
2. Cooperation and coordination of food production chain stakeholders.

Each of these sections identifies specific objectives, operational objectives, the interventions to be carried out and those in charge of their execution. The indicators and criteria to be used in monitoring and evaluation are also specified. **Given the strategic orientation of the Plan, the indicators chosen are expressed generically, so they may be capable of wider use and definition.** For this reason many of the criteria for success are formulated as an increasing trend without further specification. In the case of operational objectives, the availability or implementation of the action contemplated is usually formulated as a success criterion.

The more quantitative and qualitative aspects involved in applying and monitoring each of the parameters comprising each indicator will be carried out by the bodies in charge of management. In this way the Plan transfers much of the tactical planning to the bodies in charge of the execution of actions in the field of food safety.

The Plan is structured in the main to approach on problems from a global or group perspective. This is due to its basically strategic focus. To approach problems individually would be difficult from the methodological point of view, as it would make the document describing the food safety plan long and repetitive, and it would hardly be exhaustive due to the long list of questions requiring an answer. Furthermore, many of the interventions available are valid for the simultaneous management of different problems, so it is possible to set out objectives and interventions with a range of action for the existing set of problems. Certain cases treat particular questions in a more definite way, always bearing in mind the possibility or need to establish specific interventions over and above the more generic interventions planned. This is the case, for example, with spongiform encephalopathies and outbreaks of food poisoning.

Each of the fields identified defines existing problems and needs to be covered, as well as the objectives to be achieved and interventions to be performed, with indication of the motives, justification and essential elements for consideration in each case. A detailed definition is given below of specific objectives, operational objectives and interventions to be carried out through management statements which lay out the relevant information in an orderly fashion.

The objectives are formulated using a format of management statements which define the different elements comprising them. The objective is stated generically as a proposal, which is then defined below, establishing the indicator and the criterion for success, which identifies the situation desired at the end of the expected timeframe for each case.

Each criterion formulated defines the objective. To facilitate the reading and comprehension of the objectives in the management statements we should firstly examine the criterion for success, as this is the central element determining the objective to be achieved, and then consider the planned indicator and timeframe, since they are the elements which permit the definition of the generic statement or proposal set out in each case. The interpretation of these elements as an integrated whole defines each objective with all its elements.

Management statement models for the definition of objectives and interventions

Food Safety Plan of Catalonia 2007-2010

Risk evaluation for health and other problems related with food safety

Specific objectives Time frame: 2014

Number	Statement	Indicators	Criterion
Food-related risks			
E-001	Investigate food-related hazards in Catalonia, the risk to the population, causal factors and available scientific management options.	Studies to evaluate health risks associated with the food production chain	Available
Questions relating to food safety			
E-002	Investigate existing problems in Catalonia in terms of food safety issues, their size, causal factors and management options available.	Studies of risk evaluation in the field of food safety issues	Available

Operational objectives Time frame: 2010

Number	Statement	Indicators	Criterion
Risks to health			
O-001	Make available information on existing or foreseeable hazards relating to food and the levels of exposure of the population which could cause risk to human health.	Specific studies	Available
O-002	Make available information on the incidence and prevalence in Catalonia of food-related illnesses as well as on causal factors.	Specific studies	Available
O-003	Make available active-research systems for research into possible food aetiology and coadjutant factors of cases of illness diagnosed in Catalonia.	Specific studies	Available
O-004	Make available information on the hazards associated with each of the phases, activities and processes in the food production chain and on coadjutant factors.	Specific studies	Available
O-005	Make available information on existing needs in the field of food safety and on options available for risk management from the scientific point of view.	Specific studies	Available

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Interventions

Number	Statement	Responsible for the intervention
I-001	Prepare periodic studies to determine the level of exposure of the population to food-related hazards in a way that is significant and comparable in time, with special attention to certain risk groups such as children, pregnant women, the elderly and the sick.	ACSA
I-002	Prepare studies into food-related outbreaks and individual cases of human illnesses diagnosed in Catalonia to determine epidemiological data, causal factors and the foods associated.	DS
I-003	Compile information and prepare studies on the food production chain, including the environmental conditions where operations are performed, so as to determine the hazards and coadjutant factors associated with each of the phases, activities and processes. Make this information available to official control bodies, food production chain operators and the general public.	ACSA DMAH DAR DS ACC AL
I-004	Maintain permanent links and relations with leading scientific centres on questions of food safety for the exchange of information and permanent collaboration on questions of risk determination.	ACSA DMAH DAR DS ACC AL
I-005	Establish a scientific committee to carry out the analysis of information on questions of the determination of risk and the issue of reports and recommendations on this matter.	ACSA
I-006	Prepare studies into food risk management options from the scientific point of view.	ACSA DMAH DAR DS ACC AL

ACCS: Catalan Consumer Affairs Agency; ACSA: Catalan Food Safety Agency; AL: Local authorities; DAR: Ministry of Agriculture, Food and Rural Action; DMAH: Ministry of the Environment and Housing; DS: Ministry of Health

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The interventions are also set out in a format of statements delineating each of the actions to be implemented and indicating, via abbreviations, the body responsible for applying them, which will normally require the collaboration of the other public bodies involved. Where necessary, the phase or phases in the food production chain where the intervention is to be performed are also indicated.

In the section on management of risks and other associated issues, the body responsible is indicated, along with the stage in the food production chain at which intervention should take place. In all other sections, no distinction is made between food production chain stages, since the interventions involved are to a great extent transversal and are not linked to any specific stage.

Regarding identification of the body responsible, the Generalitat ministry charged with each intervention is generally identified; if not, the reference is to “local administrations” in general. Where a greater definition is possible, the specific body is identified, for example, the agencies attached to ministries with responsibilities in the area, and which are highly specialised in certain fields.

Some clarification is required with regard to ACSA, the Catalan Food Safety Agency. ACSA is an autonomous body, attached to the Ministry of Health, whose mission is to achieve the optimum degree of food safety in Catalonia through planning and coordinating actions in collaboration and cooperation with the various relevant public administrations. Several Generalitat ministries (Presidency; Health; Agriculture, Food and Rural Action; Environment and Housing; Trade, Tourism and Consumer Affairs; Economy and Finance; Innovation, Universities, and Enterprise) as well as Catalan local bodies, are represented on the ACSA Governing Board. For this reason, although it is attached to the Health Ministry, given its interdepartmental status, ACSA is included in the statement as a separate body. The interventions for which ACSA is made responsible under the Plan are to be carried out in cooperation with all the administrations involved in each case, and the agency may therefore be defined in the statements as directly responsible for an intervention under the Plan or as responsible only for promoting and coordinating the intervention. In the first case, the agency's acronym is stated in the same way as for all other bodies. In cases where the different stages in the food production chain are specified, however, the transversal nature of the agency's intervention by its inclusion at all the stages represented.

On a similar note, Barcelona Public Health Agency exercises, within its jurisdiction, local authority powers over food safety, carrying out interventions that are performed by the Health Ministry and ACSA, the health safety agency attached to it, in the rest of Catalonia. To help the interpretation of the statements, we should explain that, within the City of Barcelona, Barcelona Public Health Agency is responsible for interventions assigned to the Health Ministry, to ACSA and to local authorities.

Abbreviations used in the statements of objectives and interventions

- **ACA:** Catalan Water Agency
- **ACC:** Catalan Consumer Affairs Agency
- **ACSA:** Catalan Food Safety Agency
- **AL:** Local authorities
- **APS:** Health Protection Agency
- **ARC:** Catalan Waste Agency
- **DAR:** Ministry of Agriculture, Food and Rural Action
- **DE:** Ministry of Education
- **DEF:** Ministry of Economy and Finance
- **DMAH:** Ministry of the Environment and Housing
- **DP:** Ministry of the Presidency
- **DS:** Ministry of Health

IV

1.2 Official bodies responsible for interventions under the Food Safety Plan of Catalonia

As we have indicated, the Food Safety Plan of Catalonia states the objectives to be achieved and the interventions to be performed by the public administrations competent in food safety. The bodies responsible for carrying out interventions under the Plan are attached to various public administrations and intervene at different stages in the food production chain within the scope of their respective power. The public bodies responsible for implementing the Plan are briefly described below, along with their respective functions.

Generalitat (Autonomous Government) of Catalonia

Ministry of Health

The following bodies attached to the Ministry of Health should be mentioned:

The **Directorate-General for Public Health**, whose principal functions are epidemiological surveillance of contagious illnesses and outbreaks of epidemics; and the design and implementation of health programmes to protect and promote health. The Sub-Directorate General for Surveillance and Response to Public Health Emergencies is responsible for epidemiological surveillance.

Particularly important here are activities aimed at promoting good practice and official control with regard to preventing harmful effects to public health which could be caused by the presence of chemical, physical or biological agents in the environment and in food, work which is carried out by the Health Protection Agency.

The **Health Protection Agency**, which is currently being deployed all over Catalonia, is responsible for integrating all health protection services and activities, coordinating them with the other health protection services to protect the population from any dangers to human health that may arise, either in the environment or in food.

Besides divisions devoted to legal issues and general support services, another important body attached to the Health Protection Agency is the **Objectives and Programmes Division**, which is responsible for studying and drawing up criteria, directives and policies for health protection, both within the Generalitat and for local authorities all over Catalonia, staying within the lines drawn by current arrangements as regards the distribution of power and promoting inter-administration cooperation. For its part, the **Risk Management Division** is responsible for planning, programming and implementing programmes, protocols and guides for action, as well as planning the activities of the Agency's own laboratories and coordinating health authorisations and registers.

The activities involved in the applying programmes in Catalonia are carried out by local services, supported by the Public Health laboratories in Girona, Lleida, Tarragona, Tortosa, Manresa and La Seu d'Urgell, as well as that run by Barcelona Public Health Agency, all of which carry out analyses of water, food and other materials (clinical samples, surfaces, etc).

The **Catalan Food Safety Agency** (ACSA) is responsible for assessing and communicating health risks related to the food production chain, and for strategic planning, coordination and supervision of action taken by the competent public administrations in the field. ACSA also promotes cooperation and participation by all those involved in food safety, such as the production industries, consumer associations and users, and scientific and research centres.

Ministry of Agriculture, Food and Rural Action

The following ministry departments are relevant here:

The **Directorate-General for Production, Innovation and Agri-food Industries**, whose functions are to control and promote improvements in agricultural, livestock and agri-food production, and to control plant and animal health. This directorate-general is organised into the following sub-directorates:

- The Sub-Directorate General for Agriculture, which is responsible for evaluation, analysis and guidance in agricultural production; promotion and surveillance; integrated agricultural production and ecological agricultural production; and promotion and official control of plant health, including everything relating to the official control of production, retail and the use of phytosanitary products.
- The Sub-Directorate General for Livestock, which promotes improvements and official controls of livestock production and animal health, including everything relating to the production, retail and use of veterinary medications.
- The Sub-Directorate General for Livestock, which promotes improvements and official controls of livestock production and animal health, including everything relating to the production, retail and use of veterinary medications.

The functions of the **Directorate-General for Food, Quality and Agri-Food Industries** are to draw up and put forward proposals for policies and strategies governing food, quality and the agri-food business. The Directorate-General is organised into the following sub-directorates:

- The Sub-Directorate-General for Agri-Food Industries implements policies and strategies governing the agri-food business; sale and distribution of food products; fairs, markets and shows; and aid for agrarian and food product processing and sale.
- The Sub-Directorate-General for Agri-Food Quality promotes: agri-food product quality and official controls of compliance with laws governing quality; the fight against fraud in the agri-food industry; and official control of compulsory beef product labelling and traceability.

The **Directorate-General for Fisheries and Maritime Affairs**, which regulates and applies official controls in maritime fisheries, marine resources and coastal protection, aquaculture and shellfish through the Sub-Directorate General for Fisheries.

The functions of the **Institute of Agri-food Research and Technology** (IRTA) are focused on research and development, particularly technology transfer, the publication of research results and the provision of information on the progress of research and development projects.

The **Centre for Avian Health of Catalonia** (CESAC) was established through a collaboration agreement between the Generalitat of Catalonia Ministry of Agriculture, Food and Rural Action, the Catalan Avian Federation and cooperatives. Its functions are analysis and diagnosis and the issue of technical reports relating to avian illnesses.

The principal functions of the **Catalan Institute for the Vine and Wine** (INCAVI) are: to promote and foster improvement in fields associated with wine production; to research into and promote increased awareness and consumption; to study, research and experimentation with processes, techniques and materials; and to organise specialisation and refresher courses for technicians and professionals.

The **Training Centre for Agricultural and Rural Studies** (CFEA) is responsible for providing lifelong training for civil servants at the Ministry of Agriculture, Food and Rural Action in the areas of administrative organisation and quality of service; agricultural, livestock and fisheries production; agri-food industry and quality; Community policies; and rural development and technological transfer.

Official control activities are performed by the Local Services of the Ministry of Agriculture, Food and Rural Action, supported by the Laboratories for Livestock Health in Barcelona, Lleida, La Pobla de Segur, Girona, Reus, La Seu d'Urgell and Vic, Laboratory for Plant health in Barcelona and the Agri-food Laboratory in Cabriels.

Catalan Consumer Affairs Agency

Since it was first established, the Catalan Consumer Affairs Agency has been attached to various Catalan Government ministries (at present, it is attached to Economy and Finance). It is responsible for: official controls of information and safety of products and services provided for consumers and users; the detection and control of fraud, incomplete or erroneous information, deceitful publicity and the use of unfair wording; informing and advising consumers and users about their rights and how to exercise them; promoting consumer and user training and financial players; empowering mediators and arbitrators; and institutional relations and direct public participation through consumer and user associations and financial and social stakeholders. Within the Catalan Consumer Affairs Agency, the Sub-Directorate-General for Consumer Affairs is mainly concerned with coordinating the inspection service; market discipline and consumer affairs; and promoting action to improve information provided to consumers and to protect their rights.

Within the Catalan Consumer Affairs Agency, the Sub-Directorate-General for Consumer Affairs is responsible particularly for action aimed at improving information provided to both individual consumers and consumer associations.

Ministry of the Environment and Housing

Within this department we should mention particularly the following bodies:

The **General Directorate for Environmental Quality**, which is responsible for ensuring the rational use of environmental resources and for coordinating official controls of activities that have impact on the environment, as well as surveillance, prediction and control of air quality and protection of the atmosphere.

The **General Directorate for the Natural Environment** is responsible for carrying out studies and drawing up proposals relating to conservation, management and improvement of natural heritage; minimisation and control of impacts on the natural environment, protected areas and animal protection; coordinating environmental surveillance, control and inspection activities; promoting actions to prevent offences; and guiding and raising public awareness in order to promote environmentally-friendly behaviour.

Within this General Directorate we should mention the functions of the Area of Hunting Activities, which plans and manages hunting activities, and the Area of Continental Fisheries, which is responsible for planning and managing fisheries and fish factories in continental waters.

The **Catalan Water Agency** (ACA) is responsible for drawing up and reviewing water programmes and projects; controlling water resources and qualitative and quantitative aspects of water resources in the public domain; control, surveillance and inspection of the basic network and other water facilities, the use of existing surface and underground waters and discharges which could affect surface, underground and maritime waters; control of water contamination by setting limit levels for emissions and quality targets for the receptor medium; and coordinating any action by the competent administrations that involves water supply and sanitation in Catalonia.

Attached to the ACA, the Inspection and Control Division carries out official controls of water resources, discharges, analytical water control and river and maritime environmental controls.

The Catalan Water Agency laboratory, which is based in Barcelona, provides analytical support for official control activities.

The **Catalan Waste Agency** is responsible for promoting and applying waste management programmes. Through its Industry Division, the agency is also responsible for: studies relating to waste management; actions to promote industrial waste minimisation and recycling; evaluation of projects for public and private waste management facilities; control of activities to manage waste, and all industrial activities relating to waste production and management; waste identification, analysis and characterisation; and the promotion and control of suitable treatment of contaminated soils through agency's laboratory, which is located in Barcelona.

Local authorities

In compliance with Law 7/2003, of April 25, on the protection of public health, and Law 8/1987, of April 15, on municipal and local government in Catalonia, in the area of food safety, local authorities are responsible for managing health risks deriving from environmental contamination and, particularly, health risks concerning water for public consumption and food products in retail trade, restaurants (direct sale of prepared foods to consumers, with or without home delivery), and local production and transport.

Some supramunicipal local bodies, such as provincial and county councils, are also responsible for coordinating and providing technical, legal and financial support to assist local authorities in developing official control programmes concerning public health and consumer affairs.

Special mention should also be made of the **Barcelona Public Health Agency**, which carries out the functions of a local administration within the city of Barcelona, as well as taking responsibilities regarding epidemiological surveillance and the protection and promotion of health which are dealt with by the Ministry of Health in the rest of Catalonia. Through the **Institute for Food Safety and Health**, Barcelona Public Health Agency carries out official control of food processing and sale, both at businesses and at central markets, retail establishments and restaurants, including street establishments.

Also important are: the **Laboratory**, which provides chemical and microbiological analysis services for the Agency itself, the Generalitat and the City Council; the **Public Health Observatory**, which is responsible for epidemiological surveillance; and the **Directorate for Environmental Surveillance Services**.

IV

2 Risk analysis: objectives and interventions

IV

2.1 Evaluation of health risks and other food safety issues

The objectives and actions for management and communication involved in food safety must be sustained by an efficient system to determine and evaluate existing problems concerning both risks to health and questions relating to food safety. In these areas there is a clear need for information and quality studies permitting continuous improvement in the orientation of interventions.

Legal framework

EC Ruling no. 178/2002 of the European Parliament and the Council, of January 28, established the general principles and requisites of food legislation and created the European Food Safety Authority (EFSA). EFSA has as its function the facilitation of scientific and technical assessment to the legislative and political branches of the Community in all those areas with direct or indirect influence on food safety by compiling and analysing data and by issuing reports.

Law 11/2001, of July 5, created the Spanish Food Safety Agency (AESAs), which has specific functions in the field of risk evaluation, the preparation and promotion of research work, prospective studies involved in food safety and the preparation of reports by its Scientific Committee.

Furthermore, Law 20/2002, of July 5, on food safety, created the Catalan Food Safety Agency (ACSA), which has the functions of preparing and promoting scientific studies aimed at evaluating public exposure to health risks caused by foods and which consider the whole of the food production chain.

Decree 162/2003, of July 8, approved the statutes of the Catalan Food Safety Agency, and detailed the functions of the Agency within the area of risk evaluation.

- Carry out the actions involved in risk evaluation in all the phases of the food production chain, from primary production to final distribution.
- Analyse, process and manage scientific and technical information on food safety.
- Maintain permanent systems for compiling the available scientific and technical information on food safety.

One of the important bodies in ACSA is the Scientific Committee, which has the following functions:

- Preparation of scientific studies on risk evaluation without prejudicing the competencies of AESA and EFSA.
- The issue of medical and other reports on questions in the field of food safety.
- To promote and carry out scientific studies evaluating public exposure to foodborne hazards in Catalonia.
- To analyse available data, reports, studies and knowledge about food safety.

These functions must be carried out in collaboration and coordination with the Spanish Food Safety Agency and the European Food Safety Authority, on the basis of the principles of complementarity, efficiency and suitability to needs in Catalonia.

Objectives and interventions

The compilation and analysis of data and the availability of reliable and up to date information from various sources are required elements for evaluation and for taking management and communication decisions. Analysis of this information should permit an understanding of existing problems, specific needs and the most suitable options for action in each case.

Conditions which should be met by risk evaluation in the context of the Food Safety Plan of Catalonia
■ Provision of quality information for those in charge of risk management.
■ Complementarity with the work carried out by international institutions, particularly the European Food Safety Authority, so avoiding the duplication of work.
■ Identification of the bodies which can offer quality data and studies, as well as the promotion of relationships and exchange of information aimed at creating risk evaluation networks.
■ Compilation, integration and analysis of information.
■ Consideration of the effects of the globalisation of trade.
■ Promotion and development of studies with the aim of determining the particular situation in Catalonia.

Within the framework of the Food Safety Plan of Catalonia, we must differentiate between questions relating to food safety itself, and problems limited to the area of so-called “food safety issues”.

In the area of food safety proper, we must have at our disposal information on risk evaluation work of a national, European and international nature, at the same time as studies are performed which are necessary for risk evaluation within the specific context of Catalonia. All the information deriving from these studies should be made available to the bodies in charge of risk management, as well as to all food production chain stakeholders, including consumers.

Furthermore, we must promote and improve surveillance systems. Surveillance is defined as the compilation, analysis and interpretation of data and is essential for both the management and the evaluation of risk. It is an element directly related to these two phases of risk analysis, since it should supply valuable information for the preparation of risk profiles for orientation and periodic revision of management measures. Surveillance activities must include the compilation and analysis of data from different fields:

- Illnesses, epidemiological data and studies of outbreaks in the human population.
- Illnesses, epidemiological data and studies of outbreaks in animals and plant populations.
- Data from the analytical surveillance of people, animals, plants, foods and the environment.
- Data on environmental practices and procedures.
- Risk factors deriving from processes applied in the food production chain.
- Habits and practices of both workers and consumers.

The surveillance and risk evaluation systems in a territory must serve to estimate the proportion of illnesses and deaths really caused by transmission through food, as well as to determine which foods and processes are involved and other coadjutants or associated factors. It should also favour a better understanding of the impact of management interventions implemented in order to evaluate their efficacy and be able to rethink them or plan new measures when necessary.

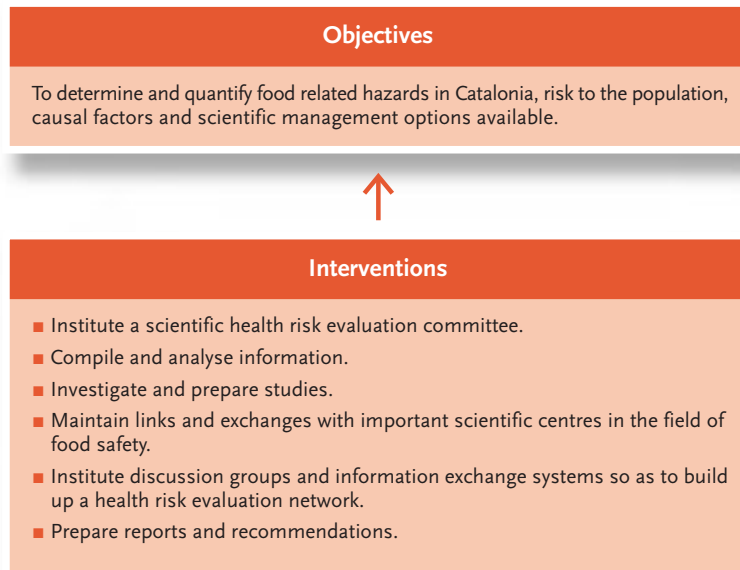
It is especially important to determine the most frequent food hazards in Catalonia, and levels of public exposure. The data must be significant and comparable in time, so that studies to map evolutionary trends may be carried out over the years.

Special attention should be given to particular groups which could have greater sensitivity than the average population, as is the case with infants, pregnant women, the elderly and people with particular types of illness or specific sensitivity such as, for example, adverse reactions to certain foods.

We also need to determine cases of foodborne illnesses diagnosed in Catalonia and their incidence and prevalence. The compilation of information and research should not be limited only to outbreaks of food poisoning and illnesses which must be reported by law, but should also include individual cases of illness diagnosed. It is essential to establish effective connections between different systems which can offer epidemiological data and to analyse them from a multidisciplinary perspective, for which we need a real risk surveillance and evaluation network.

Many foodborne illnesses are not transmitted exclusively through food. We should therefore be aware of the proportion of cases associated directly with foods in comparison with those proceeding via other transmission routes. This knowledge should permit us more effectively to direct the interventions provided for under the Plan and to determine their real potential impact.

Objectives and interventions in the field of health risk evaluation



We should also investigate the associated factors and coadjutants to each health problem or level of exposure so as to be able to study and evaluate the management options available. To this end, all the factors involved must be identified, including habits, cultural factors, foods and associated processes, any lack of information or training, as well as the importance of these elements as causal factors, so as to be able to seek the best alternatives for intervention and evaluate the suitability of those applied.

Moreover, a detailed analysis should be performed in the food production chain of all the phases and activities therein and the processes applied to identify associated risks. This research and study task should permit the determination of management options applicable for each activity and each step in the food production chain, with the aim of implementing measures constituting a complete, proportional, coherent and efficient safety system. For example, information should be available about ambient conditions for the activities in the food production chain, with the objective of evaluating the risk of environmental contamination. We should also consider the procedures and treatments applied, and the production processes, including the new technologies, to determine how they can affect the increase or decrease of risks.

A complete evaluation of the possible sources of risk also must include the determination of risks in the case of possible actions of sabotage and/or terrorism in the food production chain so as to plan prevention and management systems.

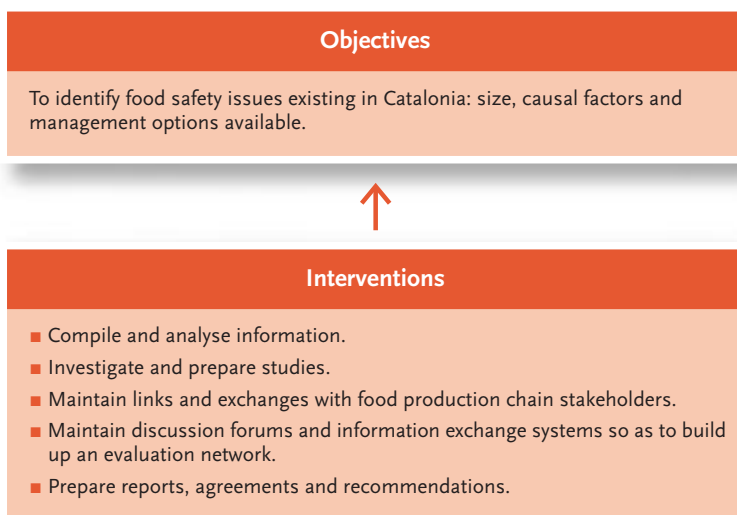
Those participating in the food production chain must be supplied with scientific and technical information deriving from evaluation and surveillance, as well as reports and recommendations which aid in the application of measures aimed at giving safety guarantees to products. This information should be especially useful to the controlling bodies and agents so they have up to date knowledge at their disposal on the hazards and techniques of prevention and control.

All the information mentioned must be collected in suitable databases and be of easy access to all stakeholders, including consumers, who must be able to access this information in such a way that it is comprehensible and useful to their needs.

The collection of information and knowledge referred to here should be based on a network of relationships and permanent exchanges with the participation of research centres as well as bodies and institutions with an important role in food safety.

In the field of the so-called food safety issues, we must apply a similar procedure to that described for health risks. We must compile the information and consider the opinions of those involved in the food production chain so as to identify the problems and determine the causal and associated factors as well as the management options available.

Objectives and interventions aimed at identifying food safety issues



All the information collected, both in the field of areas and in other related food safety, should be subjected to periodic expert analysis so as to have available reports and recommendations permitting the direction of more suitable measures to be implemented in the management and communication sectors. Evaluation and surveillance must be integrated and suitably interrelated with communication and risk management in a coherent risk analysis process.

Risk evaluation for health and other problems related with food safety

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
Food-related risks			
E-001	Investigate food-related hazards in Catalonia, the risk to the population, causal factors and available scientific management options.	Studies to evaluate health risks associated with the food production chain	Available
Questions relating to food safety			
E-002	Investigate existing problems in Catalonia in terms of food safety issues, their size, causal factors and management options available.	Studies of risk evaluation in the field of food safety issues	Available

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
Risks to health			
O-001	Make available information on existing or foreseeable hazards relating to food and the levels of exposure of the population which could cause risk to human health.	Specific studies	Available
O-002	Make available information on the incidence and prevalence in Catalonia of food-related illnesses as well as on causal factors.	Specific studies	Available
O-003	Make available active research systems for research into possible food aetiology and coadjutant factors of cases of illness diagnosed in Catalonia.	Specific studies	Available
O-004	Make available information on the hazards associated with each of the phases, activities and processes in the food production chain and on coadjutant factors.	Specific studies	Available
O-005	Make available information on existing needs in the field of food safety and on options available for risk management from the scientific point of view.	Specific studies	Available

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
Questions relating to food safety			
O-006	Make available information on existing or foreseeable problems in terms of questions related with food safety and the number of these in Catalonia, as well as causal factors.	Specific studies	Available
O-007	Make available information on existing needs and on available options for problem management in the field of food safety issues.	Specific studies	Available

Interventions

Number	Statement	Responsible for the intervention
Health risks		
I-001	Prepare periodic studies to determine the level of exposure of the population to food related hazards in a way that is significant and comparable in time, with special attention to certain risk groups such as children, pregnant women, the elderly and the sick.	ACSA
I-002	Prepare studies into food-related outbreaks and individual cases of human illnesses diagnosed in Catalonia to determine epidemiological data, causal factors and the foods associated.	DS
I-003	Compile information and prepare studies on the food production chain, including the environmental conditions where operations are performed, so as to determine the hazards and coadjutant factors associated with each of the phases, activities and processes. Make this information available to official control bodies, food production chain operators and the general public	ACSA DMAH DAR DS ACC AL
I-004	Maintain permanent links and relations with leading scientific centres on questions of food safety for the exchange of information and permanent collaboration on questions of risk determination.	ACSA DMAH DAR DS ACC AL
I-005	Establish a scientific committee to carry out the analysis of information on questions of the determination of risk and the issue of reports and recommendations on this matter.	ACSA
I-006	Prepare studies into food risk management options from the scientific point of view.	ACSA DMAH DAR DS ACC AL

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing. DS: Ministry of Health

Interventions (cont.)

Number	Statement	Responsible for the intervention
Questions to food safety		
I-007	Compile information and prepare studies on problems relating to safety, causal factors and management options theoretically available.	ACSA DMAH DAR DS ACC AL
I-008	Establish forums and systems for dialogue and relations with representatives from the sectors participating in the food production chain to analyse and monitor problems.	ACSA DMAH DAR DS ACC AL
I-009	Establish a monitoring commission with representation from the sectors in the food production chain and consumers so as to compile information, analyse problems relating to safety and prepare reports and recommendations.	ACSA DMAH DAR DS ACC AL

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing. DS: Ministry of Health

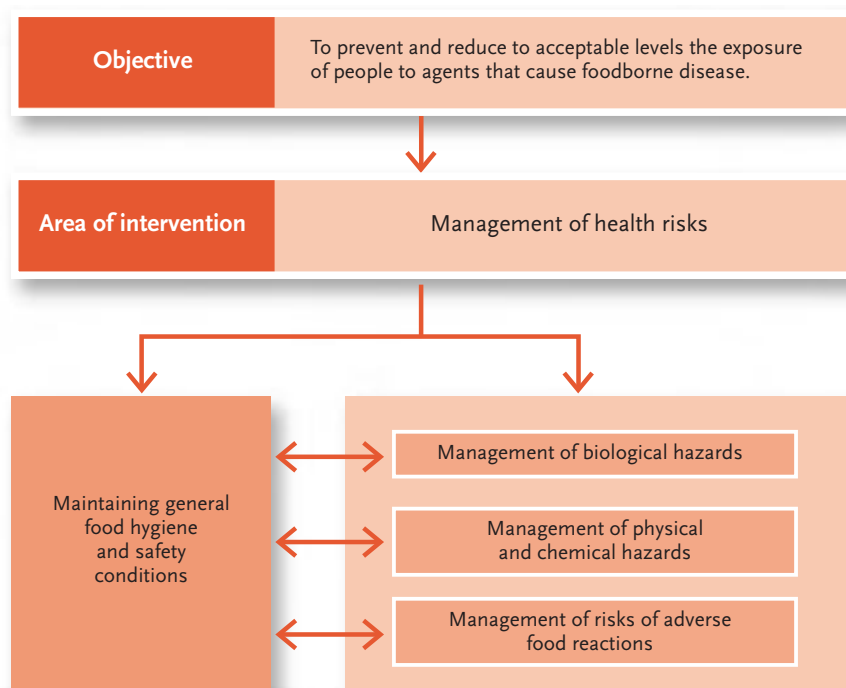
IV

2.2 Health risk management

One of the purposes of the Food Safety Plan of Catalonia is to prevent and reduce to acceptable levels human exposure to agents likely to cause foodborne disease. This should enable us to advance in preventing related diseases and reducing their incidence and prevalence to the minimum levels possible. Guidance towards meeting these goals requires laying down risk management rules in two clearly differentiated areas that are, at the same time, directly interrelated.

An initial area of intervention is that of maintaining general conditions of food hygiene and safety to ensure that activities in the food production chain fulfil a series of general requirements with regard to facilities, processes, equipment, self-control, traceability, staff training and waste management. Fulfilling these requirements will enable suitable conditions to be maintained to prevent, eliminate or reduce the frequency or concentration of a broad range of hazards in the food production chain through a general, non-specific approach. A key aim of intervention by the responsible authorities in this area is to promote and control the introduction of, and compliance with, the food safety rules laid down by current legislation.

Food risk management



The second area of intervention refers to more specific actions aimed at minimising the presence of hazards throughout the entire food production chain. Current management trends proposed by the Codex Alimentarius Commission are based on the application of food safety objectives (FSOs) and performance objectives (PO), defined as the maximum frequency and/or concentration of a hazard in a food at a given stage in the food production chain before the moment of consumption, that enables or contributes to achieving a food safety objective or a suitable level of protection, as appropriate. Setting these objectives requires time and careful reflection on risk management. In any case, this definition of objectives must be implemented in a gradual, appropriate way, in coordination with current regulations and the responsible organisations at state and European Union level. This new focus is taken into consideration, therefore, when corresponding specific objectives are formulated, while a more detailed approach remains pending, to be established in collaboration with the managing bodies within the structural and operational development that the Plan will follow during its period of introduction.

The measures that the public administrations are called on to apply are mainly aimed at informing, raising awareness and promoting good practices, as well as monitoring and controlling hazards, particularly those that are considered to be priorities at any time according to the experience acquired and the risk assessment studies available.

What shapes the structure of this part of the Plan is this risk management approach, based on maintaining general, basic conditions for food safety in all activities in the food production chain, to which we should add more specific actions adapted to priority hazards and to the needs of each moment. To make the document easier to follow and understand, description of health risk management takes these various areas into consideration separately, although they should be understood as forming interrelated and complementary series of measures.

The actions envisaged in the areas described also have effects that go beyond the management of health risks. Sustained maintenance of the measures mentioned, together with opportune measures of risk communication, should have a favourable influence, fostering an increase of consumer confidence in the safety of the food production chain. In addition, assurances by commercial operators that they will comply with uniform or equivalent food law will favour the free circulation of goods in national and international markets, as well as guaranteeing the fairness of commercial transactions, goals that are laid down in the mission and the objectives of the Plan.

2.2.1 General food safety conditions

We define general food safety conditions, also known as general hygiene conditions, as those that are necessary to control the hazards and guarantee the suitability for human consumption of food products, taking into account their envisaged use. This concept includes guidelines for facilities, plant and equipment, the safety of processes, self-controls, staff training, traceability and appropriate waste management throughout all stages in the food production chain.

Non-compliance with the general hygiene conditions by operators or those responsible for activities can lead to an increase in risks as, under these circumstances, many food hazards could contaminate food or exceed acceptable levels. This constitutes a food safety issue in itself. Therefore, we suggest the need for food production chain company owners to act by complying with the hygiene rules according to their responsibilities and to current food law. The competent authorities must carry out the necessary measures to promote and ensure compliance with the conditions laid down in the above-mentioned food law.

Legal framework

The approval and publication of binding legislation is the first measure of intervention necessary in the context of a state of law in order to achieve the objectives for which general hygiene rules can be applied to the food production chain.

There is a long tradition of published food law on the matter, both in Catalonia and in Spain and in the European Union, as this is an activity that has historically been undertaken by the public authorities. In 1964, in the area of the European Economic Community (EEC), measures began with the standardisation of food laws in the different Member States, especially with regard to foods of animal origin. This successfully eliminated obstacles to trade and, at the same time, helped to create a context aimed at guaranteeing a high level of consumer protection.

European food hygiene legislation since the 1960s has been enacted in various Community directives, all of which have been duly transposed into the internal law of each Member State.

Although we refer here to legislative texts that were most useful during the second half of the last century, it has been necessary to reform this legislation to simplify them, removing certain contradictions, redundancies and inconsistencies that had been detected in them, and to make their interpretation and compliance with them easier. They have also been updated, explicitly including certain key principles in food safety, such as the integrated concept of the food production chain, from primary production to consumption, or the principle of the responsibility of commercial operators.

The simplification and updating of food law with regard to general food hygiene conditions was materialised with the approval of Regulation (EC) 852/2004 of the European Parliament and of the Council, of April 20.

In some cases, we need to specify in greater detail the conditions that must be fulfilled, enshrined, to date, in different vertical or sectoral legislation. In the area of foodstuffs of animal origin, this legislation was the object of the corresponding updating and simplification through Regulation (EC) 853/2004, of the European Parliament and of the Council, of April 29, laying down specific hygiene rules for food of animal origin.

Council Directive 93/43/EEC of June 14, laid down the general rules of hygiene for foodstuffs with the exclusion of primary production. With the approval and publication of these new Regulations, the food hygiene rules that are to be complied with during the various stages in the food production chain are regulated. The primary stage is explicitly included, and a series of general obligations are laid down for food business operators with regard to authorisation and registration of their activities, and a series of minimum conditions that must be met in each stage of the corresponding food production chain are specified.

As far as the primary production stage is concerned, these rules refer to the protection of products in the food production chain with regard to any source of contamination in the air, soil, water, feed, fertilisers, veterinary drugs and plant health products and biocides; compliance with animal health and animal welfare rules; and registers of the measures applied to control hazards, taking into account the nature and size of each company. They also refer to the preparation and application of good practice guides as an instrument for complying with hygiene rules in general, applying the principles of hazard analysis and critical control points (HACCP) in particular. With regard to questions which in primary production are not dealt with as obligatory for the moment, the need is stressed to promote the application of these principles as far as possible. On this point, we should mention the exception of Regulation (EC) 183/2005, of the European Parliament and of the Council, of January 12, laying down requirements for feed hygiene, which establishes the responsibility of the owners of certain feed companies to apply and maintain permanent written procedures based on the principles of the HACCP system.

As far as later stages of primary production are concerned, the hygiene rules lay down conditions concerning the layout, design, maintenance, cleaning and disinfection of premises and equipment, as well as other requirements aimed at preventing any contamination of the products in the food production chain, such as the application of processes based on the HACCP system.

We can see, then, that far-reaching, modern food law currently exists in the European Union, legislation that lays down the minimum requirements to be met. Considering the legal imperative that requires compliance with Community legislation, as well as the solid scientific base and accumulated experience upon which its contents are sustained, we can understand that the above-mentioned hygiene rules are now a reference for appropriate intervention under the framework of the Food Safety Plan of Catalonia.

Apart from conditions concerning facilities and equipment, the safety of the processes, self-control, staff training and waste management, we should expressly mention traceability as a key tool in food safety.

Article 18 of Regulation (EC) 178/2002 of the European Parliament and of the Council lays down the need for all companies in the food production chain to implement a traceability system as from 1 January 2005.

Article 5 of Law 20/2002, of July 5, on food safety, lays down that in all the stages of production, transformation and distribution, the traceability of foodstuffs, feed, animals intended for food production and any substance that is incorporated or could be incorporated into foodstuffs or feed must be guaranteed. Law 14/2003, of June 13, on food and agriculture quality, also expressly refers to traceability, understanding this to be an instrument that enables the quality of food and agricultural products to be guaranteed, as it is essential for ascertaining the nature of a product with regard to its origin, production process, ingredients and any other of the characteristics that define it.

Food companies must be able to identify the people, bodies or companies that have supplied them with products, and those they themselves have supplied. With this aim in mind, sys-

tems and procedures must be applied to make such information available to the competent authorities when requested. Both foodstuffs and feed that is sold or could be sold in Catalonia must be suitably labelled or identified to make traceability easier.

In addition to the general food legislation mentioned here, specific laws governing traceability also exist in certain sectors. For example, legislation has been introduced to govern identification and documentation for transporting food-producing animals, a key condition for traceability at the animal production stage.

Objectives and interventions

Specific objectives must be aimed at ensuring that activities in the food production chain are carried out under appropriate general conditions for controlling food hazards and preventing them from contaminating food and, if necessary, eliminating them or reducing them to acceptable levels. These conditions concern facilities, equipment, processes, self-control systems, traceability, training, and workers' compliance with instructions, as well as waste management and disposal.

In order to achieve these specific objectives, we need to propose interventions that enable us to:

- Provide a suitable legal framework describing the conditions that must be fulfilled and specifying the distribution of responsibilities.
- Make the necessary information available to operators in the food production chain and the general public so that they can fulfil their responsibilities appropriately, raising awareness and promoting good practices.
- Provide systems for authorising and registering activities in the food production chain that include, as appropriate, preliminary verifying compliance with the general hygiene rules laid down in current legislation.
- Maintain regular and periodical official control systems to verify compliance with general hygiene rules, planned and applied according to criteria for assessing the hazard in each stage, sector and activity of the food production chain.

Food production chain operators and the general public must have access to current legislation, as well as the information necessary to make this legislation easy to understand and obtain, with clear specification of the rules applicable and the distribution of responsibilities. We also need to analyse the possibilities for improving the current legislative framework and promote development and reform in the necessary areas.

To guarantee compliance with current legislation, activities in the food production chain must follow a procedure of preliminary authorisation from the very first stages in the process. Data must also be entered in the corresponding registers to ensure the availability of the necessary information for the official control measures to which they must be regularly and periodically subjected.

Official control systems must ensure compliance with the general rules for food safety, including all the elements already described, which must be assessed and controlled as an interrelated whole.

Similarly, data obtained from official control programmes carried out in recent years indicates that the rules governing facilities, equipment and processes present higher rates of compliance than those corresponding to self-control systems and staff training. This is due to historic reasons, as many of the rules governing self-control, traceability and staff training have been incorporated recently compared to the other legislation mentioned.

Waste management and disposal is also a complex question that has been the subject of new legislation in recent years, as is the case of Regulation (EC) 1774/2002, of the European Parliament and of the Council, of October 3, and the later modifications which lay down the health rules applicable to sub-products of animal origin not intended for human consumption. That is why it has been decided here to define specific, differentiated objectives and interventions in this sphere, although management of sub-products and waste at facilities must also be understood as another part of the general conditions for food safety.

In view of the peculiarities mentioned here, in this first Plan it was considered opportune to formulate specific, differentiated objectives for self-control, traceability, staff training and waste management, although conceptually they should be considered as an integrated whole with the rest of the general hygiene rules.

Objectives and specific interventions referring to activities concerned with providing services to companies in the food production chain must also be provided for, such as the laboratories that participate in self-control, accredited companies for training staff, and companies engaged in pest control or waste management, as these can have considerable effects on the general conditions of food safety and the efficiency of food production chain companies' efforts to guarantee the safety of their products.

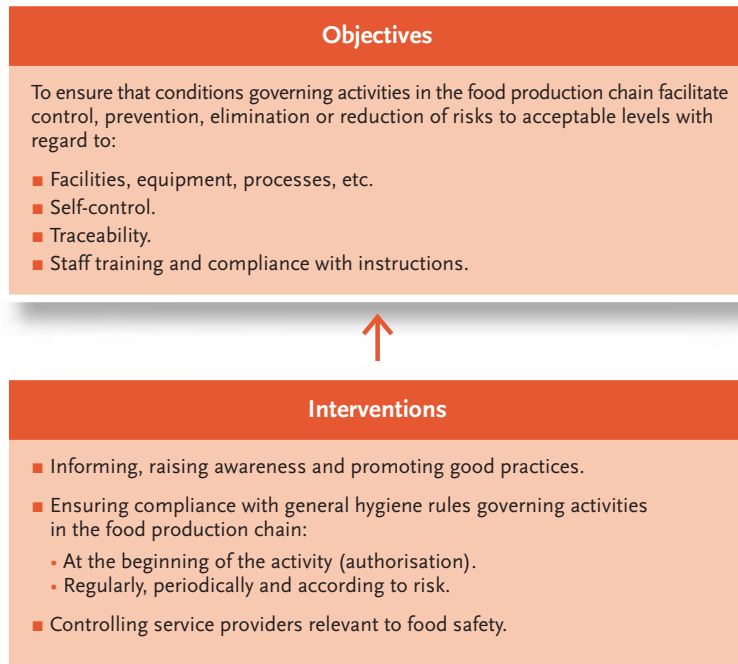
All sectors and groups of activities at the various stages in the food production chain must be subject to official, regular, periodical control programmes without previous warning, intended to ensure compliance with general food safety rules. Official control programmes will adopt a frequency and intensity to be determined according to different parameters, such as:

- The hazards identified.
- The type and volume of activity.
- Records of compliance with current legislation.
- The reliability of self-controls.
- Any other information that could indicate the level of compliance with food safety rules.

We should pay special attention to food production activities aimed at particularly vulnerable population groups, such as children, the elderly, pregnant women or people suffering from certain diseases.

Some outbreaks of food poisoning described in recent years have been linked to the fact that the establishment involved had exceeded production capacity. Maximum storage capacity at appropriate temperatures, the time necessary to complete a given heat treatment and other production processes often place an objective limit on maximum production capacity without danger to health for many of the activities in the food production chain. Therefore, we need to introduce measures so that activities in the food production chain do not exceed real production capacities when this could mean an increase in risk. To this end, we must provide for interventions aimed at identifying those food production chain activities in which exceeding real production capacity is critical to the safety of products, implementing appropriate control measures.

Objectives and interventions in the field of general hygiene conditions



Assessment of objectives

Assessment of the specific objectives established in the area of general food safety rules presents certain methodological difficulties. We need to ascertain the levels of compliance with current legislation regarding general food safety rules, as well as their evolution over time. In order to meet this requirement, the objective is established of making a quantitative estimate of compliance with rules, based on a numerical scale points system. This system should take into account, in a weighted and differentiated way, a whole series of criteria concerning facilities and equipment, hygiene in production processes, self-control systems, traceability, staff training and attitudes, and waste management. Differentiated assessment of each of these elements should enable us to ascertain both general evolution and the evolution of each individual element. This information will be obtained, in the main, from results obtained from official controls, and will require standardised assessment protocols to be developed that are appropriate to the different groups of activity in the food production chain. The information obtained will be useful not only as an indicator of the extent to which specific objectives laid down by the Plan are achieved, but also to enable managing bodies to gauge the operational efficiency of the programmes they apply.

It is important to clarify that the specific and operative objectives described in this section are formulated in an overall way, and concern the entire whole food production chain. However, significant variations may be made at each different stage and for each different sector of activity, so that it will be useful to make an independent analysis of the results corresponding to the various stages and sectors in the food production chain as part of Plan surveillance and assessment work.

We should also take into account that, in certain sectors, a small proportion of companies are responsible for most of the production. When carrying out a study to assess the results in this area, we should take into account in a weighted and/or differentiated way the different volumes of companies' production, so that our assessment can be correlated with the real impact on the total foodstuffs placed on the market that are produced in Catalonia.

The indicator chosen for assessing the results indicates the level of compliance with the standards established in the legislation.

The indicator chosen for evaluating results is the rate of compliance with standards laid down by legislation. The final aim is to achieve the maximum level of compliance, though it is accepted that, in practice, conformity levels of 100% are not frequent. The aim to achieve a growing trend towards this forms part of a strategy for continuous improvement in which priority is given to critical failures to comply rather than those that do not have a direct, immediate effect on the safety of products. In any case, the failures to comply detected are subject to specific corrective measures applied by the competent administrations. This is particularly important with regard to critical laws, which are those where failure to comply, whether individually or in concurrence with other failures, entails an immediate, unequivocal risk to the safety of products. The targets set for compliance with these laws will be very high, seeking the highest levels of compliance. Laws considered critical must be subject to priority controls, and any failures to comply detected must always be the object of urgent corrective measures proportional to the risk, including the most radical steps, such as closing facilities or confiscating products and equipment.

General food safety conditions

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
General rules			
E-003	Activities in the food production chain must be carried out under conditions that enable food hazards to be controlled in order to prevent, eliminate and/or reduce them to acceptable levels.	Level of compliance with rules considered to be critical	> 95 %
		Proportion of companies in critical conditions detected in the official controls that are the object of the urgent administrative measures to correct them	100 %
	Note: this section includes conditions that are broken down below, and dealt with separately in view of their importance.	Rates of compliance with the conditions laid down by legislation not considered to be critical	Growing trend
Self-control			
E-004	The owners of companies in the food production chain must guarantee that the processes under their responsibility are subject to auto-control systems that enable food hazards to be controlled in order to prevent, eliminate and/or reduce them to acceptable levels.	Proportion of companies that have introduced self-controls	> 95 %
		Rates of compliance with rules not considered to be critical under current legislation	Growing trend
Traceability			
E-005	Owners of companies in the food production chain must guarantee that the processes under their responsibility are subject to traceability systems in line with current legislation.	Proportion of companies that have introduced traceability systems	> 95 %
		Rates of compliance with rules not considered to be critical under current legislation	Growing trend
Staff training			
E-006	Owners of companies in the food production chain must guarantee that staff receive training appropriate to the activity to be carried out, and ensure that they comply with the rules and instructions to guarantee food safety.	Proportion of companies that have introduced staff training	> 95 %
		Rates of compliance with rules not considered to be critical under current legislation	Growing trend
Waste			
E-007	Owners of companies in the food production chain must guarantee that the waste generated by the activities carried out is managed in a way that does not involve any kind of risk.	Proportion of companies that have introduced waste management systems	> 95 %
		Rates of compliance with rules not considered to be critical under current legislation	Growing trend

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
Regulatory framework			
O-008	A regulatory framework should be provided that is appropriate to needs as regards general food safety rules.	Assessment studies and needs detection	Available
		Improvement procedures promoted concerning the needs detected	100 %
Informing, raising awareness and promoting good practices			
O-009	There should be programmes of information, awareness raising and promotion of good practices aimed at ensuring that company owners comply with general food safety rules.	Information, promotion and awareness-raising programmes	Available and introduced
O-010	Operators in the food production chain should be provided with useful, easily-accessible information on procedures and requirements for authorising and registering activities, conditions, legislation, recommendations and responsibilities concerning food safety.	Information	Available
Authorisation and registration			
O-011	Appropriate procedures should be provided for authorising and registering activities in the food production chain, including, when appropriate, verification of compliance with conditions for authorisation.	Procedures	Available and introduced
O-012	Registers should be introduced in which updated information on authorised activities in the food production chain is compiled.	Registers of authorised activities in the various stages and sectors of the food production chain	Available
O-013	Appropriate measures should be adopted to ensure that activities in the food production chain do not exceed real production capacities where this could entail an increase in risk.	Assessment studies to identify the activities in which exceeding real production capacities is critical	Available
		Inclusion in authorisation procedures of systems to define maximum production capacities	Introduced
		Control programmes	Introduced

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
Official control of compliance with general food safety conditions			
O-014	Official surveillance and control programmes should be planned for and implemented as appropriate to risk, aimed at ensuring compliance with general food safety rules in all the sectors and groups of activity of the various stages in food production.	Specific official surveillance and control programmes for each sector and group of activity at the different food production chain stages	Introduced
O-015	The activities in the food production chain should be the object of objective and quantifiable overall assessment regarding rates of compliance with general food safety rules. Note: this overall assessment includes, in a weighted way, questions concerning facilities, hygiene of processes, self-control, traceability, staff training and waste management.	Overall assessment programmes which are objective and quantifiable for each sector and group of activity in the food production chain	Introduced
O-016	Conditions considered to be critical must be defined for each sector and group of activity in the food production chain.	Definition of critical conditions for all sectors and groups of activity in the food production chain	Available
Self-control			
O-017	Promotional measures so that operators in the food production chain fully develop their self-control systems and/or good practice guides in accordance with the principles of the HACCP system.	Programmes to promote the introduction of self-control systems	Introduced
O-018	The sectors and groups of activity of the different stages in the food production chain should be subject to official controls to ensure that they have introduced self-control procedures in accordance with current legislation.	Official assessment programmes for self-control systems in all sectors and groups of activity in the food production chain	Introduced
O-019	There should be an objective, quantifiable system to assess the degree to which each sector and group of activity in the food production chain has introduced self-control systems.	Assessment programmes to ascertain the degree to which self-control systems have been introduced	Introduced
Traceability			
O-020	Promotional measures so that company owners in the food production chain are encouraged to fully develop their traceability systems.	Programmes for promoting the introduction of traceability systems	Introduced

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-021	The sectors and groups of activity of the stages in the food production chain should be subject to official controls to ensure that they have introduced traceability systems and programmes of information and product recall if necessary, in accordance with current legislation.	Official control programmes for traceability, information and product recall in all the sectors and groups of activity in the food production chain	Introduced
O-022	There should be a system of objective and quantifiable assessment of the degree to which traceability systems have been introduced for each sector and group of activity in the food production chain.	Assessment programmes on the degree to which traceability systems have been introduced	Introduced
Staff training			
O-023	A study should be carried out to ascertain the sectors and activities in which training and compliance with instructions by the staff should be considered critical to food safety.	Specific study	Available
O-024	Promotional measures should be implemented to encourage company owners in the food production chain to fully develop training systems for staff and to ensure compliance with work instructions aimed at guaranteeing food safety.	Specific information, training and awareness programmes	Introduced
O-025	Training systems and systems to ensure compliance with instructions given to staff by companies in the food production chain need to be the object of official control, with special attention to the activities in which this factor is critical to food safety.	Official control programmes	Introduced
O-026	Operators and workers at the initial stages in the food production chain (farmers, stock breeders, hunters, fishermen, etc) need to be the object of measures aimed at informing, training and raising awareness about food safety issues.	Specific information, training and awareness programmes	Introduced
O-027	Objective and quantifiable systems are required to assess the degree to which training has been introduced in each sector and group of activity in the food production chain.	Programmes to assess the degree to which training has been introduced	Available and introduced

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
Companies that provide services to the activities in the food production chain			
O-028	There should be suitable procedures, in accordance with current legislation, for authorising and registering companies that provide services linked to food safety, such as laboratories, training companies, biocide treatment companies and waste management enterprises.	Authorisation procedure	Available and introduced
O-029	Stakeholders should be provided with useful, easily-accessible information available on procedures and requirements for authorising and registering activities, conditions to be met, food law, recommendations and responsibilities that affect the provision of services to activities in the food production chain.	Information	Available
O-030	Registers should be established to provide updated information about the companies that provide services linked to food safety.	Registers	Available
O-031	Companies that provide services for activities in the food production chain with possible effects on food safety should be the object of official controls to verify their compliance with current legislation.	Specific official control programmes	Introduced
Waste			
O-032	The sectors and the activities at the various stages in the food production chain should be subject to official control to ensure that they have established appropriate waste management systems.	Official control programmes	Introduced

Interventions

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Regulatory framework						
I-010	To prepare studies to detect the needs for modification of the regulatory framework in matters of general food safety conditions.	DAR	APS DAR	APS AL	–	DMAH ARC
ACSA						
I-011	To promote, when necessary, development, criteria for application and/or modification of legislation at local, autonomous, state and European level.	DAR	APS DAR	APS AL	–	DMAH ARC
ACSA						
I-012	To define criteria for interpreting current food law and to implement appropriate legislative measures as regards staff training, self-control and traceability.	DAR	APS DAR	APS AL	–	DMAH ARC
ACSA						
Informing, raising awareness and promoting good practices						
I-013	To maintain awareness raising programmes and promote compliance with general food safety conditions, with food production chain company owners and staff in mind.	DAR	APS DAR	APS AL	–	DMAH ARC
ACSA						
I-014	To make available to operators useful information about the applicable legislation, the procedures and the requirements for authorisation and registration, the conditions to be met, the responsibilities and recommendations concerning activities in the food production chain.	DAR	APS DAR	APS AL	–	DMAH ARC
ACSA						
Authorisation and registration						
I-015	To make available to operators useful, detailed information about procedures to be followed for authorising and registering activities.	DAR	APS DAR	APS AL	–	ARC
I-016	To maintain efficient procedures of updated authorisation and registration of activities in the food production chain. These include checking authorisation conditions concerning food safety.	DAR	APS DAR	APS AL	–	ARC
I-017	To include in authorisation and/or registration processes the obligation, as appropriate, to declare the parameters of maximum production of each activity according to real capacity in accordance with current food law.	DAR	APS DAR	APS AL	–	ARC

ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing.

Interventions (cont.)

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Compliance with general food safety conditions						
I-018	<p>To establish and maintain official controls, with suitable regularity and periodicity, aimed at verifying compliance with general food safety conditions in all stages, sectors and groups of activity of the food production chain, planned according to:</p> <ul style="list-style-type: none"> ■ The risks identified ■ Current legislation, the development of the situation and available information and experience. ■ The peculiar characteristics of food production activities for specific groups such as children, sick people, the elderly, etc. <p>Note: official control of general food safety conditions also includes conditions concerning facilities, hygiene in processes, self-control, traceability, staff training and waste management.</p>	DAR	APS	APS AL	–	ARC
I-019	To maintain official programmes to control general safety conditions for water used in activities in the food production chain, from irrigation to drinking water.	DAR DMAH	APS AL	APS AL	–	–
I-020	<p>To carry out an overall, objective and quantifiable assessment on a numerical scale of the degree of compliance with general food safety conditions by companies in the food production chain.</p> <p>Note: weighted overall assessment of food safety conditions includes issues concerning facilities, hygiene in processes, self-control, traceability, staff training and management of by-products and waste.</p>	DAR	APS	APS AL	–	ARC
I-021	To develop, for each sector and group of activity, a procedure for assessing the level of compliance with general food safety conditions which enables the quantification of compliance on a numerical scale based on partial, weighted assessment of the various elements of which it is composed, such as facilities, hygiene in processes, self-control, traceability, staff training and waste management.	DAR	APS	APS AL	–	ARC

AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
I-022	To define the conditions considered to be critical for each sector and group of activities in the various stages in the food production chain .	DAR	APS	APS AL	–	ARC
Self-control						
I-023	To maintain specific programmes for informing, raising awareness and promoting good practices in knowledge and application of the principles of the HACCP system and/or good practice guides in all activities in the food production chain.	DAR	APS	APS AL	–	ARC
ACSA						
I-024	To produce an assessment study of the capacity of the owners and/or staff responsible for safety and self-control at companies in the food production chain, enabling them to ascertain the needs and strategies to be followed to make improvements in this area. To propose appropriate actions for improvement.	ACSA				
I-025	To maintain official control programmes on the introduction of self-control systems in food production chain activities.	DAR	APS	APS AL	–	ARC
I-026	To develop an objective system of assessment of the degree of introduction of self-control systems for each sector and group of activity of the food production chain within the overall assessment system for compliance with general food safety rules.	DAR	APS	APS AL	–	ARC
I-027	To carry out official controls to ascertain the existence at companies of pre-established procedures for communicating with the competent authorities and adopting the necessary measures when any safety issue is detected with regard to foodstuffs, including their recall from the market and informing consumers where appropriate.	DAR	APS	APS ACC AL	–	ARC

ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Traceability						
I-028	To maintain specific programmes to inform, raise awareness and promote good practices to foster understanding and the application of a traceability system in all activities in the food production chain.	DAR	APS DAR	APS AL	–	ARC
ACSA						
I-029	To maintain official control programmes on the introduction of traceability systems in activities in the food production chain.	DAR	APS DAR	APS AL	–	ARC
I-030	To develop an objective system of assessment of the degree to which traceability systems have been introduced, by sector and group of activity of the food production chain, within the overall system for assessing compliance with general food safety rules.	DAR	APS DAR	APS AL	–	ARC
Training staff in the food production chain						
I-031	To maintain specific programmes to inform, raise awareness and promote good practices aimed at enhancing understanding and encouraging the introduction of staff training systems in all the activities in the food production chain.	DAR	APS DAR	APS AL ACC	–	ARC
ACSA						
I-032	To promote the preparation of good practice guides for staff training in all sectors in the food production chain.	DAR	APS DAR	APS AL ACC	–	ARC
ACSA						
I-033	To draw up a study of activities in which staff training and compliance with instructions are critical factors for food safety.	DAR	APS DAR	APS AL ACC	–	ARC
ACSA						
I-034	To develop programmes to inform, raise awareness and promote good practices by staff in activities in the initial stages in the food production chain: farmers, stock breeders, hunters, fishermen, etc.	DAR ACSA	–	–	–	–

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Interventions (cont.)

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
I-035	To develop programmes to inform, raise awareness and promote good practices by staff in the activities in which training and compliance with instructions is critical for safety.	DAR	APS DAR	APS ACC AL	–	ARC
ACSA						
I-036	To develop programmes to inform, raise awareness and promote good practices amongst workers in activities where training and compliance with instructions is critical to food safety.	DAR	APS	APS AL	–	ARC
I-037	To develop and introduce an objective assessment system to ascertain the degree to which training systems have been introduced in each sector or group of activity in the food production chain, within the system of overall assessment of compliance with general food safety rules.	DAR	APS	APS AL	–	ARC
Companies that provide services to the activities in the food production chain						
I-038	To develop programmes aimed at providing information on food safety to companies offering services linked to activities in the food production chain as appropriate to the needs of the services they provide.	DAR	APS	APS AL	–	ARC
ACSA						
I-039	To maintain efficient programmes and procedures for authorising and registering service providers for activities in the food production chain for which specific legislation exists. <ul style="list-style-type: none"> ■ Analysis laboratories. ■ Staff training companies. ■ Biocide treatment companies. ■ By-product and waste management companies. 	DAR	APS DAR	APS	–	ARC
I-040	To maintain updated registers on companies providing services for activities in the food production chain for which specific legislation exists.	DAR	APS DAR	APS AL	–	ARC
I-041	To maintain official control programmes on companies providing services for activities in the food production chain, to verify compliance with the applicable legislation.	DAR	APS DAR	APS AL	–	ARC

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Interventions (cont.)

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Waste						
I-042	To maintain official control programmes on waste management inside centres of food production chain activities.	DAR	APS	APS AL	–	ARC
I-043	To maintain official control programmes on waste management outside centres of food production chain activities.			ARC AL		

AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action.

2.2.2 Biological hazards

As we have indicated in previous sections, reducing exposure to food hazards to levels as low as is reasonably possible is one of the main purposes behind the Food Safety Plan. Minimising the frequency and concentration of biological agents that cause disease in the food production chain is a key element for this achieving this goal. The entire package of actions put together in the area of general food safety conditions specified in the previous section will significantly contribute to this objective. Owners of companies are those who, through self-control systems and other food safety measures, must offer the necessary guarantees with regard to the products for which they are responsible. Similarly, we must envisage specific interventions by the relevant administrations to contribute in an effective way to monitoring, preventing and reducing the entry of biological hazards into the various stages in the food production chain, as well as preventing any increase in their frequency and/or concentration.

The diversity of the hazards indicated, the variations that are produced over time and other reasons of an operational nature mean that a broad, flexible approach is needed, one based on the idea of biological hazards as a group rather than as individual hazards. This approach should make it possible to introduce management through programmes aimed at covering an extensive list of existing hazards in a way that is compatible with the prioritisation, within the programmes, of certain agents depending on the circumstances of each moment and the results of risk assessment studies. The actions to be introduced must be appropriate to the peculiarities of each stage in the food production chain and must prioritise the biological hazards that are most frequently associated with each stage and those that entail the highest risks to human health.

The particular characteristics of certain concerns, the severity of their potential consequences, the frequency of their appearance in a given territory, social sensitivity with regard to them, etc, are all motives that may make it necessary to define specific targets and measures in certain cases. Transmissible spongiform encephalopathies are one such instance. Moreover, the biological hazards that may be present in the food production chain are not the only pathogens that are potential and possible causes of disease. Pathogens cause health concerns amongst the general public and are the cause of almost all the foodborne diseases that are described each year in Catalonia. This means that it is necessary to deal with this matter in a specific way and to formulate specific objectives with regard to foodborne diseases.

Below, we analyse the issues concerned with biological hazard management in two sections:

1. Foodborne diseases of biological origin
2. Transmissible spongiform encephalopathies

1. *Foodborne diseases of biological origin*

The World Health Organisation (WHO) defines foodborne diseases (FBD) as those which, with our current knowledge, can be attributed to a specific foodstuff due to the presence of some food hazard. This concept refers both to diseases caused by biological agents and those caused by toxins of all kinds. We talk about infection when the pathogens ingested are developed in the host and cause a disease, and about food poisoning when the disease is produced by a toxic substance present in the food ingested, whether it is a toxin of biological or chemical origin.

Under the Food Safety Plan, health risk management is mainly aimed at minimising exposure to hazards that could be carried by foodstuffs. Similarly, in some instances, the existing

issues are not merely concerned with a potential risk and its management, but are real problems of health that affect the population. In Catalonia, health problems related to exposure to food hazards are specified in some diseases produced by biological agents and in particular, so-called food poisoning. As far as these kinds of issue are concerned, our priority should be to seek health targets and interventions which exercise a very direct influence on contributory factors due to their direct effects on the health of the population both in individual and sporadic cases as well as in outbreaks of disease.

The WHO defines outbreaks of foodborne disease as incidents in which two or more people experience a similar disease after ingesting the same food or after drinking water from the same source and in which the epidemiological tests show that the food or the water is the origin of the disease.

Within the general setting of foodborne disease, some authors distinguish food poisoning as a differentiated subgroup. Food poisoning is defined as a group of foodborne diseases with the following characteristics:

- They have a short incubation period.
- They are caused by pathogenic microorganisms or their toxins.
- The foodstuffs are an active support to the microbial multiplication or release of the toxins.
- They give rise to clinical symptoms that are mainly gastrointestinal.
- They have as the main contributing factors errors in hygiene in the final stages in the food production chain.

Included in this group is the specific case of toxic infections caused by noroviruses, whose main cause is the contamination of food when handled by people who carry these viruses. For this reason, prevention depends largely on ensuring that infected people do not handle food until at least 48 hours after all symptoms have disappeared.

The above is a definition that is open to question, and the inclusion or not of certain diseases in this group is arguable. Some sources even use this concept as a synonym for foodborne disease.

Independently of terminological questions, there is a clear and evident need to specifically act on foodborne diseases that pose a real public health concern due to the high number of outbreaks and cases registered yearly. The study of available epidemiological information shows that FBD outbreaks notified in Catalonia are mainly caused by pathogenic microorganisms or their toxins, and that their causes are strongly rooted in errors in hygiene during the final stages in the food production chain, which are normally the main cause of contamination and the spread or persistence of microbes or the generation of toxins.

This approach aims at prioritising management measures that are much more specific in the areas most frequently associated with the concentration of contributing factors, which fundamentally correspond to the activities of preparing and serving food for consumption, both in the domestic sector and in mass catering. In this way, it is possible to prioritise action that focuses on the main factors that contribute to outbreaks of foodborne disease reported in Catalonia, and which mainly coincide with the pattern defined for food poisoning.

Although this guidance is useful in almost all cases, a small proportion of the foodborne diseases that are described annually in Catalonia do not fully respond to the pattern described, such as, for example, certain cases of diseases caused by viruses, as well as others of a parasitic origin, in which the main contributing factors can be more associated to the initial stages in the food production chain. In these cases we should apply specific measures at certain points in the food production chain, according to the peculiarities of each hazard.

Appropriate studies of each outbreak and sporadic cases should enable us to ascertain the causes better, making it possible to take the specific management measures necessary in the corresponding areas.

However, in these cases, applying measures to reduce the risks in the final stages in the food production chain can also be highly effective. Applying the correct temperatures for cold conservation, appropriate heat treatment, and in general, suitable hygiene provisions, together with a high level of information and training for food handlers in the domestic and catering areas are key elements we should stress in order to reduce the incidence of both food poisoning and other foodborne diseases caused by biological agents.

Despite the exceptions and peculiarities mentioned, an approach based on the concept of food poisoning described previously is useful for planning actions, as it can guide direct, specific action with regard to the main contributing factors in almost 90% of foodborne diseases described yearly in Catalonia, a figure that corresponds to cases of so-called food poisoning. Similarly, the measures applied involve a significant contribution to minimising risks from all other foodborne diseases, especially those of biological origin. The final stages in the food production chain are critical stages requiring particular attention, as this is where efficient risk-reduction measures can be applied.

We should indicate that the definition of operational objectives and interventions aimed at the final stages in the food production chain should not at any time be detrimental to the objectives and the interventions aimed at risk management that are to be applied throughout the chain. Certain microbiological risk assessment studies indicate directly proportional relations between the prevalence of some agents such as, for example, *Salmonella Enteritidis* on livestock farms and the risk to human health. For this reason, measures will be brought to bear at all the stages in the food production chain, forming a strategic approach based on complementary actions within the basic principles of integral, effective intervention proportional to the risk throughout the food production chain, in which the interventions considered most efficient at each moment are given priority.

Foodborne diseases in Catalonia. Evolution in recent years and main characteristics

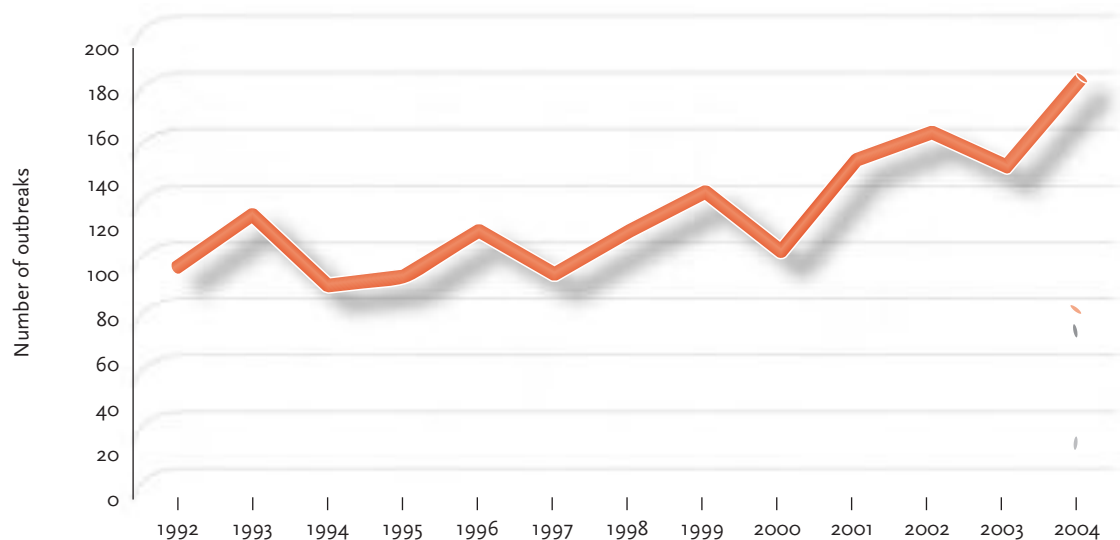
An outbreak of a foodborne disease (FBD) is suspected when there are two or more cases in which similar clinical symptoms have appeared after consuming the same foodstuff. After receiving the information, epidemiological surveillance units, together with food safety personnel, launch an epidemiological investigation with the aim of ascertaining the number of people affected and admitted to hospitals, deaths, the foodstuff carrier, the causal agent and the factors that have contributed to the appearance of the outbreak. All this investigation leads finally to the application of corrective measures to the original causes of the outbreak, should this origin be found to be a food establishment.

Early notification is very important because it makes it possible to gather clinical samples of foodstuffs. Microbiological analysis of these foodstuffs is of great importance in order to ascertain the cause of the outbreak. Moreover, early notification enables those exposed to be interviewed within a reasonably short period after consumption of the foodstuffs possibly involved, meaning that it is more probable that the information provided will be accurate; otherwise, they may not remember very well what they ate or what symptoms they had and when these appeared.

In Catalonia, as in other countries, outbreaks of foodborne diseases must be notified, so health care doctors should inform about any suspicion they may have as a matter of urgency. On the other hand, sporadic cases of foodborne diseases do not usually have to be notified, as it is very difficult to relate a single case of gastroenteritis to the consumption of one particular foodstuff. However, cases of botulism and gastroenteritis caused by Verotoxigenic *E. coli* O157 must be individually and urgently notified, as the seriousness of even a single case justifies the launch of an investigation to ascertain the food involved and recall it immediately.

Epidemiological information compiled in recent years indicates that increasing numbers of outbreaks are being notified. It is not easy to decide whether the increase registered is such, or whether it is the result of improving health care and diagnostic systems, analysis, identification of microorganisms, epidemiological surveillance and data collection. In any case, intervention measures need to be established in order to bring this problem under control.

Outbreaks of foodborne diseases



Source: *Butlletí Epidemiològic de Catalunya*. Various bulletins between 1992 and 2006.

Distribution of outbreaks notified in Catalonia from 1992 to 2004				
Year	Outbreaks	Cases	Hospital admissions	Deaths
1992	103	1.624	155	–
1993	126	1.817	119	0
1994	95	1.168	114	1
1995	99	1.468	146	1
1996	119	1.793	79	1
1997	100	1.167	69	0
1998	119	1.874	142	0
1999	136	1.716	130	2
2000	110	1.884	88	0
2001	150	2.281	155	0
2002	162	3.827	267	0
2003	147	1.660	125	1
2004	185	1.437	154	0

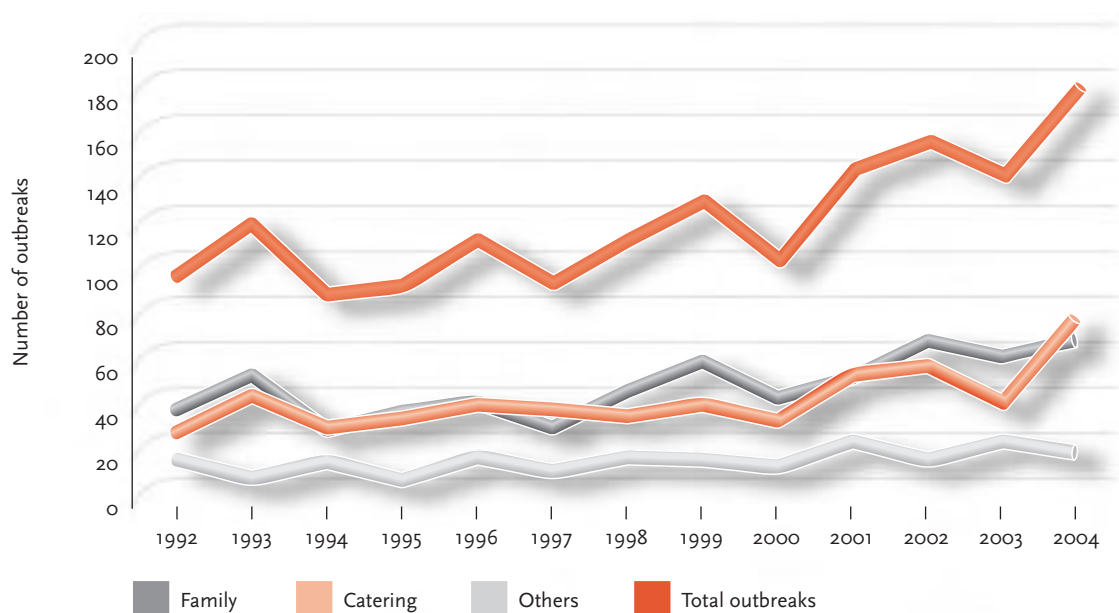
Source: *Butlletí Epidemiològic de Catalunya*. Various bulletins between 1992 and 2006.

Most people are vulnerable to foodborne diseases, although there are certain population groups that are particularly vulnerable, such as children, elderly people or people with immunodeficiencies of any kind. Therefore, in these population groups, the symptoms can be more serious, as they are more likely to become dehydrated or to be affected by sepsis, which significantly complicates the prognosis. Certain groups of the population with decreased humoral and cellular immunity or gastric acid deficiency are more likely to become ill if they consume contaminated products.

The demographic changes that have taken place in recent years, such as: population ageing; the increase in the number of people with immunosuppression problems due to infections or through receiving certain specific treatments; the globalisation of trade; the increase in consumption of pre-prepared food; the lack of training aggravated by the high turnover of people working in the catering business; and the lack of suitable prevention measures in the domestic area, are elements that, without doubt, contribute to the increase in food poisoning incidents in recent years and the fact that at the start of the 21st century, food poisoning is still a significant community health concern. In addition, current trends are expected to continue in much the same way over the coming years, meaning that we should assume that the natural tendency, if there is no intervention, is towards further increases in such incidents.

Study of outbreaks notified in Catalonia since 1992 enables us to extract some useful conclusions with a view to planning risk management. The data concerning the distribution area of outbreaks is worthy of special attention.

Main areas of outbreaks of foodborne diseases notified in Catalonia (1992-2004)



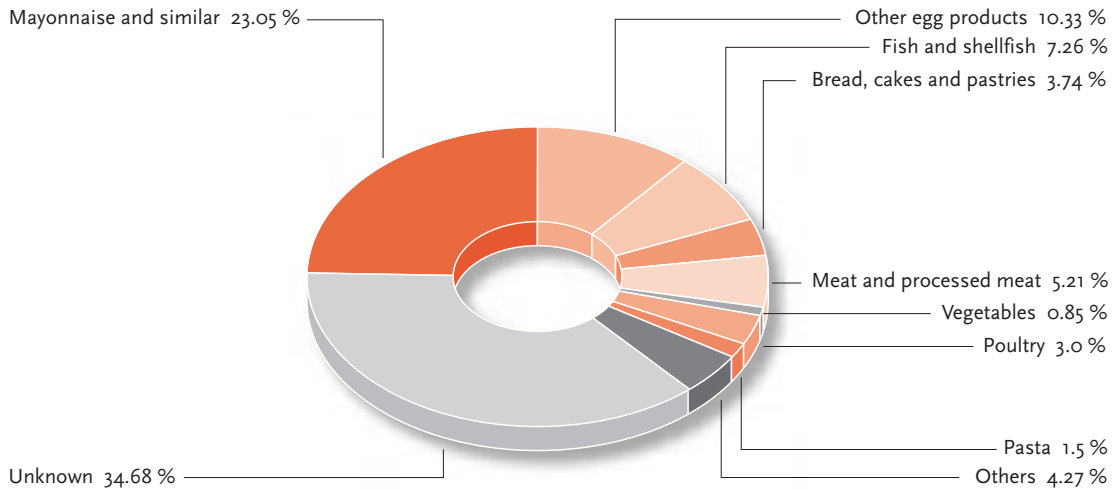
Source: *Butlletí Epidemiològic de Catalunya*. Various bulletins between 1992 and 2006.

The data available enables us to conclude that most of the outbreaks are concentrated in the domestic sector and in catering, followed, in a smaller proportion, by other areas such as school dining rooms, the workplace, homes for the elderly, school holiday camps, small shops, cake shops, and bakeries. This conclusion indicates the need to intervene in a more intensive way in the family or domestic sector and in catering because, as a whole, these account for more than 70% of food poisoning incidents notified in Catalonia over the last ten

years. We also need to plan specific intervention measures in areas associated with population groups most at risk, such as the elderly, very young children or sick people, because of their particular vulnerability and the severity of the consequences in cases of food poisoning.

We can also obtain useful information for guiding appropriate intervention measures by studying the data on carrier foodstuffs and contributing factors.

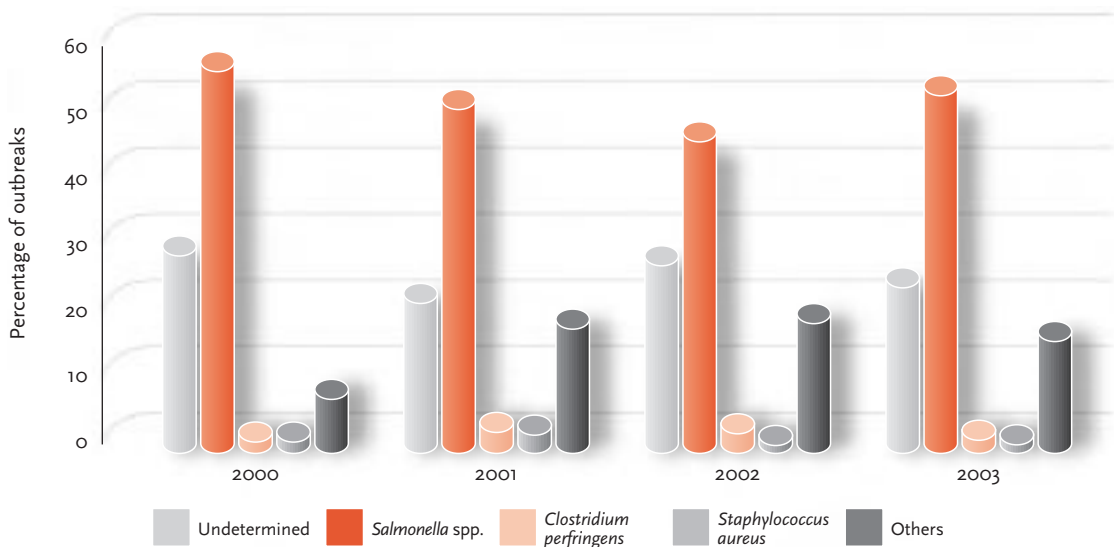
Percentage distribution of outbreaks of foodborne diseases notified in Catalonia according to the foodstuff involved (2000-2003)



Source: *Butlletí Epidemiològic de Catalunya*. October 2002 and October 2004.

As far as the most frequently involved etiological agents are concerned, we should expressly refer to the various species of the *Salmonella* genus, which in 2003 accounted for 72.7% of the outbreaks in which it was possible to identify the etiological agent.

Percentage distribution of outbreaks of foodborne diseases notified in Catalonia by etiological agent involved (2000-2003)



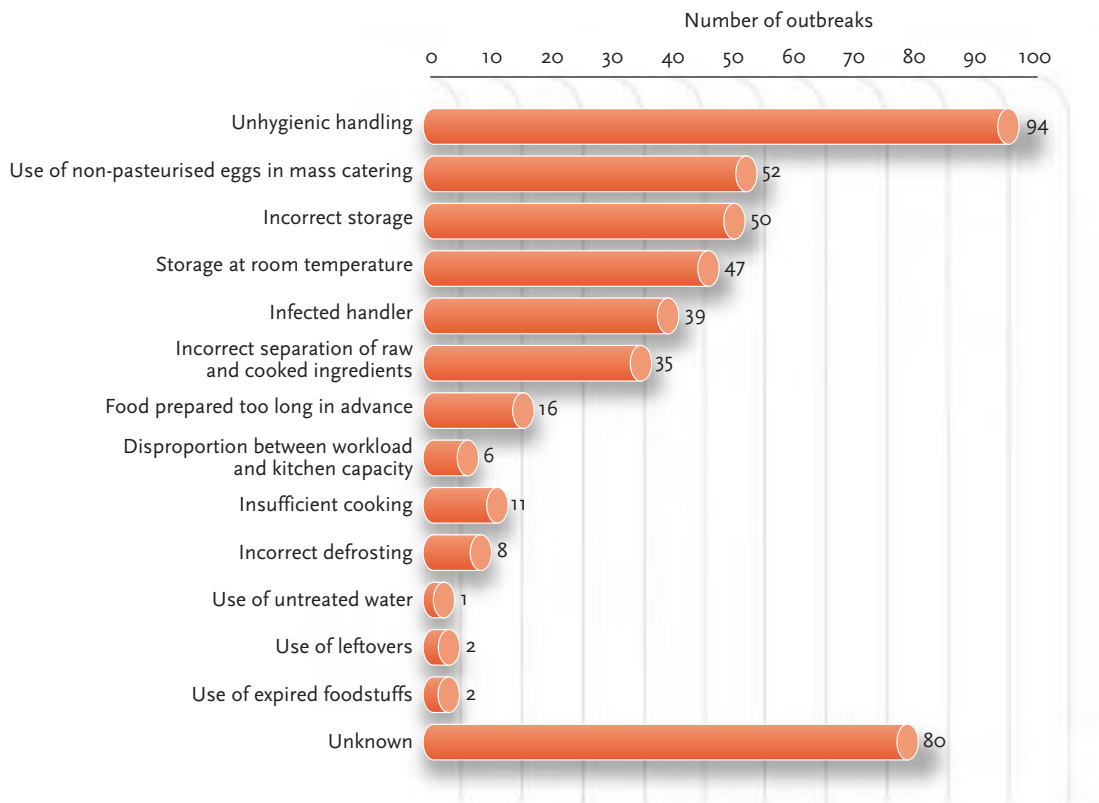
Source: *Butlletí Epidemiològic de Catalunya*. October 2002 and October 2004.

Distribution of outbreaks of foodborne disease notified in Catalonia in which the causal agent was identified according to the group of etiological agents involved (2000-2003)						
Etiological agents	2000	2001	2002	2003	Total	%
Bacteria and bacterial toxins	76	108	95	95	374	89.4
Virus	-	5	14	1.2	31	7.5
Others agents (poisonous mushrooms, etc.)	1	2	7	3	13	3.1

Source: *Butlletí Epidemiològic de Catalunya*. October 2002 and October 2004.

The contributory factors include, particularly, unhygienic handling, incorrect storage, storage at room temperature, cross contamination and the use of non-pasteurised eggs in mass catering.

Distribution of the total number of outbreaks of foodborne disease notified in Catalonia between 2000 and 2003 according to the contributory factors involved



Note: more than one factor may be involved in an outbreak.

Source: *Butlletí Epidemiològic de Catalunya*. October 2002 and October 2004.

As regards the incidence of foodborne disease caused by biological agents and that are diagnosed individually, the information available shows a wide margin for improvement because, in most cases, they are diseases that are subject to mandatory notification. Such voluntary notification may include cases related to sporadic cases and outbreaks. Moreover, sporadic cases caused by agents that are not subject to compulsory separate notification are not normally investigated, making it impossible to ascertain whether any links exist between them or what food or other factors they may have in common. All this generates important biases when it comes to analysing data, and steps should be taken in future to correct these through

appropriate measures. Similarly, based on data on microbiological notifications from laboratories, it is possible to obtain information that enables us to estimate incidence and draw comparisons with other regions.

Estimates of the incidence (cases per 100,000 inhabitants) of foodborne diseases in different countries					
Agent	France	United States	England and Wales	Spain	Catalonia
Bacteria					
<i>Bacillus cereus</i>	1.18	9.5	39	–	–
<i>Brucella</i> spp.	0.22	0.27	–	3.9	0.9
<i>Campylobacter</i> spp.	29.3	686.4	541.9	11.1	51.2
<i>Clostridium botulinum</i>	0.03	0.02	n.e.	0.03	–
<i>Clostridium perfringens</i>	15.1	86.8	225.7	–	–
<i>Listeria monocytogenes</i>	0.5	0.8	0.3	0.04	0.3
<i>Salmonella no-typhi</i>	69.7	469.1	180.09	16.8	61.3
<i>Salmonella typhi</i>	0.09	0.23	0.21	0.8	0.3
<i>Shigella</i> spp.	0.39	31.3	1.6	0.4	2.01
<i>Staphylococcus aureus</i>	17.66	64.7	25.8	36	–
Non-cholera vibrio	0.02	1.8	0.52	2	0.08
<i>Yersinia</i> spp.	3.2	30.3	564.3	–	0.3
Viruses					
Norovirus	118.9	3,216.7	133.9	–	15.8
Hepatitis A	0.68	1.4	–	1.92	0.85
Parasites					
<i>Toxoplasma gondii</i>	87.5	39.3	–	–	–
<i>Trichinella</i> spp.	0.06	0.018	–	0.1	–

Sources: *Morbilité et mortalité dues aux maladies infectieuses d'origine alimentaire en France*. Institut de Veille Sanitaire. France. *Butlletí Epidemiològic de Catalunya*. August 2003. *The present state of foodborne disease in OECD countries*. J. Rocourt, G. Moy, K. Vierk and J. Schlundt, Food Safety Department WHO, Geneva.

The information available enables us to extract a series of useful conclusions with a view to formulating specific objectives and intervention measures in Catalonia.

- These are a series of illnesses for which a significant number of cases and outbreaks are quantified yearly with a high number of people affected and which constitute a public health concern. Moreover, a growing tendency is observed with regard to the number of outbreaks and people affected in Catalonia in recent years.
- Almost 90% of outbreaks respond to the common pattern of so-called food poisoning: they are caused by pathogenic microorganisms or their toxins; the foods are generally an active support for the microbial multiplication or release of toxins; they lead to clinical symptoms that are predominantly gastrointestinal and have as their main contributing factor deficiencies in hygiene at the final stages in the food production chain.
- More than 70% of the outbreaks in which a causal agent has been identified are associated to a very specific group of agents: *Salmonella* spp., *Staphylococcus aureus*, *Norovirus*, *Bacillus cereus* and *Clostridium perfringens*. Particularly important amongst these is *Salmonella* spp., which is responsible for most of the outbreaks notified.

- The carrier foodstuffs most frequently involved are identified in more than 60% of cases. Those particularly involved are mayonnaise and other sauces, omelettes and other products made using fresh eggs, fish and shellfish, as well as pastries.
- The contributing factors most frequently associated are unhygienic handling, incorrect conservation or storage at room temperature, the use of non-pasteurised eggs and cross contamination. These unhygienic practices are associated to specific areas in the final stages in the food production chain and to the family or domestic area, as well as activities in which food is prepared and served for direct consumption *in situ* or to take away, particularly catering.

Legal framework

Regulation (EC) 852/2004, of the European Parliament and of the Council, of April 29, lays down the hygiene standards for foodstuffs. Through Regulation (EC) 882/2004, of the European Parliament and of the Council, of April 29, the rules for official controls made to guarantee the verification of compliance with the legislation in matters of feed and foods and animal health and animal welfare rules are established. These rules have an across-the-board effect on the entire food production chain, concerning both compliance with general food safety regulations and specific management of the main biological, chemical and physical hazards.

In view of the peculiarities of food of animal origin and the associated hazards, Regulation (EC) 854/2004, of the European Parliament and of the Council, of April 29, lays down specific requirements for organising official controls. Under this Regulation, specific measures for prevention, surveillance and control of food hazards associated with certain foodstuffs and production processes are laid down. The Regulation mentions particularly zoonotic diseases that can be transmitted through meat and its derivatives, such as transmissible spongiform encephalopathies, cysticercosis, trichinosis and tuberculosis. It also specifically mentions measures to control biological and chemical hazards associated with bivalve molluscs, fish products and milk and dairy products.

The following are amongst the most important intervention measures established in these areas: sampling and analytical control of foodstuffs and other products in the food production chain; *ante mortem* and *post mortem* inspection of the animals used; control of the production and reinstallation areas of bivalve molluscs, as well as control of parasites, histamine and waste; and microbiological tests on fish products.

Amongst these risk management measures, we should particularly mention *ante mortem* and *post mortem* veterinary inspection of animals slaughtered for human consumption as another of the basic elements for monitoring and controlling food hazards in general and zoonosis hazards in particular. Information obtained during the *ante mortem* inspection is used in *post mortem* inspection. The tracts and remains are subject to an inspection procedure that can be complemented by supplementary examinations, if these are considered to be necessary, to detect the presence of animal disease, zoonosis, waste or contaminants, non-compliance with microbiological criteria or any other factor indicating that the meat is not suitable for human consumption. The procedures established for *post mortem* inspections include procedures for detecting highly specific hazards, such as the agents that cause trichinosis, cysticercosis, tuberculosis and brucellosis, among others. Such inspections are interventions that we can well consider to be traditional in the food production chain, the subject of successive legislative modifications over the years. The conditions that regulate *ante mortem* and *post mortem* veterinary inspections at present are contained in aforementioned Regulation (EC) 854/2004, of the European Parliament and of the Council, of April 29.

We should also mention specific legislation governing feed, as regards restrictions on banned raw materials and specific official control conditions aimed at managing the most frequent risks associated with its production and distribution.

Within legislation governing biological hazards, we should also mention State and European Union regulations on microbiological criteria as a reference for monitoring and control.

Zoonotic agents

Zoonoses are diseases that can be directly or indirectly transmitted between animals and human beings. A large number of zoonotic diseases are transmissible through ingestion. Data must be compiled on the presence of zoonoses and zoonotic agents in animals, food, feed and people in order to determine trends and sources of zoonoses. In the report on zoonoses approved on 12 April 2000, the Scientific Committee of the EU on veterinary measures related to public health considered that the epidemiological data collected so far was insufficient. Moreover, the Committee highlighted as priorities for public health the genera *Salmonella*, *Campylobacter*, *Verotoxigenic Escherichia coli*, *Listeria monocytogenes*, *Cryptosporidium*, *Echinococcus granulosus/mulilocularis* and *Trichinella spiralis*.

The aim of Directive 2003/99/EC, of the European Parliament and of the Council, of November 17, on monitoring zoonoses and zoonotic agents, is to ensure appropriate surveillance in matters of zoonosis and antibiotic resistance, as well as epidemiological investigation into outbreaks of foodborne diseases. This Directive was transposed to Spanish internal law through Royal Decree 1940/2004, of September 27. As far as antibiotic resistance is concerned, the information collected will complement that which is obtained in the surveillance programmes of human strains carried out in accordance with Royal Decree 2210/1995.

Directive 2003/99/EC lays down the minimum requirements for epidemiological investigation into outbreaks of foodborne diseases. It makes provision for investigation into epidemiological characteristics, suspicious foodstuffs, laboratory analyses and the probable causes of outbreaks, as well as for collecting and communicating information. According to this Directive, the competent authorities should compile information on tendencies and sources of zoonosis, in particular with regard to brucellosis, campylobacteriosis, echinococcosis, listeriosis, salmonellosis, trichinosis, tuberculosis, verotoxigenic colibacillosis and its causal agents, antibiotic-resistant microorganisms and others when the epidemiological situation makes it necessary. When there are specific needs for assessing risks, the directive also provides for the development of coordinated surveillance programmes.

Directive 2003/99/EC also envisages the minimum regulations with which surveillance programmes must comply. These include provisions concerning particularly: the purpose; the duration; the geographical area; the agents that are the object of the surveillance; the animals or the stages in the food production chain at which they must be aimed; the nature and the type of data to be collected; the type of samples; minimum sampling plans; analysis methods; resources assigned; and systems for compiling and processing information.

The information collected will be gathered in an annually-published summary report on tendencies and sources of zoonoses, zoonotic agents and antibiotic resistance at State and Community level. The purpose of the legislation is to provide for surveillance and information gathering to enable assessment of the need and appropriateness of implementing additional risk management measures.

Regulation (EC) 2160/2003, of the European Parliament and of the Council, of November 17, lays down the requirements for controlling *Salmonella* and other foodborne zoonotic agents. The purpose of this Regulation is to ensure that proper and effective measures are taken to detect and to control *Salmonella* and other zoonotic agents at all the stages in the food pro-

duction chain. It sets Community-wide targets for reducing the prevalence of certain zoonoses and zoonotic agents in certain animal populations, with an indication of the level of prevalence and a deadline for achieving these, establishing the epidemiological units of reference and detection programmes for ensuring that objectives are met, amongst other things. It also lays down objectives in accordance with a cost-benefit analysis that takes into account the frequency of the appearance of diseases, the severity of their effects on public health, animal health and the economy, epidemiological trends, the feasibility of the control options available and scientific assessments.

Establishing objectives to reduce the prevalence of zoonoses is a complex matter in which multiple factors need to be considered. With this in mind, Regulation (EC) 2160/2003 lays down objectives with regard to the prevalence of *Salmonella* in certain animal populations. Under the Plan, these objectives must be included by risk managers as programmed objectives within the interventions established for controlling zoonoses.

Control and eradication of animal diseases

In the context of measures to control zoonotic diseases, we should also mention specific animal disease control and eradication programmes, now a traditional element in the field of animal health, and which include various important zoonoses.

Specific legislation exists to govern national programmes for eradicating animal diseases. According to this legislation, eradication programmes should be implemented with regard to the following animal diseases: bovine brucellosis, bovine tuberculosis, enzootic bovine leukosis, contagious bovine peripneumonia and ovine and caprine brucellosis caused by *Brucella melitensis*. Although the objectives of these programmes are also aimed at non-zoonotic diseases, they focus particularly on such pathologies as tuberculosis and brucellosis, zoonotic diseases that can be transmitted through food. Similarly, the legislation provides for the application of eradication programmes for any other infectious or parasitic diseases, if necessary.

Objectives and interventions

The basic approach for formulating specific objectives in this area should be aimed at palliating risk by minimising the prevalence of biological hazards at all the stages in the food production chain. However, biological hazards not only give rise to a risk of exposure, but also constitute a real health concern with a direct influence on the population. This is why we need to establish health objectives in which the most important indicators are data on the incidence of disease. In the case of food poisoning, targets aimed at reducing incidents are suggested, whilst for all other FBDs, low incidence levels should be achieved. The concept of low incidence should be defined case by case for each different disease according to its severity and epidemiological characteristics.

In accordance with the strategic approach taken by the Plan, the indicators selected are described generically, making it easier to deploy them. Once results have been assessed, it will be necessary to complete a more detailed study of the evolution and individual situation of the most important foodborne hazards and/or diseases, whether individually or according to classification groups. Moreover, the degree of notification and the effectiveness of data collection systems should also be taken into account in surveillance and assessment work, since an increase in efficiency could generate biases in indicator monitoring.

Objectives and interventions in the area of biological hazard management

Objectives

- To minimise the prevalence of biological hazards at all the stages in the food production chain.
- To reduce the total number of cases of food poisoning in general and particularly in the following areas:
 - Family or domestic.
 - Catering.
 - Mass catering serving more vulnerable population groups
- To minimise the incidence of other foodborne diseases caused by biological agents.



Interventions

- Implementing measures aimed at ensuring compliance with general food safety conditions.
- Developing a suitable regulatory framework.
- Informing, raising awareness and promoting good practices.
- Official analytical surveillance and control of biological hazards throughout the food production chain, with particular emphasis on agents considered priorities.
- Official surveillance and control, aimed particularly at contributory factors in food poisoning in the final stages of the food production chain.
- Information exchange systems and alerts throughout the food production chain.
- Epidemiological investigation and management of outbreaks.

The interventions applied should be proportional to the contribution of each stage and/or activity to the final exposure of the population, taking into account the different agents and characteristics involved.

As mentioned, the data available on foodstuffs and the contributory factors most frequently associated with outbreaks of foodborne diseases notified in Catalonia enable us to conclude that a large majority of cases –almost 90%– respond to the patterns found in food poisoning. If we take contributory factors into account, the **final stages in the food production chain can be seen to be a critical stage for controlling this problem**. In the domestic sector, intervention measures should be aimed particularly at providing information, training and raising public awareness about the need to adopt good food handling practices. In the other problem areas identified, it is possible to combine awareness-raising measures, informing and promoting good practices with others involving official surveillance and control. Specific objectives should be established for mass catering, as this is the area in which most incidents are reported, and for homes for the elderly, centres for people with health problems, playschools and schools, due to the particular vulnerability of these social groups.

Moreover, in cases where this is necessary, effective and proportionate measures should be brought to bear with regard to earlier stages in the food production chain in order to palliate the prevalence of biological hazards, thereby helping to reduce the risk to human health.

Parallel to this approach to intervention, we should also maintain efficient research systems and procedures to identify the causes of outbreaks and individual cases diagnosed in Catalonia. It is important to provide for improved epidemiological surveillance systems, amongst other objectives, in order to ensure that these take into account not only outbreaks, but also sporadic cases.

Some cases that are considered to be sporadic are, in fact, not. Epidemiological and microbiological research should be carried out in order to ascertain possible relations between these. At present, epidemiological surveillance and notification systems are biased towards detecting outbreaks caused by foodstuffs in which various people have been involved together, and at a particular place and time, generally restaurants or homes, whilst it is difficult to find relations when the outbreak is caused by a foodstuff sold at different times and places. We therefore need to develop case research systems that enable us to find out more about them, as well as to detect outbreaks not so clearly apparent or more dispersed in time and place. By establishing the direct causes, we can bring effective management measures to bear, with more specific interventions at the appropriate stages in the food production chain as necessary in each case.

2. *Transmissible spongiform encephalopathies*

Transmissible spongiform encephalopathies, although not a health concern in Catalonia, should be treated in a specific way due to a series of historic and regulatory reasons, as well as the severe nature of the prognosis should humans be affected. These reasons lead to the need to apply a series of very specific preventive measures that should be provided for under the Food Safety Plan of Catalonia.

Transmissible spongiform encephalopathies are neurological conditions that affect different species and that are anatomopathologically characterised by damage to the nervous system in the form of vacuoles or empty areas, which is why they are known as spongiform. Transmissible spongiform encephalopathies (TSE) are lethal neurodegenerative diseases which are differentiated from other transmissible diseases in that they are caused by proteinaceous infectious particles called prions. The cells of all mammals contain normal prions known as PrP^c, whose function we are still not very familiar with. Pathogenic prions, known as PrP^{sc}, are different because they have an abnormal development which makes them insoluble. This means that they accumulate until they cause the death of neurons and the appearance of small microscopic gaps and, therefore, damage to the nerve tissue, which causes the disease to develop.

The pathogenic mechanism of TSE therefore includes depositing an abnormal protein, PrP^{sc}, into the central nervous system, causing a change in the conformation of a normal protein that the animal already possesses in its cells, PrP^c. The prion hypothesis maintains that the PrP^{sc} is the only component of the infectious agent, which acts as a mould for the transformation of the PrP^c into more PrP^{sc}. This is a protein that is highly resistant to environmental exposure and the usual sterilisation procedures.

Human transmissible spongiform encephalopathies

Human TSE can be classified, according to origin, into three categories: infectious, hereditary and sporadic. The first group includes: Kuru, which is a disease limited to a Fore speaking community in Papua New Guinea; iatrogenic Creutzfeldt-Jakob Disease (CJD), accidentally transmitted in the attempt to treat another disease; and the new variant of CJD (vCJD), associated to an infection by the agent of bovine spongiform encephalopathy (BSE).

Of this new variant of CJD, up to 1 August 2005, 150 cases had been confirmed in the United Kingdom, 9 in France and 1 each in Ireland, Canada, the United States, Saudi Arabia, Japan, Holland and Spain (a case confirmed in the Community of Madrid). Although there is a high level of uncertainty, estimates of incidence of vCJD in Spain carried out by the National Epidemiology Centre are two cases in all, with exposure levels twenty times lower than in the United Kingdom.

Between 10 and 15 per cent of cases of human TSE are hereditary, due to a mutation in the PrP gene (family Creutzfeldt-Jakob disease, Gerstmann-Sträussler-Scheinker disease and fatal familial insomnia). In all other cases, the origin of the disease is unknown and are considered to be sporadic cases.

Independently of origin, TSE can be transmitted within the same species and between different species through inoculation or ingestion of the tissues of the individuals affected. Human TSE is a very infrequent disease, and classically has an incidence of around one or two cases per million inhabitants. TSE became a significant food safety concern when vCJD was identified in the United Kingdom, an incident which led to the creation of epidemiological surveillance systems in different countries of the European Union.

The aim of epidemiological surveillance of human TSE is to ascertain the clinical, epidemiological, anatomopathological and molecular characteristics of the disease, and to identify cases of human TSE that have an infectious origin (iatrogenic Creutzfeldt-Jakob and the new variant of Creutzfeldt-Jakob Disease).

Between January 1993 and August 2004, 104 confirmed or probable cases of human TSE were identified in Catalonia, and numbers have risen over the last six years. The origin of the disease was infectious in one case (a *dura mater* implant), hereditary in 12 cases (12%) and sporadic in the rest. There were no cases that corresponded to vCJD. It should be pointed out that interest in TSE has increased since the identification of epidemics of BSE and vCJD, and that an apparent increase in long-term incidence in countries in which epidemiological surveillance has been carried for prolonged periods has been observed, probably reflecting an improvement in the identification of cases due to the greater attention given to these diseases and the development of medical services and epidemiological surveillance. Although most human TSE is not infectious in origin, we should maintain epidemiological surveillance in order to detect possible changes in the epidemiological, clinical or neuropathological profile associated with transmission.*

Transmissible spongiform encephalopathies in animals

Transmissible spongiform encephalopathies (TSE) in animals are neurodegenerative diseases that affect both domestic and wild animals, and are caused by the same infectious protein, known as prion PrP^{sc}. These diseases include scrapie, transmissible mink encephalopathy (TME), chronic wasting disease (CWD) in deer, bovine spongiform encephalopathy (BSE) and feline spongiform encephalopathy (FSE).

Despite their diversity and the different species they affect, these diseases are all similar etiopathogenically and it is probable that they have a historic relationship, and that ovine and caprine scrapie lie at the root of all of them, whether directly or indirectly.

The TSE that are of most interest from a food safety point of view are BSE and scrapie, the latter due to the role it may have had in the origin of TSE, as it has not been classified as a zoonosis. Bovine spongiform encephalopathy was described for the first time in bovine species in the United Kingdom in 1986. In 1988, the possible leap of the infectious agent from the ovine to the bovine species led people to believe in the possible transmission to human beings through the consumption of contaminated bovine products.

Although the hypothetical risk of this second interspecies leap was considered to be very low, ten years later the first indications of the transmission of BSE to human beings was detect-

* Updated data on morbidity and mortality of spongiform encephalopathies in Spain and Catalonia is available from the website of the National Epidemiology Centre <<http://cne.isciii.es/>> and the website of the Catalan Ministry of Health <www.gencat.net/salut>.

ed, and in 1996 this possibility was officially admitted. It is currently considered that the BSE agent is responsible for the disease known as the new variant of Creutzfeldt-Jakob.

As far as animal TSE are concerned, more than 183,000 cases of BSE have been confirmed in the United Kingdom since November 1986. Since 1989, when the first case outside the United Kingdom was notified, 4,800 cases have been found in autochthonous animals, particularly in different European countries such as Ireland, France, Portugal, Spain, Switzerland and Germany. Outside Europe, cases have been described in Japan, Israel, Canada and the United States (updated information about the incidence of the disease can be consulted on the website of the World Organisation for Animal Health: www.oie.int).

Towards the end of 2000, the number of cases notified increased in France, probably as a result of the detection tests carried out on a greater scale and, for the first time, cases appeared in Spain, Germany and Italy. In January 2001, a EU regulation came into effect that obliged all the Member States to analyse, through rapid detection tests, all animals over 30 months of age intended for human consumption and that had died on farms. This age was lowered to 24 months in Catalonia in February 2001 and in the rest of Spain in July 2001.

The evolution of epizootics in the United Kingdom shows a rising trend until 1992, when there was an inflection and a clear downward trend started. This change in the trend occurred five years after feeding ruminants with feed produced from meat flours was banned.

In Catalonia, the first case of BSE was detected in March 2001, and an increase in the number of cases was observed until 2003, when 19 cases were confirmed. The ten cases confirmed in 2004 and the five cases in 2005 lead us to believe that 2005 could be the year in which the point of inflection was reached and that it could mark the start of a change of epizootic trends in Catalonia.

On 28 January 2005, a positive case of BSE was confirmed in a goat born in France in March 2000 and slaughtered in October 2002. Until then, BSE had not been detected in caprines under natural conditions. The result corresponded to a healthy animal analysed at the headquarters of the TSE surveillance programme that is carried out in all the Member States. As a result of this initial positive result of a TSE that was different from scrapie, complementary studies were initiated in the Reference Community Laboratory, confirming the case as BSE positive. The result was not made available until a series of complementary tests had been carried out that included analysis in live mice, with a duration of two years.

In view of the large number of analytical tests practised at the headquarters of the TSE community surveillance programme, the European Union estimated that the detection of an isolated case did not mean that we were facing a generalised concern. Nonetheless, from that moment, it was decided to reinforce monitoring of goat species through analysis of all reproductive goats intended to be slaughtered and all reproductive goats that died on the farm, and to continue with all other risk management measures concerning TSE.

Legal framework

Current legislation sets out in a detailed way a whole series of activities that should be applied to manage the risk of transmissible spongiform encephalopathies. This is one of the most heavily regulated food safety issues, due to the potential risk it poses, the severity of its effects on the health of people and the consequences for the economy and consumer confidence. Regulation (EC) 999/2001, of the European Parliament and the Council of May 22, lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. Important measures in Spain include Royal Decree 3454/2000, of December 22, which lays down and regulates the coordinated integral surveillance and con-

trol programme for transmissible spongiform encephalopathies in animals, and Royal Decree 1911/2000, of November 24, which regulates the destruction of specified risk material linked to transmissible spongiform encephalopathies.

These laws establish measures to be applied in cases of transmissible spongiform encephalopathies, and are aimed at: providing for the epidemiological surveillance of sub-populations likely to present the disease through analyses, and systems for case detection and confirmation; mandatory notification of suspected cases; training of related staff such as stock breeders and veterinary surgeons; prevention of transmission of the agent to people and animals through analytical procedures prior to human consumption; elimination and management of risk tissues; prohibition of certain substances in feedstuffs; and restrictions on trading in animals and products from territories with a high incidence of the disease. Moreover, they provide for epidemiological investigation and eradication measures in matters of animal health if an incident involving the disease is confirmed.

The measures established by these regulations are the result of studies and research carried out over the last 15 years, increasing current knowledge in issues concerning TSE in the EU. For this reason, when formulating objectives and interventions, we should take the conclusions from the results obtained and current legislation as a priority consideration.

Objectives and interventions

The objectives and interventions in the area of transmissible spongiform encephalopathies are established within the area of biological risk management, but with certain peculiarities that should be considered.

The very long incubation period of TSE, which can be as long as decades; the absence of cases of the variant of the Creutzfeldt-Jakob disease (CJD) described in Catalonia; the possibility that there are people in the incubation period in whom it is not possible to intervene from the food safety area; the existence of other non-foodborne forms of transmission; and the possibility of contact with the causal agent in previous periods or in other territorial areas; all these factors create a serious difficulty for proposing health objectives with regard to the variant of the Creutzfeldt-Jakob disease (vCJD). For the reasons explained, the objective of maintaining the prevalence of the disease in the population at current levels of absence is not enough. What is much more appropriate is to establish the specific objective of decreasing the risk, in this way providing guarantees of the absence of the causal agent of TSE in the food and feed production chain. This objective can be met by satisfying requirements that enable Catalonia to be qualified as a BSE- and scrapie-free area and the country's inclusion in the group of lowest risk in accordance with Community regulations. Health qualification is carried out according to a series of criteria that take into account epidemiological data and levels of compliance with risk management measures provided for in current regulations, matters that could undergo variation over time, as they are subject to continuous review by the European Union.

With regard to scrapie, we should also provide for the specific objective of guaranteeing the absence of the causal agent in the food and feed production chain since, although it is not described as a zoonotic agent, it is attributed with possible involvement in the origin of BSE.

These objectives require actions at various stages in the food production chain, to which end the following lines of action should be applied simultaneously and in a complementary way:

- 1. Epidemiological surveillance and control of subpopulations likely to present the disease** through controls at farms, detection and notification of suspected cases and taking and analysing samples from certain subpopulations likely to catch the disease.

2. **Prohibition of certain substances in feedstuffs.** This consists of banning the use of certain categories of raw materials of animal origin to feed certain classes of animals. Such prohibition should be proportional to the existing risks and should help to prevent exposure of productive animals to causal agents of TSE.
3. **Measures for epidemiological investigation and eradication if any case of the disease is confirmed.** In such cases, a detailed epidemiological investigation will be carried out to ascertain the origin of the disease as well as the animals or products that could run the risk of being affected. Based on the results of the epidemiological investigation, the necessary eradication measures are applied, slaughtering animals and destroying the carcasses, as well as eliminating any other products that could be affected.
4. **Elimination of specified risk material (SRM).** Specified risk material is defined as all the tissues and organs from a slaughtered animal intended for human consumption that could be infectious if the animal were BSE infected, according to experimental work to date. Similarly, the regulation that defines these materials and regulates their elimination considers SRM to include those tissues that could be contaminated due to anatomical proximity or handling practices involving potentially infected tissues.

According to the scientific studies available, the removal of SRM containing components from the central nervous system ensures the elimination of 95% of the infectious load in products obtained from an animal that could be affected by the disease. If we add to the list of SRM other organs and tissues with very low infectivity, this percentage rises to about 99.7%, a degree of protection. This together with other applicable measures and, in particular, with systematic analysis of animals at risk and animal health and stock breeding farm measures to eradicate the disease, offers the population very high levels of protection.

Specified risk material is removed at the beginning of the meat production circuit, according to the moment when it can be removed with the highest safety guarantees. Most is therefore extracted at the abattoir and is separated from the food production chain at that moment, given that this is the ideal time from the point of view of efficiency and control. Only certain parts can be extracted outside the abattoir, at specifically authorised establishments and under certain conditions.

Veterinary officials are constantly present at all abattoirs in Catalonia to control slaughter and procedures to prepare and sell meat. Supervision of the removal of SRM during slaughterhouse operations is included in official veterinary controls for abattoirs and constitutes one of the most relevant interventions in this area.

After removal, SRM should be identified by tinting and treatment at establishments authorised to manage these subproducts in compliance with Regulation (EC) 1774/2002, which classifies them as Category 1 materials that are to be managed (tinted, stored, transported and treated) in such a way as to prevent any risk of reintroduction into the food production chain.

5. **Surveillance for the detection of suspicious animals in *ante mortem* inspection and control of animals slaughtered urgently.** TSE can present symptoms which, apart from being varied, can be very unclear during the initial moments of the clinical stage. For this reason, a search is carried out in the abattoir in the form of a detailed examination during the *ante mortem* inspection, aimed particularly at detecting any symptom compatible with these pathologies.

When animals brought to the abattoir arouse suspicion because they present symptoms compatible with TSE and it is not possible to discard the possibility of them having the disease, official veterinary services should declare the animals not suitable for slaughter, tak-

ing precautionary measures with the live animals. The Ministry of Agriculture, Food and Rural Action is then informed, and carries out the slaughter of suspect animals, implementing special measures, and later analysing the remains.

Animals to be urgently slaughtered are a risk group, as many of the pathologies that they frequently present, such as broken bones, can be the result of neurological disorders, requiring that special attention be paid to these cases.

- 6. Analysis for investigation into the causal agent of TSE in animals slaughtered at abattoirs.** Compulsory epidemiological surveillance for all TSE diseases in animals in the EU was introduced in 1998, along with measures that Member States were to adopt in cases of suspected TSE in an animal, the minimum conditions for BSE and scrapie surveillance and sampling procedures and the laboratory tests to detect the presence of TSE (specifically, histological analyses and immunohistochemical confirmation). In 1999, the EU approved the rapid diagnostic tests for carrying out systematic analyses on animals at risk of suffering from the disease. In January 2001, the use of these tests became compulsory in all EU countries, so that no bovine animal can be released for consumption over a certain age unless it has given a negative result to a BSE detection test using an authorised rapid technique.

Dubious or positive results from rapid diagnostic tests should be confirmed at an official laboratory, and a second histopathological confirmation should be carried out to detect the presence of vacuoles, immunocytochemical confirmation effected to determine the presence of prion protein, and the presence of characteristic fibrils should be confirmed by electronic microscopy.

The systematic testing of bovines of over 24 months makes it possible to detect affected animals, even if they do not present symptoms compatible with BSE.

While BSE detection tests are being carried out, all parts of the body of the sampled animal, including the skin and the blood, are retained until the results of the test are known. Only if a negative result is obtained from the detection test is the carcass marked as healthy and released for consumption.

Bovine analytical controls prevent affected animal meat from being sold for human consumption, as well as providing an important source of information for epidemiological surveillance of the disease in animal populations. In order to enable epidemiological surveillance of small ruminants, the TSE programme includes, in addition to the systematic testing of bovines and caprines to which we have referred, the random sampling of ovines over the age of 18 months in order to detect scrapie.

- 7. Professional training.** An important aspect here is training to update the theoretical and practical knowledge of clinical veterinarians and vets responsible for official controls at the stages of stock breeding production and slaughter at the abattoir. This training should also include other groups, such as stockbreeders and other related professionals.
- 8. Territorial restrictions on trade and controls at destination of animals and products from other territories.** Legislation has been enacted to govern trade in certain categories of animals and products from territories with a high incidence of the disease. Depending on the case, these restrictions may involve the complete prohibition of movements, or may restrict movements, to ensure appropriate levels of risk management at source.

An important measure in this area is control at destination of animals from the bovine, ovine and caprine species and of their meat and derived products, to ensure compliance with legal provisions to protect human health, particularly territorial restrictions on trade and conditions concerning the absence of SRM.

Animals, feedstuffs, meat and meat products, as well as waste generated by these, must be subject to official control to ensure compliance with the applicable regulations. Compliance must be ensured with rules governing origin, identification and documentation of such products in order to detect any irregularity. If necessary, immediate corrective action should be taken as appropriate. Depending on the particular case, such action may entail destruction or return to source. These measures are particularly necessary when dealing with animals or products from territories with a high incidence of disease or a greater risk of disease, for whatever reason.

Objectives and interventions in the field of transmissible spongiform encephalopathies

Objectives

- Absence of the causal agent of bovine spongiform encephalopathy (BSE) in the food and feed production chain.
- Absence of the causal agent of scrapie in the food and feed production chain.



Interventions

- Developing a suitable regulatory framework.
- Informing, raising awareness and promoting good practices.
- Epidemiological surveillance and control of subpopulations prone to presenting the disease.
- Banning certain matters in feedstuffs.
- Epidemiological investigation and eradication measures.
- Elimination of specified risk material.
- Surveillance to detect suspect animals in *ante mortem* inspection.
- Research into the causal agent of TSE in animals slaughtered at abattoirs.
- Professional training..

Management of biological risks

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
Presence of biological hazards in the food production chain			
E-008	To minimise the presence of biological hazards at all stages in the food production chain.	Rates of compliance with current legislation and/or internationally recognised standards	95 %
Foodborne diseases caused by biological agents			
E-009	To lower the incidence of food poisoning.	Number of outbreaks Incidence	Reduction Reduction
E-010	To lower the incidence of food poisoning in mass catering.	Number of outbreaks Incidence	15 % reduction Reduction
E-011	To lower the incidence of food poisoning in school dining rooms, homes for the elderly and amongst other particularly sensitive population groups.	Number of outbreaks Incidence	25 % reduction Reduction
E-012	To lower the incidence of food poisoning in the domestic sector.	Number of outbreaks Incidence	Reduction Reduction
E-013	To minimise the incidence of other foodborne diseases of biological origin.	Number of outbreaks Incidence	Low incidence Low incidence
Transmissible spongiform encephalopathies			
E-014	Absence of the causal agent of bovine spongiform encephalopathies (BSE) in the food and feed production chain.	Epidemiological situation and rates of compliance with BSE risk management measures	Compliance with the requirements for the health classification of Catalonia as a BSE-free area
E-015	Absence of the casual agents of scrapie in the food and feed production chain.	Epidemiological situation and rates of compliance with scrapie management measures	Compliance with the requirements for the health classification of Catalonia as a scrapie-free area

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
General food safety conditions			
O-033	Achieve the objectives and implement the interventions relating to maintaining the general conditions for food safety.	See the section "General food safety conditions"	
Regulatory framework			
O-034	Provide a suitable legal framework for biological risk management needs.	Needs detection and assessment studies Promote procedures for improvement according to needs detected	Available 100%
Informing, awareness raising and promoting good practices			
Biological hazards, food poisoning and other foodborne diseases of biological origin			
O-035	To inform, raise awareness and promote good practices aimed at food production chain stakeholders, including the general public, in matters of biological hazards, hazard-product-process associations and specific preventive measures that should be applied in each case.	Informing, raising awareness and promoting good practice	Available
O-036	The general public should be provided with useful information for preventing foodborne diseases in the domestic area, particularly with regard to food poisoning.	Appropriate information aimed at the domestic sector	Available
O-037	The owners of businesses that prepare and/or serve food <i>in situ</i> or to be taken away create awareness useful information for preventing food poisoning.	Information aimed at the food preparing and/or serving sector	Available
Transmissible spongiform encephalopathies			
O-038	Veterinary clinics and stock breeders should be provided with information, awareness raising and promotional material on good practices with regard to TSE, focusing particularly on detecting and managing suspect cases on farms.	Information, awareness raising and good practice promotion	Available and introduced
O-039	Operators in the food production chain should be provided with information, awareness raising and promotional material on good practices with regard to TSE, focusing particularly on preventive measures for feedstuffs and separating and removing SRM.	Information, awareness raising and good practice promotion	Available and introduced

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
Official surveillance and control			
Biological hazards, food poisoning and other foodborne diseases of biological origin			
O-040	All the stages in the food production chain should be subject to official surveillance and control programmes designed and carried out according to existing risks and aimed at minimising the presence of biological hazards, particularly those related to foodborne diseases caused by biological agents that are diagnosed in Catalonia.	Official surveillance and control programmes	Introduced
Food poisoning			
O-041	Activities concerned with preparing and/or serving food <i>in situ</i> or to be taken away, in particular companies most frequently associated with outbreaks of food poisoning and those serving the most vulnerable population groups, should be subject specific official surveillance and control programmes aimed particularly at palliating factors that contribute to cases of food poisoning.	Specific surveillance and control programmes	Introduced
Transmissible spongiform encephalopathies			
O-042	Official surveillance and control programmes should be provided to ensure that feed does not contain material might entail the risk of TSE transmission.	Official programmes to ensure compliance with TSE prevention measures in feedstuffs	Introduced
O-043	Action should be taken so that animals presenting symptoms compatible with TSE are subject to specific detection, management and confirmation procedures.	Specific control programmes for notifying, managing and confirming suspected cases of TSE	Introduced
O-044	Animals from subpopulations or groups considered to be at risk from TSE should be subject to control and epidemiological surveillance through the necessary detection tests.	Analytical surveillance programmes for animals in subpopulations at risk and animals that die on farms Subpopulations and proportion of animals tested	Introduced Compliance with current legislation
O-045	In positive TSE cases, careful epidemiological investigation must be carried out to ascertain the associated factors and the animals and products potentially affected, as well as how to apply appropriate eradication measures.	Positive cases in which an epidemiological investigation is carried out and eradication measures are applied	100 %

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-046	Animals intended for human consumption considered to be at risk due to species, age, geographic origin or other reasons should be subjected to TSE detection tests that enable the disease to be discarded as a pre-requisite for them being declared suitable for consumption.	Analytical control programmes of all animals involved/belonging to risk subpopulations intended for consumption Proportion of animals subject detection tests compared to regulatory specifications	Introduced 100 %
Official surveillance and control in the transport, transformation and destruction of waste			
O-047	Official surveillance and control measures should be provided for managing carcasses at stock breeding farms, ensuring that they are eliminated and destroyed without causing biological risks, particularly TSE transmission.	Official control programmes for managing carcasses at stock breeding farms	Introduced
O-048	The separation, transport, transformation and destruction of waste, in particular SRM, should be subject to official controls and surveillance.	Official surveillance and control programmes for the transport, transformation and destruction of waste, including SRM	Introduced
Self-control and traceability			
O-049	Activities in the food production chain that are directly linked to foodborne diseases with incidence in Catalonia and/or to TSE prevention should be subject to official controls to ensure that self-control and traceability procedures are implemented which specifically take into account biological hazards considered to be a priority in accordance with risk assessment results.	Official programmes to monitor self-control and traceability systems to ensure that these specifically take into account biological hazards considered to be a priority in accordance with risk assessment results	Introduced
Information exchange and alert systems			
O-050	Provision of information exchange and alert systems on biological hazards to ensure quick, effective risk management throughout the food production chain. These systems should include health and epidemiological services to monitor any possible effects on human health.	Alert and information exchange systems embracing the entire food production chain	Available and introduced
Epidemiological investigation and outbreak management			
O-051	To ascertain the etiology of notified outbreaks of foodborne diseases caused by biological agents.	Percentage of outbreaks notified for which the etiology is known	75 %

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-052	To ascertain the factors contributing to notified outbreaks of foodborne diseases caused by biological agents.	Percentage of outbreaks notified in which the associated factors are known	90 %
O-053	To reduce the deadlines for notifying and applying management measures in cases of outbreaks of foodborne diseases caused by biological agents.	Average time taken to notify clinical suspicions.	24 hours
		Average time for starting management actions after notification.	12 hours
O-054	Provision of appropriate standard procedures for investigating and managing outbreaks of foodborne diseases caused by biological agents.	Standard procedures.	Available and introduced
O-055	Provision of effective systems for collecting epidemiological information on cases and outbreaks of foodborne diseases caused by biological agents.	Epidemiological information collection systems.	Available and introduced

Interventions

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Regulatory framework						
I-044	Draw up studies to detect needs to change regulatory framework with regard to biological risk management.	DAR	APS DAR	APS ACC AL	–	DMAH
ACSA						
I-045	To promote, as appropriate, the development and criteria for application and/or modification of regulations at local, autonomous, regional, state and European level.	DAR	APS DAR	APS ACC AL	–	DMAH
ACSA						
Informing, awareness raising and promoting good practices						
Biological hazards, food poisoning and other foodborne diseases of biological origin						
I-046	To provide stakeholders in the food production chain with necessary and appropriate information about biological hazards and foodborne diseases, the products and/or processes most frequently related to them, current legislation and the measures to be applied to ensure correct prevention and management.	DAR	DAR APS	APS ACC AL	APS AL	DMAH ARC
ACSA						
I-047	To inform operators in the food production chain about the results from the reports aimed at determining biological risks and to actively promote, where appropriate, the application of additional management measures, particularly in cases of well-grounded suspicion or proven existence of severe, imminent risks to human health.	DAR	DAR APS	APS ACC AL	APS AL	DMAH ARC
ACSA						
I-048	To disseminate and promote the application of recommendations aimed at reducing the presence and/or increased presence of biological hazards in the domestic sector.	–	–	–	APS AL ACSA	–
I-049	To develop programmes for raising awareness and disseminating information about food poisoning and other foodborne diseases, aimed at the operators in the food production most directly involved, particularly owners of companies that prepare and serve food, and the general public.	DAR	APS DAR	APS AL	APS AL	–
ACSA						

ACSA: Catalan Food Safety Agency. ACC: Catalan Consumer Affairs Agency. AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
I-050	To publish educational material about food poisoning and other foodborne diseases aimed at workers in activities concerned with preparing and/or serving food <i>in situ</i> or to be taken away, and the general public.	–	–	APS AL ACSA	ACSA APS AL	–
Transmissible spongiform encephalopathies						
I-051	To provide veterinary clinics and stock breeders with suitable information and to implement activities aimed at raising awareness and promoting good practice with regard to TSE in general and the detection and management of suspicious cases on farms in particular.	DAR	–	–	–	–
I-052	To provide operators in the food production chain with suitable information and to implement activities aimed at raising awareness and promoting good practice with regard to TSE, focusing particularly on preventive measures for feed and separating, managing and eliminating SRM.	DAR ARC	APS ARC	APS AL ARC	–	ARC
Surveillance and control of hazards throughout the food production chain						
Official environmental surveillance and control						
I-053	Surveillance and control of activities that produce emissions of biological agents that may affect food safety.	DMAH	–	–	–	–
I-054	Surveillance and control of biological hazards with repercussions on food safety in the air, the soil, and marine and continental waters, as well as wild flora and fauna.	DMAH DAR	–	–	–	–
Official surveillance and control at the primary stage						
Raw materials and means of production						
I-055	Official surveillance and control of the production and sale of raw materials and other production means intended for the food production chain.	DAR DMAH	–	–	–	–
I-056	Official analytical surveillance and control of biological hazards in feed production and distribution.	DAR	–	–	–	–

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<i>Interventions (cont.)</i>		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
Animal product						
I-057	Official analytical surveillance and control of biological hazards on animal production farms.	DAR APS	–	–	–	–
I-058	Epidemiological surveillance and eradication of zoonotic diseases on animal production farms.	DAR	–	–	–	–
I-059	Official analytical surveillance and control of biological hazards in fishing and fish farming activities.	DAR ACA	–	–	–	–
I-060	Monitoring of biological hazards in hunting and fishing species.	DMAH	–	–	–	–
I-061	Analytical surveillance and control of biological hazards in marine and continental waters for fish farm production and reintroduction.	DAR	–	–	–	–
Transmissible spongiform encephalopathies						
I-062	Official analytical surveillance and control of the production and distribution of feedstuffs and, in particular, the raw materials used, and preventive measures against TSE.	DAR	–	–	–	–
I-063	Official surveillance and control of correct notification and management of animals suspected of contracting TSE at stock breeding farms.	DAR	APS	–	–	–
I-064	Analysis of animals that have died or been slaughtered at farms and that belong to certain subpopulations requiring epidemiological surveillance for TSE (in accordance with current regulations).	DAR	APS	–	–	–
I-065	Epidemiological investigation and application of eradication measures in positive cases of TSE.	DAR	–	–	–	–
Supply waters						
I-066	Official analytical surveillance and control of biological hazards in irrigation and drinking water for activities at the primary stage in the food production chain.	DAR ACA	–	–	–	–

ACA: Catalan Water Agency. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing.

<i>Interventions (cont.)</i>		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Official surveillance and control at the transformation and distribution stage						
I-067	<p>Official surveillance and control of meat and fish products at the initial stages in the processing and distribution stage:</p> <ul style="list-style-type: none"> ■ Veterinary inspection of animals intended for human consumption at abattoirs and wild game processing plants. ■ Surveillance and control of biological hazards in fish products during initial distribution stage after capture. 	–	DAR APS	–	–	–
I-068	Official analytical surveillance and control of biological hazards and contributing factors in foodborne diseases at the processing and distribution stages.	–	APS	–	–	–
Food poisoning						
I-069	<p>Official control of compliance with regulations on staff training and self-control in the industrial activities of preparing food with the highest risk of food poisoning, such as central kitchens and ready-to-eat foods, with particular emphasis on:</p> <ul style="list-style-type: none"> ■ Companies most frequently related with outbreaks of food poisoning and those serving the most vulnerable population groups. ■ Companies which, due to their volume of production, could affect the highest numbers of people. 	–	APS	–	–	–
Transmissible spongiform encephalopathies						
I-070	Analysis before certification of suitability of all animals intended for human consumption considered to be at risk due to their species, age, geographic origin or other relevant reasons, in accordance with current regulations.	–	APS	–	–	–
I-071	Surveillance and control of the withdrawal of specified risk material from meat intended for human consumption.	–	APS	–	–	–

APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action.

Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
Supply waters						
I-072	Official analytical surveillance and control of biological hazards in waters used at the food processing and distribution stages.	–	APS	–	–	–
Official surveillance and control at the retail trade stage						
I-073	Official analytical surveillance and control of hazards in retail trade activities and in foodstuffs made available to the end consumer.	–	–	APS ACC AL	–	–
Supply waters						
I-074	Official analytical surveillance and control in publicly supplied waters.	–	–	APS AL	–	–
Food poisoning						
I-075	<p>Official control of compliance with staff training and self-control requirements in activities for preparing and serving meals, with particular emphasis on:</p> <ul style="list-style-type: none"> ■ Companies most frequently linked to outbreaks of food poisoning, and those related to the most vulnerable population groups. ■ Companies which, due to their volume of production, could affect the highest numbers of people. 	–	–	APS AL	–	–
Official surveillance and control of waste management and disposal						
I-076	Official surveillance and control of correct separation, identification and internal management at waste treatment plants, particularly animal carcasses at farms and abattoirs, tissues not suitable for human consumption and SRM.	DAR	APS	APS AL	–	–
I-077	Official surveillance and control of transport and destination of waste, particularly SRM.	–	–	–	–	ARC DAR
I-078	Official surveillance and control of waste treatment companies.	–	–	–	–	ARC DAR
I-079	Official surveillance and control of final destination of waste treatment products, particularly SRM.	DAR	–	–	–	ARC

ACC: Catalan Consumer Affairs Agency. AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action

Interventions (cont.)

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Self-control and traceability						
I-080	Official surveillance and control of activities in the food production chain direct linked to foodborne diseases detected in Catalonia and/or to prevention of TSE, to ensure that self-control and traceability procedures have been introduced that specifically take into account biological hazards considered priorities.	DAR	APS	APS AL	–	ARC DAR
Exchange of information and management of alerts						
I-081	To provide rapid information exchange and food alert systems that include informing consumers where necessary.	DAR DMAH	APS DAR	APS ACC AL	DS ACC AL	APS ACC AL
ACSA						
I-082	To set up and maintain systems for information exchanges about zoonotic diseases and other biological hazards between risk managers with a view to improving preventive and management actions. These systems should also include health care and epidemiology services to monitor any possible effects on human health.	DAR DMAH	APS DAR	APS ACC AL	DS ACC AL	APS ACC AL
ACSA						
I-083	To introduce systems and protocols for communication, collaboration, coordination and control to ensure that owners of activities in the food production chain inform the competent authorities and adopt the necessary measures when they detect biological safety issues in foodstuffs, including provisions to withdraw these from the market and to inform consumers if necessary.	DAR DMAH	APS DAR	APS ACC AL	DS ACC AL	APS ACC AL
ACSA						
Epidemiological investigation and outbreak management						
I-084	To develop and introduce standard, rapid, effective notification systems and procedures for food poisoning and other foodborne diseases.	–	–	–	DS	–

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<i>Interventions (cont.)</i>		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
I-085	To develop control systems and ensure constant improvements to mandatory notification procedures.	–	–	–	DS	–
I-086	To develop and introduce standard, rapid, effective systems for investigating food poisoning and other foodborne diseases. These should include informing risk management and assessment bodies about the etiology and contributing factors behind these diseases.	–	–	–	DS	–
I-087	Active surveillance of foodborne diseases that are non-notifiable or do not cause outbreaks.	–	–	–	DS	–
I-088	To develop a system for detecting outbreaks that are not clearly apparent or are dispersed in time and space.	–	–	–	DS	–
I-089	To study the microbiological notification system and cases of diseases diagnosed in Catalonia to ascertain the importance of foodborne transmission.	–	–	–	DS ACSA	–
I-090	To develop and introduce standard, rapid, effective management procedures for outbreaks of food poisoning and foodborne diseases.	–	–	–	DS	–
I-091	To produce manuals and provide appropriate training in research and management of food poisoning and other foodborne diseases aimed at professionals engaged in investigating and managing outbreaks.	–	–	–	DS ACSA	–
I-092	To improve epidemiological surveillance systems with regard to laboratory notification, investigation into isolated cases, molecular epidemiology and identifying and creating a database on isolated strains, both in humans and in animals and food.	–	–	–	DS DAR ACSA	–

ACSA: Catalan Food Safety Agency. DAR: Ministry of Agriculture, Food and Rural Action. DS: Ministry of Health

2.2.3 Chemical and physical risks

As with biological hazards, objectives and management interventions for chemical and physical risks have also been established with the purpose of reducing the population's exposure to food hazards to levels as low as are reasonably possible and/or acceptable. The minimisation of the frequency and concentration of chemical and physical hazards in the different stages required in the production and distribution of foodstuffs is therefore another key element for this objective.

Business owners throughout the entire food production chain must provide necessary guarantees with regard to the products for which they are responsible, especially through the application of adequate systems of self-control. As such, specific interventions by authorised administrative bodies aimed at promoting awareness, informing and promoting good practices must be provided for, in addition to official surveillance and control interventions to effectively prevent and reduce to a minimum the introduction of chemical and physical hazards into the different stages in the food production chain and avoid, where applicable, any increase in the frequency and concentration of these hazards.

Although the different chemical hazards can be identified in an individual manner, these courses of intervention must have a wide, flexible character, based on a conception of these hazards as a group. This focus must ensure management through the application of programmes aimed at a wide range of existing hazards, a focus which is compatible with a prioritisation of those hazards in each programme which are the most important in relation to the circumstances of each moment, the surveillance and the risk assessment results. The actions to be introduced must be suited to the characteristics of each stage in the food production chain, giving priority to the most frequent hazards related to each stage and to those which may involve a greater health risk to the public.

Serious incidents of acute poisoning due to chemical hazards have been described in the past. In our most immediate environment, evidence of poisoning can be cited from the beta-agonists used in the illegal fattening of stock in the 1992, and the famous case of toxic syndrome from adulterated rapeseed oil at the beginning of the 1980s. These episodes, although highly serious, may be considered as exceptional situations in which a series of one-off factors occurred.

Apart from these highly specific cases, and in contrast to what has been possible to demonstrate in the case of biological hazards, there are no epidemiological figures which allow the establishment of direct correlations between the chemical hazards which may be found in different products in the food production chain and the incidence or prevalence of illnesses among the population. This is due to the difficulty involved in undertaking epidemiological investigations with a retrospective character on those possibly affected, given the influence of diverse variable factors which must be considered, such as long periods between exposure and the appearance of the adverse effects, the difficulty in compiling data on the real exposure to which the people affected have been submitted, the effect of repeated exposure over extended periods of time, and possible synergic effects between substances, among others.

The lack of sufficient epidemiological data means that assessment research into chemical risks must be undertaken using data from experimental models which applies broad safety margins, where the human species is considered to be one hundred times more vulnerable than the most sensitive animal species. These margins are used to establish maximum residue limits in current regulations. The legally established limits in the European Union, and the other conditions established in statutory form, must be considered as key reference elements in defining objectives and interventions under the plan, not only due to the legal imperative of meeting European Union legislation in the field, but also due to their solven-

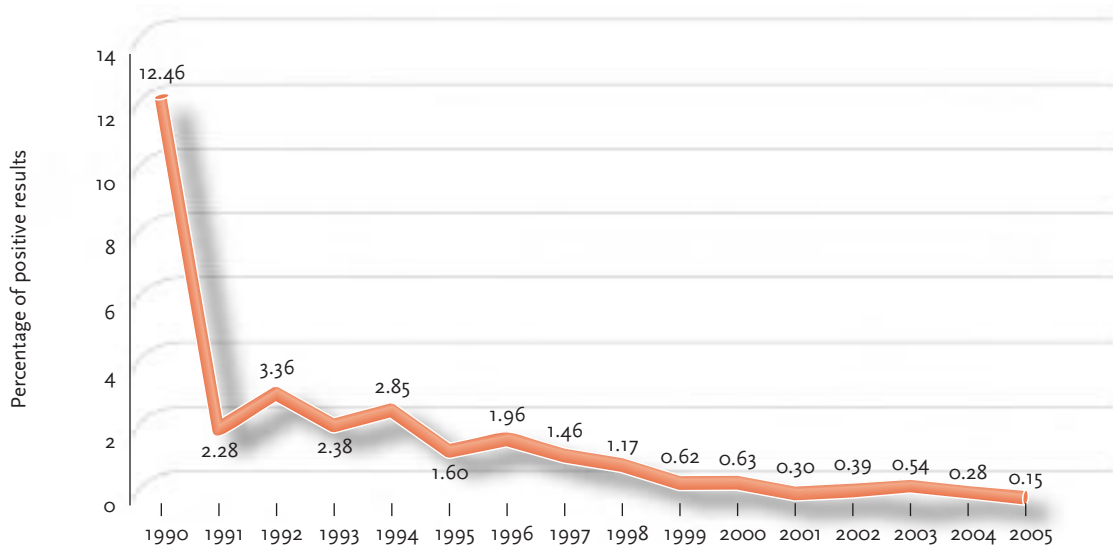
cy from a scientific viewpoint, as these laws are based on well-founded risk assessment studies.

According to available data from studies and official controls undertaken in the area of Catalonia, these substances are usually found at low levels. In the cases where detection is possible, they are frequently found below the maximum accepted levels, or in quantities which do not exceed these levels enough to involve severe poisoning risks or any other type of serious and immediate risk to public health according to existing scientific knowledge.

Although in the majority of the cases health risks are low, certain population groups –children, the elderly or people who follow insufficiently varied diets– may be more vulnerable. As this subject involves hazards which may have cumulative, long-term effects, a varied, balanced diet is a recommended measure for reducing exposure to those chemical hazards which are inevitably found in foodstuffs.

The data available on chemical residues at the different stages in the food production chain, and the tendencies observed over the last few years indicate that there has been a highly positive development towards high compliance levels. The results of investigations into animal waste and its products, and those corresponding to investigations into plant health waste in plant products indicate compliance rates of over 95%.

Results from the research plan into foodstuffs of animal origin in Catalonia (1990-2005)



Source: Directorate-General for Public Health. Ministry of Health.

With regard to environmental pollutants, the data available from investigation into total diet indicates that the exposure levels for the population of Catalonia are below the maximum WHO recommended limits.

Exposure to contaminants through diet in Catalonia in comparison with WHO safety levels		
Poison	Estimated ingestion by an adult male	Safety levels established by the WHO
Arsenic	4.2 µg/kg/week	15 µg/kg/week
Cadmium	1.56 µg/kg/week	7 µg/kg/week
Total mercury	2.1 µg/kg/week	5 µg/kg/week
Methylmercury	0.8 µg/kg/week	1,6 µg/kg/week
Lead	3.9 µg/kg/week	25 µg/kg/week
Dioxins and polychlorated biphenyls (PCB)	3.51 pg/OMS/TEQ/kg/day	1-4 pg/OMS/TEQ/kg/day
Hexachlorobenzè	0.0024 µg/kg/day	0.16 µg/kg/day

Source: *Contaminants químics, estudi en dieta total a Catalunya*. Catalan Food Safety Agency. Directorate-General for Public Health. Ministry of Health.

Although the information available leads to the idea that risks from chemical hazards are not high in Catalonia, there is no absolute scientific certainty in this area, as some issues should be subject to careful and continual assessment with a view to improving risk management.

- Identification of new hazards as a result of new technologies or new scientific knowledge.
- The possibility that exposure levels amongst certain population subgroups may be higher than overall figures.
- Combined exposure to different chemical hazards and possible synergic effects.
- The existence of important individual variations in the population regarding vulnerability to the effects of chemical hazards.

Due to the reasons outlined above, investigations must be continued in the area of risk assessment and maintenance of adequate surveillance systems in order to ascertain the prevalence of chemical hazards in the food production chain and population exposure levels and so offer the best risk management possible.

Legal framework

As has been outlined in the section concerning biological risks, EC Regulations 852/2004 and EC 882/2004, of the European Parliament and Council, of April 29, must be taken into account. The horizontal nature of these regulations means that they are applied throughout the entire food production chain, in the management of biological as well as chemical and physical hazards.

Regulation (EC) 854/2004, of the European Parliament and Council, of April 29, establishes specific standards for the organisation of official controls in which references are included to biological, chemical and physical hazards related to certain foodstuffs and production processes, such as meat, bivalve molluscs, fish products, milk and milk products. Notable intervention measures outlined in these standards deal with sampling and analytical controls of foodstuffs and other products in the food production chain.

Legislation specific to feedstuffs includes restrictions on prohibited raw materials and specific conditions for official control, all of which are aimed at managing the risks most frequently related to the production and distribution of feedstuffs.

More specific laws exist with regard to chemical hazards as a complement to the horizontal standards referred to. These are mainly based on hazard definition, maximum permitted

limits, and surveillance and control of those foodstuffs and feeds in which they are more likely to be present.

European Union, State and Autonomous Community or regional legislation establishes Community precedents with regard to: contaminants; animal health products in living animals and their products; insecticides; materials in contact with food, and other substances that, in certain circumstances, might constitute a hazard, such as additives and technological coadjuvants when used incorrectly in the production of food or feed or in quantities greater than those authorised.

Current legislation expressly prohibits the introduction of food products onto the market which contain contaminant substances, residues or additives in proportions which are unacceptable for health reasons. Assessment procedures are also specified for authorisation and conditions of manufacture, distribution and the use of chemical substances in the food production chain. Dosage limits and/or maximum content limits are established, in addition to display procedures and specifications for the analytical methods used in official controls. These standards expressly establish the responsibility of the food safety authorities to carry out official surveillance and control programmes to verify the presence of contaminating substances and residues in products in the food production chain.

A contaminant is defined as any substance found in the foodstuff which is not intentionally present, but which is a residue of the production (including treatments applied to crops, stock and in the practice of veterinary medicine), manufacture, transformation, preparation, treatment, conditioning, packaging, transport or storage of the foodstuff, or as a consequence of environmental contamination. Although this is the definition established in Regulation (EC) 315/93 of the Council, of February 8, a distinction must be made between the term contaminant, which refers to substances which are introduced involuntarily without there being an intentional use, such as contaminants of an environmental origin, and the term residue, used when the origin of the contaminant is a substance used during normal production processes.

To date, legislation on contaminants has established maximum amounts of certain substances in certain foods. These contaminants include, for example, heavy metals (lead, mercury, cadmium), dioxins, certain mycotoxins and polycyclic aromatic hydrocarbons, among others.

Specific regulation also exists regarding aspects related to the above-mentioned undesirable substances in feedstuffs, in which maximum contents are established for determined substances which may involve risks to the health of humans or animals, including arsenic, lead, mercury, cadmium and nitrites.

Specific legislation exists to govern surveillance and control of certain substances and their residues in living animals and their products. This legislation provides for investigation into substances in living animals, their excrements and biological liquids, as well as in any organ or animal tissue, products of animal origin, feed, water and other components used in feeding. The substances subject to surveillance and control in accordance with this standard belong to different groups such as those with an anabolic effect and illegal substances, veterinary medicines, environmental contaminants and mycotoxins and colorants, among others.

The maximum limits for the substances subject to these surveillance programmes are detailed in various specific, periodically updated laws. The addition of animal health products into feed is also regulated, as is the manufacture, distribution and application of animal health products.

We should also mention here the law which regulates and harmonises issues regarding waste from animal health products and their control. This law follows the same line in regu-

lating use, setting maximum levels and establishing that the competent authorities should set up a surveillance system.

Additives and flavourings used in feed and in food for human consumption are also subject to specific laws, which establish the procedures for authorisation, rules and standards for manufacturing, distribution, labelling and use, and maximum authorised levels.

Regarding contaminants which may originate from materials which come into contact with food, there exists considerable legislation governing the positive list of materials and objects that enter into contact with foodstuffs, in addition to the conditions which must be met for authorisation, production and sale.

Objectives and interventions

The formulation of objectives and the application of interventions in the area of chemical risks present several characteristics which must be taken into account. The establishment of health objectives is certainly difficult due to the determined characteristics of the majority of risks which are derived from chemical hazards in foodstuffs, among which the following should be noted:

- The long periods of time necessary for the manifestation of possible adverse health effects, hindering epidemiological links to exposure to the agent, should such exist.
- The existence of other channels of exposure, other than food, where intervention is not possible through a food safety approach.
- The existence of people, at the development stages of adverse effects, who may have been exposed to the causal agents in the past or in other territorial areas.

These limitations show why it is difficult to formulate health targets and indicators that can provide full information. That is why it is necessary to apply an approach based on parameters for reducing risk such as the prevalence of hazards (frequency and concentration) in the food production chain and human exposure in overall diet. Nonetheless, these limitations should not prevent formulation of a health target aimed at maintaining the complete absence of foodborne outbreaks of a chemical nature.

Achieving these objectives requires the introduction of systems to reduce the presence of and/or human exposure to such hazards. Those responsible for this are the owners of companies in the food production chain, which must be subject to control by food safety authorities.

Here it should be pointed out that the legislation takes a different approach according to whether the products in question are included or used voluntarily during production processes or whether they are products added involuntarily, from the environment or as the undesired result of certain production processes.

On the one hand, the concepts of maximum residue limit (MRL) applied to plant health and animal health products must be considered, in addition to the maximum authorised quantity applied to the additives. In these two cases, the maximum limit of a determined substance is established through toxicological studies using animal experimentation. This allows an estimate to be made for tolerable ingestion without adverse effects, information which, together with the information related to the average normal diet of the population, enables us to calculate the maximum tolerable limit for each type of food and to apply safety margins.

However, in the case of substances for which it is impossible to establish any risk-free level, which are introduced involuntarily during the production process and in storage, and which involve a chronic exposure risk at very low doses, and for which there is no possibility of

ensuring either their control or their total absence in foodstuffs, maximum threshold levels are established which are considered acceptable at an international level. These maximum threshold levels are fixed in line with the ALARA concept (“As Low As Reasonably Achievable”), a concept used to minimise risks which takes into account different factors such as profit or feasibility. This is the case of certain contaminants of environmental origin (dioxins, certain heavy metals, etc), certain residues generated during the production processes (acrylamide, polycyclic hydrocarbons, mycotoxins, etc) and certain natural toxins from the foodstuffs themselves, whose presence in small quantities is inevitable, and which are accepted provided they are kept below levels based on studies that have considered, in a balanced way, the risks, benefits and feasibility of levels.

However, this approach is beginning to change. The ALARA approach is based on the concept that no dose can be considered safe. Most studies extrapolate from data on animal experimentation in which very high doses were used. But this does not reflect human reality, as it does not take into account metabolic processes or repair mechanisms, factors which may modify the results. Moreover, analytic techniques are becoming more and more sensitive, and allow the detection of substances in very low doses, a fact which, together with the application of the ALARA principle, means that a continual revision, lowering threshold levels has to be made.

On 7 April 2005, the EFSA Scientific Committee published an opinion with reference to carcinogenic and genotoxic ingredients, according to which these concerns should be dealt with through an approach based on the use of safety margins with regard to a point of comparison (PoC). Using experimental studies, a reference dosage is calculated which produces measurable effects in animals used in experimentation, either using a BMDL (below minimum detectable limits) reference or, if no BMDL exists, a T25 (a chronic dose which produces effects on 25% of the animals exposed). This process also includes an estimate of the population’s average ingestion based on total diet investigations. In order to consider the risk insignificant, the relation between the point of comparison (PoC) and estimated ingestion must be above a magnitude of 10,000 if the BMDL reference is used, and 25,000 if the T25 reference is used. This safety margin is established on the basis of an estimate of possible inter- and intraspecific differences and the nature of the pathological processes involved, among other factors.

This new approach enables risk assessment to be made which is more proportional and better adjusted to the real risk and, furthermore, one which is highly useful for risk managers in prioritising actions aimed at avoiding a continual drift towards increasingly lower levels and alarm situations caused by the mere presence of hazards, which may not be justified if one takes into account the true magnitude of the risk that really exists.

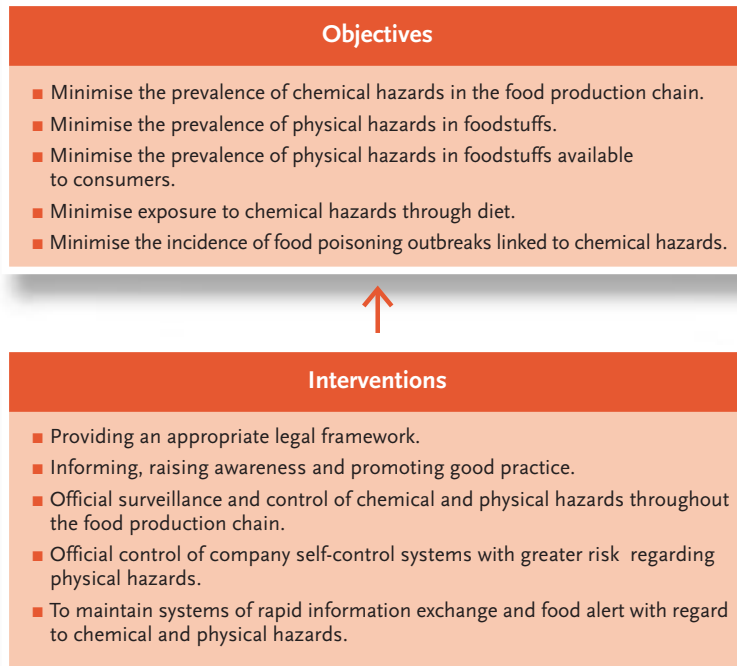
Establishing and complying with maximum residue limits or authorised maximum amounts provides an instrument for keeping population exposure rates within acceptable safety levels. Results assessment should take into account the degree to which these limits are observed, taking the corresponding estimates of exposure as the final reference point.

In the case of physical hazards, defined as foreign materials present in food which may cause traumatic type injuries to the digestive apparatus, the approach taken must be aimed at minimising their presence in food available to the consumer, taking into account the characteristics and the forms of action of the hazards included in this group.

From an operational point of view, an approach which takes into account the different stages in the food production chain is suitable for managing chemical and physical risks, analysing existing concerns and applying the necessary measures to each stage and sector of activity. The interventions to be introduced should address the hazards which are in each case the most frequent, the most likely and/or which involve a higher risk, considering the

contribution of each stage to the real exposure of the population. For a specific stage or process, the related hazards must be identified, and programmes for informing, raising awareness and promoting correct actions must be established, in addition to official surveillance and control.

Objectives and interventions in chemical and physical risk management



The specific hazards which are the subject of surveillance and control programmes vary over time according to various factors, such as, for example the results obtained in previous years, the scientific studies available, the experience acquired or the hazards identified in food alerts.

However, it must be taken into account that the a different management approach needs to be applied for each different group of hazards. For example, the problems caused by contaminants must be managed in a different way from those related to residues from substances used in production processes. The presence of contaminants is not usually due to negligence or intentional behaviour. Exposure to these hazards can usually be reduced by applying mid- and long-term strategies closely linked to environmental protection policies. However, it is often possible to bring more immediate strategies to bear in order to control residues, as improvements can normally be made by the owners of companies in the food production chain increasing the controls they carry out of their production processes. Here, we should note that surveillance programmes may often be addressed simultaneously to monitoring both contaminants and residues, independently of the fact that the management measures to be applied need to be different in each case according to the causes behind each different issue.

For their part, physical hazards can normally be managed appropriately through measures introduced at the final stages in the food production chain, such as, for example, the processing and distribution stage, particularly the final processes of handling and packaging. At this stage, companies generally apply effective control systems such as sifting or metal and

foreign body detection systems. Food production chain operators have been highly aware of these issues for many years now, and have generally introduced adequate self-control systems. The most appropriate interventions for minimising physical hazards revolve around the supervision of companies' self-control systems, particularly to verify that they have identified these hazards and have implemented the corresponding preventive, surveillance and improvement measures in accordance with HAPCC principles.

AAs in all other sections of the Plan, the indicators selected have been established in a generic manner, in order to encourage the broadest possible deployment and definition, taking into account the different stages in the food production chain, and the different hazards or groups of hazards. This is why the detailed deployment of specific measures must be carried out by management bodies at the operational planning stage.

The results of official analytical surveillance and control programmes monitoring the presence of hazards in the different products in the food production chain should provide a useful source of data for to evaluate compliance with these objectives, although they may be somewhat biased, since official controls are normally focused on areas where low levels of compliance are expected to be found. That is why it will be necessary to complement this information with random studies and data on population exposure levels in total population diet. Moreover, this is an area in which there is a wide margin for improvement and in which it will be necessary to advance by carrying out the pertinent studies in order to provide data that is both sufficient in quantity and comparable over time.

In order to promote continued improvements, it is important to ascertain the source of hazards, when they are introduced, the factors which influence them and the measures most suitable from the scientific point of view to reduce, eliminate or control them. These objectives, which are focused on improving existing knowledge, are formulated and developed in the section devoted to risk assessment.

In order to achieve the objective of minimising the presence of chemical and physical hazards in the food production chain, operational objectives and interventions must be established which allow:

- Development of a regulatory framework for the prevention and control of disease-causing agents throughout the entire food production chain.
- Provision of useful information for food production chain operators and the public in general about: the hazards that exist at each different stage, and in each different product or process in the food production chain; related factors; and the most suitable measures for preventing, reducing and/or eliminating these hazards.
- Awareness-raising and the promotion of good practices by food production chain stakeholders.
- Maintenance of official systems for the analytical surveillance and control of the physical and chemical hazards linked to each of the stages in the food production chain. Surveillance and control of the chemical hazards should be undertaken through two main lines of action: analytical surveillance of products in the food production chain; and inspection to verify compliance with conditions for production, sale and restrictions on or conditions for the use of substances such as plant health and animal health products.
- Maintenance of rapid information exchange and food alert systems for the chemical and physical hazards in the food production chain and, when necessary, provision to the public of information concerning batches of foodstuffs or feed which may present a hazard.

Management of Chemical and Physical Hazards

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
Presence of chemical and physical hazards			
E-016	To minimise chemical hazards at all stages in the food production chain.	Rates of compliance with current legislation and/or internationally recognised standards	> 95 %
E-017	To minimise physical hazards at all stages in the food production chain.	Rates of compliance with self-control systems with regard to physical hazards	> 95 %
Exposure to foodborne chemical agents, and illnesses caused			
E-018	Minimise human exposure to chemical hazards in diet.	Rates of compliance with overall diet according to internationally recognised standards	> 99 %
E-019	Maintain absence of foodborne outbreaks caused by chemical agents	Number of outbreaks	0

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
General conditions for food safety			
O-056	To achieve objectives and implement interventions relating to maintenance of general of food safety conditions.	See section "General Food Safety Conditions"	
Legal framework			
O-057	To provide a regulatory framework appropriate to the needs of physical and chemical hazard management.	Needs detection and assessment studies Improvement procedures deriving from the detected needs	Available 100 %
Informing, awareness raising and promoting good practices			
O-058	To provide systems for informing, raising awareness and promoting good practices aimed at food production chain stakeholders, including the public, with reference to chemical and physical hazards, the hazard-product-process association and specific preventive measures to be applied in each case.	Measures for informing, raising awareness and promoting good practices	Available
O-059	Updated information should be made available to the public concerning foods or feeds which may involve a physical or chemical hazard, defining the risk they represent and the measures to prevent, reduce or eliminate this risk, including the recommendation to follow a varied diet.	Updated information systems available to the public	Available

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
Official surveillance and control			
O-060	<p>All stages in the food production chain must be subject to official surveillance and control programmes, designed and carried out on the basis of existing risks and aimed at minimising the presence of chemical and physical hazards, with special attention to the following groups:</p> <ul style="list-style-type: none"> ■ Contaminants ■ Residues from animal health products ■ Residues from plant health products and fertilisers ■ Residues from unauthorised substances ■ Additives and technological contributions exceeding authorised limits ■ Residues from materials in contact ■ Residues generated in the production processes ■ Physical hazards in foodstuffs available to the consumer 	Official surveillance and control programmes	Introduced
Self-control and traceability			
O-061	<p>Activities in the food production chain must be subject to official controls in order to verify that self-control and traceability procedures have been introduced which specifically take into account priority chemical and physical hazards considered priorities in accordance with risk assessment results.</p>	Programmes of official control for self-control and traceability focused on verifying that these specifically take into account the chemical hazards deemed to be priorities based on risk assessment results	Introduced
Information exchanges and alerts			
O-062	<p>To provide alert and information exchange systems concerning physical and chemical hazards with a view to effective and rapid risk management throughout the food production chain. These systems should also include health care and epidemiology services to monitor any possible effects on human health</p>	Alert and information exchange systems embracing the entire food production chain	Available and introduced
Epidemiological investigation and outbreak management			
O-063	<p>Ascertaining the etiology of notified outbreaks of diseases caused by chemical agents.</p>	Percentage of notified outbreaks whose etiology is known	99 %
O-064	<p>Ascertaining contributory factors in notified outbreaks of diseases caused by chemical agents.</p>	Percentage of notified outbreaks for which the contributory factors are known	99 %

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-065	To reduce time required to notify outbreaks of diseases caused by chemical agents, and to apply management measures.	Average time before notification of outbreaks after clinical suspicion.	24 hours
		Average time following notification before launch of management measures.	12 hours
O-066	To provide appropriate regulatory procedures for research and management concerning outbreaks of diseases caused by chemical agents.	Standard procedure.	Available and introduced
O-067	To provide effective systems to gather epidemiological information about cases and outbreaks of diseases caused by chemical agents.	Epidemiological information gathering systems.	Available and introduced

Interventions

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Legal framework						
I-093	To draw up studies for the detection of requirements in the modification of the regulatory framework with reference to physical and chemical hazard management.	DAR	APS DAR	APS ACC AL	–	DMAH
ACSA						
I-094	To promote, where necessary, the development of application criteria and/or the modification of legislation at local, autonomous region, state and European level.	DAR	APS DAR	APS ACC AL	–	DMAH
ACSA						
Information, awareness raising and the promotion of good practices						
I-095	To provide food production chain stakeholders with: necessary and appropriate information concerning chemical and physical hazards; the products and/or processes most frequently related to them; current standards; and the measures to be applied for correct management and prevention.	DAR	DAR APS	APS ACC AL	APS AL	DMAH
ACSA						

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
I-096	To inform food production chain operators about the results of reports determining chemical hazards and to actively promote, where necessary, the application of appropriate management measures, especially in cases of justified suspicion or evidence of serious and imminent risks to public health.	DAR	DAR APS	APS ACC AL	APS AL	DMAH
ACSA						
I-097	To disseminate and promote the application of recommendations aimed at preventing the entry and/or increased presence of chemical and physical hazards, and exposure levels to them in the domestic sector.	DAR	DAR APS	APS ACC AL	APS AL	DMAH
ACSA						
Surveillance and control of hazards throughout the food production chain						
Official surveillance and control in the environment						
I-098	Surveillance and control of activities which generate contaminant emissions with effects on food safety.	DMAH DAR	–	–	–	–
I-099	Surveillance and control of contaminants with effects on food safety, air, the soil and marine and continental water, as well as wild flora and fauna.	DMAH DAR	–	–	–	–
Official surveillance and control at the primary stage						
Raw materials and means of production						
I-100	Official surveillance and control of the production and sale of raw materials and other production means in the food production chain, particularly in areas related to: <ul style="list-style-type: none"> ■ Fertilisers ■ Plant health products ■ Animal health products ■ Other raw materials of plant or mineral origin. 	DAR DMAH	–	–	–	–
Animal produce						
I-101	Analytical surveillance and official control of chemical hazards in the production and distribution of feedstuffs.	DAR	–	–	–	–
I-102	Analytical surveillance and official control of chemical hazards at stock farms.	DAR APS	–	–	–	–

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
I-103	Analytical surveillance and official control of chemical hazards in fishing and fish-farming activities.	DAR ACA	–	–	–	–
I-104	The monitoring of chemical hazards in game species.	DMAH	–	–	–	–
I-105	Official surveillance and control of the use of animal health products in stockbreeding and on fish farms.	DAR	–	–	–	–
I-106	Analytical surveillance and control of marine and continental water used for fish production and repopulation.	DAR	–	–	–	–
Plant products						
I-107	Official analytical surveillance and control of chemical hazards in wild plant products.	DAR DMAH	–	–	–	–
I-108	Official analytical surveillance and control of chemical hazards in plant production activities on farms.	DAR	–	–	–	–
I-109	Official surveillance and control of the application of plant health products and fertilisers.	DAR	–	–	–	–
Supply waters						
I-110	Official analytical surveillance and control of chemical hazards in supply waters for primary stage activities in the food production chain.	DAR ACA	–	–	–	–
Official surveillance and control at the transformation and distribution stages						
I-111	Veterinary inspection at abattoirs and cutting rooms for wild game intended for human consumption.	–	APS	–	–	–
I-112	Official surveillance and control of the production, sale and use of auxiliary manufacturing ingredients (additives, flavourings, technological contributions and materials in contact with foodstuffs).	–	APS	–	–	–
I-113	Official analytical surveillance and control of chemical hazards at the processing and distribution stages.	–	APS	–	–	–

ACA: Catalan Water Agency. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
Supply waters						
I-114	Official analytical surveillance and control of chemical hazards in waters used at the foodstuff processing and distribution stages.	–	APS	–	–	–
Official surveillance and control in the retail						
I-115	Official analytical surveillance and control of chemical hazards in foodstuffs available to the final consumer.	–	–	APS ACC AL	–	–
Supply waters						
I-116	Official analytical surveillance and control of chemical hazards in public supply waters.	–	–	APS AL	–	–
Self-control and traceability						
I-117	Official surveillance and control of activities in the food production chain in order to verify the adoption of self-control and traceability procedures which specifically consider chemical and physical hazards as priorities.	DAR	APS	APS AL	–	ARC DAR
Information exchange and alert management						
I-118	To provide rapid information exchange and alert systems for chemical and physical hazards, informing consumers when necessary as well as including health care and epidemiology services to monitor any possible effects on human health.			DMAH DAR APS ACC AL ACSA		
I-119	To set up and maintain information exchange systems on physical and chemical hazards among risk management organisers with a view to improving preventive management actions.			DMAH DAR APS AL ACSA		
I-120	To implement communication, cooperation, coordination and control systems and protocols in order to guarantee that the owners of activities in the food production chain inform the competent authorities and adopt the necessary measures when a chemical safety concern is detected in foodstuffs, including withdrawal from the market and informing consumers where necessary.			DAR ACSA APS AL DMAH		

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. ARC: Catalan Waste Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

<i>Interventions (cont.)</i>		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
Epidemiological investigation and management of outbreaks						
I-121	To develop standard, rapid, effective systems to notify of suspected food poisoning by chemical agents.	–	–	–	DS	–
I-122	To develop and introduce standard, rapid, effective systems for investigating cases of food poisoning by chemical agents, including provision of information about etiology and contributing factors to risk assessment and management authorities.	–	–	–	DS	–
I-123	Active surveillance for possible foodborne illnesses caused by chemical agents that are not manifested in the form of outbreaks.	–	–	–	DS	–
I-124	To develop a system to detect outbreaks that are less apparent or are more dispersed in time and space.	–	–	–	DS	–
I-125	To develop and introduce standard, rapid, effective management procedures for outbreaks of foodborne diseases caused by chemical agents.	–	–	–	DS	–
I-126	To produce manuals and provide appropriate training for research and management of food poisoning and other foodborne diseases aimed at professionals engaged investigating and managing outbreaks.	–	–	–	DS	–

DS: Ministry of Health

2.2.4 Adverse food reactions

In the general context of food safety, the risks related to determined substances, components or ingredients which do not involve a risk to the population in general but which do incur health concerns in determined individuals with special sensitivities must be taken into account. This involves so-called adverse food reactions, which are normally manifested in the form of allergies and food intolerances, and with regard to which it is necessary to establish specific objectives and interventions.

Food allergies are adverse bodily reactions which appear as a consequence of contact with, ingestion or inhalation of a foodstuff or one of its components. For an adverse reaction to a foodstuff to be considered as an allergy there must be an immunological basis. Allergens are proteins or glycoproteins which are naturally present in food. In some people these proteins stimulate the immune system and provoke an excessive, pathological response. The immune system responds to the allergen as if it were a threat and develops an attack with antibodies. These antibodies, known as immunoglobulin IgE, interact with the allergens and stimulate the secretion of histamine, prostaglandins and leukotrienes by certain tissues and blood cells such as mastocytes and basophiles. These substances are the causes of the symptoms of the allergy, such as nasal congestion, skin inflammation and eruptions, mucous or itchiness. In some cases more serious symptoms may occur such as asthma, diarrhoea or colic. In the most serious cases an anaphylactic shock may occur, which seriously affects the circulatory system through a loss of arterial pressure, which may lead to death.

Although any food or its components may lead to allergic reactions, certain groups have been identified which are the most frequently associated with allergies. This is the case of crustaceans, eggs, fish, peanuts, soy, milk, fruit in general, nuts, celery, mustard, sesame seeds and their respective derivatives.

The European Scientific Committee on Food has estimated a 3% prevalence of food allergies in the population in general, a figure which is higher in infants, for whom the figure is 7%, although this decreases to average population levels at around three years of age. A certain hereditary predisposition has been observed and as such, this type of adverse reaction is more frequent in the children of parents who suffer from allergies themselves.

One of the most frequent allergens is protein from cow's milk, especially in young children, although this condition normally disappears over time. Allergies to peanuts and other nuts are far more worrying as they begin early and are lifelong conditions. They are also more frequently related to serious symptoms, and to anaphylactic shock, even where contact has been at a minimum level.

Food intolerances may present symptoms similar to those of some allergies, such as diarrhoea or abdominal pain, but in this case there is no intervention from the immune system. These intolerances are produced by some kind of alteration which impedes appropriate digestion of the food or one of its components. The two most common causes of food intolerance are lactose and gluten.

Lactose is a sugar which is found in milk and which can only be absorbed by the intestinal enzyme lactase. When this enzyme is inactive, the lactose is not absorbed, but is passed into the large intestine and is fermented by bacteria in the intestinal flora. As a consequence, symptoms of flatulence, pain and diarrhoea occur. In Europe, lactase deficiency figures stand at 5%, while in certain ethnic groups this figure may reach 50-80%.

Gluten is a protein found in some cereals such as wheat, barley, rye and oats. Intolerance appears when there is an adverse reaction to this protein. In this case the term coeliac disease is used. For reasons which are not yet fully understood, the mucous in the small intestine is damaged and loses its capacity to absorb nutrients, giving way to the appearance of diarrhoea, weight loss, fatigue and symptoms of malnutrition. Coeliac disease affects 1 in every 1,000 people in Europe. There are even studies that estimate that 1 in every 100 people is affected. The only effective measure for the prevention of these adverse effects in those affected is to avoid food containing gluten. The absence of gluten allows the intestinal mucous to regenerate and the symptoms disappear.

Generally speaking, the most effective way of preventing reactions from allergies and food intolerances is to eliminate the components which provoke the adverse effect in sensitive people. For affected people to be able to follow this recommendation, what is required in the first place is appropriate educational measures regarding the issue which affects them and the way of preventing it. They should also have all the necessary information on the composition of foodstuffs in order to be able to make a suitable choice with regard to their needs. Food labelling is of key importance in these cases, and has become an indispensable element in food safety. However it must be taken into account that there may be deficiencies in this information, especially in non-labelled foods which are made available to consumers, as in the case of restaurants. Public bodies must ensure labelling standards are met through official controls, promoting both awareness among consumers and correct information practices with regard to non-labelled products.

Legal framework

Directive 2000/13/EC, of the European Parliament and Council, of March 20, was enacted to ensure the approximation of the laws in the Member States relating to the labelling, presentation and advertising of foodstuffs aimed at the final consumer. In order to achieve a high level of consumer health protection, and to guarantee the right to information, provisions must be made to ensure that consumers are provided with appropriate information about food products, indicating all the ingredients on the label.

Before the modification in 2003 of Directive 2000/13/EC, of the European Parliament and Council, of March 20, on labelling, presenting and advertising food products, certain substances were not necessarily included in lists of ingredients. Some ingredients and other substances, when found in a finished product, may cause allergies or intolerances and constitute a health risk for those people affected.

The Scientific Committee on Food concluded that food allergies and intolerances can affect many people and produce illnesses which, in some cases, may prove fatal. The committee noted that among the most common food allergens are cow's milk, fruit, pulses (particularly peanuts and soy), eggs, crustaceans, nuts, fish, vegetables (celery and other foods from the umbellifer family), wheat and other cereals that contain gluten.

The most common food allergens are present in the composition of a large variety of prepared foods. The Scientific Committee also established that food additives may cause adverse reactions, and that it was difficult to avoid food additives, as these are not always mentioned on labels. This is why it was necessary to submit additives, technological auxiliaries and other substances with allergenic effects to the labelling standards in order to provide adequate information to consumers who suffer from allergies and other types of adverse food reactions.

Ingredients frequently associated with adverse reactions which must be shown on food labels in accordance with Directive 2003/89/EC, of the European Parliament and Council, of November 10

- Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof (including lactose)
- Nuts, i.e., almond (*Amygdalus communis* L.), hazelnut (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.

Even though labelling should not be considered as the sole instrument of information, it was considered necessary to help consumers affected by allergies or intolerances as much as possible, by facilitating more comprehensive information concerning the ingredients in the food and making the inclusion of all the ingredients and other substances present in the foods on the label compulsory.

As a response to this need Directive 2003/89/EC, of the European Parliament and Commission, of November 10, was published and transposed to internal State law by Royal Decree 2220/2004, of November 26, making it compulsory to state the presence of a series of ingredients considered to be the most common allergens on labels.

In order to stay abreast with new scientific and technological advances this legislation provides for the revision of the above-mentioned list in order to include or eliminate determined ingredients when necessary. These revisions must be based on scientific criteria determined by the European Food Safety Authority.

On the basis of this possibility, the European Commission approved Directive 2005/26, of March 21, which establishes a list of substances or food ingredients which are provisionally excluded from Annex III A of Directive 2000/13/EC. In the new Directive, the Commission responds to the opinions of the Scientific Committee of the European Food Safety Authority on the likelihood that certain products may cause adverse reactions in sensitive people by establishing a list of ingredients or substances provisionally exempted from compulsory listing on the labels of certain beverages and food products when they are used in production and are still present in the final product, although in a modified form.

This Directive has been transposed to State legislation by Royal Decree 1164/2005, which temporarily suspends application of part of Annex V on the general rules for labelling, presentation and advertising of food products as approved by Royal Decree 1334/1999.

The list of derived products from provisionally excluded allergenic elements includes:

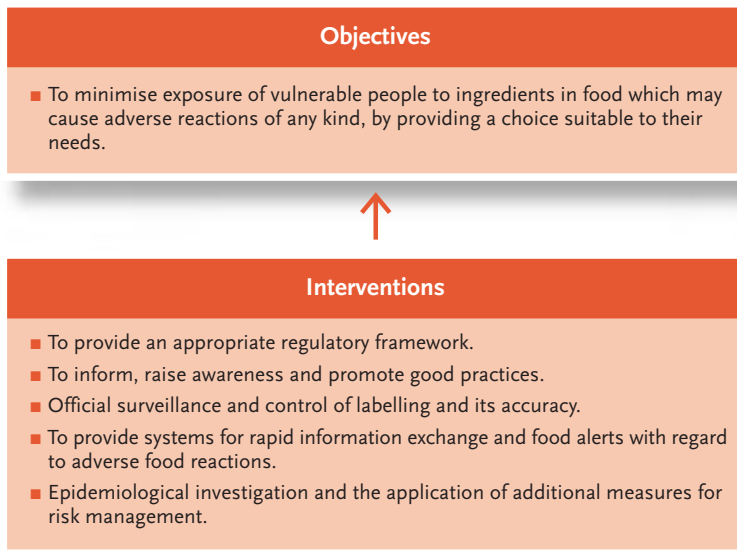
Ingredients	Provisionally excluded derived products
Cereals which contain gluten	<ul style="list-style-type: none"> ■ Glucose syrups made with wheat, including dextrose. ■ Maltodextrins made with wheat. ■ Glucose syrups made with barley. ■ Cereals used in distilled beverages in the manufacture of spirits.
Eggs	<ul style="list-style-type: none"> ■ Lysozyme (produced from eggs) used in wine. ■ Albumin produced from eggs) used as a clarifying agent in wine and cider.
Fish	<ul style="list-style-type: none"> ■ Fish gelatin used as a support for vitamins and flavourings. ■ Fish gelatin or ichthyol, used as a clarifying agent in beer, cider and wine.
Soy	<ul style="list-style-type: none"> ■ Totally refined soy fats and oils. ■ Natural mixed tocopherols (E-306), natural d-alpha tocopherol, acetate of natural d-alpha tocopherol and succinate natural d-alpha tocopherol made from soy. ■ Phytosterols and esters of phytosterol made from soy vegetable oils. ■ Phytostanol esters derived from phytosterols of soy oil.
Milk	<ul style="list-style-type: none"> ■ Serum used in distilled beverages for spirits. ■ Lactitol. ■ Lactic products (casein) used as clarifying agents in cider and wine.
Nuts	<ul style="list-style-type: none"> ■ Nuts used in distilled beverages for spirits. ■ Nuts (almonds and walnuts) used as flavourings in spirits.

Although labelling must not be considered as the sole instrument of information, consumers must be able to access information on food ingredients easily. The objective of this standard is to facilitate adequate information to the public on product ingredients through full labelling with regard to the ingredients or components which are more frequently associated with adverse reactions.

Objectives and interventions

With regard to the risks of adverse food reactions, the fact that the majority of the prevention possibilities are in the hands of those affected must be taken as a basis. These people must take appropriate steps to comply with the recommendations of specialists in the field.

Objectives and interventions in the area of adverse food reactions



The public must have easy access to necessary information in order to be able to make an appropriate choice with regard to their particular needs. The plan must actively contribute to facilitating this choice through objectives and interventions in different areas, particularly with regard to monitoring and ensuring the reliability of the information provided on labels and in food advertising.

The owners of food production activities must be made aware of these types of concern so that appropriate measures can be included in their self-control programmes. If one takes into account the complexity of the production processes, and the number of ingredients in many foods, this awareness must also be addressed at operators in the food production chain, who must themselves establish the means with which to offer the additional information which is requested by those who suffer from adverse reactions to food or some of its ingredients in a rapid and suitable manner. This awareness must be especially developed in sectors where foodstuffs are not the subject of compulsory labelling, such as in the case of restaurants.

Adverse food reactions risk management

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
E-020	To minimise exposure of vulnerable groups to ingredients in food which may cause adverse reactions of any kind by facilitating a choice adapted to needs .	Compliance rates for food labelling and ingredients in accordance with current legislation	> 95 %

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
Legal framework			
O-068	To provide a regulatory framework appropriate to the needs of risk management with regard to adverse food reactions.	Assessment and needs studies	Available
		Improvement procedures deriving from the needs detected	100 %
Informing, awareness raising and promoting good practices			
O-069	To provide systems for improving the knowledge and awareness of food production chain stakeholders, including the public, particularly with regard to specific measures to be applied to prevent this type of risk.	Informing, raising awareness and promoting good practices	Available and introduced
O-070	The public should be provided with the necessary information enabling them to make appropriate choices according to individual needs in the area of adverse food reactions.	Information, awareness-raising and good practice promotion programmes	Introduced
Official surveillance and control			
O-071	Official surveillance and control programmes should be established, specifically directed at ensuring fulfilment of the regulations intended to minimise the risks of adverse food reactions, particularly with regard to ingredients in food, the accuracy and appropriateness of the information provided on labelling, and the inclusion of measures to manage such hazards in company self-control programmes.	Official surveillance and control programmes	Introduced

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
Information exchange and alert systems			
O-072	Provision of information exchange and alert systems on irregularities that may cause adverse reactions, with a view to quick, effective risk management throughout the food production chain. These systems should also include health care and epidemiology services to monitor any possible effects on human health.	Information exchange and alert systems embracing the entire food production chain	Available and introduced
Epidemiological investigation			
O-073	To provide effective epidemiological information gathering systems for cases of adverse reactions in food that may occur in Catalonia.	Information gathering programmes on cases of adverse food reactions occurring each year in Catalonia	Introduced
O-074	To ascertain the contributory and related factors in cases of adverse food reactions notified in Catalonia.	Research programme into cases of adverse food reaction	Introduced
O-075	To provide active research systems for researching into the possible food etiology and contributory factors in cases of adverse reactions diagnosed in Catalonia.	Research systems	Available
Cooperation with affected groups			
O-076	To provide systems of cooperation and information exchange with affected groups in order to assess the information available and detect needs.	Systems for cooperation and information exchange with affected groups	Available

Interventions

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Legal framework						
I-127	To draw up needs detection studies in order to modify the regulatory framework with regard to adverse food reaction risk management.	–	DAR APS	APS ACC AL	–	–
ACSA						
I-128	To promote, in necessary cases, development, application criteria and/or modification of legislation at local, autonomous region, State and European level.	–	DAR APS	APS ACC AL	–	–
ACSA						
Informing, awareness raising and promoting good practices						
I-129	To provide food production chain operators with necessary and appropriate information on risks from adverse food reactions, the factors, ingredients and products most frequently related with them and the appropriate preventive measures to be applied.	–	APS ACSA	APS AL ACSA	–	–
I-130	To promote the development by catering establishment owners of information systems for consumers with regard to the ingredients used in the meals they provide.	–	–	APS AL ACSA	–	–
I-131	To disseminate and promote the adoption of recommendations aimed at preventing adverse food reactions in the domestic sector.	–	–	–	APS ACSA	–
Official surveillance and control						
I-132	Official surveillance and control to ensure compliance with labelling regulations concerning issues related to possible adverse food reactions.	–	DAR APS	APS ACC AL	–	–
I-133	Surveillance and control of food ingredients and the accuracy of information provided on labels and other information systems.	–	DAR APS	APS ACC AL	–	–
I-134	Surveillance and control of the appropriate consideration of risks from adverse reactions in food activity self-control programmes.	–	DAR APS	APS AL	–	–

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Information exchange and alert systems						
I-135	To maintain rapid information exchange and food alert systems which include, where necessary, updated information for consumers and associations of people affected by food allergies and intolerances. These systems should also include health care and epidemiology services to monitor any possible effects on human health.	–	APS	APS AL	APS	–
ACSA						
Epidemiological investigation and case management						
I-136	To develop and implement standard, rapid, effective systems for notifying suspected cases of adverse food reactions.	–	–	–	DS	–
I-137	To develop and implement standard, rapid, effective systems for the investigation of adverse food reactions, including the processing of information about the etiology and contributory factors, to risk management and assessment bodies.	–	–	–	DS	–
I-138	To carry out studies of adverse food reactions diagnosed in Catalonia in order to ascertain the importance of foodborne disease.	–	–	–	DS ACSA	–
I-139	To develop and implement standard, rapid, effective management procedures for cases of adverse food reactions.	–	–	–	DS	–
I-140	To produce manuals and provide appropriate training in research and management of adverse food reactions aimed at professionals engaged investigating and managing outbreaks.	–	–	–	DS ACSA	–
Cooperation with groups of people affected						
I-141	To work together with the associations of those affected by adverse food reactions, to evaluate the information available in order to detect needs and promote the application of additional risk management measures where necessary.	–	–	–	APS ACC AL DAR ACSA	–

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DS: Ministry of Health

IV

2.3 Management of food safety related issues

As indicated in Chapter 1, regarding the context of the Food Safety Plan of Catalonia, there is a whole series of issues linked to food safety due to their direct or indirect effect on human health and/or on the perception, trust and expectations both of the public and of society in general. These issues exist independently and are of great importance in their corresponding contexts, but at the same time they have implications for food safety. Without prejudice to the prioritisation of issues concerning food safety, we must plan objectives and interventions regarding these issues so that the Plan has a global and integrated character within a broad conception of food safety.

It is not easy to establish a full list of the issues which must be included in this section. The approach from the food safety angle and inclusion in the Plan is justified by the existence of links which could be more or less consistent depending on the case and the analysis perspective. For these reasons the inclusion of some of them in this section may be open to discussion and those included vary over time, in accordance with scientific advances, conceptual changes and new social demands.

In the present context, the following issues relating to food safety must be addressed by the Food Safety Plan:

- a) Food quality.
- b) Animal feed, health and welfare.
- c) Plant health.
- d) New technologies, new ingredients and new foods, particularly genetically modified organisms.

a) **Food quality**

Some authors define the term quality as the accommodation of a product or service to the demands of customers or recipients. Thus, quality could be defined as the difference between what is expected and what is received. The concept of quality thus defined is intangible, as it depends on the expectations of the recipient. It is obvious that the consumer is free to have the expectations they desire and that these vary greatly depending on the person and situation.

In order to be able to take action and measure results, we must be able to define in more detail the limits of reference of this expectation. In terms of interventions by public administrations, we must consider as legitimate expectations those which are the product of quantifiable referents. We must guarantee the right of the consumer to products which correspond to the characteristics that might reasonably be expected.

Thus, in terms of the Plan, the term quality should define the extent to which a product, process or service meets the previously indicated or established characteristics. Quality is, therefore, compliance with expected attributes or properties depending on a certain standard which may be determined by the natural properties of the product, those established by legislation or those defined by the commercial operator and made known to the consumer. This concept includes aspects as varied as food composition, nutritional claims or logos, health, origin or production systems.

All these aspects are associated with consumers' beliefs, expectations and perceptions, which may have financial, ecological, religious or any other type of motivation. In any case, the expectation that market products will comply with the norms and attributions indicated by the commercial operator is a legitimate and unquestionable expectation for which consumers must have the maximum guarantees possible.

Current legislation establishes a clear separation between quality and issues relating to the health and safety of foods. However, food quality and safety cannot be separated into independent sealed compartments. Some of the issues found in the field of quality can have repercussions on public health. The substitution of one ingredient for another, without express indication on the labelling, could mean a risk for persons with problems of adverse reactions to certain ingredients. Furthermore, the fact that a product incorporates ingredients in amounts above those expected or advertised such as, for example, saturated fats, cholesterol, salt or sugars, might lead the consumer to make decisions that have negative repercussions on their health. In the same way, products which, as a consequence of fraudulent activity, contain certain ingredients in amounts lower than those advertised or expected could also mean, in the long term, a risk factor for health from the nutritional point of view. This would be the case, for example, of foods which are expected to supply a certain amount of iodine, calcium, vitamins, fibre or other substances and which present quantities below those expected in normal conditions or those advertised in the publicity and/or on labelling, as a consequence of adulteration or any other type of fraud, error or negligence.

We also have to consider the possible relation between food fraud and product safety. Secrecy, a lack of knowledge and the desire for illegal gains, associated with many cases of fraud, could lead to the use of techniques or ingredients involving a risk for consumer health. A paradigmatic example of this statement is the case of the toxic syndrome associated with the consumption of rapeseed oil, described in Spain in 1981 and which affected more than 20,000 people.

Consideration must also be given to labelling and advertising which attribute nutritional, preventive or curative properties relating to health which have no bearing on reality or have not been scientifically proven.

The issues most directly related to health, such as agents capable of causing disease or aspects concerning adverse reactions in persons with a special sensitivity, have already been discussed in the section dealing with the management of health risks. However, we must consider other aspects relating to the concept of quality which, although they do not have such a direct, serious and immediate bearing on human health, can have longer term effects and/or significant influence on public perceptions of the food production chain and the trust which it inspires.

On this issue, Law 1/1990, of January 8, on market discipline and consumer and user protection, classifies as offences of alteration, adulteration, fraud or deceit, the processing for distribution of goods and services or the sale of goods from which any substance or element has been added or removed that alters its composition, structure, weight or volume to the detriment of its qualities, to correct defects through processes that are not recorded, if applicable, or that are not expressly authorised or regulated, or to conceal the inferior quality, alter-

ation or origin of products that breach legislation governing origin, quality, composition, quantity, weight or volume, and their presentation by packaging, labelling, signs, seals, or any information or advertising that may lead to deceit or confusion or which conceals the true nature of the product.

And so we see that different aspects coincide in the field of quality relating more or less directly to consumer health. Considering this diversity, it is advisable to concentrate our efforts on the specific objective of ensuring that the products available to consumers have the expected characteristics described in the information supplied to them in the labelling, advertising or other means by the owners of businesses in the food production chain as well as those laid down by current legislation. The achievement of this objective requires action aimed at proving that products correspond to the regulated characteristics and/or to the information given, not only for composition but also for aspects such as their origin, production methods, extraction systems and other issues which might be of interest to consumers due to religious, ethical, cultural, private or other reasons.

b) *Animal feed, health and welfare*

The link between animal feed, welfare and health, and food safety must be understood from two very different points of view. The first, and most important, refers to chemical and biological hazards, such as zoonotic diseases, which are discussed in other sections. **Although on the whole these factors can be attributed a relatively small repercussion on resistance to diseases, since stress and malnourishment are predisposing factors for many pathologies,** there is an approach in the field of animal food, welfare and health referring to concerns unrelated to food safety. This sector has important repercussions on economics, competitiveness and consumer perception. We must bear in mind the legitimate expectation of the public that the foods it consumes come from animals free from disease and not subjected to unnecessary suffering independently of whether these factors have any repercussions on food safety. In the Food Safety Plan we must consider very seriously the growing social sensitivity towards animal feed, health and welfare.

Furthermore, EC Ruling number 882/2004, of the European Parliament and Council, of April 29, on official controls made to guarantee verification of compliance with the legislation on the issue of feedstuffs and food products and legislation on animal health and welfare, includes these issues as directly related factors which must be subject to coordinated official control measures.

Links between food safety and the legal and structural interrelationship within the European Union make it advisable to include in the Plan the relevant objectives and interventions directed at avoiding any unnecessary suffering to food producing animals and achieving a good state of health nutrition.

c) *Plant health*

Unlike many diseases that affect animals, those that affect plants do not present a direct risk to consumer health except in certain highly specific cases of agents that infect or act as parasites on plants and may present such hazards as, for example, the development of fungi that may contaminate plants during growth, sowing or storage, placing the safety of the product at risk.

The need to apply biocides in phytosanitary treatment for the control of plant diseases involves the risk of adding chemical hazards in the primary phase of the food production chain, both at the cultivation stage and in the agricultural product warehouse. The existence of efficient preventive systems for plant health should lead to a reduced need for the use of phytosanitary products. Therefore, improvements in plant health bring with them an improvement in safety as regards the risk of waste from phytosanitary products entering the food production chain.

There are other aspects of plant health not directly related with food safety, but which could have important effects on economics, competitiveness and public perception concerning foods deriving from plants. In the same way that was indicated with regard to animal production, the public has a legitimate expectation to consume foods from plants which are in the best of health, independently of whether any infections are transmissible to humans.

EC Ruling number 882/2004, of the European Parliament and Council, of April 29, also includes plant health in integrated multi-annual official control programmes within an integrated concept of safety in the food production chain.

We should therefore plan actions on the issue of plant health over and above aspects directly relating to food safety.

d) *New technologies, new ingredients and new foods, in particular genetically modified organisms*

Science and technology have made available new resources relating to processes and products in the food production chain such as, for example, ionisation or irradiation techniques, and other pressures as well as new ingredients and foods such as genetically modified organisms.

These advances permit us to achieve results which would not be possible using traditional procedures and systems. Thus, for example, it is possible to transfer genetic material between different species, which can broaden the range of genetic changes introduced in the species involved in the food production chain and open up a great number of possibilities for improvement. The new techniques and new ingredients permit: an increase in nutrient content, preventive and curative effects; reduction of microbiological risks; decrease in allergenic potential; and increase in food production efficiency. However, there are considerable differences of opinion between scientists and society concerning the safety, nutritional value and environmental effects of these new methods and products.

In general, it is considered that the consequences of some new methods and products are less predictable than those resulting from traditionally used techniques. For this reason the European Union demands a great deal of evidence to authorise them, evidence in particular relating to the analysis of consequences concerning safety, environmental effects and socio-economic consequences.

Although mechanisms for authorisation and control established in the European Union should provide sufficient guarantees, a negative perception has been observed among consumers concerning certain types of product and technologies. We must, therefore, appropriately monitor their use throughout the entire food production chain so as to ensure compliance with mandatory regulations as well as to guarantee consumer access to useful information permitting the public to make a conscious choice based on reliable information. These measures must be directed especially toward ensuring compliance with legally established labelling and traceability conditions, which must be complemented by communication efforts.

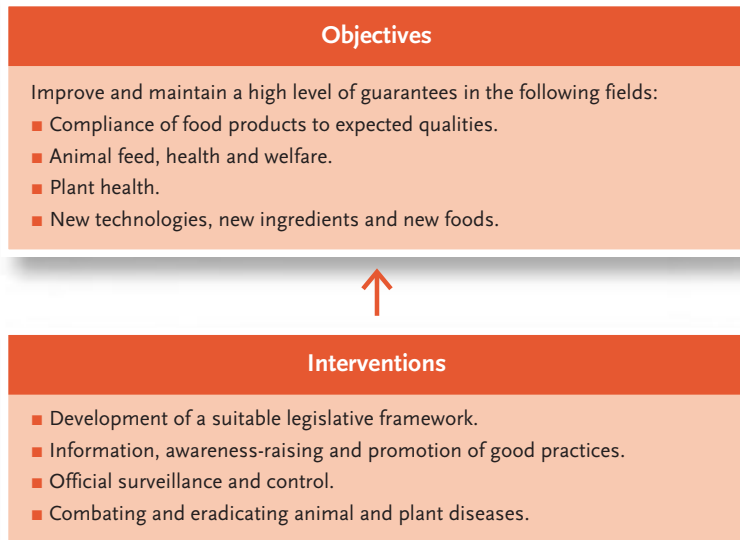
Objectives and interventions

As has been indicated, so-called food safety issues include a great many fields with important interrelations with food safety.

From the approach of the concept and guarantee of quality, we must set out objectives and plan interventions aimed at ensuring that the information referring to products in the food production chain and made available to the public by economic stakeholders responds to the reality of those products, and also that they meet expected attributes.

In the same way, we must establish objectives aimed at improving and maintaining a high standard of compliance with suitable conditions regarding animal feed, health and welfare, as well as plant health.

Objectives and interventions concerning food safety issues



To guarantee fair trade principles, which is one of the aims of the Plan, requires setting out objectives and implementing interventions aimed at ensuring compliance with the legally established conditions for food safety and the related issues referred to in this document. Compliance with these conditions should not mean any unfair market disadvantage for food production chain operators. The planned objectives in the field of food safety issues should be an important contribution to this proposal.

Furthermore, there is a need for the food production chain to fulfil legitimate public expectations concerning any aspect that the public considers to be associated to it, independently of aspects relating to food safety. This concept is rather vague, indeterminate, but aims to satisfy public expectations by adapting to any changes that may occur, bearing in mind that this is a constantly-evolving issue. Satisfying this demand will require us to ascertain the opinions, perceptions and expectations of the public and of society as a whole, as well as to identify existing concerns and needs in order to implement the necessary management measures. These questions have already been discussed in the section on risk evaluation and other concerns relating to food safety, as well as in the section on food safety communication.

Achieving the specific objectives established in the field of food safety issues requires such action as the development of a suitable legislative framework, the provision of information and training for economic stakeholders and the general public, awareness-raising, information about and promotion of good practice, and measures to provide official surveillance and control, and to combat and eradicate animal and plant diseases.

Since these issues are collateral to food safety, the planned interventions are formulated in a very generic fashion so as to leave considerable freedom in the hands of the managing bodies with regard to structural and operational planning, as well as to allow for the necessary adaptation and compatibility with strategic planning in each of the respective fields, a task which is to be carried out by the authorities responsible for each.

Management of food safety related issues

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
Correspondence of food products with expected qualities			
E-021	Food products must meet the qualities laid down in current legislation and in the information provided by food production chain operators so that consumers may exercise their right to take consumer affairs decisions suited to their needs and based on reliable information.	Rates of compliance with current legislation	Growing tendency
Animal welfare			
E-022	Activities in the food production chain must be performed so as to avoid any unnecessary suffering or pain to food producing animals.	Rates of compliance with current legislation	Growing tendency
Nutrition and animal health			
E-023	Activities in the food production chain must be performed in appropriate nutritional and feedstuff and health conditions and meet current legislation for this issue.	Incidence and prevalence of diseases which have to be reported by law in food producing animals	Decreasing tendency and/or maintenance of low incidence
		Rates of compliance with current legislation	Growing tendency
Plant health			
E-024	Activities in the food production chain must be performed in suitable plant health conditions and meet current legislation in this regard.	Incidence and prevalence of diseases which have to be reported by law in food producing plants	Decreasing tendency and/or maintenance of low incidence
		Rates of compliance with current legislation.	Growing tendency

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
Legal framework			
O-077	Provide an appropriate legislative framework to meet needs regarding food safety related issues.	Studies of evaluation and detection of needs. Improvement procedures promoted as a response to needs detected.	Available 100 %
Information, awareness-raising and the promotion of correct practices			
O-078	The food production chain operators and the general public must be provided with useful information, easy to access, concerning legislation, conditions, recommendations and responsibilities relating to food safety issues.	Updated information systems available to the public.	Available
O-079	Systems should be established to promote understanding, awareness and compliance with rules by food production chain stakeholders with regard to food safety.	Systems to promote understanding, awareness and compliance with rules.	Available and introduced
Official surveillance and control			
O-080	Maintain in all phases of the food production chain specific official surveillance and control measures depending on the importance of concerns in the following fields: <ul style="list-style-type: none"> ■ Food labelling. ■ Veracity of information provided to consumers. ■ Composition of foods. ■ New technologies, new ingredients and new foods. ■ Genetically modified organisms (GMOs). ■ Nutritional and health claims. ■ Animal welfare. ■ Feedstuff. ■ Animal health (non-zoonotic agents). ■ Plant health. 	Official control programmes	Available and introduced
O-081	Maintain actions to eradicate animal and plant diseases.	Programmes to fight and eradicate animal and plant diseases.	Introduced
Information exchange and alerts			
O-082	Establish information exchange systems and management of alerts in the fields relating to food safety issues.	Information exchange and alert management systems.	Available

Interventions

Number	Description	Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Legal framework						
I-142	Produce studies to detect needs for modification of the legislative framework for food related safety.	DAR DMAH	APS	APS AL ACC	–	–
ACSA						
I-143	Promote, where necessary, the development of criteria for the application and/or modification of legislation at local, regional, national and European level.	DAR DMAH	APS	APS AL ACC	–	–
ACSA						
Information, awareness-raising and promotion of correct practices						
I-144	Provide operators and the general public with clear and comprehensible information on applicable legislation, conditions to be met, recommendations and responsibilities relating to food safety issues.	DAR	APS	DS AL	DAR APS ACC AL	DMAH
ACSA						
I-145	Design and implement programmes aimed at improving the understanding, awareness and compliance with rules by food production chain stakeholders in safety related aspects.	DAR	APS	DS AL	DAR APS ACC AL	DMAH
ACSA						
I-146	Promote provision of non-mandatory information to consumers.	DAR	DS	DS AL	DAR APS ACC AL	DMAH
ACSA						
Official surveillance and control						
I-147	Official surveillance and control of the veracity of the information supplied to the public via labelling, publicity and other information systems.	DAR	DAR APS	ACC APS AL	–	–
ACSA						
I-148	Official surveillance and control of the welfare of food producing animals in the phases of rearing, transport and sacrifice.	DAR	–	–	–	–

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Interventions (cont.)		Responsible for the intervention				
		Primary stage	Processing and distribution stage	Retail and catering stage	Consumption stage	Others
Number	Description					
I-149	Official surveillance and control of feedstuffs.	DAR	–	–	–	–
I-150	Official surveillance and control and measures to combat and eradicate animal diseases (not food-borne).	DAR	–	–	–	–
I-151	Official surveillance and control and measures to combat and eradicate plant diseases.	DAR	–	–	–	–
I-152	Official surveillance and control of the use of GMOs* in the food production chain.	DAR	DAR	ACC	–	–
I-153	Official surveillance and control of food composition.	DAR	DAR APS	DAR ACC	–	–
I-154	Official surveillance and control in the field of nutritional and health claims.	DAR	DAR APS	APS ACC	–	–
Exchange of information and management of alerts						
I-155	To establish, where necessary, standard rapid food safety information exchange and alert management systems in order to improve preventive and management actions.	DAR	DAR APS	APS AL ACC	APS	–
ACSA						

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* GMOs: genetically modified organisms.

IV

2.4 Food safety communication

Since the second half of the 1990s, the main element of strategy in food safety in Europe has focused on efforts to improve risk analysis processes. Risk communication has an important place in these processes, and should be carried out in an integrated fashion with risk evaluation and management. The creation of specialised bodies, together with improvements introduced into the legislation, have influenced risk evaluation and management and will contribute to improving communication and reduce perceptions of risks in the field of food safety.

Although the EU has introduced reforms, the problem of risk communication and perception continues to be important because new reasons for public alarm continue to appear such as, for example, that caused by the publication of scientific reports on acrylamide in fried foods in 2002, on semicarbazide in baby food in 2003, and on dioxins in salmon in 2004.

Risk communication is defined generically as an interactive exchange of information and opinions which should include the explanation of the results of risk determination and management decisions. There is a close relationship between effective risk communication and public perception and trust in the food safety system.

We should also bear in mind the need to include in communication all those elements or issues related with food safety, given their impact on public perception. For this reason, concerning the Plan, these issues are also included in the global communication strategy, whilst those relating to health risk constitute the main priority.

A key element in risk communication consists of determining public perceptions of risk. Five basic factors influence the perception of risk:

Basic factors influencing risk perception

- The relationship between all levels of government and society in general concerning perceptions about the transparency and efficacy of management.
- The relationship between the scientific community and society regarding levels of commitment and trust.
- The participation of civil society and non-governmental organisations in risk analysis procedure.
- Cultural values, paradigms or referents held by individuals and societies.
- The role of the media, since the way an issue is described considerably influences perceptions of it.

Among the factors which influence risk perception, and which have already been analysed in the chapter concerning the main elements of the Plan, we should emphasise that of voluntary or involuntary nature of risk and that of the existence of balances. The public finds itself more and more distant from food production, so that the related risks are considered involuntary and are perceived as the consequence of a process which generates profits for third parties and in which it does not take part.

These considerations are important, but do not offer a complete picture of risk perception since among the set of risks associated with foods, some cause more alarm than others. This is the case, for example, with genetically modified organisms (GMOs) which, although there are no described cases of effects to human health, cause more alarm than some food hazards which are of real concern, such as *Salmonella*. We should also mention the differences in perception from one society to another. Thus, for example, genetically modified organisms cause far more alarm in Europe than in the United States, although these societies are relatively close in terms of culture and economics. Differences in perception are described not only between countries but also within national populations, since they are associated with beliefs, values and past experience.

Some authors link perception of risk to three groups of factors: personal factors, such as age, sex or cultural baggage; external factors, such as the media, public opinion, the political and economic situation and available scientific information; and risk factors referring to the seriousness and magnitude of the consequences, voluntary nature, equity, capacity of direct control and existence or otherwise of associated benefits.

The interrelationships between values, culture and risk perception are very complex and are not yet fully understood. However, there are some avenues for study which should be examined. The communication of risk should not merely be a presentation of calculations and scientific data, but also a place for wider discussion of issues of concern in the social, ethical and moral spheres. Special importance should be attached to public debate with active participation by the public, since the involvement of non-government organisations such as consumer groups in the process of risk evaluation and management helps to create trust. It is equally important to note that this participation highlights aspects of social and cultural values which must be considered together with the scientific information, since science offers many possibilities but acceptance of this is not a scientific question, but rather social and ethical.

It should be borne in mind that debate, dialogue and scientific information may not necessarily lead public perception to vary substantially. There have even been cases where distrust has increased as more data scientific has become available on the subject. **We have to accept that it is very difficult to change public perceptions. For this reason we should also make efforts to improve understanding regarding risk management, since it is possible to tolerate certain risks if there is trust in the efficacy of the prevention and control systems.**

In any case, risk communication is a difficult task. Reinforcing public trust in risk evaluation and management processes should be a major line of action. In this area, it is essential that the process should be open and should take into account concerns, as well as achieving a high degree of effectiveness in terms of risk evaluation and management, since these are all crucial prerequisites.

The public is more aware than ever of differing points of view in science and of the limits of scientific knowledge. Furthermore, citizens and civil society associations are making their own interpretations instead of trusting only in government experts. We must also accept the fact that there will always be areas of uncertainty which must be recognised in correct risk evaluation. The importance of these varies according to cultural background and reference values. Risk managers must be aware that people perceive risks in very different ways and that human beings act on their own perceptions, independently of what the scientific data say.

Objectives and interventions

In the field of risk communication and the recovery and maintenance of public trust in the food safety system, we must establish objectives and interventions that take into account the basic recommendations described below.

We must achieve a high degree of exchange of information and opinions between food safety stakeholders (the media, all levels of government, the scientific community, food production chain operators and the public) concerning the nature of the risks and the procedures for managing them in order to construct the bases for a collective food safety culture with common referents amongst all those involved, based on transparency and scientific rigour. Moreover, we must raise the level of public understanding regarding this issue.

The planned objectives are to be achieved using two types of intervention. Firstly we must plan interventions aimed at promoting dialogue and the participation of all those involved through the creation of suitable areas for dialogue and systems such as working groups, monitoring commissions, discussion forums or interactive websites, among others. Secondly, we must plan interventions in the field of broadcasting, information and education in food safety to include the entire risk analysis process. Quality informative material must be produced which is suited to the needs of its planned recipients, and all available channels of information, broadcasting and training must be effectively employed.

Also, consumers must be able to access concrete information on foods made available so they are able to make decisions based on reliable knowledge and information. Part of this information should come from public initiative, but the owners in the production must also be involved, and they must be able to supply all possible information to the consumer through the addition of non-mandatory information on labelling and through other routes or channels available to the private sector such as publicity, websites, customer attention services, etc.

We must transmit objective and transparent information to the public in a suitable format and in a context in which roles are properly defined. Scientists must participate actively in the preparation of information and the materials used to communicate scientific evidence; the authorities must provide information about measures taken for risk management and the public must be able to participate, contributing their values and beliefs and deciding how far they are disposed to accept risks. All this information should be presentable in an integrated and consistent fashion.

This process encounters particular obstacles which have to be considered. The authorities are obliged to make decisions on the basis of the results of interpretation, due to the impossibility of disposing of absolute conclusions or zero risk levels. This task can be made more difficult if there is an atmosphere of sensationalist alarm.

Risk communication must be performed with responsibility, transparency and sincerity and on the basis of current scientific knowledge. We must present the information available calmly, without making the mistake of offering only favourable data. Interested members of the public should have access to serious, concise and independent information on each issue. All levels of government should have the required resources available to generate this information via quality research and to supply the results to the public, to the media and to food production chain operators. It is particularly advisable to establish a permanent public information service. The transfer of reliable information is the best measure of safety, both as an element of direct risk management and as a way of avoiding exaggerated perceptions.

Main elements of the strategy for effective risk communication
■ Determine the scientific bases of risk and the associated uncertainties.
■ Determine public perception using techniques like general questionnaires or directed at significant groups (<i>focus group</i>).
■ Determine what information is available, and the concerns, motivations and information desired by the public.
■ Bear in mind that the manner of informing about a risk is as important as the risk itself.
■ Be aware that the risk may be perceived differently by social groups and at different moments.
■ Use comparisons with familiar risks only when relevant and with suitable previous preparation.
■ Bear in mind emotional aspects, since data and logic may not be useful for an emotionally affected audience.
■ Be proactive in communication. Communicate properly in periods between crises.
■ Determine the appropriate channels for the most suitable communication in each case.
■ Explain the risk in different ways ensuring that the central issues are not avoided.
■ Explain any existing factors of uncertainty.
■ Make known any advantages associated with the risk.
■ Involve society in the entire risk analysis process, promoting the interactive exchange of information and opinions.
■ Explain how the risk evaluation was carried out, and the results obtained, including any existing uncertainties.
■ Explain the measures applied for risk management as well as those which can be applied by individuals at home.
■ Attach the same importance to public concerns as to the risk itself.
■ Coordinate and collaborate with other credible sources of information.
■ Be alert to and resolve the needs of the media.
■ Evaluate the efficacy of communication actions implemented. Monitor the results of communication.

Source: *Report of joint FAO/WHO expert consultation*. Rome, 2-6 February 1998.

We should maintain an active, not reactive, policy on scientific documentation and information, which must be applied constantly in periods between crises with permanent updating of results. We must initiate communication processes as soon as information is available and establish dialogue as soon as possible. The public must see that all levels of government act with anticipation and responsibility and engage with the issue from the start. In this phase we should be aware that a lack of information will have worse effects in the mid-term, since the public demands the information as soon as it is available and reacts with distrust when it believes that information has been withheld or kept back intentionally. In any case, it is easier to help people to make opinions than to modify already existing beliefs. Furthermore, once a crisis begins, it is much more difficult effectively to conduct risk communication and obtain good results due to existing pressure and the atmosphere of distrust. Systems must be sought to establish regular communications, an area in which a regularly updated website can be very useful.

We must plan communication strategies in times of calm for the suitable management of communication during crises. The identification of public concerns and perceptions is important in a global proactive approach to resolving issues. We must provide scientific information as well as informing about opinions, feelings and other relevant factors, to be able to develop suitable and credible arguments based on scientific evaluation and reason-

Principal elements in the strategy for effective risk communication during crises

- Inform the public regarding:
 - Nature and spread of risk and the measures applied to control it.
 - Contaminated foods, the way to identify them and what should be done with them if found at home.
 - Identified hazard, consequences and when to ask for medical attention.
 - Measures which the public should apply as individuals.
- Establish suitable mechanisms to supply information (the media, help line for specific information, website, etc).
- Supply regular information on the crisis both to the public and the professionals involved.
- Ensure suitable communication and coordination between all stakeholders: hospitals, authorities, businesses, research centres, etc.

Source: *Report of joint FAO/WHO expert consultation*. Roma, 2-6 February 1998.

ing, but without forgetting emotional and social factors. We must determine what information the public wants to know and supply it, as well as anticipating future requirements.

We must identify the main stakeholders with regard to each issue, as well as players who could have an important role in the development of communication. Among the players to be considered the following are especially important:

- The scientific community, which is crucial to the process of understanding the phenomena, the benefits and risks involved, as well as to evaluating management options and the consequences of the different decisions. Their independence and knowledge give them the function of explaining scientific information, as well as aiding in the process of helping people understand the situation, sources and motives for uncertainty and foreseeable future perspectives.
- Food production chain operators, who on many occasions are considered to be an interested party and generate distrust. Their participation and anticipation in risk communication must be of key interest. Society must perceive them as providers of services and the first parties interested in supplying products that are safe and satisfy consumer expectations. Open door policies and information and communication actions on the part of operators can contribute to generating the necessary trust.
- Citizens and organisations representing them have more and more information at their disposal and a greater capacity to make a mature and realistic approximation to the concerns raised and to participate in the taking of decisions. Organisations with social representation must be integrated into the decision and communication processes. They must be offered sufficient information so that society can decide the level of risk it is prepared to accept. In democratic societies, although it may take a long time, it is the community and not government that ends up deciding the acceptable level of risk. The public decides in the economic and political field, since it has the capacity to choose the products it consumes and the politicians who represent it, as well as other important issues; for these reasons mechanisms must be created to ensure public participation from the first moment.
- The media, which play an essential role in communication and have a great impact on the way risks and the measures to manage them are perceived. They are very efficient in the distribution of information, both correct and erroneous, and for this reason they are of key importance in communication processes.
- Certain social groups, such as doctors and other health professionals, or teachers and professionals in the food production chain, due to the authority conferred on them by society and the strong influence their messages may have.

We should remember –as studies of this issue make clear– that, at times when there is no crisis, most citizens do not actively seek information about food safety, but base their action on their own knowledge and beliefs, their representations and their values. In calm situations, influencers (health care and teaching professionals, retailers, etc) and, above all, the immediate social environment (friends, relatives, knowledgeable people within the circle of acquaintance, etc) also help to shape behaviour, along with personal representations, values and experiences, the attitude of other citizens, whilst the information available is relegated to a secondary, accessory role. Only those particularly interested actively seek information, becoming influencers within their own social environment. It is, therefore, important that influencers and citizens, even though they form a minority, should be provided with easily-accessible, quality information to enable them to play an active role in shaping social perceptions, even though they are not the only factors to be taken into account.

We should also bear in mind that, in a situation of calm, not everyone is equally receptive to information about food safety. Certain groups, such as parents with young children, may be particularly so, whilst others may be completely indifferent.

In a situation of crisis or alarm, the situation changes. Citizens do not base themselves so much on their own representations, values and experiences and, at a time when they realise their lack of both information and experience, they come to depend more on the media. This dependence on the media can, however, generate negative effects. It is therefore particularly important that other influencers should play an important role, as people tend also to turn to them in times of crisis and, in order to play this role, they need to be able avail themselves of the solid formation they acquired during periods of calm.

Messages must be expressed in comprehensible and objective language, allowing the public to make conscious decisions based on reliable information. Scientists and government should present the information in a comprehensible way. If not, then the media will tackle this task, with the associated danger of distortion, especially if they do not have food safety specialists available to them, though this lack has begun to be remedied in recent years.

Key messages to be transmitted and the objectives of information must be determined and classified. The messages must be simplified, whilst avoiding excessive simplification and stating that they are being simplified at the same time as offering additional sources of information for those people who wish to know more. Generally, one of the most accepted sources of information, both for the public and for the media, are panels of independent experts who periodically supply summaries of the present state of knowledge.

Another key element consists of giving the context and the way information is transmitted as much importance as the content of the message. The means of communication is as important as the message to be communicated.

Suitable communication of the existence of a degree of scientific uncertainty, which is inherent to all evaluation processes, should be made. This fact can frequently be interpreted as an implicit declaration of the real existence of risk. Measures must be taken to correct this perception. In any case, we should not make the mistake of restricting communication to issues on which scientific certainty exists, since this practice can make the public believe they are not being sufficiently informed or that they are not considered a mature interlocutor.

It is important to inform the public of the process followed to carry out evaluation studies, the way conclusions have been reached on the limits of exposure, which management options exist and the motives leading to the application of a particular action or actions. It is also advisable to give information concerning levels of exposure from the very outset and, when possible, preventive measures which can be taken at home, since risks which are controllable directly by the public are normally better accepted.

The relationship between evaluation results and management measures must be consistent and proportional so as to avoid the perception of contradiction. Also the existence of ongoing research should be communicated, with the possible application or modification of management measures in the future depending on the evolution of scientific knowledge, so as to avoid the perception of a lack of consistency that this sometimes brings.

Sources and the probable level of exposure must be indicated. It is possible to use comparisons to communicate the level of risk, although previous accurate analysis must be carried out since the inappropriate use of this technique can be counterproductive. For example, cases of voluntary exposure should not be compared to those of involuntary exposure, since many people might perceive it as criticism of their conduct or as a trivialisation of the issue. We must seek comparisons appropriate to the social and cultural characteristics of audiences.

Objectives and interventions in the field of communication in food safety



Information should be provided as to the high degree of safety guaranteed by national and international regulations or recommendations, without underplaying the risks, however small. Trust in the efficacy of management measures is a good instrument to reduce risk perception.

We must make a continuous analysis of the evolution and effects of risk communication actions so as to find scope for improvement via the continuous evaluation of communication and the results obtained.

It is necessary to construct and sustain a relationship of credibility, trust, sincerity and respect with the public. As is indicated in the Phillips report to the Government of the United Kingdom on the BSE crisis, credibility is established by generating trust, and the latter is generated only through sincerity. Sincerity requires knowledge of all the information available, including any existing uncertainty. When there is no response to a particular issue, this should be openly admitted. This level of sincerity generates trust and is generally accepted as long as research measures implemented and measures applied on the basis of the principle of precaution are communicated immediately to fill any gaps in knowledge.

Communication in food safety

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
E-025	Maintain a high degree of understanding and comprehension amongst the public with regard to food safety and all related issues.	Results of specific study	Growing tendency
E-026	Ensure that public perceptions of food risk are balanced, consistent, in proportion to the general context and based on scientific information.	Results of specific study	Growing tendency

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
Knowledge and information			
O-083	Provide mechanisms to determine and analyse the state of public perception and opinion on the issue of food safety and the results from the interventions carried out, as well considering the adoption of additional measures.	Risk communication assessment mechanisms and instruments	Available and implemented
O-084	Accurate, objective and consistent information about food safety should be made available to all food production chain stakeholders and, especially, the public.	Information of quality	Available

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-085	Primary and secondary teaching should include education on food safety issues.	Incorporation of food safety into the primary and secondary education syllabus	Implemented
O-086	Measures should be aimed at encouraging economic players to provide appropriate information about the products they put on the market, enabling consumers to exercise the right to an informed choice, based on reliable information, and to adopt the necessary measures for all products used in the domestic sector.	Promotion measures	Implemented
O-087	Measures should be aimed at encouraging groups and organisations with particular social influence due to their function, proximity to the public and social authority, to play a leading role in food safety communication.	Promotion measures	Implemented
Dialogue and participation			
O-088	Provide a permanent framework for exchange of information and productive dialogue between food safety stakeholders so as to construct the bases for a collective culture with shared reference points, based on transparency and scientific rigour.	Permanent forums, systems and frameworks for dialogue and coordination between stakeholders	Available and implemented
O-089	Provide facilities and systems enabling consumers to participate in the food security risk assessment process and related issues.	Forums and systems for consumer dialogue and participation	Available and implemented
O-090	Measures should be aimed at encouraging the active participation of consumer associations in the food safety communication process.	Promotion measures	Implemented
O-091	Promotion of the active participation of food production chain operators in communicating all matters relating to food safety.	Promotion measures	Implemented
Crisis management			
O-092	Establish a protocol of actions in case of food related crisis.	Protocol of actions in case of crisis	Available

Interventions

Number	Statement	Responsible for the intervention	
Knowledge and information			
I-156	Produce studies to investigate the degree of public knowledge, perception and trust regarding food safety.	ACSA	
I-157	Establish a group of experts on risk communication to continuously analyse the situation of public perception and opinion on the issue of food safety and the results of interventions in the field, as well as to recommend additional measures which should be adopted.	ACSA	
I-158	Develop coordinated systems to produce explanatory, informative and educational material with the participation of the different stakeholders, particularly scientists, experts and consumer representatives.	DMAH DAR APS	ACC AL ACSA
I-159	Provide useful, comprehensible, consistent, integrated, quality information on: <ul style="list-style-type: none"> ■ Scientific reports and management policies in a consistent and integrated fashion. ■ Prevention measures to be applied in the home. ■ Activities by public administrations and private bodies involved in food safety. ■ Other issues favouring a high degree of understanding of food safety related issues. 	DMAH DAR APS	ACC AL ACSA
I-160	Establish coordinated public consultation and information programmes and services on food safety.	DMAH DAR APS	ACC AL ACSA
I-161	Integrate basic knowledge of food safety into primary and secondary education, particularly everything relating to production systems, food and dietary risks.	DE ACSA	
I-162	Inform and train teaching staff and education monitors so they can communicate accurate, scientifically proven, comprehensible and useful information in schools regarding food safety.	DE ACSA	
I-163	Inform and train health care personnel so they can provide the public with accurate, scientific, comprehensible and useful information on issues relating to food safety.	DS APS ACSA	
I-164	Develop information and training programmes so that personnel handling food and those responsible for activities in the food production chain are appropriately aware and trained in an all-round way to participate in the communication process.	DMAH DAR APS	ACC AL ACSA

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DE: Ministry of Education. DMAH: Ministry of the Environment and Housing. DS: Ministry of Health

Interventions (cont.)

Number	Statement	Responsible for the intervention	
I-165	<p>Promote the addition of useful non-mandatory information on labelling.</p> <ul style="list-style-type: none"> ■ Evaluate non-mandatory information in the form of warnings, recommendations or other information which might usefully be added to the food safety labelling. ■ Establish contacts with those involved in the food production chain to determine their opinion and promote the addition of certain non-mandatory information which could be useful in food safety. 	DAR APS ACC AL ACSA	
Dialogue and participation			
I-166	Establish and maintain permanent multilateral mechanisms for the exchange of information and dialogue between the different stakeholders in the food production chain through periodic joint meetings and other types of discussion forums.	DMAH DAR APS	ACC AL ACSA
I-167	Strengthen the role of consumer associations in the risk assessment process, as well as in food safety training and information, establishing contacts and working groups to analyse existing possibilities and carry out relevant actions and initiatives.	DMAH DAR APS	ACC AL ACSA
I-168	Establish systems of relations with the media to provide them with all the required information so they can accomplish their function to inform appropriately.	DMAH DAR APS	ACC AL ACSA
I-169	Promote initiatives and agreements with business associations in food industry sectors to encourage their active participation in the field of food safety communication.	DMAH DAR APS	ACC AL ACSA
I-170	Establish channels to provide the media with all necessary information enabling them to fulfil their role of informing the public.	DMAH DAR APS	ACC AL ACSA
I-171	Establish communication channels with scientific and political communities to ensure that they are completely integrated into a global food safety communication system which is consistent and creditable to the public.	DMAH DAR APS	ACC AL ACSA
Crisis management			
I-172	Produce an action protocol in case of food crisis and provide resources required to implement it.	DMAH DAR APS	ACC AL ACSA

ACC: Catalan Consumer Affairs Agency. ACSA: Catalan Food Safety Agency. AL: Local authorities. APS: Health Protection Agency. DAR: Ministry of Agriculture, Food and Rural Action. DMAH: Ministry of the Environment and Housing

IV

3 Objectives and interventions for quality and cooperation amongst stakeholders in the food chain

In the previous section, on risk analysis objectives and interventions, a whole series of central and priority objectives is contemplated in the fields of management and communication of risks to health and other related concerns. These are objectives which have an impact on the concerns identified, objectives which are to be achieved through interventions by the public administrations involved. These must act in accordance with principles of coordination and quality, without which it would be impossible to implement interventions enabling the expected results to be achieved.

Achieving these central objectives in the Plan also requires, apart from compliance with obligations and responsibilities by the owners of businesses in the food production chain, real collaboration and even a partnership with the relevant public administrations and with the general public. Food safety is a shared responsibility in which all the agents involved must participate in a coordinated and loyal manner.

We must, therefore, set out objectives and interventions aimed at achieving, first and foremost, a high degree of quality, efficiency and coordination amongst the services provided by the relevant administrations, whilst it is also necessary to promote everything related with coordinating efforts by all food production chain stakeholders through the establishment of the necessary alliances and cooperation mechanisms.

Although these are objectives which we could consider auxiliary or intermediate and which only make sense as elements necessary in order to achieve the central objectives of the Plan, the importance, size and complexity of these issues makes it necessary to dedicate specific and differentiated sections to them.

The development of the objectives and interventions corresponding to these needs is detailed in two differentiated subsections:

- 3.1** Quality, efficiency and coordination of public administration services involved in food safety
- 3.2** Cooperation and coordination of stakeholders in the food chain

IV

3.1

Quality, efficiency and coordination of public administration services involved in food safety

The Food Safety Plan of Catalonia provides for a complete set of objectives and interventions in the fields of evaluation, management and communication of food safety concerns. There is a clear need for planned interventions to be implemented by the relevant public administrations following principles of quality, impartiality, efficacy, efficiency and legal safeguards. We must, therefore, establish specific objectives and interventions directed expressly toward the achievement of these proposals, which are especially necessary in the field of official control, which without forgetting evaluation and communication actions, should occupy an important place in the series of actions contemplated by the Plan given its size and repercussion.

Legal framework

Among the interventions provided for under the Plan, we should mention those of official control, given its importance. Regulation (EC) 882/2004, of the European Parliament and Council, establishes a harmonised Community approach to official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The Ruling establishes the conditions to be met by authorities in the Member States, including the obligation to produce multi-annual official control plans and annual reports on the application of these plans.

Regulation (EC) 854/2004, of the European Parliament and Council, lays specific norms for the organisation of official controls of products of animal origin destined for human consumption. The Regulation describes certain particular official control conditions for the prevention, control and reduction of risks associated specifically with certain products of animal origin such as fresh meat, bivalve molluscs, fisheries products, untreated milk or lactic products.

Regulation (EC) 882/2004 establishes general norms for the practice of official controls with the aim of monitoring compliance with the Regulations as regards:

- Preventing, eliminating or reducing to acceptable levels the risks threatening persons and animals directly or through the environment.
- Guaranteeing fair practices in the feedstuff and food products trade and protecting consumer interests, including the labelling of feedstuffs and food products and other types of information to the consumer.

Official control

The objective of official control is to enforce legislation affecting the human and animal food production chain and to verify that operators meet the requisites that this legislation establishes at all stages in the food production chain.

The official controls will consist of the following activities:

- Inspections of businesses in the food production chain and their immediate vicinity, facilities, offices, equipment, installations and machinery, as well as of feedstuffs and food products.
- Monitoring hygiene conditions in food and feedstuffs businesses.
- Assessing good manufacturing practice procedures, correct hygiene practices and HACCP, bearing in mind the use of the guidelines produced to this end.
- Examining written documentation and other relevant records to evaluate compliance with the legislation on feedstuffs or food legislation.
- Examining the entire control and verification system introduced by the company and the results of this.
- Interviews with the owners of food and feedstuff businesses and with the staff working there.
- Checking data recorded by measuring instruments installed by the company.
- Controls using the instruments of the appropriate authority to verify the measures adopted by the food and feedstuff business.
- Any other appropriate activity to verify compliance with the legislation concerning feedstuff and food products.

The official controls must be carried out using suitable control methods and techniques, such as monitoring, surveillance, verification, auditing, inspection, sampling and analysis.

We must have suitably structured and sized systems which permit appropriate surveillance of the food production chain and associated concerns. This surveillance must be carried out through specialised analytical research systems and other forms of data collection.

We must also promote the analytical capacity and quality of both the laboratories involved in official control, whether public or state approved, and those which provide a service to businesses in their in-house monitoring activities. We must plan for actions directed toward verifying and guaranteeing the quality of the services they provide.

Information from monitoring systems constitutes the basis of food safety policies. This information must be available to those responsible for decision making so as to protect consumer health when necessary in an appropriate and reliable manner.

The intensity of controls depends on many factors. We must dispose of basic monitoring programmes which are regular and proportionate to the nature of the risk, the workings of the businesses and their internal controls. We must also apply specific controls based on suspicions of failures to comply and possible offences.

Similarly, we should have emergency contingency plans at our disposal with suitably trained staff to carry them out. We must also establish appropriate coordination procedures to ensure efficient cooperation between the different departments or bodies participating in official control activities. In the same way, when delegating control tasks to non-governmental bodies, we must guarantee compliance with very strict conditions and verify their competence and independence. We must also bear in mind that certain actions cannot be delegated.

There are plans for joint official sampling and analysis principles in the future. For the moment, however, we shall have to apply the methods validated by international protocols. The role of analysis and reference laboratories and the correct equipping and functioning of these are key factors in official control.

Another facet of official control is that of the importation of feedstuffs and food products. The Community proposal provides for regular controls through statistical sampling at any distribution point, before or after dispatch into free circulation. This will require close cooperation between national customs services and other relevant authorities in each country.

Furthermore, we must consider that in the EU, where goods circulate freely, we should not establish the obligation that batches of food products should be systematically accompanied by official certificates. However, situations are foreseen where official certification might be necessary due to exceptional emergency circumstances or with a view to exporting to third countries. This is another of the official control sectors where objectives and actions should be planned for better management.

New approach to control based on a single integrated process

According to afore-mentioned Regulation (EC) 882/2004, of the European Parliament and Council, a new approach to control is introduced via a single integrated process. According to this new approach, the control cycle is composed of the following main phases:

- a) The Commission shall draw up general directives to promote a harmonised approach to controls, so that all the legislation is included, together with all the production sectors and all the stages in the human and animal food production chains. The Regulation also describes the main performance indicators to be applied in assessing multi-annual national control plans.
- b) The relevant authorities in the Member States must draw up and execute an integrated and multi-annual national control Plan.
- c) The Commission shall make regular general audits of control activities in each Member State, which may include selective regional controls.
- d) The Commission shall produce a general report on the functioning of the national control systems.

Each year, Member States must present a report updating the initial plan with the corresponding adaptations concerning new legislation, as well as changes in structure and in functions.

Main directive elements of official control included in EC Ruling 882/2004, of the European Parliament and Council

- Development of Community-defined criteria for functioning and national control plans which national authorities must respect and which will serve as a basis for the Food and Veterinary Office in audits by the relevant authorities.
- Preparation of global, integrated and consistent strategies based on the determination of priorities according to risk and the most efficient control procedures.
- Organisation of official controls by the relevant authorities:
 - In all the phases of the food production chain and as regards importation.
 - Regularly, without previous warning and with suitable frequency.
 - Based on normalised and documented procedures of consistently high quality.
 - Bearing in mind the risks identified, the experience and knowledge acquired, the reliability of controls adopted by business owners and suspicions of possible lack of compliance.
 - Verified by the competent authority and with the application of any required corrective measures.
- Development of systems and indicators to record the efficiency and results of control measures.
- Existence of contingency plans which establish the measures to be applied in case of emergency.
- Products for exportation outside the Community subjected to controls as strict as for recipients in the Community market.
- Efficiency, impartiality, sufficient capacity and resources of the competent authority to manage controls and other measures in the field of official controls.
- Training of agents responsible for official controls so as to guarantee their full competence.
- Adoption of appropriate effective, dissuasive and proportionate measures when official controls indicate a lack of compliance.
- Preparation of specific official control reports which must be presented to the businesses subjected to the control.
- Right of operators to appeal against the decisions adopted by the competent authority relating to official controls and to be suitably informed of this right.
- Coordination, cooperation and assistance between the local, regional and state administrative units involved, with the aim of developing appropriate exchange of information and execution of activities.
- Application of safeguard measures, such as the suspension from sale of particular feed-stuffs and food products, when there is proof that the control system of a Member State is unsuitable or when there is a serious risk to public or animal health.

Single Integrated Multi-Annual National Control Plans

To comply with Regulation (EC) 178/2002 and Regulation (EC) 882/2004, Member States must produce multi-annual integrated national control plans. The Member States themselves will be responsible for these plans, which must be presented to the Commission on demand. The first reports must be presented no later than 1 January 2007.

The plans are required to contain general information on the structure and organisation of the Member States systems of official controls covering all sectors and all stages of the feed and food production chain, animal health, animal welfare. They should be specific in particular:

- The strategic objectives of the plan and how the prioritisation of controls and allocation of resources reflect these objectives.
- The designation of competent authorities and their tasks at central, regional and local level and the resources available to these authorities.

- The general organisation and management of official controls at national, regional and local level, including official controls in individual establishments
- Control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors
- Where appropriate the delegation of tasks to control bodies
- Methods to ensure compliance with the operational criteria regarding material, human, technical and legal resources
- The training of staff performing official controls
- The procedures and directives used in official controls, verification and supervision; reports on the controls performed.
- The organisation and operation of contingency plans for animal or foodborne disease emergencies, feed and food contamination incidents and other human health risks
- The organisation of cooperation and mutual assistance.

Multi annual national control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of factors including:

- New legislation
- The emergence of new diseases or other health risks
- Significant changes to the structure, management or operation of the competent authorities
- The results of Member States' official controls
- The results of Community controls carried out
- Any amendment of the Commission's guidelines
- Scientific findings
- The outcome of audits performed.

General guidelines issued by the European Commission for the preparation of official control plans

The multi-annual control plans must bear in mind the following Commission guidelines:

- They will promote a uniform, exhaustive and comprehensive approach to the official controls of feedstuffs and food products and to legislation on animal health and welfare, including all sectors and phases of the food production chain.
- They will determine priorities based on the risks and most efficient control procedures.
- They will determine other priorities and the most efficient control procedures.
- They will determine the points in the processes of production, processing and distribution of foods and feedstuffs which will provide the most reliable and indicative information on compliance with legislation on feedstuffs and food products.
- They will promote the adoption of best practice at all levels of the control system.
- They will promote the development of efficient controls of the traceability systems.
- They will promote the development of systems to maintain a record of the functioning and results of control actions.
- They will bear in mind the rules and recommendations issued by the relevant international bodies relating to the organisation and functioning of official services.
- They will establish criteria for carrying out audits to monitor the achievement of objectives by the relevant authorities.

- They will establish the structure and information to be contained in the annual reports that the Member States have to present to the Commission.
- They will set the main performance indicators to be applied for evaluation of the national control plans.

When required, the guidelines may be amended, based on analysis of the annual reports presented by the Member States or the audits and controls carried out by the Commission.

Annual reports on the national control plans

One year after the national control plans become compulsory, and on a yearly basis, the Member States will present to the Commission a report including:

- An update of the initial national control plan, in light of planned modification factors.
- The results of the controls and audits applied in the previous year in compliance with the provisions of the national control plan.
- The type and number of offences catalogued.
- The actions aimed at ensuring the efficient functioning of the national control plans, including the measures of execution and their results.

To ensure the uniform presentation of these reports and, in particular, of the results of the official controls, the information will be produced bearing in mind the guidelines established by the Commission. The annual report must be produced in the first six months of the year after the reference year, and must be sent to the Commission.

Community controls in the Member States

The Community will apply controls via general and specific audits in the Member States which will be carried out by experts from the Commission. The audits will be organised frequently in collaboration with the relevant authorities in each state.

The principal aim of the audits will be to verify that the official set of control activities practised in the Member States is in accordance with national control plans and meets community legislation.

Additionally to the general audits, specific audits and inspections may be carried out covering one or more particular fields.

The specific audits and inspections will serve, in particular, to:

- Verify the application of the national control plan of legislation on feedstuffs and food products and of legislation on the health and welfare of animals. They may include, when necessary, *in situ* inspections of official departments and facilities.
- Verify the functioning and organisation of the relevant authorities.
- Investigate important or recurrent concerns.
- Investigate emergency situations, emerging concerns or new situations in the Member States.

For each control carried out, the Commission will draw up a report with the conclusions it has made. This report will contain, when applicable, recommendations directed at the Member States to improve compliance with the legislation. These reports will be available to the public.

Based on the annual reports, the result of Commission controls of the Member States and any other relevant information, the Commission will draw up a report on the overall functioning of the official control systems of the Member States which will include, when applicable, recommendations on the following:

- a) Possible improvements to the official control systems and audits implemented in the Member States, in terms of the field, management and application.
- b) Particular control actions in sectors or activities whether included or not in the national control plan.
- c) Coordinated plans to tackle issues of particular interest.

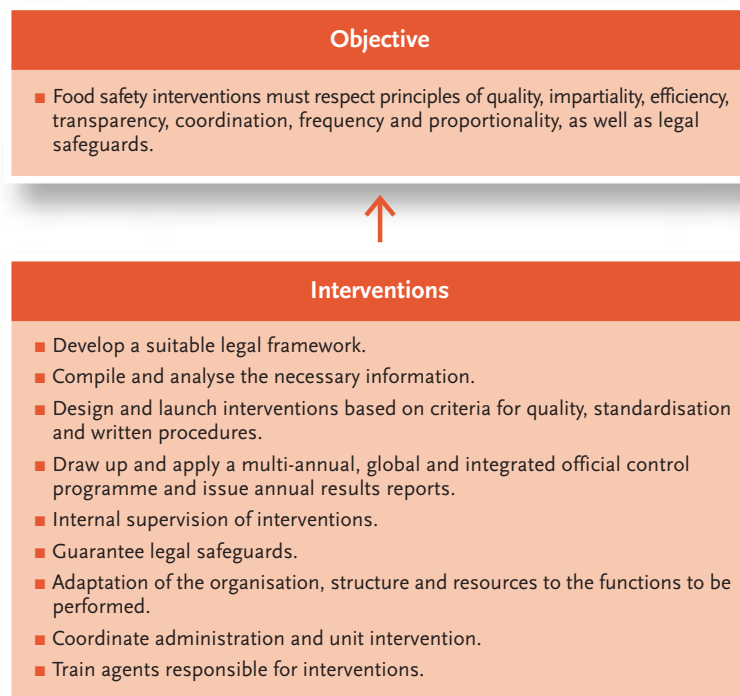
When applicable, the national control plans and directives will be adapted depending on the conclusions and recommendations contained in the report, which will be presented to the European Parliament and the Council and will be available to the public.

Member States are responsible for ensuring that recommendations generated by Community controls are appropriately monitored, and they will provide all the assistance, documentation and technical support required.

Objectives and interventions

The competent authorities will promote and ensure compliance with food safety norms without prejudice to the responsibilities of the food production chain operators. With this aim, they will launch the corresponding dissemination and promotional actions as well as the corresponding monitoring and verification activities. The objectives and interventions of the Food Safety Plan are aimed mainly at covering these needs.

Objectives and interventions for quality, efficiency and coordination of the administrations involved



We must ensure that the actions carried out by the public administrations adapt to the principles of quality, impartiality, efficacy, efficiency, coordination and administrative assistance between authorities, written processing, consistency, standardisation of criteria, transparency, frequency, proportionality to the nature of the concerns and legal safeguards. The objectives and interventions formulated in this section are specifically aimed at achieving excellence in these fields. They do not refer, therefore, to interventions to be implemented in the food production chain, which are the subject of other sections in the Plan, but to the functioning and organisation of the public administrations involved.

In pursuing the principles mentioned, we must apply and respect the principles of quality, innovation and continuous improvement. The application of methodologies to ensure quality constitutes a key element in this field. We can define this concept as the set of planned and systematic actions required for a product or service to satisfy previously defined requirements. The periodic standardisation and supervision of procedures, which should serve to verify that they are of the expected standard, as well as to detect any defects and encourage innovation and improvement, are crucial elements in ensuring the quality of services provided.

A standard procedure is the documented description of the activities to be carried out and the objectives to be achieved within a particular intervention programme. It should include, among other subjects: the objectives to be achieved; the scope of application; the distribution of responsibilities between the persons and/or units taking part in the process; the exact definition of the terms to be used; a complete description of the activities involved; the necessary reference documentation and detailed technical instructions.

The standardisation of procedures favours rationalisation, improves internal communication, promotes agreement concerning actions among those responsible for carrying them out, reduces errors and increases efficacy and efficiency, with a consequent increase in productivity.

The intervention programmes designed and launched in the framework of the Food Safety Plan of Catalonia must be inspired by the quality principle, whether they concern research interventions, information research, promotion of attitudes or dissemination of information, or if they come under the umbrella of official control. The aspects mentioned are all the more important if the associated needs for impartiality, efficiency, coordination, integrity and legal safeguards are considered.

For the administrations involved in food safety to act efficiently they must dispose of the relevant and applicable legislation as well as the necessary legal resources. There should be a legal framework available offering the authorities the necessary tools to enable them to monitor compliance with food safety norms and to take relevant corrective measures if any anomalies are observed. Such measures include, for example, the withdrawal of the affected products from the market, punishment of those responsible if necessary, and preventive closure of businesses or production lines.

An official control system cannot achieve the optimum degree of efficacy without the necessary resources and procedures for the application of efficient and proportionate dissuasive measures to achieve the correction of any anomalies detected. The application of administrative measures has the advantage of permitting rapid action for the resolution of the concerns observed. However, legal measures should also be available when required.

The application of administrative procedures should carry the corresponding guarantees of legal safeguards, among which should be mentioned the right of operators to appeal against the decisions adopted and to be informed of this right. The transparency of the procedures must be guaranteed, as must that of the measures applied as well as the interested parties' to review or appeal.

The approach to the interventions in general and to official controls in particular should be comprehensive, integrated and consistent, for which reason mid-term planning becomes necessary, as does suitable coordination. Whilst on this subject, it should be mentioned that systems containing multiple bodies are capable of presenting certain drawbacks, such as: a lack of coordination and general consistency; legal loopholes; differences in the level of resources and the uneven application of measures; conflict between food safety objectives and other commercial and financial objectives; and a clear difficulty in integrating the evaluation, management and communication of risk into decision taking

We should, therefore, evolve toward a truly integrated model so as to achieve the appropriate level of coordination and integration of actions of all the official bodies involved in food safety. This model requires the existence of mechanisms which permit the definition of general policy and strategy as well as the suitable coordination of activities. The existing managing bodies would, in this way, retain their responsibilities, but the drawbacks are minimised, so that an increase in system coherency is favoured, as well as an improvement in coordination of actions and a more uniform and balanced application of measures throughout the food production chain in Catalonia.

The suitable training and qualification of staff responsible for implementing the planned interventions is a necessary requisite for an efficient intervention system in the issue of food safety, especially in the field of official control. There is definitely a need for the qualification and permanent updating of staff knowledge as well as the training of specialists in the inspection of particular technical areas without prejudice to the application of the principles of multidisciplinary and versatility by official control agents and services.

Moreover, particular importance should be attached to laboratories as an essential component of the food safety system. We should bear in mind that many corrective actions and measures, both administrative and legal, are based on the analytical results generated by official laboratories. These structures and resources require considerable investment to maintain and operate them. For this reason, careful planning is required as to the number, location, resources and organisation of laboratories. Laboratories must be provided with the necessary materials and technical and human resources. As well as having suitable equipment, we must ensure a high level of staff training and skills.

The objective of high quality raises the need to provide the necessary human, material and financial resources for the functions to be performed, which must be sized following an efficiency principle bearing in mind the relationship between costs and efficiency. It should also guarantee the existence of bodies and procedures for suitable coordination, especially necessary in the current organisational model in Catalonia, characterised by strong decentralisation and local organisation of functions. All this must be complemented by suitable supervision and internal audits to contribute to ensuring the necessary rigour and transparency.

The achievement of specific objectives of improvement in quality, efficiency and coordination is of key importance to meeting many of the objectives formulated in the field of evaluation, management and communication of food safety concerns. Achieving these two types of objectives should contribute to achieving the established aims of the Plan.

Quality, efficiency and coordination of the public administration departments involved

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
E-027	The interventions of the public administrations involved in food safety must respond to the principles of quality, impartiality, efficiency, transparency, coordination, regularity, proportionality and legal safeguards.	Rates of compliance with quality standards	> 95 %

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
Legal framework			
O-093	Provide a suitable legal framework for the food safety interventions required.	Evaluation studies and detection of needs Procedures for improvement promoted taking into account the needs detected	Available 100 %
Quality of the interventions			
O-094	The necessary updated information should be available on activities in the food production chain with a view to suitable design, execution and supervision of intervention programmes.	Updated information regarding activities in the food production chain	Available
O-095	The design and execution of the intervention programmes, and especially official control programmes, must respond to quality criteria (see p. 232).	Results from supervision programmes Compliance with programme quality criteria	> 95 %
O-096	Anomalies detected as the result of official controls must be addressed by suitable and proportionate measures on the part of the competent authority so as to promote their correction, especially in cases where urgent measures are required.	Official standard procedures to be applied in the case of anomalies Percentage of anomalies detected and addressed by corrective measures	Available 100 %
O-097	There should be a multi-annual integrated official control plan including all phases and sectors in the food production chain.	Multi-annual integrated official control	Available

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-098	Specific annual reports and an annual global report should be available concerning official control programmes applied and other interventions, which detail the activities, results and corrective measures applied, as well as an analysis of the results and necessary recommendations for improvement.	Reports	Available
Legal safeguards			
O-099	Stakeholders should have the required information at their disposal and have suitable procedures available for the defence of their rights when they are subject to official controls or other food safety interventions.	Standard information procedures aimed at guaranteeing the rights of stakeholders in the design and execution of food safety interventions	Available and introduced
		Information and standard procedures available to stakeholders so they can appeal against reports, decisions and/or resolutions adopted by the competent authority and their agents, as well as disposing of the additional expert report where necessary	Available
O-100	The official measures to be applied when official controls demonstrate a lack of compliance must be established on the basis of the principles of written processing, speed, efficiency, dissuasion, proportionality, suitability, harmonisation and rapid resolution of the situation, including the definition of the sanctions to be applied.	Standard procedures for the measures to be applied	Available and introduced
Structure, organisation and resources			
O-101	A study should be available of needs concerning structural, organisational and resource conditions in the units and departments responsible for interventions with a view to improving the efficacy of functions and activities to be performed.	Studies of needs for each organisation involved in food safety	Available
O-102	The necessary innovation and structural, organisational, procedural and resource improvements must be carried out in the units and departments responsible for the interventions with a view to an improvement in the efficacy of the activities to be carried out.	Proportion of improvements implemented concerning needs detected	Growing tendency
		Relationship between resources available and needs detected	Growing tendency

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-103	Local administrations must be able to participate actively in the periodic authorisation and health control of activities in their responsibility and especially in those of the retail trade, water supply and preparation and/or service of meals <i>in situ</i> or for take away.	Percentage of local authorities with active participation in health control activities in their responsibility	Growing tendency
Coordination			
O-104	Public administrations involved in food safety should establish coordinating bodies and mechanisms to facilitate exchanges of information, the design and execution of activities in all necessary fields, and administrative cooperation and assistance between the competent authorities.	Coordinating bodies and mechanisms	Available
O-105	Suitable response procedures should be made available for emergencies relating to food safety which must specify the authorities which will be involved, their competencies and responsibilities, information exchange systems between stakeholders and the procedures to be followed.	Contingency plans	Available
O-106	The information exchange systems and the alarm systems relating to food safety must be maintained and must improve efficiency, coordination and scope regarding points of contact.	Results of specific study	Growing positive evaluation
Training and qualification of agents			
O-107	The agents responsible for interventions in the issue of food safety, including laboratory staff, must have suitable regularly updated training and information to enable them suitably to exercise their functions.	Percentage of agents including specific information programmes	100 %
Official control laboratories			
O-108	The services provided by the laboratories responsible for analysis of official control samples must respond to quality criteria according current legislation and be subject to periodic quality controls of the services they provide.	Supervision programmes for the quality of the services provided by the laboratories	Implemented Growing positive evaluation

Operational objectives (cont.)

Time frame: 2010

Number	Statement	Indicators	Criterion
O-109	There should be constant improvement and adaptation of the analytical capacity of the laboratories to official control needs.	Percentage of needs covered against the total identified	100 %
Private bodies collaborating with public administrations			
O-110	The services provided by private bodies collaborating with the public administration in the intervention programmes must respond to quality criteria according to current legislation and subject to periodic quality control of the services they provide.	Supervision programmes of the quality of the services provided by the private bodies collaborating with the public administrations	Available
Supervision and evaluation			
O-111	Supervision and internal evaluation systems should be established to monitor efficiency and compliance with quality criteria for the intervention programmes in food safety, aimed at continuous improvement and innovation.	Proportion of programmes subject to supervision and evaluation	Growing tendency
Transparency and information to the public			
O-112	The public should have access to information concerning activities relating to official controls and other food safety interventions.	Information on food safety interventions available to the public	Available

Interventions

Number	Statement	Responsible for the intervention	
Legal framework			
I-173	Produce studies for the detection of needs to modify the legal framework on the issue of official control and other interventions required in the field of food safety.	DMAH DAR APS	ACC AL ACSA
I-174	Promote, where necessary, the development of application criteria and/or modification of local, regional, national and Community legislation.	DMAH DAR APS	ACC AL ACSA
Quality of interventions			
I-175	Maintain updated information relating to activities, production data and other data considered necessary concerning the sectors involved in the different phases of the food production chain. Make this information available to official control bodies, the food industry and the general public, without prejudicing compliance with data protection norms.	DMAH DAR APS ACC AL ACSA	
I-176	Draw up and execute intervention programmes, ensuring that they meet quality criteria (see p. 227).	DMAH DAR APS	ACC AL ACSA
I-177	Plan and execute the specific intervention programmes required in all phases of the food production chain within the framework of the food safety plan and considering the specific needs of Catalonia, the current legislation and coordinated state and Community programmes established.	DMAH DAR APS	ACC AL ACSA
I-178	Draw up a multi-annual comprehensive official control programme for the food production chain in collaboration with the managing bodies, including integrated specific official control programmes applied throughout the food production chain.	DMAH DAR APS	ACC AL ACSA
I-179	Produce, during the first trimester of each year, an annual report containing the results from each official control programme and other interventions involved in food safety, specifying the activities performed, the results obtained concerning planned objectives, compliance with programme quality criteria, type and number of cases of lack of compliance and corrective measures applied and, if necessary, any improvements required for future programmes.	DMAH DAR APS ACC AL ACSA	
I-180	Produce an annual report on the multi-annual comprehensive official control programme in Catalonia.	DMAH DAR APS	ACC AL ACSA
I-181	Produce an annual report analysing the food safety situation and its management in Catalonia, including data on food safety interventions carried out.	DMAH DAR APS	ACC AL ACSA

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Interventions (cont.)

Number	Statement	Responsible for the intervention	
Legal safeguards			
I-182	Produce, for each official control action, specific reports describing the purposes and control methods applied, the results obtained and any corrective measures the operator should adopt. Provide the natural or legal entity subject to official control with a copy of the report.	DMAH DAR APS ACC AL ACSA	
I-183	Draw up comprehensible procedures for application so that food production chain operators can exercise their rights to appeal against reports, decisions and/or resolutions adopted by the competent authority and their agents and produce an additional independent report when applicable. Make available to stakeholders and the general public the necessary information to exercise these rights.	DMAH DAR APS ACC AL ACSA	
I-184	Produce documentation on: <ul style="list-style-type: none">■ Breaches and offences against current legislation, classifying them on a scale according to seriousness (including those considered critical).■ The measures to be applied when official controls show breaches of the principles of written processing, due action, notification of interested parties, legal safeguards and the right to review and appeal, dissuasion, proportionality and suitability. Make this information available to operators and the general public.	DMAH DAR APS ACC AL ACSA	
Structure, organisation and resources			
I-185	Produce catalogues of services, containing information relating to the identification of the authorities competent in food safety, their organisation, management units, functions, activities, material, humans, technical and legal resources, as well as other necessary information. Make this information available to food production chain stakeholders.	DMAH DAR APS ACC AL ACSA	
I-186	Produce needs studies on the structural, organisational, procedural, means and innovation requirements of the units and services engaged in food safety, with a view to continuous improvement. Implement the required structural, organisational and resource improvements, as well as adopting appropriate innovation.	DMAH DAR APS ACC AL ACSA	
I-187	Produce a study of the needs of local administrations in the field of official control	DMAH DAR APS	ACC AL ACSA

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Interventions (cont.)

Number	Statement	Responsible for the intervention	
I-188	Develop programmes to support and promote the participation of local administrations on the issue of food safety in general and official control in particular, especially concerning the activities of the retail trade, water supply and preparation and/or meals service <i>in situ</i> or for takeaway.	DMAH DAR APS	ACC AL ACSA
I-189	Review and update the organisation, methods and techniques used for official control so as to guarantee the quality and homogeneity of official controls.	DMAH DAR APS	ACC AL ACSA
I-190	Carry out the necessary studies, from the legal and technical point of view, of the possibilities of outsourcing food safety interventions.	DMAH DAR APS	ACC AL ACSA
I-191	Outsource food safety interventions as appropriate.	DMAH DAR APS	ACC AL ACSA
Coordination			
I-192	Establish coordination systems with the Spanish Food Safety Agency (AESAs) and the European Food Safety Authority (EFSA) to facilitate coordination of activities, information exchange, specialised knowledge and designs and putting into practice of joint projects.	DMAH DAR APS	ACC AL ACSA
I-193	Establish working groups for inter-departmental and inter-administrative coordination to carry out analyses, monitor issues and detect needs in food safety, promote dialogue, the exchange of information and coordination of public administrations and periodic debates on the situation, and propose and agree coordinated actions aimed at constant improvement on this issue.	DMAH DAR APS	ACC AL ACSA
I-194	Establish a contingency plan for food safety emergencies, specifying the authorities involved, powers and responsibilities, the information exchange systems between stakeholders and the procedures to be followed, as well as review and continuous improvement procedures resulting from organisational changes and the experience acquired.	DMAH DAR APS	ACC AL ACSA
I-195	Draw up an evaluation report on the needs for improvement of the rapid information exchange systems and food alerts. Improve the efficacy of the systems for rapid information exchange and food alerts, incorporating all the competent administrations and public bodies involved in food safety and integrating relevant elements from new fields such as feedstuffs and animal health. Produce a guideline or manual containing a description of rapid information exchange and food alert systems and the procedures to be followed by each of those participating.	DMAH DAR APS	ACC AL ACSA

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Interventions (cont.)

Number	Statement	Responsible for the intervention	
I-196	Develop and maintain coordination mechanisms for controls at the initial destination or in subsequent importation phases.	DMAH DAR APS	ACC AL ACSA
I-197	Establish coordination mechanisms for collaborating with visits that the agents of international organisations and from other countries might make to Catalonia relating to food safety.	DMAH DAR APS	ACC AL ACSA
I-198	Establish collaboration and mutual assistance systems in the investigation of alleged crimes involving food safety and legitimately related issues.	DMAH DAR APS	ACC AL ACSA
Training and qualification of agents			
I-199	Launch training and information programmes for the agents responsible for intervention programmes, especially those in official control and laboratories, to enable them to exercise their functions competently and consistently. Design and apply systems to guarantee access to useful information by personnel in the intervention bodies relating to food safety in general and to programmes and official control programmes and results in particular.	DMAH DAR APS ACC AL ACSA	
Official control laboratories			
I-200	Design and apply programmes so that the services rendered by the laboratories responsible for analysis of official control samples respond to quality criteria laid down under current legislation. Design and apply supervision and internal audit programmes to verify the quality of the services that laboratories provide.	DMAH DAR APS	ACC AL ACSA
I-201	Produce studies to identify needs for improvement and adaptation to official control requirements of the analytical capacity of the official control laboratories. Implement structural improvements and improvements of necessary resources.	DMAH DAR APS	ACC AL ACSA
Private bodies collaborating with the public administration			
I-202	Design and apply programmes to provide periodic verification of the quality of the services rendered by the private bodies collaborating with the public administration.	DMAH DAR APS	ACC AL ACSA
Supervision and assessment			
I-203	Establish criteria and requirements that must be met by internal supervision procedures for food safety intervention programmes and the resulting reports, drawn up by a working group created for this purpose.	DMAH DAR APS	ACC AL ACSA

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Interventions (cont.)

Number	Statement	Responsible for the intervention	
I-204	Design and apply programmes for supervision, evaluation and internal audits of official control and other food safety interventions in order to monitor efficacy and compliance with quality criteria with a view to adopting continuous improvement measures and innovation.	DMAH DAR APS	ACC AL ACSA
I-205	Develop the programmes and studies required to monitor, supervise and audit interventions assigned to the Food Safety Plan of Catalonia, as well as for the evaluation of planned objectives.	DMAH DAR APS	ACC AL ACSA
Transparency and public information			
I-206	Make available to the public up to date and easily understood information concerning interventions carried out in the field of food safety.	DMAH DAR APS	ACC AL ACSA

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Quality criteria for intervention programmes relating to food safety

Food safety intervention programmes must define the following elements:

1. Relevant authorities and units, functions and tasks.
2. Objectives to achieve through a consistent, exhaustive and integrated approach as well as directives and laws established regionally, nationally, in Europe and in the Food Safety Plan of Catalonia.
3. Standard procedures established in document form and which describe the activities to be performed, the organisation, the techniques and the procedures used.
4. Priorities based on the categorisation of risk as well as on more efficient procedures and the identification of the phases of the production processes which must be prioritised.
5. Regularity and frequency adapted to identified risks, existing experience and current legislation, especially in the case of official control programmes.
6. Responsibilities and instructions which the personnel involved must follow.
7. Systems of coordination and mutual assistance between authorities and participating units.
8. The necessary material, human and financial resources.
9. Legal framework available and application criteria in the framework of the programme.
10. Specific training of personnel responsible for applying the programme.
11. Systems for recording activities and results.
12. Information procedures and guarantee of the rights of stakeholders, especially in the case of official control programmes.
13. Criteria for interpreting results, decisions and actions to be applied; corrective measures for anomalies or issues observed in the official control.
14. Performance indicators of efficiency and suitability to the planned objectives.
15. Procedures for the supervision, evaluation and verification of the efficacy of programmes.
16. Mechanisms for modification, adaptation and improvement based on new legislation, the emergence of new issues, organisational changes, results from official controls and other interventions, Community Directives, scientific discoveries, etc.

IV

3.2 Cooperation and coordination amongst stakeholders in the food chain

There are a great many stakeholders in the field of food safety, among which special reference should be made to the owners of businesses in the food production chain and consumers, due to the important central role they play. The former are mainly responsible for the safety of products and the latter are the main recipients or beneficiaries. Other stakeholders in the food production chain are public administrations with responsibilities for intervention, and scientific institutions, which play an important role in the whole risk analysis process and especially in the evaluation phase.

Traditionally, systems of relations were based on a principle of authority, in which there were not many opportunities for cooperative relationships. Food business owners had to comply with the law, and the relevant administrations had to ensure their compliance, so that the public could enjoy a suitable guarantee standard. Although this distribution of responsibilities is still retained, it is possible to establish a framework of relations between food production chain stakeholders that generates value added and more opportunities for constant improvement via the application of cooperation and coordination mechanisms in the common objective of food safety.

Cooperation may be defined as working together to achieve certain objectives. This concept implicitly entails a certain voluntary element within a situation of equality. Coordination can be defined as establishing resources and systems of relationships to facilitate reciprocal information and joint action aimed at common objectives within the respective fields of activity. It is the harmonious combination of various participants or players toward a common action or objective.

Some authors associate the word coordination with a certain degree of supremacy of a coordinating body. This is not true of the relations between those participating in food safety. Coordination should be based on the previous comparison of criteria of all those participating and the will to achieve common objectives through coordinated action systems.

Cooperation and coordination in food safety is a need, due not only to the great many players participating, but also because of the perspective of better potential results as a consequence of an action with synergic effects. The full achievement of the aims proposed in the Plan is not possible without the understanding, mutual loyalty and even the complicity of stakeholders. Furthermore, this is a public demand, and is vital to the recovery and maintenance of public trust. The public must perceive food production chain stakeholders as a solid body with credibility due to their commitment to common objectives to guarantee food safety. In the same way, large-scale direct public participation should be encouraged through various mechanisms, among which we should emphasise consumer associations.

So as to achieve suitable cooperation and coordination we must establish appropriate instruments, such as groups, commissions and multilateral working groups to promote exchanges of opinions, comparison of criteria and integration into the decision making systems. Negotiation and consensus must be the main principles inspiring these contacts. The development of pacts, agreements, common positions and joint programmes must be the normal routes for implementing coordinated cooperation actions.

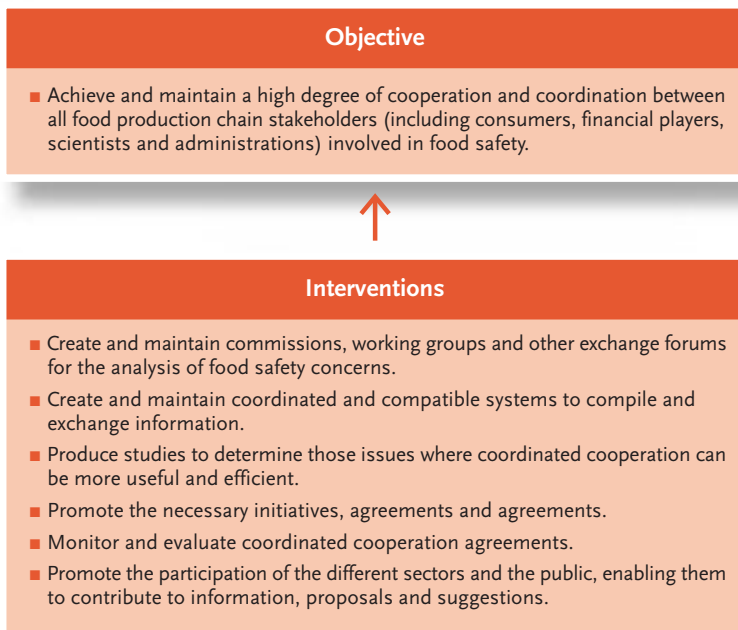
In any case, this is a complex and dynamic process which must be adjusted constantly and in accordance with each issue or field of action.

Objectives and interventions

The different chapters in the Plan provide for a whole series of specific objectives to be achieved through interventions undertaken by the relevant authorities and administrations. Many of these interventions are based on legislation which must be obeyed. However, as has been indicated, cooperation and coordination with the other participants in the food production chain must be voluntary. The complete achievement of the aims and specific objectives of the Plan requires the collaboration of all those involved in food safety and the suitable coordination of actions. Therefore we must plan for specific objectives and interventions aimed at promoting this coordinated collaboration.

The specific objective here is the achievement of a high degree of cooperation and coordination between all food production chain stakeholders in the process of evaluation, management and communication of food safety concerns. We must involve particularly the more important groups and their organisations, such as consumers, the owners of the businesses in the food production chain, scientists and the relevant administrations.

Objectives and interventions in the field of cooperation and coordination of all those involved in the food production chain regarding food-related risks



We must firstly determine the existing concerns and those fields where coordinated cooperation can be most useful and necessary, as well as the points of view of the related groups and sectors. To achieve this objective we must create and maintain systems to exchange information and opinions among which we should mention forums, commissions and working groups which permit a productive dialogue aimed not only at resolving existing concerns, but also at planning for and preventing future or emerging concerns through a proactive approach. Compiling information in updated and compatible databases, together with the preparation of specific studies, should permit better understanding and exploration of the coordinated cooperation strategies to be applied.

Where a need for joint action by different actors in the food production chain is determined, we must promote the necessary initiatives for effective implementation via pacts, agreements, common positions, joint programmes or other instruments of cooperation suitable to existing needs. These programmes must be capable of being directed toward both evaluation and the management and communication of food safety issues.

To ensure correct compliance with the initiatives described here, these must be subject to the corresponding surveillance and evaluation systems to monitor both compliance and the results obtained.

Cooperation and coordination of food production chain stakeholders

Specific objectives

Time frame: 2014

Number	Statement	Indicators	Criterion
E-028	Achieve and maintain a high degree of cooperation and coordination in food safety amongst all food production chain stakeholders, including consumers, financial players, scientists and the administrations involved.	Proportion of sectors in the food production chain integrated into groups for exchange and participation Proportion of needs covered against those detected	> 95 % Growing tendency

Operational objectives

Time frame: 2010

Number	Statement	Indicators	Criterion
O-113	Provide systems for the collection and exchange of data and information between food production chain stakeholders.	Data and information exchange systems	Available
O-114	Determine the issues and fields where the coordinated cooperation of the different participants in the food production chain is useful and/or necessary.	Reports and specific studies	Available
O-115	Maintain cooperation and coordination between the different food production chain stakeholders to achieve common objectives aimed at preventing and resolving food safety issues.	Proportion of needs detected that can be resolved through cooperation and coordination	Growing tendency

Interventions

Number	Statement	Responsible for the intervention	
I-207	Identify all the sectors participating in food safety and their representatives.	DMAH DAR APS	ACC AL ACSA
I-208	Create and maintain commissions, working groups and other forums of exchange between all food production chain stakeholders so as to maintain a dialogue and determine food safety concerns, as well as to reach coordinated agreements on the objectives to be achieved and activities to be performed.	DMAH DAR APS	ACC AL ACSA
I-209	Produce studies and reports to identify the fields and concerns where cooperation and coordination of food production chain stakeholders can be most useful and effective.	DMAH DAR APS	ACC AL ACSA
I-210	Promote initiatives and agreements among and between the sectors aimed at the coordinated management of the issues detected and to the achievement of the planned objectives.	DMAH DAR APS	ACC AL ACSA
I-211	Establish and maintain compatible systems for compiling and exchanging useful data and information between all the sectors involved in the food production chain.	DMAH DAR APS	ACC AL ACSA
I-212	Monitor cooperation and coordination agreements, promote compliance with them and evaluate results.	DMAH DAR APS	ACC AL ACSA
I-213	Maintain an efficient and coordinated system to enable consumers and food production chain operators, either directly or through their associations, to collaborate in monitoring and continuous improvement by communicating information, proposals and suggestions.	DMAH DAR APS	ACC AL ACSA

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V

Annexes





Annex 1 Hazards present in food and foodborne diseases

According to the WHO, foodborne diseases are diseases of an infectious or toxic nature caused by agents which enter the body through the ingestion of food.

The scientific community, following the risk assessment approach recommended by the WHO and the FAO on an analysis of the risk, have identified the hazards in the food production chain through the creation of a comprehensive list, submitted to constant investigation and assessment by scientific communities, and taking into account new scientific information on emerging pathogenic agents.

Risk assessment consists of identifying and studying food safety hazards and estimating the direct and indirect risk they present to consumers.

In the food safety sector, any biological, chemical or physical agent present or inherent in food which may cause adverse health effects is considered a food related health risk. We define the concept of risk as an estimation of the probability that an adverse health effect has of appearing, and of the severity of this effect, as a consequence of the presence of one or of more hazards in food.

The hazards related to the food production chain are presented in five groups:

1. Biological hazards
 - Bacteria and bacterial toxins
 - Viruses
 - Parasites
 - Mycotoxins
 - Unicellular algae and marine toxins
 - Non-conventional agents: prions
2. Chemical hazards
 - Environmental pollutants
 - Health products: phytosanitary products, veterinary medicine and disinfectants
 - Natural toxins present in food
 - Compounds generated in food processing
 - Radionuclides
3. Non-authorized additives or additives at levels above those permitted
4. Allergens
5. Physical hazards

1 Biological hazards¹

Foodborne diseases are present the world over. Some of their causal agents are distributed in a determined geographical manner due to their ecology, the type of food involved or consumption and preparation habits. In developing countries, enteric transmitted diseases continue to be an important cause of disease and death. However, in the industrialised world, toxic infections through food are paradoxically also an increasing source of disease. The World Health Organisation estimates that 30% of the population in industrialised countries annually suffers from foodborne diseases, and no reduction in this tendency has been observed.

The reason for this occurrence has many causes: the globalisation of food sales means that foodstuffs are consumed far from where they were produced, in terms of time and space, and lifestyle modifications which involve a trend in the preparation and consumption of food away from home, with previous handling procedures which increase risks. To these problems one has to add the appearances of changes in microbial ecology with the emergence of new pathogenic germs, the development of virulent strains of old pathogenic germs, the phenomenon of resistance to antibiotics, and the adaptation of microorganisms to hostile media.

Bacteria, fungi, viruses, parasites and unicellular algae form part of ecosystems, and their presence is ubiquitous. Food is not a sterile product, and the animal and plant tissues which food is made of contain large numbers of germs on their surface, and occasionally inside. This microflora is varied and must not be evaluated as a health risk in an overall sense. In fact, some of these microorganisms are introduced into the food production chain in a controlled manner, and are indispensable for the production of some foodstuffs such as cheese, wine, yoghurt and beer. Other microorganisms cause the deterioration of food but cannot be considered as health dangers. However, in addition to these beneficial organisms, and the undesirable, but harmless presence of others, there are a large number of pathogenic germs which, in conditions which allow for their subsistence, may proliferate and reach numbers high enough to produce diseases. There are also agents which may be transmitted through foodstuffs although they do not have an active reproductive phase (parasites, viruses, prions and some bacteria).

Bacteria and bacterial toxins

Amongst foodborne pathogens of bacterial aetiology, we need to differentiate here the case of bacteria which require time and conditions to proliferate and/or release toxins into food from others in which the presence of a single microorganism or extremely low quantities of this microorganism (1-10) may cause illnesses in the population (parasites, many viruses and some bacteria): brucellosis, campylobacteriosis, haemorrhagic colitis). This distinction is important in the context of food health for the adoption of risk prevention and reduction measures are based on different initiatives. Those aimed at avoiding microbial reproduction maintained throughout all the stages of the food production chain are effective in the first case, but they are not effective when dealing with microbial foodborne diseases of a low infectious dose; in this case other initiatives are important, such as preventing raw material contamination and the inactivation of these agents during food processing, mainly through the application of heat treatment.

1. We also include here pluricellular macroscopic parasites.

The table below lists the bacterial agents which are most often involved in food poisoning infections:

Table 1. Bacterial aetiology with the highest frequency in foodborne diseases

Invasive agents	Toxigenic agents
■ <i>Salmonella</i> spp.	■ <i>Escherichia coli</i> O157:H7
■ <i>Campylobacter jejuni</i>	■ <i>Escherichia coli</i> enterotoxigenic
■ <i>Vibrio parahaemolyticus</i>	■ <i>Staphylococcus aureus</i>
■ <i>Shigella</i> spp.	■ <i>Clostridium perfringens</i>
■ <i>Yersinia enterocolitica</i>	■ <i>Clostridium botulinum</i>
■ <i>Escherichia coli</i>	■ <i>Bacillus cereus</i>
■ <i>Escherichia coli</i> enteroinvasive	

The causal pathogens of gastroenteritis are presented in two groups in accordance with the agents which cause the illness: invasive and toxicogenic.

Invasive agents

Salmonella

Salmonella is a zoonosis which is fundamentally found in foodstuffs. It is the main cause of toxic infections from food and gastro-enteric disorders in Catalonia, Spain and many other European countries.

Traditionally, egg products and egg-based preparations have been the foodstuffs involved in *Salmonella* outbreaks, and those which are of a greater health risk, especially those which contain raw eggs, such as mayonnaise. Foods such as raw eggs, sauces, ice creams, creams, pastry, non-pasteurised milk, seed shoots from soy or alfalfa, and under-cooked meat, mainly pork and poultry and fermented meat products have been involved in cases of salmonella.

The main sources of *Salmonella* are farmed poultry, cattle and pigs, and therefore the meat (and eggs) from these animals are an important source of infection, as are their handlers and transporters. Water and fresh plants eaten raw in salads have also been identified as a source of infection.

Campylobacter

Campylobacter spp. thermophilics and in particular *C. jejuni*, are, together with *Salmonella* spp., the zoonotic agents which are most frequently isolated in cases of enteritis in Catalonia, Spain and many countries in Europe; many of the infections are sporadic or occur in isolated cases in families, and identifiable outbreaks do not usually occur.

The foodstuffs related to campylobacteriosis are highly varied and the handling of raw poultry meat and the consumption of meat and poultry products have been identified as the most important risk factors in sporadic campylobacteriosis, through cross-contamination in ready-to-eat food.

Campylobacter is widely present in nature. Its main reservoir is the digestive tract of domestic and wild mammals and birds. It has been detected in beef, pork and meat products, untreated milk and milk-based products, fish and fish products, fresh vegetables and food in modified atmospheres, such as in prepared meals or raw vegetables.

In many cases campylobacteriosis is contracted on journeys to areas of high prevalence. Other risk factors include contact with pets and farm animals, and the consumption of contaminated water or untreated milk.

Vibrio parahaemolyticus and other Vibrios

These marine bacteria are a habitual cause of foodborne diseases in the USA and Asia, but are reported only rarely in Europe.

V. parahaemolyticus and *V. vulnificus* usually provoke gastroenteritis related almost exclusively to the consumption of raw, undercooked or post-cooking recontaminated on fish and seafood, and are specially related to the consumption of oysters, clams, crabs, prawns and shrimps. *V. parahaemolyticus* is found in estuarine waters around the world, but not in open sea water, while *V. vulnificus* is a marine microorganism which is concentrated in filter-feeding molluscs. *Vibrio cholerae* serotype O1 or O139 causes cholera, a secretory enteritis caused by a cholera exotoxin. It is an endemic disease in some parts of Central and South America and Asia, and is mainly water-transmitted, but transmission through the consumption of fish, seafood or raw or under-cooked vegetables also occurs. It originates through the presence of carriers which contaminate wastewater dumped into rivers and coastal waters.

Shigella spp.

This is the causal agent of shigellosis or bacillary dysentery, especially in certain risk groups such as children's nursery schools or old people's homes. Outbreaks are related to the consumption of salads with potatoes, prawns, chicken, milk products, poultry meat and other faecal-oral contaminants, due to poor professional practices by handlers or through water with faecal contamination and peer-to-peer transmission.

It is a microorganism associated with humans, chimpanzees and other primates, but rarely found in other animals. It is mainly found in water with faecal contamination.

Yersinia

Yersiniosis is a zoonosis caused by *Y. enterocolitica* and *Y. pseudotuberculosis*. The most frequent sources of infection are pork and sheep meat, milk and milk-based products such as ice creams and milkshakes. Outbreaks are related to meat consumption, especially undercooked pork, and non-pasteurised milk and milk-based products. Cross contamination on surfaces, utensils or contaminated hands are also risk factors, as is non-treated well water.

The main reservoir of *Y. enterocolitica* is pork, while feral *Y. pseudotuberculosis* has been isolated in ungulates (deer, goats, cattle and sheep), in rodents (rats, rabbits, squirrels and beavers), in many bird species and in non-disinfected water. It does not form part of the natural human flora.

Escherichia coli invasives

E. coli are habitual integrants of the intestinal flora of warm-blooded humans and animals. Though the majority of strains are harmless, others, such as those cited here, are causal agents of zoonosis. There are four known groups of *E. coli* enterovirulents which provoke gastro-enteritis, two of which are invasive: enteropathogenic *E. coli* (EPEC) and enteroinvasive *E. coli* (EIEC).

E. coli contaminates food during meat production and milking and transmission to humans is derived mainly from the consumption of food contaminated with animal excrements such as meat products which use minced, raw or undercooked meat, or untreated milk. Faecal contamination of water and other foodstuffs such as cross-contamination during the preparation of meals may also transmit the infection. Contact between people (faecal-to-oral transmission) is an important form of transmission.

Enteropathogenic *E. coli* (EPEC) causes infant diarrhoea. Undercooked contaminated beef or pork can cause infant diarrhoea, as can any faecally-contaminated food or water. EPEC strains form part of normal flora in humans, cattle and pigs.

Enteroinvasive *E. coli* (EIEC) causes bacillary dysentery which is often confused with that caused by *Shigella*, due to the appearance of blood and mucus in the excrement. The foods related to outbreaks are minced meat and cured cheese. Any food with faecal contamination as a consequence of deficient practices by handlers may cause an outbreak of this illness.

Toxigenic agents

E. coli O157 and other toxigenic *E. coli*

Among the enterovirulent *E. coli* there are two toxigenic types: Enterohaemorrhagic *E. coli* (EHEC) and Enterotoxigenic *E. coli* (ETEC).

Enterohaemorrhagic *E. coli* (EHEC) includes the O serotypes, which are capable of producing verotoxins. The most well known of these is *E. coli* O157:H7, an emergent pathogen which causes outbreaks which, although not frequent, may be serious. It is related to the consumption of pork or beef preparations (minced meat, hamburgers, or sausages) which are either cooked or have been re-contaminated by a raw product. It is also related to the consumption of cured meat products, non-pasteurised apple juice, yoghurt, cheese, and milk, fruit, and vegetables (soy and salad shoots). *E. coli* may contaminate food during meat preparation and milking, and in fruit and vegetable production contamination may result directly through contact with animal excrement or water. Secondary peer-to-peer infection is highly prevalent. The most susceptible population sectors are children and the elderly, who may be affected by fatal complications, such as Haemolytic Uraemic Syndrome (HUS). *E. coli* O157:H7 is a bacteria normally found in the digestive tract of warm-blooded animals, even human beings, and above all in cattle, which are the main reservoir of the bacteria, although sheep are also carriers.

The **enterotoxigenic *E. coli* (ETEC)** strains cause diarrhoeas which especially affect children in under-developed countries and tourists who visit these countries. The related foods are raw vegetables and some prepared foods. It is transmitted by faecal re-contamination, although water-borne transmission is also significant.

Staphylococcus aureus

This is a frequent cause of food poisoning outbreaks in many countries. Outbreaks are caused by the ingestion of foods which contain thermally stable staphylococcal enterotoxins and have been related to meat products, egg-based products, pastries, creams, filled pastries and sandwiches and, in general, those products which have been subject to various handling processes and which have been kept at relatively high temperatures.

S. aureus is found in the air, in the water, in waste, in food and in machinery. However, animals and people are its main source. It is found in the nostrils, the larynx, and the skin and hair.

Clostridium perfringens

C. perfringens is a spore type germ which produces enterotoxin in the intestinal lumen. Outbreaks have been related to food rich in protein such as meat or poultry, either stuffed or in sauce, and broths, etc, and in large quantities of pre-prepared food in collective catering establishments –meal services, institutional dining rooms, etc. It is ubiquitous in the environment, and can therefore be found in the majority of raw foodstuffs, including vegetables and meat products.

Clostridium botulinum

Botulism is a rare food poison, but one with serious consequences. It is caused by the ingestion of botulinum toxin (BoNT) —one of the most powerful natural toxins— which have previously formed in the food. Traditionally, outbreaks of botulism have been related to the consumption of homemade preserves. Other foods which cause botulism are cured or fermented meat, fish which has been subject to superficial conservation processes, i.e., cold smoked or vacuum packed, semi-preserved vegetables and oils flavoured with herbs and other condiments. Infant botulisms related to the ingestion of honey have also been observed. The germ reproduces in the honey and the toxin is produced in the intestine.

C. botulinum spores are widely distributed and are found in soil, on the seashore, in sediments and in the digestive tract of land and sea animals. *C. botulinum* grows in the absence of air, in preserved foods, vacuum packed foods, or in bones inside pieces of meat.

Bacillus cereus

Bacillus cereus is an important cause of foodborne diseases in humans. Foods related to outbreaks of poisoning are stewed meat and vegetables, creams, soups and raw vegetable shoots, especially fried or boiled rice and pasta. It may provoke an emetic syndrome caused by the poison cereulide which has previously formed in the food and which is relatively heat-resistant, or it may provoke a diarrhoea type food poisoning caused by enterotoxic proteins.

This ubiquitous spore-type pathogen is found in soil, water and, habitually, in a large variety of raw materials and products of both animal and plant origin.

Other bacteria which produce foodborne illnesses

These include particularly *Listeria monocytogenes*, *Enterobacter sakazakii*, *Brucella* and streptococci.

Listeria monocytogenes

Listeriosis is a relatively rare yet serious illness with high mortality rates (between 20% and 30%). The importance of foodstuffs as the main via of transmission of *L. monocytogenes* to humans was not recognised until the 1980s. The most frequently related foodstuffs in outbreaks and sporadic cases of listeriosis are prepared meals, milk products (especially in soft, paste-type cheeses), pâtés and raw or cold smoked fish products (salmon), chicken and cooked and cured sausage type meats.

The bacteria is ubiquitous, and is widely distributed in nature. Animals and humans act in general as subclinical carriers. It is highly resistant in the atmosphere and is usually very difficult to eradicate in food manufacturing establishments.

The likelihood of falling ill through the ingestion of *L. monocytogenes* is much higher in vulnerable population groups, such as people with low immunity, the elderly, and perinatal children (foetus and newborn children) than in the general population.

Brucella

The habitual transmission vehicles of this bacteria are milk and milk products from sick animals, especially in those countries where standard hygiene measures are not applied, and where health infrastructure in the milk industry is deficient.

In developed countries, where milk hygiene processes are generally applied, the predominant via of transmission is not from food, but from direct contact with sick animals, and as a consequence it has now practically become a professional illness related to veterinarians, stock-breeders and butchers.

Brucellosis is produced by bacteria of the *Brucella*, genus, especially *B. melitensis*, from goats and sheep, and *B. abortus*, from cattle.

Enterobacter sakazakii

E. sakazakii is an emergent pathogen involved in sporadic cases of serious infections in newborn children of up to 4-6 weeks old. The origin of the organism has not been discovered. In many cases the reservoir is unknown. *E. sakazakii* has been identified in the environment of powdered milk production facilities, and in other food production plants, as well as in homes. Infections have often been related to the consumption of baby food containing powdered milk.

E. sakazakii is ubiquitous in nature, and control of this pathogen requires strict hygiene measures in processing rooms. The bacteria do not survive the pasteurisation process in production, but re-contamination may occur in packing and handling phases.

High-risk groups include premature babies, those with low weight at birth, and those with low resistance to infection. Little is known about the factors which determine the virulence and pathology of *E. sakazakii*, which is a gram negative bacteria which does not form spores and belongs to the *Enterobacteriaceae* family.

Streptococci

The streptococci of the Lancefield A and D groups may be transmitted through food. The foodstuffs involved in their transmission are milk, ice creams, eggs, seafood, ham, potato salads, prawns or eggs, creams and rice pudding. Outbreaks have been related to transmissions via untreated milk, pasteurised or evaporated milk, fresh cheese, sausages and croquettes or meat pies.

It is generally transmitted in complex foodstuffs as a consequence of handling by infected people.

Other bacteria have occasionally been described as causing severe gastroenteritis. These are germs of the *Klebsiella*, *Enterobacter*, *Proteus*, *Citrobacter*, *Aerobacter*, *Providencia* and *Serratia* genera. Pathologies caused by *Aeromonas hydrophila*, *caviae* and *sobria*, and *Plesiomonas shigelloides*, have also been described. These normally affect people in the developing countries where there is a lack of sanitation and the population is affected by chronic illnesses and malnutrition. They are not so usual in developed countries, where they may affect those with chronic illnesses or immunodeficiency. The associated foodstuffs include those of aquatic origin, i.e., fish and seafood, and those prepared using contaminated water.

Viruses

Practically all enteropathogenic viruses can be transmitted via water and food. Food transmission of the Norwalk virus, calicivirus, astrovirus, enteric adenoviruses, rotaviruses and parvoviruses have all been documented. Water-borne transmission and secondary peer-to-peer transmission are highly relevant in this viral gastro-enteritis group.

The foods related to outbreaks caused by viruses are those which are not subject to sufficient heat treatment, or food which is consumed raw, such as salads, pickled fish or raw seafood. Food contamination is produced by poor handling practices, by carriers or by the use of contaminated water in the first stages of production, such as in the case of bivalve molluscs and plants. Viruses cannot reproduce or produce toxins in the food, but they can continue to thrive in food kept at refrigeration temperatures and in a marine environment, and in some cases may cause illnesses with low doses of infection.

The most common enteric viruses

The Norwalk Virus

This virus owes its name to an outbreak which occurred in Norwalk, Ohio, in 1972. Noroviruses belong to the calcivirus group. They are small RNA viruses, round in structure, and are recognised as being one of the most important causes of non-bacterial poisoning in Europe, one which is more frequent in adults and young people than in children. The most frequent origin of this type of food poisoning is water, but the infection has also been caused by the consumption of bivalve molluscs, salads, meals subject to handling, and food preparations with raw ingredients. Meat, ice cream and fruit have also been related to outbreaks. Transmission may also occur through handlers who are sick or merely symptomatic, becoming carriers.

The Hepatitis A Virus

Hepatitis A is a viral disease frequently transmitted through foodstuffs. Food related to outbreaks is seafood caught in areas of contaminated water which is eaten either raw or is undercooked, and prepared meals contaminated by handlers who are carriers, especially meals which are not cooked after handling (vegetables, salads, fruit, fish, milk and milk products such as ice cream). Water-borne transmission is also frequent, as is transmission through contaminated ice.

Rotaviruses

These cause outbreaks of food poisoning through the ingestion of prepared meals which have been handled, and raw foods such as salad, prepared fruit dishes, nibbles or sandwiches. Transmission via contaminated water is significant, as well as via handlers and peer-to-peer secondary infection. Poisoning provokes a severe viral gastroenteritis known as infant diarrhoea or winter diarrhoea. Outbreaks have occurred in nurseries in which food transmission is occasionally responsible, although faecal-oral transmission among children is the most important.

Other enteric viruses

These are known as the small round-structured viruses, or SRSV group, and are some of the causes of paediatric diarrhoea also known as viral gastroenteritis or non-bacterial infant gastroenteritis.

In general, the origin of the poisoning are handlers who do not follow appropriate handling or hygiene practices, and contaminate prepared foods which are eaten in children's centres. Secondary peer-to-peer transmission is also significant. The consumption of bivalve molluscs is also a cause of the illness.

Caliciviruses are included in this group, with RNA as those mentioned in the section above, but which affect children from 6 to 24 months old.

RNA astroviruses cause sporadic gastroenteritis in children aged under four, whilst enteric adenoviruses with DNA provoke gastroenteritis in breastfeeding children and infants. The DNA parvovirus provokes gastroenteritis at any age.

Parasites

As with viruses, parasites do not reproduce in foodstuffs, nor do they produce toxins. However, they are highly resistant to refrigeration and freezing, and the ingestion of a single parasite or food infested with parasites is sufficient to provoke the illness.

Protozoa

There are diverse pathogenic protozoa which may be transmitted by food and cause enteritis (*Giardia lamblia*, *Entamoeba histolytica*, *Cryptosporidium parvum* and *Cyclospora cayetanensis*) or generalised illnesses (*Toxoplasma gondii*).

Cryptosporidium parvum

This parasite is mainly water-transmitted, but can also be transmitted through food. Raw vegetables are a potential source of infection, especially in situations where hygiene is deficient. Foods related to outbreaks are milk-based products, apple cider, meat products and salads which include animal products.

The agent is an intestinal coccid parasite, with a life cycle which takes place in a single host. It has been detected in domestic and wild animal excrement. The reservoirs of human infection are ruminants, mainly cattle and sheep, which eliminate stable oocysts in their excrement. Humans are infected after ingesting the oocysts. In immunodeficient people, the infection may have fatal results.

Giardia lamblia, *Entamoeba histolytica* and *Cyclospora cayetanensis*

These are parasites of humans, and are characterised by taking a resistant form of cysts during their life cycle, which facilitates their survival and extension.

They contaminate food via direct handling by carriers or through water contaminated with faecal waste. Foods involved are therefore vegetables and those which undergo complex handling processes and which are not subject to posterior heat treatment (salads). Water-borne transmission is also frequent through the ingestion of water contaminated with cysts, or through recreational activities in water (swimming pools, lakes).

Toxoplasma

T. gondii is an obligate intracellular parasite which causes toxoplasmosis, a zoonosis which affects mammals and birds. In industrialised countries, food transmission seems to be the main channel of infection, through the consumption of raw or undercooked meat which is infested with cysts. The primary host is the domestic cat, which eliminates the oocysts in its excrement, and these may then be ingested by animals or humans. They penetrate the intestinal epithelium and reach the muscles, where they form cysts. Congenital toxoplasmosis is produced when a mother is infected shortly before or during pregnancy with severe neurological consequences for the foetus.

Helminths

Helminths (or parasitic worms) have complex life cycles and produce illnesses in humans when these act as either intermediary or definitive hosts. The infestation form may be present in the environment or integrated in tissues of the intermediary host; this fact is relevant when determining the transmission form via food.

From this standpoint, the cestodes *Taenia solium*, *Taenia saginata* and *Diphyllobotrium latum*, and the nematodes of the genera *Trichinella*, *Anisakis*, *Strongyloides*, *Ascaris*, *Capillaria* and *Trichuris* are important.

Taenia saginata and *Taenia solium*

Taeniasis is the infection of humans with the adult tapeworm of the *Taenia* genus. In cows and pigs, it causes cysticercosis, when the larvae, called cysticerci, form cysts in muscles and organs.

Humans are the definitive host for *Taenia saginata*, whilst cattle are an intermediate host, becoming affected by bovine cysticercosis. Humans are also the definitive host for *Taenia solium*, whilst pigs are the main intermediate host, becoming affected by porcine cysticercosis.

Humans eliminate the proglottids with parasite eggs by the faecal route. Animals become infected by accidental ingestion of eggs. The cycle is completed when humans are infected by ingesting raw or insufficiently cooked meat containing viable cysticerci. Moreover, in the case of *T. solium*, human ingestion of the eggs can also cause the parasite to spread to the organs (as in the pig). In humans, the illness related to the presence of *T. solium* cysticerci is called neurocysticercosis.

Trichinella spiralis

Meat may be the transmission vehicle of parasitic zoonosis such as trichinosis, the incidence of which has diminished notably in the developing countries due to the adoption of hygiene measures, feeding requirements in stockbreeding farms, and veterinary inspections in slaughterhouses. However reservoirs still continue to exist in the wild (ruminants and wild boars), and precautions must be taken in the consumption of game meat and animals slaughtered at home.

Echinococcus spp.

Two cestodes of different genus cause a chronic zoonosis. The definitive hosts are carnivores which, while carrying the adult worm (3-6 mm) in their small intestine, release hundreds of microscopic eggs in their excrement, contaminating water and foodstuffs which will then be the infection vehicle for human beings when these are ingested raw.

Dogs are the definitive hosts of *E. granulosus*, while sheep, cattle, deer, pigs, horses and occasionally wild fauna are intermediary hosts. The risk factor for humans derives from direct or indirect contact with dog excrement through close contact with the animal or through or foodborne contamination (water and food).

In the wild, (*E. multilocularis*) the fox has been adopted as its definitive host.

Anisakis

Anisakidosis is an infestation produced by nematodes of the *Anisakis* genus. The consumption of raw fish in dishes such as ceviche, sushi or other forms of preparation (the use of vinegar, light salting or smoking) which do not ensure the inactivation of the larvae constitute risk factors.

Anisakis are parasites with a highly complex cycle in which the intermediate hosts are crustaceans, cephalopods and fish, and as definitive hosts, marine mammals. Man enters into this biological cycle by ingesting raw fish or cephalopods which contain anisakis larvae.

Furthermore, the ingestion of live *A. Simplex* larvae may provoke immediate hypersensitive allergic reactions. The allergy may occur after the consumption of host fish with larvae which have been inactivated through freezing or cooking, due to the presence of allergens resistant to cooking or freezing.

Other fish-borne parasites

There have been cases reported caused by the consumption of fish infected by diverse species of cestodes: (*Diphyllobotrium latum*), nematodes (*Eustrogylydes* sp. and *Anisakis simplex*) and trematodes (*Nanophyetus salmincola*), always related to the consumption of raw or undercooked fish.

Mycotoxins

Mycotoxins are toxins produced by certain fungi which contaminate food such as nuts, cereals, dried fruit, coffee and spices, among others. The fungi may contaminate plants during harvesting and initiate the production of alpha toxins.

Foodstuffs may be contaminated during storage and handling due to poor practices. Mycotoxins may enter the food production chain through meat, milk or other animal products as a result of the ingestion by animals of feed contaminated by these toxins.

Despite advances in food production and storage, the complete reduction of contamination and proliferation of this type of fungi is still not possible today. The effects on health depend on the quantity and type of mycotoxin ingested.

More than 80 mycotoxin-producing fungi species have been identified. No specific type of mycotoxin production can be attributed to any one species of fungi. The same fungi may produce either one kind of fungi or another, depending on the substrate which it contaminates, the temperature and humidity conditions, and water activity, and a mycotoxin may be produced by more than one fungi species.

Aflatoxins

Aflatoxins are produced by fungi of the genus *Aspergillus*. This is a widespread fungi and easily develops in temperatures of between 20°C and 30°C, with a relative external humidity of 80% and a humidity of the feeding substrate of 9%. These characteristics favour proliferation in countries with warm climates where, moreover, food storage procedures are not highly developed. Contamination by the fungi may occur during harvesting, and may proliferate throughout all the stages of the food production chain. Aflatoxins may have serious effects on people and animals when ingested in high quantities. Chronic consumption of small quantities of aflatoxins may cause diverse effects in both humans and animals, including carcinogenic, mutagenic and teratogenic effects.

Aflatoxins are the most commonly known mycotoxins and are found in peanuts, maize, nuts and some fruit, such as figs. Feeds contaminated with aflatoxins are also a problem for food safety as they may build up in animals destined for food production. This has particular importance in dairy cows, which may excrete aflatoxins in their milk.

Ochratoxin A

This is a mycotoxin with carcinogenic, nephrotoxic, immunotoxic teratogens which probably has neurotoxic properties. Ochratoxin A is found in a whole series of plant products such as cereals, coffee grains, cocoa and dried fruit. It has been detected in cereal-based foodstuffs, coffee, wine, beer and grape juice, as well as in animal products such as pig's kidneys.

Patulin

Patulin may be present in fruit, grains and other food contaminated by fungi. However, the main source of contamination by patulin is derived from apple-based products: apple juice, preserves and jams.

Fumonisin

These are toxins produced by different fungi of the genus *Fusarium* which mainly contaminate maize and products containing maize. Fumonisin B₁ is the most prevalent and most toxic toxin within the group.

Desoxinivalenol, nivalenol, T₂ and HT₂ toxins

Some fungi of the genus *Fusarium* produce these mycotoxins, which belong to the tricotecens group. These mycotoxins are well-distributed in the food production chain and are found in cereals and products derived from wheat and maize, the main sources of ingestion of these toxins.

Zearalenone

This is a toxin produced by certain species of *Fusarium*. Both zearalenone and its metabolite, zearalenol, are found in maize and other cereals, as well as in cereal-based products. This toxin is responsible for estrogen dominance syndrome in farm animals. It is genotoxic and carcinogenic in animals as a consequence of its estrogenic effects; it has been given a Group 3 classification by the International Agency for Research on Cancer (IARC).

Unicellular algae and marine toxins

Food poisoning by marine biotoxins related to so-called "red tides" are a health problem in our geographical environment, and are produced by diverse species of dinoflagellate algae which produce serious intoxications as a consequence of fish or mollusc filter-feeders which feed on these algae and accumulate the toxins without being affected themselves. The molluscs most frequently involved are clams, and occasionally scallops and oysters. Paralyzing (PSP), diarrhoeal (DSP), neurotoxic (NSP) and amnesic (ASP) poisoning have been reported in this group.

Paralyzing Shellfish Poisoning (PSP)

This is caused by a certain genus of the dinoflagellates *Alexandrium*, *Gonyaulax*, *Gymnodinium* and *Pyrodinium*, which contain saxitoxins. These, when ingested with molluscs, cause a paralysis of the extremities to a degree which depends on the type of toxin involved, the quantity ingested, and the capacity for elimination.

Diarrhoeal Shellfish Poisoning (DSP)

Caused by okadaic acid from the enterotoxins produced by the genera *Dinophysis* and *Prorocentrum*. Ingested with molluscs, they cause gastrointestinal symptoms.

Neurotoxic Shellfish Poisoning (NSP)

NSP is caused by *Gymnodinium breve*, which contains brevetoxin, and produces poisoning through the consumption of molluscs, with mild paralysis of the members, gastrointestinal symptoms and bronchospasms.

Amnesic Shellfish Poisoning (ASP)

Amnesic or domoic acid poisoning is caused by a toxin which acts as an agonist of glutamic acid, which is a neurotransmitter of the central nervous system. It is found in certain varieties of diatomea nitzschia, and provokes digestive alterations and, in serious cases, dizziness, disorientation, memory loss, respiratory alterations and coma.

Ciguatera

This is a frequent form of poisoning in warm countries. It is caused by the consumption of coastal dwelling fish and tropical fish such as the barracuda, moray, and the black grouper, which feed on dinoflagellates. These contain a neurotoxin, ciguatoxin, which is resistant to gastric fluids, heat and freezing.

Non-conventional agents: Prions

Prions are the agents that cause a group of illnesses known as transmissible spongiform encephalopathies (TSE), which affect both humans and animals. This family of diseases includes Creutzfeldt-Jakob Disease in humans, bovine spongiform encephalopathy (BSE) in cattle and scrapie in sheep and goats.

A new variant of Creutzfeldt-Jakob Disease (v-CJD) was reported in the United Kingdom in 1996. The variant is related to exposure, probably through food, to bovine spongiform encephalitis (BSE). An etiological protein-based agent called a prion has been identified as the cause.

This agent causes the appearance of lesions in the central nervous system in the form of vacuoles which produce an anatomopathological image in the shape of a sponge, hence the name of the illness. The beef tissues where prions have been detected are the tonsils, the thymus, the eyes, the encephalon, the spinal cord, the spleen, the mesentery and the small intestine. These tissues have been eliminated from the food production chain in areas where BSE has been detected. Since BSE was discovered, large-scale surveillance and control systems have also been put in place for BSE and scrapie in sheep and goats.

2 Chemical hazards

The risks related to the contamination of food by chemical agents constitute a growing concern for public health. The environmental contamination of the air, earth and water, from natural and anthropogenic sources, the use of chemical substances in food and agricultural production such as pesticides and veterinary medicine, which may involve a health risk if they are not used appropriately, are subject to regulations and continual monitoring in order to guarantee that they are not found in food in quantities which endanger the health of the population.

Natural toxic substances which are inherent in some foods must be taken into account. These substances may represent a risk for certain population groups, and in some cases may cause serious intoxications due to confusion of edible species with toxic species.

Environmental contaminants

The release into the environment of substances derived from industrialisation and the technological progress of human activities results in the presence of compounds in foods which, in determined quantities, may be toxic when ingested.

Two groups of environmental contaminants may be distinguished: heavy metals and persistent organic contaminants (POC).

Both substance groups are characterised by their persistence in the environment, their resistance to degradation and the accumulation in the body. POCs are also characterised by their high liposolubility and their capacity for bioamplification in the food production chain.

Metals

Arsenic (As), cadmium (Cd), mercury (Hg) and lead (Pb) are metals which are found naturally in the earth's crust in diverse chemical forms, that is to say, they are ubiquitous environmental contaminants. All of them have specific forms of toxicity which depend largely on their concentrations and, in some cases, their chemical shape. No homeostatic method which regulates them is known, and it is well-known that chronic exposure to these elements, even in low doses, may have adverse effects on health. These metals are highly persistent and bioaccumulable, and are widely distributed across the planet. Once they have entered the tissues of plants and animals, they enter the food production chain and, thus, the foods which constitute one of the main paths of transmission to Man. Owing to their anthropogenic uses, the proportion of these metals released into the environment and their later dispersion are much higher than those which would occur in their natural biological and geological cycles.

Mercury

Mercury may enter the environment as a result of industrial activity. Methylmercury, which originates in aquatic environments through the action of different bacteria, is generated from its inorganic form. This inorganic form is much more poisonous than inorganic mercury; it affects the central nervous system and is capable of passing through the placental barrier. Methylmercury may cause alterations in the normal development of the brain in lactating infants and, at higher levels, neurological disorders in adults.

Lead

This is an element which may provoke retarded mental and intellectual development in infants, and which can also cause hypertension and cardiovascular disorders in adults.

Lead may contaminate certain foods preserved in glazed pottery, wines bottled with stoppers which contain lead, and even public water supplies which use lead pipes. The reduction in the use of leaded petrol has led to a reduction in environmental lead levels, and obviously the lead present in food.

Cadmium

Cadmium causes renal and bone disorders and problems in the reproductive apparatus. It is an ARC classification Category 1 carcinogenic substance with sufficient epidemiological evidence.

The most famous case of mass cadmium poisoning comes from a small town in Japan where contaminated rice was eaten. The population suffered an illness which is characterised by osteomalacia, tubular proteinuria and intense pain in the bones. The cause of the contamination in the area were the activities of a mine which was dumping cadmium into a river which fed local paddy fields. Cadmium can build up in large quantities in marine organisms such as oysters, mussels and molluscs in general. This fact has led to proposals to use these species as indicators of cadmium contamination.

Arsenic

Chronic ingestion of low quantities of arsenic causes digestive, neurological, dermatological and heart alterations. It is an ARC Category 1 classified substance: carcinogenic for human beings, with sufficient epidemiological evidence.

Fish, crustaceans, molluscs and other aquatic animals have the capacity to metabolise arsenic and accumulate it as dimethylarsenic, an inorganic form with a far lower toxicity than that of inorganic forms.

Persistent Organic Contaminants (POC)

Persistent organic contaminant (POCs) are chemical substances which are resistant to decay in natural conditions and which, when dispersed in the environment, are transported a considerable distance from the emission point. These substances bio-accumulate through the food production chain and constitute a proven danger both to health and the environment. Their harmful effects have been widely demonstrated, and have been generally recognised.

Substances related to persistent organic contaminants are those such as dioxins and polychlorinated biphenyls (PCB), hexachlorobenzene, polybrominated diphenyl ethers, polychlorinated diphenyl ethers and polychlorinated naphthalenes. The main concern for public health lies not in the serious effects which derive from POCs in foods, but in chronic exposure in small quantities related to the deterioration of the immune system, the developing nervous system, the endocrine system, and the reproductive functions.

Dioxins

Dioxins originate as by-products from industrial processes and the incineration of residues. They are found at low levels in all parts of the world, and in practically all foodstuffs, although especially in milk-based products, meat, fish and seafood. In 1999, an incident occurred in Belgium, when high levels of dioxins and PCBs were found in animal products derived from the use of industrial oils in the manufacture of feeds which were highly contaminated with dioxins.

Polychlorinated biphenyls (PCB)

PCBs are produced in an intentional manner for industrial purposes. Their use has been reduced since their toxicity was discovered. In the environment they act in a way highly sim-

ilar to that of dioxins; they are highly persistent, liposoluble and bioaccumulable. They have a marked tendency to accumulate in the fatty tissues of both humans and animals, especially in fish and seafood, where they may reach extremely high levels of concentration.

Some of the possible PCB congeners may adopt a coplanar structure, similar to that of dioxins, which gives them a similar toxicity; these are the so-called dioxin-like PCBs.

Polycyclic Aromatic Hydrocarbons (PAHs)

PAHs are a group of lipophilic substances with varying degrees of persistence, and which may undergo intense decay phenomena in the environment, and as such, are not considered persistent. They constitute a group of substances with highly elevated carcinogenic potential and which are widely distributed in marine-type ecosystems.

Raw foods normally have relatively low PAH levels, which notably increase when the food is cooked, and especially when the food is subject to intense processes such as toasting, grilling, barbecuing or smoking, in which values detected may reach up to 100 µg/kg.

PAHs can also be found in a wide variety of foods such as plants and their oils, in addition to various types of fish and roast and smoked meats. Meat, when roasted, and when temperatures reach the order of 500°C, produces pyrolysis from carbohydrates and fats, which is the main cause for the appearance of these compounds, and as such their presence is directly proportional to cooking temperatures. Content also increases in relation to fat content in meat.

Other Persistent Organic Contaminants

Other contaminants are also taken into account for which legal levels have not been established, but whose presence in food is investigated due to their toxicity and behaviour and that fact that they are known to be released into the environment.

Hexachlorobenzene (HCB)

This is an organic chlorate substance which has low water solubility, is persistent, and has an extremely high level of liposolubility; characteristics which make it highly bioaccumulable.

There are no natural sources of hexachlorobenzene; however, it is produced intentionally for industrial purposes or as a by-product when inappropriate methods are used for the production of chloride compounds (solvents, aromatic compounds, insecticides, etc).

HCB is found in low concentrations in the air and in drinking water. A significant bioamplification occurs through the food production chain.

Variable concentrations are found in foods which have a high fat content.

The main source of population exposure is through food, which represents 92% (other sources are through inhalation from the air and from drinking water).

Pentachlorobenzene

This is a chlorobenzene which is used for the manufacture of the fungicide pentachloronitrobenzene. Contaminated food and water result in a higher daily total ingestion percentage than from the air.

Polychlorinated Naphthalenes (PCNs)

These are lipophilic, volatile compounds with a low water solubility and which are highly soluble in organic solvents. Some PCNs are synthesised for industrial applications, others

are created as by-products or as the result of combustion processes. The main sources of environmental emission are waste incineration and the dumping of products which contain these compounds.

The main channel of exposure to PCNs is in working environments. Although little data is available on the ingestion of PCNs in diet, environmental studies have observed evidence of PCN bio-accumulations in fish (especially tetra and pentachloronaphthalenes).

Polychlorostyrenes

Polychlorostyrenes have acquired international attention due to their potential for persistence and bioaccumulation in the environment. Little data is available concerning the presence of these compounds in the environment, in food, or concerning toxicological safety levels.

Waste from food and agriculture production

Medicines in animal production

The correct use of medicines in animals destined for human consumption is highly beneficial in both economic and health terms, with evident improvements in animal health. However, inappropriate or even illegal use of these pharmacological substances may mean that their residual traces reach the consumer in quantities sufficient to produce harmful effects.

The hazard for consumers is derived from residues from medical products, which include both the original compound and the products created when it is broken down.

The veterinary medicines subject to investigation in accordance with established legislation are:

- Stilbenes, stilbene derivatives, their salts and esters (diethylstilbestrol, etc)
- Antithyroids
- Steroids
- Resorcylic acid lactones (zeranol)
- Beta-agonists (clenbuterol, clenproperol, etc)
- Antibacterial substances, including sulphamides and quinolones
- Anthelmintics
- Anticoccidials
- Carbamates and pyrethroids
- Tranquillisers
- Non-steroid anti-inflammatory products
- Other pharmacological substances

Anti-microbial Resistance

The emergence and spread of resistance to anti-microbial products has become a public health problem. Microorganisms have an extraordinary ability to adapt and to acquire and transmit resistance to antimicrobial products. The excessive and erroneous use of substances which kill microorganisms or which inhibit their growth has favoured the development of resistant microorganisms. Although a natural resistance to antimicrobial agents previous to their use in medical treatment already exists, it is generally accepted that an association exists between the quantities used and the increase in resistant organisms.

Microbial resistance can spread into other microbial populations. Infections by resistant organisms threaten human, animal and plant populations, and therefore microbial agents must be used prudently in order to limit the appearance and propagation of new resistant germs.

The use of antibiotics in stock is one of the causes for the emergence of bacterial resistance. However, the principal cause is the inappropriate use of antibiotics in the treatment of humans.

Pesticides

The use of herbicides, insecticides and fungicides in vegetable farming has substantially increased efficiency in food production. Pesticides may enter food via plant health treatment or as a result of environmental impregnation. Exposure to these agents from agricultural use or from environmental contamination is a cause for public concern. Generally speaking, "human exposure to these substances is below tolerable daily ingestion levels and established maximum residue limits (MRLs)". Hazards may derive from their inadequate use in quantities which exceed established MRLs or the use of unauthorised substances in products.

Three well-differentiated groups can be distinguished amongst pesticides, organochlorides, organophosphonates and carbamates. The first are more important with respect to toxicity as they have a marked affinity with fats and therefore a marked accumulative character. Quantities of organochlorides have been detected in mother's milk years after the prohibition of these compounds, a fact which corroborates their presence in the environment and food. Organophosphonates are more important as strong acetylcholinesterase inhibitors in accidental or intentional intoxications as they decay easily in the environment; nonetheless, concentrations to the order of 0.001 ppm have been detected in various foodstuffs. The same is true of carbamates, as they decay rapidly and without difficulty in the environment.

Nitrates, nitrites and nitrosamines

Nitrate is naturally present in the environment as a consequence of the nitrogen cycle, which may be altered by agricultural and industrial activities.

Nitrate is widely distributed in food. The main sources of exposure are plants and drinking water. Some leafy plants have an extensive capacity to accumulate it. Nitrates and nitrites are used as preservative additives in foods, especially in meat products, where nitrite effectively impedes the development of *Clostridium botulinum* spores and as a result the formation of botulinum toxin.

In general terms, nitrite content in foods is barely significant. Nitrate may become nitrite through bacterial reduction in foods during processing and storage and in the body itself (in saliva and the gastrointestinal tract). It has been estimated that 5% of the nitrate ingested is endogenously transformed into nitrite, which accounts for the greater part of total exposure to this compound.

With regard to public health, the toxicity of nitrate is determined by its transformation into nitrite, which may produce methemoglobinemia through the oxidation of Fe⁺² in haemoglobin and reduce oxygen transportation capacity, which is especially significant in infants.

However the most important health risk derived from exposure to these substances is due to the fact that nitrite may react with amines or amides to form nitrous compounds, many of which are powerful carcinogens. Nitrosation reactions may occur during the maturing or processing of foodstuffs or in the gastrointestinal tract due to precursors.

Natural toxins in foods

The toxic substances in poisonous food and plants which appear edible are significant causes of illness in many areas of the world.

Solanine

This is a glycoalkaloid found in potatoes which plays a protective role in the plant and which, in determined conditions –such as parasitic infection or exposure to the light– may increase notably in concentration. Solanine is a cholinesterase inhibitor and may be teratogenic.

Xanthines

Caffeine, theobromine and theophylline are alkaloids found in many exotic plants, and are CNS stimulants. They are found in varying proportions in beverages prepared from these plants and form part of our culinary habits.

Glycyrrhizin

Glycyrrhizinic acid is present in liquorice; it is a compound with a triterpenoid structure which is related to hypertension, hypercalcaemia and water retention when consumed in large amounts. Repeated consumption in large amounts may cause hyperaldosteronism.

Tetrodotoxin

This toxin is found in the gonads, the liver or skin of sea stars (tetraodontiforms) and puffer fish (tetraodontidae) the entrails of which contain powerful neurotoxins: tetrodotoxin and fuguotoxin. These fish are consumed in Japan and poisoning is extremely serious. Minimum lethal doses are very low, and death rates are over 50%.

Toxins from wild mushrooms

In Catalonia the confusion between toxic fungi and edible fungi is without doubt the main cause of illness and death in this category.

Over one hundred wild mushrooms which are recognised as being toxic grow in our woods. Over time, species taken to be edible have come to be considered poisonous. Such is the case of *Tricholoma equestre* (Man-on-Horseback or Yellow Knight); a recent investigation, published in the *New England Journal of Medicine*, noted that health dangers may arise if the fungi is consumed repeatedly over a relatively short period of time.

Interest in wild mushrooms has increased notably in the last few years, and there are increasing numbers of mushroom-pickers, a fact which leads to poisoning through either ignorance or confusion with edible species. The only effective way to prevent these accidents is to consume only those wild mushrooms which can be identified without doubt.

Compounds produced in food processing

Improvements in monitoring and analytical techniques enable the identification of compounds which may affect food safety in such a way that new emerging risks may be identified in normal food preparation processes.

This improvement in the identification of emerging risks may in the long term become an important preventative instrument in order to guarantee the highest degree of consumer health protection.

Acrylamide

Acrylamide may form in foods which are rich in carbohydrates, such as potatoes or starchy products, in energetic food cooking processes such as deep frying or oven cooking for long periods of time where temperatures of 120 °C or above are reached. Their concentration increases according to the temperature the food is subjected to.

The harmful effects of this substance are due to its neurotoxic potential and its carcinogenic nature. Available data indicates that acrylamide is carcinogenic and genotoxic in laboratory animals.

Semicarbazide

Semicarbazide (SEM), a hydrazine compound, is a contaminant which has been found in a large variety of foods, and its presence may have different origins.

SEM is a metabolite of the veterinary medicine nitrofurazone, which is unauthorised in the EU, and as such it is, in principle, highly unlikely to be found in such sources.

It may be present in food as a result of the migration from plastic material used in the seals for metal lids in glass containers. Its origin is the thermal decay of azodicarbonamide, an expansive additive used in plastic seals.

SEM is a product derived from the reaction which results from the attack of hypochlorite to food additives such as carrageenan and food substances such as powdered egg white. Finally, SEM may be naturally present in low quantities in the drying of certain foods, and it may also derive from sources which are as yet unknown.

SEM is a weak, non-genotoxic carcinogenic substance. The prohibition of the use of azodicarbonamide in materials which come into contact with food, established on 2 August of 2005, (Directive 2004/1/CE) should contribute significantly to reducing of exposure to this substance.

3-monochloropropane-1.2-diol (3-MCPD)

3-MCPD originates during the processing of elements under determined conditions. In particular, it may be produced during the processing of hydrolysed vegetable protein through acid hydrolysis. It has also been detected in soy sauces made using this process.

Recent toxicological processes have demonstrated that this substance acts as a carcinogenic genotoxic substance *in vivo*.

Histamine in food

Histamine is produced in certain foods such as sea fish (scombrids), cheese (Swiss type), cured meats and wine. When it deteriorates, it releases histidine, which enterobacters transform into histamine; this occurs when fish is subject to temperatures above 14 °C. In the case of cheese and other transformed products, histamine is formed by a defect in the fermentation process. Histamine provokes an indistinguishable allergic reaction mediated by IgE, and may contribute to the concomitant ingestion of non-specific histamine releasing medicines (codeine, B complex vitamins, ACTH, etc). Histamine is included in this section in accordance with the criteria explained above, considered as a food poison resulting from bacterial proliferation in certain types of food, and which can be prevented by rapid refrigeration and by maintaining the cold chain.

Radionuclides

Radionuclides are chemical elements with an unstable configuration which experience a radioactive disintegration manifested in the emission of radiation in the form of alpha or beta particles and X or gamma rays.

Human beings may be exposed to natural and artificial sources of radiation. Among natural radiation sources are: gamma rays, which are emitted by natural radioactive materials on the earth; and ^{222}Rn , which is a gas derived from ^{226}Ra , found in the earth and in rocks. Artificial sources include industrial activities which involve the use of ionised radiations and those derived from accidents in nuclear industry.

Radionuclides lead to different contamination problems depending on their average lives. Those with a short average life only involve an important food contamination problem when levels are high, such as in an accident. However, radionuclides have extremely long average lives, and once released into the environment they may be considered to be permanent.

The most important effect of chronic exposure to radiation is the increase in the number of cancer cases in the exposed population in comparison to a population which receives less exposure. Furthermore, experiments with animals indicate that in exposed populations hereditary effects are to be expected.

Isotopes ^{90}Sr , ^{137}Cs , and ^{131}I may appear in food and have carcinogenic effects on humans.

Radionuclides are incorporated into plants directly through deposition and irrigation, or indirectly through the earth, and into animals through diet and water.

3 Unauthorised additives or additives in levels above those permitted

Food additives comprise a wide and varied group of substances –some of which have been used for many years– which are added to food to improve or maintain their conservation, nutritional quality, or sensory qualities (flavour, appearance, texture, etc) and other qualities required for their processing or storage.

Despite having passed the toxicological evaluation tests, certain additives may provoke adverse reactions in some vulnerable population groups. This is the case of sulphurous anhydride and sulphites, which may cause reactions of hypersensitivity in the asthmatic, and some azo dyes, such as tartrazine, which provoke adverse reactions in those sensitive to aspirin.

The hazards related to additives derive from their incorrect use, that is to say, when the maximum permitted dose is exceeded in food, when they are used in food in which their use is not permitted, and/or when unauthorised substances are used as food additives.

4 Allergenicity

Certain components of foods may cause adverse reactions, allergies or intolerances, some of which may be serious, and which constitute a health risk for those affected

It is not easy to estimate the incidence and prevalence of adverse food reactions for many reasons. Among others, because precise diagnosis is not simple, and often crossed reactions occur in sensitive individuals. Many investigations do not differentiate between allergies and intolerances. EU scientific reports (SCF, 1995 and EFSA, 2004)² estimate that between 1% and 3% of the adult population, and between 4% and 6% of the infant population are allergic to food.

The prevalence of food allergies varies with age and the specific characteristics of the allergy. Allergies to milk or eggs are relatively frequent in children, but most cases disappear in adulthood. Seafood allergy is related more to adults, while peanut allergy affects both infants and adults.

The most common food allergens, and those which are generally resistant to food processing, and which have the capacity to provoke allergic reactions in susceptible people are, according to the report from the Scientific Committee on Food (SCF): cow's milk and its derivatives, crustaceans, products which use crustaceans, eggs and products containing eggs, fish and products containing fish, cereals which contain gluten, peanuts, soy, nuts (hazelnuts, almonds, walnuts, cashews, pistachios, macadamia nuts and products containing them), celery, mustard and sesame seeds.

This list has to be constantly updated with respect to new clinical observations, new scientific discoveries and progress relative to technological means for the elimination of the allergenicity of the ingredients and other substances.

2. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies in response to a request from the Commission relating to the evaluation of allergenic foods for labelling purposes. Request No. EFSA-Q- 2003-016. Adopted on 19th February 2004.

5 Physical hazards

Physical hazards are considered foreign bodies present in food that, when ingested, may cause mechanical or traumatic injuries such as cuts, wounds and respiratory tract obstruction, amongst others.

Physical hazards include:

- Fragments of packing or packaging materials or parts from machines used in food processing, such as glass, metal, plastic, nuts, seals, etc, which may accidentally enter food during the production process.
- Foreign bodies which may be found in raw materials, such as stones, twigs, bone, teeth, etc.

The nature and severity of any injuries which such hazards may cause depend on the specific nature of the hazard and the characteristics of the people exposed to it.

Annex 2 Method for prioritising by criteria weighting

This method is based on the methodologies proposed by Hanlon and Blom, adapted to the field of food safety. It consists of applying a mathematical formula enabling the analyst to obtain, for each issue studied, a global prioritisation value (NS₁) based on the weighted evaluation of different criteria. The selection and definition of the criteria contained in the formula is based on a group consensus system, so the results are obtained according to a pre-defined methodology which takes into account the information available and the opinion of a group of experts.

$$NS_1 = A \times B \times C$$

$$A = (P_a S_{1a} + P_b S_{1b} + \dots P_n S_{1n}) / n$$

n = number of criteria used to determine priorities

A = magnitude and severity of the issue

B = efficacy of the solution or solvability of the issue

C = feasibility of the intervention

NS₁ = level of significance or priority score for issue number 1

P_n = relative weight of criterion n

S_{1n} = value obtained for issue number 1 when it is evaluated according to criterion n.

When applying this method, a value must be assigned within a predetermined scale for each of the components of the formula. Before applying the formula, the group will have agreed the relative importance to be given to each of the components.

The description of the components used to apply the method within the framework of the Food Safety Plan is as follows:

A) Magnitude and severity of the issue. To obtain the value for this section (A), a value (S_{1n}) must be assigned to each criterion on a scale of 1 to 10, which must subsequently be multiplied by the relative weight which has been decided for each criterion (P_n) on a scale of 1 to 5. Finally, the sum of the values obtained is divided by the number of criteria to obtain the value for A.

Next, by way of example, proposed criteria for application are specified together with their corresponding relative weights.

a) Incidence associated with the foodborne route (P_a = 5)

b) Severity of the issue or effects on health: severity of the illness and potential incidence (P_b = 5)

c) Social perception of the issue (P_c = 3)

d) Influence on fair trading (P_d = 2)

B) Efficacy and effectiveness of the solution (0.5-1.5). The question arises as to whether the resources and technology available can have a definite influence on the issue. Actions which have proven their capability to solve or prevent the issue must be available or must be pro-

vided. The lack of efficient solutions must be seen as an issue in itself that determines the need to seek efficient solutions via investigative action, without prejudice to the application of any provisional actions considered necessary.

Some authors suggest giving the latter component a score on a scale of 0.5 to 1.5, in which 0.5 corresponds to issues which are difficult to resolve and 1.5 to those easier to resolve. The effect of this type of scoring is to multiply the sum of component A by a factor which increases or reduces the result obtained depending on whether the solution is more or less available.

C) Feasibility of the solution (0 or 1). This refers to a series of factors which determine whether the actions available can be applied. It refers to their appropriateness, feasibility in financial terms, acceptability, the availability of resources and legality.

This component is evaluated responding to the question of whether or not an action can be applied. If affirmative the score is 1 and if negative the score is 0. The result for component C is multiplied by the result of the remaining components in the formula so that the case of a 0 zero value gives a final product of 0 in the prioritisation score when the solution is not feasible. In these circumstances, if the issue has high scores for magnitude and severity, then the lack of feasible solutions will have to be considered as an issue in itself, with the result that the search for feasible solutions is prioritised.

As a result of applying the method described here, it is possible to obtain an evaluation table enabling an order of priorities to be established. As an example, the table below shows the results for different groups of issues provided for under the Plan.

Example table for the evaluation of food safety priorities

Issue	A			B	C	NST	Order of priority
	Real incidence associated to transmission via food	Severity of effects on health	Social perception of issue				
	P _a = 5	P _a = 5	P _a = 3	P _a = 2			
Foodborne hazards							
Biological agents causing severe food poisoning	5 (25)	10 (50)	5 (15)	9 (18)	1	1	27
Biological agents causing mild food poisoning	7 (35)	3 (15)	4 (12)	6 (12)	1	1	18.5
Other biological agents causing severe FBD	1 (5)	10 (50)	9 (27)	9 (18)	1	1	25
Other biological agents causing mild FBD	3 (15)	5 (25)	4 (12)	6 (12)	1	1	16
Agent causing transmissible spongiform encephalopathies	0 (0)	10 (50)	4 (12)	9 (18)	1	1	20
Environmental contaminants	0 (0)	10 (50)	5 (15)	9 (18)	1	0,5	10.3
Residues from authorised substances	0 (0)	3 (15)	5 (15)	7 (14)	1	1	11
Residues from banned substances	0 (0)	10 (50)	5 (15)	9 (18)	1	1	20.75
Substances that cause allergies, intolerance or other problems due to individual sensitivities	1 (5)	8 (40)	3 (9)	5 (10)	1	1	16
Concerns relating to food safety							
Quality	0 (0)	0 (0)	7 (21)	9 (18)	1	1	9.7
Animal health	0 (0)	0 (0)	3 (9)	8 (16)	1	1	6.2
Animal welfare	0 (0)	0 (0)	3 (9)	5 (10)	1	1	9.5
Feed	0 (0)	0 (0)	2 (6)	5 (10)	1	1	8
Plant health	0 (0)	0 (0)	2 (6)	5 (10)	1	1	8
New technologies, new ingredients and new foodstuffs	0 (0)	0 (0)	2 (6)	8 (16)	1	1	7
Genetically modified organisms	0 (0)	0 (0)	3 (9)	8 (16)	1	1	6.2
Food ionisation	0 (0)	0 (0)	3 (9)	8 (16)	1	1	6.2

Nota: The criteria applied and their relative weight mean that priority is given to issues concerning food safety. FBD: foodborne diseases.

Glossary (for the purpose of this document)

Acceptable daily intake: measure or estimate of the amount, expressed by body mass, of a specific substance that can be ingested daily over a lifetime without appreciable health risk to the consumer, according to information known at the moment of evaluation, and taking into account vulnerable population groups (for example, children and unborn babies).

Activity: an action carried out on products in the food chain such as, for example, obtaining agricultural and livestock farming produce, food handling, processing, storage and distribution and other more specific actions relating to certain types of product.

Adverse reactions: abnormal clinical response presented by certain individuals, attributed to the consumption of a food or additive which the vast majority of people can tolerate perfectly.

Analytical surveillance: controls carried out using samples and laboratory testing.

Assessment of the food safety plan: stage in the planning process whose aim is to ascertain the level to which the proposed objectives have been achieved.

Attenuation: measures to reduce a given parameter to reasonable, feasible and acceptable minimal levels.

Audit: a systematic, independent examination carried out to determine whether activities and processes comply with established referral regulations or standards, whether they comply with written procedures and documentary procedures, and whether such regulations are implemented effectively and are appropriate to achieve the objectives established.

Batch: number of food chain product units that are produced, manufactured or packed in practically identical circumstances.

Biological hazard: live agent present in food or feed which may pose a threat to human health, whether directly or through the toxins it contains.

Causal factor or cause: characteristic, element or condition that plays an essential role in the appearance of an effect. We refer to principal causes as direct, immediate or determinant, and of secondary or indirect causes as coadjuvant causes or factors.

Chemical hazard: chemical substance present in food or feed which may pose a threat to human health.

Chemical residues: remains of substances that may appear in a food or feed as a consequence of using veterinary medicines, phytosanitary products or other substances used in production processes.

Competent authority: central, autonomous (regional) or local authority enabled to organise and carry out food safety interventions under the powers legally attributed to them.

Consumption stage: stage in the food chain which includes transport, storage, handling, production and/or consumption activities by final consumers in the domestic sphere.

Contamination: the introduction or presence of a hazard.

Contaminant: a hazard that may be present in a product in the food chain and which is not included for a use or application as part of the normal production process.

Control: the performance of a programmed series of actions, observations and measurements to verify compliance with previously specified requirements.

Control plan: description drawn up by the competent authority containing general information about the structure and organisation of their official control systems.

Effectiveness: the capacity of an intervention to produce the desired results when applied under real conditions.

Efficacy: the capacity of an intervention to produce the desired results when applied under theoretical, experimental or study conditions.

Efficiency: the capacity to achieve planned objectives and goals with the minimum resources and time, ensuring their optimal use.

Note: in some contexts, efficiency is understood as the relation between the economic cost of an intervention and its effectiveness.

Epidemiology: the study of diseases and their distribution in human or animal populations, along with their incidence and prevalence and the factors that determine these.

Note: some authors use the term “epizootiology” to refer to this discipline with regard to animal populations.

Epidemiological surveillance: the systematic collection, analysis and interpretation of health data and risk factors within a given population, with a view to disseminating this information to those responsible for safeguarding public health in order to prevent and control disease.

Eradication: the complete elimination of a disease in a given area.

Facility: any unit in a food chain enterprise.

Feed or feedstuff: any substance or product, including additives, destined for consumption by animals in the food chain, whether unprocessed or wholly or partially processed.

Final consumer: the end consumer of a food product who does not use this product as part of any commercial operation or activity in the food and beverage industry.

Food (or foodstuff): any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. Includes beverages, chewing gum and any substance, including water, intentionally incorporated into the food during its handling, preparation or treatment.

Food does not include: feed; live animals unless they are prepared for placing on the market for human consumption; plants prior to harvesting; medicinal products; cosmetics; tobacco and tobacco products; narcotic or psychotropic substances; residues and contaminants.

Food alert or emergency: situation in which there is a risk to human health as a result of the presence or one or more hazards in a product or group of products in the food chain, requiring specific, immediate measures in order to mitigate such a hazard or hazards.

Note: a “food alert” is a message sent out by members of alert or rapid information exchange networks to warn about serious, potentially immediate risks to consumer health.

Food chain activity: any public or private company, whether for profit or not, which carries out any activity related to any stage in food or feedstuff production, processing or distribution.

Food chain hygiene or general food safety conditions: measures and conditions necessary to control hazards and ensure the safety of food chain products, taking into account the uses to which these are to be put.

Food chain operator or food chain company owner: the natural or legal person that performs activities in the food chain and is responsible for ensuring compliance with the food safety requirements established by the current legislation.

Food chain products: a generic concept that includes all animals and materials used or generated at any stage or in any activity in the food chain to produce feed and food, including agricultural products, live animals, food products, products that come into contact with food and materials and substances that are or may be used to produce them.

Food crisis: extraordinary event with loss of public confidence or alarm in the field of food safety which may or may not be linked to the existence of a real threat to human health.

Food infection: foodborne disease involving the spread in the host of living pathogenic agents.

Food poisoning: an illness falling within the general concept of foodborne disease, responding to a given pattern: it is caused by pathogenic bacteria or their toxins, resulting in gastrointestinal infection. The main cause is improper, unhygienic handling, preparation or storage of food during the final stages of the chain.

Food production chain: the sequence of stages or phases, from primary food and feedstuff production to final consumption, including the production of any inputs, raw material, product or service necessary for its production, processing and/or distribution.

Food safety: conditions and measures aimed at ensuring that food is safe.

Note: a global, integral concept of food safety also includes everything related to public perceptions, confidence and expectations with regard to the food chain and food products.

Food safety factors: elements or areas which, though independent of food safety, directly or indirectly affect it. The concept includes health, nutrition, animal welfare, plant health and the qualities of products in the food chain.

Food safety objective (FSO): maximum frequency and/or concentration of a food hazard at the moment of consumption, and which assures or contributes to attaining acceptable protection levels (APLs).

Food risk assessment: science-based process aimed at identifying and qualitatively and quantitatively evaluating hazards and evaluating and characterising the risk to public health posed by exposure to a physical, chemical or biological agent in food.

Foodborne disease: an illness which, according to current knowledge, can be attributed to a specific food product containing a food hazard. The term also refers to both illnesses caused by biological agents and those caused by toxins of all kinds. We speak of infection when the pathogens ingested develop in the host and cause illness, and intoxication when the illness is caused by a toxic substance present in the food consumed, whether of biological or chemical origin.

Foodborne disease outbreak: incident in which two or more people contract a similar illness after ingesting the same food or water from the same source, and in which epidemiological tests show that the food or water is the source of the illness.

Foodborne intoxication: foodborne illness caused by a toxic substance, whether biological or chemical in origin, which is present in food consumed.

From the farm to the table: principle according to which food safety policies and strategies should include all stages relating to food production, storage, handling, distribution and preparation, from primary production to consumption.

Genetically modified organisms (GMOs): microorganisms, plants or animals whose genetic material (DNA) has been artificially modified.

HACCP system: the Hazard Analysis Critical Control Point (HACCP) system is a systematic scientific approach to food safety that anticipates and prevents specific hazards and provides for measures to control them in order to guarantee that foodstuffs are harmless. The HACCP approach provides a tool to evaluate hazards and establish control systems with the emphasis on prevention rather than on testing final products.

Hazard: any biological, chemical or physical agent present in feed or food, and any biological, chemical or physical condition of feed or food that may harm health.

Incidence: the frequency of new occurrences of disease within a defined time interval.

Incompliance or nonconformity: failure to comply with specific requirements forming part of regulations.

Indicator: variable, marker or parameter that provides partial or complete information about a phenomenon

and/or its importance, as well as measuring changes in its situation in time. Indicators enable us to evaluate to what extent the objectives of a plan, project, programme or activity are achieved. Percentages, rates and other quantifiable data are used as indicators, since they permit comparison.

Import: the release for free circulation of feed or food or the intention to release feed or food for free circulation.

Input, raw material or production means: the amount of energy, product, service or other element necessary to complete any given production process.

Inspection: control activity based on examination to determine whether all requirements in current regulation are complied with.

Intervention: any action carried out by an organisation with the aim of achieving an operational objective.

Note: the terms intervention, action and measure are often used as synonyms to designate this concept, often linked to a group of activities. We speak of a programme in the case of a series of programmed activities. The word task is used to designate a basic unit of the activity.

Marketing: possession of food or feedstuffs with the intention of selling or delivering it to a third party, whether at a cost or free of charge.

Mission: the final objective pursued, the general direction or orientation taken by an organisation and which represents its reason for existing and the basic values on which it rests. The mission is defined more specifically and concretely through the determination of goals.

Monitoring: conducting a planned sequence of observations or measurements of control parameters to ascertain compliance with previously determined conditions or requirements.

Official certification: the procedure by which the competent authority or authorised control body provides written, electronic or equivalent guarantee that any given conditions or requirements have been complied with.

Official control: any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare regulations, or food businesses, feed or food business operators or their activities within the scope of its powers.

Note: this also includes the application of measures necessary to correct any failures to comply with regulations that may be encountered.

Operational objective: a goal expressed in a concrete, precise, quantifiable way, with the corresponding indicators, criteria for success and time schedules, establishing the results that the managing bodies should obtain. Operational objectives comprise a mandate for executive bodies as regards the desired situation in the operational sphere, and provide guidelines for interventions to be developed with a view to achieving specific objectives.

Performance objective (PO): maximum frequency and/or concentration of a hazard in a food at a particular stage in the food chain before the moment of consumption, which ensures or contributes to attaining acceptable levels of protection or safety.

Physical hazard: foreign matter present in food which may cause mechanical or traumatic harm if ingested. For example, pieces of glass, metal, plastic, stones, bone, etc.

Precautions: activities to prevent, eliminate or reduce threats in the absence of full scientific certainty.

Prevalence: The number of cases of a disease present in a statistical population at a specified time.

Note: the term prevalence is also used as a synonym for presence (frequency and concentration) of hazards that may be found in the food chain.

Prevention: activities to avoid, eliminate or reduce a known threat.

Primary production: producing, raising, growing or gathering agricultural, livestock, fishing, hunting, wild or mineral products destined to form part of the food chain, and which result only in products not subjected to any other transformation operation.

Primary stage: stage in the food chain that embraces primary production.

Processed products: food products that have been subjected to some form of treatment that has substantially altered its initial state. These products may contain ingredients necessary for their manufacture or to give them specific characteristics.

Processing: any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of these processes.

Processing and/or distribution stage: stage in the food chain that embraces the sale of products from the primary stage, with or without previous processing.

Production, processing and distribution stages: all the phases, from the primary production of a foodstuff

to its sale or supply to the final consumer, inclusive, and, when they affect food safety, all feed production, food handling and distribution phases.

Programme: series of actions organised with the aim of achieving previously established specific and operational objectives. Programmes embody the practical application of strategic and tactical planning and are the principle instrument for intervention in the methodology based on objective-based planning.

Document describing a series of actions organised to achieve certain specific and operational goals, including the programme objectives, the procedures to be followed, the necessary resources, assignment of responsibilities, the schedule and assessment systems.

Purpose: any of the general goals or objectives into which the final mission, objectives or goals forming the mission can be broken down.

Quality: the characteristics of a product, process or service that enable pre-established requirements and conditions to be satisfied. Degree to which the inherent characteristics of a product, process or service conform to pre-established requirements.

Rate of conformity: percentage or proportion of compliance with a standard over the total number of inspections carried out.

Regulation: rule or standard to be followed or which behaviour, processes or activities must obey.

Residue: any substance or object generated by production, processing, use, consumption or cleaning in food chain activities or use and which the owner or producer intends or is obliged to dispose of.

Retail or restaurant stage: stage in the food chain which includes retail sales or service activities aimed directly at the final consumer, including collective catering operations, bars and cafeterias.

Retail trade: the sale or delivery of food to the final consumer, including, if appropriate, handling and processing food, as well as its storage at the point of sale or delivery to the final consumer.

Risk: a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

Risk analysis: a process consisting of three related steps: risk assessment, risk management and risk communication.

Note: risk analyses are also carried out in areas other than food safety in which other types of risks and hazards exist.

Risk communication: the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and all other stakeholders, including description of risk assessment findings and the bases for risk management decisions.

Risk management: process in risk analysis concerned with selecting the most appropriate options to guarantee public health, taking risk assessment and other appropriate issues into account and, if necessary, selecting and applying the most appropriate prevention and control options.

Safety: condition of food guaranteed not to cause any harm to consumers if prepared and/or consumed according to its designated use.

Sector: each of the parts into which each stage in the food chain can be divided, grouping together activities related to each other according to certain criteria, for example, the type of product or group of products concerned.

Self-control: the methods and procedures that food chain operators must implement in order to guarantee that their products are safe.

Specific objective: a goal expressed in a concrete, precise, quantifiable way, with the corresponding indicators, criteria for success and time schedules, aimed at helping to attain certain overall goals and objectives set out under the Plan.

Specific Risk Materials (SRMs): all the tissues and body parts of a slaughtered animal destined for human consumption which could be infectious in a BSE-infected animal according to available scientific knowledge.

Stakeholders: all those who can or do take part in the food chain, including economic operators, consumers, scientific organisations and administrations that intervene in the food chain.

Strategic planning: process organised to define the mission, purposes and goals of an organisation, and to establish the strategies, policies and actions planned to achieve them, as well as designating those responsible for carrying them out and the corresponding assessment systems and instruments.

Note: generally brought together under a strategic plan.

Supervision: evaluation aimed at determining whether an organisation, programme, activity, process, etc, complies with established quality standards and criteria, have been adequately implemented and are appro-

priate to achieving the desired objectives. Supervision may be internal or external and is usually implemented according to auditing techniques.

Surveillance: the systematic collection, analysis and interpretation of data with a view to disseminating it as appropriate amongst those responsible for risk determination, management and communication, as well as amongst other stakeholders.

Traceability: the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed.

Transmissible spongiform encephalopathy: lethal neurodegenerative disease caused by a protein infectious agent known as a prion, and which affects certain animal species as well as humans.

Unprocessed products: food products that have not undergone any treatment that has substantially altered their initial state. It includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed.

Validation: obtaining evidence to demonstrate that any measure or measures selected to control a hazard are effectively capable of controlling it constantly and to the specified level.

Verification: confirmation by examination and study of objective evidence that specified requirements have been fulfilled.

Vision: representation of the ideal situation an organisation aspires to reach in the future through strategic planning.

Zoonosis: any infection or disease shared in nature by humans and animals, whether directly or indirectly.

Zoonotic agent: any virus, bacterium, fungus, parasite or other biological agent that may cause a zoonosis (see "zoonosis").

Abbreviations

- ACA:** Catalan Water Agency
- ACC:** Catalan Consumer Affairs Agency
- ACSA:** Catalan Food Safety Agency
- AESAN:** Spanish Food Safety and Nutrition Agency
- AL:** Local authorities
- ALARA:** As Low as Reasonably Achievable
- SPS:** WHO Agreement on Sanitary and Phytosanitary Measures
- APS:** Health Protection Agency
- HACCP:** Hazard Analysis Critical Control Point
- ARC:** Catalan Waste Agency
- ASPB:** Barcelona Public Health Agency
- BOE:** Official Spanish Gazette
- EC:** European Community
- POCs:** persistent organic contaminants
- DS:** Ministry of Health
- DAR:** Ministry of Agriculture, Food and Rural Action
- DMAH:** Ministry of Environment and Housing
- OJEC:** Official Journal of the European Communities
- DOGC:** Official Journal of the Autonomous Government of Catalonia
- TSE:** transmissible spongiform encephalopathies
- EFSA:** European Food Safety Agency
- FAO:** Food and Agriculture Organisation of the United Nations
- GHPG:** good hygiene practice guide
- PAH:** polycyclic aromatic hydrocarbons
- IARC:** International Agency for Research on Cancer
- SRM:** specific risk materials
- FBD:** foodborne disease
- OIE:** International Office of Epizootics
- GMO:** Genetically modified organisms
- WTO:** World Trade Organisation
- WHO:** World Health Organisation
- PAC:** EU Common Agricultural Policy
- PCBs:** polychlorinated biphenyls
- EU:** European Union

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Legislation, classified by theme

General legislation

Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs. (OJEC L 186, 30.06.1989, p. 23).

Decision No. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJEC L 268, 3.10.1998, p. 1).

Decision No. 2000/96/EC of the Commission of 22 December 1999, on the communicable diseases to be progressively covered by the Community network under Decision No. 2119/98/EC of the European Parliament and Council (OJEC L 28, 3.02.2000, p. 50).

Council Directive 2002/99/EC of 16 December 2002, laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJEC L 18, 23.01.2003, p. 11).

Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJEC L 31, 1.02.2002, p. 1).

Decision No. 2004/478/EC of the Commission of 29 April 2004, concerning the adoption of a general plan for food/feed crisis management (OJEC L 160, 30.04.2004, p. 98).

Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004, on the hygiene of foodstuffs (OJEC L 226, 25.06.2004, p. 3).

Regulation (EC) No. 851/2004 of the European Parliament and of the Council of 21 April 2004, establishing a European Centre for Disease Prevention and Control (OJEC L 142 de 30.04.2004, p. 1).

Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004, laying down specific hygiene rules for food of animal origin (OJEC L 226, 25.06.2004, p. 22).

Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004, laying down specific rules for the organisation of official controls on products of animal origin

intended for human consumption (OJEC L 226, 25.06.2004, p. 83).

Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules (OJEC L 191, 28.05.2004, p. 1).

Regulation (EC) No. 2230/2004 of the Commission of 23 December 2004, laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJEC L 379, 24.12.2004, p. 64).

Regulation (EC) No. 2073/2005 of the Commission of 15 November 2005, on microbiological criteria for foodstuffs (OJEC L 338, 22.12.2005, p. 1).

Crown Decree No. 2210/1995 of 28 December 1995 on the establishment of the National Epidemiological Surveillance Network (BOE 21, 24.01.1996, p. 2153).

Law 11/2001 of 5 July 2001 establishing the Spanish Food Safety Agency (BOE 161, 6.07.2001, p. 24250).

Crown Decree No. 1801/2003 of 26 December, on the general safety of products (BOE 9, 10.01.2004, p. 906).

Law 13/1989 of 14 December, on the organisation, procedure and legal status of the Generalitat of Catalonia administration (DOGC 1234, 22.12.1989, p. 4876).

Law 20/2002, of 5 July, on food safety (DOGC 3679, 17.07.2002, p. 13041).

Law 7/2003, of 25 April, on health protection (DOGC 3879, 8.05.2003, p. 9297).

Decree 302/2004, of 25 May, establishing and approving the functioning of the Register of Agrarian and Food Industries of Catalonia (RIAAC) (DOGC 4142, 27.05.2004, p. 10042).

Transmissible spongiform encephalopathies

Regulation (EC) No. 999/2001 of the European Parliament and of the Council of 22 May 2001, laying down rules for the prevention, control, and eradication of certain transmissible spongiform encephalopathies (OJEC L 147, 31.05.2001, p. 1).

Regulation (EC) No. 1774/2002 of the European Parliament and of the Council of 3 October, laying down health rules concerning animal by-products not intended for human consumption (OJEC L 273, 10.10.2002, p. 1).

Traceability

Council Directive 92/102/EEC of 27 November 1992, on the identification and registration of animals (OJEC L 355, 5.12.1992, p. 32).

Regulation (EC) No. 1760/2000 of the European Parliament and of the Council of 17 July 2000, establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJEC L 204, 11.08.2000, p. 1).

Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJEC L 5, 9.01.2004, p. 8).

Crown Decree No. 1377/200, of 7 December, amending Crown Decree No. 1980/1998, of 18 September, establishing a system for identifying and registering bovine animals (BOE 311, 28.12.2001, p. 49997).

Order APA/3164/2002, of 11 December 2002, establishing and regulating the National Porcine Movement Identification and Registration System computer database (SIMOPORC) (BOE 300, 16.12.2002, p. 43810).

Crown Decree No. 1698/2003 of 12 December, establishing dispositions to apply Community regulations governing the bovine meat labelling system (BOE 1, 1.01.2004, p. 45345).

Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJEC L 268, 18.10.2003, p. 24).

Regulation (EC) No. 65/2004 of the Commission of 14 January 2004, establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJEC L 10, 16.01.2004, p. 5).

Crown Decree No. 1808/1991 of 13 December, regulating the mentions or marks that enable the identification of the batch to which a food product belongs (BOE 308, 25.12.1991, p. 41511).

Zoonoses and zoonotic agents

Directive 2003/99/EC of the European Parliament and Council of 17 November 2003, on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJEC L 325, 12.12.2003, p. 31).

Regulation (EC) No. 2160/2003 of the European Parliament and of the Council of 17 November 2003, on the control of salmonella and other specified food-borne zoonotic agents (OJEC L 325, 12.12.2003, p. 1).

Regulation (EC) No. 1003/2005 of the Commission of 30 June 2005, implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in breeding flocks of *Gallus gallus* and amending Regulation (EC) No. 2160/2003 (OJEC L 170, 1.07.2005, p. 12).

Crown Decree No. 1940/2004 of 27 September, on the surveillance of zoonoses and zoonotic agents (BOE 237, 1.10.2004, p. 32772).

Order PRE/1377/2005 of 16 May, establishing surveillance and monitoring measures for certain salmonellas at egg-laying poultry farms, with a view to establishing a national programme (BOE 118, 18.05.2005, p. 16641).

Contaminants

Council Regulation (EEC) No. 315/93 of 8 February 1993, laying down Community procedures for contaminants in food (OJEC L 37, 13.02.1993, p. 1).

Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs (OJEC L 77, 16.03.2001, p. 1).

Chemical residues in live animals and their products

Council Regulation (EEC) No. 2377/90 of 26 June 1990, laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJEC L 224, 18.08.1990, p. 1).

Council Directive 96/22/EC of 29 April 1996, concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJEC L 125, 23.05.96, p. 3). [Amended by Directive 2003/74/EC of the European Parliament and Council of 22 September 2003 (OJEC L 262, 14.10.2003, p. 17)].

Council Directive 96/23/EC of 29 April 1996, n measures to monitor certain substances and residues thereof in live animals and animal products

and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJEC L 125, 23.05.1996, p. 10).

Crown Decree No. 109/1995 of 27 January, on veterinary medicines (BOE 53, 3.03.1995, p. 7353).

Crown Decree No. 1749/1998 of 31 July, establishing control measures for certain substances and their residues in live animals and their products (BOE 188, 7.08.1998, p. 26910).

Crown Decree No. 2178/2004 of 12 November, prohibiting the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists (BOE 274, 13.11.2004, p. 37490).

Decree 241/1990 of 4 September, establishing control and investigation into residues in animals and fresh meat in Catalonia (DOGC 1360, 29.10.1990, p. 4838).

Decree 141/2000 of 3 April, on the legal status and authorisation procedure for centres distributing and supplying medicines for veterinary use in Catalonia (DOGC 3120, 13.04.2000, p. 4416).

Pesticides

Council Directive 79/117/EEC of 21 December 1978, prohibiting the placing on the market and use of plant protection products containing certain active substances (OJEC L 33, 8.02.79, p. 36).

Council Directive 90/642/EEC of 27 November 1990, fixing the maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (OJEC L 350, 14.12.1990, p. 71).

Council Directive 91/414/EEC of 15 July 1991, concerning the placing of plant protection products on the market (OJEC L 230, 19.08.1991, p. 1).

Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJEC L 70, 16.3.2005, p. 1).

Crown Decree No. 3349/1983 of 30 November, approving the technical and sanitary regulations for the manufacture, sale and use of pesticides (BOE 20, 24.01.1984, p. 1850).

Crown Decree No. 280/1994 of 18 February, establishing the maximum limits for pesticide residues and their control in and on certain products of plant origin (BOE 58, 9.03.1994, p. 7723).

Decree 149/1997 of 10 June, regulating the official register of pesticide facilities and services (DOGC 2418, 23.06.1997, p. 7119).

Materials in contact with food

Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004, on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJEC L 338, 13.11.2004, p. 4).

Crown Decree No. 397/1990 of 16 March, approving the general conditions for materials for food use other than polymerics (BOE 74, 27.03.1990, p. 8562).

Crown Decree No. 118/2003 of 31 January, approving the list of permitted substances for the manufacture of plastic materials and objects in contact with food and regulating certain test conditions (BOE 36, 11.02.2003, p. 5310). [Correction of errata published in BOE 279, 19.11.2004, p. 38192].

Additives

Crown Decree No. 2001/1995 of 7 December, approving the positive list of colorant additives authorised used in food production, and the conditions for their use (BOE 19, 22.01.1996, p. 1884).

Crown Decree No. 2002/1995 of 7 December, approving the positive list of sweeteners authorised used in food production, and the conditions for their use (BOE 11, 12.01.1996, p. 838).

Crown Decree No. 142/2002, of 1 February, approving the positive list of additives other than colorants and sweeteners used in food production, and the conditions for their use (BOE 44, 20.02.2002, p. 6756).

Labelling

Directive 2000/13/EC of the European Parliament and Council of 20 March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJEC L 109, 06.05.2000, p. 29).

Directive 2003/89/EC of the European Parliament and Council of 10 November 2003, amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJEC L 308, 25.11.2003, p. 15).

Crown Decree No. 1334/1999 of 31 July, approving the general law on labelling, presentation and advertising of foodstuffs (BOE 202, 24.08.1999, p. 31410).

Crown Decree No. 2220/2004 of 26 November, amending the general law on labelling, presentation and advertising of foodstuffs approved by Crown Decree No. 1334/1999 of 31 July (BOE 286, 27.11.2004, p. 39355).

Agri-food quality

Decree 2257/1972 of 21 July, regulating standards governing agricultural products in the internal market (BOE 205, 26.08.1972, p. 15717).

Crown Decree No. 1945/1983 of 22 June, on infringements and penalties with regard to consumer rights and agri-food production (BOE 168, 15.07.1983, p. 19830).

Law 26/1984 of 19 July, on general consumer and user rights (BOE 176, 24.07.1984, p. 21686).

Law 14/2003 of 13 June, on agri-food quality (DOGC 3915, 1.07.2003, p. 13142).

Animal health

Council Directive 82/894/EEC of 21 December 1982, on the notification of animal diseases within the Community (OJEC L 378, 31.12.1982, p. 58).

Crown Decree No. 2459/1996 of 2 December, establishing the list of animal illnesses compulsory to report, and the procedure for reporting them (BOE 3, 3.01.1997, p. 96).

Crown Decree No. 2611/1996 of 20 December, regulating national plans to eradicate animal illnesses (BOE 307, 21.12.1996, p. 38115).

Crown Decree No. 1440/2001 of 21 December, establishing the veterinary health alert system (BOE 12, 14.01.2002, p. 1612).

Law 8/2003 of 24 April, on animal health (BOE 99, 25.04.2003, p. 16006).

Regulation of livestock farms

Crown Decree No. 324/2000 of 3 March, establishing basic regulations governing pig farms (BOE 58, 8.03.2000, p. 9505).

Crown Decree No. 209/2002 of 22 February, establishing regulations governing bee farms (BOE 62, 13.03.2002, p. 10366).

Crown Decree No. 479/2004 of 26 March, establishing and regulating the general livestock farm register (BOE 89, 13.04.2004, p. 14978).

Crown Decree No. 1547/2004 of 25 June, establishing regulations governing rabbit farms (BOE 154, 26.06.2004, p. 23472).

Animal welfare

Crown Decree No. 54/1995 of 20 January, on protection of animals at the time of slaughter (BOE 39, 15.02.1995, p. 15146).

Crown Decree No. 1041/1997 of 27 June, establishing regulations for the protection of animals during transport (BOE 163, 9.07.1997, p. 21093).

Crown Decree No. 348/2000 of 10 March, transposing into Spanish law Directive 98/58/EC, concerning the protection of animals kept for farming purposes (BOE 61, 11.03.2000, p. 10192).

Law 22/2003 of 4 July, on the protection of animals (DOGC 3926, 16.07.2003, p. 14226).

Feed

Council Directive 95/53/EC of 25 October 1995, fixing the principles governing the organization of official inspections in the field of animal nutrition (OJEC L 265, 8.11.1995, p. 17).

Council Directive 70/524/EEC of 23 November 1970, concerning additives in feedingstuffs (OJEC L 270, 14.12.1970, p. 1).

Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs (OJEC L 86, 6.04.1979, p. 30).

Council Directive 96/25/EC of 29 April 1996, on the circulation and use of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC (OJEC L 125, 23.05.1996, p. 35).

Directive 2002/32/EC of the European Parliament and Council of 7 May 2002, on undesirable substances in animal feed (OJEC L 140, 30.05.2002, p. 10).

Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003, on additives for use in animal nutrition (OJEC L 268, 18.10.2003, p. 29).

Commission Decision 2004/217/EC of 1 March 2004, adopting a list of materials whose circulation or use for animal nutrition purposes is prohibited [notified under document number C (2004) 583] (OJEC L 67, 5.03.2004, p. 31).

Crown Decree No. 465/2003 of 25 April, on undesirable substances in animal feed (BOE 102, 29.04.2003, p. 16485).

Regulation (EC) No. 183/2005 of the European Parliament and of the Council of 12 January 2005,

laying down requirements for feed hygiene (OJEC L 35, 8.02.2005, p. 1).

Plant health

Law 43/2002 of 20 November, on plant health (BOE 279, 21.11.2002, p. 40970).

Crown Decree No. 58/2005 of 21 January, adopting protective measures against the introduction and spread in national and European Community territory of organisms harmful to plant or plant products and to exportation or transportation to Third Countries (BOE 19, 22.01.2005, p. 2583).

New ingredients, new foodstuffs and genetically modified organisms

Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997, concerning novel foods and novel food ingredients (OJEC L 43, 14.02.1997, p. 1).

Commission Regulation (EC) No. 50/2000 of 10 January 2000, on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms (OJEC L 6, 11.01.2000, p. 15).

Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003, on genetically modified food and feed (OJEC L 268, 18.10.2003, p. 1).

Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJEC L 268, 18.10.2003, p. 24).

Crown Decree No. 348/2001 of 4 April, regulating the production, marketing and importation of foodstuffs and food ingredients treated with ionising radiation (BOE 82, 5.04.2001, p. 12825).

Law 9/2003 of 25 April, establishing the legal framework for confined use, voluntary release and marketing of genetically modified organisms (BOE 100, 26.04.2003, p. 16214).

Online resources

Catalonia

Catalan Consumer Affairs Agency: <<http://www.consum.cat>>
Catalan Food Safety Agency: <<http://gencat.net/salut/acsa>>
Barcelona Public Health Agency: <<http://www.aspb.es>>
Ministry of Agriculture, Food and Rural Action: <<http://www.gencat.net/darp>>
Ministry of Trade, Tourism and Consumer Affairs: <<http://www.gencat.net/ctc>>
Ministry of Environment and Housing: <<http://mediambient.gencat.net>>
Ministry of Health: <<http://www.gencat.net/salut>>
Ruralcat: <<http://www.ruralcat.net>>

Spain

Spanish Food Safety and Nutrition Agency: <<http://www.aesa.msc.es>>
Ministry of Agriculture, Fisheries and Food: <<http://www.mapya.es>>
Ministry of Health and Consumer Affairs: <<http://www.msc.es>>

European Union

Biotechnology: <<http://europa.eu.int/comm/biotechnology>>
Directorate-General for Agriculture and Rural Development: <<http://europa.eu.int/comm/agriculture>>
Environment: <<http://europa.eu.int/comm/environment>>
European Food Safety Authority (EFSA): <<http://www.efsa.eu.int/>>
Directorate-General for Health and Consumer Protection:
<http://europa.eu.int/comm/dgs/health_consumer>
Summaries of legislation-Food Safety: <<http://europa.eu.int/scadplus/leg/es/s80000.htm>>

International organisations

Codex Alimentarius – Reports: <<http://www.codexalimentarius.net/web/reports.jsp>>
Food and Agriculture Organization of the United Nations (FAO) – Food and Nutrition – ESN:
<<http://www.fao.org/es/ESN>>
International Plant Protection Convention – International Phytosanitary Portal (IPP):
<<https://www.ippc.int/IPP/En/default.jsp>>
The Joint FAO/WHO Expert Committee on Food Additives (JECFA):
<<http://www.codexalimentarius.net/web/jecfa.jsp>>
The Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA):
<<http://www.codexalimentarius.net/web/jemra.jsp>>
The Joint FAO/WHO Meetings on Pesticides Residues (JMPR):
<<http://www.codexalimentarius.net/web/jmpr.jsp>>
World Health Organization Food Safety (WHO): <<http://www.who.int/foodsafety/en>>
WHO – Regional Office for Europe: <<http://www.euro.who.int/foodsafety>>
World Trade Organization – Sanitary and Phytosanitary Measures:
<http://www.wto.org/spanish/tratop_s/sps_s/sps_s.htm>

Germany

Federal Institute for Risk Assessment: <<http://www.bgvv.de>>

Federal Ministry of Consumer Protection, Food and Agriculture:
<<http://www.verbraucherministerium.de>>

Belgium

L'Agence fédérale pour la Sécurité de la Chaîne Alimentaire (AFSCA):
<<http://www.favv-afsca.fgov.be>>

Canada

Canadian Food Inspection Agency (CFIA): <<http://www.inspection.gc.ca>>

Canadian Health Products and Food Branch: <<http://www.hc-sc.gc.ca/hpfb-dgpsa>>

Denmark

Danish Veterinary and Food Administration: <<http://www.uk.foedevarestyrelsen.dk>>

United States

Food and Drug Administration (FDA): <<http://www.fda.gov>>

Food Safety and Inspection Service –FSIS (USDA): <<http://www.fsis.usda.gov>>

National Food Safety Programs and Activities: <<http://vm.cfsan.fda.gov/~dms/fs-toc.html>>

France

Agence Française de Sécurité Sanitaire des Aliments (AFSSA): <<http://www.afssa.fr>>

Ireland

Food Safety Authority of Ireland (FSAI): <<http://www.fsai.ie>>

United Kingdom

Food Standards Agency (FSA): <<http://www.food.gov.uk>>

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