

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 and 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.

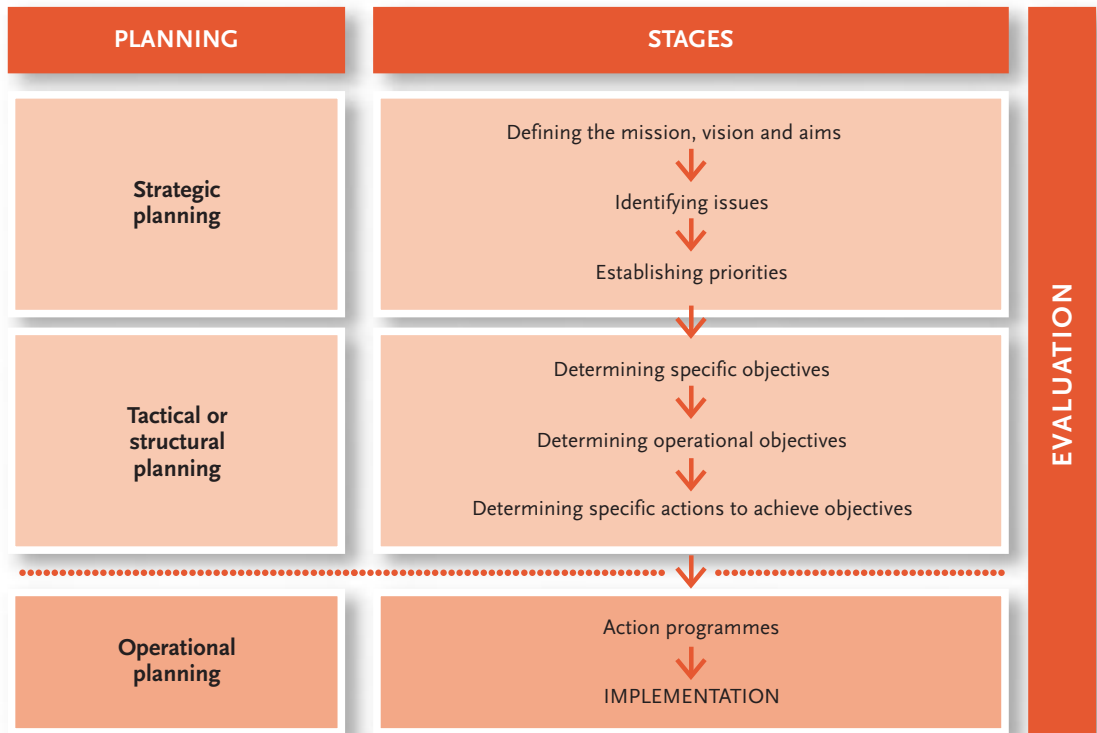
Study of the environment. This is aimed at ascertaining the external circumstances and factors which define the real situation in the environment in which the plan is to be applied. The factors studied include threats, unfavourable situations, opportunities and environmental factors that might provide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

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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,

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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.

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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.