

Chapter 1

Basic food safety concepts

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1.1. Food safety: facts and figures

1.1.1. A global problem

Every day in every country people fall ill from the food they have eaten. These **foodborne illnesses** are caused by dangerous micro-organisms and/or toxic chemicals.

Even though governments throughout the world do their utmost to improve the safety and quality of food, the high number of foodborne illnesses is a major public health issue for all countries. The WHO (World Health Organisation) has estimated that **1 800 000 people die each year** from diarrhoeal diseases, and most cases can be attributed to contaminated food or drinking water (WHO, 2007). The cost in human suffering is thus far too high, in particular for the most vulnerable population groups (infants and young children, pregnant women, the elderly, the ill, etc.). Malnutrition, coupled with diarrhoea caused by unsanitary food, can be devastating and this vicious combination is the primary cause of child mortality in hygiene-deficient countries.

The WHO has also recognised that foodborne illnesses:

- ▶ are a problem in developing and developed countries alike;
- ▶ place a burden on healthcare systems;
- ▶ seriously affect infants, young children, the elderly and those who are already ill;
- ▶ spawn a vicious circle of diarrhoea and malnutrition;
- ▶ undermine the economy and national development efforts, as well as international trade.



Participants in the WHO/FAO International Conference on Nutrition (Rome, 1992) recognised that '*Access to ... safe food is a right of each individual*'. In this context, the availability of suitable food should be seen as a top priority by governments, industry and consumers.

Yet cases of food poisoning are **constantly rising**. It is estimated that foodborne illnesses affect from 5 to 10 % of the population in industrialised countries (WHO, 1999). Epidemics caused by bacteria such as *Campylobacter jejuni*, *Escherichia coli* O157, *Listeria monocytogenes*, *Salmonella*, etc. or by viruses have struck thousands of victims in Europe, Japan and the USA. **New hazards** are discovered every year, associated with the presence of chemical contaminants or toxins that form when food is processed or prepared. Food allergies are also on the rise.

Food hygiene is regularly cited as a cause of food poisoning. Those who produce and distribute food obviously must respect rules of hygiene, but individuals should also be concerned about the food they eat. This point will be discussed in Chapter 2 of this manual.

Main factors leading to foodborne illness outbreaks (FBI) in France (Source 'Conserver mieux' - CTCPA, 1997)

Contamination of raw materials:	54 %
Non-respect for the cold chain during meal preparation:	40 %
Error in the preparation process:	35 %
Too much time between preparation and consumption:	25 %
Contamination by equipment:	21 %
Contamination by employees:	17 %
Non-respect for the hot chain:	14 %

Nonetheless, food poisoning is not **caused solely by insufficient hygiene but also by** various types of **contaminants** which, at certain concentrations, can be toxic for the consumer. Despite the recognised health benefits of regular fruit and vegetable consumption, recent studies on consumer exposure to pesticide residues point to an identifiable risk of poisoning for **some groups** such as children. (W. Claeys *et al.*, 2010).¹

Risks for the average consumer, however, remain low, but they can be reduced further when simple and efficient hygiene rules are applied and all operators implement food safety management systems based on an analysis of the hazards linked to their professional practices and the type of product they handle.

1.1.3. Evolution of the concept of product 'quality'

The international standard ISO 9000 defines terms related to quality. Quality is defined as the degree to which a set of inherent characteristics fulfils requirements. Quality comprises multiple characteristics, or components, that depend on the product or service under consideration.

¹ W. Claeys, J.F. Schmit, C. Bragard, G. Maghuin-Rogister, L. Pussemier & B.Schiffers (2010) - Exposure of several Belgian consumer groups to pesticide residues through fresh fruit and vegetable consumption. Food Control 22 (2011): 508-516.

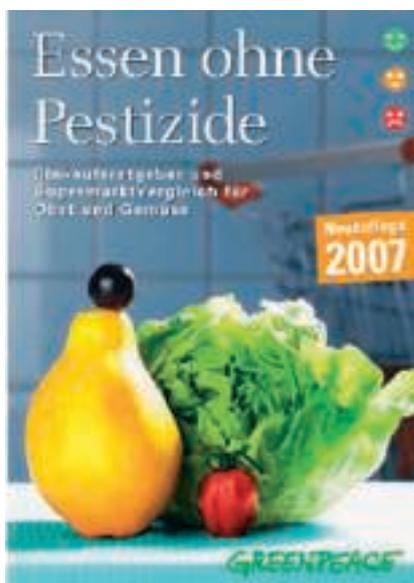
The final objective of any 'quality strategy' will be to reconcile 'needs / specifications / actual production' in all circumstances - for **controlled quality** is found at the centre where the three circles intersect! Quality strategies will be discussed in Chapter 6 of this manual.



Food safety and traceability requirements reflect the desire of buyers and consumers to know **where, how, and when** the food on their plate was produced in order to have a guarantee that it is safe.

1.1.4. Significant evolution in retailers' approach

Food safety **cannot be used as a sales argument** because it is illogical to sell foods that are 'safer' than others (they are either safe or not!). This aspect is nevertheless promoted by some retailers who oblige suppliers to apply **their own private standards** in the place of regulations such as MRL (maximum residue levels authorised for pesticides).



In Germany, for example, after the Greenpeace campaigns in the retail sector on pesticide residues in fruit and vegetables ('Eating pesticide-free') the main supermarket chains imposed MRLs well below those authorised by the EU, even though reducing the limit considered as acceptable by 20 to 30 % has no effect on the consumer's level of risk!



Campaign in the Netherlands (with the 'Hypermarket C1000' label): Mandatory limit of 80 % of MRL and maximum of 3 detectable residues authorised in products.

Examples of residue requirements set by various supermarket chains:
Maximum % of the European MRL considered as acceptable

			
80 % MRL	70 % MRL	33.3 % MRL	50 % MRL

Moreover, the above list does not include retailers that impose their own lists of authorised active substances for use on crops, which are more restrictive than official authorisations.

Food safety and quality have become a major concern for the **European retailing and distribution industry**, which uses it as a marketing argument to address consumers' concerns and calls for change from some pressure groups. Retailers have thus also become 'standards developers' and given their economic clout they can easily take the place of regulations.

In this context, it is clear that the **retail industries are particularly keen to know** whether ACP fruit and vegetable producers master production and packaging techniques, especially as regards food hygiene and the use of pesticides!

Whether food is sold locally or exported it must be produced in accordance with general principles of hygiene that are recognised throughout the world (such as those laid down in the *Codex Alimentarius*).



Food exported to the European Union from other countries, however, must also comply with the general requirements of European regulations. This is because the **regulations of the destination market apply *de facto*** to ACP producers. They cannot ignore these requirements if they wish to access these markets or merely to keep their present share of the market. For this reason, even though the **regulations of the place of production apply as a priority**, this manual will regularly refer to European regulations.

1.1.5. Restoring the confidence of stakeholders and consumers

One connotation of the word 'safe' is '*trustworthy, reliable*'. A series of food crises, however, has shaken European consumers' trust in the safety of their food. Despite efforts deployed in the European Union since 2000 to revise its regulations and operator monitoring systems, the latest opinion polls show that consumers still worry about food safety. The latest 'Eurobarometer',² published in 2010 after a survey of 26 691 individuals in all 27 Member States, shows for example that:

- ▶ 79 % of those surveyed stated they were deeply concerned about the safety of their food (much more important than dietary matters);
- ▶ 48 % worry about food affecting their health (compared to 44 % for road accidents);
- ▶ 72 % are worried about pesticide residues. **This is the number one 'risk'** (freshness ranks fourth and GMOs rank sixth)!

To ensure that food is harmless and restore consumers' confidence and sense of security, it is necessary:

- ▶ **to reinforce and continually update the regulatory framework** to reflect technical changes and the results of risk analyses;
- ▶ **for operators to organise self-evaluation and risk control systems** based on HACCP principles;
- ▶ to identify the data to be recorded to **ensure product traceability**: to be able to trace the history, destination or origin of a product;
- ▶ to guarantee application of these measures through **inspections, monitoring plans, and internal and external audits**.

Confidence can only be restored when:

1. **Food hygiene is guaranteed** (by taking measures and organising the conditions to prevent hazards and ensure that food products are suitable for consumption).
2. **Food safety is guaranteed** (by using production modes that assure that the food is not harmful to health: good practices and quality strategies).
3. Efforts are taken to **provide correct information** to all stakeholders and the population in general (information, traceability, withdrawal and recall procedures).
4. All actors in the food chain adopt an approach towards food safety that entails a **continuity** of responsibility through the whole life cycle of the product, in other words from **farm to fork**.



² Eurobarometer, 2010 - <http://www.efsa.europa.eu/en/riskcommunication/riskperception.htm>.

1.2. Food safety: key concepts

1.2.1. The concepts of 'hazard', 'risk' and 'crisis'

In order to meet food quality and safety requirements, agricultural businesses must identify all aspects of their activities that are decisive factors for the safety of their products. They must be able to **control all hazards at all stages** of product life cycle (development, production, storage, transport, marketing) in order to meet specifications (regulatory and market) and assure consumers that their food is safe.

The operators must therefore be able to **identify all hazards** (physical, biological or chemical) that can potentially contaminate their products at different stages of production. They must also be able to **assess the level of each risk** (probability) according to their working conditions, procedures and practices. On the basis of these analyses, the appropriate control measures, adapted to the type and level of risk, can be adopted. The company must then make sure that these measures are effectively implemented, complied with and regularly reviewed.

It is important to understand the difference between the terms 'hazard' and 'risk':

Hazard: a physical or biological agent or substance with the potential to cause a proven adverse effect on health. The main 'hazards' will be discussed in Chapter 3.

Risk: probability of an adverse health effect. The degree of risk is a combination of the probability and the severity of the effect (type of harm, number of people affected, etc.). 'Risk' refers to exposure to a hazard, in other words to consumption of a contaminated food (quantity and frequency of consumption).

Risk analysis at every stage of production and packaging is thus indispensable and must precede any preventive action. **The analysis method must be one that has been tested and validated.** In the agri-food sector, HACCP (Hazard Analysis Critical Control Point) is considered to be the most efficient and is the most widely used. It is generally **mandatory by regulation** for all food processing firms. The *Codex Alimentarius*³ recognises HACCP as the benchmark for identifying hazards and controlling risks in the food sector.

³ The *Codex Alimentarius* is a set of internationally recognised laws and standards applicable for processes, guidelines and recommendations on food, food production and food safety. The Codex standards are the authority in the agri-food sector and most of the recommendations issued by this body have been integrated into European and other regulations.

Many private standards also recommend and encourage application of HACCP principles. For primary production,⁴ however, at present it is only **recommended** (in the framework of European regulations). As we shall see below (Chapter 2), on the one hand programmes to control hygiene conditions (or PRP) must be introduced before a HACCP plan can be implemented, and on the other HACCP alone cannot guarantee food safety.

It is also important to clarify the meaning of the term '**food crisis**'. According to terminology accepted by experts, a 'crisis' is a situation in which a **real or hypothetical risk** can lead to **collective misgivings** throughout a population group. It is clear that a crisis can occur even if the risk never materialises.

The crisis occurs when a **malfunction** is measured or when a gap between reality and expected standards is either measured or suspected. This can occur, for example, when **results of an internal or external control** (including documentary controls) or **of analyses** reveal that insufficient mastery of a process has resulted in non-conformity with a standard (e.g.: MRL exceeded) or product contamination (e.g.: traces of dioxin in eggs, avian flu virus detected, etc.).

A crisis is also a situation where organisations, private firms and competent authorities (ministries, inspection agents, laboratories, etc.) strive to cope with a situation considered as 'critical'. For a given period of time they find themselves in the forefront where, under **heavy external pressure and acute internal tensions**, they enter into conflict with one another, often under the media's watchful eyes!

Europe has gone through a series of 'crises', all with repercussions among the public, regardless of how serious the crises actually were. Over the past decade alone we can cite:

1997	Numerous cases of BSE (mad cow disease)
1999	Listeria – Illegal dioxin levels in chickens – Contaminated Coca-Cola
2001-2002	Foot and Mouth disease, GMOs, various meat origin frauds
2004	Avian (bird) flu
2006	BTV - Catarrhal fever (blue tongue disease)
2008	Melamine-tainted milk powder in China

To restore consumer confidence, private firms and public authorities alike must prepare **crisis management procedures**, establish mutual trust and get into the habit of communicating together when a malfunction is observed.

⁴ Primary production: The set of steps taken in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc.

1.2.2. The concept of 'hygiene' and respecting the cold chain

It is up to each actor in the food production and distribution chain to take all steps to make sure that products placed on the market are free of all risks to consumers' health.

Many of the hazards attributed to food originate in the **failure to respect hygiene rules at the place of production**. This can be in the field or on the packaging line, or during storage or transport. For this reason general rules of hygiene applicable to the food industry are also valid for primary production. As a large portion of **fruit and vegetables are eaten raw**, hygiene is an essential requirement for the conformity of these products.

Simple or cross-contamination of fruit and vegetables, either before or after harvest, can have **several causes**. Growing areas, soil, inputs (manure), equipment and staff are all potential germ vectors. Each producer or firm should organise hygiene measures and practices that are adapted to the specific conditions of their production area, type of products, methods and techniques, and staff in order to monitor and control risks to food safety and promote the production of wholesome fruit and vegetables. Chapter 2 will discuss sources of contamination and ways to understand the mechanisms involved.

Following basic principles of hygiene considerably reduces risks that food will be contaminated with germs.

Preservation conditions during storage and transport also have a **considerable impact on food quality**. Fruit and vegetables must be handled with care to avoid injuries that make the products more vulnerable to pathogens.

Failure to keep food at the right **temperature and relative humidity** can lead to spoilage and favour the development of pathogenic micro-organisms. The 'cold chain' must be respected absolutely!



*To ensure the stability of physiological and organoleptic properties of fresh produce, the **optimal temperature and relative humidity of storage must be known for each product**. If required, fruit and vegetables must be harvested, transported and preserved at low temperatures (examples: green beans, tomatoes, etc.).*

1.2.3. The concept of 'product'



'Product' is understood to mean the **result of production**, in other words a coherent sequence of operations (the term 'process' is discussed below).

In the broad sense of the term, products are all foods of plant or animal origin that a producer **places on the market**.

When we speak of a 'product' we are referring to products that have been harvested, possibly processed, and packaged.

Other foods are not considered to be '*products*' in the strict sense of the term, even though they are marketed. This is the case for products that have been picked or collected in natural conditions, such as mushrooms, berries, small fruits, aromatic herbs, edible insect larvae or gastropods snails, or even honey produced by colonies in the wild. This is also the case for food that has been fished or hunted.

Despite the fact that these foods were not produced under someone's responsibility, but were merely 'collected', **the person selling these foods nonetheless remains completely responsible** for ensuring that they do not harm consumers' health. **Conformity with health and safety standards must be ascertained.**

Each type of food product is associated with different types of risks due to their:

- ▶ **nature** (origin, composition, sensitivity);
- ▶ **production mode**;
- ▶ **preservation mode**;
- ▶ **mode of preparation and consumption** (raw or cooked).

It is thus important for the producer to be fully aware of the **characteristics** of the products and processes in order to **evaluate the risks**.

Some types of food can be considered as '**high-risk foods**'. A majority of cases of food poisoning are in fact caused by:

- ▶ Eggs and egg-based products, which account for about one third of foodborne illness outbreaks (FBI);
- ▶ Poultry, in particular chicken and minced chicken meat;
- ▶ Food **eaten raw** (fruit, vegetables, fish, meat or shellfish).

❑ Eggs and egg-based products



According to the US Department of Agriculture (USDA) about 2.3 million of the 50 billion eggs produced each year are infected with *Salmonella* (primarily *Salmonella* Enteritidis).

The main means of prevention is to respect the **cold chain** and to pay scrupulous attention to use-by dates.

❑ Poultry and poultry-based products

Chicken is often a *Salmonella* carrier. The mere presence of these bacteria does not pose any particular risk because chicken is almost always eaten cooked. However, *Salmonella* brought into the kitchen by this means can **contaminate other food items that are not cooked** (such as vegetables) (see Chapters 2 and 3 of this manual). Food can be contaminated:



- ▶ Either **directly**: if the chicken directly touches other food, in the refrigerator for example;
- ▶ Or through **surfaces** that later come into contact with other food.

The bywords therefore are strict hygiene – from hatching to slaughter and cutting – and thorough cooking.

❑ Foods eaten raw or only slightly cooked



Fruit and vegetables, even when eaten raw, should in principle not pose high risks for consumers, apart from allergies that some people may have to exotic fruit which is often allergenic.

Eaten raw, they are rarely harmful and are even highly recommended by nutritionists ('eat five portions of fruit and vegetables per day').

Nonetheless they can pose **serious risks** for consumers due to the presence of:

- ▶ **pathogenic micro-organisms**, especially of faecal origin, through accidental contamination during production (e.g.: tainted irrigation water), harvest (e.g.: unwashed hands), transport (e.g.: insufficiently disinfected containers), or packaging (e.g.: insufficient hygiene);
- ▶ **'toxins'** (mycotoxins) caused by poor storage conditions and overlong preservation;
- ▶ chemical residues (nitrates, pesticides, biocides) or heavy metals which contaminate the food.

Prevention essentially means respecting Good Agricultural Practices and applying good hygiene measures during harvest and packaging.



Meat and fish in principle should be no more risky than other foods, since they are generally only eaten after cooking, which eliminates most parasites and pathogenic bacteria.

Nevertheless, with changing preparation and consumption habits (the sushi fad, for instance), these foods become more risky with respect to **food poisoning**.

When eaten raw they pose a much higher risk than other products for the following reasons:

- ▶ Animals are **natural carriers of certain parasites** (such as *Anisakis*, which can reproduce or survive in the human intestine after being consumed in raw fish: herring, mackerel, tuna, salmon, etc., or *Ascaris*, found in the intestines of many animals). This will be discussed in further detail in Chapter 3 of this manual.
- ▶ Animals are **naturally contaminated on the surface** (skin) by excrement and thus carry germs. Even washing after slaughter cannot totally eliminate these germs.
- ▶ Sale and distribution of meat and fish imply **cutting/slicing operations**, or mincing and mixing, all occasions where the food is liable to be contaminated by staff, equipment, work surfaces or the food products themselves. In the case of minced meat, contaminants spread all the way to the centre of the mix and only thorough cooking can eliminate the bacteria.

Prevention does not require complicated measures: fish and meat must be cooked to 70°C (at least). Fish can be eaten raw after it has been deep frozen for a few days at -20°C.

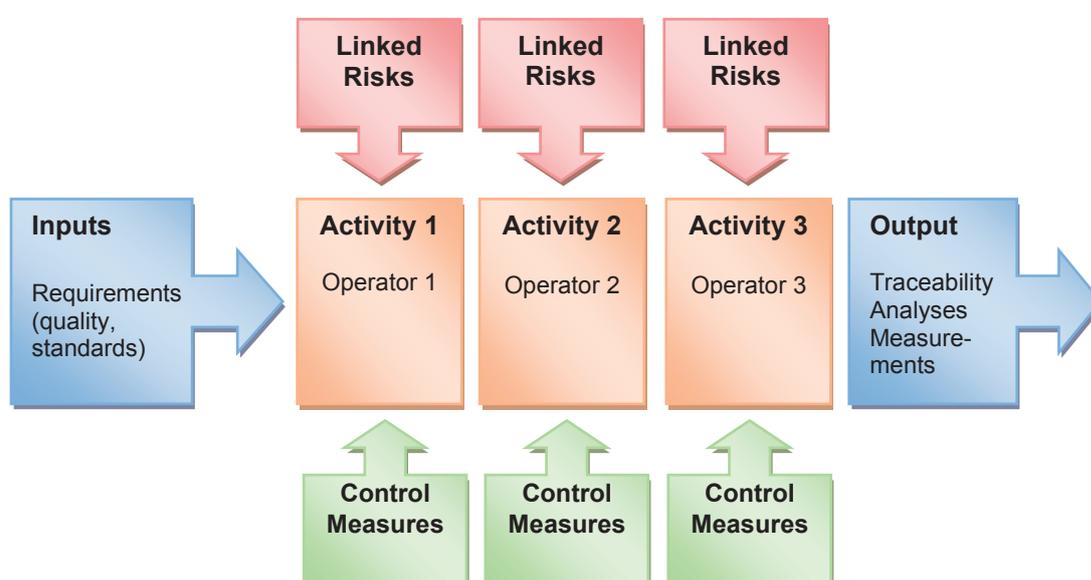
□ Allergy-causing foods

In addition to risks of biological or chemical contaminants, there is also the risk of allergy that the presence (even traces) of certain foods or food components (such as egg yolks, celery, groundnuts) can pose for sensitive consumers. The producer must be aware of the risk of cross-contamination between products.

1.2.5. The concept of 'process'

A process can be described as a **chain of activities** that transforms 'input data' into 'output data'. According to ISO 9000 a process is a sequence of activities accomplished by different players in order to meet an internal or external need by making a product or service available to the customer. Process inputs can be a product, raw material or information.

'Placing a food product on the market' is a **complex process** that requires the **involvement of several operators**. It is also one that requires a combination of **different skills** to attain an objective. A company's production process approach can be depicted as follows:



An objective and meticulous analysis of the processes is important in order to identify:

- ▶ The *sequence of operations* (steps in the process), and to be able to distinguish between **operations that can directly influence the safety** of a product and those that are production 'process supports' (which, although important, do not have a direct or indirect influence). This analysis is a crucial step in organising hygiene measures, drawing up an HACCP plan and choosing the appropriate control measures. As each company has its own organisation mode, this type of analysis **cannot be transposed** from one to another.
- ▶ The *risks linked to each operation* (e.g.: crop management, harvest, transport, cleaning, etc.).
- ▶ The *responsibilities of each entity involved* and the skills required for each.
- ▶ The *inspection measures* (records necessary for traceability) and *control measures* that are relevant for each step in the process.

Describing the overall process, in other words the chronological sequence of key steps and the operations carried out, **is something that must be validated on site**. The analysis consists of examining the whole process and methodically calculating the relative importance of each relevant parameter. This involves visits to the various process

sites, interviews with staff and customers, measurements and analyses, all of which in a fact-finding approach.

The **complete analysis of the process will yield a picture of how a company operates**. It will be used to ascertain its results in terms of quality and conformity of its products, and also to foresee the risks associated with its organisational and functional mode.

1.2.6. The concept of 'system'

Food safety must be **conceived as an 'organised system'** with the aim of meeting a regulatory objective (producing safe and suitable food) and, if relevant, other contractual objectives (complying with one or more private certification schemes). The industry refers to this as a **Food Safety Management System, or FSMS⁵** (see Chapter 6).

All food safety management systems must be grounded in the elements that the ISO 22000:2005 standard deems as essential to guarantee the safety of food at every link in the food chain:

1. interactive communication between all players in the food chain;
2. systemic approach (system-based management);
3. prerequisite programmes;
4. HACCP principles.



As for any system, a company's FSMS must be designed and prepared. It is then built, managed, evaluated regularly, adjusted and improved (principle of ongoing improvement).

Although a management system can be certified if the customer requires this or if it represents a competitive advantage, **certification in itself does not guarantee** that food safety objectives have been met. The company's objective should be quality and conformity of the products, not mere *certification*.

⁵ In reality this system often covers management of *food and phytosanitary* quality. It deals with regulatory requirements concerning quarantine organisms in relation to phytosanitary certification for exports.

1.2.7. The concept of 'traceability'

Traceability of a product means the ability to identify:

- ▶ all stages of its manufacture,
- ▶ the origin of its components and their suppliers,
- ▶ where the product and its components have been stored,
- ▶ checks and tests on the product and its components,
- ▶ equipment used in manufacturing or handling,
- ▶ direct customers who bought the product.

Traceability aims to meet **two different yet complementary objectives**:

1. It must be able to **locate** the product in space and time. *Tracking* means the ability to physically follow a product consignment. This is especially useful in a food crisis, to locate products that have to be withdrawn or recalled.
2. Traceability, however, also means being able to *trace* information on the **history and composition of the product**: origin of the seed or plants, crop management practices, inputs used in production, plant protection treatments, processing methods and steps, and so on.

Setting up a 'traceability system' is a *sine qua non* for food safety and is also mandatory by regulation. The steps to follow when organising such a system are described in PIP manual 2.



1.3. The key role of operators in ensuring food safety

1.3.1. The operator's responsibility is the cornerstone of the regulatory approach



There have been **fundamental changes** in the management of food safety over the past 20 years, through efforts to implement and extend a **new approach to food safety**.

The result of this evolution in Europe is the '*food hygiene package*', introduced in 2004, which was the foundation for the new European regulations.

Before these innovations, food safety was primarily based on the obligation for operators to respect a long list of '*requirements*' (laid down in laws and increasingly detailed and precise with each revision). These **requirements** (or control measures) ranged from compliance with hygiene measures to **details** relating to equipment and installations (such as the height of tiled walls in slaughterhouses), mandatory inspections and registrations, etc.

These requirements stemmed more from the accumulated experience of agri-business professionals (producers and inspectors) about which requirements were effective, than from a true *a priori* risk analysis. Over time and with the need to adopt new preventive measures as a result of real incidents, measures were reinforced and new requirements were set out in legal texts and ever more voluminous professional guides.⁶

The concept of food safety at the time was based on the hypothesis that strict compliance with all requirements would guarantee the production of safe and suitable food (**best endeavour obligation** to guarantee a satisfactory result).

This approach was **reassuring for producers**, who merely had to apply the regulations strictly to be absolved of all responsibility. It also made it **easy for inspectors to assess conformity** because it was enough to follow predefined checklists, without worrying about the importance or usefulness of a given hygiene measure in the context of the company being inspected, or the usefulness of their records on the safety of the product in the context of the process. Under this approach, the risk analysis was deemed to be definitive and the measures required therefore applied to all operators in a given sector, regardless of the size of the company, the nature of its products, the qualification of its staff or the characteristics of the natural or work environment.

⁶ The US and Canada's approach to food safety is still based on the principle of 'written food protection guidelines for industry' (according to Eric Poudelet, DG SANCO, in a personal memo, 2010). It is not surprising that this 'diagnosis and solutions' approach developed everywhere, because veterinarians were the first professionals to adopt a health policy for the meat and fish industry.

This approach **carried the seeds** of what would later bloom into the '*food crises*' of the late 1990s that shook Europe's faith in its food safety system. As the whole system revolved around the *inspection* of operators, producers who passed these inspections were not held responsible. The concept at this time – precisely those years when '*quality assurance*' was the hot topic – can be grossly summed up as follows: the inspector, and thus the administration responsible for controls, on signing the certificate of conformity, assumed responsibility for the safety of products placed on the market by the producer.

Furthermore, under this system, the need for stronger safety guarantees equates with more controls. However, simple statistical analysis shows that, for substances with a low accepted prevalence level, the absence of a micro-organism can only be guaranteed with a sufficient level of confidence by analysing a very large number of samples, which is neither economically feasible nor manageable given the capacity of laboratories. So this approach quickly reaches its limits.

The **current approach** to food safety has completely reversed the role of each party.

The 'new approach' is **non-prescriptive** and **focuses on the operator's accountability**. It sets general objectives without imposing methods. It is up to operators to define means (for example in Good Practice Guides) and apply them. Operators now have the **duty to achieve a given result**, in contrast with the earlier best endeavour obligation.

- ▶ **Safety objectives** are regulatory, thus **mandatory!**
- ▶ The **means** to attain these objectives are guidelines, therefore their **application is voluntary!**

The defining feature of the 'new approach' is **greater liberty and margin of manoeuvre for operators**, who bear prime responsibility for food safety management: this is the principle of active accountability (Bolnot, 2008).

It is based on the principle of guiding the development of control measures and monitoring such measures, based on **analysis of the risks linked to the production processes employed in the producer's context**, with the company's own realities, means, resources, equipment, staff qualifications, regulatory requirements for its products and for its customers, and so on⁷.

'*Risk analysis*' is at the heart of the system, and producers are held accountable for organising efficient health quality management systems, based on **HACCP** and **self-evaluation of their practices**.

⁷ See for example: SAFE FOODS - *Promoting Food Safety through a New Integrated Risk Analysis Approach* - EUFIC, The European Food Information Council.

The HACCP method establishes **7 basic principles that the producer must respect:**

1. Identify the hazards relevant to its activities and product.
2. Identify the 'critical points' where control is absolutely essential. These are called Critical Control Points, or CCP.
3. Establish critical limits (that must not be exceeded) for each control point.
4. Establish CCP monitoring requirements (self-evaluation).
5. Plan corrective actions in case of malfunction (which can occur in the best of companies).
6. Establish procedures to verify and validate that the system is working as intended (internal audits).
7. Document its activities, record data on its procedures and keep this information on file.

It is worth noting that the risk of a 'mistake' is not excluded under this approach. What is unacceptable is not the malfunction itself, but rather the failure to identify it or to react immediately when a problem is detected

Traceability must enable the operator to show that the problem has been identified in time and that it was solved quickly and effectively.

This approach is less 'reassuring' for the producer (who will need advice, training and guides, since the **'critical points' are not pre-determined**). It is also less 'comfortable' for the control authority, who for each firm and each product must verify that the risk analysis has been correctly conducted and that control measures are appropriate and being applied. This approach goes well beyond the 'checklist' and 'inspection' logic, applying 'audit' principles instead!

Although Europe has deliberately moved towards simpler regulations with fewer constraints but more responsibilities, the major wholesalers and retailers have set up schemes to evaluate their suppliers on the basis of their own **reference standards** (such as GLOBALG.A.P. or TNC). Analysis of different specifications for such standards reveals a strong convergence of their basic requirements: in accordance with the '*due diligence*' principle, producers must prove that they have taken **all possible precautions** to make sure that their fruit and vegetables are not dangerous for the consumer. They tend to fall back on the principle of 'requirements' **but these are not based on an analysis of real risks in the producer's context.**

The plethora of *private standards* does not make it easy for producers to adopt a coherent approach to their food safety management systems: one that combines a 'responsible approach' in terms of regulations and a 'standards approach' in terms of market requirements.

1.3.2. Operators' responsibilities and obligations under regulations

Regulation (EC) 178/2002⁸ (*General Food Law*) clearly defined the responsibilities of the various players (adapted from E. Poudelet, 2010):

Operators must

- Ensure that food hygiene conditions are met at every stage of production
- Place on the market products that comply with standards
- Ensure the traceability of processes and products
- Be able to withdraw non-compliant products immediately and to warn customers.
- Keep the authorities informed and cooperate with them

Competent Authorities must

- Establish the regulations and standards applicable to the products
- Evaluate sanitary and phytosanitary risks transparently and independently
- Define a food safety policy (objectives)
- Draw up a programme for official controls and set up these controls
- Communicate information on food safety and risks



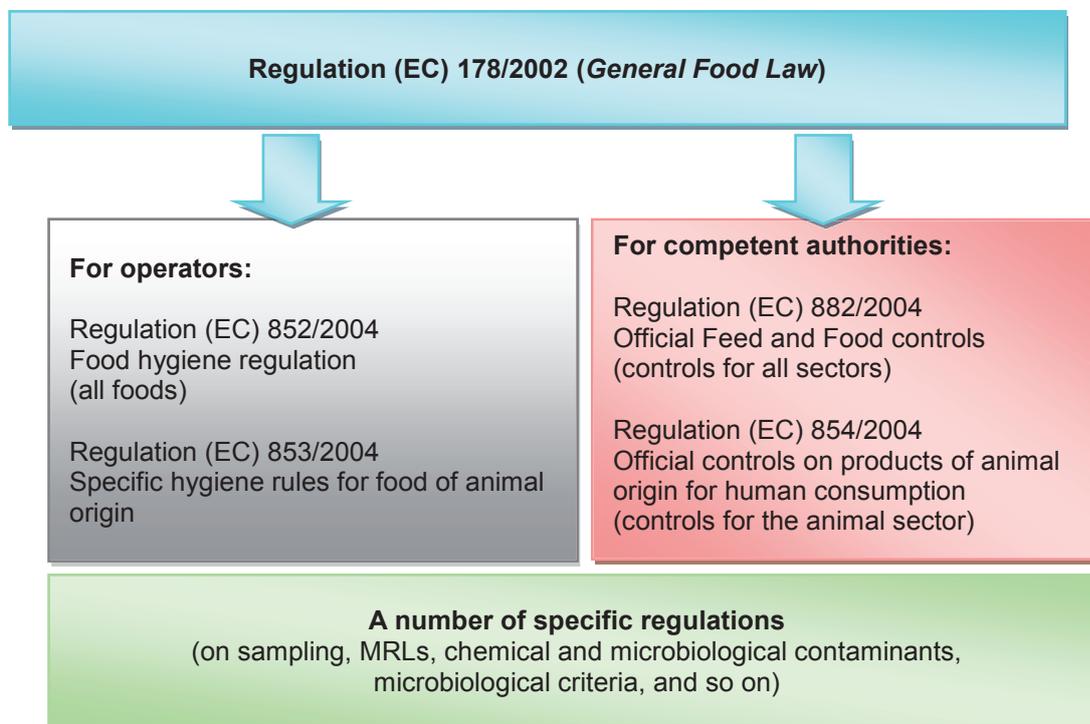
European regulations on the safety of food and plant protection products grew from the 84 recommendations laid out in the White Paper on Food Safety (published in January 2000).⁹

At present, 99 % of food hygiene and pesticide legislation has been harmonised at the European level!

⁸ Regulation (EC) 178/2002 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. Official Journal of the European Communities, L31/1, 1.2.2002.

⁹ In January 2000 the Commission adopted a White Paper on food safety. It was a response to the major food crises the EU had faced in the years leading up to this document, in particular 'mad cow disease' (1996) and the dioxin crisis (1999). The Prodi Commission, which inherited the trauma these events caused in the EU's executive branch (the Commission), quickly identified food safety as 'one of its main policy priorities'. The objective of the white paper was to re-establish and consolidate European consumers' trust.

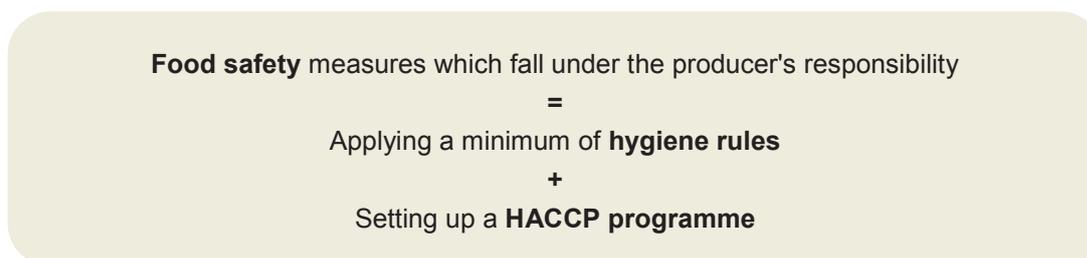
The organisation of European regulations can be summarised as follows:



This strong regulatory framework has been formulated on the basis of general international guidelines issued by the *Codex Alimentarius*.

Even if these regulations taken as a whole may seem somewhat complicated, it should be kept in mind that Europe has endeavoured to set up rules **based on simplicity, flexibility and the responsibility of each stakeholder**, starting with the producers themselves.

The philosophy underlying these rules can be summarised quite simply as follows:



Europe sought rules that could be applied flexibly for small operators (flexible HACCP) and with less red tape in primary production (HACCP not mandatory, but compliance with general hygiene measures). This will be discussed in Chapter 2 of this manual. International and European regulations as a whole are presented in PIP Manual 5.