

**A MANUAL OF  
GOOD  
PRACTICES  
IN  
FOOD QUALITY  
MANAGEMENT**

**Concepts and Practical  
Approaches in  
Agrifood Sectors**



Education and Culture

## Leonardo da Vinci

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A MANUAL OF GOOD PRACTICES IN FOOD QUALITY MANAGEMENT  
Concepts and Practical Approaches in Agrifood Sectors

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## Overview of topics to be answered

**The main problems of the quality system on the food industry sector, the possible ways of development and the main activities in quality systems and the ways of improving education related to Quality Management**

### 1. Revealing the main problems of the current quality system focusing on the food industry sector

- Is it true that the amount of ISO 9000-2000 certifications is showing a decreasing tendency? Is ISO 9000-2000 good for everyone? Is it in whose interest actually to produce a large amount of certifications of ISO 9000? Do they really use ISO? Does everyone elaborate the needed documentation in an appropriate depth, or is it rather just a framed document on the wall of the director?
- Spreading of ISO has not reduced too much the quality assurance of the products and services?
- Is it true that HACCP is a significant step forward? Have we reached an optimal level in exploiting its positive effect? Can a system without certification be efficient at all?
- Do those interested know that HACCP does not make ISO and/or TQM superfluous?
- Is the National Quality Award dying? Why are there so few companies in the field of food industry among those awarded with the National Quality Award?

1.1. However significant development can be noted in the field of knowledge circulation of quality management during the past years, there is a **great lagging behind**, since several leaders and experts of middle and big sized companies have high-level knowledge of quality

management, this is **not general in the case of the whole staff of companies or small sized companies**. Therefore, quality management is not efficient enough, since the majority of the employees should have sufficient knowledge –at their level. This lack of knowledge decreases the possibilities for ensuring the implementation of safety related specifications of quality, including food safety.

- 1.2. The Hungarian consumer protection system does not meet completely the requirements of EU, since it deals not only with life, health and property protection of consumers but with other factors of quality as well. The reason for this is the fact that in Hungary, those manufacturers who produce poor quality products - compared to the old EU-member countries - and the companies that circulate these products are able to gain significant advantage in the market unless the relevant authorities intervene.
- 1.3. The proposals of the Economic Competitiveness Operational Programme (ECOP) that is based on co-financing (EU and domestic) and promotes the implementation of quality management, greatly supports the development of quality management, but has lead to the strengthening of several disadvantageous phenomena in the same time. A group of consulting, certificating companies being quite active in writing proposals have been formed, the quality management expertise of which can be questioned. Many of the companies asking for the support want to and able to get a turn-key job including the certification and the introduction of the HACCP system. This, in itself, pulls back the efficient building out of the quality management system, since it is only possible if the responsible directors of the companies to be certificated take an active part in it at their own level.

The proposal system requires relatively low price level of preparation and certificating, which causes, however, the decay of quality. Hence the companies with ISO 9000 certification have the documents needed for the certification (quality assurance manual), but their content has not been implemented many times (e.g. division into processes).

- 1.4. Similar problems occur at HACCP systems. The HACCP system descriptions are prepared by copy-paste procedure in a lot of cases (this is the cheapest), they are at a poor level, specific features related to the company, business are hardly present in them.

- 1.5. Building out quality management systems is a relatively good business. Several domestic and international companies are dealing with the preparation for them or the certification of them. These companies carry out great and professional PR and marketing activities to acquire new orders. **The result is that the quality assurance of the products and services is far below the suitable level – especially in the aspect of knowledge. Although, these consist the basis for the development of quality management and competitiveness. Without these basics, the system quality cannot be suitable.**
  
- 1.6. Experiences in connection with HACCP not only in Hungary but in the old member states of EU have revealed that the system is vulnerable and not efficient enough. Eagerness is shown in several countries in making it more efficient – e.g. with certification. The implementation of ISO 22000, the development of which is in the final stage, might help, and if the implementation of it will be obligatory in some particular fields.

## 2. Specifying the possible ways of development and the main activities

- Can HACCP system remain without certification? Is the accreditation of the certifier necessary if the certification is introduced?
- Can the violation of food safety be a remissible sin, i.e. very good business for those committing it?
- Is it possible to include quality management in the 2nd National Development Plan? If yes, how?
- Is the National Quality Award needed yet? If yes, what should we do to revitalize it?
- Is it certain that there are no resources for the revitalization of quality?  
Is it certain that the obtaining of certifications should be supported primarily?
- How could the importance of quality management be communicated in a better way?

- 2.1. The **elaboration of the testing, certifying system of HACCP systems** is worth considering. It seems to be necessary to accept the ISO 22000 standard as soon as possible, and to make its implementation obligatory in some fields. In case the certification is required, the acquisition of the certification according to ISO 22000 could supplement for the certification. (We are aware of the fact, of course, that it is not reasonable for all the companies obliged to implementing HACCP to gain certification under ISO 22000.)
- 2.2. Violating the food safety specifications is not a “forgivable sin”. It can endanger the health or life of a big group of people while it causes significant profit increase for a few people. The legislation and legal practice should be developed further in a way that if risk is induced – especially if it is on purpose – the company and its directors should be excluded from the market for a long time.
- 2.3. It would be reasonable to include quality development in the 2nd National Development Plan (NDP2). There is a little chance for it to comprise a separate chapter of NDP2, though it seems to be necessary that all the main chapters of NDP2 contain a quality development part.

It should be aimed at supporting the highly quality implementation of the awarded projects of the particular chapters on the one hand, and at the quality development of the whole field to be developed by the means of the chapter, on the other hand.

Establishing a system encouraging quality development should be considered. For instance, **quality awards** connected to the chapters of NDP2 could be established, and these awards could be gained by those projects that have been accomplished at the highest quality levels. Furthermore, those realizing these awarded projects could obtain **extra points for their further proposals**.

- 2.4. The proposal of ECOP that supports the introduction of quality management as well (Supporting up-to-date management systems and techniques for small and medium sized companies – ECOP-2005-2.1.2.) is a good and effective proposal, but it is not sure that this is the most efficient way of spending the amount of support (2,3 milliard HUF totally in 2005.) Furthermore, the supporting system has a market disturbing effect as well. Since those having great proposal writing practice are supported and those lacking this knowledge but would really need the support are not. In our opinion, if this amount would be spent not so much partitioned for the development and implementation of the quality development tasks – especially for the quality awareness and the human resources- of NDP2.

### **3. Determining the possible ways of improving education related to quality management**

- Is it sensible that education of quality management is focused on ISO (HACCP) to such an extent?
- How could the product quality and safety assurance be taught at a higher level?
- Is it sensible that the terminology of quality management cannot be understood and used by anyone but the experts of quality management?
- Should not be useful to teach quality management in each department of the universities?

3.1. Subjects in connection with system quality have been over-emphasized recently at universities and colleges, while teaching product and service quality is in the background, despite the fact that this latter forms the basis of the former. Hence we suggest that education in connection with product and service quality should be more stressed.

3.2. It should be achieved through proper education that employees at least from a lower leader level in all kinds of field would have an appropriate level of knowledge of quality management.

Experts of other fields are not aware of the terminology of quality management; therefore it should be made understandable for them either.

3.3. It is necessary that quality management – primarily product and service quality - would be integrated in each level of all the fields of professional education.

It would be reasonable to teach product and service quality related subjects in Bsc level, while system quality subjects should be integrated in Msc level education.

# chapter 1

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## General concepts about food quality management

### 1.1. Food quality attributes: classifications, technical and managerial view

#### 1.1.1. Introduction

Quality has become an important issue in agri-business and food industry.

In the last two decades many scientists, technologists and managers, contributed largely to the thinking about quality.

The described quality concepts range from simple illustrations to complex models reflecting factors that might influence quality expectation and perception by consumers or customers. General concepts for quality as well as specific concepts for quality perception of agrifood products have been summarized.

*Van den Berg and Delsing (1999)* describe quality as a necessary condition and relationship between suppliers or companies delivering products dedicated to the satisfaction and expectations of the customers or consumers.

According to *Evans and Lindsay* (1996), the concept of quality is described by different criteria, based on judgments, product-, user-, and manufacturing-based criteria.

From a *judgmental point*, quality is considered as synonym of excellence or superiority. From this viewpoint quality is loosely related to a comparison of product characteristics, it is (sometimes) more a quality image created by marketing.

From a *product-based* view, quality is defined as a function of a specific, measurable variable, reflected in quantitative differences and often associated with price: higher price for better product.

The *user-based* definition of quality reflects the consumer's wishes.

The *value-based* criteria, is related to the price of the product. From this point of view, quality is represented by a competitor sold at a lower price or a product that offers greater usefulness or satisfaction at a comparable price.

The *manufacturing-based* quality is described as the desirable outcome of engineering and manufacturing practice, or conformation to specifications. These specifications include targets with tolerances, as specified by the designers of products and services.

## Quality dimensions

Several authors attempted to define factors, attributes or dimensions, which are assumed to be relevant for the quality perception of a product.

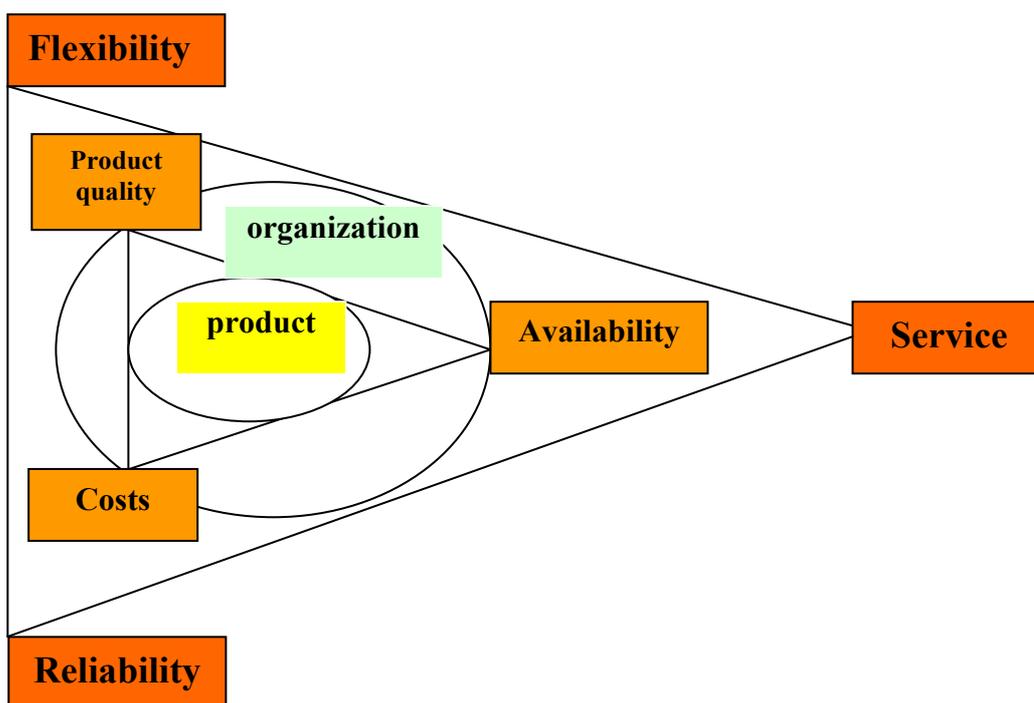
Table 1 includes the quality characteristics of goods related to food.

**Table 1**  
**Quality characteristics of goods in relation to food**

<b>GOODS</b>	<b>FOOD</b>
<ul style="list-style-type: none"> <li>• Performance</li> <li>• Features: additional properties</li> <li>• Conformity: physical and performance characteristics corresponding to pre-established standards</li> <li>• Durability: duration before physical deterioration or reparation</li> <li>• Reliability</li> <li>• Aesthetics: how a product looks, feels, or sounds</li> <li>• Serviceability: speed, courtesy, and competence of repair</li> <li>• Perceived quality: subjective assessment of quality delivered by image, advertising, or brand names</li> </ul>	<ul style="list-style-type: none"> <li>• Physical product features: (sensory properties) such as taste, odours, texture</li> <li>• Additional features: e.g. convenience of ready-to-eat meal</li> <li>• Product safety: no risks for the consumer</li> <li>• Shelf life: storage time for agri and food products</li> <li>• Reliability: constant behaviour of a product (appearance colour, size, image)</li> <li>• Complaint service: quick response to rejected food products</li> <li>• Availability of the product at food service market</li> <li>• Perceived quality: advertisement or brands with influence on quality perception.</li> <li>• Price of the product</li> </ul>

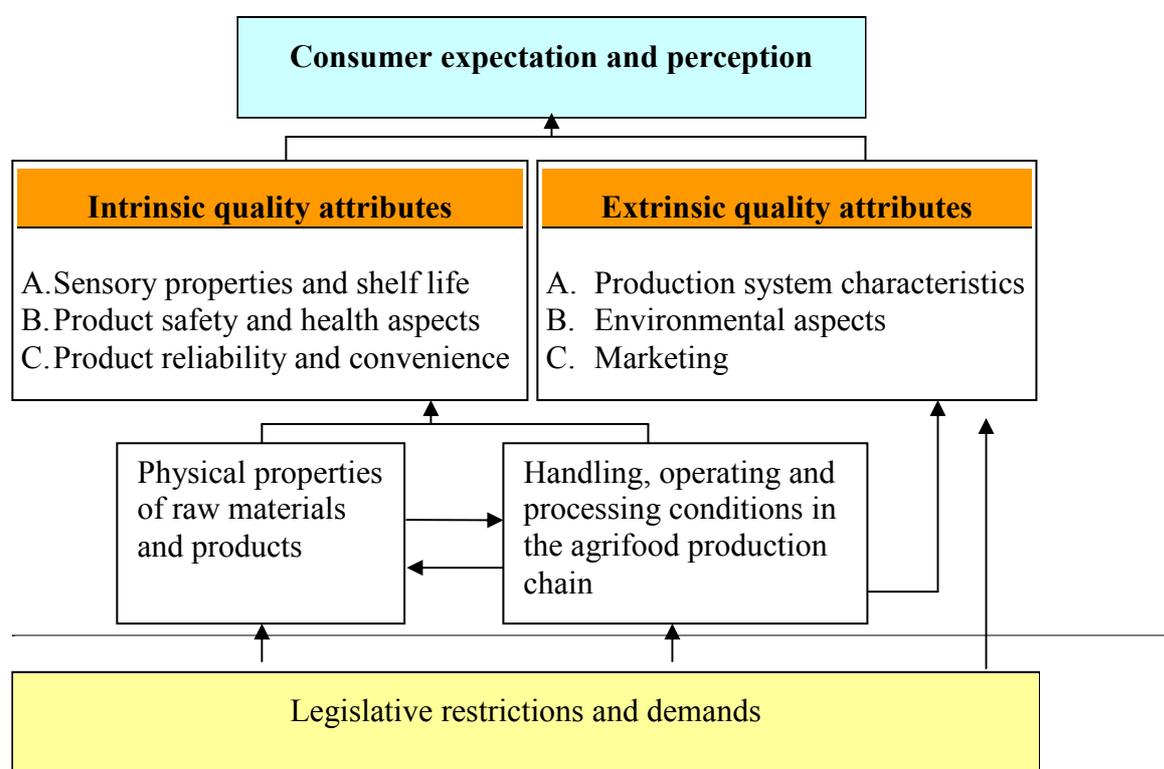
## Intrinsic and extrinsic attributes

The quality concept is focused on technological attributes and factors that can contribute to product quality performance (Figure 1). They are represented as a **Quality triangle**. A product has physical features that are turned into quality attributes by the perception of a consumer. With respect to agrifood products, quality perception appeared to be affected by different types of attributes. Relevant attributes for consumers involve safety, nutritional value (health aspect), sensory properties (like taste, flavour, texture, and appearance), shelf life, convenience (e.g. ready-to-eat meal) and product reliability (correct weight, right composition etc.). These attributes can be defined as *intrinsic attributes* and are directly related to the physical product properties. (Luning & al, 2002).



*Figure 1*  
*The Quality Triangle Concept*  
*(Luning & al, 2002)*

*Extrinsic attributes* refer to production system characteristics and other aspects, like environmental impact or marketing influence. They do not necessary have a direct influence on physical properties but may affect acceptance of products by consumers. For example, the use of pesticides, of antibiotics to improve animal growth, or the application of biotechnologies to modify product properties, can have a significant effect on food acceptance. These intrinsic and extrinsic attributes and the factors (parameters) in the food production chain that can influence these attributes are reflected in Figure 2.



*Figure 2*  
 General intrinsic and extrinsic attributes affecting consumer expectation and perception  
 (Luning & al, 2002)

Intrinsic attributes characterize the physical product, whereas marketing efforts mainly determine extrinsic attributes. According to this classification, typical intrinsic attributes include appearance, colour, shape and texture. Typical extrinsic attributes are price, brand name, packaging, labelling, product information. According to this classification extrinsic attributes are mainly related to marketing variables, whereas in our model typical food aspects like production characteristics and environmental impact are included.

According to *Van Trijp and Steenkamp* their concept quality perception is formed at two different moments: when the product is purchased, consumers have a quality expectation, whereas upon consumption, the actual quality is experienced. Quality expectation is an important factor in consumer choice behaviour, while quality experience is important for repetitive purchase.

Extrinsic attributes are related to the product but are not part of it, like price, brand or store name. These cues have a predicted value for the consumer and thus influence the quality expectation. Generally, the intrinsic cues are more considered than extrinsic cues.

Production system characteristics do not necessarily affect the physical attributes, e.g. use of pesticides will not directly influence product features but might affect quality expectations but a change in production system characteristics may influence the physical features.

In a case study in the biological meat production chain, it was shown that if meat was biologically produced, it influenced positively the quality expectation. Appearance was negatively judged and overruled the positive effect of the production system characteristics.

## **1.1.2. Quality attributes of food**

To control and assure the quality, a good understanding of factors and parameters which affect these attributes in agrifood production chain is needed.

### **INTRINSIC QUALITY ATTRIBUTES**

There are different classifications with respect to intrinsic and extrinsic quality attributes, one being presented in Figure 2.

The intrinsic attributes are safety and health aspects of a product, shelf life and sensory properties, convenience and product reliability.

## A. Sensory properties and shelf life

Figure 2 shows how the sensory perception of food is determined by the overall sensation of taste, odour, colour, appearance, texture.

The physical features and chemical composition of a product determine the sensory properties.

In general agrifood products are perishable. After harvesting a fresh product or after processing, the food deterioration process starts, which affects negatively the sensory properties. Processing and/or packaging are aimed at delaying, inhibiting or reducing the deterioration processes in order to extend the shelf life period.

The shelf life of a product can be defined as the time between harvesting or processing and packaging of the product and the point at which it becomes unacceptable for consumption.

Shelf life can be restricted by microbiological, and/or (bio) chemical and/or physiological and/or physical processes. For example, freshly harvested peas are spoiled within 12 hours, whereas canned peas can be kept for 2 years at room temperature.

The unacceptability is usually reflected by altered sensory properties, for example formation of rotten odour or sour taste by bacteria spoilage. The actual shelf life of a product depends on the rate of the deterioration processes, e.g. although a product is safe, not spoiled by bacteria it will become unacceptable because of its grey colour.

**Microbiological** processes in foods can result in food spoilage with the development of undesirable sensory characteristics, including loss of texture, development of off-flavours and off-colours. In some situations the food contains pathogens and becomes unsafe prior detecting any changes in sensory characteristics.

Typical **chemical reactions** that can limit product shelf life are non-enzymatic browning (Maillard) and oxidative reactions, which causes changes in appearance and lowers the nutritional value and oxidative reactions, especially auto-oxidation of lipids which alter the flavour, bleaching of plant pigments (carotenoids).

Generally chemical changes occur during processing and storage of agrifood products. The non-enzymatic browning reaction also leads to desirable quality characteristics such as browning of bread crust and brown colour of fried meat.

**Biochemical reactions** involve enzymes released by disruption of the integrity of plant or animal tissue. For example, cutting of fresh vegetables initiates several enzymatic reactions, such as browning by phenolases and formation of off-flavours by lipoxigenase.

In similar circumstances biochemical reactions are controlled and used to produce better digestible food, e.g. fermentation of cabbage. A typical example is meat ageing by increased temperatures while surface growth of bacteria is controlled by ultra violet light.

**Physical** changes are often due to mishandling of agrifood products during harvesting, processing and distribution. During storage and distribution, fluctuating temperature and humidity conditions can result in desiccation of humid products, swelling of dried products or phase changes. The breaking of emulsions and phase separation are also typical physical processes resulting in negative product features.

**Physiological** reactions commonly occur during post-harvest storage of fruits and vegetables and strongly depend on storage conditions. The products still have a respiration rate and ethylene is still produced having a considerable effect on typical post harvest defects.

The **shelf life** of a product is often limited by one major reaction, but sometimes a typical quality defect may be due to different mechanisms.

For example, rancid off-flavour can be due to lipase activity producing short fatty acids chains or by oxidation of fatty acids. It is therefore necessary, to control this quality defect, to identify the responsible mechanism generally, the fastest reaction is responsible for the shelf life limitation. For example, undesirable changes in texture of bread usually occur prior to growth of moulds. In this case physical degradation is faster than microbiological changes, degradation being the shelf life limiting factor.

Inhibition, reduction or prevention of the main shelf life limiting factor often results in an extended shelf life for that specific factor. During the extended storage slower degradation processes may become prominent.

For example freezing of foods extends the microbial-free shelf life but after 1 - 1 ½ year colour and texture changes occur by chemical and physical reactions.

To control the technological product quality it is important to understand the different processes that limit product shelf life and affect sensory properties.

**Table 3**  
**An overview of major shelf life limiting reactions in agrifood products**

Shelf limiting (changes)	Causes or type of reaction	Undesirable effects
<b>Microbiological changes</b>	Growth of spoilage micro-organisms; spoilage bacteria, moulds and yeast's: <ul style="list-style-type: none"> <li>• Acetobacter (fresh meat, poultry)</li> <li>• Aeromonas (fresh meat)</li> <li>• Envinia (fruit and vegetables)</li> <li>• Pseudomonas (fresh meat, poultry)</li> <li>• Cladosporium (fresh/frozen meat)</li> <li>• Lactic acid bacteria (various food)</li> </ul>	Common effects: <ul style="list-style-type: none"> <li>• loss of texture                             <ul style="list-style-type: none"> <li>– development of off-flavours, off-taste and off-colours</li> <li>– formation of slime</li> <li>– rotting</li> </ul> </li> </ul>
<b>Chemical reactions</b>	1. Non enzymatic browning (Maillard reaction)  2. Oxidation reactions	1. • Browning, e.g. dried milk powder • Formation of toxic compounds  2. • Formation of rancid off-flavours by lipid oxidation • Bleaching of carotenoids by autoxidation
<b>Biochemical reactions</b>	Enzymatic reactions; catalyzed by: <ol style="list-style-type: none"> <li>a) Phenolases</li> <li>b) Milk proteinase</li> <li>c) Lipases</li> <li>d) Lipoxygenase</li> <li>e) Chlorophyllase</li> <li>f) Phospholipase</li> </ol>	a) Browning of cut surfaces of light coloured fruits and vegetables b) Gelation of milk subjected to ultra-high short-time (UHST) temperature processing c) Short-chain fatty acids in milk lead to undesirable hydrolytic rancidity; and undesirable flavours; d) Degradation products of the polyunsaturated fatty acids with undesirable effects on flavour, colour, texture and nutritional value e) Degradation of green chlorophyll pigments during post harvest storage f) Released fatty acids are substrates for lipoxygenase leading to off-flavours in plant foods or undesirable textural changes in frozen fish
<b>Physical changes</b>	1. Mishandling of agrifood products <ul style="list-style-type: none"> <li>• Bruising or crushing</li> <li>• Temperature fluctuations</li> <li>• Humidity conditions</li> </ul> 2. Other typical physical reactions <ul style="list-style-type: none"> <li>• Retrogradation of starch</li> </ul>	1. • Decomposition during post harvest storage of fruits and vegetables • Phase changes due to thawing and re-freezing of foods • Undesirable desiccation or moisture pick-up  2. • Undesirable texture changes of starch containing bakery products
<b>Physiological reactions</b>	Processes in respiring agrifoods <ul style="list-style-type: none"> <li>• Respiration process</li> <li>• Post harvest defects by ethylene</li> <li>• Chilling injury</li> </ul>	<ul style="list-style-type: none"> <li>• Accelerated ripening by ethylene or by incorrect storage conditions</li> <li>• Typical effects like bittering of sprouts, browning of leaf nerves</li> <li>• Some fruits and vegetables get brown spots upon storage at too low temperatures</li> </ul>

## **B. Product safety and health**

Product safety and health aspects are important intrinsic quality attributes. Health aspects refer to food composition and diet, nutritional imbalance having negative consequences on human health. Nowadays, the food industry anticipates these nutritional needs by the development of functional foods. These products are assumed to contribute positively to human health, e.g. low-fat and low-cholesterol products, but also vitamin or mineral enriched foods.

Food safety refers to the requirement that products must be free of hazards with an acceptable risk. A hazard can be defined as a potential source of danger, while risk can be described as a measure of the probability and severity of harm to human health.

Different sources can affect food safety: growth of pathogen micro-organisms, presence toxic compounds, physical agents and occurrence of calamities. Negative health effect can have a different time span and can be acute (such as allergic reactions or food poisoning) whereas others induce long-term, chronic effects via cancer, heart and vascular diseases. These chronic effects can be due also to unhealthy balances of diet or long term exposure to chemical agents. An overview of major hazardous agents is presented in Table 2.

**Table 2**  
**Overview of factors that can affect safety, including examples**

<p><b>Pathogenic micro-organism</b>  <b>Pathogenic bacteria</b></p> <ul style="list-style-type: none"> <li>▪ <b>FOOD INFECTION</b> <ul style="list-style-type: none"> <li>• <i>Salmonella ssp.</i></li> <li>• <i>Shigella ssp.</i></li> <li>• <i>Escherichia coli</i></li> <li>• <i>Listeria monocitogenes</i></li> <li>• <i>Campylobacter jejuni</i></li> </ul> </li> <li>▪ <b>FOOD TOXINS</b> <ul style="list-style-type: none"> <li>• <i>Clostridium botulinum</i> can produce highly toxic neurotoxins</li> <li>• <i>Straphylococcus aureus</i> may produce different enterotoxins</li> </ul> </li> </ul>		<p><b>Toxegenic moulds</b></p> <p><b>FOOD MYCOTOXINS</b></p> <ul style="list-style-type: none"> <li>• <i>Aspergillus flavus</i> and <i>A. parasiticus</i> can produce aflatoxins</li> <li>• <i>Penicilium citrinum</i> may produce citrinin</li> <li>• <i>Penicilium patulum</i> and other penicillia may produce patulin</li> <li>• <i>Fusarium ssp</i> can produce zearalenone and trichothecens, such as DON (deozynivalenoal)</li> </ul>
<p><b>Chemical Toxic Compounds</b></p>		
<p><b>Natural toxins</b></p> <ul style="list-style-type: none"> <li>• Protease inhibitors in beans, peas, potatoes and cereals</li> <li>• Glucosinolates in cabbage and related species</li> <li>• Cyanogenes in peas, beans, cassava, bitter almonds</li> <li>• Pyrrolizidine alkaloids in potatoes, tomatoes</li> <li>• Hydrazine in mushrooms</li> <li>• Hemagglutininins in beans and peas</li> </ul>	<p><b>Toxins formed during processing, storage and handling</b></p> <p>STORAGE AND HANDLING</p> <ul style="list-style-type: none"> <li>• Seafood poisoning</li> </ul> <p>PROCESSING E.G.</p> <ul style="list-style-type: none"> <li>• Heterocyclic amines</li> <li>• Maillard reaction products</li> <li>• Formation of nitrate at cooking</li> </ul>	<p><b>Contaminants</b></p> <p>ENVIRONMENTAL CONTAMINANTS</p> <ul style="list-style-type: none"> <li>• PCB's</li> <li>• Nitrate</li> </ul> <p>RESIDUES E.G.</p> <ul style="list-style-type: none"> <li>• Pesticides, like DDT</li> <li>• Veterinary drugs, i.e. antibiotics and hormones</li> <li>• Disinfectants and detergents</li> <li>• Packaging compounds, such as teraphthalic acid, BADGE</li> </ul>
<p><b>Physical Agents</b></p>		
<p>Glass, wood, metal pieces, stones, pests and insects, etc</p>		

### **Pathogenic micro-organisms**

Pathogenic micro-organisms include both bacteria and moulds. A distinction must be made between food infection and food poisoning (Table 2).

**Food infection** is caused by the presence of living pathogens in food, which are transferred from food to the human body. Major bacteria that are responsible for food infections are *Salmonella*, *Shigella ssp* and some certain strains of *Escherichia coli*, *Campylobacter jejuni*.

Beef, turkey, chicken, eggs, pork and raw milk products are typical vehicle foods for Salmonellosis outbreaks.

Poor personal hygiene is a common factor in food-borne Shigellosis, with shellfish, chicken, salads, fruits and vegetables being prominent among vehicle foods.

Traveller's diarrhoea is often caused by specific strains of *Escherichia coli*.

Another source of food infection is caused by *Listeria monocitogenes*. *Listeria* species are widely distributed in soils, animal faeces, sewage, silage and water. *Listeria* infections also occur in foods, especially raw milk, soft cheeses and other dairy products. It is suggested that *Listeria* infections in some foods might be due to zoonotic transmissions, i.e. disease transmission from animals to human.

*Campylobacter jejuni* is assumed to be the most common cause to acute bacterial diarrhoea in humans, it is an environmental organism but the bacteria are carried through the animal intestinal tract. A large percentage of all major meat animals contain *C. jejuni* in the faeces, especially poultry.

**Food poisoning** is caused by toxic compounds produced by pathogenic bacteria (enterotoxins) and moulds (mycotoxins) in food. The compounds can be released in raw materials or processed food products. Consumption of the poisoned food can result in symptoms that range from acute abdominal pain and diarrhoea to long term diseases such as cancer or histological changes in the liver.

*Clostridium botulinum*, *Staphylococcus aureus* and *Campylobacter jejuni* are well known bacteria responsible for production of enterotoxins in food.

*Clostridium botulinum* is an anaerobic spore forming bacteria widely spread in soil and water. Especially food packed under low oxygen concentrations containing low-acid foods may function as vehicle food for *Clostridium*.

*Staphylococci* have been detected in a large number of vehicle foods (like meat, chicken and bakery products).

*Moulds* can also cause poisoning, by mycotoxins, which can be produced by *Aspergillus flavus* and *A. parasiticus*. Major vehicle products are peas and cereals such as rice, corn and wheat stored under warm and humid conditions.

### **Toxic compounds**

Toxic compounds can originate from different sources in the agrifood production chain toxins can occur as natural compounds in raw materials (natural toxins), but they can also be formed during storage and processing. Other sources of toxic compounds are contaminants from the environment, residues from pesticides, veterinary drugs and disinfectants. In addition, consumers often consider food and colour additives as unsafe toxic compounds as well (Table 2).

To estimate the risk of toxicants for food safety, the following points have to be considered:

- The **origin** of the compounds: natural, formed during processing.  
For example, fresh raw mushrooms contain hydrazine, a toxin, while formation is favoured by humid and warm storage. Toxic substances formed during processing, such as the development of heterocyclic amines in broiled, smoked or deep-fried fish or meat.
- What are the **properties** of the toxic compounds?
  - The *fat solubility*. Fat-soluble toxic compounds can accumulate in the food cycle production. For example, small amounts of polychlorinated biphenyls (PCBs) accumulate in the adipose tissue of fatty fish species; by far the biggest source of PCBs in the human diet is fatty fish.
  - The *degradability or inactivation*. Some toxic compounds are very stable and therefore remain in the food production cycle for a long period. DDT, a very stable pesticide that has been used in the 40-50's, has accumulated in the food production cycle via milk fat, meat and breast milk. For many years human breast milk contained higher amounts of DDT compared to cow milk.

The intrinsic toxicity of the compound and the toxicity of its degradation products determine the risk. For example, the enterotoxin produced by *Clostridium botulinum* is highly toxic and the fatality rate is much higher than the enterotoxin produced by *Clostridium perfringens*. Oxalates and alkaloids have an indirect effect; they can bind bivalent metals and thus their bioavailability.

### **Physical agents**

The physical agent includes pieces of glass, stones but also pests and insects and radioactive isotopes.

## **C. Product reliability and convenience**

Two other intrinsic quality attributes, shown in Figure 2, are represented by products reliability and convenience.

**Product reliability** refers to the compliance of actual product composition with its description. For example, the weight of the product must be correct within specified tolerances. If it is claimed as enriched with vitamin C it must be in agreement with actual concentration in the product after processing, packaging and storage. Deliberate modification of the product composition will cause damage to the product reliability, i.e. product falsification. An example is when alternative (cheaper) raw materials are used and not mentioned on the label. Product reliability is generally an implicit expectation, consumers expect that a product is in compliance with the information mentioned on the packaging.

**Convenience** relates to ease of use or consumption of the product for the consumer. Product convenience can be accomplished by preparation, composition and packaging aspects.

Convenience foods range from sliced and washed vegetables to complete ready-to-eat meals that only have to be warmed in the microwave or oven. Much attention is paid in the food industry to development of ready-to-eat meals that can be easily and quickly prepared while having good sensory and nutritional properties. Also packaging concepts are more and more designed to fulfil the consumer's need for convenience.

## **EXTRINSIC QUALITY ATTRIBUTES**

Production system characteristics, environmental implications of food products and their production and marketing aspects can be considered as extrinsic quality attributes (Figure 2).

Extrinsic quality attributes do not necessarily have a direct influence on physical product properties, but can influence consumer's quality perception. For example, marketing activities can influence consumer expectations but have no relationship with any physical property.

### **A. Production systems characteristics**

Production characteristics refer to the way a food product is manufactured. It includes factors such as the use of pesticides while growing fruit and vegetables, animal welfare during cattle breeding, use of genetic engineering to modify product properties or use of specific food preservation techniques. The influence of production systems characteristics on product acceptance is very complex. For example, there has been much concern about public acceptance of new genetically modified food products and genetic engineering in general.

### **B. Environmental aspects**

Environmental implications of agrifood products refer mainly to use of packaging and food waste management. Intrinsic quality properties such as taste or nutritional value are related to personal interests, whereas environmental properties of food may be related to wider community oriented interest. Consumers express interest in buying foods from environmentally sound production, either because of concern for their own health or because of concern for the external environment. With respect to the environmental consequences of packaging waste, European directives have been enacted to reduce this environmental impact. Since 1997 the food packaging industry is legally liable to improve material recycling and thus reducing packaging waste. With respect to waste management, inefficient processing is mainly a cost problem for processors and not yet a major quality concern of consumers.

## **C. Marketing**

The effect of marketing on product quality is complex.

The marketing efforts (communication via branding, pricing and labelling) determine extrinsic quality attributes, affecting quality expectation. Marketing can also affect credence attributes (which can be checked by consumers themselves) influencing quality experience.

## **1.2. Quality Management: Blocks of Interrelated Activities**

### **1.2.1. Introduction**

Legal regulations on food production and distribution are specific and general at the same time. General, since the regulations controlling consumer protection, the general product safety and responsibility are applied to food as well. Parallel with these – since the characteristics of these products significantly differ from those of the produced goods or the services – the field of production and distribution is regulated by specific measures on food. Our aim here is to demonstrate how it is realized in the European Union.

### **1.2.2. Food safety in the European Union**

#### **Food related diseases**

Epidemics of the 80-90s originating from food turned attention to the fact that diseases caused by food might occur in great quantities even in those countries where the level of hygiene is pretty high. Professional organizations publicize some data on food related diseases; however, statistics only show the peak of the iceberg, since only a small percent of the cases take air.

The number of diseases emerging via the transmission of food or from food itself has grown in the past years. The following factors can play a role in it:

1. Alteration of traditional pathogens
2. Emergence of new forms of diseases and pathogens
3. Change of technologies of food and fodder production and livestock husbandry
4. Unbeneficial change in the immunity state of the population
5. Increasing environmental pollution
6. Increasing tourism and international food trade.

## Safe food

Safe and good quality food is necessary to prevent diseases from food, and to reduce their occurrence to a minimum. This means that it shall be ensured throughout the whole process of the production, processing and distribution that food would not endanger the consumers' health provided that the way of consumption is in line with the intended purpose.

## Food safety

Food safety is a global issue of increasing concern for governments, food producers, food processors and handlers, as well as consumers. Safe wholesome food supplies play a key role in ensuring the health of populations worldwide. Food safety is achieved by improving knowledge of the causal agents of food-borne illness, providing information on how to control these agents and, ultimately, reducing the occurrence of sources of food hazards that result in morbidity and mortality.

## Institutional background for food safety in the European Union

Access to a secure supply of safe food is a human right. Everyone who is involved in food production, processing, sale and service has a role in ensuring that the food reaching our tables will not be a hazard to human health.

Previously food related legislation and co-ordination among the member states in the Union formed in part activities of the **Health and Consumer Protection Directorate General**. The European Commission decided to establish a new **Food Safety Authority** without modifying the sphere of activities of the Directorate General, whose main roles are to co-ordinate food safety of the member states, to introduce hazard analysis and to apply the newest scientific results in each phase of the food chain.

According to the principles of the European objectives food safety policy shall be integrated and comprehensive. Besides, the European Commission suggested that the member states should establish their national agencies, aimed at harmonizing measures, building and operating efficient institutional systems that integrate and properly co-ordinates appropriate implementation and control in the field of food safety.

**National Food Control Systems** are designed to ensure the existence of a safe food supply, and promote the good health of local populations. Food legislation in many countries around the world requires that food businesses have conducted a hazard analysis and introduced measures necessary to ensure the production of safe food. Guidelines for food safety management systems (FSMS), based on general requirements for hygiene and principles for Hazard Analysis Critical Control Point (HACCP) are defined internationally by the FAO/WHO (**CODEX - 2001**).

### 1.2.3. Food Quality

#### **Quality Management Systems**

**Quality Management Systems (QMS)** are used to control the quality and safety of products. The use of a QMS will ensure that all aspects of a business are working efficiently and cost effectively. A system will provide a competitive advantage, which can increase marketing and sales opportunities, this will help a company gain new customers as well as retaining existing business. By working within a QMS the whole workforce will be involved which improves communication, morale and job satisfaction.

The **ISO 9001-2000** standard is a guide for the establishment of a quality system. ISO 9001 comprises 6 clauses and is designed to be used as a guide for the quality management process of an organisation. It is not prescriptive, but allows managers to design and implement a quality management system appropriate for their business needs.

## **Food Quality Management Systems**

**Food quality management**, which assures the health and safety of food, has become increasingly important during the last decade. This is due primarily to changing consumer requirements, increased competition, environmental issues and governmental interests.

A turbulent situation on the food market and in the agrifood production chain has resulted. The situation is further complicated by the complex characteristics of food and food ingredients, which include such factors as variability, restricted shelf life, potential safety hazards, and many chemical, biochemical, physical, and microbial processes.

To face this challenge, continuous improvement in food quality management methods is required, where knowledge of modern technologies and management methods play a crucial role.

Moreover, human handling plays a crucial role in quality management and is rather unpredictable and changeable. As a consequence, the result of agri-business and food industry, as the combined action of individuals striving for quality, is much more uncertain than often is assumed.

The food sector utilises various quality assurance systems, such as **HACCP** (Hazard Analysis Critical Control Point), **ISO** (International Organisation for Standardisation) and **BRC** (British Retail Consortium). These systems, and combinations of these systems, are applied in order to assure food quality.

### **Application of HACCP system in the particular phases of the food chain**

The Committee for Food Safety of FAO (Food and Agriculture Organization) and WHO (World Health Organization) contended in 1984 that one of the biggest problems today is the diseases caused by food. Therefore, the safety of consumers, i.e. food safety, shall be increased in order to prevent health damages caused by food.

This goal can be achieved by creating a production system that specifies, evaluates and checks hazards besides observing and applying the food hygienic and public health regulations.

The **HACCP** (Hazard Analysis and Critical Control Point) system is such a system, created in the 60s for NASA to achieve the greatest safety and minimize end-product control while manufacturing food for astronauts.

Later on the HACCP system has become common in other fields as well. The USFDA (United States Federal Food and Drug Administration) applied it after initiating the NASA space programme. The larger food companies also introduced it in the 1980s. Later several international associations recommended introducing HACCP to achieve food safety. It was built in the Hungarian legislation in the 1990s (*Codex Alimentarius Hungaricus*).

### **Fields of application of HACCP**

According to the valid measures, food manufacturers shall apply hazard control and prevention systems (HACCP) or particular elements of them in order to meet the public health and hygiene requirements. Both the manufacturer and the distributor are responsible for food safety. Manufacturers shall ensure that the food is safe, healthy and its quality meets the requirements.

Therefore, the manufacturer shall consider the requirements of the Union, and shall adjust him/herself to the Community practice. HACCP system is applied in the fields of food industry and food distribution in the EU member states to identify food safety hazards and the causes of quality defects.

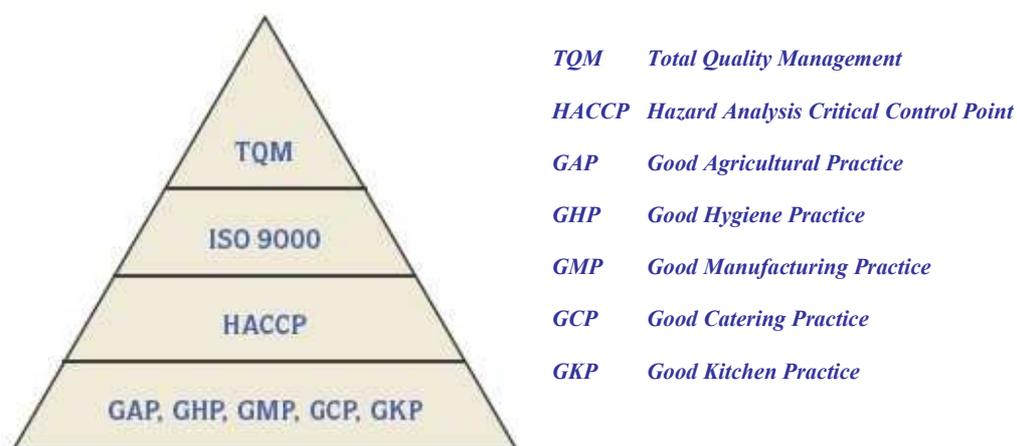
### **Results of HACCP application**

During the past few decades, food safety related events: infections, intoxications, adulterations in connection with food have occurred more frequently throughout the whole world. Previously, ensuring food safety was a governmental duty, carried out by a controlling apparatus assigned by the state. The controlling process mainly comprised on-site inspections and laboratory analyses based on sampling. However, measures taken in case of problems only had impact on the security of the next items. This method did not prove efficient enough, which forced the experts of the EU and the developed countries to reconsider and revise the legal regulations and practices related to food safety.

A more efficient process monitoring and control system was introduced instead of end-product checking. The responsibility of the manufacturer and the distributor is incontestable with respect to food production; however, the application of quality assurance systems is indispensable in the process.

Although the ISO 9000 standard series can be applied throughout the entire economic life – accomplishing a systematic approach by turning the processes controlled, clear-cut, assigning competences to tasks, and creating unambiguous responsibility relations, it does not touch upon food safety questions. Therefore, a quality assurance system specific to food safety must be introduced, that can be applied to the entire food chain, supports official control and international trade.

HACCP system meets these requirements. Good Hygiene Practice (GHP) and Good Manufacturing Practice (GMP) comprise a precondition for HACCP. An additional advantage of the system is that GHP and GMP guidelines, HACCP and the quality assurance part of the ISO 9000 standard series are built on one another. The favourable effects, advantages of each system comprising the pyramid can be added together (see Figure 3.).



*Figure 3*

The interrelation between food safety and quality assurance systems can also be observed in Good Agricultural Practice (GAP), in Good Catering Practice (GCP) and in Good Kitchen Practice (GKP), hence in the entire spectrum of economic life.

## 1.2.4. Institutional system for food control in Hungary

### Legal background

Food control in Hungary is based on the following acts and directives:

1. Act LXXXII of 2003 on Food
2. Act XCI of 1995 on veterinary issues
3. Act XXII of 2001 on the amendment of the veterinary act
4. Act XCII of 1995 on feeding-stuffs
5. Act XXVIII of 1998 on the welfare of animals
6. 1/1996. (I. 9.) FM-NM-IKM joint decree
7. 21/1998. (IV. 8.) FM-BM-HM-IKIM-NM joint decree

### Official food control

Tasks of official control, divided according to expertise and provided for in specific legislation, shall be carried out by:

- a) the Stations
- b) the national (capital) or municipal (district) institutes of the National Public Health and Medical Officer's Service (hereinafter : ÁNTSZ institutes)
- c) the consumer protection inspectorates and the Central Inspectorate for Consumer Protection.

The control work of authorities shall be co-ordinated by the Hungarian Food Safety Office. In the framework of this co-ordination, the following shall take place in particular:

- a) the co-ordination and harmonisation of inspection programmes and/or methods
- b) organisation of harmonised joint inspections as appropriate
- c) exchange of inspection findings and/or inspection reports.

Furthermore, the Office carries out preparatory tasks in the professional decision-making process, hazard analyses, gives scientific and technical advices, expert opinions, provides information, elaborates studies, etc.

## Food regulation

In the food regulation the rules and recommendations of international associations –especially FAO/WHO Codex Alimentarius – shall be taken into consideration. The Hungarian National Committee of Codex Alimentarius shall be responsible for the professional direction of the Codex work of Hungary.

The Minister of Agriculture and Rural Development is authorised to regulate by joint decree with the Minister of Health, Social and Family Affairs and Minister of Economy and Transport:

- a) the labelling of food
- b) rules of official food control
- c) conditions of food production
- d) rules concerning the bottling and distribution of drinking water and mineral water and
- e) the fees of necessary licences and analyses, the payment and uses thereof, in agreement with the Minister of Finance.

The Ministry of Agriculture and Rural Development is authorised to regulate by joint decree with the Ministry of Health, Social and Family Affairs and the Minister of Economy and Transport the food hygiene conditions of food production and placing food on the market.

The Minister of Agriculture and Rural Development is authorised to issue by decree in agreement with the Minister of Economy and Transport and the Minister of Health, Social and Family Affairs the mandatory provisions of the Hungarian Food Codex.

The Minister of Agriculture and Rural Development is authorised to regulate by decree in agreement with the Minister of Economy and Transport the operation of the certification system concerning the specific character of agricultural products and foodstuffs.

The Minister of Agriculture and Rural Development is authorised to regulate by decree:

- a) the control of fruits and vegetables, and
- b) the conformity of the certification of foodstuffs of excellent quality.

The Minister of Health, Social and Family Affairs is authorised to regulate by joint decree with the Minister of Agriculture and Rural Development and Minister of Economy and Transport:

- a) nutritional claims, and
- b) processing aids.

The Minister of Health, Social and Family Affairs is authorised to regulate by joint decree with the Minister of Economy and Transport and the Minister of Agriculture and Rural Development the hygiene conditions of catering.

The Minister of Health, Social and Family Affairs is authorised to regulate by decree in agreement with the Minister of Agriculture and Rural Development the admissible levels of microbiological contaminants and the provisions on radioactive and chemical contamination.

The Minister of Health, Social and Family Affairs is authorised to regulate by decree:

- a) food for particular nutritional uses, and
- b) food supplements.

## 1.3. Quality control process characteristic to agrifood production

The manufacturing of agrifood aims an extended shelf life by controlling the restricting factors and keeping the food quality. With respect to control from a technological perspective, it is important to understand where in the agrifood chain and how intrinsic and extrinsic quality attributes are affected. In which stages of production can potential hazards occur? It is possible to remove these hazards.

Are preventive measures needed to obtain a safe food product? For example, processing can eliminate many pathogens and spoilage micro-organisms, whereas heat-stable toxins, many environmental contaminants and various residues cannot be removed by processing. Their occurrence should be kept low by preventive measures as early in the food production chain as possible. Figure 4 represents the agrifood chain. Different conditions in the sub-chains that can affect quality attributes are presented.

### A. Plant production and products

*Cultivation and harvesting conditions* influence properties of fresh and processed products, including nutritional composition, sensory properties (taste, odour, texture and colour), and presence of natural toxins, anti-microbial agents and anti-oxidants.

Important quality affecting factors during cultivation, as shown in Figure 1, include:

- Selection of best plant varieties
- Best cultivation

With respect to *harvesting conditions*, time of harvesting and occurrence of mechanical injury during harvesting are factors that influence product quality.

During growth and ripening of fruits and vegetables many biochemical changes take place, including: changes in cell wall, starch–sugar transformations, and pigment metabolism.

During *transport and storage*, damage to plants may occur, causing formation of stress-metabolites, enzymatic-browning, and ethylene production.

## **B. Animal production and products**

Animal production can be divided into meat production (i.e. pork, beef, poultry, sheep, fish and shellfish), and animal products like eggs and milk. Production conditions can have a direct or indirect effect (e.g. via milk) on intrinsic quality attributes, such as food safety and sensory properties. The conditions applied determine the production system characteristics and thus contribute to extrinsic quality. Major aspects involved in animal production are choice of breed, feeding, living conditions and animal health.

*Animal breed*: most breeding programmes are more focused on yield increase than on improving product quality. The breed choice of cattle has a profound effect on milk yield but has less impact on nutritional quality. Some pig breeds have a genetic predisposition for typical quality parameters of meat. The breeds are often crossed with other breeds to improve the meat quality. Attention is shifted towards varieties with high quality meat characteristics.

*Animal feeding* can affect food quality in different ways, directly and indirectly. It can directly influence nutritional value by affecting composition of the product. In the diets of cattle change in fermentation can affect milk fat content.

Starch is also needed to maintain microbial digestion and subsequent protein synthesis; both are positively correlated with the yield and percentage of milk content.

The quality of the animal feed itself, i.e. presence or absence of environmental contaminants, can have an indirect effect regarding safety of the final food product.

For instance, aflatoxin-containing forage fed to dairy cows, can be hydroxylated to a metabolite of aflatoxin. About one-fifth of the ingested aflatoxin is carried over to milk as the hydroxylated metabolite.

The ***housing conditions*** of animals determine the bacterial load at their surface. In general, the cleaner the housing conditions the lower the load. To achieve product quality at farm level it is important for farmers to know the sources of contamination and to understand how to control them. Large numbers and a great variety of micro-organisms are found on the surface and in the intestinal tract of cattle, sheep and pigs; pigs generally have higher counts of micro-organisms than cattle.

For meat production both the exterior and interior load are important factors for food safety. Although the underlying tissue of the slaughter animals is assumed to be sterile, high bacterial loads on the interior and/or exterior surfaces can lead to contamination of other animals during transport or contamination of the sterile meat in the estuary.

For milk production, hygienic preventive measures must be taken including the cleaning of teats, correct sterilizing of milk equipment and exclusion of milk from mastitis cattle.

For fish, the bacteria on the skin and gill surfaces are affected by variations in marine environments. Psychrophiles and micrococci are the major spoilage bacteria.

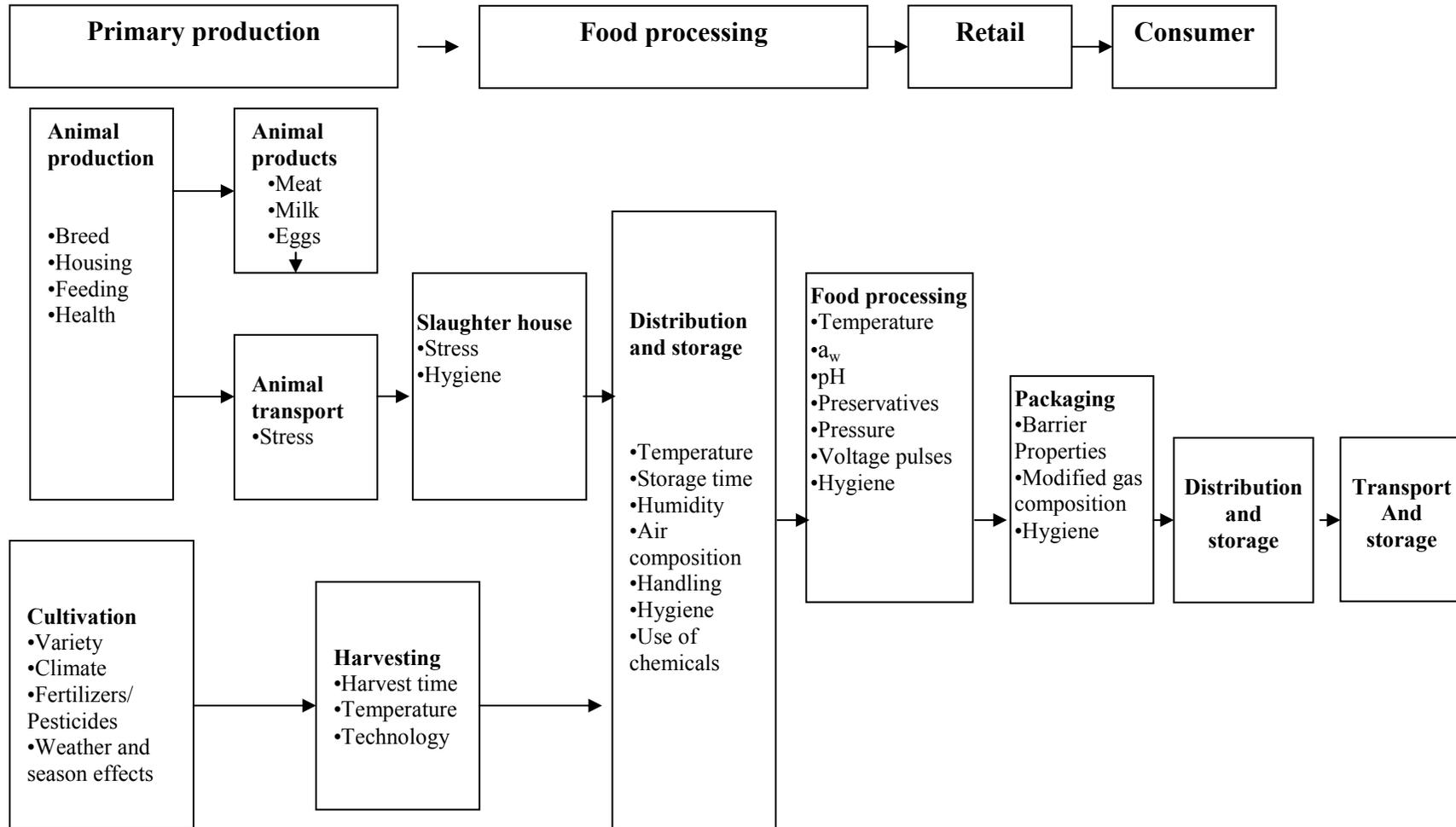
Another aspect of housing is the stocking ratio, i.e. intensive versus extensive housing. Differences in product quality were tenderness from outdoor reared animals.

In a sensory evaluation study it was shown that when panelists were aware of the origin of the animals, they rated free-range pork as juicier, less bland, tenderer and more palatable. When the panelists were unaware of the origin, no significant differences were observed in sensory attributes. Peoples' merits perception of a production system seems to influence their perception of the quality of the product produced by the system.

***Animal health*** and use of veterinary drugs can also influence product quality. For example, occurrence of mastitis leads to alterations in the composition and chemical-physical properties of the milk. The number of somatic cells is an indicator of the qualitative and hygienic properties of milk and reflects the mastitis situation of the given animal. Animal diseases are often treated with antibiotics and their residues in animal products are assumed to be associated as a human health hazard.

For protection of consumers the European Union and the Codex Alimentarius have set maximum residue limits of veterinary drugs in foods of animal origin.

There is concern about the addition of antibiotics and steroids to feed, to accelerate growth of the animals. Animal pathogens may become resistant to the antibiotics and resistant pathogens might be transferred from animals to human. There is a potential risk that these resistant pathogens cannot be treated with human antibiotics and may have large consequences for human health.



*Figure 4*  
 Quality affecting factors in agrifood chain

Whereas antibiotics residues can have a direct effect on food safety, the use of veterinary drugs in itself can also be an important extrinsic quality attribute, since the production technique can affect the consumers' acceptance.

***Transport and slaughter conditions*** can affect intrinsic attributes like sensory properties, food safety and microbial shelf life.

***Stress*** factors such as exercise, fear, hot and cold temperatures can negatively affect meat quality during transport and handling of slaughter animals (Fig. 4). Stress can result in different quality defects depending on type of animal. Due to stress glycolysis is stimulated, which results in a too rapid pH decrease while cooling is not yet completed. As a consequence, the sarcoplasmic proteins degrade to contractile proteins and thus modify physical properties. In cattle, too high post mortem pH due to ante mortem stress can result in meat with dark, firm and dry characteristics (DFD meat).

Measures to prevent or reduce stress during transport and handling include:

- Proper loading density
- Loading and unloading facilities
- Duration of transport
- Mixing of animals

The ***estuary*** includes many steps like killing, bleeding, scalding, skinning and evisceration, during which the sterile underlying muscle tissue can be contaminated by the intestinal tract, the exterior surface, hands, knives and other utensils used. Total bacterial counts for freshly cut meat surfaces are likely to vary between  $10^3$  and  $10^5$  organisms per  $\text{cm}^2$ . Reduction of the microbial load of freshly killed animals can be achieved to a certain extent by spraying the carcasses with hot water containing chlorine, lactic acid, or other chemicals.

## **Food processing conditions**

Physical properties of manufactured foods are determined by compositional characteristics of individual ingredients and/or raw materials (pH, initial contamination, presence of natural anti-oxidant), composite (addition of preservatives) and by processing conditions (temperature, pressure). Effects of different processes and handling on quality attributes from a technological perspective are presented in Table 4.

When considering current food preservation techniques, there are limitations to a relatively small set of parameters, including time and temperature (t-T), pH (acidity),  $a_w$  (water activity), use of preservatives and modification of gas composition or combinations.

**Temperature-time:** elevated temperatures are applied to *reduce* the number of micro-organisms, to *inactivate* enzyme activity and to *increase* chemical reactions.

Low temperatures are used to *inhibit* growth of micro-organisms or delay chemical and physiological reactions. For all these processes not only the level of temperature (T), but also the duration (t), determines the degree at which the process occurs.

The temperature effect profiles differ for each specific reaction. For example, bacteria, yeast and mould species each have an optimum growth temperature; at high temperature they are inactivated, whereas at low temperatures their growth is delayed. Likewise, enzymes have an optimum and an inactivation temperature profile.

**Water activity ( $a_w$ )** is also an important factor in regulating growth of micro-organisms, enzyme activity and the occurrence of chemical reactions. It is obvious that no microbial growth occurs at a water activity below 0.6, whereas lipid oxidation rate increases both at very low and at higher  $a_w$  values. The exact reaction rate, position and shape of the curve, can change depending on composition, physical state and food structure. Gas composition and temperature can also influence the  $a_w$  profiles.

The **acidity (expressed by pH)** is another factor in controlling bacterial, enzymatic and chemical reactions.

Most micro-organisms grow best in the pH range 6.6 - 7.5 and a few grow below 4.0. The pH of food products range from 1.8 (limes) to 7.3 (corn). Bacteria generally have a smaller pH range than moulds and yeasts.

**Food additives** are added in food for functional purposes. Many are natural materials that influence shelf life and food safety. Food additives have to provide a useful and acceptable function to justify their use: improved shelf life, enhanced nutritional value and processing facilitation, improved physical product properties.

The **gas compositions** of headspaces in packaged foods together with properties of packaging materials greatly influence shelf life and food safety. Especially, lower oxygen concentrations delay oxidative reactions, inhibit growth of aerobic micro-organisms and decrease respiration rates, extending the shelf life of food products. Several packaging concepts such as vacuum, modified atmosphere and active oxygen scavenging are used to obtain these conditions.

Since low oxygen levels may favour the growth of some anaerobic food-borne bacteria, preventive measures must be taken, such as correct heat treatment and/or low pH, and/or low  $a_w$ , and/or hygienic handling.

**Combination of factors, technologies:** nowadays there is a shift from individual to a combination of preservation factors to guarantee food safety, while maintaining sensory properties and nutritional value.

Some typical combination treatments include:

- enhancement of the effectiveness of an anti-microbial acid by lowering the pH
- anti-microbial efficacy of carbon dioxide in modified atmosphere is greatly enhanced at reduced temperature
- foods with low water activity and/or reduced pH require a milder heating treatment because of the synergy between  $a_w$ , pH, temperature
- the combination of mild heating of vacuum-packed food with well-controlled chill storage also appeared to be successful.

**Initial contamination and hygienic production:** initial and cross contamination at food manufacturing influence shelf life and food safety. Different factors during harvesting and slaughter conditions may affect the initial contamination of raw materials. Contaminations during processing may originate from improper personal hygiene, unfiltered air, cross-contamination between products and insufficient cleaning of equipment and machines.

**Storage and distribution conditions** may influence the quality of fresh produces and manufactured foods.

*Fresh products* such as fruits and vegetables keep their respiratory activity also after harvesting, so the temperature and composition of the storage atmosphere can influence their preservation. Their exposure outside the recommended temperature range affects their quality and shelf life, e.g. chilling injury (tissue necrosis, black spots and wooliness in texture).

The major factors which affect manufactured foods are storage temperature and duration, as well as packaging materials which prevent contamination and/or diffusion of moisture and/or oxygen.

**Table 4**  
**Overview of effects regarding food processing conditions  
 and handling on quality attributes**

Processing and handling	Effects on Quality
<p><i>Current food processing systems</i></p> <ol style="list-style-type: none"> <li>1. Heating/freezing and cooling</li> <li>2. Curing and drying</li> <li>3. Fermentation</li> <li>4. Irradiation</li> <li>5. Extrudatation</li> <li>6. Separation techniques (membrane separation)</li> <li>7. Manual handling</li> <li>8. Mechanical handling (washing, slicing, deboning)</li> <li>9. Packaging (vacuum, modified atmosphere, active packaging)</li> <li>10. High pressure treatment and high electric field</li> </ol>	<ul style="list-style-type: none"> <li>• Increase of shelf life and inactivation of micro-organisms</li> <li>• Modification of texture, flavour, colour, or delay of chemical and enzymatic degradation</li> <li>• Shelf life extension and improvement of food safety by stabilization and inhibition of micro-organisms</li> <li>• Modification texture, flavour, colour by chemical and physical reactions</li> <li>• Shelf life extension and improvement of food safety by stabilization, reduction or inhibition of growth of micro-organisms</li> <li>• Modification of texture, flavour, colour by chemical and biochemical reactions</li> <li>• Shelf life extension</li> <li>• Inactivation of micro-organisms</li> <li>• Initiation of chemicals reactions (lipid oxidation)</li> <li>• Shape, texture, colour and taste formation</li> <li>• Removal of cell and fat particles</li> <li>• Microbial contamination</li> <li>• Improve product convenience</li> <li>• Microbial contamination</li> <li>• Shelf life extension</li> <li>• Delay of chemical reactions</li> <li>• Shelf life extension, inactivation of micro-organism and enzymes</li> <li>• Enhanced chemical reactions (lipid oxidation)</li> <li>• Improvement of sensory properties</li> </ul>

## 1.4. Quality improvement by organizational / business strategies and policies

### 1.4.1. Introduction

Improvement of products and processes, in food and agribusiness, is of great importance, fostering competitive demands for innovation; improvement and reduction of costs. The trilogy: planning, control and improvement is the key for progress in this area.

**Quality planning** is the continuous process of product development or services, which meet customer demands.

**Quality control** includes actions undertaken which achieve the objectives that involves evaluation of actual quality performance in comparison with quality objectives and action to annulate the differences.

**Quality improvement** is stimulated by the need for change. It implies that the companies learn to facilitate, communicate, set up procedures and reward systems on identifying changes in internal and external business environment aimed at avoiding routine and rigid structures.

An important base for quality improvement is an approach with both management and employee involvement. Management should initiate the driving force for this process; because improvement alters routine structures. In many cases within firms, routine structures exist, that cause rigidity. They hamper the improvement and will only be accepted if there is sufficient commitment.

Quality improvement is a systematic approach for improving a system. It involves documentation, measurement and analysis. Typical goals of quality improvement include increasing customer satisfaction, achieving higher quality levels, reducing cost, increasing productivity and accelerating the process.

## 1.4.2. Concepts and steps of improvement processes

Three crucial steps in the improvement of processes within a system are established through:

### Map the process

- Collect information about the process, identify each step, determine inputs and outputs, people involved and decisions to take.
- Document measurement including time, cost, working conditions, employee situation, environment and waste, accidents and/or safety hazards, revenues and/or profits, quality and customer satisfaction, as appropriate.
- Prepare a flow chart that accurately depicts the process, with key activities and decisions represented inside.

### Analyze the process

- Ask questions about the process: is it logical, are any steps or activities missing, are there any duplications?
- Ask questions about each step: is the step necessary, could it be eliminated, does the step add value, does any waste occur at this step?
- Analyze for improvement by asking: what causes induced known problems, could they be eliminated, can the process be improved by shortening time or by reducing costs, can the process be improved by providing better conditions for quality?

### Redesign the process

Use results of analyses to redesign the process. Do documents improve, potential measures such as reductions in time, space, waste, employee turnover, accidents, safety hazards, improvement of working conditions, revenues/profits, quality, for customer satisfaction.

In the 1970s, the concept of TPM (Total Productive Maintenance) came up in the manufacturing industry.

TPM is a method designed to identify and alert cause of equipment breakdowns and system downtime. Instead of accepting maintenance as necessary, TPM tried to achieve the ambitious goal of zero breakdowns.

Another improvement concept has been introduced in 1993 by *Hammer and Champy*, which they termed *business re-engineering*.

Re-engineering (also known as process redesign) is a type of improvement with the potential to improve the quality and speed of work and to reduce its cost by changing fundamental processes.

Re-engineering goes beyond the process level by including the entire value chain and reorganizing of fundamental redesign and restart. It is often used when the improvement needed are so great that incremental changes to operations will not be sufficient.

*Deming* introduced a framework (the Deming cycle - the **Plan-Do-Check-Act**) where all parties can discuss problems and suggest improvements continuously.

The use of the PDCA cycle is to co-ordinate the improvement efforts.

### **Plan**

Study the current processes and document. Collect data and identify problems. Survey data and develop a plan for improvement. Specify measures for evaluating the plan.

### **Do**

Implement the plan, on a small scale. Collect the data systematic for evaluation.

### **Check**

Evaluate the data collected during the “do” phase. Check how results match original goals of the plan phase.

### **Act**

If the results are successful, standardize the new method and communicate the new method to all people associated with the process. Implement the training for the new method. If results are unsuccessful, revise the plan and repeat the process or finish the project.

*Ishikawa* was the first expert who paid attention to the internal customer. He was a strong supporter of the need for companies to have a shared vision, being recognized for his efforts to make quality control a “user friendly” factor for workers.

His contribution can be placed in the context of the features of quality:

**A company-wide control program**

All levels and types of personnel within the company are engaged in systematic work, guided by written quality policies, which are endorsed by upper management.

**Top management is subject to quality audits**

A quality executive team visits each company department to identify, isolate and help solve any obstacles to produce quality products or services.

**Industrial education and training**

Since quality requires participation of everyone involved, by education and training in all departments at each level.

**Quality circle (QC) activities**

A quality circle is “a small group which meets voluntarily to perform quality improvement and who provides a forum to discuss the department’s problems.

**Application of statistical techniques**

### 1.4.3. Tools for quality improvement

A sustainable amount of data is required to be collected, sorted and analyzed correctly.

**The main tools are:**

- **the check sheet**, a simple tool used for problem identification: enables users to record and organize data in a way that facilitates collection and analysis.
- **the flowchart**, a visual representation of a process. As a problem-solving tool, a flowchart helps investigations in identifying where problems occur. A flow-chart consists of procedures and decision points.
- **the scatter diagram**, useful in deciding if there is a correlation between two variables, using one variable to make a prediction about another variable.
- **the histogram** representing the distribution of observed values. One can see if it is symmetrical, the range of values, if there are any unusual values, etc.
- **the control** chart displays data over time as well as computed variations of data. The charts visually depict when the data falls outside a previously set range.
- **the “cause-and-effect”** diagram offers a structured approach to the search for the cause(s) of a problem. It helps to organize problem-solving efforts by identifying categories of factors that might be causing problems.

#### **1.4.4. Basic conditions for quality improvement: personnel and team work**

Implementing a psychology of continuous improvement in an organization may be a long process with several essential steps:

1. train employees in the methods of statistical process control (SPC) and other tools for improving quality and performance
2. make SPC methods a normal aspect of daily operations
3. build work teams and employee involvements
4. utilize problem solving tools within the work teams
5. develop a sense of operator ownership in the process.

The employee involvement is central to the philosophy of continuous improvement.

The last two steps are crucial if the philosophy is to become part of every day's organization. The sense of operator ownership appears when employees feel as if they own the processes and methods they use and take pride in the quality of the product or service they produce. This sense can derive from participating to teamwork and to problem solving activities, which give employees a feeling that they have control over their workplace and tasks.

#### **Teamwork**

Evidence suggested that teams typically do better than individuals when tasks require multiple skills, judgment and experience. As organizations have restructured themselves to complete more effectively and efficiently, they have turned to teams as a way to better utilize employee talents. Management observed that teams are more flexible and responsive to changing events than traditional departments or other forms of permanent groupings. Teams have the capacity to quickly assemble, deploy, refocus and disband. Furthermore, teams facilitate employee participation to decision-making, stimulating employee motivation.

A team is a small group of people with complementary skills, who work together to achieve a shared purpose and goal, themselves mutually accountable for its accomplishment.

The difference with a workgroup is that a workgroup is a group that interacts primarily to share information and to make decisions to help each other to perform within each member's area of responsibility.

Workgroups have no need or opportunity to engage in collective work that requires joint effort. So their performance is merely the summation of all group members' individual contributions: there is no positive synergy - the creation of a whole that is greater than the sum of its parts.

However, teams have their disadvantage as well. Problems that are commonly encountered in teams include:

- personality conflicts: individual differences in personality and work style can disrupt the team
- task ambiguity: unclear agendas and/or ill-defined problems can cause teams to work too long on the wrong things
- poor readiness to work: time can be wasted when meetings lack purpose and structure
- poor teamwork: failures in communication, conflict and decision making may limit performance and/or hurt morale.

## **Committees and task forces**

Committees and task forces bring people together outside of their daily job assignments to work in small teams for a specific purpose. They typically operate with task agendas and are led by a designed chairperson who in turn, is held accountable for the results.

A committee usually operates with an ongoing purpose and its membership may change over time. An example is the quality steering committee being responsible for developing quality and quality systems.

A task force usually operates on a more temporary basis. Its official tasks are very specific and time defined. Once the stated purpose has been accomplished the taskforce may disband.

## **Cross-functional teams**

Cross-functional teams are made up of employees at about the same hierarchical level, but from different work areas, who come together to accomplish a task. They are expected to exchange information, to develop new ideas, solve problems, co-ordinate complex projects, and not to be limited in performance by purely functional concerns and demands.

## **Virtual teams**

Virtual teams use computer technology to link together physically dispersed members in order to achieve common goals.

Virtual teams can do all things that other teams do – share information, make decisions, and complete tasks.

The three primary factors that differentiate virtual teams from face-to face are:

1. the absence of para-verbal cues,
2. limited social context,
3. the ability to overcome time and space constraints. Less direct interaction among members.

## **Self-managing teams**

Self-managing teams are generally composed of people who take care of responsibilities of their former supervisors. Typically, these responsibilities include collective control over the place of work, determination of work assignments, and organization of breaks and collective choice of inspection procedures.

Fully self-management teams select their own members and the members evaluate each other's performance. As a result, supervisory positions become less important and may even be eliminated. Self-management teams operate with participation, decision-making and multi-tasking, in which team members each have the skills to perform several different jobs.

### 1.4.5. Strategies for organizational change

Organizational change is very important for the quality management, especially when human capacities are used.

The bases of continue improvement philosophy is the belief that, virtually any aspect of an operation can be improved and that people closely associated with an operation are in the best position to identify changes that should be made.

It was observed that the most difficult aspects in implementation of new technology and systems were changing the organization and people.

Choosing between *top-down* change and *bottom-up*, the latter is preferable for quality management.

- In *top-down* change strategic changes are initiated, with a comprehensive impact on the organization and its performance capacities. The success of *top-down* change is usually determined by the willingness of middle and lower level workers to actively support top management initiatives.
- In *bottom-up* change the initiatives come from persons throughout the organization and are supported by effort of middle and lower level managers. Bottom-up change is essential to organizational innovation and is very useful in terms of adapting operations and technologies in order to change requirements of work.

When change occurs, commonly there will be resistance against change. Some of the major reasons for resistance to change include uncertainty and insecurity, reaction against the way change is presented, threats to vested interests, cynicism and lack of trust, as well as lack of understanding.

Dealing with change, objectives and resistance requires a change in strategy. Elements of change strategies are education, communication, participation, facilitation, negotiation and compulsion. Different strategies prefer different elements depending on the specific situation.

**Forced coercion strategies** use the power bases of legitimacy, rewards and punishment as primary inducements to change. Forced coercion can be pursued in at least two ways, both of which can be commonly observed in organizations.

In a *direct forcing* strategy, the change agent takes direct and unilateral action to “command” that change takes place. This involves use of formal authority or legitimate power, offering special rewards, and/or threatening punishment.

In political *manoeuvring*, the change agent works indirectly to gain special advantage over other persons and thereby make them change. This involves bargaining, obtaining control of important resources, or granting small favours.

Change agents using a **rational persuasions strategy** attempt to bring out change through persuasion, by special knowledge, empirical data, and rational arguments.

The likely outcome is eventual compliance with reasonable commitment. This is an informational strategy that assumes that facts, reason and self-interest will guide rational people when deciding whether or not to support a change.

A **shared power strategy** engages people in a collaboration process of identifying values, assumptions and goals, from which support for change will naturally emerge.

The process is slow, but it is likely to yield commitment. Sometimes called a *normative-re-education strategy* this approach is based on empowerment and is highly participative in nature. It relies on involving others, in examining personal needs and values, it relies on group norms, and operating goals.

Power is shared by the change agent and other persons as they work together to develop a new consensus to support needed change.

## 1.4.6. Quality improvement in the food industry

Quality improvement is still not a success story in the food industry. Sometimes in food companies success stories are told only about e.g. good functioning of Total Productive Maintenance (TPM).

Considering the typical situation in the food industry, the following aspects maybe reasons for the fact that improvement activities are not yet very common in food:

- Low level of education sometimes combined with language problems, makes it more difficult to involve operators or employees in problem solving activities.
- The production circumstances are often hindering (noise, bad smell, and high humidity).
- Most knowledge is centralized in the specialized departments, and the responsibility for improvements is assessed by specialists coming from those departments.
- Equipment is often not very accessible for improvement. The knowledge is allocated with the supplier of the equipment who also carries out modifications.  
The users of the equipment often cannot submit any requests or needs and are restricted to the assortment of equipment as offered by suppliers.
- Poor feed back of information about quality performance results. Especially the operators in lower levels of the organization are not well informed about the quality results.
- Improvement activities are usually not rewarded.
- Soft organization methods are not very common in the food sector. In general, the culture is more solution-oriented and pro-active, whereas, for discussion and analysis less time is spent.

The techno-managerial view for quality improvement suggests focusing on core competences, which must be supported by appropriate management activities:

A managerial condition for improvement is the **appropriate measurements and information systems**. This information should include the critical quality and safety points that are related to the technological core competences.

**Training** of operators and employees must be aimed at developing relevant technological and managerial knowledge for the specific quality control points they are responsible for.

**Team building** is another important management task but cannot be forced and requires good leadership capacities. Managers should not just install teams, but should facilitate team building in such a way that teams can grow spontaneously. (*Luning, & al., 2002*)

# chapter 2

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## Quality Assurance

### 2.1. Classification of quality systems (GPs, HACCPs, ISOs)

#### 2.1.1. Organisms and legislative norms which are formulating and controlling the quality assurance systems

In recent years there has been growing pressure for consistent product quality. Moreover, there is a need for food industries to demonstrate quality management practices in order to meet requirements of both legislation and the quality demanded by consumers.

Quality assurance is the term used for describing the control, evaluation and audit of a food processing system. Its primary function is to provide confidence for management and the ultimate customer, that is, in most cases the consumer. Consumers expect consistent quality products that offer absolute safety. This is reflected on steady increase in the involvement of regulatory and advisory bodies in the area of food quality. (*Gould and Gould, 1988*)

Food quality assurance systems are necessary at every stage of the food chain and in every sector of the food industry to ensure the quality and safety of food. Governments have the responsibility of establishing the standards, legislation and enforcement programmes necessary to control food quality and safety. On the other hand, the industry has the responsibility of implementing quality assurance systems, where necessary to ensure compliance with the standards and legislation.

Legal standards are those commonly established by the States or local agencies and generally are mandatory. These mandatory standards are set up by law or through regulations and represent the minimum standards of quality. The voluntary standards generally represent a consumer image and may become a trademark or symbol of product quality.

## **INTERNATIONAL FOOD STANDARDS**

### **Food and Agriculture Organisation (FAO)**

The FAO was founded in 1945 with a mandate to raise levels of nutrition and standards of living, to improve agricultural productivity, and to better the condition of rural populations.

There is a Food and Nutrition Division that includes the Food Safety and Quality Service (ESNS) that among others maintains liaison on technical matters relating to food safety, quality and consumer protection.

### **World Health Organisation (WHO)**

WHO is the United Nations agency with a specific mandate for the protection of public health. Its role in food safety is to protect the consumer against exposure to adverse effects from hazards in food. Its Constitution, article 2, gives a mandate to develop, establish and promote international standards with respect to food. This organization has always recognized that access to adequate, nutritious and safe food is a right of each individual.

WHO's objective is the attainment by all peoples of the highest possible level of health, and an important prerequisite for health is safe food.

## **World Trade Organization (WTO)**

The World Trade Organisation was established in 1995. The WTO is the legal and institutional foundation of the multilateral trading system. It provides the principal contractual obligations determining how governments frame and implement domestic trade legislation and regulations. It is the platform on which trade relations among countries evolve through collective debate, negotiation and adjudication. The WTO aims to eliminate all trade barriers eliminating all discriminative measures.

Two of the WTO agreements, namely the Agreement on Sanitary and Phytosanitary Standards (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement), have a direct impact on food safety issues (*GATT 1994a*, *GATT 1994b*).

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) concerns the application of food safety and animal and plant health regulations.

The main purpose is to ensure that countries do not undermine international trade by imposing non-tariff barriers. The basic provisions of the SPS Agreement are that any measures that may affect international trade must not be stricter than necessary for the protection of human, animal or plant health, must be based on scientific principles, and must not be maintained without sufficient scientific evidence (*GATT 1994a*, *GATT 1994b*).

The SPS Agreement defines “international standards, guidelines and recommendations”, with reference to food safety as those established by the Codex Alimentarius Commission and with reference to zoonosis as those developed under the auspices of the Office International des Epizooties (OIE). Codex and OIE standards and guidelines therefore assumed a completely new dimension as the reference of national trade requirements.

## **FAO/WHO Codex Alimentarius**

The Codex Alimentarius Commission is a body set up to establish minimum standards for international trade. It is intended that compliance with Codex requirements should safeguard the integrity of the food in question, and preclude trade barriers preventing its entry to any participating country.

The standards are agreed, under the auspices of FAO/WHO, through a laborious and lengthy sequence of negotiation between participating countries, with one acting as a lead body.

There are numerous Codex standards covering general requirements and guidelines (food hygiene) and specific requirements for food products (fruits and vegetables, fruit juices, cereals, fat and oils, fish, meat, sugars, milk).

The FAO/WHO Codex Alimentarius Committee specifically concerned with food hygiene is the Codex Committee on Food Hygiene (CCFH).

This Committee has developed the following standards.

- General Principles of Food Hygiene (Codex Alimentarius, 1997a)
- Revised Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) (Codex Alimentarius, 1997b).

## **International Standards Organization (ISO)**

ISO is a network of the national standards institutes of 150 countries, on the basis of one member per country, with a Central Secretariat in Geneva, which co-ordinates the system.

The ISO 9000 series of standards is the International Standard for Quality Management Systems, which is:

- Designed to demonstrate a supplier's/manufacturer's/service agent's capability to control the processes that determine the acceptance of the product supplied.
- Aimed at prevention and detection of nonconformity and the implementation of means to prevent its recurrence.

The ISO 9000 series were developed in 1987, and also in that year it was adopted by CEN, the European Committee for Standardization, as EN 29000 (Surak, 1992). In 1994, they were updated (ISO, 1999). In 2000 it was further updated and republished as ISO 9001:2000 that establishes the quality management systems requirements. It is interesting to note that the requirement for ISO 9001 standard is becoming common worldwide.

ISO standards are voluntary. As a non-governmental organization, ISO has no legal authority to enforce their implementation. A certain percentage of ISO standards as ISO 9000 are referred to in legislation of some countries.

However, although ISO standards are voluntary, they may become a market requirement, as has happened in the case of ISO 9000 quality management systems.

## **NATIONAL FOOD STANDARDS**

### **Europe**

The legal framework for food control in the European Union Member States is currently in process. Serious food safety incidents during the last years urged the European Union and other countries across the world to review their food safety systems and to look for better ways to protect consumers against unsafe food. In 2000 the European Union launched its White Paper on Food Safety as a start for a new legal basis for appropriate food production and food control. According to the White Paper on Food Safety food legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and update (Commission of the European Communities, 2000).

The EU took the initiative in 1993 (Council Directive 93/43/EEC on Food Hygiene) by making HACCP mandatory across the food industry. However, within the EU, member states have been taking different approaches to their duty under Directive 93/43/EEC Article 5 to provide guidelines and support the HACCP implementation. Directive 93/43/EEC also encourages the application of ISO 9000 standards on quality assurance in order to implement general hygiene rules.

The nature of EU directive is that they have to be implemented through national legislation, unlike its regulations and decisions, which apply automatically. Each member state must introduce its own measures to implement each directive within a specific period, to achieve the objectives agreed and set out in the directive. Harmonised rules can be introduced effectively through directives, but the result is less uniform than when regulations are introduced directly and simultaneously into each state. A new hygiene package has been proposed as regulations.

Three new regulations covering the hygiene and official controls of foodstuffs have been adopted. These new regulations include HACCP principles.

1. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
2. 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.
3. 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.

On the other hand, the European Committee for standardization (CEN) promotes voluntary technical harmonization in Europe in conjunction with worldwide bodies and its partners in Europe and the conformity assessment of products and their certification.

## **USA**

The Food and Drug Administration (FDA) enforces food safety laws governing domestic and imported food, except meat and poultry. The FDA establishes good food manufacturing practices and other production standards, such as plant sanitation, packaging requirements and HACCP programmes.

The Food Safety and Inspection Service (FSIS) is a public health agency in the USDA (US Department of Agriculture). This agency enforces food safety laws governing meat and poultry products. There are mandatory HACCP requirements for all meat and poultry plants.

## **Australia and New Zealand**

Existing food hygiene regulations are contained within state and territory legislation, such as Food Acts and associated food hygiene regulations.

In 1989 the federal inspection system of Australia introduced a voluntary system called Production Quality Arrangements (PQA) and the Quality Arrangement for meat processing (AQA). Each system included HACCP. In 1994, the Meat Safety Quality Assurance (MSQA) system was introduced gradually to replace the PQA system. It incorporated most of the ISO 9000 elements and used HACCP system. A second edition of MSQA replaced the AQA system.

The Australian New Zealand Food Authority (ANZFA) was formed in 1996 as a result of a treaty signed between the two countries to develop joint food standards. This has led to the new Joint Food Code in 2000. This standard build on aspects of good manufacturing practices and link into HACCP-based programs required under food hygiene regulations.

## **NON-OFFICIAL PRIVATE STANDARDS**

Responding to the demands of consumers, retailers and their global suppliers have created and implemented a series of sector specific certification standards.

### **EUREP-GAP**

The EUREP-GAP system was developed by the Euro Retailer Produce Working Group. This system was established to control food safety related aspects at producer level. EUREP-GAP uses GAP (Good Agricultural Practice) as a production standard for the certification of good agricultural practice in the agricultural and horticultural industry. At this moment, the GAP standard is being applied in fresh fruits and vegetables. All kinds of agricultural products for human consumption can be certified with this standard. Special standards for animal production are under development. EUREP-GAP is based on the principles of risk prevention, risk analysis (among other through HACCP), sustainable agriculture by means of Integrated Pest Management (IPM) and Integrated Crop Management (ICM).

## **BRC (British Retail Consortium)**

This food standard was generated in 1990 by the British Retail Consortium (BRC). The British Retail Consortium is the lead trade association for the UK retail industry.

The objective of the BRC Standard is to specify Food Safety and Quality criteria required to be in place within a manufacturer's organization to supply product to UK retailers. The format and content of this standard is designed to allow an assessment of the supplier's premises and operational systems and procedures by a competent third party, thus standardizing food safety criteria and monitoring procedures.

The Standard requires:

- The adoption and implementation of HACCP.
- Documented and effective quality management system.
- Control of factory environment standards, product, process and personnel.

Organizations complying with this standard will receive an internationally recognized certificate displaying the BRC quality mark. This certificate of compliance will give assurance to potential customers that the product they are buying is safe for their consumers.

## **International Food Standard (IFS)**

In 2002, in order to create a common food safety standard, German food retailers from the HDE (Hauptverband des Deutschen Einzelhandels) developed a common audit standard called International Food Standard or IFS.

In 2003, French food retailers (and wholesalers) from the FCD (Fédération des entreprises du Commerce et de la Distribution) have joined the IFS Working Group and have contributed to the development of IFS version 4. The IFS standard has been established in several European countries.

IFS standard has been designed as an uniform tool to ensure food safety and to monitor the quality level of producers of retailer branded food products. The standard can apply for all steps of the processing of foods subsequent to their agricultural production.

The aim of the IFS is to create a consistent evaluation system for all companies supplying retailer branded food products with uniform formulations, uniform audit procedures and mutual acceptance of audits, which will create a high level of transparency throughout the supply chain.

The requirements of the IFS deal with five main subjects:

- Management of the Quality System
- Management Responsibility
- Resource Management
- Product Realisation
- Measurements, Analyses, Improvements

In the chapter "Management of the Quality System" requirements concerning the HACCP system, the HACCP team and the HACCP analysis are defined. It also contains rules for the quality manual and the obligation to keep reports and documents.

## 2.1.2. HACCP: Principles and stages

### 2.1.2.1. What is HACCP?

**Why do we need it?**

**How can we learn about HACCP?**

**Hazard Analysis Critical Control Point (HACCP)** is a food safety management system, which concentrates prevention strategies on known hazards and the risks of them occurring at specific points in the food chain. It is this specificity which makes HACCP so effective and the approach easily integrates into Total Quality Management or ISO 9000.

Developing HACCP assists companies to comply with legislation, supports due diligence and fulfils customer requirements for a food safety management system. The introduction of common food hygiene rules across the European Community through Directive 93/43/EEC was achieved within the UK in 1995 by the Food Safety (General Food Hygiene) regulations, which legally require the HACCP approach. Industry guides to good hygienic practice are voluntary guides providing more detailed advice on complying with the regulations as they relate to specific sectors.

Food safety should be given the highest priority, however companies are often short of time and appropriate personnel require training, especially in food safety, which needs to be widely disseminated throughout their company. Food safety management systems are much more likely to be effective if they are owned by all in production and management.

### 2.1.2.2. HACCP principles and logic sequences of application

#### HACCP PRINCIPLES

**Hazard Assessment of Critical Control Points (HACCP)** aims the identification, evaluation and control of steps that are critical to product safety in the food technological chain. HACCP enables the management of a cost-effective, ongoing food safety programme.

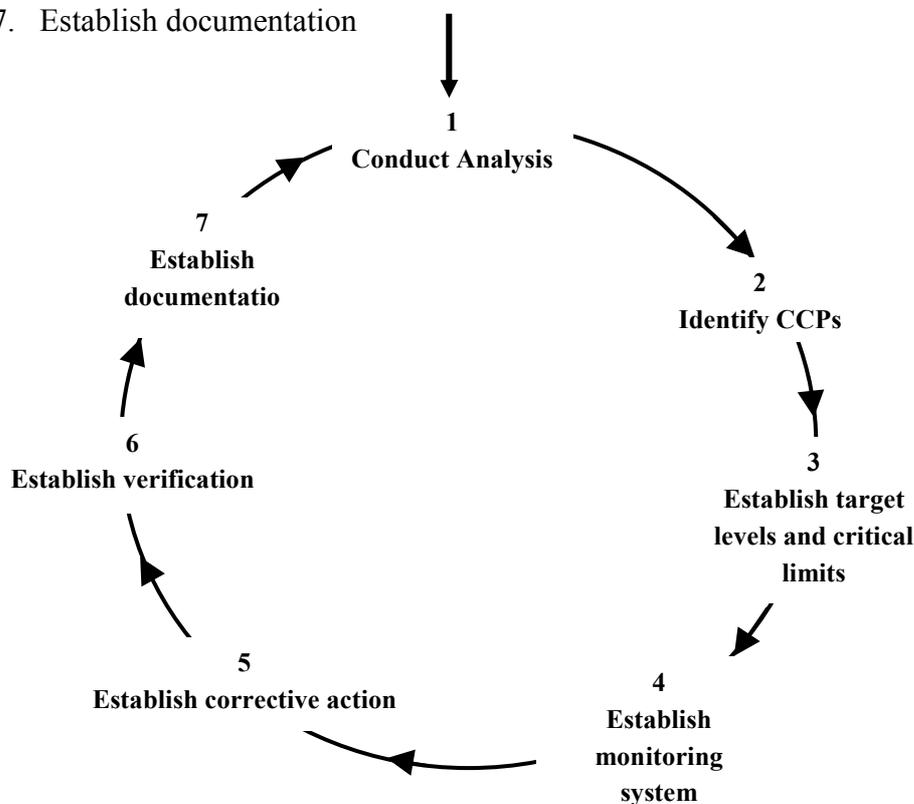
HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than end product testing. For the implementation of a HACCP based approach to food safety, the responsibility involves:

- Industries involved in food chain
- Policy makers and managers who can facilitate the adoption of HACCP systems

Government authorities, including legislators, regulatory food control officials and health education bodies.

The many activities involved in constructing a HACCP plan will be discussed in detail. The following **7 principles** should be used and considered by anyone involved in hazard analysis

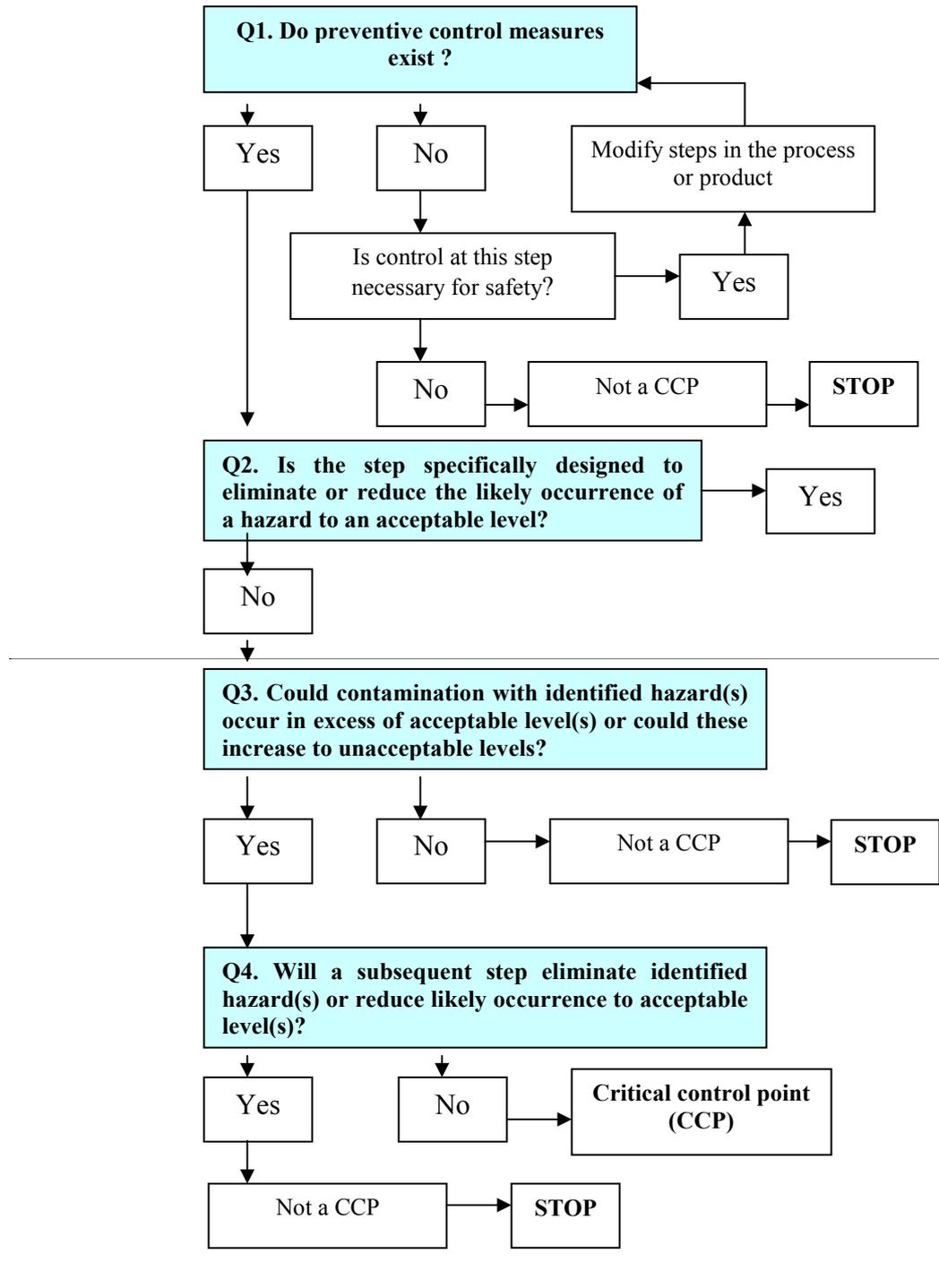
1. Conduct Analysis
2. Identify CCPs
3. Establish target levels and critical limits
4. Establish monitoring system
5. Establish corrective action
6. Establish verification
7. Establish documentation



*Figure 5*

The **HACCP system** consists of the following **seven principles**:

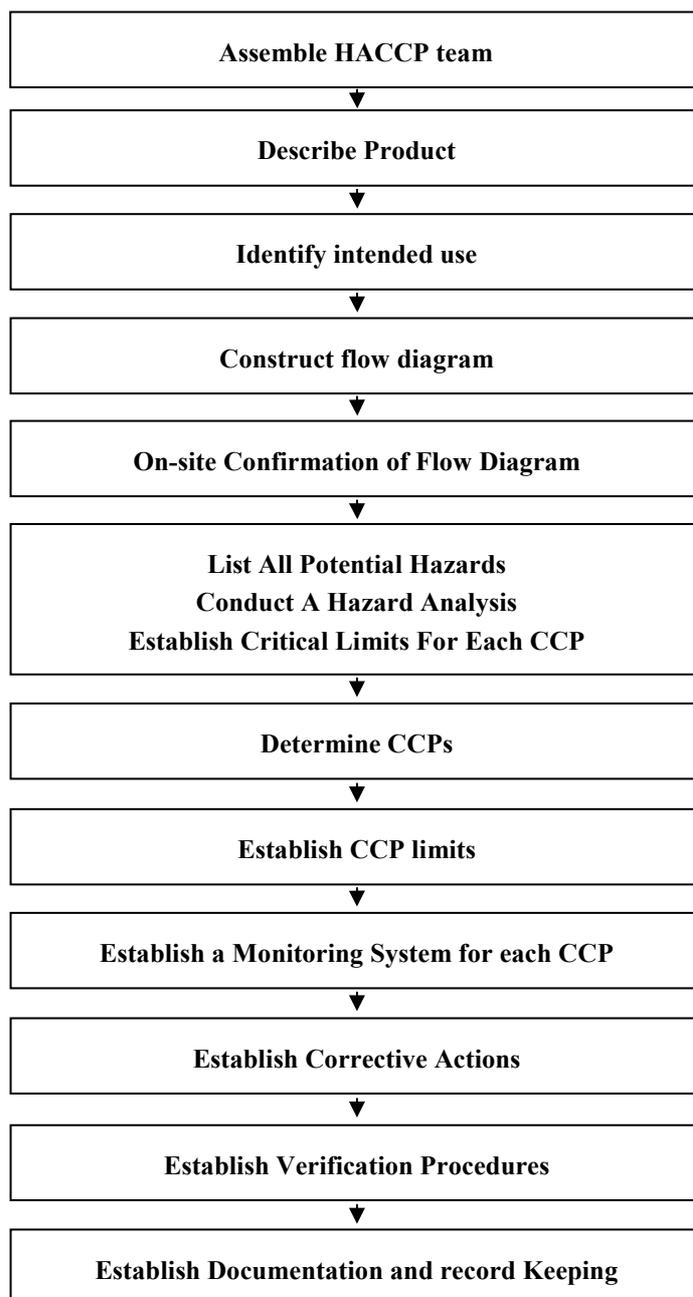
1. **Conduct a hazard analysis.** A multidisciplinary HACCP team identifies all the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution up to consumption; should identify which hazards are such nature that their elimination or reduction to acceptable levels is essential to the production of safe food; should evaluate likely occurrence of hazards and severity of their adverse effects.
2. **Identification of the Critical Control Points (CCPs)** which are “steps at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level”. A decisional tree to identify CCPs is presented as example in Fig 6.
3. **Establishment of the critical limit(s)** as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether an operation is producing safe products.
4. **Establishment of the system which monitor the CCPs** in order to allow adjustment of the process, preventing loss of its control.
5. **Establishment of the corrective action** to be taken when monitoring indicates that a particular CCP is not under control. Procedures should be in place to identify, isolate and evaluate products when critical limits are exceeded.
6. **Establishment of the verification procedures** to confirm that the HACCP system is working effectively, allowing the producer to challenge the control measures.
7. **Establishment documentation** concerning all procedures and records appropriate to these principles and their application.



*Figure 6*  
 Example of decision tree to identify CCPs

The HACCP plan must be 100 % focused on food safety. The most important HACCP concept is that it relies on prevention rather than inspection. HACCP is an evolving concept that continues to change and improve food quality.

The application of HACCP procedure includes 12 steps, in a logic sequence as presented in Figure 7.



*Figure 7*  
*Logic sequence for the application of HACCP*

## Step 1

### Assembling of an HACCP team

An HACCP study requires multidisciplinary skills and relevant departments involved in food production should be represented. This means individuals with specific knowledge and expertise appropriate to the product and process, but also people directly involved in daily activities, familiar with quality variability and limitations. The HACCP team should, at least, have the following constitution:

- *A quality assurance/quality control specialist*, who has knowledge on microbiological and/or chemical hazards and associated risks for particular product group.
- *A production specialist*, who is responsible, or is closely involved in the production process.
- *An engineer*, who has knowledge on hygienic design and engineering operation of process equipment.
- Buyers, operators, packaging experts, distribution experts and a hygienic manager.
- *A member of the management* to ensure management commitment

## Step 2

### Description of the product and its distribution

The team should make a full description of the product and its distribution. The description should include:

- Composition and physical features of final product ( $a_w$ , pH, etc.)
- Process information
- Method of packaging
- Required shelf life
- Storage and distribution conditions along the chain
- Legislative product requirement
- Instructions for use and storage by consumers

### **Step 3**

#### **Identification of product intended use and consumers**

The intended use of the product by consumers should be defined, e.g. the target consumer product group including the effects of potential abuse by consumers.

### **Step 4**

#### **Development of process flow diagrams**

Prior to the actual hazard analysis it is necessary to examine a process flow diagram, which provides a simple outline of all steps involved in the process. In the process diagram, sufficient technical data for the study must be provided, typical data that can be included are:

- All raw materials/ingredients and packaging use
- Time/temperature history of all raw material, intermediate and final products
- Process conditions like, flow rate, temperature, time, pH
- Storage and distribution conditions
- Product loops for recycling or rework
- Routes of potential cross-contamination
- High/low risk area segregation
- Overview of floors and layout of equipment
- Features of equipment design
- Efficacy of cleaning and disinfections procedures
- Personal hygiene practices
- Consumer-use instructions

### **Step 5**

#### **On-site verification of flow diagram**

The HACCP team should inspect the operation process to verify that each step in the flow diagram is an accurate representation of the actual situation.

Inspections of night-and weekend shifts should also be carried out. In case the analyses are applied to a proposed line and verification will not be possible, the team must ensure that the flow diagram represents correctly the processing options.

## **Step 6**

### **Hazard analysis (Principle 1)**

Hazard analysis is one of the most difficult steps in the HACCP procedure because identify all potential hazards and assess their risk. It is a rather complex step and requires much technological knowledge and information. The result of this step is a list of significant hazards, which must be controlled in the process. A hazard identification list, which contains all potential hazards that may cause injury or illness, must be composed.

The HACCP team must review all potential hazards linked to:

- Raw materials, ingredients and semi-finished products
- Contamination via equipment, personnel or environment
- Facility design (adequate separation of raw and processed materials guaranteed)
- Equipment (appropriate control of functions, time- temperature control, cleaning, etc.)
- Packaging, characteristics including labelling

## **Step 7**

### **Determination of Critical Control Points (Principle 2)**

A critical control point (CCP) is represented by the specific step at which control can be applied, and where control is essential to prevent or eliminate a food safety hazard or to reduce it to on acceptable level.

CCPs are unique for each process. The number of CCPs identified in the flow diagram is not limited.

CCPs are determined by applying the CCP decision tree, at each step of the process, for each potential hazard established in hazard analysis (Fig 2).

## **Step 8**

### **Establishment of critical limits for each CCP (Principle 3)**

Each CCP will have one or more preventive measures that must be controlled in order to assure prevention, elimination or reduction of hazards to an acceptable level. For each preventive measure, critical limits must be established. Critical limits can be set by legal and/or other requirements, or can be based on information from hazard analysis or quantitative risk analysis.

## **Step 9**

### **Establishment of a monitoring system for each CCP (Principle 4)**

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. It is required to assess if the CCP is under control and to provide written documentation for verification. The monitoring system and procedure for each CCP need to :

- detect the loss of control at the critical point
- inform about many to adjust the process
- assign a person with relevant knowledge to evaluate and sign the monitoring data

## **Step 10**

### **Establishment of corrective actions for each CCP (Principle 5)**

If monitoring data reveals deviation from critical limits, corrective actions must be taken, for ensure that the CCP has been brought under control.

Corrective actions include:

- determination and correction of the cause of non-compliance (non-conformance)
- characterization of the non-compliant product (non-conformance product)
- recording of corrective actions to take

The corrective actions plan must provide information about which actions should be taken when the process exceeds critical limits, and who is responsible for implementation and recording of corrective actions.

## **Step 11**

### **Verification of the HACCP plan (Principle 6)**

Verification is defined as activities (other than monitoring), that determines validity of the HACCP plan and assures that the plan is respected.

Verification can include:

- validation of initial HACCP plan
- verification if the HACCP plan is applied in practice, if it is correctly applied, if CCPs are monitored and under control, if corrective actions are recorded?
- validation of process steps by sampling and testing of CCPs
- calibration of equipment
- checking of training and knowledge of personnel responsible for monitoring CCPs.

## **Step 12**

### **Establish record keeping and documentation (Principle 7)**

Documentation and record keeping are essential for the HACCP system. The approved HACCP plan and HACCP procedures must be documented, whereas relevant data obtained during operation must be recorded. Examples of documentation are process flow diagrams, conductance of hazard and CCP analysis. Record include: information about used ingredients, processing data, specifications of packaging materials, temperature records etc. (*Luning et al., 2002*)

An example of a HACCP worksheet is presented in **Figure 8**.

1.

**Describe Product**

2.

**Diagram Process Flow**

3.

<b>LIST</b>							
<b>Step</b>	<b>Hazard (s)</b>	<b>Control measures(s)</b>	<b>CCPs</b>	<b>Critical limits</b>	<b>Monitoring procedures</b>	<b>Corrective actions</b>	<b>Records</b>

4.

**Verification**

*Figure 8  
 Example of a HACCP Worksheet*

## THE FOURTEEN STAGES OF HACCP

It is possible to implement the seven principles of HACCP in 14 separate stages. The Codex documentation identifies 12 stages; an additional stage has been added at the beginning and end within the UK HACCP approach. The approach outlined here reflects the sequence of the Codex documentation with verification procedures preceding record keeping.

The stages are presented in outline form in this section

1. Define the terms of reference. Choose the product and start with safety hazards
2. Assemble a HACCP team / if relevant
3. Describe the product / attach label
4. Identify intended use
5. Construct a flow diagram
6. Confirm on site
7. Identify and list all relevant hazards and preventative measures
8. Identify CCPs and apply the decision tree
9. Establish target levels and critical limits for CCPs
10. Establish monitoring system
11. Establish corrective action plan
12. Establish verification procedures
13. Establish documentation and record keeping
14. Review HACCP plan

### Stage 1

#### Define the Terms of Reference and Scope of the Plan

It is all too easy, when starting to construct a HACCP plan, to be over ambitious.

**It is better to complete a simple HACCP plan which can be expanded later than a complex plan which is never implemented or finished.**

Therefore, the terms of reference should be outlined clearly at the outset. Decide upon the process line, product and whether physical, chemical and microbiological hazards are to be considered.

When developing a HACCP plan for the first time, consideration of only one of these types of hazard is often practical.

The end point of the plan also needs to be defined, i.e. does the plan finish when the food leaves the factory. Initially this may be simpler and the plan may be subsequently developed to include reasonable expected abuse at later stages e.g. by retailers, caterers or consumers.

## **Stage 2**

### **Select and Assemble a Team**

Assembling the team provides a useful opportunity to motivate and inform employees about HACCP. Team selection should be done by the chairperson or an external HACCP specialist. It is essential to get the right blend of expertise as the team will collect, collate and evaluate technical data, and identify hazards and identify critical control points. People typically involved include quality assurance or control staff, production personnel, an engineer and a microbiologist.

**In smaller companies, one person may fulfil several roles  
or even constitute the whole team.**

**In the latter case use of external consultants or advice may be necessary.**

Ideally the team should not be larger than about six, although additional members may be co-opted when necessary. The team should have some initial training in HACCP. Adequate financial and human resources should be available to the team.

## **Stage 3**

### **Describe the Product**

The HACCP team needs to have as complete an understanding of the product as possible. All details of the product composition and processing should be known and understood. This information will be essential for microbiological hazards because the products composition needs to be judged in relation to the ability of different pathogens to grow (Stage 7).

This can be summarized as:

**Know your friends (the food – its composition and processing)**

**Know your enemies (the hazards – their severity and risk)**

The following structured checklist can help the HACCP team to record comprehensive information although small business may only be able to complete the general checklist.

## **Stage 4**

### **Identify the Intended Use**

It will be useful if you identify who are the likely purchasers or consumers of the product. Some groups of the population, elderly, very young, sick or immunologic ally compromised are much more susceptible to some hazards.

You may need to label appropriately. If there is a risk of *Listeria monocytogenes* being present, label “not recommended to be eaten during pregnancy”. Other examples include specific reactions to the product or its constituents e.g. nuts, azo-dyes, histamine, phenylalanine etc. The intended consumer group may affect your “level of concern”.

It will also be of benefit to understand how the food is likely to be handled or abused by consumers.

## **Stage 5**

### **Construct a Flow Diagram**

It will be much easier to understand the life history of the product if you produce a comprehensive flow diagram.

#### **A picture is worth a thousand words**

It is easier to identify routes of potential contamination, suggest controls and discuss this with others if you are looking at a diagram. The level of pictorial information on a flow diagram can be more detailed, if needed at specific stages, to enable a more thorough discussion.

## **Stage 6**

### **Confirm the Flow Diagram**

Once a flow diagram has been produced it needs to be checked for accuracy. Variations in work practices often occur when different line managers are in control, for example small differences can easily occur between one shift and another. The original flow diagram may have been produced from outdated documentation and may not include new machinery which may have been installed.

Remember:

**Because you're mine we walk the line  
You must verify if you have to testify**

This check will involve all members of the HACCP team and at different times with different shifts and can vary from simple inspection to a completion of comprehensive checklists. The more thorough the assessment the more likely the accuracy of the HACCP plan. The completed checklists can form a record of the assessment and provide a baseline for the assessment of change. Amendments or discrepancies from the original flow diagram should be noted.

## **Stage 7**

### **Identify and List all Relevant Hazards and Preventative Measures**

This stage is often the first problem for people producing their first HACCP plan, especially if they do not have access to current microbiological information and data. It is at this point that the chairperson has to ensure the HACCP team sticks to their terms of reference. Are all hazards to be identified or only one category e.g. chemical or microbiological? The latter do represent the largest known danger to health from food. Additionally operational malpractices and contamination points such as improper cleaning also need to be identified. Identification of hazards should start with raw materials and may finish, for example, with the product leaving the plant, or at the point consumption.

Once the hazards have been identified, preventative control measures based on knowledge of the hazards, and their normal sources and contamination points can be constructed.

## **Stage 8**

### **Identify CCPs – Apply the Decision Tree**

The HACCP team by now will have completed stages 1 to 7. A complete list of hazards will have been identified along with how the hazards can contaminate the food, plus a list of preventative measures. If a hazard does not have a preventative measure then the product or process should be re-designed. It is likely that a large number of preventative measures will have been identified and for the sake of good manufacturing practice (GMP) it may be desirable to implement many or all of them.

The raw material tree can be used to identify critical raw materials and ensure that the appropriate preventative measures are included within the final Supplier Quality Assurance system. Worked examples of the raw material decision tree are given in appendix 3. Not all however, will be essential for food safety and the next stage in the HACCP is to identify those points in the process at which safety control is critical.

These points can be identified by using the codex decision tree or other means and are known as critical control points (CCPs). They highlight for the manufacturer where particular care has to be concentrated in the implementation of preventative measures. There is no limit to the number of CCPs and it will vary considerably on the complexity of the process and the type of product.

## **Stage 9**

### **Establish Target Levels and Critical Limits**

The HACCP team will now have identified those preventative measures and specific points which are deemed critical to the safety of the product.

In some cases it will be relatively easy to establish a target value, and there may be no critical limit. For example, absence of metal determined by metal detection. The presence of metal indicates unacceptable, absence is therefore acceptable; the target has no metal present.

In other instances setting target levels and critical limits is not as easy. For example if the preventative measure is heat processing, a target temperature has to be selected and the critical limits (acceptable tolerance) stated. Selecting the appropriate temperature will require knowledge of any hazards and their heat sensitivity and also knowledge of the product including pH, surface area, heat penetration data, original temperature, weight and size, see appendix 2. It is essential that technical decisions about targets and critical limits are made by appropriate staff based upon evidence and not arrived by guesswork.

Results from preventative measures should be obtained rapidly and in time for remedial action to be taken. For example an increasingly used method of determining cleanliness at CCPs is to use luminometry or measurement of ATP.

A reading which is a measure of cleanliness can be obtained in minutes in the form of RLUs (Relative Light Units). Work need to be carried out, based on thorough cleaning, to establish the target level of cleanliness. Repeated determinations enable statistically based critical limits to be established, Critical limits based upon subjective data e.g. visual inspection, should contain clear specification of the target and examples that are unacceptable. This can be achieved by descriptive statements, photography and charts.

## **Stage 10**

### **Establish Monitoring System**

Monitoring is the series of observations or measurements to ensure that the preventative measures are being implemented correctly.

#### **If it's worth measuring, it's worth recording**

Monitoring enables management to detect loss of control at a CCP. Therefore, it is important to fully specify who, how and when monitoring is to be performed and recorded. Result from monitoring should be used pro-actively and illustrate how statistical process control (SPC) can be incorporated into HACCP. For example, results from cleaning at a critical control point, can be used to produce a process control chart. Some luminometers include software which automatically record results. These can be plotted to illustrate mean or range values. A low coefficient of variation (CV) indicates the consistency of the cleaning process.

$$\%CV = \frac{SD}{\text{Mean}} \times 100$$

## **Stage 11**

### **Establish Corrective Action Plans**

Work completed in Stages 9 and 10 will have specified the test to be implemented and monitored as well as target levels and critical limits. A corrective action plan describes what should happen if a deviation is found i.e. if the value of a measurement lies outside the critical limit. For this to have occurred there must have been a loss of control, e.g. failure to achieve a specified pasteurization temperature or failure to clean properly.

Additionally, corrective action plans are used to specify what should occur if the results obtained at a critical control point are not outside the critical limit, but trends e.g. from process control charts, suggest that they soon will be i.e. the process is approaching an uncontrollable state.

The action plan should contain written details of:

- immediate action to be taken, who is to be informed and the type of report to be produced
- what to do with the product that has been produced
- investigate how loss of control occurred i.e. what has caused the problem and how a recurrence is to be prevented. (Prevention of recurrence should be an essential element of any HACCP plan)
- who is to assume responsibility for decision making.

Ideally the person who assumes responsibility should have been involved in the original HACCP plan construction. Advice given on what to do with the product, produced under loss of control conditions, should be based on facts or deduction and not guesswork. For microbial hazards, predictive modelling packages e.g. MAFF micro model, may be useful.

A full corrective action plan requires that, either based on experience, prediction or modelling, all the likely problems have been anticipated. Details of how the defective product is handled and whose responsibility it is should be specified.

## **Stage 12**

### **Establish Verification Procedures**

Microbial examination and analysis of both intermediate and final products can play a very important role in verification. The results obtained, especially if combined with computerized storage of data and trend analysis, can be very useful. They can indicate if the HACCP process is working and, if cross referenced to other data, can help to match loss control with possible causes. Counts of end products before the introduction of HACCP tend to be much higher and more variable. If HACCP is being implemented correctly and is working, counts should be lower and much more consistent (show a lower coefficient of variation). It is likely therefore that the main use of microbiological product release or clearance to verification of HACCP, raw materials testing and providing information for use in the decision trees e.g. on effectiveness of preventative measures.

## **Stage 13**

### **Establish Documentation and Record Keeping**

Efficient and accurate record keeping within HACCP is essential and should provide the manufacturer with confidence that their product is safe and allow auditors to do their job.

#### **I want to be able to sleep at night**

*Quote from one food manufacturer.*

Auditors may wish to undertake a compliance audit i.e. is the HACCP plan being implemented correctly. Alternatively they may wish to undertake a system audit i.e. is the HACCP plan appropriate and suitable. For these reason full details of the component raw materials, the processing and the final product are required. Additionally full details of the HACCP plan, staff training, audit and verification details are needed. A number of software packages exist for computerized record keeping and if they are used, backup copies of data should be made. A person should be designated with responsibility for record keeping.

## **Stage 14**

### **Review the HACCP Plan**

A review of the HACCP plan is used to determine whether the plan is still appropriate and is additional to the process of verification. Reviews are carried out at predetermined intervals and when changes occur e.g. change in processing, processing equipment or raw materials, whatever the trigger for the review it is important that the results of review are recorded and fed back into the extant HACCP plan.

## **2.2. Good practices: general rules and classification**

### **2.2.1. Good Manufacturing Practices (GMPs): general and specific codes, requirements and guidelines – case study: milk processing – Hungarian experiences**

#### **2.2.1.1. Introduction**

The quality of milk regulated by the European Union by the directive 178/2003 EC and in Hungary based on the following EU regulations: general considerations – Hungarian Food Law (82/2003), specific requirement for the quality of milk and milk products – Hungarian National Standard (1/2003 FVM), permitted level of undesirable materials in milk and milk products (32/2004 ESzCsM).

The above mentioned regulations gives a core for establishing an GMP system but in the future the national governmental bodies will have a reduced role in defining standards. The cause is that the food, including milk-industries define the standards at European level and establish their own risk management systems. That process will support the establishment of the European Food Safety Authority (EFSA) which has primary responsibility to provide independent scientific advice on all matters with a direct or indirect impact on food safety. The activity of the EFSA will cover all stages of food production and supply; for that reason it will be a scientific basis of the regulation for GMP systems from the food safety aspect.

The main aim of establishing sustainable GMP systems is to provide and promote safer, high-quality, healthier foods for the European citizens, thus assuring their health and well-being.

Aims for solving the following problems, establish sustainable methodologies:

- decrease the incidence of food-related diseases and allergies
- establishment of traceability processes along the whole production chain (178/2002/EC)
- development of the methods of analysis, detection and control
- establishment / development of safer and environmentally friendly production methods.

According to the above mentioned criteria there are some difficulties in the establishment of a GMP in different industries because some standardisation are used in the case of Good Hygienic Practice (GHP) but are limited in the case of GMP.

Otherwise there are several specific problems establishing GMP in the milk industry.

- *the first problem* is the HACCP paradox which means that after establishment of a useful quality assurance system the food borne diseases remain at the same level as before. For that reason the system has to be revised frequently, aiming to implement those methods which would be really suitable for solving the above mentioned paradox. A possible way to improve the efficiency of HACCP – particularly in milk industry – is to use microbiological testing which seems to be an effective means of monitoring CCPs other than physical and chemical tests. Otherwise, the problems with microbiological testing is that the time required to obtain results are critical in continues production systems.
- *the second problem* is the different – largely not standardised – *term* of the quality of milk and different milk products.
- *the third problem* is the lack of expertise in the quality management system mainly in small and medium size enterprises.
- *the fourth problem* is the lack of interest of the owners/management of the processing firms because of the different customer audit systems.
- *the fifth problem* is to meet with the criteria of the new requirements in food production, such as traceability (application of HACCP to the whole production chain) and labelling of the products.

This requirement is based on the *EU White Paper on Food Safety* whose main concern is monitoring the entire food chain “from farm to fork” system and also promoting feedback from the consumers (retailers). That is a real challenge in the milk industry and particularly in those countries where the milk produced mainly in small and medium size farms for that reason the final product contains raw material – in this case milk – from different sources and mostly without possibility of individual labelling.

- *the sixth problem* is the management and utilisation of the waste materials. The list of materials which are termed as waste contains in the EU directives (2000/532/EC, 2001/ 118/ EC, 2001/199/EC). The wastes of the milk industry are in the *I.* treatment class - those not requiring special deposition, some of which may be used for utilisation as animal feed, and others requiring dehydration and biological decontamination.

## **Establishment of GMP in milk industry – general and specific criteria**

### **1. Evaluation of processing plant**

There are three main categories of milk processing plants:

1. Heat processing plants: raw milk is only heat-treated (pasteurised) for packaging and for further processing.
2. Standardisation plants: heat treated and standardise chemical composition of raw milk for packaging and further processing.
3. Milk processing plants: heat-treated and processing of raw milk for production of different milk products.

The evaluation process has to be conducted firstly by the plant management, also to be audited by external bodies, officially from National Health Service, National Veterinary Service and other independent evaluation agencies, including customers (retailers).

The *first* step of the evaluation process is to examine the technical facilities (buildings, instruments and machines) of the plant according to their activity.

The *second* step of the evaluation process is to examine the personnel of the plant according to their qualification and also health status (special requirement in all food processing plant).

The *third* step is to verify laboratory methods of analysis used for controlling the entire production chain (particularly at CCPs). All of the methods have to meet with the general criteria namely ISO standard methods. All the equipment has to be evaluated by official bodies (e.g. National Standard Office) and the methods have to be validated by internal and external bodies (e.g. National Accreditation Office).

***According to the GMP system the main criteria for all steps must be established first, according to the official standards and special requirements of the particular processing plant.***

## **2. Evaluation of raw material (milk)**

The evaluation has to be made continuously by the plant's own control group, and is independent from regular official evaluation process through the National Health Service and/or National Veterinary Service.

The first step of the evaluation process is to take samples both at farms and also at plants. The samples have to be taken by a person responsible for processing plant operations, but in several cases customer (retailer) representative, are also responsible for conducting this step.

Samples have to be taken at every collection point during transport to the plant. The main criteria of the quality of milk are that of chemical composition, its microbiological quality and residue content.

***According to the GMP system the main required criteria of the raw milk according to the official standards and also according to the special requirements of the particular processing plant, has to establish – e.g. production of special milk products and special requirements of the costumers (retailers).***

### **3. Evaluation of heat treatment (pasteurisation) process**

The evaluation has to be made by the plant's own control group continuously, and it is independent from the regular official evaluation process through the National Health Service and/or National Veterinary Service.

The effectiveness of the heat treatment process can be evaluated using both physical (heating efficiency) and microbiological methods. The heating process has to be checked continuously during the treatment while the microbiological quality must be checked after the treatment.

Both physical and microbiological methods have to be validated by independent bodies. The evaluation process has to be carried out firstly by the persons responsible for the processing plant, but in several cases customer (retailer) representative are also responsible for conducting this step.

*According to the GMP system the main required criteria of the raw milk according to the official standards and also according to the special requirements of the particular processing plant, has to establish – e.g. production of special milk products and special requirements of the costumers (retailers).*

### **4. Evaluation of product standardisation**

The evaluation has to be conducted by the plant's own control group continuously, and is independent from the regular official evaluation and /or customer (retailer) audit process.

The effectiveness of the standardisation process can be evaluated using chemical methods. The standardisation process has to be checked continuously. The methods of chemical analyses have to be validated by independent bodies. The evaluation process must be conducted by persons responsible for the processing plant.

*According to the GMP system the main required criteria of the raw milk according to the official standards and also according to the special requirements of the particular processing plant, has to establish – e.g. production of special milk products and special requirements of the costumers (retailers)*

## **5. Evaluation of the in-plant transport processes**

The evaluation has to be made by the plant's own control group continuously, and is independent from the regular official evaluation process conducted by the National Health Service and/or National Veterinary Service.

The in-plant milk transport processes can be evaluated using physical, chemical and microbiological methods. The transport processes is to be checked continuously against cross-contamination through maintaining the required temperature of the milk and evaluating the microbiological quality of milk at all critical transport points.

The cleaning process of the transport system can be evaluated both by chemical (residue) and microbiological methods after the process.

Physical, chemical and microbiological methods of analyses have to be validated by independent bodies.

The evaluation process has to be carried out by the persons responsible for the processing plant.

*According to the GMP system the main required criteria of the raw milk according to the official standards and also according to the special requirements of the particular processing plant, has to establish – e.g. production of special milk products and special requirements of the costumers (retailers).*

## **6. Evaluation of fluid milk packaging**

The evaluation has to be conducted by the plant's own control group continuously, and is independent from the regular official evaluation process through the National Veterinary Service.

The packaging process can be evaluated using physical and microbiological methods. The packaging process has to be checked continuously by physical methods while the microbiological quality of the final product can be checked regularly, monitoring for the possible cross-contamination during packaging.

Both physical and microbiological methods have to be validated by independent bodies.

The evaluation process has to be conducted firstly by the persons responsible for processing plant, and in several circumstance customers (retailer) and representatives is also responsible for conducting this step.

*According to the GMP system the main required criteria of the packaged fluid milk according to the national standards and also according to the special requirements of the customers, has to establish (retailers).*

## **7. Evaluation of further processing**

The evaluation has to be made by the plant's own control group continuously, and is independent from the regular official evaluation process through the National Health Service and/or National Veterinary Service.

The further processing procedures can be evaluated using physical, chemical and microbiological methods. The processes have to be checked continuously based on the evaluation of the final product.

All of the methods of analyses have to be validated by independent bodies.

The evaluation process has to be carried out at first by the persons responsible for processing plant, but in several cases customer (retailer) and representatives are also responsible for conducting this step.

*According to the GMP system the main required criteria of the packaged fluid milk according to the national standards and also according to the special requirements of the customers, has to establish (retailers).*

## **8. Evaluation of the elimination and/ or utilisation of waste materials**

The evaluation has to be conducted by the plant's own control group continuously and is independent from the regular official evaluation process through the National Environmental Safety Authority.

The effectiveness of the elimination process can be evaluated using both physical (dehydration) and microbiological (presence of pathogenic bacteria) methods.

The dehydration process (if available) has to be checked regularly during the treatment while the microbiological quality can be checked continuously.

The utilisation of waste materials (by-products) mainly as animal feed which are mandated by other regulations (Hungarian Feed Code, 2004, 2002/248/EC). Both physical and microbiological methods have to be validated by independent bodies.

The evaluation process has to be carried out firstly by the persons responsible for processing plant.

*According to the GMP system there has to be established a waste management protocol according to the official standards.*

## **Results of the establishment of GMP**

- The whole production/processing system will be organised and documented (traceability)
- Improvement of the quality of products (technological quality)
- The final product will meet consumer requirements (consumer's quality)
- Decrease losses (improvement of efficiency)
- Elimination of waste materials concurs with the decrease of environmental loading criteria.

## **2.2.2. Good laboratory practices (GLPs): general and specific requirements and guidelines**

### **2.2.2.1 Introduction**

This section gives a general outline of Good Laboratory Practices (GLPs) by discussing the Principles of Good Laboratory Practices and by defining the most important terms used in this field, but first we should see how these Principles emerged.

The OECD (Organization for Economic Co-operation and Development) member countries have realized that there is a strong need for international harmonisation of test methods and Good Laboratory Practices to avoid different schemes of implementation, which would have an impeding impact on international trade in chemicals.

The document concerning the “Principles of Good Laboratory Practices” was developed by an international group of experts in 1979-80, published in 1981, under the Special Programme on the Control of Chemicals. The purpose of this document is to support the generation of high quality and reliable test data, which results in the harmonising of testing procedures for the Mutual Acceptance of Data (MAD), and hence duplicative testing and the creation of technical barriers to trade can be avoided, furthermore, human health and environment protection can be improved.

Good Laboratory Practices (GLPs) define the rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded and reported.

So far 30 countries (the member states of the OECD) have signed agreements that make the OECD GLP Principles binding on them. This effectively makes the OECD Principles an international text.

The 1981 Council Decision on the Mutual Assessment of Data in the Assessment of Chemicals (revised 1997) integrates the OECD Principles of GLP. MAD is also concerned with the harmonisation procedures of GLP compliance monitoring, and it ensures that pre-clinical safety studies are performed according to the Principles of GLP.

Since 1997 non-OECD member countries can adhere to the MAD system through a procedure which has been embodied in a Council Decision (Council Decision on the Adherence of Non-Member Countries to the Council Acts Related to the Mutual Acceptance of Data in the Assessment of Chemicals C(97)114/FINAL).

### 2.2.2.2. Terminology

#### **Terms related to the organisation of the test facility**

##### **Test facility**

the persons, premises, and operational unit(s) that are necessary for conducting the study.

##### **Sponsor**

a person(s) or entity who commissions and/or supports a study.

##### **Study Director**

the individual responsible for the overall conduct of the study.

##### **Standard Operating Procedures (SOPs)**

written procedures which describe how to perform certain routine laboratory tests or activities normally not specified in detail in study plans or test guidelines.

##### **Quality Assurance Programme**

an internal control system designed to ascertain that the study is in compliance with these Principles of Good Laboratory Practice.

## **Terms related to non-clinical health and environmental safety study**

### **Study**

an experiment or set of experiments in which a test substance is examined to obtain data on its properties and/or its safety with respect to human health and the environment.

### **Study plan**

a document which defines the entire scope of the study.

### **OECD Test guideline**

a test guideline which the OECD has recommended for use in its Member countries.

### **Test system**

any animal, plant, microbial, as well as other cellular, sub-cellular, chemical, or physical system or a combination thereof used in a study.

### **Raw data**

all original laboratory records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study.

### **Specimen**

any material derived from a test system for examination, analysis, or storage.

## **Terms related to the test substance**

### **Test substance**

a chemical substance or a mixture which is under investigation.

### **Reference substance (control substance)**

any well defined chemical substance or any mixture other than the test substance used to provide a basis for comparison with the test substance.

**Batch**

a specific quantity or lot of a test or reference substance produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

**Vehicle (carrier)**

any agent which serves as a carrier used to mix, disperse, or solubilise the test or reference substance to facilitate the administration to the test system.

**Sample**

any quantity of the test or reference substance.

### **2.2.2.3. An outline of the principles of the good laboratory practices**

**The organisation of the test facility and personnel:****Management's Responsibilities**

Most of the responsibilities of test facility management are of a general nature, such as the requirements that test facility management has to ensure the availability of qualified personnel and of appropriate facilities and equipment for the timely and proper conduct of the study.

Furthermore, it has to ensure that health and safety precautions are applied according to national and/or international regulations; appropriate Standard Operating Procedures are established and followed, etc.

**Study Director's Responsibilities**

The study director continues to be the single point of study control and has the responsibility for the overall conduct and reporting of the study. He/she should agree to the study plan and ensure that the procedures specified in the study plan are followed.

## **Personnel Responsibilities**

Personnel should exercise safe working practice and health precautions; the chemicals should be handled with suitable caution until their hazard(s) has been established. Personnel known to have a health or medicinal condition that is likely to have an adverse effect on the study should be excluded from operations that may affect the study.

## **Quality Assurance Programme**

The documented Quality Assurance (QA) Programme should ensure that the performed studies are in compliance with the Principles of GLP.

The QA activities should be carried out by someone who is directly responsible for management and familiar with the test procedures.

## **Facilities**

The GLP Principles mandate in general that test facilities should be of suitable size, construction and location to meet the requirements of the studies performed therein, and an adequate degree of separation should be provided between the different activities to ensure the proper conduct of each study.

Specific regulations are valid on test system facilities, on facilities for handling test and reference substances, on archive facilities and on waste disposal according to the Principles of GLP.

## **Apparatus, material, and reagents**

Apparatus should be suitably located, be of appropriate design and adequate capacity, and should be periodically inspected, cleaned, maintained and calibrated according to SOPs. Apparatus and materials should not interfere with the test systems, and reagents should be properly labelled.

## **Test Systems**

Distinction has to be drawn between the physical/chemical and the biological test systems:

- Regarding physical/chemical test systems, the used apparatus should be properly located and have appropriate design and capacity. Reference substances should be used to ensure the integrity of the test systems.
- Considering biological test systems the housing, handling and care of animals, plants, microbial as well as other cellular and sub-cellular systems should be carried out under proper conditions to ensure the quality of the data. The isolation of newly received animal and plant test systems is highly important until their health status has been evaluated.

A number of recommendations are given in the Principles considering the acclimatisation of the test systems, the pieces of information that should be recorded, indicated.

## **Test and Reference Substances**

All the records referring to test and reference substances should be maintained; handling, sampling, and storage procedures as well as the test and reference substances should be identified. The stability of test and reference substances under storage and test condition should be known for all studies.

## **Standard Operating Procedures**

Standard Operating Procedures (SOPs) should be elaborated for test facilities, and there should be immediately available SOPs for each separate laboratory unit.

## **Performance of the Study**

Prior to initiation of a study, a study plan should exist. It should be retained as raw data, and the study should be conducted according to it. The proper form and content of a study plan is specified in the Principles of GLP.

## **Reporting of Study Results**

For each study a final report should be prepared by using the International System of Units (SI). It is the task of the Study Director and perhaps of principal scientists from co-operating disciplines to sign and date the final report.

## **Storage and Retention of Records and Material**

This final chapter specifies the proper way of storing and retention of any records and material (e.g. study plans, raw data, final reports, samples and specimens, etc.).

## **National Application of the GLP Directives**

All EU Member States have transposed the GLP Directives. This chapter gives a brief overview on the Hungarian applications.

The Ministry of Health is in charge of the GLP Monitoring Authority for medicinal products for human use, the National Institute of Pharmacy.

In every two years routine inspections are carried out. The GLP monitoring programme was launched by a Joint Decree of the Ministers of Health and of Agriculture and Rural Development (31/1999) in 1999. Hungary and the EU have signed a protocol to the Europe Agreements on Conformity Assessment (PECA). The annex on GLP has entered into force in 2002.

## Summary

While the regulations of GLP set out the rules for good practice they also help the researcher to perform his work in compliance with his own pre-established plan and they standardize procedures worldwide. The regulations do not concern the scientific or technical content of the research programmes. They do not aim to evaluate the scientific value of the studies.

All GLP texts, whatever their origin or the industry targeted, stress the importance of the following points:

1. Resources: organization, personnel, facilities and equipment.
2. Rules: protocols and written procedures.
3. Characterization: test items and test systems.
4. Documentation: raw data, final report and archives.
5. Quality assurance unit.

## 2.2.3. Good Hygienic Practices (GHPs): guidelines for general and specific requirements

### 2.2.3.1. Introduction

The General Principles of GHPs should be used in conjunction with each specific code of hygienic practice and the guidelines on microbiological criteria. The document follows the food chain from primary production to final consumption, highlighting the key hygiene controls at each stage.

It recommends a HACCP-based possible to enhance food safety as described in the *Hazard Analysis and Critical Control (HACCP) System*.

The General Principles are internationally recognized and commended to Governments, industry (from individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.

#### **The CODEX of GHP includes specific aims and objectives:**

- to identify the *essential* principles of food hygiene, applicable *throughout the food chain* (including primary production through to the final consumer), to achieve the safety of food and suitability for human consumption
- to recommend a HACCP-based approach as a means to enhance food safety
- to indicate *how* to implement its principles
- to provide a *guidance* for specific codes which may be needed (for all sectors of the food chain) and to amplify the hygiene requirements specific to those areas.

**Governments** can consider the contents of GHPs and decide how best they should encourage the implementation of these general principles to:

- provide assurance that food is suitable for human consumption
- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population
- maintain confidence in internationally traded food
- provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers.

**Industry** should apply the hygienic practices set out in this document to:

- provide food which is safe and suitable for consumption
- ensure that consumers have clear and easily-understood information, by way of labelling and other means, to enable them to protect their food from contamination and food borne pathogens by correct storing, handling and preparing

**Consumers** should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

### 2.2.3.2. Terminology

For the purpose of this Code, some specific expressions have to be defined:

#### **Cleaning**

The removal of soil, food residue, dirt, grease or other objectionable matter.

#### **Contaminant**

Any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

#### **Contamination**

The introduction or occurrence of a contaminant in food or food environment.

#### **Disinfection**

The reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

#### **Establishment**

Any building or area in which food is handled and the surroundings under the control of the same management.

#### **Food hygiene**

All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

**Hazard**

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

**HACCP**

A system which identifies, evaluates, and controls hazards which are significant for food safety.

**Food handler**

Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

**Food safety**

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

**Food suitability**

Assurance that food is acceptable for human consumption according to its intended use.

**Primary production**

Those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

### **2.2.3.3. Objectives and steps for the assurance of food safety in the agrifood chain**

#### **Step 1**

##### **Primary production**

The main objective is the avoidance of contamination / pests / diseases from the environment adopting different hygienic restrictions.

*The steps and requirements for a safe primary production include:*

- **ENVIRONMENTAL HYGIENE**
- **HYGIENIC PRODUCTION OF FOOD SOURCES**

Producers should implement:

- the control of contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- the control plant and animal health
- the protection of food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately.

- **HANDLING, STORAGE AND TRANSPORT**

The following procedures should be in place:

- sorting food and food ingredients to segregate material which is evidently unfit for human consumption
- to dispose of any rejected material in a hygienic manner;
- to protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, deterioration and spoilage through appropriate control of temperature, humidity, etc.

## ➤ **CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION**

Appropriate facilities and procedures should be in place to ensure that:

- any necessary cleaning and maintenance is carried out effectively;
- an appropriate degree of personal hygiene is maintained.

### **Step 2**

#### **Design and facilities**

Depending on the nature of the operations, and the risk associated premises, equipment and facilities should be located, designed and constructed to ensure:

- minimized contamination
- design and layout to permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination
- appropriate surfaces and materials, in particular those in contact with food, are non-toxic in intended use
- suitable facilities are available for temperature, humidity and other controls;
- effective protection against pest access and harbourage.

#### **Rationale:**

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

#### **a. Location**

**Establishments** should normally be located away from:

- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food
- areas subject to flooding unless sufficient safeguards are provided
- areas prone to infestations of pests
- areas where wastes, either solid or liquid, cannot be removed effectively.

**Equipment** should be located so that it:

- permits adequate maintenance and cleaning
- functions in accordance with its intended use;
- facilitates good hygiene practices, including monitoring.

## **b. Premises and rooms**

**The internal design and layout** of food establishments should permit good food hygiene practices, including protection against cross contamination between and during operations by foodstuffs.

### **Internal structures and fittings**

The structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected.

**Temporary/mobile premises and vending machines** should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

## **c. Equipment**

The equipment and containers coming into contact with food, should be designed and constructed to ensure that, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food.

Equipment and containers should be made of materials with no toxic effect in intended use.

Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, to facilitate inspection for pests.

## Food control and monitoring equipment

In addition to the general requirements mentioned above, the equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled.

Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food.

**Containers for waste**, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

### d. Facilities

**Water supply**: an adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

Adequate **drainage and waste disposal** systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

Adequate facilities should be provided for **cleaning** food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

**Personnel hygiene facilities** should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food.

Depending on the nature of the food operations undertaken, adequate control of temperature should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

Adequate means of natural or mechanical ventilation should be provided, in particular to: minimize air-borne contamination of food, (from aerosols and condensation droplets), control ambient temperatures, odours and humidity.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.

Adequate natural or artificial **lighting** should be provided to enable the operation in a hygienic manner. The intensity should be adequate to the nature of the operation.

Adequate facilities for the **storage of food, ingredients and non-food chemicals** (e.g. cleaning materials, lubricants, fuels) should be provided, to permit adequate maintenance and cleaning, to avoid pest access and harbourage, enable food to be effectively protected from contamination during storage and to provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

## Step 3

### Control of operation

#### Objective:

In order to produce food which is safe and suitable for human consumption, it is necessary to formulate:

- design of requirements with respect to raw materials, composition, processing, distribution;
- design, implement, monitor and review the effective control systems.

The control of operation may reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage controlling the food hazards.

#### a. Control of food hazards

Food business operators should control food hazards through the use of HACCP system. They should:

- **identify** any steps in their operations which are critical to the safety of food
- **implement** effective control procedures at those steps
- **monitor** control procedures to ensure their continuing effectiveness;
- **review** control procedures periodically, and whenever the operations change.

These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.

Control procedures may be simple, such as checking stock rotation calibrating equipment, or correctly loading refrigerated display units.

In some cases a system based on expert advice, and involving documentation, may be appropriate.

## **b. Hygiene control systems**

Inadequate food time and temperature control is one of the most common causes of forborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage.

Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.

Temperature control systems should take into account:

- the nature of the food, e.g. its water activity, pH, and likely initial level and types of micro-organisms
- the intended shelf-life of the product
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

Such systems should also specify tolerable limits for time and temperature variations.

Temperature recording devices should be checked at regular intervals and tested for accuracy.

Other steps which contribute to food hygiene may include, for example:

- chilling
- thermal processing
- irradiation
- drying
- chemical preservation
- vacuum or modified atmospheric packaging

Control of **microbiological and chemical contamination** has to be implemented, such as:

- Cross contamination with pathogens either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and where appropriate disinfection.
- Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean

protective clothing including footwear and wash their hands before entering.

- Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed.
- To prevent **contamination of foods by foreign bodies** such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals.  
In manufacturing and processing, suitable detection or screening devices should be used where necessary.
- No raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied.
- Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.

### **c. Packaging**

The packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling.

Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

#### **d. Water**

Only potable water should be used in food handling and processing, with the following exceptions:

- for steam production, fire control and other similar purposes not connected with food; and
- in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water).

Water re-circulated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored.

Re-circulated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

Potable water should be used wherever necessary to avoid food contamination.

Ice should be made from water that complies with section 4.4.1.

Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

#### **e. Management and supervision**

The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved.

Managers and supervisors should have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

## **f. Documentation and records**

Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

## **g. Recall procedures**

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for public warnings should be considered.

## **Step 4**

### **Establishment: maintenance and sanitation**

Facilitate the establishment of maintenance and sanitation and the management of waste, effective and suitable control of food hazards, pests, and other agents which contaminate food.

#### **a. Maintenance and cleaning**

Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures
- function as intended, particularly at critical steps
- prevent contamination of food, e.g. from metal shards, flaking plaster, debris and chemicals.

Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning. Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

The cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids:

Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment.

Cleaning and disinfection programmes should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

## **b. Pest control systems**

Pest infestations can occur where there are breeding sites and a supply of food. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

**Preventing access of pests:** buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry.

Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

The availability of food and water encourages pest harborage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls.

Establishments and surrounding areas should be regularly examined for **evidence of infestation.**

Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

### **c. Waste management**

Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

Waste stores must be kept appropriately clean.

### **d. Monitoring effectiveness**

Sanitation systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.

## **Step 5**

### **Personal hygiene**

To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food.

It is necessary to maintain an appropriate degree of personal cleanliness, to behave and operate in an appropriate manner.

People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

**a. Health status**

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness (jaundice, diarrhea, vomiting, and fever, sore throat with fever, visibly infected skin lesions (boils, cuts, etc.), discharges from the ear, eye or nose) or symptoms of illness to the management.

Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

**b. Personal cleanliness**

Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear.

Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personnel should always wash their hands when personal cleanliness may affect food safety.

**c. Personal behaviour and visitors**

People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example: smoking, spitting, chewing or eating, sneezing or coughing over unprotected food.

Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

## Step 6

### Transportation

Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

Protective measures should be taken to avoid the:

- contamination
- damage
- the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

#### a. Design

Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging
- can be effectively cleaned and, where necessary, disinfected
- permit effective separation of different foods or foods from non-food items where necessary during transport
- provide effective protection from contamination, including dust and fumes
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and
- allow any necessary temperature, humidity and other conditions to be checked.

## **b. Use and maintenance**

Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

## **Step 7**

### **Product information and Consumer Awareness**

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

Products should bear appropriate information to ensure that:

- adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly
- the lot or batch can be easily identified and recalled if necessary.

Consumers should have enough knowledge of food hygiene to enable them to:

- understand the importance of product information
- make informed choices appropriate to the individual; and
- prevent contamination and growth or survival of forborne pathogens by storing, preparing and using it correctly.

Information for industry or trade users should be clearly distinguishable from consumer information, particularly on food labels.

### **a. Lot identification**

Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the labelling of pre-packaged Foods (CODEX STAN 1-1985) applies.

### **b. Product information**

All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

### **c. Labelling**

Pre-packaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely.

Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) applies.

### **d. Consumer education**

Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and food borne illness.

## **Step 8**

### **Training**

Training is fundamentally important to any food hygiene system.

Inadequate hygiene training, and/or instruction and supervision of *all* people involved in food related activities pose a potential threat to the safety of food and its suitability for consumption.

Those engaged in food operations that come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform.

#### **a. Awareness and responsibilities**

Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

#### **b. Training programmes**

Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms
- the manner in which the food is handled and packed, including the probability of contamination
- the extent and nature of processing or further preparation before final consumption
- the conditions under which the food will be stored; and the expected length of time before consumption.

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

### **c. Instruction and supervision**

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

## 2.2.4. Good Agricultural Practices (GAPs): general and specific requirements and guidelines

### 2.2.4.1. Introduction

Within the European Union – upon the initiative of FAO (UN Food and Agriculture Organisation) – *Good Agricultural Practice* (GAP) forms the basis of food safety. GAP sets regulations for all players in the food chain. This logic is based on the realization of the principle: “from food to table”. GAP approach is an initiative that aims at environmental, economic and social compliance on the farm and through the stages of post-treatment and processing, one which thus guarantees safety and a healthy production of food and other agricultural products.

GAP is based on the dual principle of:

- methods used in agriculture shall be economically in harmony with the food industry regulations and shall conserve the own natural resources
- declared and latent consumer demands, on the other hand, emphasize the importance of safe, high quality food production, and products.

At the same time, GAP does not entail new standards; it provides a tool to help the harmonisation of present standards by integrating environmental and social indicators into the production process.

The principle, “from farm to table”, is very well-reflected within the *integrated production system*; this process starts with open-field plant cultivation, continues with feed process, and finishes with animal husbandry and animal process. The implementation of GAP in this process provides the following:

- apply GAP guidelines for open-field plant cultivation
- introduce Good Hygienic Practice (GHP) into all links of the chain
- introduce certified HACCP system (verified upon the relevant regulations on manufactured goods) operating in an integrated way into all links of the chain
- introduce quality and environmental management systems into all links of the chain in harmony with integrated ISO 9001:2000 and ISO 14001 standards

- introduce computer-assisted identification, tracing and controlling systems from manufactured goods to seeds
- integrated system-audit – auditing performed once on an annual basis; this procedure is an integrated assessment of all elements in the management system (MIR, KIR, HACCP, FSYS etc.)
- register trademark for strategic products upon product certification
- apply Total Quality Management (TQM) based system in the entire verticum.

#### **2.2.4.2. Objectives of the Euro-Retailer Produce Working Group (EUREP)**

The *Euro-Retailer Produce Working Group (EUREP)* was founded by the leading European food retailers in 1997, in order to realize a common product development protocol to respond to the relevant questions of sustainable agriculture. They set a framework for those aspects of “Good Agricultural Practices” (GAP) that contain all the significant elements for best management practices to be implemented in the agricultural production procedures.

The thus formed – and continuously developed – *EUREPGAP normative requirement system* complies with the requirements of international accreditation, therefore the protocol, applied in the right way, can be certified. Certification can be carried out through verification by an independent certification body accredited to *EN 45011*.

The requirement system of EUREPGAP responds to the following concerns:

- animal welfare, i.e. application of approved integrated management methods in pest control
- approval of special environmental regulations
- food-safety, with stressed regard for the criteria on health care aspects of product treatment
- occupational health, i.e. application of the general health and safety regulations regarding workers
- application of provisions for social laws regarding employees.

Retailers want guarantees that horticultural product suppliers comply with the regulations of food safety and they follow the necessary prudential norm of the rules.

At the same time, a growing number of consumers are seeking products which have “little environmental and human impact”. With the launch of *EUREPGAP*, there is no need for multiple producer verification processes on the side of the consumers as the certificates provide clear bases for business agreements, and thus, they make it easier for a producer to enter a market. Most retailers among the group of members have decided to set *EUREPGAP certificates* obligatory requirements for their suppliers.

### **2.2.4.3. EUREPGAP**

#### **EUREPGAP**

- is the global quality assurance system with “Good Agricultural Practice” as reference
- is the international certificate standard of fresh produce and unprocessed agricultural products.

The basic principles of EUREPGAP are the application of the best possible technologies in the producing sector and the supporting of food-production in compliance with the criteria set for sustainable agriculture.

On a long-term basis only such agricultural production can remain sustainable which sets the following objectives:

- producing a suitable amount of high quality food and fibre, ensuring producing that is sustainable from an economic aspect and viable, protecting nature
- optimal use of natural resources
- combined use of traditional farming procedures and the best technologies relevant to the area
- improving the living conditions of producers and country communities

EUREPGAP standards were developed for the growing of fruit and vegetables, growing of flower and ornamental plants, arable crops and animal husbandry (integrated farm management), fish farming and coffee growing. The EUREPGAP system was founded by the European food retailers (group of retail chains) and producers. The system is applied in over 45 countries.

### **The tasks of EUREPGAP**

- Responding to consumer concerns on food safety, animal welfare, environmental protection and worker health, safety and welfare
- Encouraging adoption of commercially viable farm assurance schemes, which promote the minimisation of agrochemical inputs, within Europe and worldwide
- Developing a “Good Agricultural Practice” (GAP) Framework for benchmarking existing assurance schemes and standards including traceability
- Providing guidance for continuous improvement and the development and understanding of best practice
- Communicating and consulting openly with consumers and key partners, including producers, exporters and importers.

### **The objectives of EUREPGAP**

- Compliance with Food Safety criteria: the application of HACCP principles
- Compliance with the regulations of environmental protection: the application of “Good Agricultural Practices”, which are designed to reduce negative impacts of agricultural production on the environment
- Establishment of occupational health, safety and welfare criteria for workers: the standard establishes a global level of occupational health and safety criteria on farms, as well as awareness and responsibility regarding socially related issues
- Compliance with animal welfare criteria (where applicable): the standard establishes a global level of animal welfare criteria on farms

## Operational conditions of EUREPGAP

to apply EUREPGAP standards, applicants must comply with the following:

- EUREPGAP general regulations
- EUREPGAP control points and compliance criteria
- EUREPGAP checklist regulations

Producers (individual farmers, partnerships, private limited companies, public limited companies etc.), producing groups (producing groups, Producer Organisations – PO, integrators) and existing quality assurance schemes with similar objectives that are approved by EUREPGAP benchmarking can receive EUREPGAP certificates. Certification is approved by a certification body upon EUREPGAP control points. For successful certifications, different EUREPGAP standards set different number of points to comply with.

For example:

- In EUREPGAP Fruit and Vegetables, producers must comply with 210 control points: the document contains 47 major non-compliances, 98 minor non-compliances and 65 further recommendations. Producers must comply with 100 per cent of major non-compliances and 95 per cent of minor non-compliances.
- In EUREPGAP Integrated Farm Assurance there is a three-level (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>) compliance criteria set. There must be a 100 per cent compliance with the 1<sup>st</sup> level and 90 per cent compliance with the 2<sup>nd</sup> level compliances. EUREPGAP Integrated Farm Assurance, as opposed to Fruit and Vegetables, is separated into a structure of modules. It involves all modules for farm, cattle, sheep, dairy, pig and poultry, livestock transport and open-field plant cultivation.

For further information see: [www.eurep.org](http://www.eurep.org)

### 2.2.4.4. “Good Agricultural Practice” (GAP) in Hungary

The actual regulations for “*Good Agricultural Practices*” are going to be introduced through the Hungarian regulations. The relevant regulation is *Regulation No. 156/2004, Hungarian Ministry of Agriculture*.

It is important to note that after Hungary's accession to the European Union, most assistance funds can be awarded to Hungarian producers on the condition that they undertake the activity of environmentally-aware management.

Agricultural holdings applying for assistance for development, area assistance for agrarian-environmental management or assistance funds for agricultural regions where unfavourable conditions exist must pursue agricultural activities for the *entire* of their area in compliance with strict regulations

## **“Good Agricultural Practice” Regulations**

### **Open-field plant cultivation**

- Monocultural producing cannot be applied, except for annual fodder, bee pastures and green manure plants.
- For crop rotation the following guidelines must be applied:
  - Sugar beet, beetroot, turnip, potato, field bean, soy and lupine can be grown in the same field only once in every four years;
  - Sunflower can be grown in the same field only once in every five years;
  - At least once in every five years papillonaceae or green fodder must be grown in the rotated field, including successive secondary crops;
  - Dried peas can be grown only once in every seven years;
  - Maize can be followed only by plants of low nitrogen need;
  - At least two-year period of lapse must be kept between the growing of two non-annual papillonaceae;
  - Lucerne cannot be followed by any other papillonaceae, and after lucerne, the follow-up crop must be of high nitrogen need;
  - Soy, sunflower and summer rape cannot follow one another;
  - In the crop rotation the joint rate of spicate and maize cannot exceed 75 per cent.
- Mechanic weed control must be carried out prior to weed flowering.
- Application of soil preparation at different depths annually.
- Straw bales must be removed from the field within one month after gathering

### **Pasture management**

- In cattle, sheep, goat, fallow deer, red deer, donkey, horse and buffalo pastures (other animals cannot graze there) animal density cannot exceed:
  - 1.8 animal unit per hectare in non-nitrate sensitive areas;
  - 1.4 animal unit per hectare in nitrate sensitive areas.
- Hay baling and removal must be done within a maximum period of one month.
- No burning of pastures.
- Annually, at the end of the grazing period mowing must be performed.
- No winter pasturing.
- All machine-operated tasks must be carried out without harming the pasture.

### **Nutrient management**

- Focused soil analysis is required in every five years (pH, humus content, KA, total of water soluble salts, CaCO<sub>3</sub>, NO<sub>2</sub>+NO<sub>3</sub>, P<sub>2</sub>O<sub>5</sub> and K<sub>2</sub>O)
- Soil improvement and spreading of treated sewage, sewage sludge and liquid livestock waste can be carried out with the consent of the plant and soil protection service in accordance with the relevant regulations.
- When applying nitrogen fertilisers, farmers must not exceed the maximum values calculated for unfavourable and non unfavourable areas, as well as nitrate sensitive and non-nitrate sensitive areas.
- In nitrate sensitive areas it is obligatory to follow the regulations of the action program (determined by governmental decree).
- In non-nitrate sensitive areas the following regulations are applicable:
  - Manure can be spread to steeper slopes as long as it is incorporated promptly.

- It is forbidden to spread manure within at least ten metres of a water source, such as a well that supplies human or animal consumption, as well as floodplains and immediate areas of watercourses.
  - Quick acting, soluble nitrogen fertilisers, addle and liquid waste can only be spread after harvesting in the same year, if less than fourteen days have elapsed between the spreading and the sowing of cover crop.
  - It is forbidden to spread manure between December 1 and February 15, and when the soil is frozen hard (the soil is frozen to the depth of five centimetres), waterlogged or snow covered.
  - Solid manure must be kept in an impermeable manure store with a collection channel and a below-ground tank to hold leechate, which has a storage capacity of at least eight months of livestock waste. Liquid waste is to be kept in an impermeable storage tank or lagoon with a storage capacity of at least four months of waste material.
- Farmers engaged in livestock management in non-nitrate sensitive areas are to fulfil the requirements concerning manure and slurry storage after the following deadlines in accordance with the regulations of the action program:
    - Liquid waste store for farms with more than 50 animal units: from January 1, 2006
    - Liquid waste store for farms with less than 50 animal units: from January 1, 2010
    - Solid manure store for farms with more than 50 animal units: from January 1, 2010
    - Solid manure store for farms with less than 50 animal units: from January 1, 2014.

### **Pest control**

- Only authorised pesticides and fertilisers can be used, in compliance with technological and licensing regulations.
- Pesticides must be kept in a store room or cabinet which is locked and separated from other rooms housing people or animals or used for storing human or animal food, in a way which prevents fire or explosion, and damages to health and the environment (in accordance with ministry orders on pesticide circulation and application, and the packaging, labelling, storage and transportation of pesticides).

- It is forbidden to store pesticides within at least one kilometre from:
  - the full length of the coastlines of Lake Balaton, Lake Velencei, Lake Tisza and all other natural waters designated for swimming
  - protective areas around waterworks and water resources
- Empty packages and wrappings of pesticides must be collected, treated and disposed of in accordance with the relevant regulations
- The machinery and pesticide spreaders used to protect plants must be in perfect technical condition.

**Conservation and landscape protection (in nature reserves and environmentally sensitive areas)**

- Farmers should avoid damaging natural or semi-natural habitats when performing an agricultural activity (ploughing, spreading manure or chemicals, or destroying landscape components)
- Farmers should avoid damaging or ruining historical and architectural monuments and sites situated in the territory of the farm
- Farmers cannot alter the size of the parcel of land
- Ameliorative liming, drainage and irrigation are forbidden
- Farmers are only allowed to apply environmentally favourable mowing methods and technologies (starting to mow from the centre of the land, leaving edges to the end)
- Construction of temporary or permanent buildings is possible only with the consent of the management of the given national park
- The time of mowing on protected marshes must be determined on an individual basis by consulting the experts of the given *National Park*
- Existing alleys, forest belts and old trees must be protected.

- In the course of technological operations related to cultivation (haystacks, bales, manure heaps etc.) can only be created on cultivated land
- Upon finding nests of increasingly protected birds, farmers must immediately report it to the experts of the given *National Park*
- Only natural materials (wood, cane) are allowed to be used to build night shelter for animals
- Shepherds' accommodation must fit in with the landscape and be built by using traditional building materials and methods
- Ponds and inland water spots must be preserved

### **Livestock management**

- Livestock must be provided appropriate conditions which suit the physical, physiological, breeding, behavioural and social characteristics of their species, breed, sex, age and health conditions
- Animals must be fed with forage and given water or other liquids which are not harmful for them and do not pose indirect harm to humans
- Regular veterinary supervision is also obligatory
- Livestock must be kept, transported and distributed in accordance with the relevant regulations on animal health, animal safety and environmental protection

### **Soil erosion**

- In areas exposed to erosion, the soil must be protected with crop cover until the sowing of spring crop
- Contour cultivation is required in areas exposed to erosion
- Terraces established to prevent erosion must be preserved

- It is forbidden to grow root crops on slopes with an angle higher than 12 per cent
- Green stripes (hedges, field borders) are to be preserved
- Operations resulting in soil opening must be followed by soil closing operations

### **Organic material content of soil**

- Harvesting must be followed by stubbling and stubble field protection
- It is forbidden to burn stubbles

### **Soil structure**

- It is essential to use machinery and equipment suitable for appropriate cultivation of the land
- Deterioration and compaction of the soil must be prevented by appropriate field operations and machine movement considering the water content of the soil
- Application of periodical (in every five years) deep cultivation is also essential

### **Minimum level of cultivation**

- Arable lands must be cultivated together with the provision of weed control
- Natural landscape components must be preserved
- Natural pastures should be protected
- It is essential to prevent the settlement and spread of arboreal and herbaceous plants unwanted in the cultivation

- Under- and overgrazing of pastures should be avoided by providing appropriate livestock density, and by annual mowing

### **Maintenance of farm area**

- The farm and its area must be maintained and kept free of waste in accordance with the relevant regulations by the farmer
- Farm roads must be maintained, and road defects caused by wet weather should be repaired by the farmer

### **Record keeping**

- Farmers must keep an up-to-date record of their activities they perform on agricultural lands using an official management diary, provided by the Ministry of Agriculture and Rural Development, which should include details of nutrient management
- Farmers should keep record of pesticides used in cultivation and details of application

“Good Agricultural Practice” is a set of criteria for the fulfilment of which farmers are not provided a refund. Farmers receiving support are obliged to follow the guidelines during the period of support (usually five years), which is checked on the spot by appointed organisations. If farmers fail partly or completely to meet the requirements, the controlling authority may take the following sanctions:

- call upon the farmer to follow the regulations
- reduce the amount of annual support
- withdraw the annual support
- exclude from the support

These are strict sanctions. It is not worth taking risks since the conditions are achievable. It is more advantageous to meet the requirements and fulfil the undertaken responsibilities than to avoid regulations by law.

# chapter 3

## Case Studies

### Case Study 1

Company / Organisation name **Campofrío Alimentación**

#### General Facts and Figures

Applied quality system (ISO9000, TQM, HACCP, others, special):	HACCP ISO 9001:2000 BRC ISO 14001:1996
Location, Settlement (city, country)	Burgos (Spain)
Sector	Meat products
Main market area	Worldwide
Number of consumers yearly	Unknown

**The company was established in 1952**

**Products and/or services of the company**

meat products

**Markets of the company:**

- **National or international:** international
- **Operation field of the company (local or international):** international

## The challenge

### **What challenge(s) did the business face?**

At the beginning, the company had traditional control systems that were neither written nor checked. Before the new quality management system was introduced, the staff was reluctant and there were difficulties to record and parametrize processes.

Before the new quality system was introduced, the company was operated by expert staff with a deep knowledge of the products and processes.

The company decided to introduce a new quality management system several years ago because of the industry and customer demands and the need to reduce costs.

Company growth and processes complexity were the catalysts for change. These facts made it necessary to record production.

## Solution

### **How did the company address the challenge described above?**

The company addressed the challenge by involving the Company Management and training the employees.

The main steps to introduce the new quality system were: drafting quality and procedures manuals, continuous training of the staff, involving the staff in quality programs, regular monitoring of the results and explaining them to the staff responsible for improvements.

## Advantages

### **The main advantages of the applied system are:**

- Increased control of the processes
- Improved quality of the products
- Cost decrease. Lower failure costs.
- Increased reliability for customers.

## Vision

Short- and long-term expectations about this quality system include a process of continuous improvement and updating.

## Case Study 2

Company / Organisation name **Proplanta**

### General Facts and Figures

Applied quality system (ISO9000, TQM, HACCP, others, special):	ISO 9000; TQM; HACCP for some products
Location, settlement (city, town):	Cluj-Napoca
Industry/sector:	Agrifood
Number of employees:	4
Main market located in (country):	RO & EU
Revenue (2005)	25.000
Number of consumers yearly:	unknown

**The company was established in 2000**

#### Products and/or services of the company

Elaboration, production and delivery of final and intermediate original **products** extracted from plants (PROcessed PLANT Additives). The plants processed are wild or cultivated: medicinal plants, cereals, fruits or vegetables from un-polluted regions of Romania (mainly Transylvania), or grown under controlled ecologic conditions.

Research and technology development activities (RTD Programmes), partner of the USAMV Cluj-Napoca, of EU Universities, of Technology Transfer Centers and companies (EU-SMEs). The company profile and activities are registered in EU networks “SMEs for Food” and “SMEs go Life Sciences”

#### Services

Technology transfer: product development upgraded at pilot scale

- Agrifood analysis
- Training courses for SMEs on Food Quality and Safety assurance (HACCP, GMP)
- Consultancy for the elaboration of patents and national/international projects

#### Markets of the company

- **National or international:** national, international
- **Operation field of the company (local or international):** international

## The challenge

### **What challenge(s) did the business face?**

- Concurrence on the manual for food supplements
- Problems linked to marketing
- Establishment of GMP and HACCP

### **What had been the problems/bottle necks of this mode of operation before the new quality management system was implemented?**

- Risk analyses for raw materials and final products

### **When and why did the company decide to implement the quality management system?**

Recently in 2005 in order to gain authority in the business community and to increase the confidence of consumers.

### **What was the driver, catalyst for change?**

Legislative needs of RO to implement the EU requirements.

## Solution

### **How did the company address the challenge described above?**

There were involved specialized people and trained the employees.

## Advantages

### **The main advantages of the applied system are:**

- Reliability of production
- Improved quality of product
- Lower failures

## Vision

The expectation from this quality system in short- and long-term is to improve the impact of the company on business community and consumers.

## Lessons to learn

### What are the main consequences/edifications of this case study?

It will improve the quality of products and refine the strategy and policy of managers for techno-managerial approaches of company activity.

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## Case Study 3

**Company / Organisation name**

**Polus Shopping and Entertainment Center**

### General Facts and Figures

The established quality assurance system (ISO9000, TQM, HACCP, others, special)	HACCP and special
Settlement (city, town)	Budapest
Sector	Retail, restaurant, etc.
Number of employees	about 2.500
Main market area	Hungary
Number of buyers, consumers yearly	10.000.000

**The company was established in 1996**

The Polus Center was opened in November, 1996. In the shopping center a number of retailers (e.g. clothing, shoes, electronic devices, and food), different services (e.g. cleaners, mobile and wire telephone services), several entertaining businesses (e.g. cinemas, restaurants) operate. Main consumers of the Polus Center mainly come from Budapest and from the suburbs, but tourists often appear as well.

### The challenge

On its opening day (in 1996), it was the biggest shopping center of Hungary, which was the second one in the county at that time (the first one was opened a few weeks earlier). There were 300 shops in the Pólus at the opening day, which were operated mainly by SME shopkeepers. It was a serious challenge, how this big number of SMEs and operating companies could cooperate while maintaining and increasing the competitiveness of the shopping centre.

In the first weeks, the centre had incredibly high traffic; the mass of consumers were besieging the shops. On the contrary, after the 1996 Christmas season, the customers disappeared and the traffic had decreased dramatically.

The SMEs practically operated totally independently, besides the monthly payment of the rental; they did not have any contact with the manager of the shopping centre.

The decline of the traffic, the drop in competitiveness urged the management of the shopping centre to make arrangements in order to turn back this disadvantageous tendency. Additionally, we have to note that between 1996 and 1999 several new shopping centres were opened.

## **Solution**

### **How did the company address the challenge described above?**

It was obvious that the only way to maintain and enhance the competitiveness is to improve the cooperation among the shopkeepers. For the proposal of the manager and with its help, the „Association of the Polus Businessmen” was founded, and consisted of all the interested SMEs. Then the Marketing council was also established. It mainly consisted of the leaders of interested medium and big businesses (representing international brands).

After an exhaustive work and elaboration of detailed rules, in 1999 the „Association of Hungarian Businessmen” and the Polus management established the „AWARD for Consumers of Polus”. The objective of this award is to raise the customers’ satisfaction and to activate the cooperation among the interested SMEs operating in the centre. All these facts lead to higher competitiveness, which result in greater number of visitors and higher turnover.

In the first year the „AWARD for Consumers of Polus” was TQM based. The applicants applied for this competition voluntarily, and they made self assessment. The evaluation was implemented by the „Association of businessmen”. The applicants were classified according to their activity, and in each category the best one received the award.

In the following year the application procedure had gone through in a significant development. Everybody counted to be applicant, who had been participating in certain cooperative actions. Initially, the group of examiners consisted of experts coming from the field of quality assurance and consumer protection.

Further on, every applicant received the Award, who fulfilled the requirements and reached the 80% of the scores compared to the best applicant in the same category. The effectiveness was boosted by the fact that possibility for some correction was ensured for each applicant during the competition's duration.

The main incentive for participating in the competition is the fact that nobody wants to become loser.

## Advantages

**The main advantages of the applied system are:**

- The quality of service has changed for the better. The number of consumers has risen in the face of the increasing competition among shopping centres.
- Regulations related to trade and consumer protection have been becoming well known and observed among shopkeepers, which is counted to be a significant improvement. According to the experts' opinion almost all the enterprises operate correctly.
- The competition for the Award is required by the SMEs themselves to be organized every year. This means that the system represent an effective motivator for improving the quality assurance system.
- The system supports effectively the active cooperation in the community. In some years, the cooperation level had raised from 23% to 80% within a couple of weeks during the competition.

## Vision

- Enhancement the customers' complacence in order to attract increasing number of buyers living even far from Polus.
- Enhancement of cooperation of the interested party in such way that make them capable to transact common commerce stimulating actions together.

## Lessons to learn

**What are the main consequences/edifications of this case study?**

- This competition is an effective tool for encouraging the SMEs for implementing quality development, particularly if most of the participants can receive the Award. In other words, the Award is more attractive if it does not seem to be unreachable.

- The most effective incentive is the fact that besides the weakest applicants most of the competitors win the award, since nobody wants to be part of the losers' group.
- The stimulating effect can be enhanced, if we ensure for the applicants the possibility to correct the revealed mistakes.
- The incentive based on the competition; provide possibility for the development of the SMEs' cooperation. And in a sense, we can consider the cooperation as a quality factor.
- If the competitors' representatives participate in the evaluation process, the effectiveness of the system can be raised.

### Some basic data about our experience in Polus Shopping Centre

Year	Number of evaluated shops incl. restaurants (piece)	Number of evaluated restaurants (piece)	Number of awarded shops incl. restaurants (piece)	Number of awarded restaurants (piece)	Ratio of awarded shops incl. restaurants (%)	Ratio of awarded restaurants (%)	Minimal conditions
1999	61	6	50	5	82	83	-
2000	268	22	66	14	25	64	-
2001	164	14	110	9	67	64	<i>Participation in training and acceptance of mutual voucher</i>
2002	58	6	50	6	86	100	<i>Participation in training and acceptance of mutual voucher</i>
2003-04	135	14	107	10	79	71	<i>acceptance of mutual voucher</i>

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Quality portal	<a href="http://www.minosegportal.hu">www.minosegportal.hu</a>



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