Food safety management systems (FSMS) in the dairy industry: A review

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Food safety management systems in the industry have been designed and established over the last four decades with several revisions. The dairy industry soon realised the need for proactive procedures hence implementing HACCP (Hazard Analysis and Critical Control Points) for ensuring that safe dairy products would reach the consumers. This article reviews the food safety management systems as well as the relevant EC Regulations that are currently implemented by the dairy industry. The need for rigorous controls in the dairy industry is also highlighted.

Keywords Dairy industry, Food safety, HACCP, ISO22000, Milk, Milk products.

INTRODUCTION

Milk and milk products are indispensable components of the food supply chain as milk is an excellent source of nutrients for humans. Equally important is the fact that dairy products are also known as added-value products (e.g. lactose-free, Calcium-enriched) while amongst functional foods; dairy-based functional foods (e.g. with added probiotics, omega-3, phytosterols) account for 43% of a $16 billion market (Özer and Kirmaci 2010).

The selection is large: liquid milk, concentrated milk, fermented dairy products (e.g. cheese, yoghurt), milk powder, butter, cream, ice cream, dairy beverages, to name but a few. Dairy products are consumed as is, as well as utilised in vast quantities by the food manufacturing industry (e.g. milk powder).

The total annual worldwide milk production is 695 million tons which are translated to 117 billion EU annual sales for the top 20 dairy companies. Cow’s milk represents 84% of the total milk production (IDF 2009) which most of it will be sold as a heat-treated product (e.g. pasteurised, high-pasteurised or UHT) or converted to dairy products (e.g. cheese, cultured milk, yoghurts, milk powder) (Arvanitoyiannis et al. 2009). Additionally milk and milk products are readily consumed by virtually all population groups (e.g. infants, children, teenagers, middle-aged and the elderly).

During 2009 and by February 2010, 58 notifications regarding milk and milk products have been reported by the EU Rapid Alert System for Food and Feed (EU, 2010). Most of the notifications concerned the presence of potentially pathogenic micro-organisms in dairy products (e.g. Salmonella spp., Staphylococcus spp., Listeria monocytogenes, Escherichia coli O157:H7), spoilage micro-organisms (e.g. moulds) and hygiene indicator micro-organisms (e.g. coliforms), while a recent notification regarded the presence of antibiotics in milk.

It is evident, from the aforementioned statistics and facts that milk and milk products are widely available throughout the world and that possible contamination by either a microbiological, chemical or physical hazard would affect a large population.

DEVELOPMENT OF FOOD SAFETY MANAGEMENT SYSTEMS

Arvanitoyiannis et al. (2009) described the development of HACCP as the first food safety management system in the food industry. It was initiated in the 1960’s by the need to produce the first astronaut safe meals for the Mercury, Gemini and Apollo space NASA flight programs. The project was successfully competed by the Pillsbury Company (in collaboration with NASA).

In 1971, during the National Conference on Food Protection the concepts for examining Critical Control Points (CCP’s) and Good Manufacturing Practices in producing safe foods were introduced.

Pillsbury Co. in 1972 organised the first training program to the US Food and Drugs Administration (FDA) entitled ‘Food Safety through the Hazard Analysis and Critical Control Point System’, while in 1973 FDA included HACCP in the regulations applied for low-acid canned foods (Arvanitoyiannis and Kassaveti 2009).

In 1987 The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was established and was initially responsible for...
defining HACCP’s systems and guidelines for its application. During the next decade HACCP principles became widely accepted by food manufacturers and relevant authorities hence the HACCP principles become part of National Legislations in many Western European countries.

Moreover, in 1997 the Codex Alimentarius Commission revised and adopted the seven HACCP principles. In the meantime, several food safety standards based on HACCP principles were introduced by the food market e.g. British Retail Consortium (BRC, 2005), International Food Standard (IFS).

Wright and Teplitski (2009) argued that the acceptance of HACCP was due, partly, to the fact that its main principle made intuitive sense: kill pathogens at the crucial step in the production cycle and then maintain food processing under conditions that prevent recontamination. HACCP was a much-needed solution for an industry that was meeting the needs of an increasingly suburban population that no longer produced its own food. The development and acceptance of HACCP coincided with a number of changes in the industry including an increased concentration of agricultural production and globalisation of food markets.

EU FOOD HYGIENE LEGISLATION

On the 29th April 2004 the European Parliament and the Council adopted the ‘food hygiene package’ which comprises of Regulations (EC 2004a,b,c). EC 2004a,b are addressed to food business operators (FBO) and EC 2004c on official controls. The new regulations came into force on the 1st June 2006 and extended the existing principles embodied in Council Directive 93/43/EEC. EC 2004a on the hygiene of foodstuffs applies to all foods, and begins at primary production and continues through processing, distribution and retail while EC 2004b lays down specific hygiene rules for food of animal origin. The new requirements apply from primary production to retail, and lay down that food business operators are responsible for the safety of their products and they must apply HACCP principles. However, an exception was made for producers of primary products (e.g. dairy farmers), even though they should follow the principles of food safety and hygiene codes and the best way is to use HACCP-based systems (Maunsell and Bolton 2004).

In particular, the new food hygiene package highlights: (i) the paramount concern to protect human health; (ii) the use of procedures based on HACCP principles to identify, control and monitor critical food safety points in food businesses; and (iii) the possibility of adopting microbiological criteria and temperature control measures in accordance with scientifically accepted principles.

With regards to the dairy industry the new Directives EC No.852/2004 and 853/2004 have replaced the Dairy Hygiene Directive 92/46/EEC. The new dairy hygiene legislation is extensively described by Komorowski (2006) while changes from Directive 92/46/EEC are also identified. Additional requirements to the dairy industry such as Regulations 1774/2002 and 79/2005 (dairy companies disposing milk and dairy products) and of Regulation 183/2005 (dairy products intended to be used as animal feed) are also described by Komorowski (2006).

The report of the EC to the Council and the European Council on the experience gained by the member states on the implementation of the new legislation, indicate that member states and food business operators are generally satisfied with the new hygiene regulations and that they have made good progress in adjusting to them.

On the other hand, the FVO (2008) report has identified shortcomings in the control of the quality criteria of raw milk in countries like Spain, Hungary, and Poland while some progress was noted in Greece, Cyprus, Belgium, Denmark and Lithuania.

Moreover, the same report stated that compliance with Community requirements pertaining to residues and veterinary medicines controls in foods of animal origin in Greece, Romania, Portugal and Bulgaria suffered from significant shortcomings. The above facts illustrate the need for stringent adherence to hygiene regulations (Food Safety Management Systems) by the producers and detailed, frequent audits by the competent local authorities as the safety and quality of milk and milk end-products is of paramount importance.

OVERVIEW OF FOOD SAFETY MANAGEMENT SYSTEMS

On farm HACCP

The need for rigorous application of the HACCP principles by the dairy industry and the application of on-farm HACCP programs was early recognised by many dairy experts (Cullor 1997).

Major branded dairies have introduced their own on-farm HACCP programmes. For example, Arla Foods has established a quality program entitled Arlagzreden (‘the Arla farm’) to be used by their farmers. The program specifies Arla Foods’ requirements not only for food safety and milk composition, but also for animal welfare and environmental protection (Junedahl et al. 2008). The Canadian dairy industry has recently begun implementing an on-farm food-safety program called Canadian Quality Milk (Young et al. 2010). These quality assurance programmes starting at dairy farm level deals with food safety, animal health and animal welfare issues to take account of the
demands of consumers and retailers (Noordhuizen and Metz 2005).

The HACCP concept, focused on risk management and prevention, appears to be very promising to control on-farm processes. It can be easily linked to both operational management and food chain quality assurance and is suitable for certification (Noordhuizen 2003; Heeschen and Bluthgen 2004; Noordhuizen and Metz 2005). In fact, introduction of HACCP on dairy farms has not been tested in practice, because of many objectively immeasurable processes in an on-farm situation (Noordhuizen 2003; Heeschen and Bluthgen 2004; Noordhuizen and Metz 2005). In fact, introduction of HACCP on dairy farms means nothing more than ’structuring and formalising what the truly good farmer would be doing anyway’ (Ryan et al. 1997). Until now, the introduction of HACCP principles in on-farm management has hardly been tested in practice, because of many objectively immeasurable processes in an on-farm situation (Noordhuizen 2003).

Livestock species are an important reservoir of Campylobacter jejuni, shiga-toxin producing E. coli, L. monocytogenes, Salmonella spp., and Yersinia enterocolitica (Jayarao and Henning 2001; Murinda et al. 2002; Jayarao et al. 2006) and other pathogenic bacteria that have been implicated in a number of foodborne outbreaks (Table 1). These pathogens have been recovered with various frequencies from dairy-cattle faeces, bulk milk tanks and the dairy-farm environment (Troutt et al. 1995; Jayarao and Henning 2001; Murinda et al. 2002; Van et al. 2004; Srinivasan et al. 2005; Wiedmann 2006; Karna et al. 2007; Vissers and Driehuis 2009). Molecular epidemiological studies of E. coli O157:H7 have demonstrated that subtypes of the organism can persist on cattle farms for years (Hancock et al. 2001; Aspán and Eriksson 2010). The presence of foodborne pathogens in milk is because of direct contact with contaminated sources in the dairy farm environment and to excretion from the udder of an infected animal (Oliver et al. 2005; Kousta et al. 2010). Fox et al. (2009) demonstrated the prevalence of L. monocytogenes in the dairy farm environment and the need for good hygiene practices to prevent its entry into the food chain and Hussein and Sakuma (2005) described pre- and post-harvest control measures to ensure safety of dairy cattle products. D’Amico et al. (2008) reported that the incidence of foodborne pathogens of concern in raw milk utilised for farmstead cheese production was very low, whereas, Danielsson-Tham et al. (2004) stated that the conditions on a summer farm can hardly fulfil the requirements for hygienic and strictly controlled conditions necessary for safe processing of fresh cheese.

Outbreaks because of the consumption of unpasteurised milk (Peterson 2003; Lind et al. 2008; Heuvelink et al. 2009; Lejeune and Rajala-Schultz 2009; Oliver et al. 2009a,b), inadequately pasteurised milk (Fahey et al. 1995) and cheeses made from unpasteurised milk (Honish et al. 2005, CSPI 2008, 2009) continue to occur. Campylobacteriosis and Salmonellosis were the most common zoonotic diseases in humans in the European Union during 2008, but incidences of both have fallen, whereas, the number of cases of verotoxigenic E. coli (VTEC) rose by almost 9% and the number of listeriosis cases in humans decreased by 11.1% (EFSA, 2010). In 2008, there were 5332 foodborne outbreaks in the EU, sickening over 45 000 people and causing 32 deaths. Some 35 per cent of these were triggered by Salmonella spp., with viruses and bacterial toxins detailed as the next most common causes.

Noroviruses are the leading cause of foodborne outbreaks of acute gastroenteritis and the most common cause of sporadic infectious gastroenteritis amongst persons of all ages (Tauxe 2002; Mesquita and Nascimento 2009). Fumian et al. (2009) developed a rapid and sensitive method for recovery and detection of noroviruses from cheese and fresh lettuce.

Pathogenic bacteria such as E. coli, S. aureus, Corynebacterium bovis, Klebsiella spp., or Pseudomonas spp., Streptococcus agalactiae, Streptococcus dysgalactiae and Streptococcus uberis may cause, under certain circumstances, clinical mastitis (Hahn 1996; Barkema et al. 1998). Special care should be taken for the use of antibiotics, and Sawant et al. (2007) found that enteric bacteria such as E. coli from healthy lactating cattle can be an important reservoir for tetracycline and other antimicrobial resistance determinants.

Antimicrobial residues and antimicrobial-resistant bacteria from milk and milk products can also pose potential health risks to consumers (Katz and Brady 2000; Straley et al. 2006). Other chemical hazards include herbicides, pesticides and toxic metals, and physical hazards include hairs and needles (Cullor 1997). Kan and Meijer (2007) in a recent review, up-dated the information on carry-over of toxic substances from feed to food of animal origin.

Contamination of milk via the exterior of the cows’ teats occurs when teats, and subsequently milk, are contaminated with dirt consisting of faeces, bedding material, soil, or a combination of these. Vissers et al. (2007a) applied quantitative microbial risk analysis of the microbial contamination of farm tank milk for the amount of dirt transmitted to milk via the exterior of teats using spores of mesophilic aerobic bacteria as a marker for transmitted dirt. Silage was the main source of butyric acid bacteria and clostridia spores in cheese milk (Vissers et al. 2007a,b; Julien et al. 2008). When silage fermentation conditions are not prone to rapid pH decrease and maintenance of uniformly anaerobic conditions, germination of the spores and subsequent vegetative cell multiplication can occur. Vissers et al. (2006) applied a modelling
approach to identify an effective control strategy at the farm level and found that contamination level of silage with the butyric acid bacteria was found to be the most important factor for the control of contamination of farm tank milk. In addition, Sanaa et al. (1993) found that poor quality of silage, pH >4, inadequate frequency of cleaning the exercise area, poor animal cleanliness,
insufficient lighting of milking barns and parlours, and incorrect disinfection of towels between milking were significantly associated with raw milk contamination by *L. monocytogenes*.

Cleaning and disinfection of the udder and the teats with appropriate agents before and after milking can minimise infections during milking (Burgess et al. 1994). Temperature abuse should be avoided at all stages in the farm, and temperature should not increase above 6°C during transportation to the dairy (Dijkers et al. 1995). In recent years, improved standards of housing and use of separate milking parlours have reduced the risk of raw milk contamination. Probable control points on the farm for many of these human pathogens will be: (i) housing and bedding; (ii) water and waste management areas; (iii) hospital pens; (iv) calving pens; (v) treatment areas; (vi) bulk tank milk; and (vii) young stock and cull animals (Cullor 1997).

As part of any on-farm HACCP system, cost-effective, accurate and reproducible tests should be used to monitor certain control points (Reybroeck 1996). However, the monitoring is limited by inadequacies and costs of existing testing methodologies (Gardner 1997).

The dairy industry can adapt and implement Good Dairy Farming Practice (GDFP) to aid in managing animal health problems and to begin addressing pathogens of concern for foodborne and waterborne illness. A joint guidance on GDFP was published from the International Dairy Federation and the Food and Agriculture Organization of the United Nations (IDF/FAO 2004). The objective is that milk should be produced on-farm from healthy animals under generally accepted conditions. To achieve this, dairy farmers need to apply Good Agricultural Practice in the following areas: (i) animal health; (ii) milking hygiene; (iii) animal feeding and water; (iv) animal welfare; and (v) environment.

In addition, GlobalG.A.P has recently published regulations for integrated farm assurance, which contains all the control points and compliance criteria that must be followed by the producer and which are audited to verify compliance (GlobalG.A.P 2007). For dairy farms, the protocol includes specifications for feed, housing and facilities, dairy health, milking, milking facilities (e.g. milking equipment, milking parlours, and milk collection equipment), hygiene, cleaning agents and other chemicals.

**HACCP in dairy products**

The implementation of food hygiene and HACCP system has been reported to be an effective and cost-effective approach to food safety regulation (Unnevehr and Jensen 1999; Mortimore 2001). Several studies have been published concerning the implementation of HACCP on dairy products such as pasteurised, ultra high temperature (UHT) and condensed milk (Dijkers et al. 1995; Sandrou and Arvanitoyannis 2000a,b; Ali and Fischer 2002), yoghurt (Sandrou and Arvanitoyannis 2000a,b), a variety of cheeses (Sandrou and Arvanitoyannis 2000a; Mauropolous and Arvanitoyannis 1999; Arvanitoyannis and Mavropoulos 2000; Evrensel et al. 2003; Arvanitoyannis et al. 2009), ice cream (Mortimore and Wallace 1998; Papademas and Bintsis 2002; Arvanitoyannis et al. 2009) as well as cream and butter (Sandrou and Arvanitoyannis 2000a,b; Ali and Fischer 2005).

The HACCP principles as described by the Codex Alimentarius (CAC 2003a,b) adopted by all Food Safety Management Systems e.g. ISO 22000, BRC, IFS, Dutch HACCP and SQF and implemented in the dairy industry are as follows:

**Principle 1**: Conduct a hazard analysis.
**Principle 2**: Determine the Critical Control Points (CCPs).
**Principle 3**: Establish critical limit(s).
**Principle 4**: Establish a system to monitor control of the CCP.
**Principle 5**: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
**Principle 6**: Establish procedures for verification to confirm that the HACCP system is working effectively.
**Principle 7**: Establish documentation concerning all procedures and records appropriate to these principles and their application.

Table 2 summarises the processing steps in the dairy industry that are considered critical for the safety of the end product, in case of loss of control. Consequently, types of hazard, control limits as well as preventive measures are recorded. Most of the potential hazards identified are microbiological. Therefore, temperature treatments (e.g. pasteurisation, ultra high temperature, scalding temperatures) or temperature control (cooling, freezing) are considered critical for rendering the end – product microbiologically safe. It was well understood that pasteurisation, was proved to be successful as a CCP to control classical zoonoses e.g. Brucella, (Papademas 1999) as well as newer foodborne pathogens (Schrothorst and Kleiss 1994). Filtration techniques are used in conjunction with pasteurisation to further reduce bacterial counts in the end product e.g. pasteurised milk. Bactofugation is also used to reduce anaerobic spore-forming bacteria e.g. *Clostridium* spp (Bylund 1995). Post-pasteurisation microbiological hazards e.g. cross contamination are generally controlled by applying strict rules of cleaning and disinfection as prerequisite programmes, while acidification,
Table 2 Critical control points in the dairy industry

<table>
<thead>
<tr>
<th>Product</th>
<th>Processing step</th>
<th>Hazard type</th>
<th>Description</th>
<th>Critical limits/preventive measures</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>All dairy products</td>
<td>Milk reception</td>
<td>Microbiological</td>
<td>Milk with high microbial load</td>
<td>Routine control determination pH/acidity</td>
<td>Arvanitoyiannis et al. (2009)</td>
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<td>(pH 6.4–6.6)</td>
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<td>Temperature control and vehicle cleaning</td>
<td>Arvanitoyiannis et al. (2009)</td>
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<td></td>
<td></td>
<td>Physical</td>
<td>Distribution under nonhygienic conditions</td>
<td>Filtration, macroscopic examination</td>
<td>Arvanitoyiannis et al. (2009)</td>
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<td></td>
<td></td>
<td>Physical</td>
<td>Foreign matter, hair and other material</td>
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<td></td>
<td></td>
<td>Chemical</td>
<td>Veterinary residues (antibiotics), mycotoxins,</td>
<td>Test milk for antibiotics and aflatoxin</td>
<td>Arvanitoyiannis et al. (2009)</td>
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<td></td>
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<td>pesticide residues</td>
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<tr>
<td>All pasteurised dairy products</td>
<td>Milk pasteurisation</td>
<td>Microbiological</td>
<td>Potential pathogen survival</td>
<td>Pasteurisation temperature not &lt;72.5°C/15 s</td>
<td>Kailasapathy (2008)</td>
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<td>(or a similar time/temperature profile), negative alkaline phosphatase test</td>
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<tr>
<td>UHT milk, sterilised cream</td>
<td>Sterilisation</td>
<td>Microbiological</td>
<td>Render the product microbiologically sterile</td>
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<td>Wilbey (2002)</td>
</tr>
<tr>
<td>Milk, cream, ice cream</td>
<td>Cooling</td>
<td>Microbiological</td>
<td>Potential pathogen/spoilage micro-organisms</td>
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<td>Boor and Murphy (2002)</td>
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<td></td>
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<td></td>
<td>proliferating</td>
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<td>Papademas and Bintsis (2002)</td>
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<td></td>
<td>Filling</td>
<td>Microbiological</td>
<td>Carton sealing</td>
<td></td>
<td>Kailasapathy (2008)</td>
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<td></td>
<td>Labelling</td>
<td>Physical</td>
<td>Incorrect use by date</td>
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<td>Kailasapathy (2008)</td>
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<tr>
<td>Pasta filata type cheeses and Halloumi cheese</td>
<td>Scalding/kneading</td>
<td>Microbiological</td>
<td>Potential pathogen survival</td>
<td></td>
<td>Papademas (2006)</td>
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<tr>
<td>All dairy products that require lactic</td>
<td>Starter culture</td>
<td>Microbiological</td>
<td>Potential pathogen survival</td>
<td></td>
<td>Papademas and Robinson (1998)</td>
</tr>
<tr>
<td>fermentation</td>
<td>addition/ripening</td>
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<td></td>
<td>Arvanitoyiannis et al. (2009)</td>
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<td></td>
<td></td>
<td></td>
<td>Cross contamination</td>
<td></td>
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<tr>
<td>All cheese types</td>
<td>Dry salting/curd salting</td>
<td>Microbiological</td>
<td>Potential pathogen survival</td>
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<td>Arvanitoyiannis et al. (2009)</td>
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</table>
Salting and brining ensure, especially in cheese-making, the correct proliferation of microflora.

Apart from the microbiological hazards, equally important, although much less frequent, are the chemical and physical potential hazards in dairy products. Chemical hazards in milk and milk products such as veterinary residues, Aflatoxin M1 are quite important but surely the frequency of incidents is much lower (RASFF 2008) than the identified as potential microbiological hazards. On the other hand, physical hazards are also low in numbers and are mainly related to packaging, incorrect labelling and contaminations with foreign objects, Arvanitoyiannis et al. (2009). Detecting veterinary drug residues using advanced rapid on-line techniques such as Liquid Chromatography/Mass Spectrometry (LC/MS) or biosensors are described by Vanhoof et al. (2003) and Sternesjo (2003). Physical hazards can be detected by X-ray based inspection systems that detect metal, stone, bone or glass in sealed packages. Relatively recent developments of phase contrast X-ray imaging may provide the necessary level of discrimination needed to detect foreign bodies such as insects, hair and extraneous vegetable matter (Righelato 2003).

The microbiological criteria for pasteurised milk and milk products, as end products, are described in the EU Directive 1441/2007, while the EU Directive 853/2004 governs all the quality/safety criteria for raw milk and milk products e.g. hygiene of raw milk production (animal hygiene), hygiene at farm level, temperature control limits, microbiological quality of raw milk, labelling of milk products, packaging of milk products. These directives are essential for setting up control limits for the identified CCP’s.

Apart from the above described HACCP principles, the prerequisite program implementation in food businesses regardless of size or complexity is considered essential. Recently, the British Standards Institute (BSI) developed the Publicly Available Specification – BS PAS 220 (2008), which specifies requirements for prerequisite programmes to assist in controlling food safety hazards. BS PAS 220 2008 is to be used in conjunction with ISO 22000 2005a,b. BS PAS 220 2008 specifies detailed requirements to be considered including:

1. Construction and layout of buildings and associated utilities.
2. Layout of premises, including workspace and employee facilities.
3. Supplies of air, water, energy and other utilities.
4. Supporting services, including waste and sewage disposal.
5. Suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance.
6 Management of purchased materials.
7 Measures for the prevention of cross contamination.
8 Cleaning and sanitising.
9 Pest control.
10 Personnel hygiene.

It also adds other aspects that are considered relevant to manufacturing operations:
1 Rework.
2 Product recall procedures.
3 Warehousing.
4 Product information and consumer awareness.
5 Food defence, biovigilance and bioterrorism.

During recent years, the need for assessing the risk associated with the identified as potential hazard has grown to be a very important tool for an effective food safety management system.

It is true that regarding dairy products an increased degree of biological safety will only be achieved through a thorough understanding of the genetic, genomic, and physiological mechanisms underlying interactions within these edible ecosystems. This can give rise to novel control measures (e.g. bacteriophages specific to certain pathogens, probiotic cultures to out-grow the harmful bacteria). New advancements in technology would help improve food product traceability e.g. Radio Frequency Identification (RFID).

**Risk assessment**

Risk assessment has been set as a top priority issue on the basic food legislation document, EC Regulation 178/2002 (EC 2002), and is defined as a ‘scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation’. Risk is a ‘function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard’ (EC 2002). Thus, risk assessment requires the collection of scientific data regarding the nature, frequency and impact on public health in Europe of food safety hazards. Indeed, the severity of a foodborne illness caused by a biological hazard must be combined with its occurrence in humans to accurately define risk (FAO/WHO 2004).

The level of risk can be expressed in a qualitative way (e.g. high, medium or low risk), or when possible, quantified (e.g. as the number of cases of foodborne disease per number of people per year, dose-response relationships and exposure assessment). Guidelines for chemicals in foods will inevitably have to address the differences between safety evaluation and a genuine risk assessment approach. With respect to microbiological hazards, the unique problems associated with risk assessment of living organisms in food make is likely that application of guidelines in the medium term will more commonly use qualitative approaches.

As risk assessment is increasing applied and internationally accepted guidelines become established, decision criteria for risk management arguably present the greatest challenge in establishing and maintaining quantitative SPS measures for food in international trade and judging their equivalence (Hathaway 1997).

The International Commission on Microbiological Specifications for Foods (ICMSF) has proposed a scheme for the management of microbial hazards for food that involves the concept of Food Safety Objectives (FSOs), i.e., the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the Appropriate.

Level of Protection (ALOP) (ICMSF 2002). To ensure that an FSO is met, it is required to set performance objectives (POs), which correspond to the levels that must be met at earlier steps in the food chain before consumption. The FSO gives flexibility to the food chain to use different operations and processing techniques that best suit their situation, as long as the maximum hazard level specified at consumption is not exceeded (e.g. the replacement of heat treatment with another equivalent technique, e.g. microfiltration). Microbiological standards (Buchanan 1995) have been included in European Legislation (EC 2005).

Risk communication between risk managers and stakeholders is simplified when the results of a qualitative assessment are available (Clough et al. 2006; Hauser et al. 2007). However, quantitative assessments are much more useful tools (Peeler and Bunning 1994; Bemrah et al. 1999; Sanaa et al. 2004) for microbial risk assessments, and Monte Carlo exposure assessment model for mycotoxins in dairy milk was developed by Coffie et al. (2009).

Brouillaud-Delattre et al. (1997) used predictive microbiology to study the influence of biological factors affecting the growth of *L. monocytogenes* in sterilised milk and raw dairy products and postulated that it was influenced greatly by bacterial interactions and physiological state of inoculum cells and Albert et al. (2005) described a Monte Carlo simulation that forecasts bacterial growth and exposure assessment for *L. monocytogenes* in milk. Predictive models are now essential part of risk assessments (McMeekin and Ross 2002; Notermans et al. 2002).

The development and use of a simple tool for food safety risk assessment has been described by Ross and Sumner (2002) in spreadsheet software format that embodies established principles of food safety risk assessment. Microbial predictive modelling techniques have been developed by many workers (George et al. 1996; Murphy et al. 1996; McClure et al. 1997; Xanthiakos et al. 2006; Membré and Lambert 2008). The validation of
such models has been investigated (Murphy et al. 1996; Ross 1996; Baranyi et al. 1999; te Griffel and Zwietering 1999). Notermans et al. (1995) suggested the use of quantitative risk assessment for setting critical limits at the CCPs of a HACCP system for realistic levels of control.

Several computer programs have been launched for estimating bacterial growth and inactivation in different products: Pathogen Modeling Program, PMP, (USDA-ARS 2006), Combase Predictor (Combase 2010), the online resource for food safety risk analysis (JIFSAN 2010) and Seafood Spoilage and Safety Predictor (National Institute of Aquatic Resources 2009), and (Safe Foods 2010) for helping in development of HACCP-systems or in performing quantitative risk assessment (McMeekin et al. 2006, 2008; Hignette et al. 2008).

International agencies and all levels of government are increasingly relying on, or at least recognising the need to rely on, risk assessments for decision-making in public health protection, international trade, and to support cost-effective resource allocation including prioritising research directions (CAST 1994; ILSI 1996, 2005, FAO/-WHO 1997) and several authors have highlighted the need for the application of risk assessment methods to food safety (Jaykus 1996; Kindred 1996; Lammerding 1997; Buchanan et al. 1998; Voysey and Brown 2000). Full quantitative assessment of the risk can be achieved if the distributions of values of the factors in the system that contribute to the risk are known (Vose 1996; Cassin et al. 1998). Methods for microbial food safety risk assessment are being developed by various organisations (FAO/-WHO 1995; ILSI 1996; PCCRARM 1997; CAC 1999; ILSI 2005) and, since the mid-1990, a number of microbiological risk assessments have been presented (Schlundt 2000).

The integration of HACCP plans with the development of dynamic risk-assessment models offers a means for considering the entire farm-to-table continuum and for relating food-manufacturing operations to public health goals (Buchanan and Whiting 1998).

ISO 22000 2005 A, B

The HACCP system per se does not make food safe, but it is its proper implementation that can make a difference: this should not be a tool for politicians to gain the confidence of consumers (Motarjemi and Käferstein 1999). Although the food hygiene basic text from Codex Alimentarius (CAC 2003a;b; CAC 2009) serves as the basis for all food safety management systems, a number of countries have developed national standards for the supply of safe food (Faergemand and Jespersen 2004; Arvanitoyannis and Traikou 2005) and individual companies and groupings in the food sector have developed their own standards or programmes for auditing their suppliers such as BRC, IFS, Dutch HACCP etc. (NACMCF 1997; Bernard 1998; Forsythe and Hayes 1998; Mitchell 1998; Arvanitoyannis and Traikou 2005; Frost 2006). The plethora of more than 20 different such schemes worldwide generates risks of uneven levels of food safety, confusion over requirements, and increased cost and complication for suppliers that find themselves obliged to conform to multiple programmes.

On 1st September 2005, the International Organization for Standardization (ISO) published a new food safety management system, the ISO 22000 2005a,b – Food safety management systems – Requirements for any organisation in the food chain (ISO 2005a,b), providing a framework of internationally harmonised requirements for the global approach to food safety issues. ISO 22000 2005a,b was designed to allow all types of organisation within the food chain to implement a food safety management system. These range from feed producers, primary producers, food manufacturers, transport and storage operators and subcontractors to retail and food service outlets – together with related organisations such as producers of equipment, packaging material, cleaning agents, additives e.g. starter cultures and ingredients (ISO 2005a).

Certain new requirements can be seen, such as the creation of interactive communication systems within and outside the company, the creation of a system for the prevention of unforeseen situations, implementation of certain necessary programs, risk assessment etc. An effective communication management system must be created between the producer, suppliers, subcontractors and consumers, government institutions or other organisations, which will affect or be affected by the results of the food safety management system.

In line with all other management systems e.g. ISO 9001:2008, the systemic approach adopted by the ISO 22000 standard is based on the application of process management principles. In this context, the management system of an organisation can be viewed as a single large process, based on the Deming cycle (Plan-Do-Check-Act), which may be broken down to several sub-processes (Bluivan and Alam 2005). Effective management of food safety oriented processes ensures effective management of the whole organisation (Armstead et al. 1999; ISO 2005a). The development of ISO 22000 2005a,b was based on the assumption that the most effective food safety systems are designed, operated and continually improved within the framework of a structured management system, and incorporated into the overall management activities of the organisation.

Hazard assessment serves to determine which of the potential hazards identified require specific
control measures. To ensure such control, the standard requires the selection of, or combination of, control measures. In conducting the hazard assessment, the following should be taken into consideration: (i) the sources of the hazard; (ii) the probability of occurrence of the hazard; (iii) the nature of the hazard; and (iv) the severity of the adverse health effects that can be caused by the hazard (ISO 2005a).

As ISO 22000 2005a,b was developed in cooperation with the European Committee for Standardization (CEN), and this means that all CEN members (29 countries at present) have to adopt this standard as national standard within 6 months after its publication and withdraw any national standard which is contradictory with it.

The Food Business Forum, the only independent global food business network, very early, in 2000, identified the need to enhance food safety, to ensure consumer protection, to strengthen consumer confidence, to set requirements for food safety schemes, and to improve cost efficiency throughout the food supply chain and published certain guidance documents (GFSI 2007). In response to this need the Global Food Safety Initiative (GFSI) was born (GFSI 2010).

Adopting the ISO 22000 2005a standard provides the company with competitive efficiencies and a great number of advantages (Surak 2003; Pilley and Muliyil 2005; Faergemand 2008; Junedahl et al. 2008; Magro 2008; Overbosch et al. 2008; Arvanitoyannis and Kassaveti 2009; SGS 2010). However, ISO 22000 2005a,b does not contain the nonexhaustive list of Good Manufacturing Practices present in the GFSI guidance document (GFSI 2007).

Recently, the Publicly Available Specification – BS PAS 220 2008 was developed by British Standards Institution (BSI) in association with major branded dairies (Unilever, Kraft, Nestle, Danone). It was published in Oct 2008 (BSI 2008) and is now a new complementary standard to ISO 22000 2005a,b. It specifies, as already mentioned, the prerequisite programmes requirements in detail to assist in controlling food safety hazards. In fact, it provides harmonisation of prerequisite programmes and industry best practice for food manufacturing. GFSI agreed that the combination of ISO 22000 2005a,b and BS PAS 220 2008 contained adequate content for approval, but also highlighted the need for an industry-owned scheme governing the combination of these two standards.

Consequently, the foundation for food safety certification developed the FSSC 22000, an auditable standard which incorporates food safety elements already known from previous standards such as HACCP, ISO 22000 2005a,b, BRC and IFS as well as from specifications such as BS PAS 220 2008 (Sansawat and Muliyil 2009), which was recently approved by the GFSI as a global benchmark in food safety management.

CONCLUSIONS

The design and implementation of Food Safety Management Systems have come a long way since the very early systems of the 1960’s, to the implementation of the ISO 22000 2005a,b and the BS PAS 220 2008.

It is quite possible that HACCP-based programmes, building on Good Agriculture Practices, will become compulsory for dairy farmers within a few years. Dairy farmers have to show – as demanded from retailers – their farm status with respect to food safety and public health as well as animal health and welfare. In addition, on-farm procedures to monitor the presence of emerging and re-emerging human pathogens will need to be established in the near future.

ISO 22000 2005a,b provides an auditable standard that can be used for internal audits or third-party certification. It provides a set of tools for use by all interested parties, that is, consultants, certification bodies, accreditation bodies, public authorities and all members in the food supply chain, from farmer to retailer and aids organisations to demonstrate their ability to conform to its own sated food safety policy by planning, implementing, operating, maintaining and updating a food safety management system.

REFERENCES


