Food Hygiene in Aseptic Processing and Packaging Systems

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Cycle *XXI*

... to Maya, Merilú and Victoria ...

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Abstract

A comprehensive bibliographic study on foodborne outbreaks in the western world, on the main food safety problems in the food industry, and on the implementation of *Hygienic Design* in the food industry has been carried out.

An alarming scenery appears: foodborne infections cause several millions cases of human illness and many thousands deaths annually in the western world. On the other hand the most part of the reported cases of foodborne outbreaks are attributable to poor handling at the home or at retail food establishments rather than failures at the food processing level. The study shows that the lack of hygienic design of equipment is probably the most important food safety problem in the shelf-stable food industry. Shelf-stable foods are not high-risk foods, anyhow they can be the cause of botulism outbreaks, really not so rare public health emergencies.

Unfortunately *Hygienic Design* is an unfamiliar issue and the awareness of the food industry about the importance of this topic is quite low. Thermal processing is one of the most important operations in food processing but, also for this equipment typology, the manufacturers are far from a really scientific approach to the design, which obviously includes also the *Hygienic Design*. Moreover, from the academic point of view, a few articles on this topic are available in the literature and are mostly related to CFD simulation of cleaning processes. The most part of available documents are from the organization European Hygienic Engineering and Design Group, a consortium of equipment manufacturers, food industries, research institutes and public health authorities, working since 1989.

A huge lack of knowledge and research on the above said topics has been found and so a whole approach for the assurance of the Food Hygiene has been developed in this PhD thesis. The case of aseptic processing and packaging systems has been handled. Several procedures, tools and methods have been developed. Firstly it is necessary to have regard to the in force regulations (not so obvious), and the use of available standards and guidelines should be expected.

- A check list for the evaluation of compliance of aseptic processing and packaging systems to the European and US regulations, the European and international standards and the European and international guidelines has been developed.

Secondly a scientific knowledge about the physical phenomena involved in the process should be desirable.

- A method (software + measuring cell) for the determination of the most important physical property of foods (thermal diffusivity) involved in heat treatment has been developed.
- A procedure (simple software also developed) for the correct design and setting of the flow diversion device, a critical point of aseptic processing and packaging systems, has been developed.

Thirdly the opportunity to perform validation procedure should be always taken into account.

- A method for the validation of aseptic packing machines has been developed.

The created instruments have been tested on real equipments and products. A good survey on the implementation of Hygienic Design in the Italian food industry is the result of the wide use of the check-list. In some cases the developed approach allowed to solve food hygiene problems.

Since there is the need, not only for scientific research, but also for dissemination and training, the Italian Section of the EHEDG has been set up in Parma, which is, at the present time, also the site of the European Food Safety Authority. Several companies have been involved and the activities of the section are increasing and spreading.

Contents

Nomenclature

α thermal diffusivity

ψ error function

ρ density

c_p specific heat capacity

d dilution ratio of the first countable dilution

H height of the sample

k thermal conductivity

N axial space-nodes number

na number of plates of the first countable dilution

nb number of plates of the second countable dilution

nc number of plates of the third countable dilution

N_s active spores number

Q time-intervals number

R radius of the sample

S radial space-nodes number

t time

T temperature

Subscripts

b imposed at the surface

e_k experimental at time $(k \cdot \Delta t)$

i initial

n axial distance step index

p time step index

s radial distance step index

s_k simulated at time $(k \cdot \Delta t)$

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Chapter 1

Justification

THERE is a continuing increase in the involvement of regulatory and advisory bodies in the area of food process hygiene. There are many reasons for this, as in the case of well known incidents such as BSE and Foot and Mouth outbreaks in Europe (Cocker, 2003). On the contrary, consumers have the right to expect the food they eat to be safe and suitable for consumption: foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal (CodexAlimentarius, 2003). There are also other consequences: according to statistical data in 1996 in the USA, additional costs of more than 30 Trillion US$ were attributed to recall campaigns caused by contamination of food (Stouzby *et al.*, 1996).

The above quoted CAC statement (Codex Alimentarius Commission) introduces two important concepts, Safety and Suitability, as prerequisites for foods. How do we achieve safety and suitability? The answer in the European Regulation EC/852/2004 is *Food Hygiene*, defined as the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff ((Anon, 2004)). *Food Hygiene* is a very wide goal for the food industry which includes hygienic design and engineering of equipment, integration of components, hygienic engineering of installation and facilities, maintenance, services and others.

Thermal processing is one of the most important operations in food processing (Balsa-Canto *et al.*, 2002). Aseptic processing is of considerable interest as it involves continuous sterilization and packaging of food products of high quality

(mainly low-acid foodstuffs) (Sandeep *et al.*, 1999). It is used to sterilize a wide range of liquid foods, including milk, cream, yoghurt, wine, salad dressing, egg and ice cream mix and it can be also used to process foods which contain small discrete particles (Fellows, 2000). In order to completely understand and correctly design an Aseptic System, one needs to take into account many issues, including fluid flow, heat transfer, monitoring, microbiological aspects, transient states and others, in addition to general requirements for Food Hygiene mentioned above.

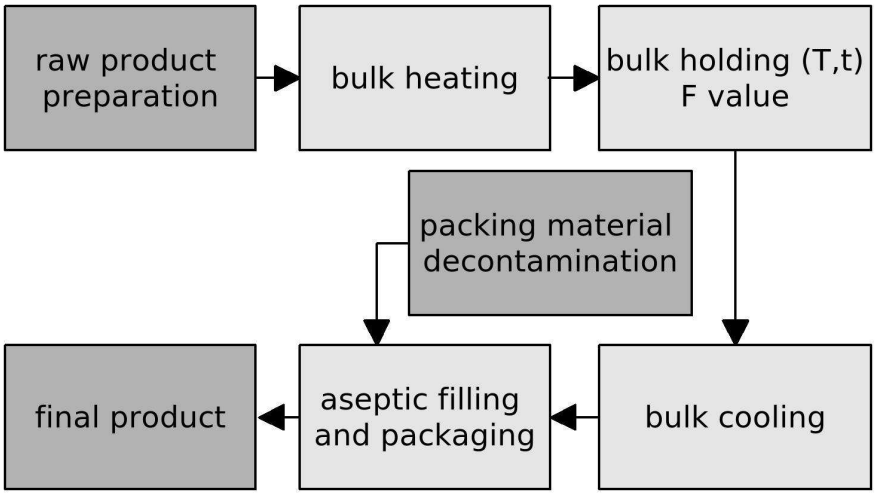

Figure 1.1: Simplified diagram of an Aseptic Processing and Packaging System

To assist in the discussion of aseptic processing some definitions are necessary: Aseptic means commercially sterile. Aseptic processing and packaging means the processing and packaging of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product. Commercial sterility means the absence of micro-organisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage. (CodexAlimentarius, 1993)

A basic diagram of an Aseptic System is shown in Fig. 1.1. Raw or unprocessed product is heated, sterilized by holding at high temperature for a predetermined amount of time, then cooled and delivered to a packaging unit. Com-

mercial sterility is maintained throughout the system, from product heating to the discharge of hermetically sealed containers (Stevenson & Chandarana, 1999).

1.1 Food Hygiene - Regulatory Context

1.1.1 EU and USA Regulation

Hygiene regulation in EU is made up of a set of vertical regulations, each covering a restricted range of foodstuffs, in great measure adopted by September 1992. An horizontal directive (93/43/EEC) providing general hygiene rules has been adopted by June 1993. This directive has been replaced by the Regulation EC/852/2004 in force by April 2004, followed by Regulation EC/853/2004 laying down specific hygiene rules for food of animal origin. Regulation EC/1935/2004 on materials and articles intended to come into contact with food has also to be kept into account (other regulations and directives are available for specific materials). Finally the Regulation EC/178/2002 has to be considered because it lays down the general principles and requirements of food law.

The Directive 2006/42/EC Of The European Parliament And Of The Council of 17 May 2006 on machinery (the new version of the Directive 98/37/EC, well know mainly for the safety of workers) is a reference directive for the mechanical industry. Unluckily food equipment manufacturers often forget to consider the section 2.1 of the Annex I of the directive, laying down essential health and safety requirements relating to the the design and construction of foodstuffs machinery and machinery for cosmetics or pharmaceutical products (also safety and health of the final consumer).

The US health authority responsible for regulating food and many other product is The Food and Drug Administration (FDA), agency of the United States Department of Health and Human Services. Regulations on food and drug are collected in the title 21 of Code of Federal Regulations.

Regulation EC/852/2004 (Anon, 2004) encourages to have regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the Codex Alimentarius. On the US side the Food and Drug Administration also participates to Food Hygiene Committee of the Codex Alimentarius. Much

of the new legislation is then based on the internationally developed FAO/WHO Codex.

As observed by Cocker (2003) Europe and USA may also have a significant influence beyond their geographical boundaries jurisdiction because they have highly developed legislation in the area of food safety. In the case of the EU, for example, some neighbours such as Switzerland implement adaptations of EU legislation to ensure they can trade freely with the EU. Then the Codex Alimentarius is actually a benchmark for good practice for hygiene in the whole world, to such an extent that it is sometimes written as International Regulation (Cocker, 2003).

1.1.2 From Regulation to Standards and Guidelines

Article 3 of the Regulation EC/852/2004 asserts that Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation (Anon, 2004). In addition the Chapter V of Annex II of the Regulation asserts that All articles, fittings and equipment with which food comes into contact are to be effectively cleaned and, where necessary, disinfected (Anon, 2004).

Moreover the Directive 2006/42/EC of the European Parliament and of the Council (EU Machinery Directive) asserts that the food machinery must be so designed and constructed that these materials can be clean before each use and that All surfaces in contact with the foodstuffs must be easily cleaned and disinfected (Anon, 2006a) On the US side, section 110.40(a) of Code of Federal Regulation asserts that All plants equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable (Anon, 1998). These all are very general requirements. Nevertheless compliance achievement would require a great effort to equipments suppliers in developing a lot of suitable design solutions. For this reason, a comprehensive compliance is very unusual and at least very difficult, for example about cleanability.

Regulation EC/852/2004 (Anon, 2004) encourages the development of national guides and Community guides to good practice for hygiene. Moreover

in order to support compliance to the EU Machinery Directive (Anon, 2006a), the European Commission has committed to the European Committee for Standardization (CEN) the development of the standard EN1672-2: Food Processing Machinery Basic Concepts Hygiene Requirements, followed by a set of vertical standards on specific machineries. Similar standards are the EN-ISO-14159 (see also Murray (2006)) e the 2nd Fair-Flow Europe Technical Manual (Holah). Several organizations in the world have developed design criteria and guidelines on equipment, building and processing. In Europe, the European Hygienic Design Group (EHEDG), have also developed equipment performance test to validate compliance with the design criteria. Compliance to regulations must be a prerequisite for all food manufacturers and for all foodstuff. Guidelines suggest a possible solution able to achieve compliance to regulations.

Thanks to the aid given by guidelines and standards, every food company and food machinery supplier, apart from its size, would be able to assure conformity to law requirements, without investing a lot of resources in research and development. The standardization due to the use of guidelines shouldnt damage commercial competition. Law requirements have to be considered as pre-competitive requisites which allow to improve the minimum level of Hygiene (as intended above) in the food industry. Standard and Guidelines are then fundamental instruments to achieve Safety and Suitability of food.

1.2 Foodborne outbreaks

Foodborne infections cause an estimated 6.5 million cases of human illness and 9000 deaths annually in the United States (Bennett *et al.*, 1987). About Europe, for instance in the Netherlands there are an estimated 2 million food-borne infections every year (Oosterom, 1998). Pathogenic bacteria are the most commonly reported agents of foodborne illness, closely followed by viruses (CDC, 2004). Further, most reported cases of foodborne illness are attributable to poor handling at the home (Evans *et al.*, 2006; Jackson *et al.*, 2007), or at retail food establishments (Bolton *et al.*, 2008) rather than failures at the food processing level (CDC, 2000). It is not possible to determine (with certainty) the cause of foodborne illness in roughly 50 percent of all foodborne illness cases.

Moreover, many foodborne illness cases go unreported (ERG, 2004). A survey carried out on the information source "CAMBRIDGE JOURNALS" (*http* : *//journals.cambridge.org/action/login*) gave the following results: the enquiry for the keyword "foodborne" returned 362 matches (Table 1.1). *Salmonella spp* turns out to be the most reported cause of foodborne outbreaks (e.g. Beatty *et al.* (2008), Collard *et al.* (2007), Currie *et al.* (2005), Ellis *et al.* (2000), Espi *et al.* (2004), Ethelberg *et al.* (2007), Fell *et al.* (2000), Gikas *et al.* (2007), Gillespie *et al.* (2005b), Gupta *et al.* (2007), Hedberg *et al.* (2000), Hess *et al.* (2007), Kimura *et al.* (2005), Kirk *et al.* (2004), Liming & Bhagwat (2004), Lo Fo Wong *et al.* (2002), Matsui *et al.* (2004), Munnoch *et al.* (2008), Pakalniskiene *et al.* (2008), Pontello *et al.* (2000), Roels *et al.* (2000a), Ward *et al.* (2002)), followed by *E. Coli spp* (e.g. Espi *et al.* (2005), Gillespie *et al.* (2005a), MacDonald *et al.* (2004)), *campylobacter spp* (e.g. Evans *et al.* (2000), Roels *et al.* (2000b)), *listeria spp* (e.g. Collins-Thompson & Slade (1991), Francis & O'Beirne (2005), Mead *et al.* (2005), Okutani *et al.* (2004)), *clostridium spp* (e.g. Lund (1990)) and *bacillus spp* (e.g. Lund (1990)). Virus are en emerging problem (Koopmans & Duizer, 2004): several groups of viruses may infect persons after ingestion and then are shed via stool. Of these, the norovirus (NoV) (e.g. Doyle *et al.* (2008), Fretz *et al.* (2005), Friedman *et al.* (2005), Kelly *et al.* (2008), Sala *et al.* (2008)) and hepatitis A virus (HAV) (e.g. Pebody *et al.* (2000)) are currently recognised as the most important human foodborne pathogens with regard to the number of outbreaks and people affected in the Western world. Protozoa (mainly *Cryptosporidium*, *Giardia*, *Cyclospora*, and *Toxoplasma*) are also a matter of concern (e.g. Dawson (2005), Ferguson *et al.* (2003))

According to the returned matches, several surveys show that non-typhoidal salmonellosis and campylobacteriosis are the two most frequently reported foodborne illnesses in Belgium (Collard *et al.*, 2007); *Salmonella* is the most commonly reported cause of foodborne outbreaks (MMWR, 1993) in the USA (see Table 1.2 for more details); in Italy non-typhoidal salmonellosis causes more than 50% of all foodborne gastroenteritis (ISS, 2008) with an estimated $10000 - 15000$ cases of human illness and 20 deaths annually.

The enquiry for the keyword "foodborne" and "clostridium" returned 44 matches and, among them, 9 matched have been returned for the *clostridium*

Table 1.1: CAMBRIDGE JOURNALS Search Results

Keywords	**Returned Matches**
Foodborne	362
Foodborne & *Salmonella*	280
Foodborne & *Coli*	260
Foodborne & *Campylobacter*	175
Foodborne & *Listeria*	48
Foodborne & *Clostridium*	44
Foodborne & *Bacillus*	40
Foodborne & *Clostridium Botulinum*	9
Foodborne & *Virus*	105
Foodborne & *Hepatits A*	42
Foodborne & *Norovirus*	29
Foodborne & *Cryptosporidium*	40

Table 1.2: Reported *Salmonella enteritidis* outbreaks in the U.S. (MMWR (1993))

Keywords	Returned Matches		
Year	Outbreaks	Cases	Deaths
1985	26	1,166	1
1986	48	1,539	6
1987	53	2,498	15
1988	40	1,010	8
1989	77	2,394	14
1990*	49	1,646	2

botulinum spp.

1.2.1 Botulism

Botulism is caused by a neurotoxin produced from the anaerobic, spore-forming bacterium Clostridium botulinum. Botulism in humans is usually caused by toxin types A, B, and E. Although rare, botulism outbreaks are a public health emergency that require rapid recognition to prevent additional cases and to effectively treat patients. Because clinicians are the first to treat patients in any type of botulism outbreak, they must know how to recognize, diagnose, and treat this rare but potentially lethal disease. (Shapiro *et al.*, 1998). Some reported outbreaks of foodborne botulism type A and B are shown in Table 1.3

LACFs (Low Acid Canned Foods) are susceptible for the grow of *Clostridium botulinum* and their production must comply to the specific part 21 of the CFR (Code of Federal Regulation). REPFEDs (Refrigerated pasteurized foods with extended durability) are a matter of concern for botulism, also for the toxin type E. , since the non-proteolytic *Clostridium botulinum* (group II) is psychrotrophic and so it can grow at refrigeration temperature. Although group II spores are less heat-resistant than group I (proteolytic) spores, they can tolerate the heat treatments employed in the chilled food industry (Gould, 1999; Hyyti *et al.*, 1999; Lindstrm *et al.*, 2006; Peck, 1997; Peck & Stringer, 2005).

1.2.2 High-risk foods

The level of risk to public health varies by type of food. Some food products, such as refrigerated RTE (ready to eat) foods, have a higher risk of being contaminated by pathogenic bacteria than others (ERG, 2004). For these product the effectiveness of the cold chain plays a key role. The shelf life of food is extended by refrigeration because the metabolic processes of food-associated microorganisms are slowed by the lowered temperature (Russell, 2002). Kovats *et al.* (2004) found out a relationship between environmental temperature and reported Salmonella infections in 10 European populations. Some studies were carried out in order to estimate proliferation of human pathogenic and spoilage micro-organisms on several products as a function of storage temperature (Jacxsens *et al.*, 2002; Okamura

Table 1.3: Some reported type A and B botulism outbreaks

Year	Location	Cases	Food	Toxin	Reference
1967	USA	4 of 8 family members	- home-canned "pickled" beans	B	Koenig *et al.* (1967)
1989	UK	27	- hazelnut yoghurt	B	O'Mahony *et al.* (1990)
1993	Georgia	8	- commercial cheese sauce	A	Townes *et al.* (1996)
1996	Italy	8 (from 6 to 23 years old)	- commercial cream cheese	A	Aureli *et al.* (2000)
1997	Iran	27	- cheese	A	Pourshafie *et al.* (1998)
2000	France	9	- home-canned asparagus	B	Abgueguen *et al.* (2003)
2003	USA	15	- chili dish	A	Kalluri *et al.* (2003)
2005	France	1 (74 years old)	—	—	Boyadjiev *et al.* (2005)
2006	Thailand	209	- bamboo shoots	A	Kongsaengdao *et al.* (2006)
2006	Taiwan	5	- fermented food	B	Tseng *et al.*
2007	USA	5	- Castleberry's hot dog chili sauce	A	CDC (2007)
1973 – 1998	USA	600 + 1775 infant	—	—	Shapiro *et al.* (1998)
1980 – 2002	Georgia	879	- home-preserved vegetables (80%)	—	Varma *et al.* (2004)
1990 – 2000	USA	263	- home-canned vegetables (44%)	—	Sobel *et al.* (2004)
1998 – 2003	Georgia	217	- home-canned vegetables (63%), long term consequences also reported	—	Gottlieb *et al.* (2007)

et al., 2007; Soboleva *et al.*, 2001). Unluckily retail display cabinets are critical points in the cold chain of minimally processed, modified atmosphere packed (MAP) foods. A survey was performed by Willocx *et al.* (1994): variations in residence time of three categories of minimally processed MAP vegetables were analysed in two local supermarkets using a stimulus-response technique. More than 50% of the packages (median) were sold in the first day, but the range indicates that some of the packages were sold after the 'use by' date. Mean residence time increases with increasing shelf-life, and for products with a shelf-life of 3 and 4 days, the mean residence time was almost the same in both supermarkets. Temperature performance of the display cabinets was influenced by both ambient temperatures and day/night regime. Temperature differences of more than $5°C$ were measured on the decks. Temperature in one place increases towards the end of the day by $4°C$ and towards the end of the week by almost $7°C$. Temperature monitoring and control based on the thermometer of the cabinets was impossible. Differences between the actual and read-out temperature of up to $10°C$ were observed. This survey showed the necessity of a close control of temperature conditions and residence time of minimally processed MAP vegetables in retail display cabinets. There is a need to improve safety design of foods relying solely on refrigeration to control pathogens. The preservation hurdles, which can be applied to such foods, are double heating, irradiation, hydrostatic pressure, modified atmosphere packaging, low pH, salt, spices, lactate, bacteriocins, protective cultures and their combination (Rybka-Rodgers, 2001).

1.3 Food safety problems in the food industry

Due to recent so-called food crises in Europe, food quality and food safety have become a hot topic in the media. Most often the terms food quality and food safety are interchangeably used. There are substantial differences especially when talking about the communication of food manufacturers and consumer perceptions. Prior to incidents such as the BSE crisis, most consumers simply expected that each food placed on the market had met these two characteristics. This was self-evident and there was no necessity to communicate food safety to the consumer. This situation has changed in the past years, food safety has become

a food quality characteristic. Public authorities are pushing the food and the feed industry to develop comprehensive quality management systems to improve food safety, restructure the food inspection system and try to enhance consumer information to regain consumers trust in food (Rohr *et al.*, 2005). Food safety is commonly related to three categories of hazards, microbiological, chemical and physical.

1.3.1 Microbiological hazards

The microbiological safety hazards include pathogenic bacteria, viruses, and parasites. Some of the problems that lead to the contamination of food with these microorganisms at the processor level can be easily remedied with improved employee training programs and effective hygienic practices. Others are more difficult to control, such as post-processing contamination with Listeria monocytogenes, a pathogen that is ubiquitous in the processing environment. See also Table 1.4.

- *Inefficient hygienic practices among employees.* Employee hygiene is paramount to plant sanitation and is one of the leading causes of food contamination (Higgins, 2002 as citet by ERG (2004)). One of the challenges that food processors have to overcome is how to motivate employees to comply with hygienic practices. Training is one step in the process, but is often not enough to ensure employee compliance. Companies have adopted several aids to ensure employee compliance. For example, Atlantas Buckhead Beef Company requires workers to key in their Social Security Numbers to activate the hand sanitizer dispensers on the plant floor. The company then uses the collected data to impose financial reprisals on employees found to be deficient in hand-sanitizing practices. Other controls include a sensor-equipped towel that prevents the cross-contamination that can occur with hand cranks. These units also count the number of towels dispensed. A signal dispenser that beeps when users have washed their hands sufficiently is also available to ensure adequate hand-washing time.

- *Language barriers.* Current training programs, even those that include Spanish signage and instructional manuals, can be inadequate if the first language of plant employees is one other than English or Spanish. Even Spanish training materials can be problematic due to dialectical differences in translations. Some industry experts therefore recommend a picture-and-symbol approach to training to overcome language barriers (Higgins, 2002 as citet by ERG (2004)).

- Ineffective training of employees. Although effective training is crucial to ensuring that sanitation standards are met, it is not clear that current training methods are sufficient. In the third Annual Best Manufacturing Practices Survey conducted by the Food Engineering magazine in 2002, a panel of food manufacturing professionals rated employee training as the lowest among all food safety measures in terms of effectiveness (Gregerson, 2002 as citet by ERG (2004)). Employee training that companies conduct may be too generic. For example, external consultants may not be familiar enough with a plants operations and requirements to give effective advice. Other impediments to effective training might include training the wrong people, not training enough people, or not providing enough training (Blackburn and McClure, 2002 as citet by ERG (2004)).

- *Biofilms.* Biofilms occur when bacteria form a slime layer upon a surface and provide an environment for pathogens to proliferate. The adhesion of pathogenic bacteria to a biofilm is a food safety hazard because the biofilm can detach and become a significant source of food contamination. Cleaning to remove biofilms prior to sanitation is often sufficient to prevent this problem. However, studies have shown that attached bacteria may survive conventional cleaning methods (Austin and Berferon, as cited in Stopforth et al, 2002 as citet by ERG (2004)). Adequate cleaning prior to sanitizing is therefore paramount to controlling this problem. Further, coating drains and equipment parts with antimicrobial material can counteract biofilms although it does not eliminate the need for proper cleaning and sanitizing (Higgins, 2003 as citet by ERG (2004)).

- Niche environments. Niche environments are sites within the manufacturing environment where bacteria can get established, multiply, and contaminate the food processed. These sites may be impossible to reach and clean with normal cleaning and sanitizing procedures. Examples include hollow rollers on conveyors, cracked tubular support rods, the space between close-fitting metal-to-metal or metal-to- plastic parts, worn or cracked rubber seals around doors, and on-off valves and switches (Tompkin, 2002). Tompkin (2002), as citet by ERG (2004), provides an extensive list of potential niches. Manufacturers must identify and eliminate niches. Microbiological sampling of the environment and equipment can detect a niche. Third- party validation of test results might be useful to further establish confidence in environmental sampling results. Further, sanitary equipment design can help prevent niches (AMI, 2003, as citet by ERG (2004)). Proper maintenance to keep equipment parts from providing potential niches is also essential.

- *Plant renovations.* Outbreaks of listeriosis have been linked to environmental contamination of food caused by plant renovations (FDA/CFSAN, 2001a as citet by ERG (2004)). While no data were identified in the literature on this issue, plant renovations are likely to require revisions in standard operating procedures (SOPs) to prevent contamination due to changes in processes.

- *Ineffective use of cleaning agents and disinfectants.* Different cleaning agents vary in their ability to remove different soil types (Blackburn and McClure, 2002 as citet by ERG (2004)). Thus, the correct choice of cleaning agent is essential to ensure effective cleaning in a food processing facility. The efficacy of disinfectants is dependent on microbial species, pH, presence of biofilms, temperature, concentration, and contact time (Stopforth et al., 2002 and Blackburn and McClure, 2002 as citet by ERG (2004)). Stopforth et al. (2002), as citet by ERG (2004), found that commonly used disinfectants were not as effective as desired, possibly due to inadequate pre-cleaning steps. While there were no examples in the literature of plants having problems with this issue, the potential for ineffective sanitation is

clearly present. Food manufacturers should always confirm the efficacy of their cleaning and disinfection programs with tests from the supplying companies or in-house trials (Blackburn and McClure, 2002 as citet by ERG (2004)).

- *Lack of sanitary equipment design.* Good hygienic design of equipment prevents or minimises microbiological contamination of food. The materials used for food processing equipment should be easily cleanable. As noted earlier, niche environments are known sources of pathogens; surfaces also deteriorate with age, and this abrasion makes cleaning more difficult (Blackburn and McClure, 2002 as citet by ERG (2004)). For cleaning and sanitation to be effective, all parts of the equipment should be readily accessible. Another way to improve equipment hygiene is to use antimicrobial coatings on equipment parts (Higgins, 2003). Reactive rather than routine/predictive maintenance. In the Best Manufacturing Practices Survey conducted by Food Engineering magazine in 2001, 56 percent of respondents reported having routine preventive programs (Gregerson, 2002 as citet by ERG (2004)). Only 8.5 percent of respondents noted having predictive maintenance programs; the remaining respondents described their programs as reactive in nature, i.e., run it til it breaks. Reactive maintenance can result in food contamination before a failure is identified. Niches can develop or controls can become defective in processing equipment that is not routinely maintained. For example, in 1994, a Listeria monocytogenes outbreak was linked to the use of defective processing equipment in the production of chocolate milk (FDA/CFSAN, 2001a as citet by ERG (2004)).

- *Ineffective application of sanitation principles.* It may be difficult for a food processor to apply sanitation principles consistently and effectively to each batch of product. Food processors have found that improving the effectiveness of sanitation principles is dependent on using redundant processing controls (FDA/CFSAN, 1999c as citet by ERG (2004)). Validation of cleaning processes may also be necessary. Automation that makes it unnecessary for humans to conduct the cleaning, such as robotic spray washers,

may also improve sanitation. The extent to which these practices are used in the industry is unclear and should be explored with industry experts.

- *Internalization of pathogens in fruit.* Fruit is usually contaminated by direct or indirect contact with animal feces. Studies have shown that pathogens can infiltrate fruit through damaged or decayed areas or through the flower end of the fruit (FDA/CFSAN, 1999a and FDA/CFSAN, 1999b and FDA/CFSAN, 1999c as citet by ERG (2004)). While employing best control practicessuch as not using dropped fruit, removing damaged fruit, and washing/brushing fruit prior to processingminimizes these risks, the problem can only be controlled with some certainty by a kill step, such as pasteurization. Other possible controls are listed in the FDA Report of 1997 Inspections of Fresh, Unpasteurized Apple Cider Manufacturers and listed again in the annotated bibliography.

- *Contamination of raw materials.* Many pathogens, like *E. coli* and *Salmonella*, enter the food processing environment via raw materials contaminated with those pathogens. A number of studies have shown that methods currently in place to prevent this are not sufficient (FDA/CFSAN, 1999a and FDA/CFSAN, 1999b and FDA/CFSAN, 1999c and Riordan et al., 2001 and Tilden et al., 2002 as citet by ERG (2004)). Raw material contamination can affect any industry, but is more common in industries that use animal-derived products or products at risk of cross-contamination by animal feces. There are numerous preventive controls available to address the hazard. Some controls minimize the risks of raw material contamination (i.e., ensuring that raw material suppliers comply with good agricultural practices) and others (i.e., irradiation, pasteurization) involve a kill-step to eliminate any pathogens.

- *Post-processing contamination.* Products can also be contaminated if the post-processing environment, utensils, or equipment have been contaminated with a pathogen. This issue is especially relevant to the pathogen *Listeria monocytogenes*, due to its hardiness and pervasiveness in the environment. Effective controls against post-process contamination include

Table 1.4: Range of processor-level problems of microbiological food safety hazard posed (ERG (2004))

Inefficient employee hygiene practices
Language barriers
Ineffective training of employees
Biofilms
Niche environments
Plant renovations
Ineffective use of cleaning agents/disinfectants
Lack of sanitary equipment design
Reactive instead of routine maintenance
Ineffective application of sanitation principles
Internalization of pathogens in fruit
Contamination of raw materials
Post-processing contamination

eliminating the pathogen from the post-processing environment by using environmental sampling to eliminate niches, effective sanitation, and various in-package pasteurization methods. Use of preservatives, such as nisin, to slow down the growth of *Listeria monocytogenes* are also becoming more common.

1.3.2 Chemical hazards

Chemical safety hazards include intentionally added chemicals (e.g., allergens), unintentionally added chemicals (e.g., cleaners and solvents), and natural toxins (e.g., mycotoxins). Chemicals can also contaminate food through corrosion of metal processing equipment/utensils and residues of cleaning chemicals left on processing equipment. Further, adding too much of an approved ingredient, such as a vitamin in vitamin-fortified products, may compromise the safety of foods.

- *Raw material contamination with pesticides.* FDA has found that roughly 1 percent of sampled domestic produce has pesticide residue in violation of

EPA standards (FDA/CFSAN, 2002 as citet by ERG (2004)). While the incidence of contamination is low, consumers remain concerned about pesticide residues. Aside from washing and testing the produce, manufacturers can select produce from organic suppliers to avoid raw material contaminated with pesticides. Other alternative farming systems, such as low-input sustainable agriculture (LISA) and integrated pest management, are also control options at the farm level (Moulton, 1992 as citet by ERG (2004)). These systems, which use much less pesticide than conventional agricultural systems, rely on biological, chemical, cultural, and physical principles and tools to control pests throughout the farming operation. Other preventive control options may include genetic engineering with resistance against pests or developing safer chemicals (Moulton, 1992 as citet by ERG (2004)).

- *Indiscriminate spraying of facilities against pests.* Chemicals can contaminate food if pesticides against insects and rodents are used indiscriminately in a processing facility. Therefore, food experts generally recommend that pest control be performed only by professionals to avoid residues in food (Folks, 2001 as citet by ERG (2004)).

- *Mistaken identity of pesticides.* Food can become contaminated with pesticides if pesticide container labels are misread or when products are stored in containers that have had another use. The best way to control the risk of mistaken identity is to store pesticides away from food ingredients, keep an inventory of pesticides, and store the products in their original containers (Tybor, 1990 and Folks, 2001 and Bryan, 1997 as citet by ERG (2004)).

- *Spillage of pesticides or other chemicals.* Pesticides should be handled like poisons to avoid potential spillage. Storing chemicals away from food and packaging materials will minimize accidental spillage of pesticides and other chemicals (Tybor, 1990 as citet by ERG (2004)). Further, processors should only use food-grade lubricants and greases in manufacturing.

- *Corrosion of metal containers/equipment/utensils.* Metal poisoning can occur when heavy metals leach into food from equipment, containers, or utensils. When highly acidic foods (e.g., citrus fruits, fruit drinks, fruit pie

fillings, tomato products, sauerkraut, or carbonated beverages) come into contact with potentially corrosive materials, the metals can leach into the food (Tybor, 1990 as citet by ERG (2004)). One solution to the problem is to use appropriate, non-corrosive materials in food processing.

- *Residue from cleaning and sanitizing.* If equipment and other food handling materials are not rinsed well, then residue from detergents, cleaning compounds, drain cleaners, polishers, and sanitizers can contaminate a food product. This problem can best be controlled by properly training personnel about cleaning and sanitizing (Folks, 2001 adn Tybor, 1990 as citet by ERG (2004)).

- *Accidentally adding too much of an approved ingredient.* Some substances, such as preservatives, nutritional additives, colour additives, and flavor enhancers, are intentionally added to food products. But adding an approved ingredient in inordinate amounts by accidentsuch as adding too much nitrite to cured meatcan result in a toxic product (Bryan et al., 1997 as citet by ERG (2004)). Thus, Tybor (1990), as citet by ERG (2004), recommends that nitrite be stored in a locked cabinet and weighed and bagged separately before being added to any product. Nutritional safety issues can also arise when product labels nutrition information is incorrect. Thus, it can be dangerous to public health when too little or too much of a specified nutrient is added. For example, malnutrition can occur if infant formula does not deliver the expected nutrient content during its shelf life. Due to the risk involved, infant formula quality control procedures and labelling requirements are addressed outside of GMPs in 21 CFR 106 and 107, respectively. There are also many examples of nutritional food safety issues arising when too much of a nutrient gets added to a product unintentionally. For example, some vitamins that are added to fortified foods (such as Vitamin A) are known to be toxic at high doses. And iron, a necessary dietary component, can cause severe illness and death if too much is ingested. Controlling chemicals by keeping an inventory of additives minimizes the occurrence of this type of contamination (Folks, 2001 as citet by ERG (2004)).

- *Natural toxins.* Food can be contaminated with naturally occurring chemicals that cause disease. Toxins such as mycotoxins (discussed further below) and marine toxins are naturally produced under certain conditions. Given that these toxins generally occur in raw materials, especially crops and seafood, manufacturers should require suppliers to certify hat the products they purchase are free from natural toxins.

- *Cross-contamination with allergens on production lines.* A product can become cross- contaminated with allergens on the production line. To minimize the risk of cross-contamination, equipment must be cleaned and sanitized to remove all traces of allergens when the next run includes product that should not contain allergens (Minnesota Department of Agriculture, 2003 as citet by ERG (2004)). Wash-down techniques may need adjustment to ensure that they remove allergens as well as pathogens (Higgins, 2000 as citet by ERG (2004)). Rinsing with water only or only cleaning at the end of the day is not adequate (FDA/CFSAN, 2001a as citet by ERG (2004)). Some equipment may need to be disassembled to be cleaned. The cleaning process should be verified by visual inspection. Enzyme-linked immunosorbent assay (ELISA) tests can also help verify cleaning procedures (Deibel et al., 1997 and Morris, 2002 as citet by ERG (2004)). Manufacturers may choose to physically separate lines for allergen- and nonallergen-containing products (Morris, 2002 as citet by ERG (2004)). This may be too costly for most plants; scheduling longer production runs to minimize changeovers, with allergen-containing product runs scheduled at the end of the day, may be a more suitable alternative (Deibel et al., 1997 and FDA/CFSAN, 2001b and Floyd, 2000 and Gregerson, 2003 and Minnesota Department of Agriculture, 2003 adn Morris, 2002 as citet by ERG (2004)). Crossover points on production lines, including conveyor belts that transport products, should be enclosed to prevent cross-contamination. Physical detachments and lockouts can be used for equipment common to allergen- and nonallergen-containing foods (Deibel et al., 1997 as citet by ERG (2004)). Maintenance tools should be colour-coded to prevent cross-contamination

(FDA/CFSAN, 2001b and Morris, 2002 as citet by ERG (2004)). Allergenic materials should be stored separately from nonallergenic materials, with dedicated utensils and containers. Putting all of the ingredients for a specific batch on a pallet before taking them to the processing area, or staging, will also minimize the risk of cross-contamination. Line clearance, such as removing all the ingredients from the production area and checking for cleanliness, can also help prevent cross-contamination (Floyd, 2000 as citet by ERG (2004)). Product can also be tested for the presence of allergens, although this does not appear to be a common industry practice (FDA/CFSAN, 2001a as citet by ERG (2004)). Finally, allergens should be evaluated as part of a hazard analysis, and a HACCP plan or similar approach can be taken to identify process areas that are at high risk for contamination with allergens (Morris, 2002 as citet by ERG (2004)).

- *Raw material contamination with allergens.* When controlling a production process for allergens, manufacturers must maintain a close working relationship with suppliers of raw materials. The ingredient specification should provide assurance that the product is allergen free (Deibel et al., 1997 and FDA/CFSAN, 2001c as citet by ERG (2004)). Manufacturers should also obtain full ingredient lists from their suppliers (Deibel et al., 1997 and Gregerson, 2003 as citet by ERG (2004)). Reconditioned ingredients and oils should not be purchased (Minnesota Department of Agriculture, 2003 as citet by ERG (2004)). The manufacturer should also audit suppliers each year to determine other products that are run on the same production line, whether any allergenic processing aids or rework have been used in the product, and whether any contamination from other common equipment could have occurred (Gregerson, 2003 as citet by ERG (2004)). A training program may be necessary to educate suppliers about allergen control, especially if suppliers have not implemented an allergen control plan (Deibel et al., 1997 and Minnesota Department of Agriculture, 2003 as citet by ERG (2004)).

- *Contamination with allergens by utilization of rework.* Proper use of rework is essential to prevent contamination of product with allergens. A

documented rework plan should be available. Rework areas, equipment, and containers must be clearly identified and documented, as well as the rework itself (Deibel et al., 1997 and Gregerson, 2003 as citet by ERG (2004)). This can be done through the use of colour tags, plastic liners, or bar coding.

- *Not declaring an allergen on labelling.* Unavoidable product contamination with allergens may occur if it is impossible to verify that all residue has been removed from a line or if other controls cannot be put in place (Floyd, 2000 as citet by ERG (2004)). A good manufacturing practice includes reviewing the labelling to ensure that the allergen is declared. However, a study of inspections conducted by FDA/ CFSAN (2001a), as citet by ERG (2004), indicated that many firms do not have label review policies. Further, a large percentage of these manufacturers had undeclared allergens in their products. Controls to prevent this problem can include removing old label and packaging inventories from plants, verifying labels by scanning bar codes, and conducting label audits (FDA/CFSAN, 2001 and FDA/CFSAN, 2001c and Minnesota Department of Agriculture, 2003 as citet by ERG (2004)).

- *Older equipment.* Effective cleaning is paramount to controlling allergen contamination. Older equipment, however, may not be designed to verify cleaning with a visual inspection (Deibel et al., 1997 as citet by ERG (2004)). As noted in the section on microbiological issues and controls, all parts of the equipment should be readily accessible and visible for cleaning and sanitation to be effective. Further, equipment surfaces should not harbour allergens. Gregerson (2003), as citet by ERG (2004), reports one such case in which cross-contamination with allergens occurred due to the surface nicks on the processing table. Thus, sanitary equipment design is necessary to ensure proper removal of allergens from equipment.

- *Infestation of mycotoxins due to drought.* Toxigenic fungi, or mycotoxins, are found primarily in foods of plant origin, although they can also pass through the food chain in milk and meat. Drought can encourage the

growth of mycotoxins in certain crops. For example, drought stress can cause aflatoxin, a type of mycotoxin, to grow in corn and treenuts (Moss, 2002 as citet by ERG (2004)). Drought can be minimized through adequate irrigation schedules (Park et al., 1999 as citet by ERG (2004)). Thermal and chemical treatments are also available for use on crop that is already affected by mycotoxins (Park et al., 1999 as citet by ERG (2004)). Thermal inactivation, however, is not effective on certain types of mycotoxins, such as aflatoxin. Chemical treatments, such as ammoniation and activated carbons and clays, are other possible controls (Boutrif, 1999 and Horne et al., 1989 and Park et al., 1999 and Suttajit, 1989 as citet by ERG (2004)).

- *Infestation of mycotoxins due to damage.* Insect damage is associated with high levels of mycotoxin infection, as is mechanical damage from harvesters (Boutrif, 1999 and Moss, 2002 and Park et al., 1999 as citet by ERG (2004)). Diseases, such as ear rot in corn, also cause damage that leaves the crop susceptible to mycotoxin infestation (Moss, 2002 as citet by ERG (2004)). Delayed harvesting can also make crops more susceptible to disease due to higher moisture levels (Park et al., 1999 as citet by ERG (2004)). Damage to the product, whether through insect feeding or mechanical harvesters, provides a potential entry point for the mold that produces the mycotoxin. Controls available include pest management to prevent insect damage, breeding cultivars that are resistant to pest damage, timely harvesting, hand picking or electronic sorting to remove damaged crops, and thermal or chemical treatment as noted above (Boutrif, 1999 and Moss, 2002 and Park et al., 1999 and Suttajit, 1989 as citet by ERG (2004)). Possible biological control of insects and diseases in the field is also being investigated (Moss, 2002 as citet by ERG (2004)).

- *Infestation of mycotoxins due to moisture/heat during storage.* Post-harvest storage that protects the product from heat and moisture is essential to prevent mycotoxin infestation (Boutrif, 1999 as citet by ERG (2004)). Grains should be dried as soon as feasible, and storage under modified atmospheric conditions is desirable (GASCA/CTA, 1997 as citet by ERG (2004)). Products should be dried rapidly to less than 10 percent moisture (Park et al.,

1999 as citet by ERG (2004)). Products can also be sampled for mycotoxins during storage (Boutrif, 1999). Methods include visual inspection with black light, ELISA tests, and complex laboratory analysis using high-pressure liquid chromatography (Horne et al., 1989 as citet by ERG (2004)). While prevention with proper storage conditions is the best way to control mycotoxin infestation, thermal and chemical inactivation, as described earlier, can control any mycotoxins that do form under storage.

- *Patulin production in apples.* Patulin is a mycotoxin that is produced by a number of molds associated with fruit spoilage (Bisessur et al., 2001 as citet by ERG (2004)). Control methods often used in the production of apple juice include using tree-picked apples, culling apples, washing apples, charcoal treatment, chemical preservation using sulfur dioxide, gamma radiation, fermentation, trimming of fungus-infected apples, and clarification methods (Bisessur et al., 2001 and Jackson, et al., 2003 as citet by ERG (2004)).

See also Table 1.5.

1.3.3 Physical hazards

Materials that do not belong in food, like glass or metal, cause physical safety hazards. A physical safety hazard is any extraneous object or foreign matter in food that can cause injury or illness in the person consuming the product (Folks, 2001 as citet by ERG (2004)). Rocks, metal, wood, and other objects are sometimes found in raw ingredients. Further, contamination can occur during transport, processing, and distribution of foods due to equipment failure, accidents, or negligence (Institute of Medicine/National Research Council, 1998 as citet by ERG (2004)). Separation equipment should be used to separate the foreign bodies from the product. Detection methods include metal detectors, x-ray machines, and optical systems (Wallin and Haycock, 1998 as citet by ERG (2004)). In the literature there are a few articles about physical hazards in foods. Particularly only one specific book on the detection of foreign bodies in food was found (Edwards (2004); Smith (2005))

Table 1.5: Range of processor-level problems of chemical food safety hazard posed (ERG (2004))

Raw material contamination with pesticides
Indiscriminate spraying of facilities against pests
Mistaken identity of pesticides
Spillage of pesticides
Adding too much of an approved ingredient
Raw material contamination with an allergen
In-line cross-contamination with an allergen
Contamination by utilization of rework
Cross-contamination from maintenance tools
Cross-contamination from conveyor belts
Incorrect labelling or packaging
Older equipment (more difficult to clean)
Raw material contamination with natural toxins
Mycotoxin infestation due to drought
Mycotoxin infestation due to insect damage
Mycotoxin infestation due to delayed harvesting
Mycotoxin infestation due to mechanical damage
Mycotoxin infestation due to moisture/heat
Patulin production in apples
Corrosion of metal containers/equipment/utensils
Contamination with cleaner/sanitizer residue
Adding too much of an approved ingredient

- *Foreign matter in raw materials.* Sources of foreign matter in raw materials can include nails from pallets and boxes, ingested metal from animals, harvesting machinery parts, elements from the field, veterinary instruments, caps, lids, closures, and more (Wallin and Haycock, 1998 as citet by ERG (2004)). Mechanical harvesters will often collect more than the product. Processors can include separation equipment, such as destoners, air cleaners, magnets, screens, sieves, traps, scalpers, and washers as part of their production lines. For example, grain processors use four screens to remove foreign materials (Stier, 2001 as citet by ERG (2004)). Foreign matter in raw materials can be controlled with raw material inspections and vendor certifications or guarantees from suppliers. X-ray technology is also available to examine incoming material (Folks, 2001 as citet by ERG (2004)).

- *Poorly maintained equipment and lines.* Pieces of equipment can break off and enter food products during processing if equipment is poorly maintained. Routine or preventive maintenance and other periodic checks of equipment can minimize the risk from this safety issue. Risk is further minimized with the use of metal detectors and x-ray machinery. Proper calibration of equipment and minimizing contact between pieces of machinery is also helpful (Folks, 2001 and Stier, 2001 as citet by ERG (2004)).

- *Lighting fixture/other glass breakage.* Glass can be controlled by having a glass breakage policy, such as throwing away all food and containers within 10 feet of the incident (Stier, 2001 as citet by ERG (2004)). Light fixtures can be protected so that if they break, the glass does not spill out (Folks, 2001 as citet by ERG (2004)). Other controls include examining of empty glass containers visually or cleaning a container with water or compressed air and inverting the container to remove any shards. Capping equipment should be properly calibrated and lines should be monitored for evidence of glass breakage. X-ray technology can also be helpful in identifying glass pieces in food (Olson, 2002 as citet by ERG (2004)).

- *Human factors.* Production line workers can be a major source of contamination. For example, jewelry can fall off or break, fingernails can break,

Table 1.6: Range of processor-level problems of physical food safety hazard posed (ERG (2004))

Foreign matter in raw materials
Poorly maintained equipment/lines
Light fixture breakage
Foreign matter introduction during storage

and pens can fall into food. Jewelry removal is required under GMPs. If pens are metallic, a metal detector can detect them. Production workers fingernails should be cut short and gloves should be worn under certain processing conditions.

- *Introduction of foreign matter during storage.* Pests can enter products during storage, leaving remnants behind. Effective pest control is the solution. It can include preventive measures such as filling in all non-functional openings in a building; fully sealing doors, windows, and vents; protecting intake points with filters or grills; and protecting drains and other facility intakes and exits. Professional extermination is needed once pests have established. UV light traps can also be used, although they need to be designed to prevent further contamination from the tray that collects the insect remains (Wallin and Haycock, 1998 as citet by ERG (2004)).

See also Table 1.6.

1.4 Hygienic Design: State of the Art

A Delphi study was carried out by the Eastern Research Group (ERG) (ERG (2004)) about the common food safety problems in the u.s. food processing industry: The study had two primary objectives:

- To identify the main problems that pose microbiological (i.e., pathogenic bacteria, viruses, and parasites), chemical (i.e., allergens, cleaners and solvents, and mycotoxins), and/or physical (i.e., foreign objects such as glass and metal) safety hazards to food at the processor level, and

- To determine the preventive controls and/or corrective actions that food manufacturers should implement to address each of the problems identified.

The considered food industry sector were the baked-goods sector, the dairy sector, the frozen sector, the refrigerated sector, the shelf-stable sector, the meat-and-poultry sector.

The top 4 safety problems identified by the expert panel members were: deficient employee training, contamination of raw materials, poor plant and equipment sanitation and poor plant design and construction. The complete results are shown in Table 1.7.

For the shelf-stable food industry the most voted safety problem was "poor plant and equipment sanitation" (88%). Obviously the sanitation depends on the cleanability of equipments and the cleanability depends mainly on the design. As shown by Orinda (2002), the contamination of some food equipments after cleaning is higher compared to the contamination during production (Fig. 1.2). Moreover as shown in the Fig. 1.3, the cross contamination of the seafood product is a result of heavily contaminated surfaces. The equipments are "cleaned" by the product.

As reported by Stouzby *et al.* (1996), about a quarter (and probably more in my view) of the total cost due to callback campaigns cause by infections of food, could be attributed to insufficient hygiene of equipment. Nevertheless there is not a great effort in research and development in the field of Hygienic Design. A survey carried out on several information sources corroborates the hypothesis: the enquiry for the keyword "Hygienic Design" only returned about 150 matches on the whole. About 25 articles of them were from journals such as *Verpackungs Rundschau*, *Lebensmitteltechnik*, *European Dairy Magazine*, *Suesswaren*, *Confectionery Production*, *Confectionery Manufacture and Marketing*, *Scandinavian Dairy Information*, *Brauwelt*, *Drink Technology & Marketing*, *Fruit Processing*, *Deutsche Milchwirtschaft*, *Technical Quarterly, Master Brewers' Association of the Americas*, *Food Tech Europe*, *Alimenta*, *Mineralbrunnen*, *World Pumps* and so they were mostly marketing articles. The oldest were published in 1992. A great part of the returned matches are from the European Hygienic Engineering and Design Group: extended abstracts of all EHEDG guidelines are available in

Table 1.7: Main safety problems in the U.S. food industry (ERG (2004))

Food Safety Problem	**Votes**
Deficient employee training	94%
Contamination of raw materials	75%
Poor plant and equipment sanitation	75%
Poor plant design and construction	75%
No preventive maintenance	69%
Difficult-to-clean equipment	63%
Post-process contamination at manufacturing plant	63%
Contamination during processing	56%
Poor employee hygiene	56%
Incorrect labelling or packaging	44%
Contamination by reworked product	31%
Inadequate cooling	31%
Biofilms	25%
Lack of equipment knowledge	25%
Poor pest control	25%
Stagnant water due to dead ends in plumbing	25%
Condensate on pipes and other equipment	19%
Lack of crisis management protocol	19%
Lack of knowledge of welding standards	13%
Lack of product recovery protocol	13%
Lack of allergen control programs	6%
Lack of equipment parts reconciliation after repairs	6%
Use of unpotable water	6%

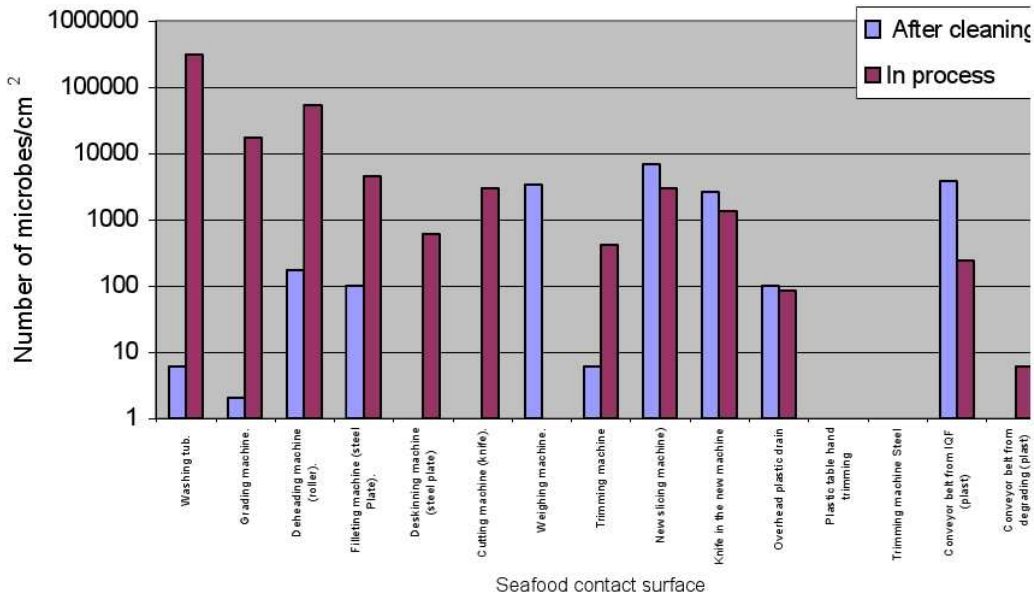

Figure 1.2: Distribution of microbes in the processing environment after cleaning and in processing after 8 working hrs in a fish plant located in Reykjavik, Iceland during December 2002 (Orinda (2002))

the journal *Trends in Food Science & Technology* (e.g. Anon (1993a,b,c,d,e,f,g, 1994a,b,c, 1995a,b, 1997a,b,c,d, 2001a,c,d,e, 2006b,c, 2007b,c,d,e); Ehedg (2001); Go Yanko (2007); Lelieveld *et al.* (1992); Maller (2007); Moens (2002, 2007); Moens-Go Yanko (2003); Mostert *et al.* (1993); Yanko (2006)); moreover several reports and reseach articles on *hygienic design* have been published by EHEDG members and partners (e.g. Abram *et al.* (1996); Anon (1994d); Cnossen *et al.* (2003); Cocker (2004); Dunn (2004); Freund (2007); Heide (2007); Lelieveld (1991, 1994, 2001); Lorenzen (1999, 2003); Mager (2002); Masters & Masters (2006); Seward (2007)). As shown in Table 1.7, *Training* was identified as one of the most important need in the food industry. Anyhow, a few articles were found about this topic, and again the most part is from the European Hygienic Engineering and Design Group (Ehiri *et al.* (1997); Jensen (2007); Moens-Go-Yanko (2004); Skovgaard (1990)). The most part of returned matches are about hygienic design of equipment. Moreover some articles have been found about the hygienic design of food factories and buildings (e.g. Birus (1997); Graham (1991a,b,c); Hauser

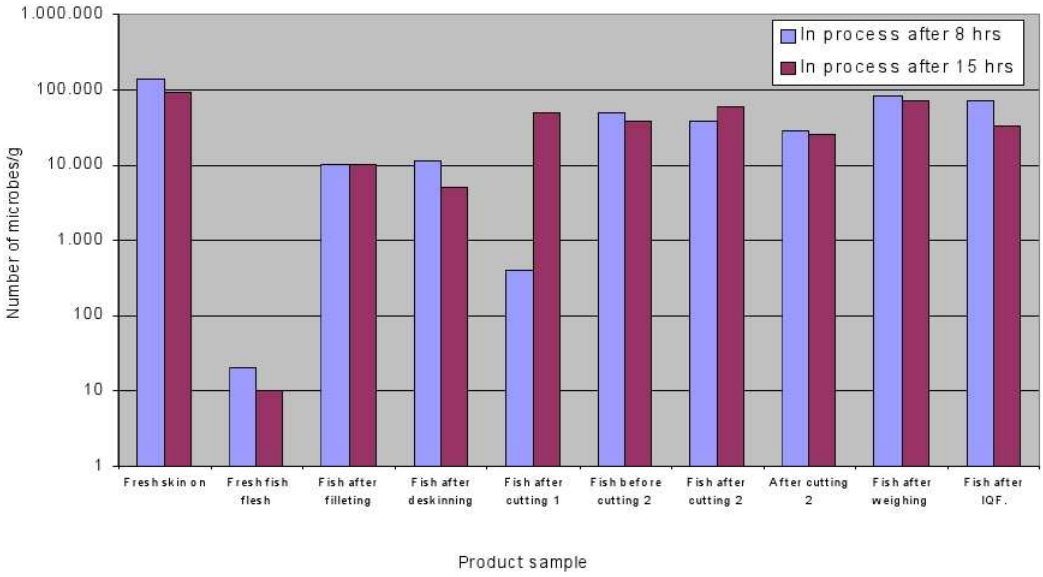

Figure 1.3: Distribution of microbes in fish and seafood products in a fish processing plant in Reykjavik, Iceland in December 2002 (Orinda (2002))

(1999); Holah (2003)).

1.5 Validation and test methods: State of the Art

The most active organization in developing test methods for the validation of food equipment is the European Hygienic Engineering and Design Group (EHEDG). The specific guideline EHEDG Doc.3 "Microbiologically safe aseptic packing of food products" (Mostert *et al.*, 1993), and the more general guideline EHEDG Doc. 11 "Hygienic packing of food product" describe the main criteria for hygienic design of packing machines but they can not be used for a certification. An aseptic packing machine can become EHEDG certified, if it fully complies to the EHEDG Doc.8 "Hygienic equipment design criteria" (Anon, 1993b). Unfortunately it is very difficult to design a complex machine fully compliant to this document but it is all the same possible to certificate the machine if the cleanability, sterilizability and bacteria-tightness are demonstrated by appropriate published EHEDG Test

Methods. Anyhow there are no EHEDG certified aseptic packing machines at the present time (January 2009).

The specific document EHEDG Doc. 21 "Challenge tests for the evaluation of the hygienic characteristics of packing machines for liquid and semi-liquid products", goes back over the available test methods for the validation of:

- Cleanability of the filling equipment (filler): EHEDG Doc. 15 "A method for the assessment of in-place cleanability of moderately-sized food processing equipment" (Anon, 1997d). The test can only be used for small filling equipment. All the more the EHEDG Doc. 2 "A method for the assessment of in-place cleanability of food processing equipment" (Anon, 2007c) can not be used since it needs the thermal equalization of the equipment.

- Cleanability of the filling zone: ELOPAK Assessment of filler cleanability by CIP (Buttermilk Test).

- Steam sterilization of the filling equipment (filler): EHEDG Doc. 5 "A method for the assessment of in-line steam sterilisation" (Anon, 1993e). The test can only be used for small filling equipment.

- Sterilization of the filling zone by H_2O_2: BOSCH Test.

- Sterilization of packing material by H_2O_2: the method described by Cerny (1992) is recommended. The method requires also checking the aseptic condition of the internal surfaces of the bags.

- Bacteria tightness of the filling equipment (filler): EHEDG Doc. 7 "A method for the assessment of bacteria tightness of food-processing equipment" (Anon, 1993c). The test can only be used for small filling equipment.

- Air sterilization: EHEDG Doc 19 "A method for assessing the bacterial retention ability of hydrophobic membrane filters". Cartridge filters are normally certified by the supplier.

Chapter 2

Developed Methods, Tools and Procedures

AN alarming scenario appears from the wide bibliographic study shown in Chapter 1. The huge lack of knowledge and research on the *Hygienic Design* topic justifies this PhD thesis in which a whole approach for the assurance of the Food Hygiene will be developed.

2.1 A Check-list for the evaluation of hygienic characteristics of food equipments

A check-list for the evaluation of compliance of continuous thermal processing plants to regulations and standards has been developed. The check-list includes requisites coming from:

- Food And Drug Administration (FDA): 21 Code of Federal Regulations, part 110.40 and part 113.40 (g);
- European Committee for Standardization (CEN): EN1672-2: Food Processing Machinery Basic Concepts Hygiene Requirements.
- (ISO): ISO 14159: Safety of machinery Hygiene requirements for the design of machinery

- Codex Alimentarius Commission (CAC): Code of hygienic practice for aseptically processed and packaged low-acid foods CAC/RCP 40-1993, section VII.
- European Hygienic Engineering and Design Group (EHEDG): Documents 1-25.

The check-list is applicable to the most part of continuous thermal processing plants both for sterilization and pasteurization, apart from heat exchange modality and heat exchangers geometry and apart from treated foodstuffs. This is possible because all considered rules are horizontal and mainly lay down general principles, even if compliant solutions are proposed for a lot of details. The check-list is applicable to aseptic or hygienic equipments, and different solutions for aseptic or hygienic conditions are proposed for some components. In some cases several rules coming from different standards or regulations are equal and they are collected in the same box. In each box all references are written. When two rules coming from different references have different restrictive levels they are separated in different boxes. Then, at the end of checking operation, its possible to state which regulations the plant is compliant to, or not.

The check-list is subdivided into three sections respectively relating to

- Main Elements Design
- Piping Design
- Process

Moreover, each section is divided into thematic paragraphs. The three sections include:

- Heat exchangers, direct heating, holding tube, tanks, valves, packing machine.
- Materials, joints, seals, pumps, shaft and bearings, dead legs, framework and equipments.
- Cleaning, presterilization, start-up, monitoring and control.

2.1 A Check-list for the evaluation of hygienic characteristics of food equipments

The check list is equipped with a column for rule compliance indication and a column for notes. See Fig. 2.1 and Fig. 2.2 as examples. The complete check-list is available in the Technical Report of the TecalNetLaboratory REFERENCE

Requirememnts	Compliance Y/N	Notes
Joints		
1. It is strongly recommended that joints are avoided where possible; it's preferable the use of prefabricated bends with couplings or the use of welding. - *Doc.10 EHEDG:1*		
2. It is preferred to use permanent joints against dismountable ones to reduce hygienic risks by projections, protrusions, edges, recesses, metal to metal contact and crevices of sealing gaskets. - *Doc.13 EHEDG :3-4*		
3. Metal to metal joints (other than welding) must not be used in a hygienic plant. - *Doc.10 EHEDG:5*		
4. Permanent metal to metal product contact joints must be continuously welded and free of imperfections. Also welds on the non-product contact side must be continuous; they must be smooth enough to allow proper cleaning. - *Fig.1-2 Doc.13 EHEDG:4 ; Fig.B.4-5-6 EN 1672-2:1998: 13-14*		

Figure 2.1: A part of the section about piping

All requirements collected into the check-list can be subdivided into three categories. Some examples are described in Table 2.1.

- The most part of rules are quite easily and immediately checkable, by means of a simple plant inspection. For example, all rules which require the presence of an equipment or a device belong to this category.
- Other rules are general but require the examination of components design, such as for joints and seals; in such cases checking operations are facilitated by some suggested compliant solutions which can be compared with the checked one. In many cases standards also describe some non-compliant design solutions.

Table 2.1: Requirements subdivided into categories: examples

Category 1	- For the connection between horizontal pipes of different diameter an eccentric reducer must be used. *EHEDG Doc.10; EN 1672-2:1998* - A temperature recording device shall be installed in the product at the holding tube outlet, between the holding tube and the inlet of the cooler. *FDA 21 CFR 113.40 (g)*
Category 2	- Supports for piping or equipment must be fabricated and installed such that no water or soil can remain on the surface or within the supports. *EHEDG Doc.8* - If a connection or fastening must be made with screw in the product area, poor design of screws and nuts creating crevices, grooves or dead areas must be avoided. *Doc.13 EHEDG*
Category 3	- The distance between the temperature probe that controls flow diversion and the flow diversion valve must be large enough to ensure that insufficiently treated product will always be diverted when the temperature is too low. *EHEDG Doc.1* - The holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. *FDA 21 CFR 113.40 (g)*

Process	Parameter to be monitored	Automatically Measured?	Automatically Recorded? (frequency)	Control	Notes
Sterilization of the packing machine by means of steam	Temperature at the coldest point of the packing machine	Y/N	Y/N	.....	.....
	Maintenance time of the set temperature at the coldest point of the packing machine	Y/N	Y/N	.....	.....
Decontamination of wrapping material by means of chemicals	Dosed quantity of the sanitizing solution	Y/N	Y/N	.....	.....
	Concentration of the active chemical in the solution	Y/N	Y/N	.....	.....
	Temperature of the sanitizing solution	Y/N	Y/N	.....	.....
	Temperature of the sterile air	Y/N	Y/N	.....	.....
	Humidity of the sterile air	Y/N	Y/N	.....	.....
	Contact time	Y/N	Y/N	.....	.....
Decontamination of wrapping by means of UV radiation	Energy	Y/N	Y/N	.....	.....
	Time	Y/N	Y/N	.....	.....
Pack sealing and integrity	Sealing time, temperature, pressure and positioning	Y/N	Y/N	.....	.....
	Integrity testing	Y/N	Y/N	.....	.....
Maintenance of the aseptic conditions of the product	Steam barriers	Y/N	Y/N		.....
Maintenance of the aseptic conditions of the packing machine. (Air decontamination by means of filters)	Air decontamination: filters cartridges effectiveness (pressure drop)	Y/N	Y/N	.....	.....
	Air flow rate	Y/N	Y/N	.....	.....
	Steam barriers	Y/N	Y/N	.....	.....

Figure 2.2: A part of the section about process (monitoring and control of the packing machine)

- Some rules, strictly related to process effectiveness, are nott well implemented by standards and therefore the conformity evaluation of them must be carried out in a much more complex way.

Compliance to requirements collected in the third category can often be critical for Food Safety. Dedicated procedures are necessary for compliance evaluation to these requirements. In these cases checking operations often depend also on treated foodstuff properties, plant layout, sensors and equipments specifications. The procedures can require the use of laboratory tests and numerical simulators.

The main requirements belonging to this category are shown in Table 2.1. The RTD (Residence Time Distribution) has been widely studied by several authors (e.g. Ditchfield *et al.* (2006), Nadeau *et al.* (1996), Torres *et al.* (1998), Zhang *et al.* (1990)) and two reviews are also available in the literature (Ramaswamy *et al.* (1995), Torres & Oliveira (1998)) No references have been found about the "flow diversion issue" and so a comprehensive research has been performed on this topic (see §2.3).

2.2 A method for thermal diffusivity estimation of foods (Betta *et al.* (2009b))

2.2.1 Introduction

Correct knowledge of thermal properties is essential for efficient and economical design and control of all food processing operations involving heat transfer such as heating, cooling, freezing, thawing, and frying. Precise and reliable values of thermal properties of foods are necessary to simulate temperature during heat treatments, transport, storage and distribution. Conductive heat exchange is an almost simple physical phenomenon: the classic mathematical model of conduction is Fourier's equation (2.1):

$$\rho \cdot c_p \cdot \frac{\partial T}{\partial t} = k \cdot \nabla^2 T \tag{2.1}$$

Conductive heat exchange depends on three physical properties: density (ρ), thermal conductivity (k) and specific heat capacity (c_p). These properties can be included in a single parameter called *thermal diffusivity*, defined by the ratio:

$$\alpha = \frac{k}{\rho \cdot c_p} \tag{2.2}$$

Thermal diffusivity (α) physically relates the ability of a material to conduct heat to the ability to store it. Many methods for determining thermal conductivity and thermal diffusivity were developed. Apart from non-conventional techniques, such as *ac method* (Calzona *et al.*, 1993), *thermal wave cavity* (Balderas-Lopez & Mandelis, 2001), *thermal lens technique* (Bernal-Alvarado *et al.*, 2003), the majority of available methods were reviewed by Reidy & Rippen (1971) and Choi & Okos (1986). Singh (1992) reported three *models based on food composition* (Choi & Okos, 1986; Dickerson, 1969; Martens, 1980). Information on thermal properties of porous foods is presented in a review paper by Wallapapan *et al.* (1983). There are two categories of measurement for thermal conductivity and several experimental techniques have been developed for each category; in some techniques, while thermal conductivity is measured, thermal diffusivity is also obtained: a) *steady-state methods*, such as *hot plate method* (Lentz, 1961),

concentric cylinder and *concentric sphere method*; and b) *transient state methods* such as *Fitch method* (Fitch, 1935) and *line heat source method* (Balaban & Pigott, 1992; Choi & Okos, 1983; Kumbhar *et al.*, 1981; Kurozawa *et al.*, 2005; Nagasaka & Nagashima, 1981; Nix *et al.*, 1967; Rahman & Potluri, 1991; Sweat & Haugh, 1974); *Thermistor probe method* has been used by Valvano *et al.* (1985), Kravets (1988), van Gelder & Diehl (1996) for the determination of thermal properties respectively of biomaterials, milk and tomato products. A reference method was proposed by Ball (Ball, 1923; Ball & Olson, 1957), who developed what is known as the *"formula" method*. It is based on the fact that when heat transfer coefficient of the surrounding medium approaches infinity, the logarithm of the rate of change of temperature becomes constant in time and space, and is proportional to the thermal diffusivity of the sample. As noted by Mohamed (2003), one of the main serious limitations of this method is that it does not handle the case of variable treatment temperature. Sweat (1986) recommended the calculation of thermal diffusivity by inserting experimental thermal conductivity, specific heat and density values in the thermal diffusivity equation (2.2). If it is difficult or even impossible to measure directly one or more components in Eq. 2.2, or if the measured values are not sufficiently reliable and precise[1], thermal diffusivity can be determined from analytical or numerical solutions of Fourier's equation (2.1) which fit well the experimental data. In this case thermal diffusivity is estimated as the value of the parameter α which maximizes the quality of approximation of temperature changes in the sample during treatments; a least-square algorithm is normally applied to determine the optimal α value. Most recent studies (Carbonera *et al.*, 2004) view numerical simulations of Fourier's equation (2.1) as the best way to obtain thermal diffusivity value from experimental temperature data. As noted by Markowski *et al.* (2004), in this case the physical meaning of the thermal diffusivity is different than that based on Eq.2.2, and thermal diffusivity determined by that method is usually referred to as *effective* or *apparent* thermal diffusivity. Many Authors developed several methods, based on *Least Square Estimation* (LSE), to investigate the thermal properties of foods. Garrote *et al.* (2000) calculated the thermal diffusivity of potatoes by using an explicit numerical solution. Carciofi *et al.* (2002) determined the

[1] e.g. for multi-phase or non homogeneous systems

thermal diffusivity of mortadella, cooked in a steam oven, by using actual cooking process data and a least-squared algorithm based on an analytical solution of Fourier's equation (2.1). Zhang *et al.* (2002) used a finite element method (FEM) for bi-dimensional heat conduction with convective boundary conditions in the precooking and cooling of skipjack tuna (*Katsuwonas pelanis*). Mohamed (2003) exploited a computer solution to calculate the thermal diffusivity value by using a tri-diagonal matrix and an alternative direction implicit finite difference method; experimental validation was carried out by using canned tomato sauce and 8% bentonite suspension. Zorrilla & Singh (2003) used a finite difference method with explicit solution mode to model the heat transfer in double-sided cooking of meat patties considering two-dimensional geometry and radial shrinkage. Carbonera *et al.* (2004) experimentally determined the thermal diffusivity of a commercial tomato paste by means of both the *"formula" method* and an optimisation method based on squared error minimisation. Markowski *et al.* (2004) determined the thermal diffusivity of Lyoner-type sausages during water bath cooking and cooling, using both a numerical and an analytical solution of Fourier's heat transfer equation (2.1). Kubasek *et al.* (2006) found out thermal diffusivity of olive oil using a numerical solution based on finite elements. Huang (2007) used a computer simulation program based on finite difference to estimate the apparent thermal diffusivity of beef frankfurters. Mariani *et al.* (2008) determined thermal diffusivity of banana using a finite difference method coupled to an optimization technique of Differential Evolution used in inverse method.

The main goal of the present study is to develop and experimentally validate a computer code based on *least square* optimization of a *finite difference* solution of *Fourier's equation* in order to adequately and quickly calculate thermal diffusivity of foods by using heat penetration curves. The second objective is to estimate thermal diffusivity of some food products intended for sterilization or pasteurization for which no references were found.

2.2.2 Modelling

2.2.2.1 Mathematical model

The assumptions considered in the simulation were as follows: two dimensional cylindrical sample, homogeneous and isotropic sample, constant thermophysical properties, negligible heat generation inside the sample, infinite heat transfer coefficient at the surface, absence of convective fluxes inside the sample. For a

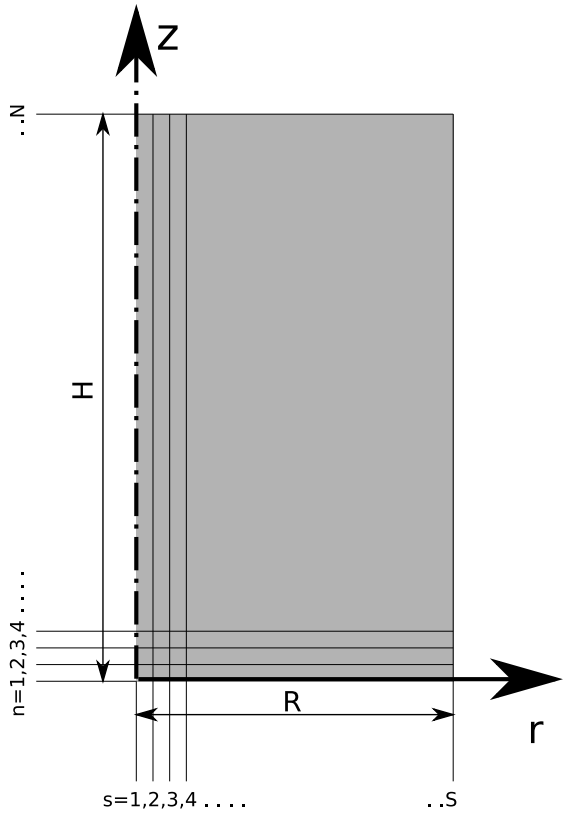

Figure 2.3: Illustration of geometry and mesh

2-D (r,z) axial-symmetric isotropic medium (Fig. 2.3), the Eq. 2.1 can be written in cylindrical coordinates:

$$\frac{1}{\alpha} \cdot \frac{\partial T}{\partial t} = \frac{\partial^2 T}{\partial r^2} + \frac{1}{r} \cdot \frac{\partial T}{\partial r} + \frac{\partial^2 T}{\partial z^2} \tag{2.3}$$

The following boundary conditions were used:

$$t = 0 \longrightarrow T(r, z, 0) = T_i \tag{2.4}$$

$$r = 0 \longrightarrow \frac{\partial T(0,z,t)}{\partial r} = 0 \tag{2.5}$$

$$r = R \longrightarrow T(R,z,t) = T_b(t) \tag{2.6}$$

$$z = 0 \longrightarrow T(r,0,t) = T_b(t) \tag{2.7}$$

$$z = H \longrightarrow T(r,H,t) = T_b(t) \tag{2.8}$$

The solution of the above governing equations is difficult to obtain using analytical methods. Therefore, approximate methods of solution are used to solve them.

2.2.2.2 Finite difference solution

The method used in the present study is the finite difference approximation. In the finite-difference approach, the continuous problem domain is discretized, so that the dependent variables are considered to exist only at discrete points. Derivatives are approximated by differences, resulting in an algebraic representation of the partial differential equation (PDE). Thus a problem involving calculus is transformed into an algebraic problem. Many finite-difference algorithms can be used to solve this equation such as *Simple Explicit*, *Richardson's Method* (Richardson, 1910), *Simple Implicit* (Laasonen, 1949), *Cranck-Nicolson Method* (Cranck & Nicolson, 1947), *Combined Method* (Richtmyer & Morton, 1997) and *DuFort-Frenkel Method* (DuFort & Frankel, 1947). The simplest is the *Explicit One-Step Method*; an explicit scheme is one for which only one unknown variable appears in the difference equation in a manner that permits evaluation in terms of known quantities. By means of this method, as described by Tannehill, Anderson & Pletcher (1997), the solution of the generic reaction-diffusion parabolic PDE in a 1-D (x)

$$\frac{\partial u}{\partial t} = \alpha \cdot \frac{\partial^2 u}{\partial x^2} \tag{2.9}$$

is:

$$\frac{u_j^{p+1} - u_j^p}{\Delta t} = \alpha \cdot \frac{u_{j+1}^p - 2u_j^p + u_{j-1}^p}{(\Delta x)^2} \tag{2.10}$$

This is first-order accurate with truncation error (T.E.) of $O[\Delta t, (\Delta x)^2]$ and this scheme is stable whenever

$$0 \leq r \leq \frac{1}{2} \tag{2.11}$$

where

$$r = \frac{\alpha \Delta t}{(\Delta x)^2} \tag{2.12}$$

Numerical grid of an axi-symmetric cylindrical object is shown in Fig. 2.3. The index s represents the mesh points in the r-direction while index n represents the mesh points in the z-direction. The explicit method allows to calculate temperature at coordinates (s, n) at instant $(p+1)$ if the temperature distribution at the previous time (p) is known. In the present study the *central-difference form* has been applied; so temperature derivative at position (s, n) depends on temperature at coordinates $(s, n-1)$, $(s, n+1)$, $(s-1, n)$, $(s+1, n)$. The solution[1] of the governing equations is as follows:

$$\begin{aligned} T_{s,n}^{p+1} = {} & \frac{\alpha \cdot \Delta t}{(\Delta r)^2} \cdot (T_{s+1,n}^{p} + T_{s-1,n}^{p}) + \\ & + \frac{\alpha \cdot \Delta t}{2r \cdot \Delta r} \cdot (T_{s+1,n}^{p} - T_{s-1,n}^{p}) + \\ & + \frac{\alpha \cdot \Delta t}{(\Delta z)^2} \cdot (T_{s,n+1}^{p} + T_{s,n-1}^{p}) + \\ & + T_{s,n}^{p} \cdot \left[1 - \frac{2\alpha \cdot \Delta t}{(\Delta r)^2} - \frac{2\alpha \cdot \Delta t}{(\Delta z)^2}\right] \end{aligned} \tag{2.13}$$

On the axis (boundary condition Eq. 2.5), as shown by Mitchell & Pearce (1963), the term of Eq. 2.3 $\frac{1}{r}\frac{\partial T}{\partial r}$ becomes $\frac{\partial^2 T}{\partial r^2}$. So the explicit finite difference solution at $r = 0$ is

$$\begin{aligned} T_{1,n}^{p+1} = {} & \frac{4\alpha \cdot \Delta t}{(\Delta r)^2} \cdot T_{2,n}^{p} + \\ & + \frac{2\alpha \cdot \Delta t}{(\Delta z)^2} \cdot (T_{1,n+1}^{p} + T_{1,n-1}^{p}) + \\ & + T_{1,n}^{p} \cdot \left[1 - \frac{4\alpha \cdot \Delta t}{(\Delta r)^2} - \frac{2\alpha \cdot \Delta t}{(\Delta z)^2}\right] \end{aligned} \tag{2.14}$$

For the scheme in Eq. 2.13 and Eq. 2.14, the stability condition (Eq. 2.11) becomes (Anderson, Sun, Erdogdu & Singh, 2004):

$$\frac{\alpha \cdot \Delta t}{(\Delta r)^2} + \frac{\alpha \cdot \Delta t}{(\Delta z)^2} \leq \frac{1}{2} \tag{2.15}$$

[1] for $s \neq 1, s \neq S, n \neq 1, n \neq N$

hence the sum

$$\frac{\Delta t}{(\Delta r)^2} + \frac{\Delta t}{(\Delta z)^2} \tag{2.16}$$

has to be maintained below a constant. A high number of time-intervals generates the same number of matrices and hence causes a high computational time. So, in order to achieve scheme stability and an acceptable computational time, a smaller number of space-nodes needs to be used; On the other hand, a smaller number of space-nodes causes a big truncation error. Then these parameters $(\Delta t, \Delta r, \Delta z)$ have to be configured step by step, taking into account computer capability.

2.2.2.3 Non linear least squares (N.L.L.S.) method

Generally, least squares is a mathematical optimisation technique which, when given a series of measured data, attempts to find a function which closely approximates the data (a "best fit"). It attempts to minimise the sum of the squares of the ordinate differences (called residuals) between points generated by the function and corresponding points in the data. N.L.L.S. method requires the experimental data and the data calculated with a numerical solver. The fundamental relation is represented by the error function ψ:

$$\psi(\alpha) = \sum_{k=0}^{Q} (Ts_k - Te_k)^2 \tag{2.17}$$

where Ts_k is the simulated temperature at time $(k \cdot \Delta t)$, Te_k is the experimental temperature at time $(k \cdot \Delta t)$ and Q is the time-intervals number.

2.2.2.4 Software development

The *Matlab*® programming environment was chosen for software development and an appropriate interface (Fig. 2.4) was created. This interface allows users to define all parameters needed for thermal diffusivity calculation. Firstly, users have to upload the experimental curves, both the treatment (boundary temperature) and the sample centre temperature, with the aid of two push-buttons. Another two push-buttons allow plotting of the curves, in order to check data and identify any wrong point due to interferences during experimental data capture. The second step is mesh definition: space-nodes number, both for radius

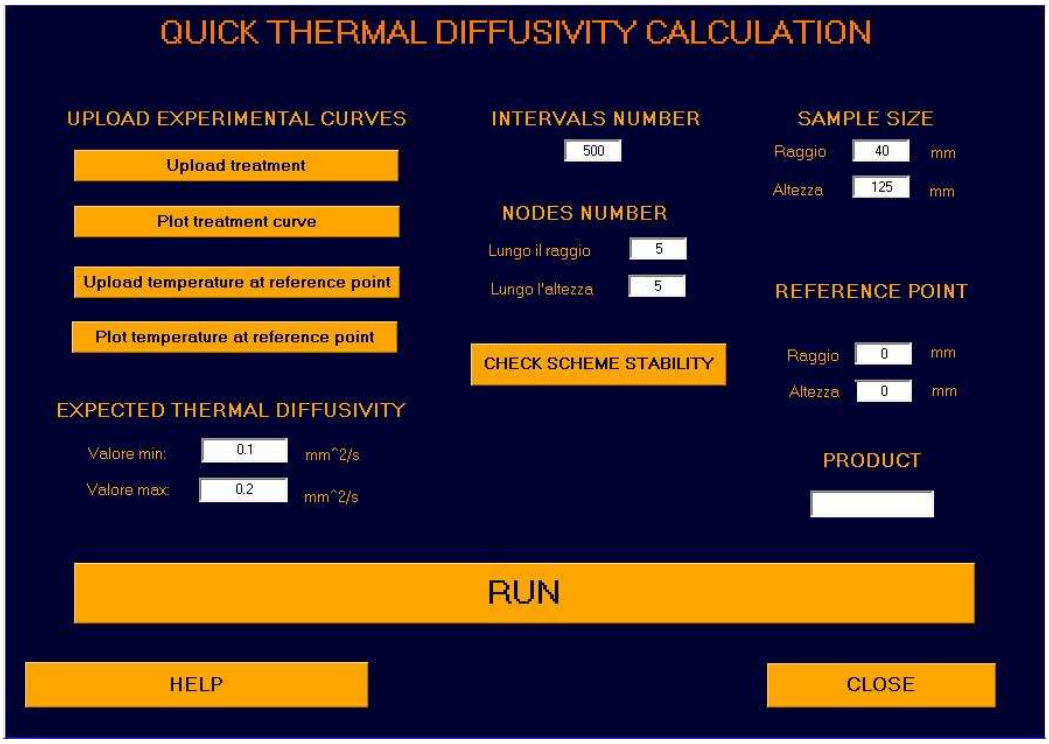

Figure 2.4: Simulator graphical interface

and for height, and time-intervals number have to be entered. A constrained minimisation algorithm (*fmincon Matlab®* function) has been used in the software in order to decrease computational time. So it is necessary to define the upper and the lower limit of expected thermal diffusivity. The upper value will be automatically evaluated in Eq. 2.15. Stability condition can also be checked by pushing the appropriate button. If the condition is respected, the schemes in Eq. 2.13 and 2.14 are stable and it is possible to run the solver by pushing the button "RUN" . The main output of the calculator is the α value which allows the best fit of experimental data. An output graph (Fig. 2.5) with treatment curve, experimental curve and best simulated curve is automatically opened at each simulation. All main input parameters are printed at the top of the graph and the optimal thermal diffusivity value is printed in the graph legend; moreover all calculated variables and parameters are reported in a data file. By pushing the "close" button it is possible to enter a switch interface which allows to open the

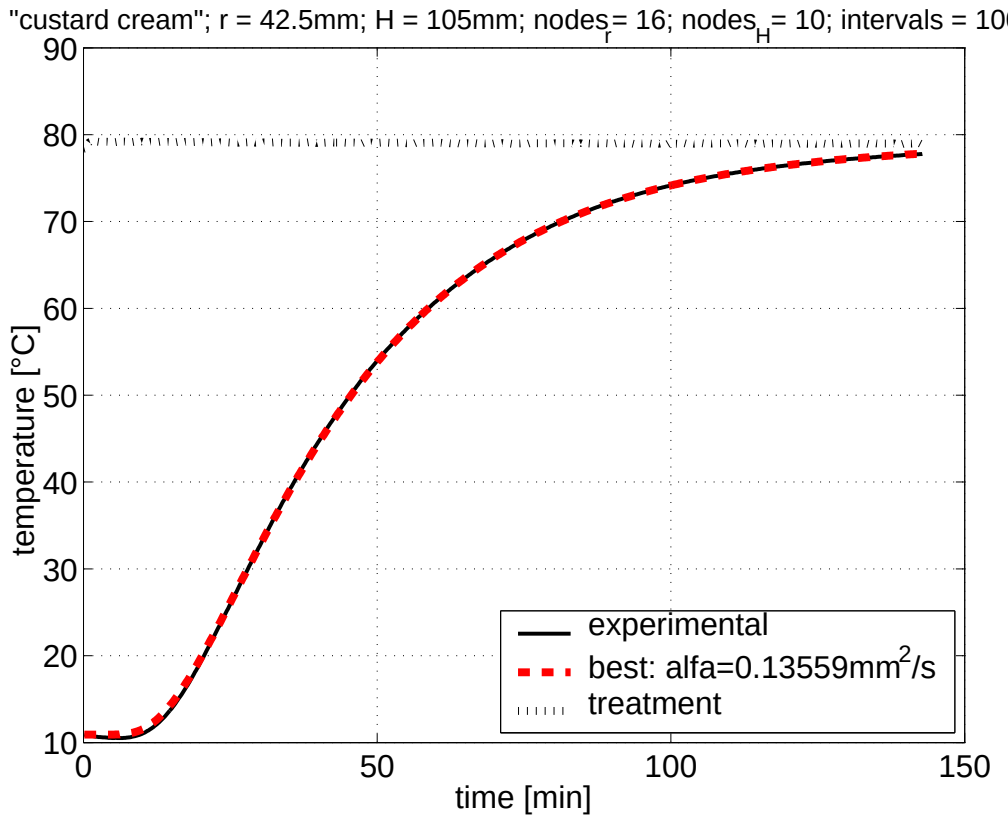

Figure 2.5: Output graphical interface

"twin" software for heat exchange simulation. The software returns temperature history at every node, and hence it allows simulating sterilization and pasteurization processes; it also calculates sterilization value F_0 (at the coldest point) and the cooking value C_0 (at the hottest point) at each simulation.

2.2.3 Experimental

2.2.3.1 Materials and methods

The first tested foodstuff was a commercial super-hot-break *tomato puree*, packed in aseptic bricks and characterized in Table 2.2.

A tin-plated can was filled with the product (Fig. 2.6a). The container was subsequently dipped into a $80°C$ preheated thermostatic bath (Julabo Cir-

Table 2.2: Tested commercial products composition

	Tomato puree	Tomato sauce	Truffle sauce
Water %	94,5	90,4	53,06
Proteins %	1,3	1,8	4,2
Carbohydrates %	4	7,5	0,49
Fats %	0,2	0,3	30,35
	Custard cream	Olive pate	Apricot jam
Water %	72,7	65,2	49,38
Proteins %	3,2	1,5	0,6
Carbohydrates %	20	1	50
Fats %	4,1	32,3	0,02
	Cheesy sauce	Mushrooms sauce	Bacon&Egg sauce
Water %	88,9	89,3	86,7
Proteins %	2,8	1,4	3,3
Carbohydrates %	4,0	1,2	1,8
Fats %	4,3	8,1	8,2

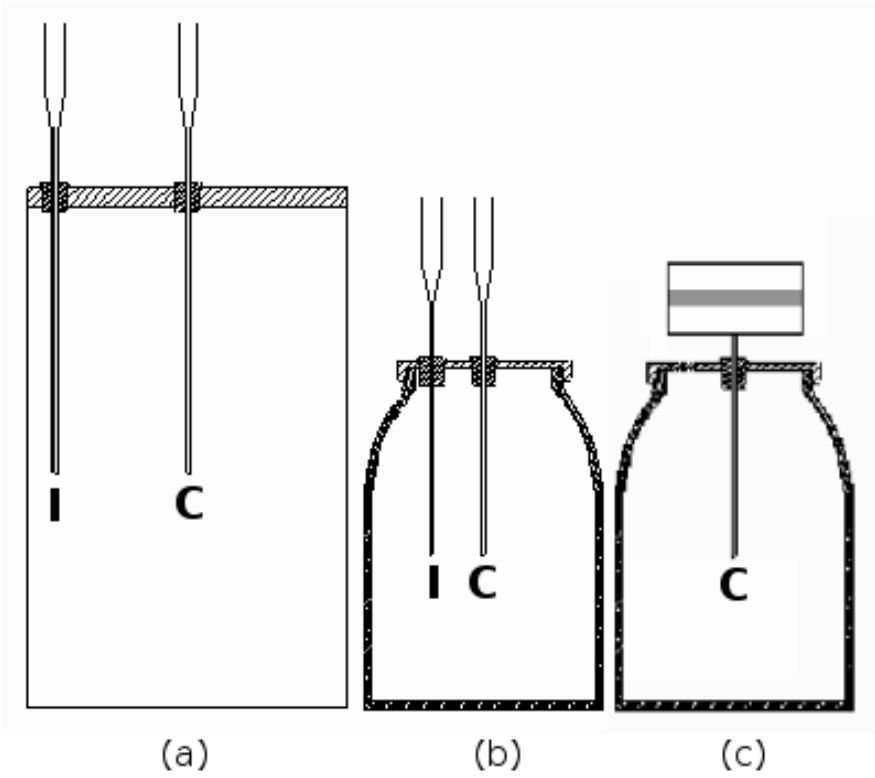

Figure 2.6: (a) Tin-plated can ($\phi 80 \times 125[mm]$) and (b) glass jar ($\phi 67 \times 86[mm]$) equipped for thermocouples data capture. (c) glass jar ($\phi 67 \times 86[mm]$) equipped with data-logger (Not to scale)

culators VC, JulaboItalia, Milano, Italy) filled with water. Temperature was measured in the geometric centre of the samples *(probe C)*, at $r = 34mm$ in the median plane *(probe I)*, and in the surroundings *(probe B)* during the whole treatment. Heat penetration curves were measured using wire thermocouples K type (Ni/Cr-Ni/Al) (HF/D-30-KK) connected with a multimeter/data acquisition system (Keithley Instruments Inc., Cleveland, Ohio, U.S.). The second tested product was a pregelatinized mixture of *starch* ($20\% w/w$) (Cerestar s.p.a. Ferrara, Italy) and water. The mixture, poured in a glass jar (Fig. 2.6b), was heated for 60 minutes at $80°C$ and then cooled inside the container at room temperature for 24 hours in order to obtain the whole gelatinization. The container was subsequently dipped in the preheated thermostatic bath ($80°C$) for

the treatment. In this case the *probe I* was at $r = 27mm$ in the median plane. The data capture period was $10s$ for all tests. The mesh parameters (Q, N, S) were differently fixed for each simulation in order obtain consequent values of $\Delta t, \Delta r$ and Δz equal to about $7s, 3mm$ and $10mm$, corresponding to a maximum computational time of $30s$ (using a Intel Pentium M Processor 740 with RAM 512MB). Similar values of Δr and Δz were used by Carciofi *et al.* (2002), whereas they fixed Δt equal to $1s$, but we did not find out any considerable benefit by increasing Q above 1000 for the longest test.

Thermal diffusivity of tomato puree and starch-water mixture was calculated by means of four methods in order to validate the developed software. Results obtained by the proposed method were compared to those found out by means of a composition-based method[1] (Choi & Okos, 1986), the "formula" method[2] (Ball, 1923) and the "SIMULA+NLLS" method[3] (Falcone *et al.*, 1999; Rinaldi, 2005). Eight replicates have been used for every test. One-way-analysis of variance (ANOVA) and Least Significant Difference test (LSD) at a 95% confidence level ($p \leq 0,05$) were used to identify differences among groups (Software SPSS 12.0). Thermal diffusivity of some sterilized and pasteurized commercial products have been estimated by means of the proposed method after the validation described above. *Olive pate* and *apricot jam* were treated in their own glass jar according to the procedure used for tomato puree. Commercial *cheesy sauce*, *mushrooms sauce*, *bacon&egg sauce* and *confectioner's custard* were poured in the developed measuring cell described in §2.2.3.2 and treated in the thermostatic bath at $80°C$ and $90°C$. Commercial *tomato sauce* and *truffle sauce* were poured in a glass jar equipped with a data-logger Pt1000 (Ebro Electronic GmbH & Co KG, Ingolstadt, Germany) (see Fig. 2.6c) and treated in a small steam retort (De Lama S.p.A., Pavia, Italy) at $119°C$. Eight replicates have been used for every tested food.

[1] Algebraic equations allow calculating thermal diffusivity if composition and temperature of the food are known

[2] See the brief description in §2.2.1

[3] This method couples a Taylor's series algorithm named "SIMULA" for the solution of Fourier's equation with the Non Linear Least Square method

2.2.3.2 Associated error and measuring cell development

As reported by Larkin & Steffe (1983), thermal diffusivity calculated from heat penetration data is mainly dependent on errors associated with temperature measurement and thermocouple probes location. The error for a k-type (HK/D-30-KK) thermocouple is the greater of the following values: $\pm 1.5°C$ or $\pm 0.4\%$ of the measurement. So the thermocouple error is $\pm 1.5°C$ between $-40°C$ and $375°C$. In this range, the measurement system error is about $0.5°C$, mainly due to the CJC (Cold Junction Compensation) accuracy (Anon, 2007a; Inc., 1995). So the total error in thermocouple measurement is about $2.0°C$. Several simulations have been performed in order to evaluate the error on thermal diffusivity due to uncertainty in temperature measurement: the most unfavourable calculation of the error provided us a value of the order of 7% ($max(\Delta\alpha/\alpha) = 0.07$). Similar results were published by Bairi *et al.* (2007). The error on thermal diffusivity measurement due to temperature measurement error could be decreased by using thermocouples type T ($\pm 0.5°C$ in the range $0°C - 125°C$) and by using an external CJC sensor with high-accuracy capability (Anon, 2007a).
Besides, several simulations have been carried out in order to assess the error on thermal diffusivity measurement due to the wrong positioning of probes. For $15mm$ thermocouples distance, a $1mm$ positioning error (6.7%), simulated by varying in the software the r-coordinate of the data capture point, generates a 13.6% thermal diffusivity error while a $2mm$ positioning error (13.4%) generates a 28.2% thermal diffusivity error. Similar results have been reported by Benigni & Rogez (1997). The use of an appropriate measuring cell is therefore necessary. The custom made measuring cell, shown in Fig. 2.7, is similar to the apparatus used by Dickerson (1965). The stainless steel apparatus is designed to be filled in the overturned position. Thus, the temperature probes are connected to a fixed part and not to the cover such as for glass jar caps, and they are not further moved except for maintenance operations. This solution allows gluing the thermocouple junction of the *probe I* to the internal surface of the cell before filling. The uncertainty in probe location is so reduced to $\pm 0,5mm$ $(1,2\%)$ corresponding to a thermal diffusivity error $< 3\%$. The cell should be as symmetrical as possible: the influence of the flange and the cover has been evaluated by means of

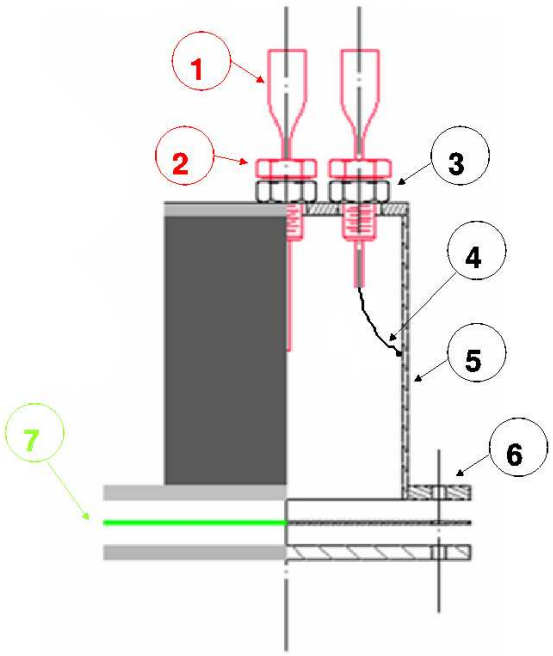

Figure 2.7: Custom made measuring cell ($\phi 85 \times 105[mm]$): (1) Glass support. (2) Polymeric holed screw. (3) Welded stainless steel nut. (4) Wire thermocouple K type. (5) Stainless steel tube. (6) Stainless steel flange. (7) Polymeric gasket

ComsolMultiphysics® simulations. For a metallic container the asymmetry due to the flange and the cover is negligible. Rigid supports must be used to introduce thermocouples because of the flexibility of the thermocouples cables, and these supports should be made of a thermal insulating material and must be as thin as possible in order to avoid any perturbation on heat flux. Three possible solutions have been compared with the aid of the software ComsolMultiphysics®. Firstly we tryed to use Teflon, but this material is not sufficiently rigid. So a solution with coupled Teflon and steel was tested: as shown in Fig. 2.8(c), the temperature field is deformed and temperature at the coldest point seriously increases. Then steel supports have been tested in order to evaluate the suitability of very thin conductive supports: as shown in Fig. 2.8(b) also this solution is unsuitable. The best solution was thin glass support (Fig. 2.8(a)) and so it was implemented.

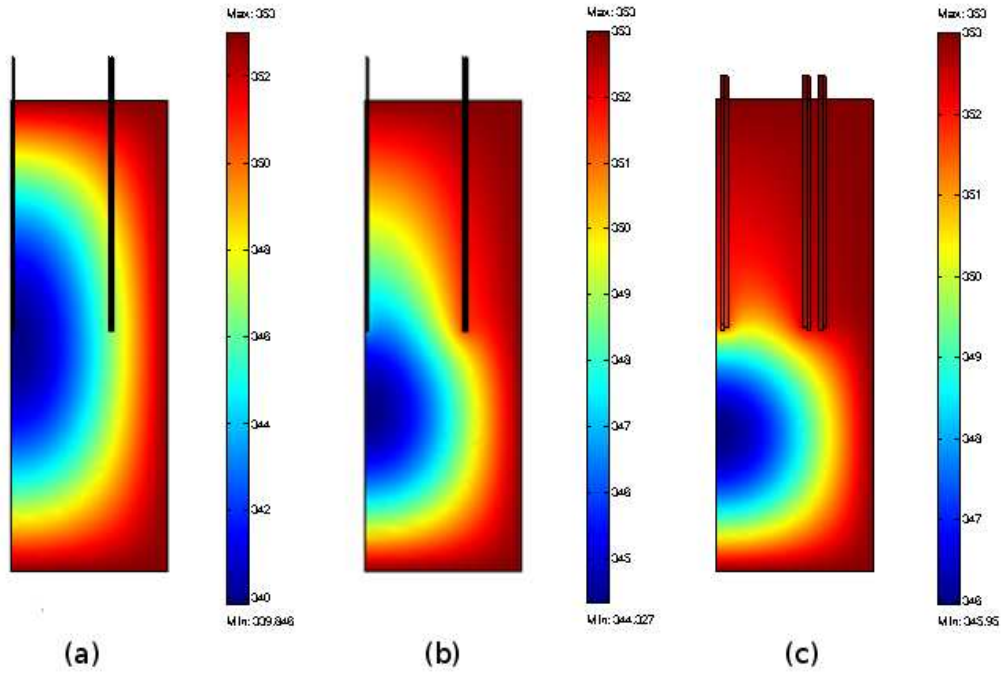

Figure 2.8: Perturbation due to different supports: (a) glass supports ($\phi 1 \times 0,1 thickness[mm]$) ($T_{min} = 339,85K$); (b) steel supports ($\phi 1 \times 0,1 th.[mm]$) ($T_{min} = 344,33K$); (c) teflon(internal)/steel supports (teflon:($\phi 1 \times 0,5 th.[mm]$); steel:($\phi 2 \times 0,2 th.[mm]$)) ($T_{min} = 345,95K$)

2.2.4 Results

Thermal diffusivity values obtained by the proposed method allowed an effective simulation of temperature for every tested product (Fig. 2.9 and Fig. 2.10). Results from the developed simulator were very similar to values obtained by Choi & Okos (1986) method for the main part of tested products.

Tests performed on tomato puree and starch-water mixture confirmed that the "formula" method can only be used for constant temperature treatments. Consequently it was not possible to estimate thermal diffusivity of liquid packed products by means of this method, but overall values (including container component) were only obtained. The statistical analysis showed non significant difference be-

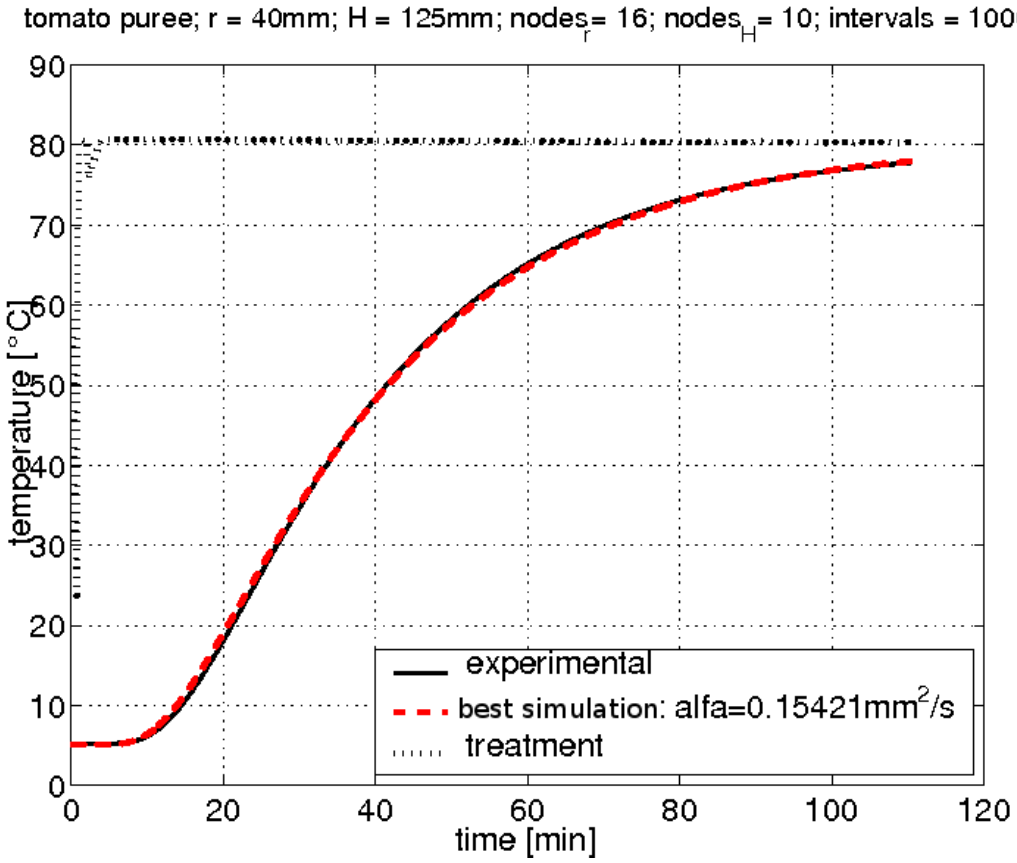

Figure 2.9: Thermal diffusivity obtained by probes C and probe B

tween values found out by means of the proposed method and those obtained by the other used methods (Ball, 1923), (Falcone *et al.*, 1999; Rinaldi, 2005); groups are shown by superscripts in Table 2.3 and Table 2.4. Thermal diffusivity values obtained by means of the proposed method for the other tested products (Table 2.2) are shown in Table 2.5; the used container, probes and the maximum temperature of respective treatments are also reported in the table. The proposed method also allowed to calculate thermal diffusivity via heat penetration curves obtained by variable temperature treatments; two main consequences occurred:

a) It was possible to estimate thermal diffusivity of liquid packed products by accounting as treatment the data captured by an internal probe (probe I). Values obtained in this way (Fig. 2.10) were lower than overall values (Fig.

Table 2.3: Tomato puree thermal diffusivity $[mm^2/s]$. See Fig. 2.6 for probes tags explanation. $^{a-b}$ same letters do not significantly differ ($n = 8$, $p \leq 0,05$)

Data capture points	bath(B)-centre(C)	internal(I)-centre(C)
Composition method (Choi & Okos, 1986)	$- - - - - - - -$	$0,149$
Formula method (Ball, 1923)	$0,155^a \pm 0,005$	$- - - - - - - -$
proposed method	$0,154^a \pm 0,004$	$0,142^b \pm 0,003$
SIMULA+LSE (Falcone *et al.*, 1999; Rinaldi, 2005)	$0,158^a \pm 0,005$	$0,149^b \pm 0,005$

Table 2.4: Starch-water mixture thermal diffusivity $[mm^2/s]$. See Fig. 2.6 for probes tags explanation. $^{a-b}$ same letters do not significantly differ ($n = 8$, $p \leq 0,05$)

Data capture points	bath(B)-centre(C)	internal(I)-centre(C)
Composition method (Choi & Okos, 1986)	$- - - - - - - -$	$0,142$
Formula method (Ball, 1923)	$0,159^a \pm 0,003$	$- - - - - - - -$
proposed method	$0,160^a \pm 0,006$	$0,139^b \pm 0,004$
SIMULA+LSE (Falcone *et al.*, 1999; Rinaldi, 2005)	$0,158^a \pm 0,005$	$0,138^b \pm 0,005$

Table 2.5: Other tested product: thermal diffusivity obtained by the proposed method

Food	Probes	Container	$T_{max}[°C]$	$\alpha[mm^2/s]$
Apricot jam	I-C	Glass jar	80	$0,122 \pm 0,005$
Bacon&Egg sauce	I(surface)-C	Measuring cell	90	$0,157 \pm 0,003$
Cheesy sauce	I(surface)-C	Measuring cell	90	$0,146 \pm 0,002$
Confectioner's custard	I(surface)-C	Measuring cell	80	$0,134 \pm 0,003$
Mushrooms sauce	I(surface)-C	Measuring cell	90	$0,153 \pm 0,001$
Olive pate	I-C	Glass jar	80	$0,116 \pm 0,002$
Tomato sauce	B-C	Glass jar	119	$0,210 \pm 0,002$
Truffle sauce	B-C	Glass jar	119	$0,139 \pm 0,005$

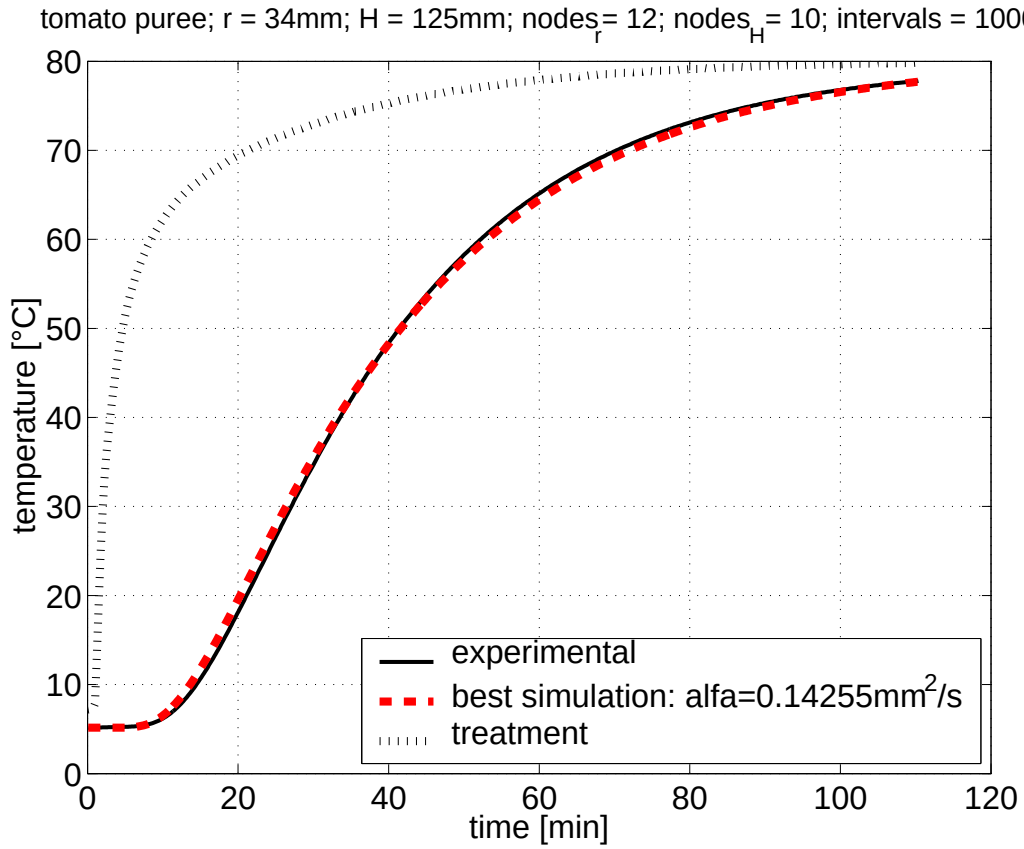

Figure 2.10: Thermal diffusivity obtained by probes C and probe I

2.9) and this was due to the higher thermal conductivity of metallic and glass container.

b) The case of variable retort temperature was also correctly studied. The variable treatment temperature benefits include improved nutrient and flavor retention, reduced heat damage, lower energy costs and shorter process time (Durance *et al.*, 1997). A test performed on truffle sauce in a vertical retort is shown in Fig. 2.11.

For foods treated in the steam retort (truffle sauce and tomato sauce) only overall values of thermal diffusivity (including container component) were obtained since it was possible to insert only one probe into the sample because of data-logger size.

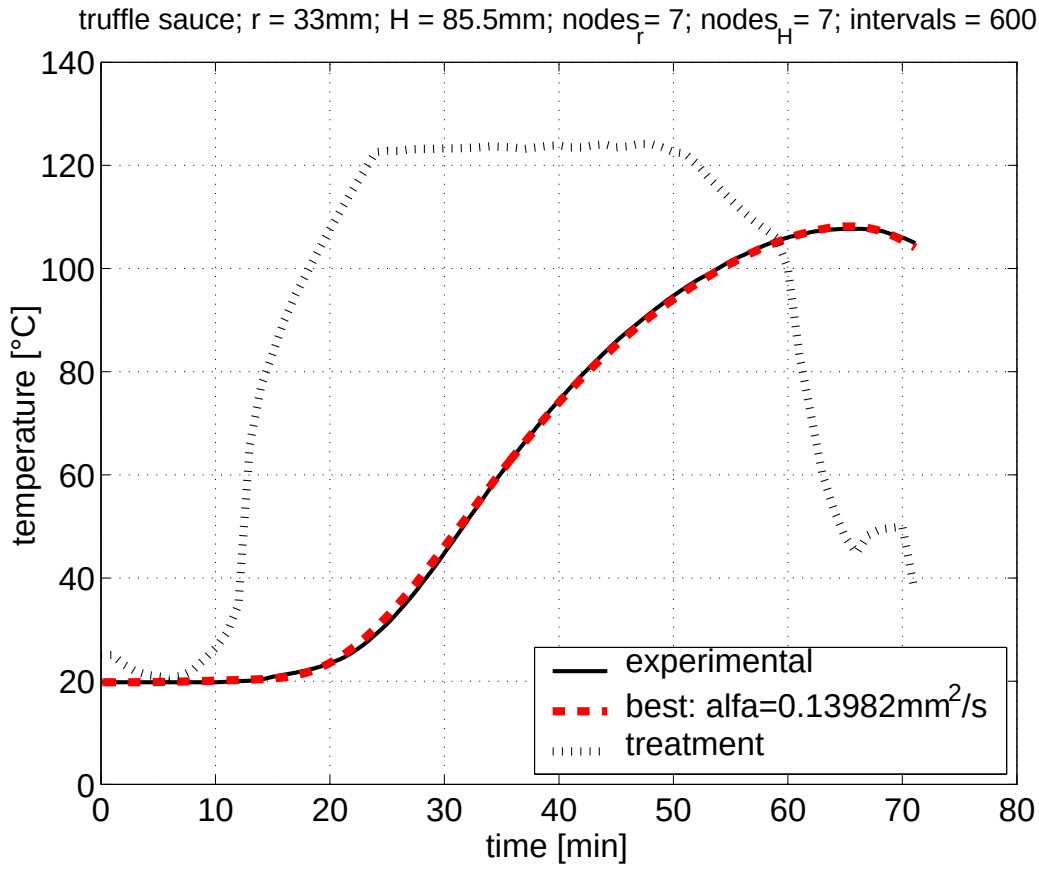

Figure 2.11: Variable treatment temperature test in vertical retort

2.2.5 Conclusions

A reliable, quick and userfriendly method for thermal diffusivity estimation has been developed. The method has been experimentally validated and its results have been compared with those obtained by three other methods. Several foods, such as tomato puree, tomato sauce, truffle sauce, cheesy sauce, mushroom sauce, bacon&egg sauce, olive pate, confectioner's custard and apricot jam were tested and in every case the method proved to be effective. The developed software also allowed estimation of thermal diffusivity via heat penetration curves obtained by variable boundary temperature. So it was possible to exclude the contribution of the container from the estimation of thermal diffusivity of liquid packed foods, and the case of variable retort temperature was also correctly studied. An appropriate

measuring cell has been designed and made in order to decrease the systematic error in probe positioning. In conclusion the proposed method turns out to be a useful tool for scientific design of several processes, such as sterilization and pasteurization, and for correct control of transport, storage and distribution of foods.

2.3 Correct design and setting of flow diversion devices (Betta *et al.* (2009a))

2.3.1 Flow diversion: what Regulations and Guidelines say

Flow diversion is a matter of concern for Food Hygiene in Aseptic Processing and Packaging Systems. The basic layout of an Aseptic System compliant to Codex Alimentarius (CodexAlimentarius (1993)) and to the Food and Drug Administration (FDA (1998)) is shown in Fig. 2.12. The Codex Alimentarius Commission (CodexAlimentarius (1993)) asserts that the flow diversion valve should be installed in the product piping located before the product filler or aseptic surge tank. The title 21 of Code of Federal Regulation (FDA (1998)) states that it should be located between the product cooler and the product filler or aseptic surge tank. If the layout shown in Fig. 2.12 is used, when product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow should be diverted away from the filler or aseptic surge by means of the flow diversion system. The product holding tube and any further system portion affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank (FDA (1998)). In order to avoid re-cleaning and re-sterilization of the system a different layout is sometimes used. As shown in Fig. 2.13, the processing plant is equipped with another flow diversion system, called short flow diversion device. The short flow diversion valve is located between the heating section and the holding section and ensures that product subjected to a temperature below the temperature specified in the scheduled process cannot get into the holding tube and the cooling section.

The EHEDG Doc.1 (Lelieveld *et al.* (1992)) proposes a similar layout in which the flow diversion valve is located after the holding tube. The authors suggest this solution for pasteurization. The EHEDG Doc.6 (Hasting *et al.* (1993)) asserts that diversion from the holding tube may be practical in a limited number of sterilization applications. In these cases a diversion cooler and back pressure control will be required to maintain stability and suppress boiling in the holding tube. *Short flow diversion systems* allow the resumption of production as soon as the product temperature return to conditions specified in the scheduled process, but the manufacturer should guarantee that measures have been taken to ensure that none of insufficiently treated product can contaminate the correctly treated product; this kind of layout requires additional effort in research and validation and also a more complex equipment design in order to ensure process effectiveness.

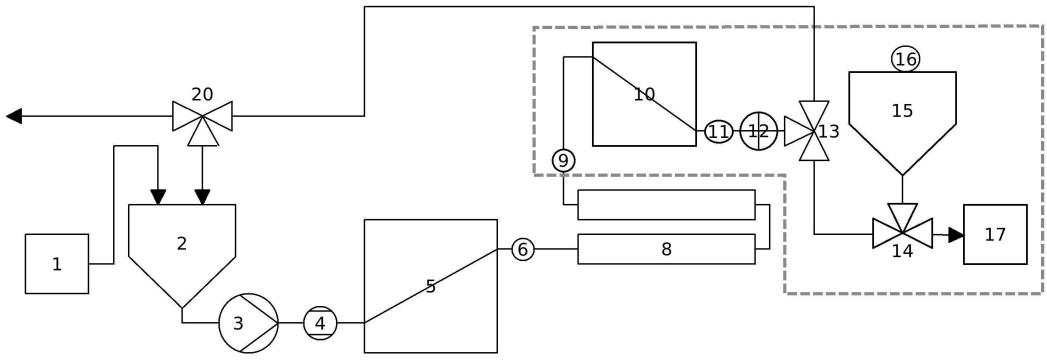

Figure 2.12: Aseptic System compliant to FDA and Codex Alimentarius. See Table 2.6 for tags explanation. Dashed grey area = Aseptic area

2.3.2 Correct choice of temperature probes

The heating section is normally controlled by a traditional PID (Proportional-Integral-Derivative) feed-back control system. Feedback controllers are preferred because they are extensively used and are relatively cheap, but they are actually effective only for quasi-steady state conditions. For serious transient conditions (for example due to changes in temperature or flow rate of product or service

Table 2.6: Tags explanation for Fig. 2.13

1	Unprocessed product preparation
2	Feeding tank
3	Pump
4	Flow-meter
5	Heating
6	Temperature probe for heating control
L	Safety length
7	Flow diversion valve
8	Holding tubes
9	Temperature probe for F determination
10	Aseptic cooling
11	Temperature probe for cooling control
12	Positive aseptic extra-pump
13	Flow diversion aseptic valve
14	Valve
15	Aseptic surge tank
16	Sterile air overpressure monitoring
17	Aseptic filling and packaging
18	Diversion Cooler
19	Back-pressure control device
20	Valve

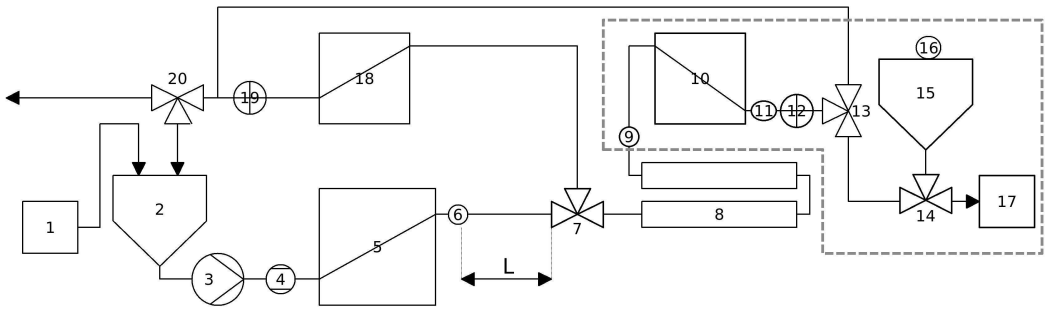

Figure 2.13: Aseptic System equipped with short flow diversion device. See Table 2.6 for tags explanation. Dashed grey area = Aseptic area

fluids) feed-back controllers are not able to ensure the scheduled process delivery. For these reasons, in such cases flow diversion is a not so much rare event, and its effectiveness is essential for achievement of commercial sterility of the product. The correct choice of the temperature probe plays an important role in the successful design of a flow diversion system. As stated by the Codex Alimentarius Commission (CodexAlimentarius (1993)) devices should respond to temperature changes sufficiently quickly to ensure that the scheduled process is delivered.

RTD probes (Resistance Temperature Detectors) are frequently used in order to monitoring and control the temperature at the heating section outlet. RTD elements consist of a length of fine coiled wire wrapped around a ceramic or glass core (bulb). The element is usually quite fragile, so it is often placed inside a sheathed probe to protect it. The dynamic response of a sensor is an important feature, particularly if it is intended to be used in a continuous processing system. When the probe is subjected to a rapid temperature change, it will take some time to respond: if the response time is slow in comparison with the rate of the change of temperature, the RTD will not be able to faithfully represent the dynamic response. For industrial application, the RTD bulb is normally protected with metal pipes. Thus the response time of the device is mainly influenced by the thermal diffusivity and mass of the sheath. The most usually installed RTDs are $6mm$ and $3mm$ $PT100$, naked or inside pocket. The response of RTDs can be modelled using a first-order differential equation. The transfer function of a first-order system in the Laplace domain is shown in Eq. 2.18. The rate at which

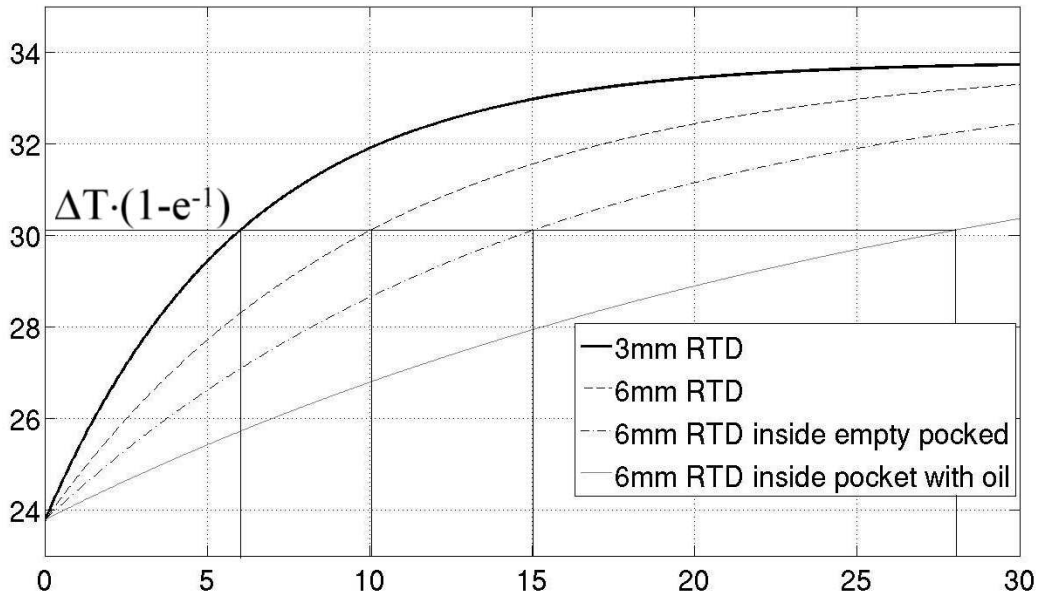

Figure 2.14: Simulink model of RTD probes

the response approaches the final value of a temperature change is determined by the time constant τ. The step response of a first order system in the time domain is shown in Eq. 2.19. When $t = \tau$, y has reached the 63.2% of its final value; when t is equal to 5τ, y has reached the 99.3% of its final value.

$$G(s) = \frac{1}{1 + \tau \cdot s} \tag{2.18}$$

$$y(t) = L^{-1}\frac{1}{1 + \tau \cdot s} = 1 - e^{-t/\tau} \tag{2.19}$$

In many cases, specifications of industrial RTD do not include any information about the dynamic response. A study has been carried out in order to determine the time constant of the above mentioned RTD models. A test device compliant to IEC 60751 for a simplified test in water has been used. As shown in Fig. 2.14, the minimum time constant τ is about $6s$ for $3mmPT100$. If an important deviation occurs, for example in the case of a failure in the steam feed line, the temperature measured by RTD probes is considerably lower then the actual

temperature during the transient state. Thus a correctly designed safety length between the probe and the valve is necessary to ensure that insufficiently treated product will always be diverted when the temperature is too low.

2.3.3 Procedure for effective flow diversion systems

The issue is clearly described by the EHEDG Doc.1 (Lelieveld *et al.* (1992)): The distance between the temperature probe that controls flow diversion and the flow diversion valve must be large enough to ensure that insufficiently treated product will always be diverted when the temperature is too low. This requirement is critical in plants equipped with short flow diversion system, in which both the temperature probe and flow diversion valve are located between the product heater and the holding tube. The minimum acceptable volume of the safety tube depends on the flow rate and has to be calculated for the maximum flow rate. This volume depends also on product rheology because it is important to know the shortest time that any particle can take to pass through the safety tube. For pseudo-plastic and Newtonian fluids the precautionary 0.5 ratio between the average and the maximum speed can be accepted, for laminar flow. The safety tube should be correctly designed, but if its length is wrong it is possible to increase the set-point at the heating section outlet in order to ensure that insufficiently treated product will always be diverted. A real case is shown in Fig. 2.15: the continuous line is the actual temperature at the heating section outlet due to a failure in the steam feed line. The measured temperature at the heating section outlet (dashed line) and the actual diversion temperature were calculated with the aid of the Simulink model described above (Fig. 2.16), using a 6mm RTD. The delay due to the whole control system (including actuator) has been also taken into account. In the case shown in Fig. 2.15, the actual diversion temperature was $2.4°C$ lower than the scheduled diversion temperature. Some simulations were carried out in order to determine the correct set-point to ensure a safe $F0$ value in the worst case.

Table 2.7: Procedure for effective flow diversion systems

Required inputs	Scheduled process Safety tube length Whole delay due to control system Rheological properties of product
Required instruments	Model of the temperature probe that controls flow diversion Model of the heating section (optional)
1	Assessment of the event able to cause the more serious transient state at the heating section outlet (failure in the steam feed line)
2	Experimental or theoretical determination of temperature trend due to the event
3	Simulation of temperature measurement by means of the probe model
4	Determination of the minimum temperature of product that will get into the holding tube
5	If actual diversion temperature is lower then the nominal diversion temperature, scheduled process is not delivered
6	Determination of the actual F value
7	If the calculated F value is not acceptable, increase the set point at the heating section outlet and the scheduled diversion temperature
8	Repeat points 3 to 6 until the minimum F value is satisfactory

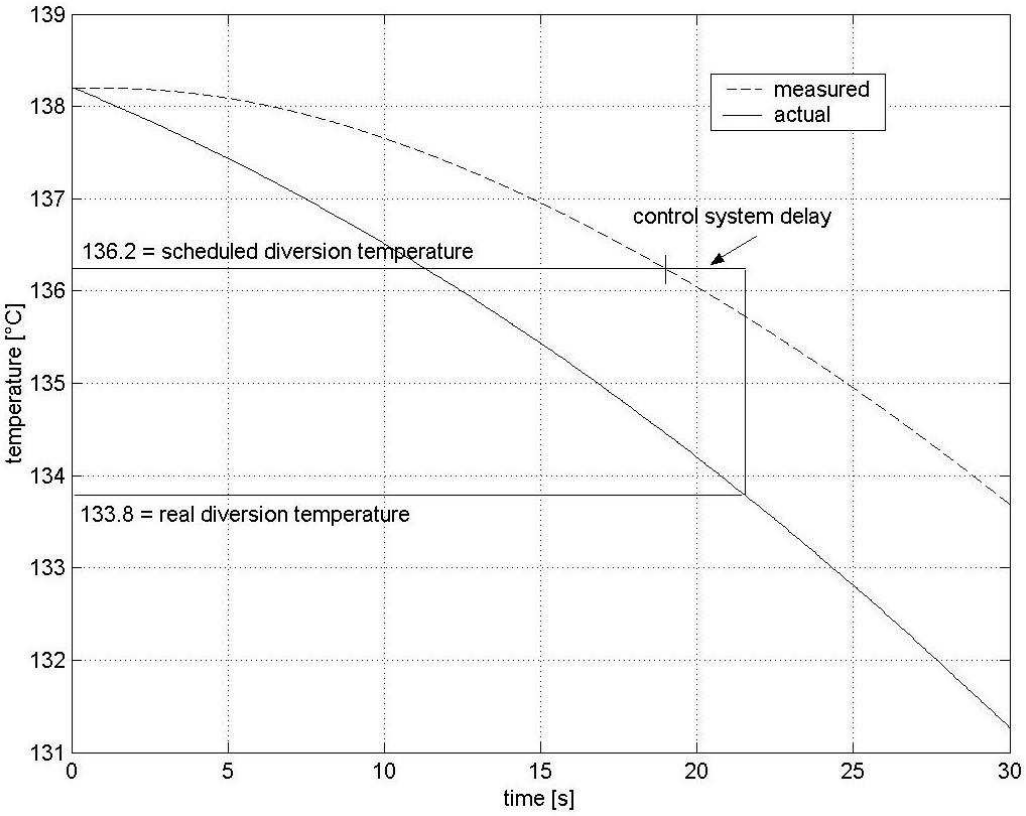

Figure 2.15: Determination of the actual diversion temperature if a RTD with $\tau = 10s$ is used

2.3.4 Conclusions

Flow diversion is a matter of concern for Food Hygiene in Aseptic Processing and Packaging Systems. The relevant standards and guidelines have been examined: since the Aseptic Processing is a widely used and well-established technology, there is quite a lot of available material. The flow diversion topic is also addressed, particularly by EHEDG Guidelines which describe the main issue to be considered during equipment design. The correct choice of the temperature probe, focusing on dynamic response, plays an important role in the successful design of a flow diversion system. A study was carried out in order to determine the time constant of some RTD models usually installed in the Aseptic Systems. A procedure, which also includes simple simulation tools, has been developed in order to properly

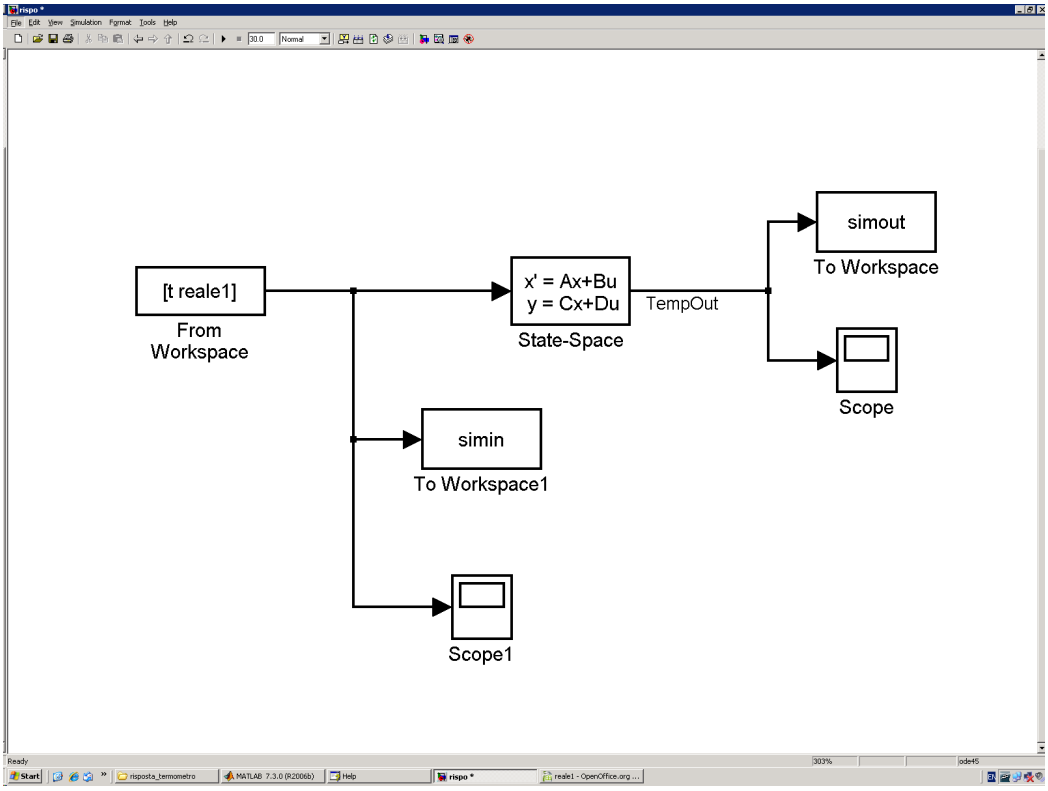

Figure 2.16: Simulink model of RTD probes

design the flow diversion device (Table 2.7).

A real case study shows that industrial RTD probes are not adequate for short flow diversion devices. A properly combined choice of components and design of process and equipment, taking into consideration the transient behaviours, is the right solution for effective flow diversion systems design. Finally this research shows that it is necessary to have more regard to standards and guidelines: the developed procedure allows the assurance of safety by properly setting the scheduled process parameters even if the safety length is not adequate. In this case a superfluous cooking value is applied, together with nutritional and sensorial damage of the final product. On the contrary fully compliant equipment will allow process optimization along with efficient energy use. Therefore the proposed procedure is a useful tool, not only for validation but also for process and equipment design.

2.4 A method for the validation of aseptic packing machines

A comprehensive procedure for the validation of an aseptic packing machine has been developed. Particularly the procedure has been developed for the aseptic packing of particulate foods into spoutless bags. Anyhow the methodology can be applied to other aseptic packing machine typologies.

The considered packing machine consists of:

- a chamber for the sprinkling of the $H_2O_2/water$ solution on the external surfaces of the internally sterilized sealed bags
- a chamber for the activation of the $H_2O_2/water$ solution by means of warm air and the sterilization of the external surfaces of the internally sterilized sealed bags
- a chamber for the cutting, filling and sealing of the bags

The last chamber is sterilized by means of steam, and the bacteria-tightness is ensured by overpressure of sterile air. The bags are internally presterilized and sealed. The external surfaces are sterilized by $H_2O_2 + hotair$.

The aim of the procedure is to validate the cleanability, sterilizability and bacteria-tightness of the packing machine, so three test methods are at least required. A preliminary check of compliance of the packing machine to the available regulations, standards and guidelines (materials, hygienic design, monitoring & control) is also scheduled.

2.4.1 Cleanability of the filling equipment (filler)

The following procedure has been developed:

1. All parts are dismantled, then all surfaces are cleaned and degreased and finally the equipment is reassembled.
2. The equipment is filled with a product with adhesiveness to stainless steel (e.g. pasteurized cream with minimum fat content 20%). The product

is recirculated for 24 hours with three 10 minutes stops. A fat-soluble colouring (e.g. β-carotene, lycopene, E110) is added to the product in order to allow visual detection of residues.

3. The scheduled draining, CIP, and rinsing are performed

4. All parts are dismantled and visually inspected.

2.4.2 Cleanability of the filling zone

The following procedure has been developed:

1. All parts are dismantled, then all relevant surfaces are cleaned and degreased and finally the equipment is reassembled.

2. The filling equipment is filled with the previously used product, and the chamber is soiled, simulating the malfunctioning of the machine.

3. 4 hours drying with air.

4. The scheduled CIP, and rinsing are performed.

5. All parts are dismantled and visually inspected.

2.4.3 Sterilization of the filling equipment (filler)

For challenge test on the effectiveness of sterilization systems based on the use of moist heat (saturated steam or water), all international scientific-technical sources suggest the use of spores of *Geobacillus stearothermophilus*, particularly strain ATCC 7953 (NCA or 1518, NCTC 10003, DSM 5934, CIP 52.81) (Bernard & et al. (1993); Ito & Stevenson (1984)). These spores are characterized by higher heat resistance ($D_1 211 - 4min.$) compared to the spores of *C. botulinum* ($D_1 210.25min.$), so $3 - D$ to an inoculum of *G. stearothermophilus* are at least equal to $12 - D$ to *C. botulinum* ($F = 3$), the "Botulinum Cook" generally accepted as appropriate by the US-FDA and explicitly stated by the Food Safety and Inspection Service of the U.S. Department of Agriculture (Anon (2001b)) and, recently, also by EFSA (4Anon (2005)). The heat resistance of bacterial spores

can greatly vary depending on the conditions of sporulation and preservation. Therefore, in the validation tests it is necessary to know in advance the effective heat resistance of the spores used, which can be purchased as a suspension ready for use or dehydrated. If heat-certified spore suspensions are not available , the heat resistance has to be be determined. To this end, you can use glass capillaries filled with a spore suspension of suitable concentration, closed to the flame and subjected to treatment as isothermal as possible at different temperatures and times, with subsequent cooling in a bath of water and ice.

The following procedure has been developed:

1. All parts are dismantled, cleaned and degreased. In the wide surfaces the critical points are located and the corresponding $1cm^2$ surfaces are highlighted with a felpt-tip pen.

2. The little parts (also gaskets) and the located areas are wet with hydroalcholic suspension (ethanol $40 - 70\%$) of about 10^6 *Geobacillus stearothermophilus* cfu/ml, with known heat resistance, dosed with an Eppendorf pipette.

3. At least 2 hours drying.

4. The equipment is reassembled

5. after 16 hours, the inoculated surfaces are wet with a Ringer solution with added 10% Tween 20, by means of swabs. Wring the swabs before use and standardize the method of swabbing (direction, force applied, number of smears).

6. Each swab is broken and entered into a container that contains appropriate Ringer solution and stirred in vortex for 2 minutes at high speed

7. Serial dilution with Ringer solution, put into plates (three replicates) with suitable nutrient and set at $55°C$ for 3 days (72 hours). Determine the most probable number of spores found active and calculate the spores recovery percentage

8. The steps 1,2,3,4 are repeated and the scheduled equipment sterilization is performed
9. The steps 6,8,9 are repeated.
10. Calculate the Log reduction applied to the spores in all located areas.

The procedure should be repeated two times (or more if results are not reliable) with minimum 10 checked areas.

2.4.4 Sterilization of the filling zone

The following procedure has been developed:

1. 10 critical areas are located. It should be examined the possibility to attach on such surfaces $5x20mm$ stainless steel strips (or different shape with the same surface area).
2. Arrange 15 stainless steel strips and attach a double-sided tape to a face.
3. Inoculate the free face of 12 strips with $0.1ml$ of a hydroalcholic suspension (ethanol $40 - 70\%$) of about 10^6 *Geobacillus stearothermophilus* cfu/ml, with known heat resistence, dosed with an Eppendorf pipette. Highlight with a felpt-tip pen the non inoculated strips.
4. At least 16 hours drying into codified opened plates.
5. Attach 10 inoculated strips to the previously located critical areas and also the 3 non inoculated strips.
6. Start the scheduled equipment sterilization process.
7. Air flux for cooling
8. Take the strips and put them into their codified plates
9. The inoculated surfaces of all strips are wet with a Ringer solution with added 10% Tween 20, by means of swabs. Wring the swabs before use and standardize the method of swabbing (direction, force applied, number of smears).

10. Each swab is broken and entered into a container that contains appropriate Ringer solution and stirred in vortex for 2 minutes at high speed

11. Serial dilution with Ringer solution, put into plates (three replicates) with suitable nutrient and set at $55°C$ for 3 days (72 hours). Determine the most probable number of spores found active in all strips

12. Calculate the Log reduction applied to the spores in all located areas.

The procedure should be repeated two times (or more if results are not reliable) with minimum 10 checked areas.

2.4.5 Decontamination of the external surfaces of the packing material

For sterilization by hydrogen peroxide, the use of spores of the following *bacillus* strains has been proposed:

- *Bacillus subtilis var. globigii* (NCIB 8058, ATCC 9372, NCA 7552): in 30% H_2O_2 at $30°C$ is much more resistant to other Bacilli (Ito *et al.* (1973)). In 25.8% H_2O_2 ,at $24°C$, $D = 2$ minutes, 0.92 minutes at at $40°C$ and, based on a *zvalue* calculated for at $30°C$, 5.5 seconds at at $80°C$ (Toledo *et al.* (1973)). In the method Elopak No. 644, 95-08-11, Filler Sterility Test (Anon (2001a)) at least 5-D are acceptable.

- *Bacillus subtilis* SA22 (NCA 72-52; DSM ATCC 4181): in 25.8% H_2O_2 at $24°C$, $D = 7.3$ minutes, compared to 2 minutes of *B. subtilis var. globigii* and 1.5 minutes for B. stearothermophilus (Toledo *et al.* (1973)). in 29.5% H_2O_2 at $65°C$, $D = 0.05$ minutes (Leaper (1984)). The method proposed by Cerny (1992) and recommended by the EHEDG Doc.21 (Anon (2001a)) for the validation of sterilization of the inner surface of packing material considers acceptable the application of at least 4-D. The VDMA 2006 / N. 14 (VDMA (2006)) for external sterilization of containers by H_2O_2, considers acceptable at least $3-D$. While the VDMA 2003 / N. 8 (VDMA (2003)) about sterilizing the sterile zone in machine interior considers acceptable at least $4 - D$ in all critical areas.

- *Bacillus subtilis A*: recommended for treatment with H_2O_2 and UV (Reidmiller *et al.* (2003)), and also for mixtures of H_2O_2 and peracetic acid (Blakistone *et al.* (1999)). In the BOSCH Machine Pre-sterilization procedures (Anon (2001a)), samples inoculated with 10^4, 10^5 and 10^6 spores are used (the acceptability of at least $5-D$ is inferred).

- *Geobacillus stearothermophilus* (ATCC 7953/12980; NCTC 10003/10007; DSM 494/22/5934; CIP 52.81): in 30% H_2O_2 at $30°C$ has much lower resistance to *B. subtilis var. globigii* but also to *B. subtilis A*, while at $87.8°C$ has a heat resistance slightly less than *B. subtilis var. globigii*, and greater than *B. subtilis A* (Ito *et al.* (1973)). In 28.5% H_2O_2 at $24°C$ it has less resistance than *B. subtilis* SA22 and just below heat resistance of *B. subtilis var. globigii* (Toledo *et al.* (1973)). In oxonia® at room temperature it has less heat resistance than *B. subtilis A* and about the same heat resistance of the *B. subtilis var. globigii* (Blakistone *et al.* (1999)). In H_2O_2 vapour, however, it has the highest resistance (McDonnell *et al.* (2002)).

There are no Bacilli spores used as biological indicators with a certificate of resistance to treatment with H_2O_2. This resistance, in fact, depends, in addition to the strain, on the operating conditions that may be very different (dip or fill, spray, spray and condensation, at different concentration and temperature, followed by sterile rinse or treatment with hot air at different temperature). The available data on resistance to treatment with H_2O_2 of spores of *C. botulinum* are very poor and mostly for dipping treatment at room temperature. The only research about post-treatment with hot air allows direct comparison with the spores of *G. stearothermophilus*, which are at least 3.3 times more resistant than those of the more resistant strain of *C. botulinum* (Ito *et al.* (1973)). Using sporicidal $H_2O_2 + air 55-85°C$, $4-D$ applied to spores of *G. stearothermophilus* are more than $12-D$ for the most resistant spores of *C. botulinum*. In cold oxonia (dipping), the spores of *G. stearothermophilus* have resistance at least 4.5 times greater compared to the more resistant spores of *C. botulinum* (Blakistone *et al.* (1999)). At the present time the spores of *G. stearothermophilus* are used as biological indicator to validate the sterilizing effect of H_2O_2 in the vapour phase

(Kokubo *et al.* (1998)). Therefore, it is considered preferable the use of spores of *G. stearothermophilus*, compared to other *Bacilli*, since it is possible to inoculate and manipulate without the need of nominally aseptic conditions.

The following procedure has been developed:

1. Locate 4 critical spots of the bags, depending on the H_2O_2 and hot air fluxes. Check the possibility to apply rectangular strips ($5x70mm$) of plastic laminate and codify their position as A, B, C and D.

2. Cut 50 strips form bag samples. Apply on a face of the strips a double-sided tape. With indelible pen, divide the other side of the samples with vertical marks so as to have, starting from the left, an area 10 mm to be used for manipulation and 3 large areas adjacent 20 mm.

3. Using a micropipette Eppendorf, inoculate the three 20 mm areas of 42 samples with $0.1ml$ of a hydroalcoholic suspension (ethanol $40 - 70\%$) at three different dilutions, approximately 10^4, 10^5 and $10^6 cfu/ml$ spores of *Geobacillus stearothermophilus*.

4. Allow to dry completely inoculated samples and store them in open Petri plates in a dryer for at least 16 hours before using. Extract the samples to be used and close and codify their plates.

5. Arrange 150 sterile tubes with suitable nutrient and $200EU/ml$ of catalase.

6. Attach with the tape the inoculated strips on 4 critical spots of 10 numbered bags, taking care not to touch the surface inoculated. Activate the cycle of H_2O_2 sterilization and hot air. Take the samples, taking care not to touch the surface inoculated, cut the three parties with different inoculation and insert each one in a tube encoded with the number of the bag, the letter of the critical point and the level of inoculation.

7. Repeat the previous step for 2 bags on which not inoculated strips have been glued.

8. Fill in the remaining 6 tubes the 6 part of the 2 strips not subjected to sterilization.

9. Set at $55°C$ for 3 days (72 hours).

10. Express the results as completely inactivated maximum inoculum for each critical point of each bag. The result is to be considered acceptable if in all the samples inoculated there was at least the complete inactivation of 10^4 cfu. The test of the not inoculated and treated should be negative, while those inoculated and untreated should be positive.

The whole procedure should be repeated at least 2 times (with more repetitions if the results differ significantly).

2.4.6 Bacteria tightness of the filling zone

1. Under a laminar flow hood, open at least 4 bags, sprinkle the culture broth TSB (trypticase soy 15gl-1) on the inner surface and close as possible to exclude the air.

2. Inoculate the outside of the chamber by sprinkling spraying or injecting in the crevices a suspension of *Serratia marcescens* (Anon (1993c)) to $10^8 cfu/ml$ in TSB (operators must wear a protective mask over the nose and mouth).

3. A bag is inserted into the packing machine and, after the introduction into the chamber with the sterile air flux running the bag is cut, maintained opened for 4 hours in the filling position,eh but with the dosing valve closed before the closure.

4. After incubation at $30°C$ for 5 days, the bags are opened to check for the growth of *Serratia marcescens*.

2 trials are required. After each test, sterilize the inside and the outside of the filling area.

Chapter 3

Results

THE created instruments, shown in Chapter 2 have been tested on real equipments and products. A good survey on the implementation of Hygienic Design in the Italian food industry is the result of the wide use of the checklist. In some cases the developed approach allowed also to solve food hygiene problems. Since there is the need, not only for scientific research, but also for dissemination and training, the Italian Section of the EHEDG has been set up in Parma, which is, at the present time, also the site of the European Food Safety Authority. Several companies have been involved and the activities of the section are increasing and spreading.

3.1 A Survey on implementation of *Hygienic Design* in the Italian Food Industry

A survey is a really demanding activity, mainly when several parties are involved. Moreover *Hygienic Design* is an unfamiliar issue and the awareness of the food industry about the importance of this topic is probably quite low. In the literature there are some surveys on the contamination of final food products (e.g. Beuchat (1996), Bijker *et al.* (1987), Bjrkroth (2005), Brackett (1999), Chavasit *et al.* (2006), Davies *et al.* (2001), Franciosa *et al.* (1999), Kolodziejska *et al.* (2002), Houben (2005), Nguz *et al.* (2005), Nrrung *et al.* (1999), Siriken *et al.* (2006), Tournas (2005), Vitas & Garcia-Jalon (2004)), several on the implementation of

quality assurance schemes and HACCP principles (e.g. Bai *et al.* (2007), Bas *et al.* (2006), Conter *et al.* (2007), Fearne *et al.* (2001), Hielm *et al.* (2006), Jin *et al.* (2008), Scott *et al.* (2009), Violaris *et al.* (2008)), some on the food safety perspective and behaviour of consumers (e.g. Angulo & Gil (2007), Jevsnik *et al.* (2008), Ragaert *et al.* (2004), Rohr *et al.* (2005), Smith DeWaal (2003), Wang *et al.* (2008), Worsfold & Griffith (1995)), a few about the contamination of food equipments (e.g. Gounadaki *et al.* (2008)) and any about implementation of hygienic design in the food industry (just one survey that deals also with hygienic design was found (Kuhn *et al.* (2004))). For this reason a survey in the Italian food industry has been carried out on this topic. The check-list described in the §2.1 was used.

With the collaboration of some food companies and one equipment manufacturer **5 heat treatment plants**

- 3 plants for the heat treatment of tomato products
- 1 plant for the heat treatment of low-acid soya products
- 1 plant for the heat treatment of low-acid pasta sauces

and **1 aseptic packing machine** were checked. Several layouts have been tested and in all cases the check-list has proved to be effective. The compliance of the material used in the packing machine has been also checked. Many non conformities were found and they were grouped into two categories: some non conformities are able to cause a lower *F value*, compared to the scheduled process (Table 3.1). The others can cause recontamination of the product (Table 3.2) (Obviously all non conformities found in the packing machine belong to the second category). There is also a non conformity that belongs to both categories: *lack of monitoring and control*.

Hygienic design mainly deals with cleanability and drenability. Many examples of lack of cleanability and drenability of the checked equipments could be shown, for instance pipe and component coupling, valves, wrong installation of components etc.. Unfortunately, for privacy reason, it is not possible to include photos of the checked equipment in this PhD thesis.

Table 3.1: Some non conformities that cause a lower *F value*

- Incorrect slope of holding tubes
- Incorrect pressure control in the holding tubes
- Not sufficient length of the "safety tube"
- Product outlet and inlet at the same height in the heat exchangers
- Cleanability problems upstream the holding section
- Drenability problems upstream the holding section
- Supports for piping or equipment not fabricated and installed such that no water or soil can remain on the surface

Table 3.2: Some non conformities that cause recontamination

- Lack of appropriate methods to ensure a positive pressure difference between the sterile product and cooling medium
- Connections and mechanical seals not aseptically designed in the sterile area
- Cleanability problems downstream the holding section
- Drenability problems downstream the holding section

3.2 Estimation of thermal diffusivity of several foods

Go to the §2.2.4 to see the estimated thermal diffusivity of some food products.

3.3 Validation on an aseptic packing machine

With the collaboration of an equipment manufacturing company it was possible to test the validation procedure shown in §2.4. Unfortunately it was not possible to test the cleanability of the filler and the filling zone, because the CIP equipment was not available at the time of the test. The microbiological tests have been carried out by the Food Microbiology Research Group of the Agriculture Faculty of the Parma University. The results of the performed tests are reported in the following:

3.3.1 Sterilizability of the filling equipment (filler)

Three critical spots has been located:

- Top gasket (external)
- Top gasket (internal)
- Bottom gasket

The located spots have been inoculated with $100\mu l$ of a suspension of about 10^6 spores $/100\mu l$. Another gasket has been inoculated as control sample. After the scheduled drying the gaskets have been reassembled in the filler and the scheduled sterilization process has been performed. The recovery of the spores have been carried out by means of sterile swabs, wet with Ringer solution. Afterwards the swabs have been inserted into sterile tubes filled with $5ml$ Ringer solution. The tubes have been stirred in vortex and then the samples have been serially diluted in Ringer solution. 1 ml of each dilution has been inoculated in Petri plates with TSA. The plates have been set at $55°C$ for 72 hours. Finally the colonies have

Table 3.3: Sterilizability of the filler

Critical spot	ufc/spot	Log	Log reductions
Top gasket (external)	< 5	0.7	4.7
Top gasket (internal)	< 5	0.7	4.7
Bottom gasket	< 5	0.7	4.7
Control sample	$2.50 \cdot 10^5$	5.40	—

been counted and the number of active spores has been calculated by means of the equation 3.1:

$$N_S = \frac{\Sigma C}{(1 \cdot na + 0.1 \cdot nb + 0.01 \cdot nc)d} \tag{3.1}$$

The control sample has been treated with the same procedure in order to determine the recovery ratio of the method. Results are shown in Table 3.3

3.3.2 Sterilizability of the filling zone

Used strips:

- little strips (P) $20x5mm$
- big strips (G) $60x10mm$

26 critical spots have been located in the filling zone. 27 strips, 23 G and 3 P and 1 control sample, have been inoculate under laminar hood with con 100 l of a suspension of about 10^6 spore/$100l$ of *Geobacillus stearothermophilus*. The strips have been dried and subsequently attached to the critical spots. The scheduled equipment sterilization process has been performed. After the cooling, the strips have been recovered ed inserted in sterile tubes filled with $5ml$ (fro strips G) or $1ml$ (for strips P) of Ringer solution. The tubes have been stirred in vortex and then the samples have been serially diluted in Ringer solution. 1 ml of each dilution has been inoculated in Petri plates with TSA. The plates have been set at $55°C$ for 72 hours. Finally the colonies have been counted and the number of active spores has been calculated by means of the equation 3.1. The

control sample has been treated with the same procedure in order to determine the recovery ratio of the method. Results are shown in Table 3.4.

3.3.3 Decontamination of the packing material

Quantitative tests: 72 strips $80x10mm$ have been divided into 3 areas and each area has been respectively inoculated with about 10^4, 10^5 e 10^6 spore *per* area. After the scheduled drying, the strips have been glued on 12 bags, in correspondence to 6 critical spots (A, B, C, D, E, F) (Fig. 3.1). 4 not inoculated bags have been arranged as control samples.

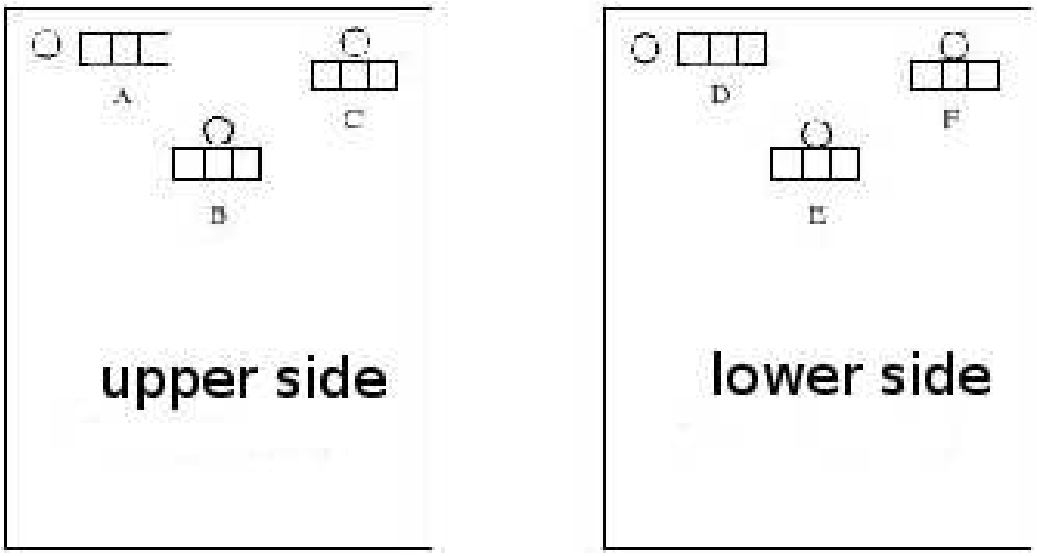

Figure 3.1: Critical spots on the external surfaces of the bags

The 16 bags have been sterilized in the machine according to 5 scheduled processes.

I .bags 1, 2, 3 e 4 (control)

II .bags 5, 6, 7 e 8 (control)

III .bags 9, 10 e 11 (control)

IV .bags 12, 13 e 14 (control)

Table 3.4: Sterilizability of the filler

Critical spot	ufc/spot	Log	Log reductions
1G	< 5	0.7	4.41
2G	< 5	0.7	4.7
3G	< 5	0.7	4.7
4G	< 5	0.7	4.41
5G	< 5	0.7	4.41
6P	< 10	1.0	4.10
7G	< 5	0.7	4.41
8P	< 10	1.0	4.10
9P	< 10	1.0	4.10
10G	< 5	0.7	4.41
11G	< 5	0.7	4.41
12G	< 5	0.7	4.41
13G	< 5	0.7	4.41
14G	< 5	0.7	4.41
15G	< 5	0.7	4.41
16G	< 5	0.7	4.41
17G	< 5	0.7	4.41
18G	< 5	0.7	4.41
19G	< 5	0.7	4.41
20G	< 5	0.7	4.41
21G	< 5	0.7	4.41
22G	< 5	0.7	4.41
23G	< 5	0.7	4.41
24G	< 5	0.7	4.41
25G	< 5	0.7	4.41
26G	< 5	0.7	4.41
27G	< 5	0.7	4.41
28G	< 5	0.7	4.41
Control sample	$< 1.27 \cdot 10^5$	5.10	—

V .bags 15 e 16

Afterwards the 3 areas of each strip have been cut and inserted in sterile tubes filled with $5ml$ TSB, set at $55°C$ for $72h$. The inactivation has been evaluated by means of turbidity test. Results are shown Appendix A Many unreliable results shows that the effectiveness of the decontamination process is heterogeneous.

Quantitative tests: 36 bags have been inoculated directly on their surfaces, in correspondence to 6 critical spots (A, B, C, D, E, F) with about $10^6 spores/spot$. 11 bags have not been inoculated (one bag for each different treatment) and have been used as reference samples. After the scheduled drying the bags have been treated according to 11 different scheduled processes. Afterwards the spores have been recovered into 2 or 3 ml of Ringer solution. The tubes have been stirred in vortex and then the samples have been serially diluted in Ringer solution. 1 ml of each dilution (until 10^{-2} has been inoculated in Petri plates with TSA. The plated have been set at $55°C$ for $72h$. Finally the colonies have been counted and the number of active spores has been calculated by means of the equation 3.1. A test has been carried out in order to estimate the recovery ratio of the method: a spot of a bag has been inoculated with 10^6 spores. After drying the spores have been recovered according to the same method described above. The recovered contamination was $1.71 \cdot 10^5 cfu$, equal to Log 5.23. Results are shown Appendix B

3.3.4 Bacteria-tightness of the filling zone

Firstly the internal sterility of the bags has been checked. 10 bags have been filled with $40ml$ TSB in aseptic conditions. The broth has been then recovered and poured into 3 sterile tubes, and set at $20°C$, $37°C$, $55°C$ for 72 hours. Finally the contamination has been evaluated by means of turbidity test. All checked bags proved to be sterile. Afterwards the bacteria-tightness of the filling zone has been checked. 4 bags have been cut under laminar hood, filled with $10ml$ sterile TSB and then thermally sealed. According to the scheduled procedure the bags has been inserted into the machine, where they stopped (opened) for 4 hours). Afterwards the bags have been set at $30°C$ for 72 hours. Finally the

contamination has been evaluated by means of turbidity test. All checked bags were sterile and so the absence of environmental contamination has been proved.

3.4 EHEDG Italian Section set-up

(From www.ehedg.org) The European Hygienic Engineering and Design Group (EHEDG) is a consortium of equipment manufacturers, food industries, research institutes and public health authorities, founded in 1989 with the aim to promote hygiene during the processing and packing of food products. European legislation requires that handling, preparation, processing, packaging, etc. of food is done hygienically, with hygienic machinery in hygienic premises (the food hygiene directive, the machine directive and the food contact materials directive). How to comply with these requirements, however, is left to the industry. EHEDG provides practical guidance on hygienic engineering aspects to help complying to these requirements. As food safety does not end at the borders of Europe, the EHEDG actively promotes global harmonization of guidelines and standards. The US-based organisations NSF and 3-A have agreed to co-operate in the development of EHEDG Guidelines and in turn, EHEDG co-operates in the development of 3-A and NSF standards. The objectives of EHEDG are :

- To provide guidance on the hygienic engineering aspects of manufacturing safe and wholesome food.
- To provide guideline documents on essential hygienic design standards and practices, based on science and technology, and to periodically review them. These provide guidance to equipment manufacturers and users on compliance with national and international legislation.
- To develop test methods that can be used by third parties for hygienic design assessment to aid compliance with relevant legislation.
- To ensure that the use of the EHEDG name and logo is properly controlled.
- To identify areas where knowledge of hygienic design is insufficient and to encourage research and development in such areas.

- To provide a balanced forum for European food processing equipment manufacturers, users and regulators to discuss issues on hygienic design to support food safety and wholesomeness.

The Regional Sections are a local extension of the EHEDG and are created to promote hygienic manufacturing of food through regional activities. The main activities of the Regional Sections are

- To translate the guidelines into the local language.
- To disseminate information to all concerned parties.
- To serve as a platform for discussion of hygienic engineering issues at national or regional level.
- To give help to equipment manufacturers for certification.
- To organize conferences and workshops about food hygiene.
- To identify areas where knowledge of hygienic design is insufficient and to encourage research and development in such areas.

At the present time (January 2009) the website of the EHEDG shows 11 Regional Sections, some of them still in development (Netherland, Germany, Spain, Italy, France, Hungary, Portugal, Japan, Nordic countries, Poland, Switzerland).

The first meeting between the EHEDG and me took place at Frankfurt on November 2006. Afterwards several companies were contacted in order to create a promoter group for the kick start of the Italian Section. The list of companies, research institutions and authorities which joined the project is shown in Table 3.5. I wide meeting between the Promoter Group and the Executive Committee of EHEDG took place at the University of Parma on March 2007. The official opening of the Italian Section was the Conference "Hygiene Requirements and Standards for Foodstuffs Machinery" which held at Fiere di Parma (CIBUSTEC2007) on 17 October 2007, organized by Fiere di Parma and the University of Parma. The speakers were Roberto Massini (University of Parma, TECAL), Riccardo Giambelli (TIFQ), Maurizio Podico (TIFQ), Knuth Lorenzen (GEA, EHEDG President), Giampaolo Betta (me) (University of Parma,

Table 3.5: Promoter group of the Italian Section of the European Hygienic Engineering and Design Group

Equipment manufacturers
CFT Rossi&Catelli
JBT FoodTech
GEA Niro-Soavi
GEA Procomac
PNR Italia
Sidel
Food companies
Barilla G.e F.Fratelli
Parmacotto
Parmalat
Sangemini
Research institutions
Universitá degli Studi di Parma
Stazione Sperimentale per l'Industria delle Conserve Alimentari
Publich heath authorities
Italian Health Ministry

Italian Section EHEDG, TECAL), Giancarlo Belluzzi (Italian Health Ministry), and Eirini Tsigarida (European Food Safety Authority EFSA). The slides of their presentations are available at the URL www.ehedg.unipr.it.

The activities completed by the Italian Section, according to the main regional sections aims (dissemination and translation), are summarized in Table 3.6.

On 7 November 2008 I joined the Regional Sections Meeting at Ljubljana. The meeting attracted 27 representatives from 12 countries many of them having recently joined the EHEDG network or willing to do so in the near future. The participants reported about their recent and future activities. President Knuth Lorenzen informed the participants about the general EHEDG tasks and objectives and some Subgroup Chairmen introduced the technical work of the EHEDG expert teams. The participants are shown in the reported photo (Fig. 3.2).

Table 3.6: EHEDG Italian Section activities

- Italian Section Web-site (www.ehedg.unipr.it)
- Conference "Hygiene Requirements and Standards for Foodstuffs Machinery" - 17 October 2007 (Fiere di Parma, CIBUSTEC2007)
- Doc.8 translation "Hygienic Equipment Design Criteria"
- Doc.34 translation "Integration of hygienic and aseptic systems" (in preparation)

Figure 3.2: EHEDG Regional Section Meeting at Ljubljana

I have also published on the journal *Trends in Food Science & Technology* a short report of the Italian Section activities (Betta (2009)).

Chapter 4

Conclusions

AN alarming scenario appears from a wide bibliographic study: foodborne infections cause several million cases of human illness and many thousands deaths annually in the western world; the lack of *Hygienic Design* of equipment is in the top 4 of the most important food safety problem in the food industry; *Hygienic Design* is an unfamiliar issue and the awareness of the food industry about the importance of this topic is quite low; moreover a few articles on this topic are available in the literature and there is in Europe just one organization (the EHEDG) really active in the development of documents on this topic.

The huge lack of knowledge and research on the above said topic justifies this PhD thesis in which a whole approach for the assurance of the Food Hygiene has been developed. The case of aseptic processing and packaging systems has been handled, since thermal processing and aseptic packing is one of the most important operations in food industry.

Several procedures, tools and methods have been developed and then tested on real equipments and products.

In order to achieve *Food Hygiene* the first step is the examination of all relevant regulations (clear but sometimes semi-forgotten, think through the EU machinery directive for instance). A check list for the evaluation of compliance

of aseptic processing and packaging systems to the European and US regulations, the European and international standards and the European and international guidelines has been developed. The use of the check-list leaded to a wide survey on the implementation of *Hygienic Design* in the Italian food industry.

Since the correct knowledge of thermal properties is essential for efficient and economical design and control of all food processing operations involving heat transfer, a method for the quick estimation of thermal diffusivity of foods has been developed. The method (software + measuring cell) has been used to calculate the thermal diffusivity of several foods intended for heat treatment.

Flow diversion is a matter of concern for *Food Hygiene* in Aseptic Processing and Packaging Systems. The above said survey showed that the most part of the checked flow diversion divices are not effective. A procedure for the correct design and setting of the flow diversion device has been created. A simple software has been also developed. The use of the procedure allowed the correct setting of a flow diversion device improperly designed. Particularly this study shows how guidelines are able to avoid bad design of equipment.

In many cases the scientific design of the process and the hygienic design of equipment are not sufficient to ensure safety and suitability of the product. In such cases validation tests are necessary to check and ensure the effectiveness of the process. Aseptic packing machines are really complex equipment and at the present time it was not possible to completely hygienically design a packing machine of this sort. A method for the validation of aseptic packing machines has been developed and the proposed tests have been used on a packing machine for filling of spoutless bags.

As shown by the bibliographic study training is one of the most important needs in the food industry. In order to spread the discussion on Hygienic Design

and the dissemination of this approach, the Italian Section of the EHEDG has been set up in Parma. It was and is a very demanding activity but also very rewarding and formative, since it requires the on-going relationship with people from the whole Europe and also from China and Japan. Several companies have been involved and the activities of the section are increasing and spreading.

Appendix A

Validation: decontamination of packing material

A.1 Appendix: qualitative test

The results of the qualitative test on the effectiveness of the decontamination of the bags by means of H_2O_2 is shown in the following Tables. "n.a" shows an unreliable result since absence of turbidity was found in sample inoculated with a higher concentration $(-)$ and growth was found in samples inoculated with a lower concentration $(+)$. The result is probably due to the heterogeneous effectiveness of the decontamination process on the bags surfaces.

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
1	A	10^4	+	n.a.
1		10^5	-	
1		10^6	+	
1	B	10^4	-	10^5
1		10^5	-	
1		10^6	+	
1	C	10^4	-	$\geq 10^6$
1		10^5	-	
1		10^6	-	
1	D	10^4	+	n.a.
1		10^5	-	
1		10^6	-	
1	E	10^4	+	n.a.
1		10^5	-	
1		10^6	-	
1	F	10^4	+	$< 10^4$
1		10^5	+	
1		10^6	+	

Figure A.1: Treatment I

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
2	A	10^4	+	$< 10^4$
2		10^5	+	
2		10^6	+	
2	B	10^4	-	10^5
2		10^5	-	
2		10^6	+	
2	C	10^4	-	$\geq 10^6$
2		10^5	-	
2		10^6	-	
2	D	10^4	-	$\geq 10^6$
2		10^5	-	
2		10^6	-	
2	E	10^4	-	10^5
2		10^5	-	
2		10^6	+	
2	F	10^4	+	n.a.
2		10^5	-	
2		10^6	+	

Figure A.2: Treatment I

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
3	A	10^4	-	10^5
3		10^5	-	
3		10^6	+	
3	B	10^4	-	$\geq 10^6$
3		10^5	-	
3		10^6	-	
3	C	10^4	+	n.a.
3		10^5	-	
3		10^6	-	
3	D	10^4	+	n.a.
3		10^5	-	
3		10^6	-	
3	E	10^4	+	$< 10^4$
3		10^5	+	
3		10^6	+	
3	F	10^4	+	n.a.
3		10^5	-	
3		10^6	-	

Figure A.3: Treatment I

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
4 cont	A	10^4	-	$\geq 10^6$
4 cont		10^5	-	
4 cont		10^6	-	
4 cont	B	10^4	-	$\geq 10^6$
4 cont		10^5	-	
4 cont		10^6	-	
4 cont	C	10^4	-	$\geq 10^6$
4 cont		10^5	-	
4 cont		10^6	-	
4 cont	D	10^4	-	$\geq 10^6$
4 cont		10^5	-	
4 cont		10^6	-	
4 cont	E	10^4	-	$\geq 10^6$
4 cont		10^5	-	
4 cont		10^6	-	
4 cont	F	10^4	-	$\geq 10^6$
4 cont		10^5	-	
4 cont		10^6	-	

Figure A.4: Treatment I

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
5	A	10^4	+	$< 10^4$
5		10^5	+	
5		10^6	+	
5	B	10^4	-	$\geq 10^6$
5		10^5	-	
5		10^6	-	
5	C	10^4	-	10^5
5		10^5	-	
5		10^6	+	
5	D	10^4	-	$\geq 10^6$
5		10^5	-	
5		10^6	-	
5	E	10^4	-	10^5
5		10^5	-	
5		10^6	+	
5	F	10^4	-	$\geq 10^6$
5		10^5	-	
5		10^6	-	

Figure A.5: Treatment II

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
6	A	10^4	+	n.a.
6		10^5	+	
6		10^6	-	
6	B	10^4	-	10^4
6		10^5	+	
6		10^6	+	
6	C	10^4	-	10^5
6		10^5	-	
6		10^6	+	
6	D	10^4	-	10^4
6		10^5	+	
6		10^6	+	
6	E	10^4	-	n.a.
6		10^5	+	
6		10^6	-	
6	F	10^4	-	$\geq 10^6$
6		10^5	-	
6		10^6	-	

Figure A.6: Treatment II

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
7	A	10^4	-	≥ 10^6
7		10^5	-	
7		10^6	-	
7	B	10^4	-	10^5
7		10^5	-	
7		10^6	+	
7	C	10^4	+	n.a.
7		10^5	-	
7		10^6	-	
7	D	10^4	-	≥ 10^6
7		10^5	-	
7		10^6	-	
7	E	10^4	-	10^4
7		10^5	+	
7		10^6	+	
7	F	10^4	+	< 10^4
7		10^5	+	
7		10^6	+	

Figure A.7: Treatment II

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
8 cont	A	10^4	+	n.a.
8 cont		10^5	-	
8 cont		10^6	-	
8 cont	B	10^4	-	≥ 10^6
8 cont		10^5	-	
8 cont		10^6	-	
8 cont	C	10^4	+	n.a.
8 cont		10^5	-	
8 cont		10^6	-	
8 cont	D	10^4	-	10^5
8 cont		10^5	-	
8 cont		10^6	+	
8 cont	E	10^4	-	≥ 10^6
8 cont		10^5	-	
8 cont		10^6	-	
8 cont	F	10^4	-	≥ 10^6
8 cont		10^5	-	
8 cont		10^6	-	

Figure A.8: Treatment II

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
9	A	10^4	-	10^5
9		10^5	-	
9		10^6	+	
9	B	10^4	-	$\geq 10^6$
9		10^5	-	
9		10^6	-	
9	C	10^4	-	10^4
9		10^5	+	
9		10^6	+	
9	D	10^4	-	10^4
9		10^5	+	
9		10^6	+	
9	E	10^4	-	$\geq 10^6$
9		10^5	-	
9		10^6	-	
9	F	10^4	-	$\geq 10^6$
9		10^5	-	
9		10^6	-	

Figure A.9: Treatment III

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
10	A	10^4	+	$< 10^4$
10		10^5	+	
10		10^6	+	
10	B	10^4	-	$\geq 10^6$
10		10^5	-	
10		10^6	-	
10	C	10^4	-	10^4
10		10^5	+	
10		10^6	+	
10	D	10^4	-	$\geq 10^6$
10		10^5	-	
10		10^6	-	
10	E	10^4	-	$\geq 10^6$
10		10^5	-	
10		10^6	-	
10	F	10^4	-	$\geq 10^6$
10		10^5	-	
10		10^6	-	

Figure A.10: Treatment III

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
11 cont	A	10^4	-	≥ 10^6
11 cont		10^5	-	
11 cont		10^6	-	
11 cont	B	10^4	-	≥ 10^6
11 cont		10^5	-	
11 cont		10^6	-	
11 cont	C	10^4	-	≥ 10^6
11 cont		10^5	-	
11 cont		10^6	-	
11 cont	D	10^4	-	≥ 10^6
11 cont		10^5	-	
11 cont		10^6	-	
11 cont	E	10^4	-	≥ 10^6
11 cont		10^5	-	
11 cont		10^6	-	
11 cont	F	10^4	-	≥ 10^6
11 cont		10^5	-	
11 cont		10^6	-	

Figure A.11: Treatment III

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
12	A	10^4	-	10^4
12		10^5	+	
12		10^6	+	
12	B	10^4	-	≥ 10^6
12		10^5	-	
12		10^6	-	
12	C	10^4	-	≥ 10^6
12		10^5	-	
12		10^6	-	
12	D	10^4	-	≥ 10^6
12		10^5	-	
12		10^6	-	
12	E	10^4	-	≥ 10^6
12		10^5	-	
12		10^6	-	
12	F	10^4	-	≥ 10^6
12		10^5	-	
12		10^6	-	

Figure A.12: Treatment IV

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
13	A	10^4	-	≥ 10^6
13		10^5	-	
13		10^6	-	
13	B	10^4	-	≥ 10^6
13		10^5	-	
13		10^6	-	
13	C	10^4	-	≥ 10^6
13		10^5	-	
13		10^6	-	
13	D	10^4	-	≥ 10^6
13		10^5	-	
13		10^6	-	
13	E	10^4	-	≥ 10^6
13		10^5	-	
13		10^6	-	
13	F	10^4	-	≥ 10^6
13		10^5	-	
13		10^6	-	

Figure A.13: Treatment IV

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
14 cont	A	10^4	-	≥ 10^6
14 cont		10^5	-	
14 cont		10^6	-	
14 cont	B	10^4	-	≥ 10^6
14 cont		10^5	-	
14 cont		10^6	-	
14 cont	C	10^4	-	≥ 10^6
14 cont		10^5	-	
14 cont		10^6	-	
14 cont	D	10^4	-	≥ 10^6
14 cont		10^5	-	
14 cont		10^6	-	
14 cont	E	10^4	-	≥ 10^6
14 cont		10^5	-	
14 cont		10^6	-	
14 cont	F	10^4	-	≥ 10^6
14 cont		10^5	-	
14 cont		10^6	-	

Figure A.14: Treatment IV

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
15	A	10^4	-	≥ 10^6
15		10^5	-	
15		10^6	-	
15	B	10^4	-	≥ 10^6
15		10^5	-	
15		10^6	-	
15	C	10^4	-	10^4
15		10^5	+	
15		10^6	+	
15	D	10^4	-	10^4
15		10^5	+	
15		10^6	+	
15	E	10^4	-	≥ 10^6
15		10^5	-	
15		10^6	-	
15	F	10^4	-	≥ 10^6
15		10^5	-	
15		10^6	-	

Figure A.15: Treatment V

BUSTA	POSIZIONE	INOCULO (ufc/settore)	RISULTATO	RIDUZIONE (ufc/punto)
16	A	10^4	-	≥ 10^6
16		10^5	-	
16		10^6	-	
16	B	10^4	-	≥ 10^6
16		10^5	-	
16		10^6	-	
16	C	10^4	-	10^4
16		10^5	+	
16		10^6	+	
16	D	10^4	-	10^4
16		10^5	+	
16		10^6	+	
16	E	10^4	-	≥ 10^6
16		10^5	-	
16		10^6	-	
16	F	10^4	-	≥ 10^6
16		10^5	-	
16		10^6	-	

Figure A.16: Treatment V

Appendix B

Validation: decontamination of packing material

B.1 Appendix: quantitative test

The results of the quantitative test on the effectiveness of the decontamination of the bags by means of H_2O_2 are shown in the following Tables.

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
1A	5,46E+01	1,74	3,50
1B	4,00E+00	0,60	4,63
1C	8,36E+02	2,92	2,31
1D	1,52E+04	4,18	1,05
1E	3,68E+03	3,57	1,67
1F	5,60E+03	3,75	1,49

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
2A	2,28E+04	4,36	0,88
2B	3,46E+03	3,54	1,69
2C	4,28E+02	2,63	2,60
2D	5,02E+03	3,70	1,53
2E	3,10E+01	1,49	3,74
2F	1,44E+04	4,16	1,08

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
3A	4,00E+02	2,60	2,63
3B	4,00E+00	0,60	4,63
3C	4,30E+03	3,63	1,60
3D	2,84E+03	3,45	1,78
3E	6,72E+01	1,83	3,41
3F	6,52E+03	3,81	1,42

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
4A cont	< 2	0,30	4,93
4B cont	< 2	0,30	4,93
4C cont	< 2	0,30	4,93
4D cont	< 2	0,30	4,93
4E cont	< 2	0,30	4,93
4F cont	< 2	0,30	4,93

Figure B.1: Treatment I

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
1A	2,82E+04	4,45	0,78
1B	3,00E+00	0,48	4,76
1C	9,27E+02	2,97	2,27
1D	2,07E+04	4,32	0,92
1E	5,11E+02	2,71	2,53
1F	5,03E+02	2,70	2,53

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
2A	2,49E+02	2,40	2,84
2B	3,00E+00	0,48	4,76
2C	2,68E+02	2,43	2,81
2D	1,44E+04	4,16	1,08
2E	4,36E+01	1,64	3,59
2F	4,02E+04	4,60	0,63

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
3A	1,89E+04	4,28	0,96
3B	< 3	0,48	4,76
3C	6,30E+01	1,80	3,43
3D	4,68E+04	4,67	0,56
3E	< 3	0,48	4,76
3F	1,53E+02	2,18	3,05

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
4A cont	< 3	0,48	4,76
4B cont	< 3	0,48	4,76
4C cont	9,27E+01	1,97	3,27
4D cont	< 3	0,48	4,76
4E cont	< 3	0,48	4,76
4F cont	< 3	0,48	4,76

Figure B.2: Treatment II

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
1A	n.d.	n.d.	n.d.
1B	n.d.	n.d.	n.d.
1C	n.d.	n.d.	n.d.
1D	n.d.	n.d.	n.d.
1E	n.d.	n.d.	n.d.
1F	n.d.	n.d.	n.d.

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
2A	< 3	0,48	4,76
2B	< 3	0,48	4,76
2C	< 3	0,48	4,76
2D	9,00E+00	0,95	4,28
2E	< 3	0,48	4,76
2F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
3A	< 3	0,48	4,76
3B	< 3	0,48	4,76
3C	1,32E+04	4,12	1,11
3D	< 3	0,48	4,76
3E	< 3	0,48	4,76
3F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
4A cont	< 3	0,48	4,76
4B cont	< 3	0,48	4,76
4C cont	< 3	0,48	4,76
4D cont	< 3	0,48	4,76
4E cont	< 3	0,48	4,76
4F cont	< 3	0,48	4,76

Figure B.3: Treatment III

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
5A	< 3	0,48	4,76
5B	< 3	0,48	4,76
5C	< 3	0,48	4,76
5D	< 3	0,48	4,76
5E	< 3	0,48	4,76
5F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
6A	< 3	0,48	4,76
6B	< 3	0,48	4,76
6C	< 3	0,48	4,76
6D	< 3	0,48	4,76
6E	< 3	0,48	4,76
6F	3,00E+00	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
7A	< 3	0,48	4,76
7B	< 3	0,48	4,76
7C	3,00E+00	0,48	4,76
7D	< 3	0,48	4,76
7E	< 3	0,48	4,76
7F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
8A cont	< 3	0,48	4,76
8B cont	< 3	0,48	4,76
8C cont	< 3	0,48	4,76
8D cont	< 3	0,48	4,76
8E cont	3,00E+00	0,48	4,76
8F cont	< 3	0,48	4,76

Figure B.4: Treatment IV

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
9A	< 3	0,48	4,76
9B	< 3	0,48	4,76
9C	< 3	0,48	4,76
9D	< 3	0,48	4,76
9E	< 3	0,48	4,76
9F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
10A	3,00E+00	0,48	4,76
10B	< 3	0,48	4,76
10C	< 3	0,48	4,76
10D	< 3	0,48	4,76
10E	< 3	0,48	4,76
10F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
11A	< 3	0,48	4,76
11B	< 3	0,48	4,76
11C	< 3	0,48	4,76
11D	< 3	0,48	4,76
11E	< 3	0,48	4,76
11F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
12A cont	< 3	0,48	4,76
12B cont	< 3	0,48	4,76
12C cont	< 3	0,48	4,76
12D cont	< 3	0,48	4,76
12E cont	< 3	0,48	4,76
12F cont	< 3	0,48	4,76

Figure B.5: Treatment V

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
13A	< 3	0,48	4,76
13B	< 3	0,48	4,76
13C	< 3	0,48	4,76
13D	< 3	0,48	4,76
13E	< 3	0,48	4,76
13F	1,09E+02	2,04	3,20

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
14A	< 3	0,48	4,76
14B	< 3	0,48	4,76
14C	9,00E+00	0,95	4,28
14D	< 3	0,48	4,76
14E	< 3	0,48	4,76
14F	9,00E+00	0,95	4,28

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
15A	< 3	0,48	4,76
15B	< 3	0,48	4,76
15C	< 3	0,48	4,76
15D	7,18E+02	2,86	2,38
15E	< 3	0,48	4,76
15F	1,50E+01	1,18	4,06

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
16A cont	< 3	0,48	4,76
16B cont	< 3	0,48	4,76
16C cont	< 3	0,48	4,76
16D cont	< 3	0,48	4,76
16E cont	< 3	0,48	4,76
16F cont	< 3	0,48	4,76

Figure B.6: Treatment VI

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
17A	< 3	0,48	4,76
17B	< 3	0,48	4,76
17C	< 3	0,48	4,76
17D	3,00E+00	0,48	4,76
17E	< 3	0,48	4,76
17F	2,45E+01	1,39	3,84

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
18A	< 3	0,48	4,76
18B	< 3	0,48	4,76
18C	< 3	0,48	4,76
18D	< 3	0,48	4,76
18E	< 3	0,48	4,76
18F	5,18E+01	1,71	3,52

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
19A	n.d.	n.d.	n.d.
19B	n.d.	n.d.	n.d.
19C	n.d.	n.d.	n.d.
19D	n.d.	n.d.	n.d.
19E	n.d.	n.d.	n.d.
19F	n.d.	n.d.	n.d.

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
20A cont	< 3	0,48	4,76
20B cont	< 3	0,48	4,76
20C cont	< 3	0,48	4,76
20D cont	< 3	0,48	4,76
20E cont	1,50E+01	1,18	4,06
20F cont	< 3	0,48	4,76

Figure B.7: Treatment VII

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
21A	< 3	0,48	4,76
21B	< 3	0,48	4,76
21C	< 3	0,48	4,76
21D	< 3	0,48	4,76
21E	< 3	0,48	4,76
21F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
22A	3,00E+00	0,48	4,76
22B	< 3	0,48	4,76
22C	< 3	0,48	4,76
22D	< 3	0,48	4,76
22E	< 3	0,48	4,76
22F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
23A	n.d.	n.d.	n.d.
23B	n.d.	n.d.	n.d.
23C	n.d.	n.d.	n.d.
23D	n.d.	n.d.	n.d.
23E	n.d.	n.d.	n.d.
23F	n.d.	n.d.	n.d.

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
24A cont	n.d.	n.d.	n.d.
24B cont	n.d.	n.d.	n.d.
24C cont	n.d.	n.d.	n.d.
24D cont	n.d.	n.d.	n.d.
24E cont	n.d.	n.d.	n.d.
24F cont	n.d.	n.d.	n.d.

Figure B.8: Treatment VIII

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
25A	< 3	0,48	4,76
25B	< 3	0,48	4,76
25C	< 3	0,48	4,76
25D	3,00E+00	0,48	4,76
25E	< 3	0,48	4,76
25F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
26A	< 3	0,48	4,76
26B	< 3	0,48	4,76
26C	< 3	0,48	4,76
26D	< 3	0,48	4,76
26E	< 3	0,48	4,76
26F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
27A	< 3	0,48	4,76
27B	< 3	0,48	4,76
27C	< 3	0,48	4,76
27D	< 3	0,48	4,76
27E	< 3	0,48	4,76
27F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
28A cont	< 3	0,48	4,76
28B cont	< 3	0,48	4,76
28C cont	< 3	0,48	4,76
28D cont	< 3	0,48	4,76
28E cont	< 3	0,48	4,76
28F cont	< 3	0,48	4,76

Figure B.9: Treatment IX

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
29A	< 3	0,48	4,76
29B	3,38E+02	2,53	2,70
29C	3,00E+00	0,48	4,76
29D	< 3	0,48	4,76
29E	< 3	0,48	4,76
29F	6,00E+00	0,78	4,46

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
30A	< 3	0,48	4,76
30B	< 3	0,48	4,76
30C	< 3	0,48	4,76
30D	< 3	0,48	4,76
30E	< 3	0,48	4,76
30F	6,00E+00	0,78	4,46

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
31A	< 3	0,48	4,76
31B	< 3	0,48	4,76
31C	< 3	0,48	4,76
31D	< 3	0,48	4,76
31E	< 3	0,48	4,76
31F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
32A cont	< 3	0,48	4,76
32B cont	< 3	0,48	4,76
32C cont	< 3	0,48	4,76
32D cont	< 3	0,48	4,76
32E cont	< 3	0,48	4,76
32F cont	< 3	0,48	4,76

Figure B.10: Treatment X

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
33A	< 3	0,48	4,76
33B	< 3	0,48	4,76
33C	< 3	0,48	4,76
33D	< 3	0,48	4,76
33E	< 3	0,48	4,76
33F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
34A	< 3	0,48	4,76
34B	< 3	0,48	4,76
34C	< 3	0,48	4,76
34D	1,20E+01	1,08	4,15
34E	< 3	0,48	4,76
34F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
35A	3,00E+00	0,48	4,76
35B	< 3	0,48	4,76
35C	< 3	0,48	4,76
35D	1,80E+01	1,26	3,98
35E	< 3	0,48	4,76
35F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
36A	6,00E+00	0,78	4,46
36B	< 3	0,48	4,76
36C	< 3	0,48	4,76
36D	3,00E+00	0,48	4,76
36E	< 3	0,48	4,76
36F	< 3	0,48	4,76

Figure B.11: Treatment XI

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
37A	< 3	0,48	4,76
37B	< 3	0,48	4,76
37C	< 3	0,48	4,76
37D	< 3	0,48	4,76
37E	< 3	0,48	4,76
37F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
38A	< 3	0,48	4,76
38B	7,80E+01	1,89	3,34
38C	< 3	0,48	4,76
38D	< 3	0,48	4,76
38E	< 3	0,48	4,76
38F	< 3	0,48	4,76

BUSTA	ufc/punto	log ufc/punto	riduzione log ufc/punto
39A cont	< 3	0,48	4,76
39B cont	< 3	0,48	4,76
39C cont	< 3	0,48	4,76
39D cont	< 3	0,48	4,76
39E cont	< 3	0,48	4,76
39F cont	< 3	0,48	4,76

Figure B.12: Treatment XI

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