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A critical assessment of the application of HACCP in different areas of public health and medicine

Master Thesis

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Not everything that can be counted counts, and not everything that counts can be counted.

(Albert Einstein)

For Hans-Jürgen
with love

Abbreviations

CCP	Critical control point
CDC	Centers for Disease Control and Prevention
DOV	Department of Health, England
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agricultural Organisation
FDA	Food and Drug Administration
FMEA	Failure, Mode, Effect Analysis
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
ICMSF	International Commission on Microbiological Specification for Foods
LFGB	Lebensmittel- und Futtermittelgesetzbuch
LMHV	Lebensmittelhygiene Verordnung
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NAS	National Academy of Science
NASA	National Aeronautics and Space Agency
QRA	Quantitative risk assessment
SARS	Severe acute respiratory syndrome
WHO	World Health Organisation

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1. Introduction

The Hazard Analysis and Critical Control Points (HACCP) is a well known and widely accepted management system initially implemented in the food industry. It is the systematic approach to control potential hazards in an operation. The target of the HACCP is to identify the problems (hazards) before they occur. The system establishes mechanisms to control all stages of a process. This kind of control is proactive which means the identification of potential hazards, preventive measures, and the establishment of monitoring and remedial actions thereby avoiding the occurrence of hazards in advance. HACCP is described as a "concept of zero error" (Null-Fehler-Konzept)[1].

1.1 Structure of HACCP

The first step requires a hazard analysis, an evaluation and knowledge of potential risks which could occur during a specific process. A hazard is defined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as "a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control"[2].

The first category of the hazards, the biological or microbiological source, is divided into three classes: bacterial, viral and parasitic. Many of the HACCP programmes were developed around these hazards[3]. The International Commission of Microbiological Specification for Food (ICMSF) has classified these hazardous microorganisms according to their severity of risk[4]. These bacterial hazards can result either in foodborne infection or intoxications. The source, the symptoms of the resulting disease and the food associated vary significantly and can be caused by a large variety of pathogens[5]. An implemented HACCP programme with regard to these hazards has three basic targets. The first one should be to reduce, eliminate or destroy the hazard. Second, the programme should be able to prevent a recontamination and the last aim is to inhibit the growth and toxin production.

The second category describes hazards of chemical origin. All food products contain chemicals and as any chemical substance, they can be toxic at a certain dosage. However, there are chemicals which are prohibited in food and others which are allowed only in limited amounts. There are two types of chemical hazards in foods, naturally occurring and

supplementary chemicals[3]. The formal limits for naturally occurring toxins have been established in the Code of Federal Regulation, title 2. The informal maximum allowable limits have been described in the Compliance Policy Guidelines of the Food and Drug Administration.

The added chemicals are inserted in foods during the time of growing, harvesting, processing, storage and distribution. These chemicals are allowed only within the permitted limits. They include agricultural chemicals, like pesticides or herbicides regulated by the Environmental Protection Agency (EPA), further the prohibited substances listed in Title 21, Part 189 of the Code of Federal Regulations and finally toxic elements, like lead or arsenic. The latter are either not allowed in food or only within established maximum limits. Finally added chemicals also include colour additives, preservatives and substances improving flavour or nutritional fortification.

In addition, there are substances which occur or belong to the production process of food, like cleaners and sanitizer which do not belong to food but might probably be incorporated. The Good Manufacturing Practices (GMP) has set the limits for these substances.

The third category, the physical hazards include hazard as extraneous matter or foreign objects. These physical matters not normally found in food, may lead to illness or injury of a person[6]. One of the most common objects complaint of in food is glass[3]. These physical hazards demonstrate a gap in the production process which can lead to an unacceptable health risk. Methods to control these kinds of hazards include the raw material specification and the inspections of certification and guarantees as well as the education and training of the employees.

1.1.1 Preparation of the HACCP application

The NACMCF has recommended to establish a prerequisite program before the application of the HACCP principles. This program describes the basic environmental and operating conditions of the process. The principles should be developed and managed separately from the HACCP plan and regularly audited to ensure the existence and effectiveness of these programs.

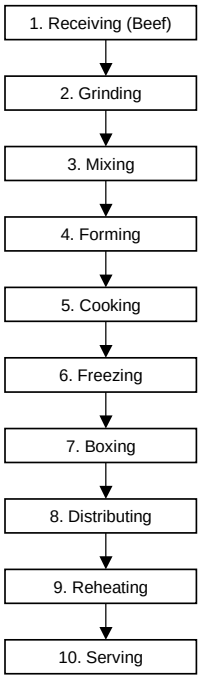
An essential part for the successful implementation and realisation of a prerequisite program is the education and training of the staff involved. The employees should learn the skills necessary to make the process successful and also should be enabled to appreciate the sense

and benefit of this method. This includes precise training activities specific to the product or process. Therefore it is recommended to develop a HACCP plan which includes a variety of different tasks.

The first task describes the assembly of a HACCP team. This team consists of people with special expertise concerning to the product or process. The composition of the group should be multidisciplinary and incorporate people from various areas involved.

The next task illustrates the product or process itself. This description should include both all general and specific information. A complete specification enables the team to get a comprehensive picture of the process and consequently they are able to identify the expectations of the end user or consumer. The final task includes the development of a flow diagram of the process. This is a diagrammatic description of the steps of the process. Each step or sequence requires an individual and specific flow chart. The flow diagram could be a simple block-type diagram (Figure 1) or very complex depending on the extent on the procedure (Figure 3). The HACCP team should carry out an on-site review of the flow diagram to confirm its suitability and usefulness. If required, modifications should be implemented and documented respectively. After completing these preliminary tasks the so called “seven principles of HACCP” can be applied. These principles demonstrate the establishment, implementation and maintenance of the HACCP. The principles have international acceptance and details of this approach have been published by the Codex Alimentarius Commission (1991)[7] and the NACMCF in 1992[8].

Figure 1: Block-type diagram



Note: Example of a Flow Diagram for the production of Frozen Cooked Beef Patries[16]

1.1.2 The HACCP principles

Principle 1:

To conduct a hazard analysis. To prepare a list of specifying steps where significant hazards can occur and describe the preventative measures.

After developing the flow diagram the potential hazards with regard to the biological, chemical or physical risks in the process must be determined. These hazards could occur at each step of the process from the very beginning to the end. A potential hazard is included in

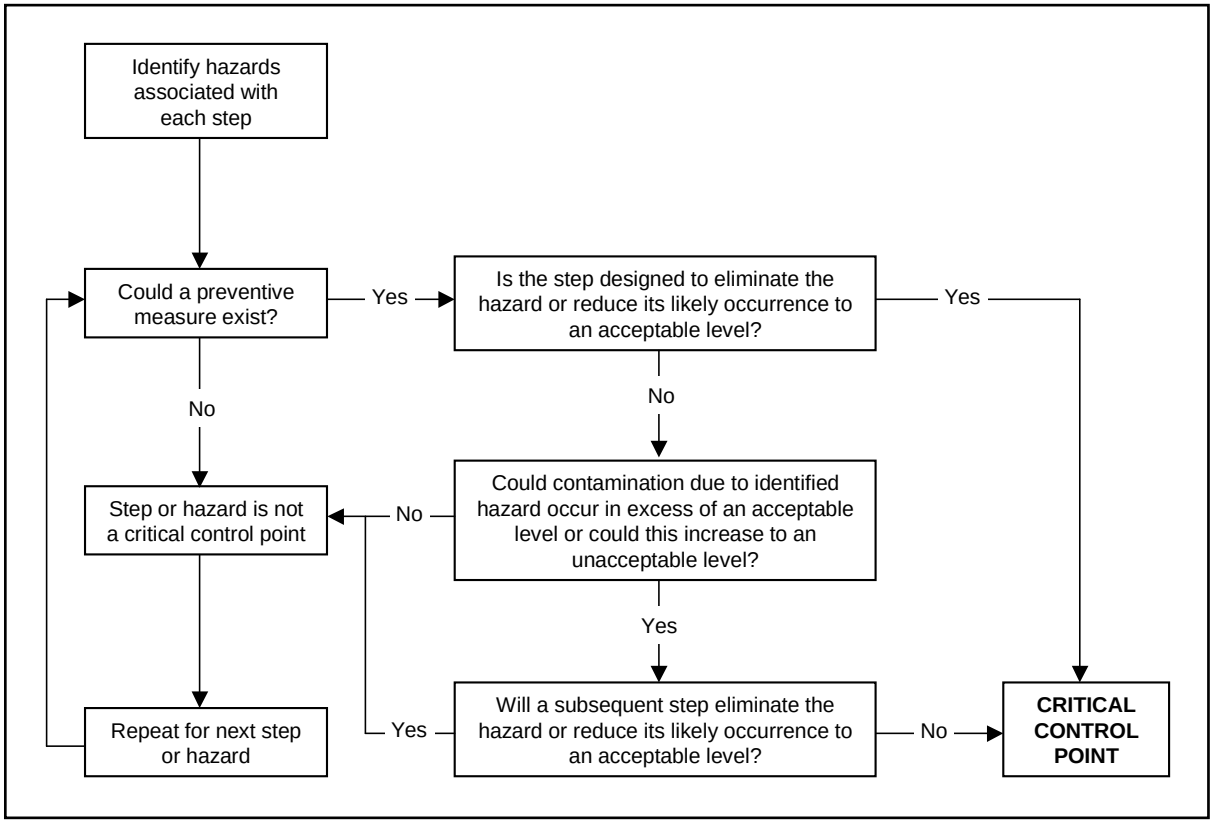
the list if the elimination or reduction of this hazard is essential for the safety and quality of the process. Hence, the HACCP team describes a preventative measure in order to control each hazard. It is possible that more than one preventative measure is necessary to control one specific hazard and that more than one hazard could be controlled by a single preventative measure.

Principle 2:

Determine the points, procedures and operational steps (critical control points – CCPs) that can be controlled to eliminate the hazards or minimise their likelihood of occurrence.

Critical control points have to be identified for each model. They should guarantee the safety or quality of a product or process. The identification of these points is very often a point of discussion within companies or institutions building their own individual HACCP plan. To determine a suitable number of critical control points might be very complex because too many points could make the system unmanageable. On the other hand, too few points would not ensure entirely the safety or quality of the product or process. An approach to identify critical control points is to use a decision tree.

Figure 2: The HACCP decision tree[9]



By applying the HACCP decision tree (Figure 2) the team is able to define those steps which are critical to the product or process. They can set targets and the acceptable tolerances for each critical control point and determine how, when and by whom the critical control point is to be measured and observed.

In addition, there have to be instructions and procedures for dealing with deviations from the acceptable tolerance. The monitoring of the critical control points is carried out by record keeping and continuous documentation.

Principle 3:

To establish target levels and tolerances which must be met to ensure the CCP is under control

Target levels and tolerances describe the difference between safe and unsafe products or processes at a critical control point. They determine the acceptable maximum and minimum of each level. Each critical control point of the sequence will have one or more control measures. These control measures should prevent, eliminate or reduce the potential hazards and each of these control measures has one or more associated critical limits. These limits must be measurable and scientifically based.

Principle 4:

To establish a monitoring system to ensure control of the CCP by scheduled testing or observation

The regular and effective monitoring of a sequence is very important and necessary. The establishment of this tool includes the answer of the questions what, why, how, where, who and when have to be monitored and observed[10]. The question “what is monitoring” elucidates that monitoring is an action. It is not something that is set up, turned on and then ignored. It is a continuously ongoing procedure. The question “why monitoring” includes not only the collection of data and information of the process. Monitoring includes observation and measurement. It also includes the fast and appropriate reaction to a possible deviation. Observation leads to qualitative indices and measurement leads to quantitative indices. It depends on the established critical limit which kind of index is the most suitable. By applying the question “where do we monitor” the team should consider where it is ideal to monitor with minimal or without interruption of the production flow. Personnel who monitor must be trained in the monitoring process for which they are responsible. They must have a full understanding of the purpose and importance of monitoring. In addition, they must be unbiased in monitoring and reporting. Moreover it is essential that the management

responsible has confidence in the employees who are responsible for the monitoring process. Lastly, regarding the question “when do we monitor” also the question includes “how often”. As mentioned above, monitoring is a continuous process, therefore a permanent monitoring must be implemented. The frequency of monitoring can be handled differently depending on the amount of acceptable risk.

Principle 5:

To establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control

The HACCP system is developed to discover potential hazards in a process and to set up strategies to prevent, reduce or eliminate their occurrence. A corrective action is necessary and should include the guidance on how to identify and correct the cause of non-compliance, how to determine the disposition of the noncompliant product and how to record the corrective actions that have been taken. These specific corrective actions should be developed in advance for each critical control point. The responsibilities must be distributed and every person involved in the process as well as in the corrective action should be properly informed.

Principle 6:

To establish procedures for verification, including supplementary tests and procedures to confirm that HACCP is working effectively

Verification describes activities that determine the validity of the HACCP plan and the operation procedures. Apart from monitoring, processes like auditing are essential. They should be established during the process of designing and implementing the HACCP plan. Such activities could be the review of the HACCP system, its records and deviations. Further it can include procedures to observe if critical control points are actually under control and also examine the validation of the established targets and tolerances.

The verification activities are screened by individual unbiased experts within a company, an institution, third party experts or regulatory agencies.

Principle 7:

To establish documentation concerning all procedures and records appropriate to these principles and their application

The overall success of the application of the HACCP system strongly depends on the efficient and accurate record keeping. A careful and precise documentation demonstrates that the system is under control. The documentation covers the entire HACCP plan including all points mentioned in the other principles and should include a summary of the hazard analysis with the description of the potential hazards and the resulting control measures.

1.2 Development and implementation

Today, the Hazard Analysis and Critical Control Points, initially implemented in the food industry is a well known and widely accepted management system. It was originally developed in 1959 by the Pillsbury Company in cooperation with the National Aeronautics and Space Agency (NASA), the Natick Laboratories of the U.S. Army and the U.S. Air Force Space Laboratory Project Group. The aim was to develop a microbiological safety system for food consumed by the astronauts[9]. At this time, most food safety systems were based on "snap-shot" inspection and end-product testing. This kind of testing could not assure a 100% safety of the product. Consequently, there was a need for a new method – a preventive system- to guarantee safe food. The successful development of the HACCP system presented a totally new approach in quality assurance. The development of such system was of great importance since every kind of contamination would lead either to a space mission failure or a catastrophe[11]. The new approach, the HACCP, was developed on the basis of an engineering system: Failure, Mode, Effect Analysis (FMEA). The system analyses which crucial points in a process could potentially go wrong[12].

In 1971 the National Conference on Food Protection (U.S. Dept. HEW 1972) presented the HACCP system to the public and in the same year the Pillsbury Company implemented the method in their company. After this convention the Food and Drug Administration (FDA) offered Pillsbury company a contract to conduct classes for FDA personnel on this method. In addition, the ICMSF recommended the HACCP to the food industry[13]. In 1985 the implementation of HACCP was officially recommended by the National Academy of Science (NAS)[14]. Later the NAS advised the foundation of an institution, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)[2] which should guarantee a continuous improvement and development of the system beyond the microbiological risk

analysis. Further, the Codex Alimentarius Commission, founded in the 1960s by the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) described the "seven principles of the HACCP" taking into consideration the developments over the last 20 years[7].

Since then, the HACCP has been further advanced and modified by different reviews in 1992, 1995 and 1997 by the NACMCF[8,15,16]. The committee made the principles concise. They revised and added definitions and also included a section on prerequisite programmes, education and training, as well as on implementation and maintenance of the HACCP plan. In addition, they provided a more detailed application of the HACCP principles and also a decision tree for identification of the critical control points (CCP).

Furthermore, the FAO/WHO in 1998 established guidelines for the regulatory assessment of HACCP and the WHO included these guidelines in their recommendation ensuring the supply of safe water[17,18].

The European Union (EU) in 1993 adopted some parts from the concept in the regulations of Hygiene of Foodstuff[19] (guideline 93/43/EWG). In Germany in 1998 the ministry responsible has established parts of this law in the Food Hygiene Ordinance (Lebensmittelhygiene-Verordnung – LMHV)[1]. Since then, this system was being successfully implemented by a variety of companies and institutions[20,21]. Since January 2005 the EU has passed a standardised Food law for all countries (basic regulation (EG) 178/2002) which has been implemented into national law of each individual European country. The actual law the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuches (LFGB)) came into force on September 1st 2005. From January 1st 2006 the German Food Hygiene Ordinance (Lebensmittelhygiene Verordnung (LMHV) has been replaced by the basic regulation (EG) Nr.852/2004 concerning Food Hygiene. This new law requires the food industry to install internal self-control measures according to the principles of HACCP and consequently this included the mandatory written documentation of the system (article 5, No.852/2004).

1.3 Areas of application of HACCP in the food industry

The HACCP has been successfully implemented in different areas in the food industry for several years and became a very important tool in food control. The control of a process is based on prevention. This approach differs from the traditional regulatory measure of food control[12] which was based on the observation and testing of samples. It was more a "snap-

shot" inspection and end-product testing. The control of the food took part at the end of the production chain, consequently the procedure of troubleshooting was always retrospective. This system provided little health protection, particularly regarding contamination[9]. The HACCP method describes a preventative approach which helps to identify potential hazards before they occur. It is possible to use this system as a method of food safety assurance. The method is able to guarantee a safe processing-line from "farm to fork" in the production of a product[1]. The resources necessary can be concentrated on the critical control points rather than being spread across the whole process. An increase of the effectiveness is only possible through training and education of the staff. This training strategy differs from the traditional approach where only parts of the staff were involved. The HACCP system requires the entire staff at all levels to be coached. This strategy represents a new approach for the staff not only to react in case of a hazard but to prevent a hazard. This involves a broader view in the identification of problems in the production or process-line regarding the potential risks. Evaluating the whole concept of HACCP, Mortimer & Wallace (1997)[12] described the technique as flexible and possible to apply in a variety of areas such as product quality, work practices and also to products outside the food industry. Primarily used in the traditional food industry, different sectors within this industry have started to implement this management system, such as catering services.

The Department of Health, England (DOV), has advised the application of these guidelines for cook-chill and cook-freeze processing of food as a system to avoid and control potential hazards. This industrial branch has not been confronted with risk assessment in the production of a single product. They are faced with a large variety of foods and therefore they have to implement more complex HACCP plans. In order to avoid foodborne infections, special expertise particularly in the field of microbiology is required. The catering industry has been aware of these risks and has developed a HACCP system suitable for catering[9].

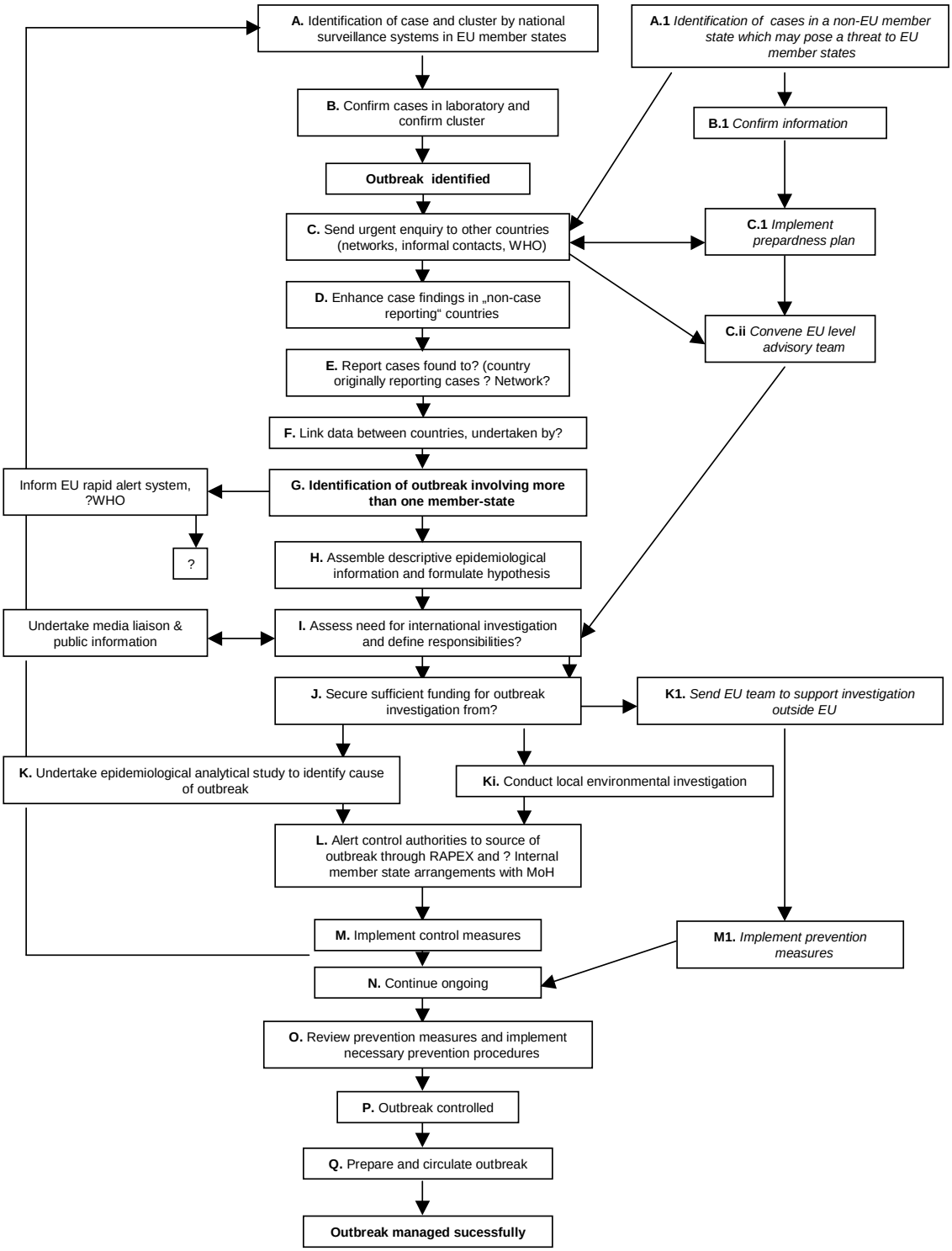
Aviation catering is a branch of steady expansion. A foodborne disease outbreak in this area could affect the passengers as well as the crew, with possible fatal consequences[22]. Few of these foodborne outbreaks in civil aviation involving a wide range of pathogens have been published[23-25]. In 1985 Beers and Mohler[26] described that food poisoning had been a long-lasting periodic problem on aircrafts and was the leading cause of in-flight pilot incapacitation at that time. Airlines were aware of these problems and have started to implement the HACCP method, like the LSG Lufthansa Service Holding AG, in the late 1980s. Since then, the LSG Lufthansa has developed a comprehensive hand book about the quality management strategy in airline catering including the HACCP[21].

1.4 HACCP in public health

One of the main aspects in the investigation of **foodborne disease** outbreak is the identification of the cause of the outbreak. In the last years research groups have started to re-evaluate the possibility of implementing the HACCP in the field of infectious diseases.

Apart from the identification of the cause of an outbreak they have used the HACCP to evaluate the management process in case of an outbreak as well as in the risk assessment and in the determination of prevention measures[28]. The implementation of HACCP to evaluate the management of epidemiological emergencies was first described in the publication of the Landesinstitut für den öffentlichen Gesundeitsdienst NRW, Germany[27].
This research group was part of an EU project which investigated outbreaks involving more than one EU member state. Their approach using the HACCP was to detect weaknesses in different areas of the surveillance network (Figure 3). Figure 3 as well as figure 4 demonstrate impressively the complexity to identify all involved internal and external factors to get a complete analysis of the process. MacLehose et al (2001)[29] investigated the context in which epidemiological emergencies were managed with the target to formulate recommendations for future activities and to define criteria for a successful management of an outbreak. Based on their results they demanded an improvement within the national surveillance systems[29].

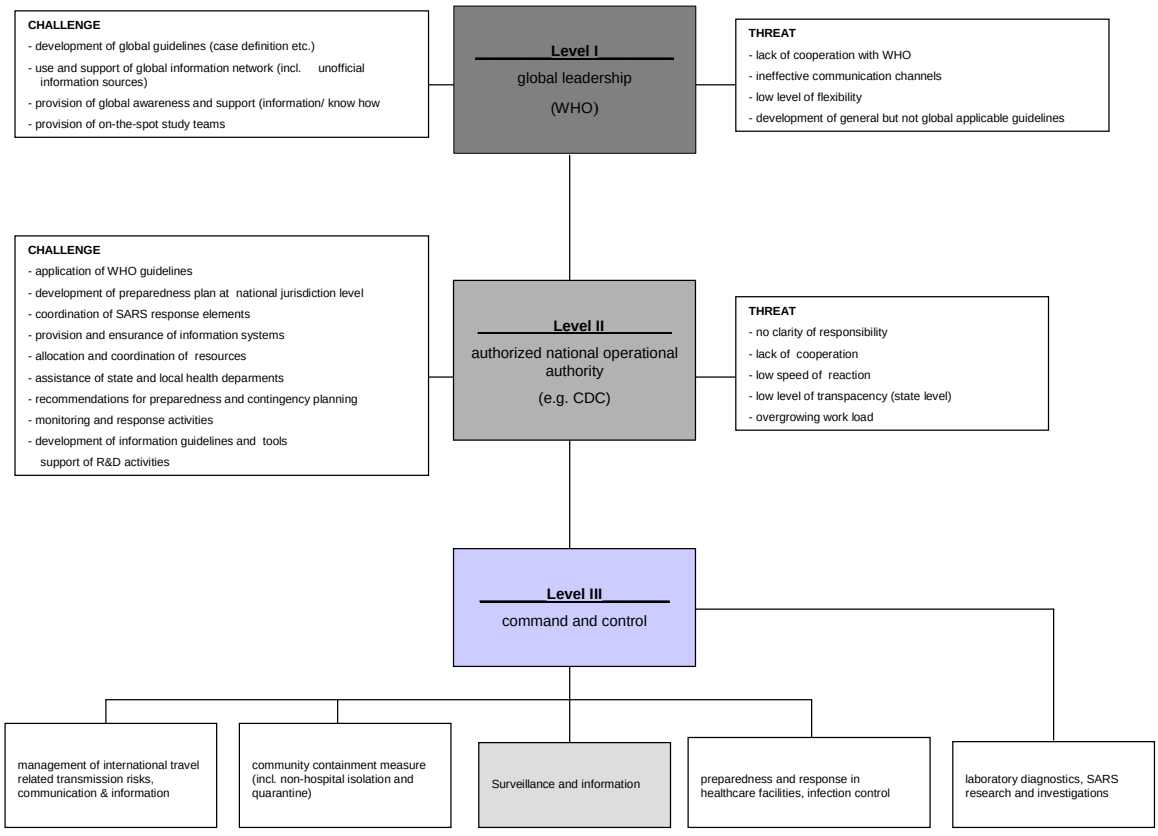
Figure 3: Basic Process Flow Diagram: the outbreak management process[27]



Kassen (2004)[30] described in her master thesis about Severe Acute Respiratory Syndrome (SARS) Control the evaluation of the Centers for Disease Control and Prevention-Guideline (CDC-GL) with HACCP[31]. The author developed a HACCP model to analyse the management of the SARS **epidemic emergency** (Figure 4). Compared to the research group of MacLehorse et al. (2001)[29] who investigated on national level, Kassen included all three different levels of a global outbreak management on global (WHO), national (e.g. CDC) and hospital levels.

The author described the weaknesses of each level as well as the complexity of the system of such an epidemic. However, the author also emphasised the necessary and the importance in accordance with MacLehorse et al. (2001)[29] of a well organised national surveillance as a basis of successful international surveillance, especially in situations of international alerts.

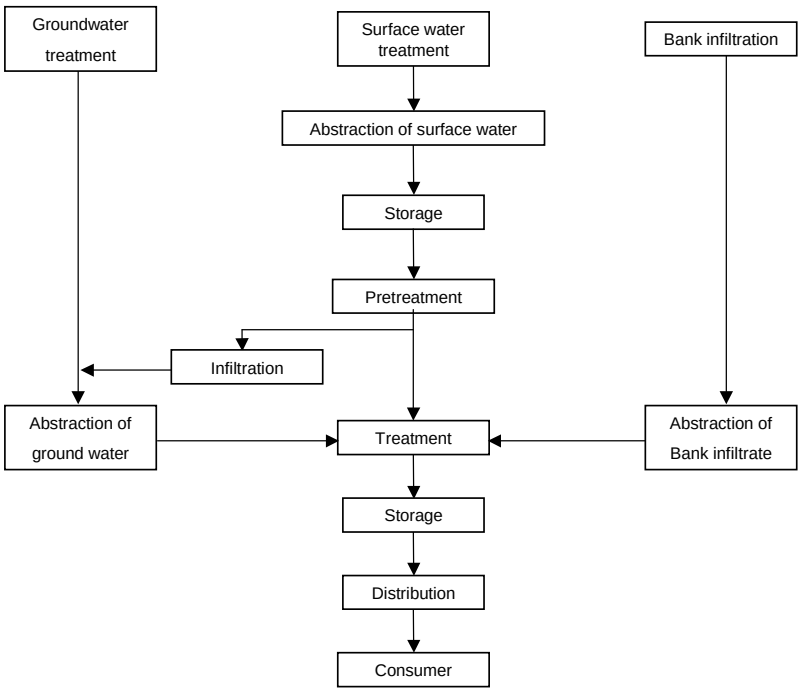
Figure 4: Outbreak management process[30]



Note: HACCP analysis of the SARS outbreak management process. Different levels of outbreak management are indicated by level I (global leadership), level II (authorized national operational authority), and level III (command and control).

A totally different field which dealt with national and international structures is the **drinking water production.** In food production the goal is to eliminate hazards and to prevent contamination[32]. In contrast, the production chain of drinking water already contains a major bacterial hazard: waste water. However, in the mid nineties the discussion has started about the applicability of HACCP in the water production. Until this time similar approaches to assure the quality of drinking water, for example total quality management on the basis of ISO 9000 and the use of quantitative risk assessment (QRA) has been introduced in this field[33]. The quantitative risk assessment also defines critical limits which fitted very well in the HACCP system. Although Havelaar (1994)[33] described the HACCP as a useful framework in this area, he assessed the system as mainly qualitative and maybe subjective, because the definition of critical control points was incumbent on the opinion of experts. Nevertheless the author emphasised the importance to implement a preventive system in this field.

Figure 5: Generalised flow-sheet for drinking water supply[33]



The implementation of HACCP in the drinking water production or safety includes very different fields of application (Figure 5). Dewettinck et al. (2001)[34] investigated the possibility to integrate treated domestic waste-water of a wastewater treatment plant in the existing potable water production process. Because there were considerations that the groundwater extraction in this area of Belgium has reached its maximum capacity and the drinking water supply could not be guaranteed anymore in the future for the public. Davison and Deere (1999)[35] discussed already the relevance of HACCP with regard to the Australian tap water supplies. Therefore Dewettinck et al. (2001)[34] implemented the HACCP concept to guarantee hygienically safe drinking water production.

Based on the HACCP analysis they developed a specific monitoring strategy to assure safe water reuse which was technically but also psychologically acceptable for the public.

Another approach using the HACCP was described by Westrell et al. (2004)[32]. The conservation of natural resources is part of the work of the Swedish Environmental Protection Agency. This includes the reuse of nutrients from wastewater and sewage sludge for agricultural land. In this context the transmission of diseases through reuse practices is possible but highly unwanted. Based on this challenge the authors described the necessity of the use of a risk management system that would be able to control possible health risks and would lead to more public acceptability towards different recycling alternatives. The study group combined in their investigation the quantitative microbial risk assessment with the HACCP, especially because HACCP has been part of the Water safety plans in the WHO Guidelines for drinking water quality since 2003[18]. In contrast to Dewettinck et al. (2001)[34] who adopted the HACCP in a wastewater reuse system for groundwater recharge and drinking water production, Westrell et al. (2004)[32] used the system to investigate the health risk regarding different exposures, such as the aerosol contamination of the workers of the wastewater treatment plant and the public who used the wetland as recreational areas.

A third approach using the HACCP within the frame of the WHO Guidelines for drinking water quality is described by Jagals & Jagals (2004)[36]. They implemented the method to control the water quality and to avoid water-related diseases. Communicable water-related diseases were described as a widespread health problem, not only in developing countries but also possible in developed country. In the United Kingdom for instance, since 1988 25 known outbreaks regarding contaminated drinking water were recorded[37]. Jagals & Jagals (2004)[36] thought that the implementation of HACCP with the estimation of critical control points through the whole production process would offer an advantage in opposite to the traditional monitoring of the intake of water and end-product investigations. The information of contaminated water is often received too late for fast corrective actions. Therefore they implemented the HACCP in their investigations and finally recommended the use of a comprehensive HACCP plan is this field.

1.5 HACCP in medicine

HACCP in medicine has been applied in two different fields: **process analysis** and **testing of products**. In 1990 a research group investigated the practicability of using HACCP with regard to the problems of hospital infection control[38]. The HACCP was implemented on a neonatal unit in Chester, United Kingdom, which did not have a milk bank to provide expressed breast milk for the babies. Therefore they were confronted with a number of hazards which could affect inpatient women as well as already discharged mothers. Control mechanisms to provide safe milk were not routinely performed, such as the microbiological testing of the expressed breast milk. After the analysis they implemented different kinds of control options. Finally, the author concluded that much of the processes of HACCP are the application of simple common sense. Nevertheless, the use of the method in a clinical setting may provide a variety of benefits. As a major benefit he described the team approach and also the involvement of several experts in combination with the preventive approach of this method which minimizes the risk to overlook important points.

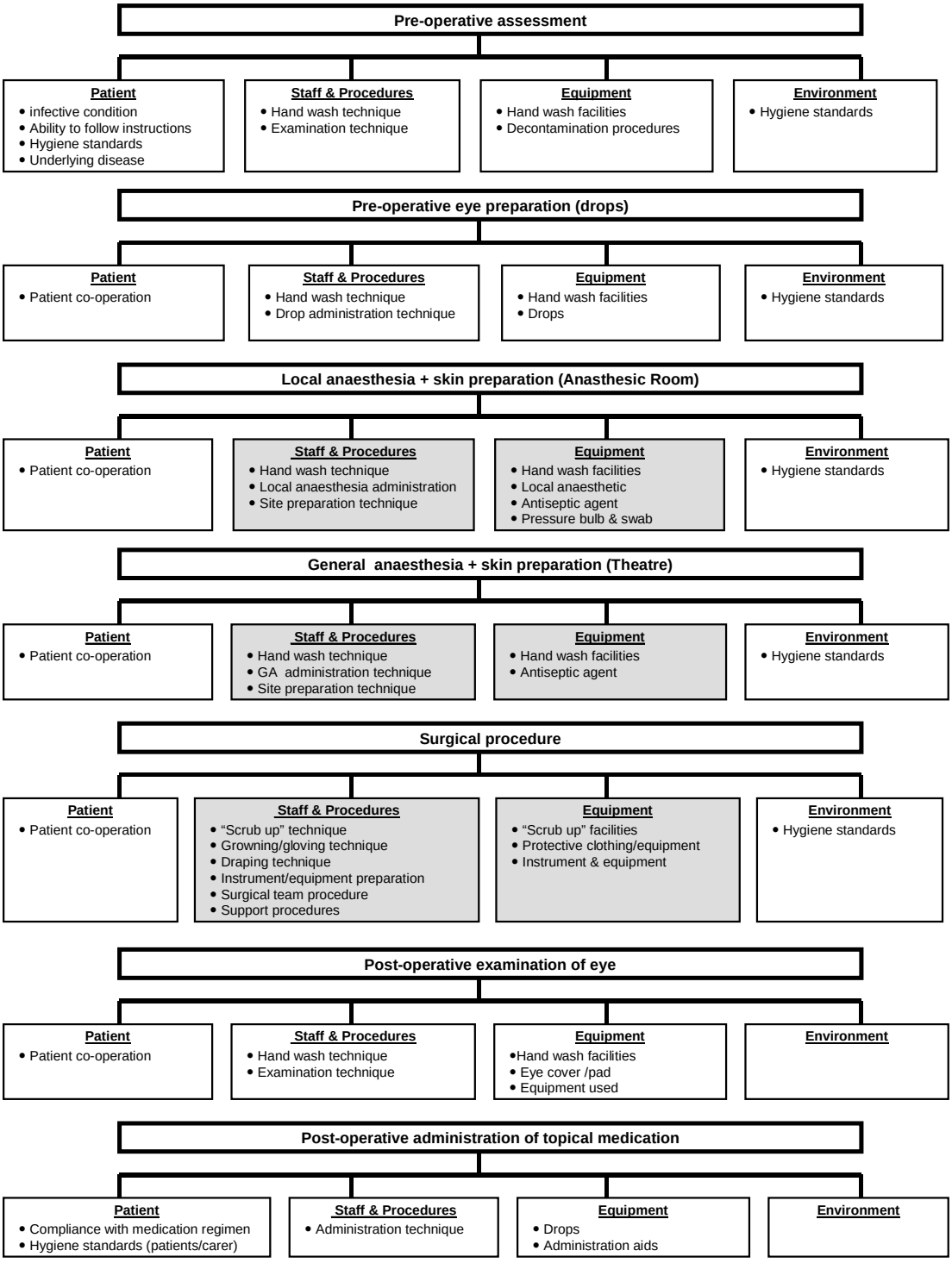
Unfortunately the research group had to realise that the control options were not practicable within the available resources and consequently the provision of expressed breast milk on this unit was stopped. Nevertheless, in his article Hunter (1991)[38] recommended to think about a wider application to hospital infection control, medical audit and parenteral nutrition.

In 2001 the study group Baird et al.[39] used the HACCP to combine infection control measures with operative procedures analysis. The ophthalmology unit informed the infection control team that the number of early infective endophthalmitis as postoperative complications had increased. The infection control team investigated the situation, recognized a lack of standardizations, evaluated the circumstances and gave recommendations for improvements. However, over the following months new cases occurred. This indicated the need for a radically different approach and implementation of HACCP was recommended.

They developed a comprehensive flow chart and assessed the critical control points. On the basis of this flow chart they recognized the most significant areas of risk and areas of postoperative complications were located in the preparation for the surgery (local and general anaesthesia) and the surgical procedure (Figure 6). After establishing different preventive measurements the number of complications decreased.

In this case, where conventional approaches to solve an existing problem had failed, the implementation of the HACCP presented a novel and appropriate method[39]. Nevertheless, the research group emphasised that the time and cost of implementing this method as well as the extent of the process analysis should not be underestimated.

Figure 6: Identification of critical control points in infection control[39]



Note: Shaded boxes represent the most significant areas of risk and are regarded as the main critical control points.

Another approach using the HACCP in process analysis combined with infection control was described in the study of Fijan et al. (2005)[40] carried out in the Republic of Slovenia. Since the laundering process must not only have a cleaning effect but also an antimicrobial effect, they evaluated the hygiene state of the hospital laundry in order to prevent recontamination of textiles. They combined two different risk management tools in their project, the HACCP to analyse the procedures and the RAL-GZ 992 standards to assess the quality standards for textile care of hospital laundry[41]. These standards have been validated by the Robert-Koch-Institute, Germany and the Research Institute Hohenstein, Germany. They decided to select these standards for their research project because they constituted important recommendation for laundries for the member states of the EU[40]. A flow chart was developed to identify the hazards and the critical control points were implemented. In addition, the hygiene level (RAL-GZ 992) was evaluated by microbiological analysis before and after sanitation measures. After implementing and analysing both methods all measured critical control points reached the recommended values with one exception of the hand hygiene of one laundry worker. Therefore, the authors concluded that using the HACCP in combination with RAL-GZ 992 clearly demonstrated the recommended reduction of the contamination of the hospital textiles.

Evaluation and re-evaluation of process analysis are also established in the field of screening programmes. Derrington et al. (2003)[42,43] described the implementation of HACCP to evaluate the quality standards of an already existing screening programme for Down's syndrome in the area of Leicester, United Kingdom. The steering group which was monitoring this screening programme raised the suspicion that there was an incomplete understanding of the screening programme by the patients as well as the staff delivering the programme. Based on the logic sequence of the HACCP they adopted the method to their existing screening programme. They developed a very comprehensive flow chart to enclose all institutions and persons involved in the project. The authors showed impressively how time and work consuming it was to establish the whole concept of the HACCP, especially in case of process analysis with a huge number of different professional groups and organizations involved. After identification of the hazards they developed critical control points. At this stage the HACCP method successfully highlighted a number of important problems divided in two main categories: general problems related to the programme per se and problems related to specific operational parts of the programme pathways. Derrington et al. (2003)[42,43] also concluded that these problems had not been clarified by the conventional, mainly quantitative evaluation methods used in the past. The systematic stepwise nature of the HACCP concept enabled a continuous clear vision of the objectives throughout the whole

process. Both research groups emphasised that the HACCP method should be repeated to evaluate the implementation of the changes.

A further approach using HACCP within the manifold procedures in hospitals was carried out in the field of the enteral tube feeding. This kind of feeding does not only include the process analysis of the nutrition itself but also the investigation of the necessary medical devices for this kind of nutrition. Enteral tube feeding provides nutritional support to patients who are unable to be fed orally but whose digestive systems are still functional. Contamination through infectious complications is well documented[44]. The main source of bacterial contamination during the enteral tube feeding is caused by the blenders[45]. Anderton described in 1999[46] the possible strength of the HACCP in this field. HACCP was implemented to identify and evaluate potential hazards during the preparation, storage and the delivery of enteral feeds to patients in a hospital in Brazil[47]. The personnel, the blender, the feed holding containers, the water or the environment were identified as potential hazards. As described in the previous study[45] the blender was the main source of contamination and consequently the correct cleaning and disinfection of the blenders eliminated the bacterial contamination. It was concluded that a systematic preventive approach such as the HACCP was able to eliminate or reduce the hazards in the procedure of enteral tube feeding.

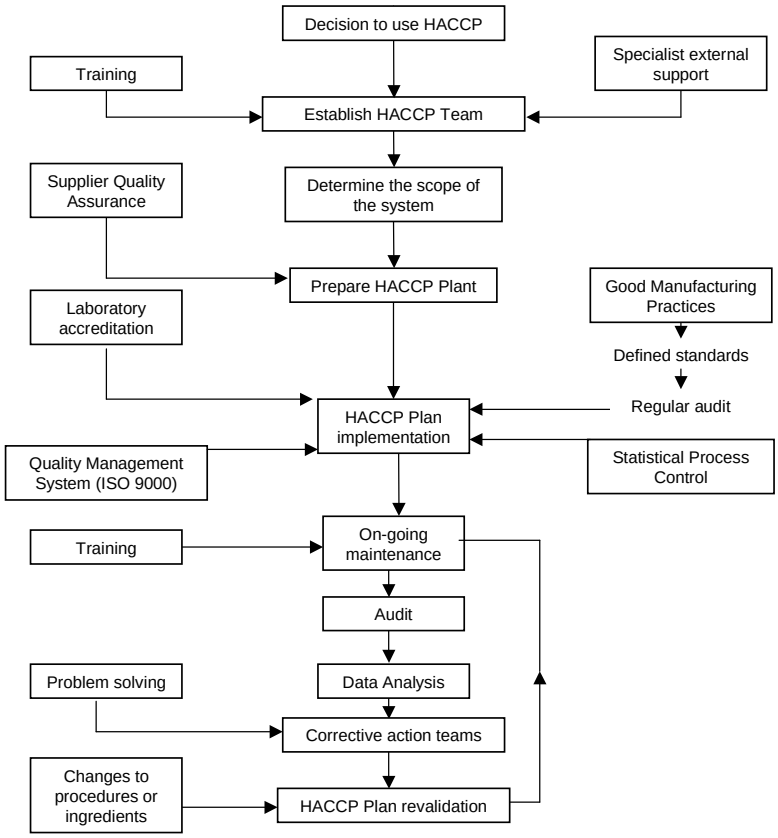
The pharmaceutical industry became increasingly aware of the impact of process conditions and quality control of the resulting product[48]. The EG guidelines require a safety and risk calculation for the manufacturing and the application of medical products[49]. Prior to the introduction of quality control processes, the manufacturing process has to be investigated regarding the possible critical points influencing the quality of the product. Jahnke & Kühn (2003)[20] described the implementation of the HACCP as a useful tool to identify potential hazards during the manufacturing process of medical devices and pharmaceutical products. The production of bone cement was used in their article as an illustrated example using HACCP in this working field. In addition, Jahnke & Kühn (2003)[20] mentioned the successful application of the HACCP system in the cosmetic industries. Another publication described the HACCP approach for cleanroom situations[50].

1.6 HACCP and Quality Management

Quality Management describes all activities that ensure the quality standards within a company or organisation. Different kinds of Quality Management have been already established in medicine[51] and in drinking water production[52]. Many companies base their Quality Management Systems on the international standard series of ISO 9000. ISO 9000 describes a method to ensure that the production of a product meets its specification 100% all the time. ISO 9000 is the equivalent to EN 29000 and BS 5750. This kind of system has the primary target to prevent and detect any non-conforming products during production and distribution[12]. This system is used in a broad spectrum of activities in many organisations.

ISO and HACCP have much in common regarding Quality and Safety Management. These methods are used for Quality Assurance and both integrate the whole staff involved. The approach in these systems is very comprehensive and structured and both systems involve the determination and precise specification of key issues. The following figure 7 demonstrates well-illustrated how these Quality Management Systems including Good Manufacturing Practise can be intertwined with each other.

Figure 7: HACCP and Quality Management Systems[12]



Consequently without an existing and implemented Quality Management Systems the implementation of the HACCP system will not be as effective as it could be. The HACCP method can be easily integrated into existing Quality Management Systems such as ISO 9000.

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2. Aim of the thesis

Aim of this master thesis was to investigate the applicability of a process management system, the Hazard Analysis and Critical Control Points (HACCP), initially implemented in the food industry, in the fields of public health and medicine.

A comprehensive literature review was carried out to search for the available literature in both fields. Selected publications were assessed with regard to the procedure and described problems of the implementation of the HACCP method as well as to the conclusion of the authors using the HACCP system in their respective field. The data were transferred in a data extraction sheet exclusively developed for this master thesis.

Main focus of this study was the evaluation of the described methodical constituents and the assessment of the conclusions and recommendations of the publications.

3. Manuscript of the publication

A critical assessment of the application of HACCP in different areas of public health and medicine: a review

3.1 Abstract

Background: Hazard analysis and critical control points (HACCP) is a well known and widely accepted management system initially implemented in the food industry. It was originally developed to build up a safety system for food consumed by astronauts. Since then, the HACCP has been adopted in public health, medicine, process analysis as well as in the assessment of product quality.

Objective: To assess the implementation of HACCP in the field of public health and medicine.

Material and Method: The systematic literature search was based on electronic bibliographic databases like Medpilot and Dimdi (between 1966 and 2005) using specific key words. Reference lists of relevant primary articles were investigated, literature was hand searched and relevant papers were identified. The study selection included all available literature describing projects or studies using the HACCP in public health and medicine regardless of their design, method or language of publication. A data extraction mask was created in Microsoft Access® for categorising the papers as well as to define reference standards and comparable parameters. In addition, the authors of the primary literature were contacted via e-mail and requested to fill out a standardised questionnaire to get additional information about their projects.

Results: 12 articles met the inclusion criteria. Seven were located in the field of medicine, of which six were focusing on process analysis. The other five were located in public health, two in the water production and three in infectious diseases. Most of the articles described the required methodical components of the HACCP and 10 described the method appropriate for the setting used. Half of the authors answered the questionnaire.

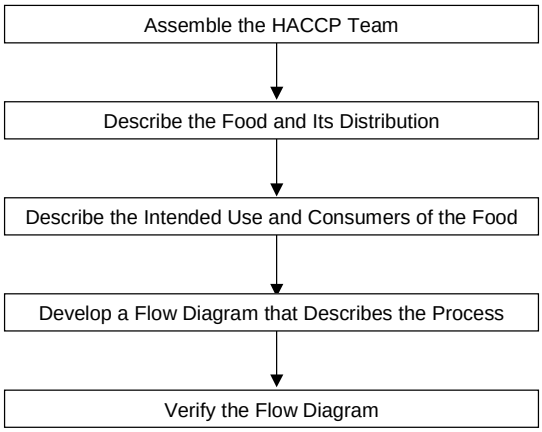
Discussion: The successful implementation of the HACCP was described in medicine and public health in different settings. However, a decisive difference was found between both fields. Whereas the method was used in medicine as a preventive system, in public health, especially in infectious diseases, the system was mainly used to evaluate management processes as well as risk assessment and to determine preventive measures. Therefore, the latter approach required a different definition apart from the classical starting position and a different declaration of the objectives and outcomes.

Conclusion: Provided that a precise definition of the starting point and the objectives is given and an exact implementation of the methodology is possible, it can be recommended to use the HACCP as an additional quality assurance method in public health and medicine.
Key words: HACCP, public health, medicine, process analysis, medical device, infectious disease

3.2 Introduction

The Hazard Analysis and Critical Control Points (HACCP) is a well known and widely accepted management system initially implemented in the food industry. The method is a systematic preventive approach to control potential hazards in operation. The target of this method is to identify problems (hazards) before they occur. The system establishes mechanisms to control all stages of a process. This control method is proactive and based on a "concept of zero-mistake" ("Null-Fehler-Konzept)[1]. The first step requires a hazard analysis, an evaluation analysis of potential risks which could occur during a specific process. A hazard as defined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) can be of biological, chemical or physical origin[2,3]. The NACMCF has recommended to establish a prerequisite program before the application of the HACCP (Figure 8). This program describes the basic environmental and operating conditions of the process. They should be developed and managed separately from the HACCP plan and regularly audited to ensure the existence and effectiveness of these programs. After completing these preliminary tasks the seven principles of HACCP are applied[4]:

Figure 8: Preliminary tasks in the development of the HACCP plan



1) Conduct a hazard analysis
2) Determine the critical control points (CCPs)
3) Establish critical limits
4) Establish monitoring procedures
5) Establish corrective actions
6) Establish verification procedures
7) Establish record-keeping and documentation procedures

These principles demonstrate the establishment, implementation and maintenance of the HACCP. They have international acceptance and details of this approach have been published by the Codex Alimentarius Commission[5] in 1991 and the NACMCF[6] in 1992.

The method was originally developed in 1959 by the Pillsbury Company in cooperation with the National Aeronautics and Space Agency (NASA), the Natick Laboratories of the U.S. Army and the U.S. Air Force Space Laboratory Project Group. The aim was to develop a microbiological safety system for food which assures a 100% safety of the product consumed by the astronauts involved in the United States space programme[7]. At this time most food safety systems were based on "snap-shot" inspection and end product testing. Therefore HACCP presented a totally new approach in quality assurance – a preventive system – to guarantee safe food[8]. Since then, HACCP has been further advanced and modified in a variety of reviews in 1992, 1995 and 1997 by the NACMCF[4,6,9].

In 1993 the European Union adopted parts of the concept in the regulations of the guideline 93/43/EWG regarding the Hygiene of Foodstuff. Since January 2005 the EU has passed a standardised Food law for all European countries (basic regulation (EG) 178/2002) which were later translated into national law.

The HACCP method has been successfully implemented in different areas in the food industry for several years. Mortimer and Wallace (1997)[11] described the technique as flexible and possible to apply in areas outside the traditional food industry. Different sectors within this industry branch have started to apply the method, such as the catering services and aviation catering. Foodborne outbreaks in civil aviation could affect passengers as well as crew members[12] and had been a long-lasting periodic problem on aircrafts[13-16]. Therefore airlines, like the Lufthansa Service Holding AG, have implemented quality management strategies including the HACCP in the late 1980s[17].

Lately, public health researchers assessed the possibility of implementing the HACCP in the field of infectious disease outbreak control. Apart from the identification of the cause of an outbreak they used the HACCP to evaluate the management process in case of an outbreak as well as in the risk assessment and in the determination of prevention measures[18,19]. They investigated the context in which epidemiological emergencies were managed with the target to formulate recommendations for future activities and to define criteria for a successful outbreak management. Based on their results they demanded an improvement within the national surveillance system as a basis of an effective international surveillance[20]. Kassen (2004)[21] analysed existing international health policies and outbreak management guidelines on SARS (Severe Acute Respiratory Syndrome) The author included in her HACCP model all three different levels of an international outbreak management on global (WHO), national

(e.g. Centers for Disease Control and Prevention) and hospital level and came to a conclusion similar to MacLehose et al (2001)[19] who demanded an improvement within the national surveillance systems as a prerequisite for successful international surveillance.

A totally different field using the HACCP in public health was applied in the process of drinking water production. The implementation of the method included very different fields of application. Dewettnick et al. (2001)[22] investigated the possibility to integrate domestic wastewater of a wastewater treatment plant in the existing potable water production process. Another approach using the HACCP was described by Westrell et al. (2004)[23]. They investigated the possibility to conserve national resources in case of the reuse of nutrients extracted from wastewater and sewage sludge for agricultural land. Based on this challenge the authors described the necessity of the value of a risk management system that would be able to control possible health risks. This approach was of special interest because HACCP has been already part of the Water safety plans in the WHO Guidelines for drinking water quality[24]. A further approach using the HACCP within the described WHO Guidelines was investigated by Jagals & Jagals (2004)[25]. They implemented the method to control the water quality and to avoid water-related diseases in water treatment facilities.

In addition, HACCP has been applied in medicine in connection with process analysis and product testing. In 1990 a research group investigated the problems of hospital infectious control considering a milk bank providing expressed breast milk on a neonatal unit as example[26]. As a major benefit they described the team approach and also the involvement of several experts who, in combination with the preventive approach of the method, minimized the risk to overlook important points. But the author had to realise that the control options necessary were incompatible with the resources available and consequently they stopped their project. Baird et al. (2001)[27] used the HACCP in combination with infection control and process analysis. They used the method to evaluate the reason for the postoperative complications rate. After the implementation they realized that the reason for the complication were already located in the preparation for the surgery. Just like Hunter (1991)[26] also Baird et al. (2001)[27] emphasised the need for resources in order to implement this method as well as the extent of the process analysis. A different approach using the HACCP process analysis combined with infection control was described in the study of Fijan et al. (2005)[28]. They evaluated the hygiene state of the hospital laundry in order to prevent recontamination of textiles. In addition, to the HACCP they also used for the microbiological analysis the quality

standard RAL-GZ 992[29]. The results of the study showed a successful combination of these two methods.

The evaluation and re-evaluation of process analysis using the HACCP in the field of screening programs was successfully demonstrated in the study of Derrington et al.(2003)[30,31]. The implementation of HACCP highlighted several problems related to the entire program but also to specific operational parts of the programme. As mentioned already by Baird et al. (2001)[27] the authors also concluded that these problems could had not been identified by the conventional, mainly quantitative evaluation methods used in the past. In addition, they also described how time and work consuming it was to establish the whole concept, especially in case of process analysis with a huge number of different professional groups and organisations.

Another approach using HACCP within the manifold procedures in hospitals was the inclusion of the quality of a specific product with regard to bacterial contamination[32]. Olivera et al. (2001)[33] described in their study the important role of the correct use of high quality medical devices in investigated procedures using the example of tube feeding. The pharmaceutical industry has become aware of the impact of process conditions and controls on the quality of the resulting product and has described the implementation the HACCP as a useful tool in their working fields[34,35].

Regarding the available literature it was the aim of the review to evaluate the suitability of the HACCP – a safety assurance procedure of the food industry – in different areas of public health and medicine.

3.3 Material & Method

3.3.1 Data sources and study selection

The systematic literature search for the primary literature was based on different data sources. Electronic bibliographic databases like Medpilot and Dimdi (DIMDI SmartSearch) from 1966 to December 2005 (Appendix 1.0) were explored using the following terms “HACCP”, “public health”, “medicine”, “hospital”, “operative procedure”, “quality assurance”, “infection control”. Literature search was carried out between August 2005 and December 2005, including a series of updating literature.

Furthermore the reference lists of the relevant primary articles were investigated with special focus on additional literature belonging to the search field. In addition, the literature was hand searched and relevant papers identified (Appendix 1.0). Finally, the authors of the primary literature were contacted via e-mail and requested to fill out a standardised questionnaire to get additional information about their research project or unpublished research data or studies. After four weeks a second questionnaire was sent as a reminder to the authors who had not responded until then.

The study selection included all available literature using HACCP in the area of public health and medicine. There were no restriction criteria concerning the publication date, language or type of publication. Double publications were excluded from the review.

3.3.2 Description of data extraction and the procedure of the analysis

A data extraction mask was created in Microsoft Access® for categorising the review papers as well as to define reference standards and comparable parameters (Appendix 2.0). The data mask consisted of 27 questions pertaining to the study characteristics. Two reviewers screened all included publications on the basis of these questions. One reviewer abstracted the data of all included studies available as full text into the data mask while the second reviewer checked the data extractions by means of the own data acquisition. The reviewers resolved disagreements by discussion and consensus.

Data was extracted on the field of research including the study location, countries involved and the target groups. In addition, data was evaluated concerning the existence of an explicitly formulated research question, a definition of objectives and description of the outcome. Moreover data was extracted regarding methodological components including the description of a study protocol, the utilization of a flow chart, the description of the critical control points, the study design (observational or interventional) and the possible intervention measures. A description of the application of quality management and quality safety instruments together with the HACCP and the duration of the intervention was also searched for. In addition, information was obtained on the quality and extent of special training given to the staff and their acceptance of the system. Information was also collected on how the authors assessed the adequacy of the research question, the definition of objectives and the setting used. Lastly, information was obtained on the costs and effectiveness of HACCP.

3.4 Results

A total of 15 articles were identified available as full text version. 12 articles published between 1991 and 2005 met the inclusion criteria. Three publications were excluded. These publications did not fulfil the inclusion criteria as they only described a theoretical model on how to implement HACCP in the working field.

Among all included articles 58% were located in the field of medicine with six studies focusing on process analysis and one on medical devices. 42% of the selected studies were focused on public health. Three of them were concerned with infectious diseases and two concentrated on water safety (Table 1).
83% of the studies were carried out in Europe with the major portion of 42% being in the United Kingdom. Four of the five studies from this country were in the field of medicine concerning process analysis. Two of the twelve projects were described as having a multinational study design (Table 1).

Table 1: Location and distribution of the study field of the included studies

Study Field	Europe					Other	
	Germany	Greece	Slovenia	Sweden	United Kingdom	Brazil	South Africa
Medicine: Process Analysis			Fijan (2005)		Baird (2001) Derrington (2003) Derrington (2003) Hunter (1991)	Olivera (2001)	
Medicine: Medical Devices	Jahnke (2003)						
Public Health: Water Production				Westrell (2004)			Jagals (2004)
Public Health: Infectious diseases	Kassen* (2004)	Lambiri (1995)			MacLehose (2001)*		

* Centre of multinational study

The investigated target groups were divided into three categories in studies targeting on populations (58%) with a focus of five studies in the area of ”medicine – process analysis”, investigations in institutions (25%) and finally testing of products (17%). Table 2 presents the exact categorization of each target group.

Table 2: Categorization of the different target groups

Study Field	Target group		
	Population	**Institution**	**Medical device**
Medicine: Process Analysis	Patients underwent cataract surgery *Baird (2001)* Pregnant women in a Health District* *Derrington (2003)* *Derrington (2003)* Babies on a neonatal unit *Hunter (1991)* User of hospital textiles *Fijan (2005)*		Enteral feeds *Olivera (2001)*
Medicine: Medical Devices			Bone cements *Jahnke (2003)*
Public Health: Water Production	Workers of a treatment plant, people living in the environment of the plant *Westrell (2004)*	Potable water treatment facilities *Jagals (2004)*	
Public Health: Infectious diseases	Flight crew and passengers *Lambiri (1995)*	National and international surveillance systems *MacLehose (2001)* WHO, authorized national authorities (e.g. CDC), local outbreak management *Kassen (2004)*	

* Study was divided in two publications

Only one study, located in "medicine – process analysis", formulated a research question. However, all twelve research groups included in their publications the definition of the objectives and description of the outcomes (Appendix 2.1, table 3).

The methodological parts are presented as follows. 83% of the studies elucidated the development of a study protocol and subsequently 75% of the research groups described the procedure of developing a flow chart. In all studies the authors described the determination of their critical control points. 75% described the possibility of an intervention and lastly 58% carried out the implementation of the critical control points in their study. In all studies in the area of "medicine – process analysis" all the above mentioned points were carried out (Appendix 2.1, table 4).

Three of twelve publications used an additional instrument for quality management or quality safety beyond the HACCP method, one study located in the area "medicine – process analysis", one study in the area "public health – water production safety" and one in the area of "public health – infectious diseases". The duration of the intervention was only mentioned in five cases (42%) and the other seven (58%) articles gave no information about the length of the intervention. Regarding special education for the involved people, six of eight publications being in the field of "medicine – process analysis" described that they offered

special training for the staff, for example qualification programs, flyers, build up project teams combined with regular meetings, written protocols and the promotion of interdisciplinary work. However, only five (42%) studies all located in “medicine – process analysis” illustrated in their publication that the staff accepted the implementation of the HACCP system and that they were more satisfied with their work. Only one article mentioned higher acceptance among the participants, in this case patients (Appendix 2.1, table 4).

In the final discussion of the publication the authors answered the research question which they had asked initially. Irrespective of the research question or the described objectives, all study groups thought that the HACCP is an appropriate approach in this field. Except for one research group in “medicine – process analysis”, all other authors deducted that the implementation of the HACCP method was an appropriate and successful tool for the chosen setting. The effect of the HACCP implementation was described as, for example “the staff was confident in knowledge and skills and they improved the multidisciplinary work”, “an improvement of the quality of product” or “a better understanding and acceptance of the screening program”. Five of twelve authors gave additional information about the costs, four in the area of “medicine – process analysis” and one in “public health – water production safety”. All five needed extra financial support for the implementation of the HACCP system and one group in the area of “medicine – process analysis” even cited that they were not able to use HACCP in their chosen setting due to lack of resources (Appendix 2.1, table 5).

After mailing the standardised questionnaire to receive additional information, six of the twelve authors responded. The reminding questionnaire sent four weeks later did not yield any further replies. The reasons for implementing the HACCP in a particular research field were manifold. It showed the whole area from a new interesting approach in a research area to an already established tool for risk analysis. Four of the six research groups declared that they had not used other quality management systems before the implementation of HACCP, one group used the HACCP before. The other group used a quality management system already established in their working field. Three authors reported that they had repeated the HACCP analysis but without description of the results. Two authors mentioned the cosmetic industry and the pharmaceutical industry as additional settings of public health and of medicine using HACCP, while four authors said that they had recommended the HACCP systems to other institutions, such as the EU (Appendix 3.0).

3.5 Discussion

It was the purpose of this review to investigate the applicability of the HACCP method in the field of public health and medicine. The literature search for the primary literature was carried out without any language restriction on different data sources. It was important to ensure that the process of identifying studies was as thorough and unbiased as possible. As most of the prestigious journals use English, there may be a tendency for the publication of reports in English by researchers. This may have implications for searches restricted by language. Beyond these factors, databases which record research tend to have geographical, language and topic emphases. It is important to be aware of potential bias (retrieval, language or publication) and to use a variety of search methods (electronically and manual) to ensure a search as comprehensive and unbiased as possible[36,37]. Therefore, the search strategies should include a range of databases. The databases in this review included bibliographic databases, such as Medpilot and Dimdi, which together consist of more than 15 different databases from different study fields. In addition, the reference lists of the relevant primary articles were searched and a thorough hand searching was carried out. Almost all included articles, except one, were published in English. Therefore, it should be taken into consideration, that as with all systematic reviews some published and unpublished papers may have been missed and consequently it was not possible to eliminate all potential bias. A comprehensive literature search and a continuously updating during the writing procedure of the thesis tried to minimize this bias.

For categorising the included articles a data extraction mask was created using Microsoft Access®. It provided a framework for selecting and describing the publications. Compared to a standardised data mask an individually developed data mask always bears the risk of subjectivity. But as the data mask was very comprehensive with the focus on methodical components an overestimation of the results should not be expected.

With regard to the use of the HACCP it was necessary to emphasise that one of the main implementation areas is the industry, such as pharmaceutical companies or aviation catering[17,34,35]. These companies usually do not publish in scientific journals. In addition, the implementation of this system is part of the internal company affaires and information and experiences are commonly not accessible for the public. Therefore, it can be assumed that several industry branches have appropriate experiences using the HACCP which could not be included in this review[17,34,35].

"Publication behaviour" differs among research fields like public health and especially medicine. Today, investigations are expected to be published in scientific paper listed in accepted and open databases. Therefore, it was not surprising that 58% of all included articles were located in the field of medicine. Six studies focused on process analysis and one on medical devices (table 1). The higher number of articles dealing with process analysis should not be over-interpreted, for reasons already mentioned above.
The majority of authors used the HACCP as an alternative to an already existing quality assurance system[26,27,30,31]. It was not the target to develop and assess a new method. Therefore it can be assumed that also less successful implementations of the HACCP would be published in contrast to clinical research where negative results often remain unpublished with a high risk of overestimating positive results (publication bias). In this master thesis the publication bias was furthermore reduced by the relatively broad inclusion criteria for the included articles. But whereas on the one hand liberal inclusion criteria reduce a potential bias, on the other hand it provides more heterogeneity with regard to study fields, objectives and applied methodology.

Almost 50% of the authors responded to the standardised questionnaire which is a satisfactory response rate. But as the number of articles is relatively small the results should be interpreted with caution and should be more seen as additional information of the individual research projects.

The intention of data synthesis in this review was to collate and summarise the results of the included primary studies with focus on methodology and their applicability. The quality of the involved primary studies was not assessed. A critical issue was the relatively small number of available articles which was intensified by the division into subgroups of different study fields.

Regarding the recommendation of the NACMCF[2] concerning the establishment of a prerequisite program, ten study groups described the development of a study protocol and nine the evaluation of a flow chart. In 1991 Hunter[26] already emphasised the importance of a careful analysis and description of the process including all possible internal and external factors. Independent from the investigated study field several authors[12,27,30,31,35] highlighted the necessity to invest sufficient workload and time into the prerequisite program to implement successfully the seven principles[2].

One of the crucial points in successfully implementing the HACCP is the correct determination and number of the Control Points and further the Critical Control Points: Stages in the process which must be controlled and consequently stages which have to be influential[7]. If these Control Point assumptions are not correct and the proper procedure is not achieved, there is a possibility that the Critical Control Point operation may be inadequate[38]. All twelve included articles described the determination of the Critical Control Points and emphasised the importance of this principle. But at the same time, this principle shows the limitation of the method because the determination of Critical Control Points is an exceptionally subjective procedure. Havelaar (1994)[39] stated that control measures in water production were often not sufficiently effective to ultimately call them Critical Control Points, for example the raw water. It should not be declared as a Critical Control Point in the classical sense because the pathogen reduction cannot be adequately controlled[39]. Nevertheless, Jagals & Jagals (2004)[25] used the raw water in their investigation as a Critical Control Point. They included it for the specific purpose to show that the level of contamination can play an important role in management of the upstream catchment. Like other studies in the field of water production[22,23] they showed that although they changed the starting position – the preventive approach of the HACCP – it is still possible to follow the methodical approach.

The same problem with the different starting position can be found in the area of infectious diseases, except foodborne diseases[12]. The hazard, in this case the infection, already exists. The study groups used successfully the methodology of the HACCP, but they defined a different starting position and consequently also different objectives. This describes a new approach implementing the HACCP. The research groups used the HACCP to evaluate the management process in case of an outbreak as well as in the risk assessment and in the determination of preventive measure[18-20]. However, Brand et al. (2000)[18] as well as Kassen (2004)[21] mentioned the difficulties to identify all involved internal and external factors to get a complete analysis of the processes. In infectious diseases it is more demanding to meet the criteria of the third principle “establishment of critical limits” because abstract procedures, like the evaluation of management processes and the maintenance of standards, are difficult to measure. Hence, MacLehorse (2001)[20] recommended additional studies in this field to decrease the subjectivity of the method[19,20].

In medicine the implementation of HACCP was also described as very complex but manageable[27,30,31]. The different research groups implemented the method following the proactive, preventive approach in the classical sense of the “concept of zero error” (Null-

Fehler-Konzept)[1]. All study groups[26-28,30,31,33] had experience with different kinds of quality assurance systems. They were looking for a supplementation or an alternative to their already established systems. Except one study group[26], they all described the HACCP as appropriate for the defined objectives and the chosen setting. Hunter (1991)[26]described like others[27,28,33] that the method was extremely demanding on time and resources and that the HACCP were not practicable within the resources available in the project. This factor should not be underestimated as this system like other quality assurance systems should be re-evaluated and improved. Consequently these follow-up cost should be kept in mind with regard to the calculation of budget, staff and available time.

Regarding the available literature there is a decisive difference in implementing the HACCP in medicine or public health. In both fields the successful implementation of the methodology was described in different settings. Whereas the method was used in medicine as a proactive preventive system to reduce the infection rates, complications and contamination, in public health, especially in infectious diseases, the system was mainly used to evaluate management processes as well as the risk assessment and to determine preventive measures. Therefore, the latter approach required a different definition apart from the classical starting position and a different declaration of the objectives and outcomes.

3.6 Conclusion

Within the limitation of the review it can be concluded that the HACCP method was successfully realised in different settings in public health and medicine. In both areas the method was implemented following the recommended methodology although the starting position and the respective endpoints had been changed in some of the public health studies. Provided that a precise definition of the starting point and the objectives is given and an exact implementation of the methodology is possible, it is recommended to use the HACCP as an additional quality assurance method in the described areas.

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Appendix **1**

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1. Sources of references

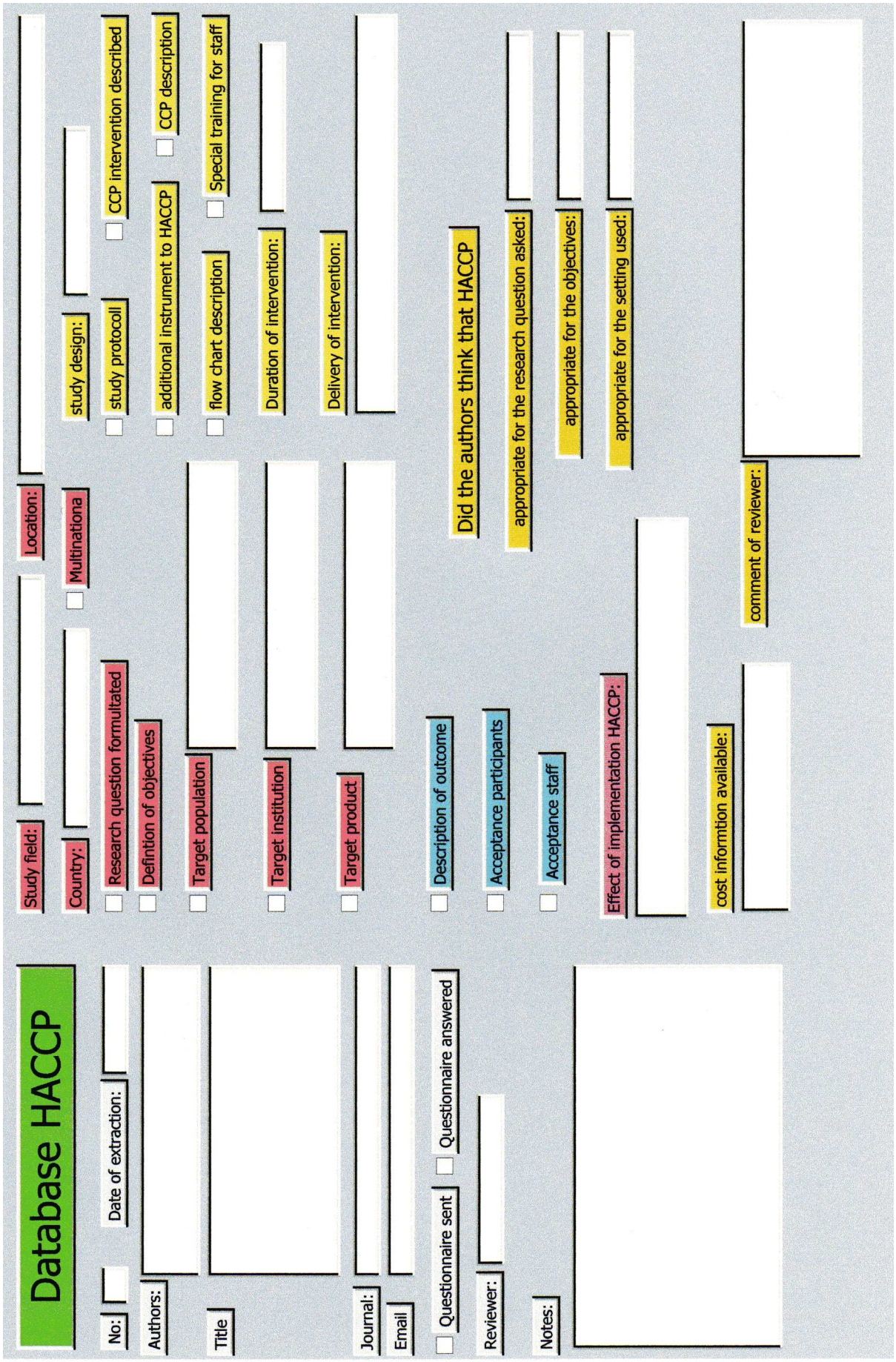
Bibliographical databases screened electronically

- Dimdi (DIMDI SmartSearch)
- Medpilot:
  - Medline
  - Medline Alert
  - AWMF-Leitlinien
  - CCMed
  - Cochrane-Rviews (CDSR)
  - Cochrane (DARE)
  - Deutsches Ärzteblatt
  - Karger-Verlagsdatenbank
  - Kluwer-Verlagsdatenbank
  - Krause & Pachernegg Publikationsdatenbank
  - Lippincott Williams & Wilkins Verlagsdatenbank
  - Springer Verlagsdatenbank
  - Thieme Verlagsdatenbank
  - CancerLit
  - ETHMED
  - Zentralbibliothek für Medizin

Journals hand screened

KA-Abwasser, Abfall	1995-2005
Journal of Epidemiology and Community Health	2000-2005
Hygiene und Medizin	1989-2005

2. Data extraction sheet (Microsoft Access®)



2.1 Tabulated presentation of the results

Table 1: Location and distribution of the study field of the included studies

Study Field	Europe					Other	
	Germany	Greece	Slovenia	Sweden	United Kingdom	Brazil	South Africa
Medicine: Process Analysis			Fijan (2005)		Baird (2001) Derrington (2003) Derrington (2003) Hunter (1991)	Olivera (2001)	
Medicine: Medical Devices	Jahnke (2003)						
Public Health: Water Production				Westrell (2004)			Jagals (2004)
Public Health: Infectious diseases	Kassen* (2004)	Lambiri (1995)			MacLehose (2001)*		

* Centre of multinational study

Table 2: Categorization of the different target groups

Study Field	Target group		
	Population	Institution	Medical device
Medicine: Process Analysis	Patients underwent cataract surgery *Baird (2001)* Pregnant women in a Health District* *Derrington (2003)* *Derrington (2003*) Babies on a neonatal unit *Hunter (1991)* User of hospital textiles *Fijan (2005)*		Enteral feeds *Olivera (2001)*
Medicine: Medical Devices			Bone cements *Jahnke (2003)*
Public Health: Water Production	Workers of a treatment plant, people living in the environment of the plant *Westrell (2004)*	Potable water treatment facilities *Jagals (2004)*	
Public Health: Infectious diseases	Flight crew and passengers *Lambiri (1995)*	National and international surveillance systems *MacLehose (2001)* WHO, authorized national authorities (e.g. CDC), local outbreak management *Kassen (2004)*	

* Study was divided in two publications

Table 3: Study objectives and estimation of HACCP applicability

	yes	no	not applicable
Did the authors formulate a			
definition of objectives	12		
research question	1	11	
Did the authors think that HACCP was			
appropriate for the research question asked	1	11	
appropriate for the objectives	11		1
appropriate for the setting	10	1	1

Table 4: Description of methodology and additional features

	yes	no
Methodology		
Study protocol	10	2
Flow chart description	9	3
Critical Control Point description	12	-
Critical Control Point intervention described	9	3
Additional instruments to HACCP	3	9
Additional features		
Duration of intervention described	5	7
Delivery of Intervention described	7	5
Special training of staff included	8	4
Acceptance of staff evaluated	5	7
Acceptance of participants evaluated	1	11
Cost information available	5	7

Table 5: Effect of the implementation of HACCP

Study Field	Target group		
	Population	**Institution**	**Medical device**
Medicine: Process Analysis	Enhanced level of care, staff confident in knowledge and skills, improved multidisciplinary work *Baird (2001)* Better understanding and acceptance of the screening programme *Derrington (2003)** Team approach, useful educational purpose *Hunter (1991)* After implementation HACCP all recommended values were reached *Fijan (2005)*		Significant reduction in the bacterial counts, improved knowledge of staff *Olivera (2001)*
Medicine: Medical Devices			Improved the quality of a product *Jahnke (2003)*
Public Health: Water Production	Propose monitoring strategies, corrective actions, prevent disease transmission *Westrell (2004)*	More effective as a quick monitoring tool to detect problems before the water reached disinfection stage *Jagals (2004)*	
Public Health: Infectious diseases	Reduction of contamination, overall improvement of hygiene *Lambiri (1995)*	Existing networks have shown their values *MacLehose (2001)* Descriptions of the strengths and weakness of the different surveillance systems and levels *Kassen (2004)*	

* Study was divided in two publications

3. Questionnaire including the results

What were the reasons to implement HACCP in this particular procedure/programme?
- HACCP is a pro-active system intend to prevent contamination of enteral feeds - postgraduate research as well as investigating the situation as it is - HACCP is well recommended for risk analysis in pharmaceutical processes. Moreover, annex 15 to EU GMP Guideline enforces risk analysis to be conducted for qualification/validation. ICH Quality Group 8/9 encourages pharmaceutical companies to use FMEA and HACCP as tools - told to do, not the personal decision of the author - It seemed an interesting approach that had not been taken before and enable us to structure the study. In particular we felt it would help identify critical control points - no answer

Who recommended the HACCP and why?
- Government agencies, companies, etc - no specific recommendation-HACCP is part of our investigation tool in Environmental Health research - HACCP is well recommended for risk analysis in pharmaceutical processes. Moreover, annex 15 to EU GMP Guideline enforces risk analysis to be conducted for qualification/validation. ICH Quality Group 8/9 encourages pharmaceutical companies to use FMEA and HACCP as tools - supervisor of the master thesis - the idea of the author- for the reason given in question 1. Other similar methods we might have used included critical path analysis-in many ways in this context HACCP amounts to the same - the co-mentor, member of the Faculty of Agriculture

Had been other programmes (QM systems or evaluation programmes) used before the implementation of HACCP?		
No 4	other 1	yes 1 - RAL-GZ992

Did you repeat the HACCP analysis?		
No 3	other 1	yes 2

Do you know other studies/programmes in which HACCP is used?		
No 4	other 0	yes 2 - Pharmaceutical Companies - Food industry, catering, food safety

Do you know other public health or medicine settings using HACCP?		
No 2	other 0	yes 2 - Cosmetic industry - We recommended HACCP to be adopted by dieticians and those in professions that involve food manufacture

Did you recommend the HACCP method to other institutions?		
No 2	other 1	yes 3 - European Union

Do you know further publications describing HACCP in medicine or public health?		
No 5	other 0	yes 1 - Landesinstitut für den öffentlichen Gesundheitsdienst (North Rhine-Westphalia)

4. Certificate of Originality

I hereby certify that the master thesis I am submitting is fully and completely original to me and that I neither copied, improperly used, nor otherwise violated any rights of any third party in preparing and submitting the master thesis and that it was not a partially or in whole written, revised or substantially edited by anyone other than me.

Kiel, February 2006

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