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Review

Evaluation of worldwide approaches to the use of HACCP to control food safety

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Hazard Analysis by Critical Control Point (HACCP) is a management tool, developed in the late 1960s, to ensure the safety of foods for space flights. It was subsequently recognised as an effective alternative to conventional end-point-testing by the World Health Organisation (WHO) and the United States Food and Agriculture Organisation (FAO), amongst others, and recommended for use in commercial food production. HACCP principles are now incorporated in national food safety legislation of many countries, as well as a likely future component of the standardisation of international food quality control and assurance practices. However, governments and food companies have interpreted HACCP differently. This paper describes the basic principles of HACCP, and evaluates its implementation in the European Union, North America, Australia and New Zealand, and in developing countries. The 'Zurich House of Food-Safety' approach was identified as the most rigorous (and possibly most effective) interpretation of HACCP, while the Australian food industry approach was identified as the most practical and readily applicable approach to HACCP.

Hazard Analysis by Critical Control Point (HACCP) is a systematic approach to the identification, assessment and control of hazards. The HACCP procedure was developed by the Pillsbury Company in the 1960s, as a practical means of ensuring the safety of foodstuffs for space flights [1,2]. Initial research, conducted in collaboration with the National Aeronautics and Space Administration, the United States Army Laboratories and the United States Air Force Space Laboratory Project Group, concluded that conventional end-point food testing could not effectively ensure food safety because:

- Significant proportions of a foodstuff have to be sub-sampled for analysis to ensure representivity.
- Food safety is only ensured with regards to tested hazards.
- Current food safety testing procedures are likely to be expensive, time-consuming, difficult to interpret and destructive.
- Control of hazards is reactive.
- Responsibility for food safety is focused upon a relatively small component of the workforce: quality assurance and control personnel.
- Food safety is only assured at the point of testing.

Consequently, HACCP was developed as a proactive alternative to end-point testing. The original Pillsbury HACCP procedure [2] contained three components:

1. The identification and assessment of all hazards associated with the final foodstuff.
2. The identification of the steps or stages within food production at which these hazards may be controlled, reduced or eliminated: the Critical Control Points (CCPs).
3. The implementation of monitoring procedures at these CCPs.

Food companies, food industry affiliated organisations and governments have interpreted HACCP in different ways. Consequently, HACCP has evolved to meet the

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specific needs of handlers (i.e., food producers, manufacturers and distributors), regulators and consumers [3]. However, despite this, the three components listed above remain inherent in all contemporary HACCP procedures. This combination of practical (prevention-orientated) primary components and a flexible approach to their implementation has been identified as HACCP's greatest attribute. It allows HACCP to remain relevant, efficient and effective, despite the introduction of new food technologies.

The HACCP procedure

HACCP is a tool for the development, implementation and management of effective safety assurance procedures, as opposed to an actual safety assurance procedure. It was intended for use by individual food companies (i.e., food producers, manufacturers, distributors and retailers) as a protocol for the development of unique safety assurance procedures to meet their individual needs. The range and severity of hazards varies significantly from case-to-case (i.e., with site, food, ingredients and production line), therefore this approach is more effective than instigating rigorously pre-defined safety assurance procedures 'across-the-board' within each food sector. Consequently, most published HACCP guidelines focus upon the implementation process and although, HACCP documentation is available from many sources, there is a surprising amount of consistency in the approaches adopted and the safety recommendations made. For example, the International Commission on Microbiological Specifications for Foods [4], the National Advisory Committee on Microbiological Criteria for Foods [5,6], the Codex Alimentarius Commission [7] and the International Life Science Institute [8] HACCP guidelines all recommend very similar implementation protocols. The seven basic steps of HACCP implementation (often referred to as 'HACCP principles') are:

1. Conduct hazard analysis, considering all ingredients, processing steps, handling procedures and other activities involved in a foodstuff's production.
2. Identify CCPs.
3. Define critical limits for ensuring the control of each CCP.
4. Establish monitoring procedures to determine if critical limits have been exceeded and define procedure(s) for maintaining control.
5. Define corrective actions to be taken if control is lost (i.e., monitoring indicates that critical limits have been exceeded).
6. Establish effective documentation and record-keeping procedures for developed HACCP procedure.
7. Establish verification procedures for routinely assessing the effectiveness of the HACCP procedure, once implemented.

To implement HACCP principles, the CAC [7] recommends five preliminary stages prior to hazard analysis, for example:

1. Assemble HACCP team to develop HACCP procedure.
2. Compile a complete description of the foodstuff.
3. Identify end-point uses of the foodstuff.
4. Construct a flow diagram of the individual food production and supply sequence.
5. Verify this flow diagram on-site.

The preliminary steps of HACCP implementation are an auditing exercise, where data is compiled for the exercise [9,10]. HACCP implementation is usually a team exercise as no individual is likely to have all the practical, technical, theoretical and managerial expertise required (see for example [7,8,11]). The selected HACCP team must have access to all relevant information, as well as the necessary range of expertise to identify all hazards, CCPs and critical limits associated with the product and/or process under consideration. Typical teams might include a chemist, engineer, food technologist, microbiologist, production manager and quality assurance manager, amongst others [7,8]. The HACCP team compiles a description of the foodstuff under investigation, identifying all ingredients, processing steps, handling procedures and other activities involved in its production. The team should also identify all potential (reasonable) uses by the end-point user or consumer [7]. A flow diagram of the production process under consideration should then be prepared [7] to make documentation more accessible, and to simplify both management and understanding of the HACCP procedure, once implemented [12–14]. The flow diagram should be compared with the food production process to confirm each stage, on-site, under all operating conditions and during all hours of operation, to ensure representativity and accuracy [14,15]. Obviously, the flow diagram should be modified as appropriate, if any discrepancies are observed [7].

Within HACCP, hazard analysis can be used to identify hazards (i.e., to score individual hazards relative to a maximum safe score) or to prioritise hazards (i.e., to score individual hazards and then rank them for selection of most significant hazards for priority consideration). A number of hazard analysis procedures have been used, including hazard characterisation, hazard assessment, semi-quantitative risk analysis and quantitative risk analysis. The simplest form of hazard analysis is rudimentary hazard characterisation e.g. the NACMCF method [5] and its subsequent developments for chemical hazards [16–22]. Under this scheme, each ingredient and each form in which the finished foodstuff is supplied to the consumer (e.g., fresh, refrigerated, frozen or canned) is assigned risk characteristics:

A Intended for 'at-risk' consumer group, e.g., infants, the elderly, the infirm or immuno-compromised individuals.
B Ingredients are a potential source of investigated chemicals.
C Production method does not contain a control step for investigated chemicals.
D Potential for contamination between manufacturing and packaging.
E Potential for contamination during distribution or consumer handling.
F No method for consumer to detect, remove or destroy hazard if present.

The associated risk level (0 to VI; lowest to highest) is then assigned on the basis of the number or types of risk characteristics identified, e.g. Risk Level:

VI Highest category; reserved for any products with 'A' characteristics.
V All five general characteristics (all five of B, C, D, E and F).
IV Any four general characteristics (any four of B, C, D, E and F).
III Any three general characteristics (any three of B, C, D, E and F).
II Any two general characteristics (any two of B, C, D, E and F).
I Any one general characteristics (any one of B, C, D, E and F).
0 No identified hazard characteristics.

Semi-quantitative approaches are also possible where the hazard analyst estimates the likelihood of hazards occurring. For example, in a recent HACCP study of packaging materials Bovee et al. [14] described a relatively simple semi-quantitative method where hazard analysts applied personal judgement to score hazards on a 1 to 4 scale for probability of occurrence (unlikely to common) and severity of hazard (low to very high). The associated risk could then be determined using a risk matrices, (e.g. see Table 1).

More quantitative risk analysis approaches estimate the likelihood of a hazard occurring by comparing the level at which a contaminant (e.g., microorganisms, chemicals or foreign bodies) is present within foodstuffs with the concentration at which it presents a risk to health, e.g., the hazard index:

$$HI = \left(\frac{[Food]_{Contaminant}}{Hazard_{Contaminant}}\right)$$

Where HI is the hazard indices, $[Food]_{Contaminant}$ is the contaminant concentration in the food, and $Hazard_{Contaminant}$ is either the lowest concentration at which the contaminant is believed to be a hazard or the highest concentration at which the contaminant is not believed to be a hazard to human health.

Although use of such procedures within the HACCP framework has been discussed [23–27] they have not been widely adopted in the food industry despite being widely used elsewhere, e.g., chemical waste management and environmental health impact studies (see for example [28–31].

Each approach has advantages and disadvantages. For example, hazard classification and semi-quantitative hazard analysis are readily applicable to many hazards, but they are subjective. More quantitative risk assessment procedures are less subjective, but require more information (e.g., estimated or quantified exposures for ingredients, assessments of exposure pathways, consumption level data, dose-response assessments for individual hazards) that may not be readily available for all hazards considered. Furthermore, a high level of skill and experience is required to employ and interpret quantitative risk analysis data, and this may limit the use of such procedures within HACCP. Realistically, HACCP is likely to be more suited to hazard assessment methods that are practical, easy-to-interpret and cost effective [32]. The approaches previously discussed by Lee and Hathaway [33] and Untermann [34] are arguably amongst the most practical hazard assessment approaches that could be employed on a routine basis (see Fig. 1).

Once the hazards to be addressed have been selected, relevant CCPs should be identified. A CCP is a point at which control is critical to assuring the safety of the foodstuff [7,8,11,35] and their accurate assignment is crucial to effective, efficient and economical deployment of monitoring, control and corrective procedures [12,14]. CCP assignment is a complex procedure [36,37], and misassignment has been identified as a major cause of ineffective HACCP [34]. The key criteria for the assignment of CCPs are typically:

1. At which point (or points) could the identified hazard either occur or develop to an unacceptable level?
2. Do preventative measures exist for identified hazard and at what point (or points) could these be employed?

Table 1. Risk ranking scheme based upon severity of risk (S) and probability of hazard (P) as described by Bovee et al. [14]

Severity of hazard (S)	Probability of occurrence (P)			
	Unlikely (1)	Occasionally (2)	Probable (3)	Common (4)
Very high (4)	2	3	4	4
High (3)	2	3	3	4
Medium (2)	1	2	3	3
Low (1)	1	1	2	2

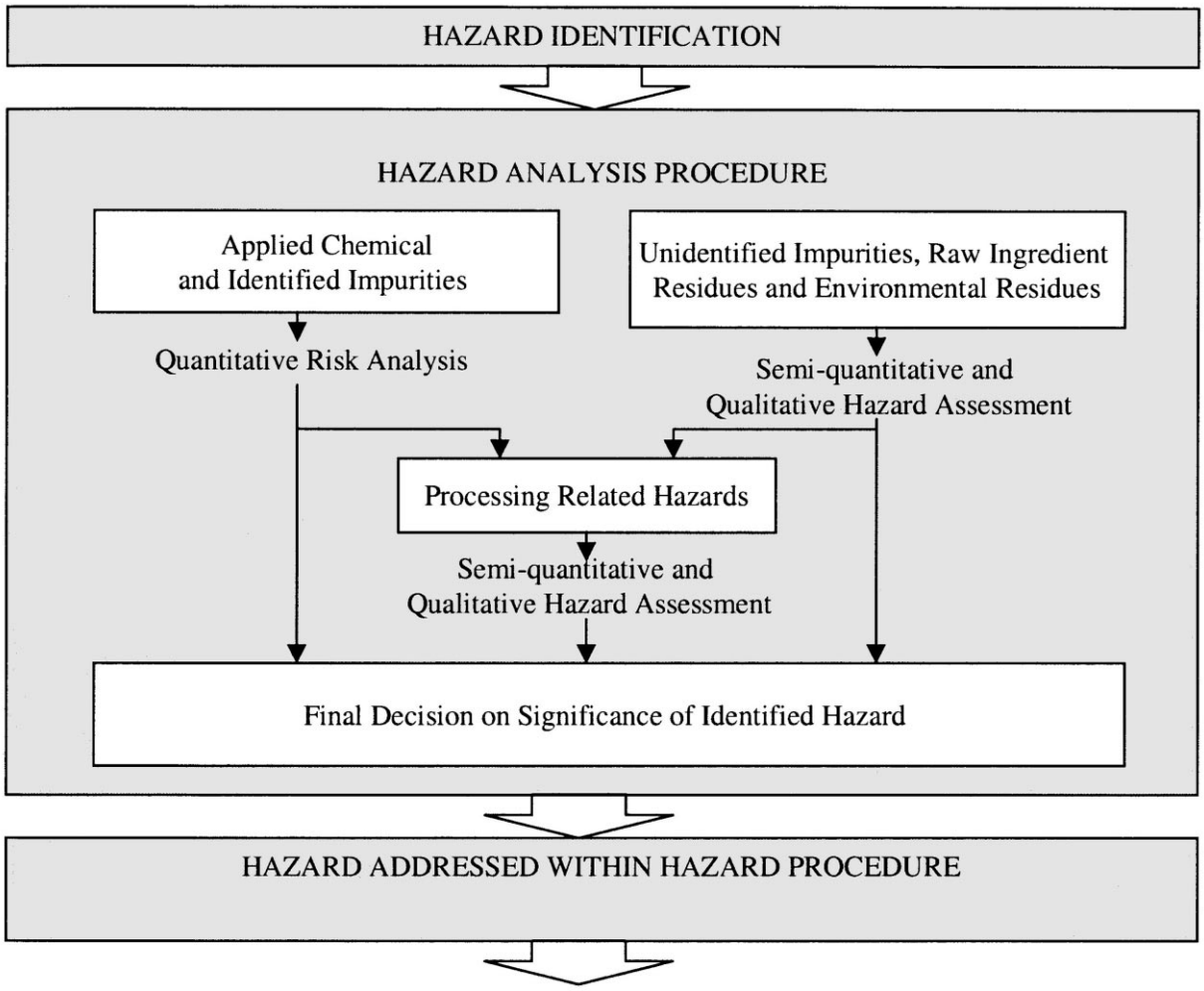

Figure 1. Example of the Combined Use of Quantitative, Semi-Quantitative and Qualitative Approaches with Hazard Analysis.

3. At what point (or points) could the identified hazard be most effectively controlled?
4. Were any steps specifically designed to eliminate or reduce the identified hazard to an acceptable level?

HACCP in the United States

Much of the early HACCP development work was conducted in the US. Following publication of the initial HACCP procedure [1,2,38], it was recognised as an effective alternative to conventional end-point-testing, and recommended for use in all areas of commercial food production. In 1973, the US Food and Drug Administration (FDA) conducted a pilot programme of random HACCP audits of low-acid canned foodstuffs manufacturing sites to develop Good Manufacturing Practices (GMP) strategies for the low-acid canned food industry [39]. Although this approach was conceptually ahead of its time, the procedures developed were criticised for focusing attention on control points that were already monitored, as opposed to identifying operations that were effective CCPs [40,41]. The initial lack of interest in HACCP has been attributed to this and the failure of other early attempts at implementation [41]. Food industry attention to HACCP principles generally remained insignificant until they were endorsed by the WHO, FAO and the NACMCF, in the 1980s. The National Marine Fisheries Service (NMFS), the Food Safety and Inspection Service (FSIS), the FDA and the US Army Research and Development Centre requested that the National Research Council convene a panel of experts to formulate general principles for the application of microbiological criteria to food safety [3]. The resulting panel (the Food and Nutrition Board Subcommittee on Microbiological Criteria) identified HACCP as an effective alternative to conventional end-point-testing for microbiological hazards and recommended the establishment of a Commission on Microbiological

Criteria for Foods [42]. The Secretary of Agriculture subsequently established the NACMCF 1988, and they reviewed and revised HACCP documentation, developing early CCP assignment decision trees [5,6]. At about this time the ICMSF attempted to rationalise CCP assignment by defining two categories of CCPs, based upon the perceived degree of control (i.e., CCP1s–CCPs at which control is assured, and CCP2s–CCPs at which hazards can only be minimised but control can not be completely assured [4]. Although this approach is now widely used [37,43,44], it has been criticised for creating the impression that CCP1s were absolute assurances of safety [27,45].

Despite the initial lack of industrial interest in the early 1970s, the FDA continued to actively encourage the adoption of HACCP within the food manufacturing sector throughout the 1970s and 1980s [46-48]. The FDA considered HACCP to be a highly comprehensive approach of food safety because it took into account the whole food supply chain. More recently, Taylor [49] described the FDA's plans for the standardisation of food safety procedures for international trading and recommended refocusing regulatory attention away from visual inspection of individual sites and site equipment and analytical monitoring of suspect foodstuffs, towards verification of HACCP procedures as a means of preventative control. Corlett [50] made similar recommendations and identified three areas for regulatory verification: (i) the HACCP plan, (ii) records associated with CCP monitoring and (iii) sampling practices used in association with CCP monitoring. Corlett [51] also identified the collaboration of food regulatory bodies during the development of HACCP strategies as a key criterion for the development of coherent food industry regulatory procedures. The FSIS investigated the feasibility of applying HACCP to microbiological hazards in meat and meat products leading to the instigation of three FSIS/industry workshops and the development of generic HACCP procedures for the meat industry [37,52]. A FDA/NMFS joint committee introduced a voluntary, fee-funded seafood inspection programme that provided certification upon the basis of routine internal site inspection but less frequent external (FDA/NMFS) inspection [3]. This approach was developed into a mandatory preventative control programme to ensure the safety of seafoods sold commercially within the US, or for export aboard [53]. More comprehensive HACCP regulations were subsequently developed and introduced into US law [54].

The legal requirement for HACCP compliance in US food industries changed the way HACCP was subsequently implemented in the US. Previously, HACCP was developed and implemented on a voluntary basis, under which individual companies identified their own safety requirements, as a means of enhancing their market potential and improving customer satisfaction. However, under the mandatory system, the first criterion for most food companies became adherence to governmental requirements and regulations [41]. Prerequisite programmes were identified as a critical component of HACCP implementation. The FDA, for example, requires that seafood companies address eight hygienic control points within safety assurance procedures prior to the development of HACCP programmes:

1. Safety of water that comes into contact with food and food-contact surfaces, or is used in the manufacture of ice.
2. Condition and cleanliness of food-contact surfaces, utensils, gloves, and outer garments.
3. Prevention of cross-contamination from unsanitary object to food-contact surfaces, utensils, gloves, and outer garments and from raw foodstuffs to cooked foodstuffs.
4. Maintenance of hand washing, sanitising and toilet facilities.
5. Protection of food, food packaging and food-contact surfaces from adulteration by lubricants, fuel, pesticides, cleaning compounds, sanitising agents, condensates and other chemical, biological and physical hazards.
6. Proper labelling, storage and use of toxic chemicals.
7. Control of employee health conditions.
8. Exclusion of pests from food production, processing and handling sites.

Subsequent documented evidence of the HACCP implementation procedures was then required, as follows:

- A written HACCP plan, identifying all hazards addressed.
- A list of CCPs identified.
- Critical limits for each control factor associated with all CCPs.
- Monitoring procedures for all critical limits.
- Corrective actions to be employed if control loss is detected (i.e., deviation from critical limits).
- Comprehensive record-keeping system.
- A list of verification procedures and a statement of their intended frequency.

Current US regulations focus attention upon hazards that are perceived as 'reasonably likely to occur' upon the basis of either historical evidence or reasonable possibility for occurrence within the type of product being produced. The failure to address the severity of consequences has recently been criticised by Bernard [41], as this creates the impression that very rare but highly dangerous hazards need not be addressed within the HACCP procedure.

HACCP in the European Union (EU)

Each of the EU member states has their own unique legal structures for food safety legislation, surveillance and assurance. Therefore, the 'across-the-board' introduction of HACCP within the EU has presented significant challenges, and the current approach can appear both complex and fragmented. A number of member nations began to develop HACCP or HACCP-like legislation independently of the EU (e.g. the Dutch Quality and Hygiene Assurance Plan [55]) which resulted in legal problems at later dates, particularly for the pan-European trading of foodstuffs. Consequently, the European Commission decided to develop a systematic approach to HACCP for adoption throughout the EU. Initial research was conducted by a HACCP subgroup within the framework of the Food Linked Agro-Industrial Research Programme (FLAIR). Jouve [56] identified a number of achievements of this HACCP subgroup, including the production of a glossary of HACCP implementation nomenclature, a database of over 250 HACCP documents and a HACCP user's guide. An international training exchange, and laboratory and institution visit programme between the UK, France, Denmark, Spain, Sweden, Portugal, Belgium, The Netherlands, Ireland and Greece was established. The EU subsequently produced a series of directives for incorporation into legal systems of all member states. Three (so-called 'vertical') directives were developed for specific foodstuffs (DIR 91/493 for fishery products, DIR 92/5 for meat and meat-based products, and DIR 92/46 for milk and dairy-products). These directives required commercial food producers to:

- Identify critical points in their individual manufacturing procedures.
- Establish and implement methods for monitoring and checking such critical points.
- Collect samples for analysis in an approved laboratory and/or by a competent authority to assure that cleaning and disinfecting methods are in accordance with the standards established in the relevant directive (i.e., DIR 91/493, 92/5 or 92/46).
- Maintain a written record of these procedures and subsequent data with a view for submission to relevant authorities and/or their representative inspectors.

The fourth HACCP directive was a 'horizontal' directive regarding hygiene of foodstuffs (DIR 93/43/EEC), and was intended as a framework for the standardisation of EU member-state's food hygiene legislation. This directive required the identification, monitoring and control of production steps critical to ensuring food safety, in accordance with the concept of HACCP principles (as previously discussed). Adoption of these directives by EU member states has varied widely because of differences in the level of compatibility of directives and (i) HACCP (or HACCP-like) procedures, schemes or legislation already in place in individual member states, (ii) HACCP principles and existing food production and handling practices in individual member states, and (iii) the complexity of individual member state's own legal structure. The HACCP approaches adopted by three different EU member states (UK, The Netherlands and Germany) are presented here both as examples of different ways in which the EU directive have been interpreted and implemented, and as a means of highlighting some of the problems currently associated with the use of HACCP according to EU directive 93/43/EEC [57].

Direct adoption (HACCP in the UK)

Before implementation of EU 93/43/EEC the UK Ministry of Agriculture Fisheries and Food (MAFF) encouraged UK food companies to adopt HACCP procedures on a voluntary basis. Consequently, many companies were already applying HACCP principles (or were at least aware of them) when EU 93/43/EEC was instigated in the UK, using the Food Safety (General Food Hygiene) Regulations 1995. This placed the emphasis for food safety activities on the identification of the critical operation steps and finding ways of controlling them, as described in the EU directive. The approach is defined in terms of five principles, developed according to HACCP:

- Hazard analysis of given foodstuff.
- Identification of all points or operation steps at which hazards may occur.
- Identification of points critical to food safety.
- Implementation of control and monitoring procedures at these critical points.
- Periodical review of food hazards, critical points, control and monitoring to ensure continued effectiveness.

The UK approach to HACCP legislation is an accurate interpretation of EU directive 93/43/EEC. However, the legislation appears carefully worded to retain a degree of flexibility (i.e., incorporating a basic overview of the HACCP procedure). Consequently, it could be considered a robust 'building block' for future UK HACCP implementation schemes and legislation. The pre-legislation awareness of HACCP among UK food companies has meant that many UK food companies had already restructured or reorganised their activities to incorporate HACCP principles prior to this legislative requirement. Consequently, a large number of UK food companies have either already instigated HACCP (or HACCP-like) procedures in accordance with current UK legislation or are activity in the process of such

food quality assurance systems. Furthermore, a number of food industry-affiliated organisations (e.g., Campden & Chorleywood Food Research Association and Leatherhead Food Research Association) have been particularly pro-active in developing HACCP guidelines, documentation, training courses and software that generally appears to be both well received and actively employed within the UK. It should however be recognised that the UK HACCP legislation incorporates a number of components of EU directive 93/43/EEC that have presented problems when implemented in other EU member nations (see below). Consequently, the current UK HACCP legislation may require some subtle restructuring if HACCP procedures developed as a result of legal requirement in the UK are to be as effective as possible.

Necessary administrative structure and distribution of responsibilities (HACCP in The Netherlands)

Adoption of EU directive 93/43/EEC in the Netherlands was a major challenge, because as de Sitter and van de Haar [58] observed "Normalization and certification are instruments, which are not widely used in the food industry in The Netherlands." Consequently, an understanding of some important criteria for developing the necessary administrative structures for HACCP legislation can be gained from the experiences of the General Inspectorate for Health Protection (GIHP), the government agency responsible for the food safety legislation within The Netherlands. The GIHP recognised that a high level of reorganisation would be required by many Dutch food companies to become compliant with EU directive 93/43/EEC. For example, under the EU directive, individual food companies were responsible for developing, implementing and maintaining their own HACCP procedures. The lack of specific details (e.g., monitoring criteria, regulatory limits or defined procedures) meant that individual food companies could each interpret directives in significantly different ways. It then became the responsibility of GIHP to judge whether these interpretations ensured food safety. Assessment was typically conducted on a case-by-case basis, i.e. there were no firm rules for implementation of HACCP, or for the assessment of the subsequently developed HACCP plans. As a result of experience gained from initial audits of food manufacturing practices that were believed to be most readily amenable to HACCP, the GIHP concluded that a 'checklist' approach was unlikely to be effective for hazard identification and control development. As of 1996, surveys of Dutch food companies indicated that 7% of companies believed that they had met the requirements of the EU directive, 60% had not yet met these directives but were in the process of developing safety assurance procedures, and 33% of companies had not began developing in-house safety assurance procedures [59]. Although no specific statistics were found, take-up and implementation of HACCP in The Netherlands is already much greater than four years ago, a trend that is likely to continue. The GIHP predicted that many food companies, especially small- and medium-scale enterprises, would require some degree of external support to develop reliable HACCP procedures, so existing Dutch Good Hygienic Practices, codes of practice and guidelines for food companies were modified to comply with EU directive 93/43/EEC. The GIHP then required that Dutch food companies were responsible for both identifying CCPs within their own activities and developing effective HACCP procedures. The GIHP, or food inspectors representing the GHIP, would then only implement legal action if they could prove that an individual Dutch Food company's HACCP procedures could not assure food safety. In terms of food company accreditation and certification, the GIHP initially explored the possibility of HACCP certificates awarded on the basis of site accreditation under the ISO 9000 scheme, which has previously proved popular with US food companies [40]. However, as there are no specific criteria for HACCP, each food company could potentially define their own criteria for ISO 9000 accreditation and certification, rendering this approach almost valueless [58]. Attempts by the Dutch Accreditation Council (Raad voor Accreditarite) to produce industry standardised criteria for ISO 9000 accreditation was also unsuccessful as the procedures developed were found to be too complex to assess efficiently. The most recent, and successful, Dutch HACCP accreditation scheme is CCvD [60]. Under this scheme four Dutch food companies are currently accredited for HACCP certification and a further three are soon expected to receive accreditation [58].

Comprehensive HACCP according to EU 93/43/EEC (HACCP in Germany)

In the Federal Republic of Germany, the Ministry of Health (MoH) is responsible for the implementation of EU directive 93/43/EEC. The MoH and associated German government agencies have developed a comprehensive legislative strategy for food industry wide adoption of HACCP principles. Consequently, many German food companies already have HACCP procedures in place and a large body of academic, government and industrial HACCP documentation has been published. The German approach to HACCP legislation provides a good example of a rigorous legislative approach to EU directive 93/43/EEC and its implications for implementation. However, there has been some criticism of EU directive 93/43/EEC and there are concerns about the effectiveness of HACCP procedures based upon it [34, 58]. Consequently, the MoH implemented a study of HACCP procedures developed in accordance with EU directive 93/43/EEC. Untermann [34] has reported

some of the initial findings and problems identified, which include:

- A significant number of food companies appear to have instigated a logical sequence of basic hygienic measures and documented this as a HACCP procedure.
- Few food companies appeared to have employed hazard analysis effectively during the development of HACCP procedures (e.g., few appeared to have conducted separate product- and process-specific hazard assessment).
- A significant number of food companies appear to have incorrectly assigned CCPs.

These findings clearly indicated that HACCP principles were not being applied as effectively as they should have been in many commercial food companies. The MoH concluded that if HACCP is not being employed effectively it was not providing the highest level of food safety assurance possible. Consequently, the MOD instigated a national review of HACCP practices. One of the most highly structured and rigorous interpretations of the 'classical' HACCP principles was developed as a means of addressing some of these problems [34]. This approach employed a basic model, the 'Zurich House of Food-Safety,' which the 'foundations' are the condition of the premises and equipment, the 'walls' are the standard hygienic procedures and the 'roof' is the HACCP procedures (i.e., the product- and process-specific safety measures). Total Quality Management (TQM) procedures developed in accordance with the 'Zurich House of Food-Safety' model would include separate site maintenance, basic hygienic procedures and HACCP procedures. This approach identifies the individual components of the TQM. It also allows the HACCP team to focus on the product- and process-specific hazards within the hazard procedure, as opposed to repeatedly addressing basic food safety issues common to all processes. Consequently, such HACCP procedures have the greatest potential to be both effective and efficient food safety assurance procedures. However, Untermann [34] also reported a number of problems that related directly to the way in which HACCP principles were interpreted within EU directive 93/43/EEC.

- EU directive 93/43/EEC only addresses stages after primary production (i.e., manufacturing and subsequent activities).
- The 'critical points' referred to in EU directive 93/43/EEC are not CCPs, as defined in conventional HACCP documentation, because they are the points where a hazard occurs, while conventional CCPs are the points at which a hazard can be controlled or eliminated.
- EU directive 93/43/EEC specifically states that monitoring must be instigated "at these critical points," which can sometimes be impractical, ineffective or inefficient.
- EU directive 93/43/EEC does not address either verification or documentation.

Consequently, rigorous adherence to EU directive 93/43/EEC might cause problems for food companies attempting to develop effective HACCP procedures.

HACCP in Canada

In Canada, food legislation falls under the federal jurisdiction of four departments: Health Canada (HC), Agriculture and Agri-Food Canada (AAFC), Industry Canada (IC) and Fisheries and Oceans Canada (FOC). All four departments are involved in the inspection, surveillance and analysis of foods sold in Canada. Consequently, they have all been actively involved in the development of HACCP legislation for Canada [61]. To co-ordinate HACCP activities, AAFC formed a new Agri-Food Safety Division to develop and assess proactive and preventative measures for food safety issues [3]. FOC introduced a mandatory quality management programme (QMP) for the fish processing industry, which employed HACCP principles [3, 62]. Spencer [63] briefly described the guidelines developed to help Canadian fish processing companies develop their own QMPs, and identified a list of minimum requirements for individual Canadian fish processing site QMPs similar to those described above for US fish and fish-product companies (see 'HACCP in the United States'). Spencer [63] also observed that fish processing was only to be assessed upon these minimum requirements, and where additional requirements had been adopted by individual fish processors, these would not be subject to external inspection and assessment by the FOC. AAFC instigated a Food Safety Enhancement Program (FSEP) to encourage the adoption of HACCP within all agri-food establishments (e.g., dairy, eggs, fresh and processed vegetables and meat) [3]. The FSEP, which was implemented between 1993 and 1996, established the following requirements for all food commodities [64]:

- Individual food enterprises are responsible for developing HACCP-based programmes.
- AAFC will assess these programmes and give additional assistance as required to aid food enterprises in meeting FSEP requirements.
- Food industry personnel are responsible for controlling, monitoring and accurate record-keeping with regards to all CCPs, as well as implementing corrective actions when control losses occur.
- AAFC will review site records, assess corrective actions, observe process site activities at CCPs and

take samples as required to verify the overall effectiveness of HACCP programmes.

AAFC is also understood to be developing a Food Safety Expert System [3,62].

HACCP in Australia and New Zealand

Although the food industry in Australia showed interest in HACCP principles at a similar time to in other countries (i.e., the early 1980s), the adoption and implementation of HACCP was much more rapid and industry-driven, by comparison to other countries. Early interest was focused on the development of HACCP procedures for export industries and special emphasis was placed upon the dairy product export industry as it represents a significant component of Australian food exports. By 1984 the majority of process control procedures within the Australian dairy industry were HACCP-orientated [65]. About this time Qantas was developing HACCP schemes for the safety assurance of in-flight meals and the Australian Quarantine Inspection Service (AQIS) were implementing a HACCP control system for all food export sectors (e.g., fruit, grain, meat seafood and vegetables). However, there was some inconsistency between food safety assurance schemes developed for the export and national food markets, and by the mid-1990s a number of HACCP-based systems were being employed in Australia (e.g., AQIS, CAC, ICMSF and NACMCF). In an effort to standardise food safety activities throughout both Australia and New Zealand, the Australian and New Zealand Food Authority endorsed the principles of HACCP as described in the 1996 CAC guidelines for HACCP development [66]. Earlier studies by the AQIS indicated that conventional accreditation systems, such as ISO 9000, were likely to be too cumbersome for use with HACCP, especially for small- and medium-sized food enterprises. ISO 9000 accreditation was not perceived as a meaningful criterion for assessing food safety so the West Australian Department of Agriculture's Trade and Development Unit (commonly referred to as AgWest) instigated the Safe Quality Food (or SQF) 2000^{TM} Quality Code [67]. This system, which is discussed in further detail by Peters (1998), employed the simple consumer-based principles that:

- In order to meet consumer expectations, appropiate food product specifications have to be developed for the assessment of both quality and safety.
- The safety assurance scheme should enable these specifications to be assessed during production.
- A flow chart should be produced for the specific food production enterprise.
- The safety assurance scheme should be developed in accordance with CAC [68].
- The safety assurance scheme should incorporate support programmes for (Good Manufacturing Practices, cleaning and sanitation, pest control, monitoring and process equipment calibration, preventative maintenance, training and record keeping).
- The process and safety assurance scheme should be assessed and certified by independent third-party audit and certification.

A second third-party certification scheme was also introduced: the Woolworths Vendors Quality Management Standard (WVQMS). WVQMS was similar to SQF 2000TH, and incorporated nine requirements:

- Preparation of a HACCP Plan.
- Document control.
- Good Manufacturing Practices.
- Cleaning procedures.
- Pest control.
- Training.
- Monitoring and process equipment calibration.
- Production identification.
- Corrective actions.

Both SQF 2000TH and WVQMS are now rapidly gaining acceptance both in Australia and other countries. Peters [65] attributed this success to a number of factors, including:

- Their focus on consumer requirements when identifying quality and safety factors and developing subsequent assessment criteria,
- A voluntary rather than mandatory requirement for certification, whilst at the same time maintaining a strict adherence to legislative requirements,
- A clear business enhancement potential from competitor differentiation, and
- Requirement for assured supply chains from primary producer, through all steps of production, and to the purchaser.

Peters [65] also recommended that these factors should be considered when introducing any new HACCP-based food safety programme.

Concerns about the effectiveness of HACCP procedures developed by commercial food enterprises in New Zealand, and other countries led to the introduction of a generic template for the development of risk-based HACCP procedures for raw food commodities by the New Zealand Ministry of Agriculture [69]. This 'generic template for development of HACCP' approach is a highly significant refinement of the 'generic' approach to HACCP training. Generic HACCP procedures have previously been identified as particularly useful tools for use in the development of new HACCP procedures [37,

70, 71]. However, most of these provide a theoretical HACCP procedure developed for a typical (or standard) food enterprise as a template that an individual food company can modify to employ within their own operation. The generic template for the development of HACCP provides a robust framework for establishing general site quality and then developing and implementing HACCP. This approach, as described by Lee and Hathway [33], can be summarised as follows:

- *Prerequisite programme*. A series of steps that mush be implemented before the HACCP can be developed.
- *The identification of the HACCP procedure scope*. A clear statement of the intended objectives of the HACCP procedure, the provision of means for achieving these objectives, identification of any limitations, and a statement of 'due diligence'.
- *HACCP development*. The development of the HACCP plan.

This approach is likely to reinforce the HACCP principles and emphasise the clear divide between HACCP and basic hygienic procedures within food production and handling operations. Consequently, it could be considered to address many of specific issues that the 'Zurich House of Food-Safety' model was also developed to address. The approach also incorporated an interesting variation on conventional hazard identification within HACCP. Hazards are divided into classes and each class of hazard is assessed separately. For example, chemical hazards are categorised as C1, identified chemical hazards, or C2, unidentified chemical hazards. Although potentially an interesting area for consideration, C2 type CCPs are rarely discussed within conventional HACCP literature. CCPs can be designed for unidentified hazards, as long as the nature of the hazard has to be defined. For example, contamination of foodstuffs by unidentified organic chemicals in production water can be minimised by ensuring the quality of water supply, instigating pre-processing clean-up procedures and/or minimising the volumes used in food production. However, it should be recognised that C2 type CCPs can not be considered true CCPs according to the classical definition, as the effectiveness of monitoring procedures and corrective actions would be unknown.

HACCP in Developing Countries

Application of HACCP procedures within developing countries has been widely recommended [4,42,72]. Despite some initial reticence, HACCP has now becomes increasingly popular in developing countries. A number of limitations and problems associated with HACCP implementation in developing countries are similar to those previously identified for small- and medium-scale enterprises in the western world, while others relate to cultural or language problems. For example, in a recent study of the implementation of HACCP in Thailand, Jirathana [73] identified a number of constraints, including:

- *Education and training*. There is often a significant lack of well educated and/or highly trained personnel within the workforces of food companies within developing countries, and this can present problems, particularly in hazard identification and assessment activities.
- *Availability of native language HACCP documents*. In most developing countries the supply of native language HACCP documentation is likely to be very limited. Consequently, there is a heavy reliance upon foreign language (predominantly English) documentation and English-speaking employees.
- *Availability of hazard information*. In most developing countries, food processing industries lack the necessary basic scientific information (i.e., national food poisoning statistics or national foodborne disease databases) required to develop reliable hazard assessments.

Concluding Remarks

This report is not intended as an exhaustive review of the methods employed in each country that has implemented HACCP. To do so would involve a large amount of repetition as many countries have adopted very similar approaches. Rather, this review attempted to provide an overview of HACCP as it is applied throughout the world, using selected examples to highlight some subtle differences in the way in which different countries have implemented HACCP. This review demonstrates that there is now widespread adoption of HACCP principles in both government and industry in a number of countries and that HACCP has been widely identified as a likely component of the standardisation of food quality control and assurance practices for international trading [74–76]. Consequently, HACCP is likely to become an increasingly important part of future food safety activities and legislation. Therefore, it is important that (i) governments ensure that effective HACCP implementation guidelines are available to their national food companies and additional guidance is available if required, and (ii) food companies ensure that the HACCP procedures they develop are as effective as possible to maximise the degree of food safety provided. Of the examples discussed here, four appear worthy of particular consideration within the framework of HACCP-based food safety assurance:

1. The Food Safety Enhancement Program developed by Agriculture Canada [64] is a particularly interesting framework for the development of HACCP procedures. Like many other national

approaches it placed the responsibility for developing HACCP-based programmes upon individual food enterprises. However, it also committed AAFC to providing additional assistance as required to aid food enterprises in developing these procedures and taking responsibility for verifying the accepted procedures. This type of approach demonstrates a strong commitment to effective HACCP by government, as well as commercial food producers.

2. The 'generic template for HACCP development', as described by the New Zealand Ministry of Agriculture [69], may provide a particularly robust framework for the development of effective HACCP procedures.
3. Untermann [34] presented one of the most highly structured and rigorous interpretations of the 'classical' HACCP principles. The approach employed a basic model, the 'Zurich House of Food-Safety', in which the 'foundations' are the condition of the premises and equipment, the 'walls' are the standard hygienic procedures and the 'roof' is the HACCP procedures (i.e., the product- and process-specific safety measures).
4. The approach adopted by the Australian food industry focused upon the development of voluntary, third party certification standards that employed HACCP principles for both food safety and quality assurance. This led to the development of two schemes: the Safe Quality Food (SQF) 2000 and the Woolworths Vendor Quality Management Standard (WVQMS) [65]. These schemes are probably the most practical and 'consumer-friendly' HACCP-type schemes currently in use, although it should be understood that they could not be described as conventional HACCP.

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