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ScienceDirect
Journal of Food Engineering 79 (2007) 1322–1328
JOURNAL OF FOOD ENGINEERING
www.elsevier.com/locate/jfoodeng

An alternative approach to HACCP system implementation

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Received 30 October 2005; accepted 11 April 2006
Available online 6 May 2006

Abstract

The practical implementation of hazard analysis and critical control point (HACCP) and in particular the definition of the critical control points (CCPs) in the food industry is usually a complex structured task. This is particularly the case of small medium enterprise (SMEs), where quality/safety manager ability, knowledge of the production processes and "sensitiveness" is usually the discriminate for the proper identification and prioritization of risks. The same applies for the definition of causes which may lead to food safety hazards.

This paper addresses the issues of how quality/safety managers can objectively and automatically implement the first and second principles of hazard analysis in the application of HACCP, which is the identification of risk priorities and of the related CCPs, by means of a structured, quantitative and qualitative methodology. The proposed methodology combines fault tree analysis (FTA) approach, for the analytical decomposition of the relevant steps in the manufacturing process of a food product, and fuzzy logic, for quantitative measures of occurrence likelihood.

The practical implications of the methodology are finally tested through a real case application.

Keywords: Hazard analysis; Critical control point; HACCP; Food safety

1. Introduction

The term "hazard analysis and critical control point (HACCP)" was first introduced in the European Directive 93/43/CE (1993). In the last decade, the HACCP technique has been progressively been recognized as a cost-effective procedure for ensuring food safety.

Today, this methodology is internationally accepted as an effective tool to deal with safety hazards which may arise in the food production process. Indeed, since the adoption of the Codex Alimentarius "Guidelines for the application of the hazard analysis and critical control point (HACCP) systems" and its subsequent revision "hazard analysis and critical control point system and guidelines for its application" (Codex, 1997), the application of its seven principles has become mandatory requisites in the food worldwide production chain, in order to prevent the occurrence of food safety hazards to final customers.

At the same time, data available from the EU indicate that about 90% of the European Union's food industry is made up of small or medium-sized enterprises (SMEs) (Taylor, 2001). In order to reinforce public health security, the EU has been forcing the implementation of full HACCP in all food businesses (Walker, Pritchard, & Forsythe, 2003). The proposed principles are different from those of the Codex and no mention is made of the need for formal HACCP plans (Serra, Domenech, Escriche, & Martorell, 1999; Untermann, 1999).

According to Mortimore (2001), HACCP can be defined as a "common-sense" approach to food safety management, whose implementation is quite demanding. To this extent, it has to be stressed how its practical roll out requires a mix of managerial, organizational and technical

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0260-8774/$ - see front matter © 2006 Elsevier Ltd. All rights reserved.
doi:10.1016/j.jfoodeng.2006.04.038

resources to cope with the technical barriers it presents (Panisello & Quantick, 2001). Taylor (2001) observed that even a large food company, with its resources of money and expertise, might face significant hurdles in developing a successful HACCP system. Thus, small and medium sized companies trying to implementing HACCP could likely face with insurmountable issue, jeopardizing the efficiency and the effectiveness of the implementation program. This point has also been particularly stressed by Ehiri, Morris, and McEwen (1995) and by the World Health Organization (1997).

It is widely recognised how the practical application of HACCP can be hindered by lack of time, expertise, training, motivation, commitment and funding, being these issues particularly true in SMEs. Authors such as Taylor (2001) consider the employment of experienced, technically qualified people as the most important factor influencing the implementation of the system. Conversely, the lack of skilled resources may lead to:

1. inability to prioritize risks deriving from physical, microbiological and chemical hazards;
2. inability to discriminate between the relative risks of different pathogens on a given food;
3. a lack of focus at the hazard identification stage that causes an inability to make technical decisions as to criticality.

The effectiveness of hazard analysis conducted by a SME could thus be low in spite of the extensive efforts profused for its development.

The scientific literature related to the HACCP system implementation issue shows haw many authors (Tuominen, Hielm, Aarnisalo, Raaska, & Maijala, 2003; Van Gerwen, de Wit, & Notermans, 1997) have tried to define procedures aimed at simplifying the hazard analysis. These authors recommend the use of specific software systems which make it easier to analyze/compare the different risks which may stem from production processes. This task is accomplished by identifying iterative cycles based on experience, regulations and databases of foods, pathogens, etc. Although these procedures could be a valid support tool to make the development of an HACCP system in a SME easier and more effective, still they lack of effectiveness in defining a straightforward and "automated" path for hazard assessment. Hazard assessment is in fact still based on a "traditional" approach, based on a simple evaluation of hazards rather like the one conducted during a brainstorming session, as recommended by the NACMCF (1998).

In this paper we try to overcome this limitation by introducing an original methodological approach to carry out handling a structured hazard analysis. The methodology considers hazards as the failures of a food production process in a fuzzy fault tree. For each step of the production process, the fault tree analysis makes it possible to define whether that stage either will be or will not be a critical control point, depending on the hazard's likelihood of occurrence and on its severity, the latter measured in terms of detectability by processes downstream. Note that this parameter is strictly correlated to the risk of bringing the food hazard directly to the final customer, since the lower the detectability, the lower the probability the risk will be eliminated downstream by removing potentially dangerous products. The decision support tool proposed here enables the automatic identification of critical control points, for subsequent implementation in a software system with a database of hazards connected with the ingredients and process steps. The main input used in the proposed methodology for implementing the first and second principles of HACCP consists in an expert knowledge of the process and procedures involved in producing the food considered.

To conclude, given an hazard, the probability of a process stage of becoming a CCP for that hazard increases for increasing values of the probability of occurrence and for decreasing values of hazard detectability downstream.

The reminder of the paper is organized as follows. In the next paragraph, for clarity' sake, fundamentals of FTA and of fuzzy logic are presented. Then, the methodology is thoroughly detailed. Next, a real case is considered to assess the practical applicability of the approach proposed and its main advantages and drawbacks.

2. Overview of fault tree analysis, fuzzy logic and fuzzy numbers

The fault tree analysis (FTA) technique has been widely used for many years in reliability evaluation of standby, protection and complete mission oriented systems. FTA is a tool for qualitatively assessing the failure process in a complex system. The method is based on the recognition of the "main system" failure (the top event, TE), that is identified through different sequences and combinations of basic events (system component failures or malfunctions) leading to TE (Billinton & Allon, 1992).

Fault tree analysis starts by considering a specific system failure mode and operates according to a top–down approach, subsequently breaking down the causes of this failure into an increasing number of hierarchical units until the effects of the system's basic components can be identified (the failures of basic components or subsystems are the basic events in a fault tree).

Since a fault tree is a logical representation of the way systems fail, it is constructed using logic gates – such as AND, OR, EOR, etc. – in a top–down approach whose outputs are intermediate events representing a combination of failure events. This logic is shown in Fig. 1.

There are two approaches to assessing the likelihood of the top event in a fault tree: the Boolean algebra approach, where every intermediate event is logically replaced by the events on the next hierarchical level until the logical statement representing the top event is in terms of basic events alone; and the direct numerical approach, where numerical values for the probability of intermediate events, starting at the lowest hierarchical level, are evaluated in a "reduction

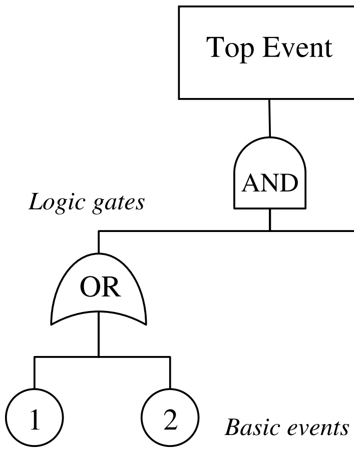

Fig. 1. Fault tree analysis logic.

process" on the fault tree, using the appropriate logic gate by which they are connected. For more details on FTA, see Schneeweiss (1999).

It may be useful to spend a few words on the fuzzy approach to fault tree analysis, which is useful in the event of uncertainties in the probabilities of failure in the system's basic events: the input parameter is the expert's opinion of the likelihood of the event (Kim, Ju, & Gens, 1996).

Fuzzy logic is a very useful tool for working directly with the linguistic terms used in criticality assessments (Bowles & Pelàez, 1995) and other analyses concerning imprecise and vague problems. A linguistic variable is a practical way to deal with situations too complex or ill-defined to be described in a conventional quantitative expression. A variable is linguistic if its values are words or sentences in natural or artificial language (Lin & Wang, 1997). Fuzzy logic can handle linguistic variables by translating them into fuzzy triangular numbers, which can be used to indicate the likelihood of an event.

The following is a brief analytical introduction to fuzzy set theory:

- Let X be the universe (a collection of objects) and x its elements. A fuzzy subset $Y \subseteq X$ is characterized by a membership function $\mu_y(x)$, which associates each element $x \in X$ with a real number $\in [0;1]$. The function value $\mu_y(x)$ represents the degree of membership of x in Y, and the larger the value of $\mu_y(x)$ the stronger the membership of x in Y.
- Let $x, a, b, c \in R$ and $a \leqslant b \leqslant c$; a fuzzy triangular number (FTN) A has a membership function

$$\mu_a(x) : R \to [0,1] \mid = \begin{cases} \dfrac{(x-a)}{(b-a)}, & a \leqslant x \leqslant b \\ \dfrac{(c-x)}{(c-b)}, & b \leqslant x \leqslant c \\ 0, & \text{otherwise} \end{cases}$$

and can be denoted as $A = (a, b, c)$. The maximum grade of $\mu_a(x)$ is in b.

3. The fuzzy FTA methodological approach for HACCP system implementation

The technique presented here is based on the following evidence:

1. the food production cycle is technologically constrained and it can be outlined as a sequence of steps;
2. each step in the process performs a function by applying "process parameters", whose application ensures that the Work In Process comes up to standard for the product.

A process parameter is an executive state previously defined as ideal for the proper realization of the production step. To clarify this point, consider for example a cooking step in an oven: possible process parameters may be oven temperature, cooking time, internal humidity, etc.

After these considerations comes the next hypothesis: if a process parameter is not satisfied, a hazard may occur. This hypothesis is fundamental because it assumes that the production process is hazard-proof, a circumstance not always achieved in existing food production plants nowadays, but achievable if plant is designed according to EC standards, so that a hazard can only occur as a consequence of process deviations.

The proposed method involves developing a fault tree FT_{kl} for each step k in the production process and for each hazard l that might be generated in the step considered. It is important to emphasize that it is essential to consider every potential hazard identifiable in a given step (if a process parameter is not satisfied) after reviewing the sensitive ingredient lists, the scientific literature and the regulations, and after consulting the process experts ("in future, this knowledge should be available in a database"). At every step, a fault tree must be developed for every possible hazard, from the most obvious and significant to the least.

An example of a fault tree is given in Fig. 2.

The basic events in fault trees are process deviations (e.g., component or subsystem malfunctions) and failures of other kinds (such as a procedure not followed by an operator).

These basic events are combined by an OR logic gate defining the intermediate event "Process parameter not satisfied", which is then combined by an AND logic gate with the event "Occurrence of the hazard considered in the step due to the process parameter not being satisfied". The resulting intermediate event is then joined by an OR logic gate to similar events to achieve a logical representation of the top event "Occurrence of the hazard considered in the step considered".

Once a fault tree has been constructed, the events "Occurrence of the hazard considered in the step due to the process parameter not being satisfied" are assumed to be certain, so that the fault trees can be broken down to become a simple OR function of basic events.

To qualitatively assess the top event, production cycle experts are then asked to judge the Occurrence and Detect-

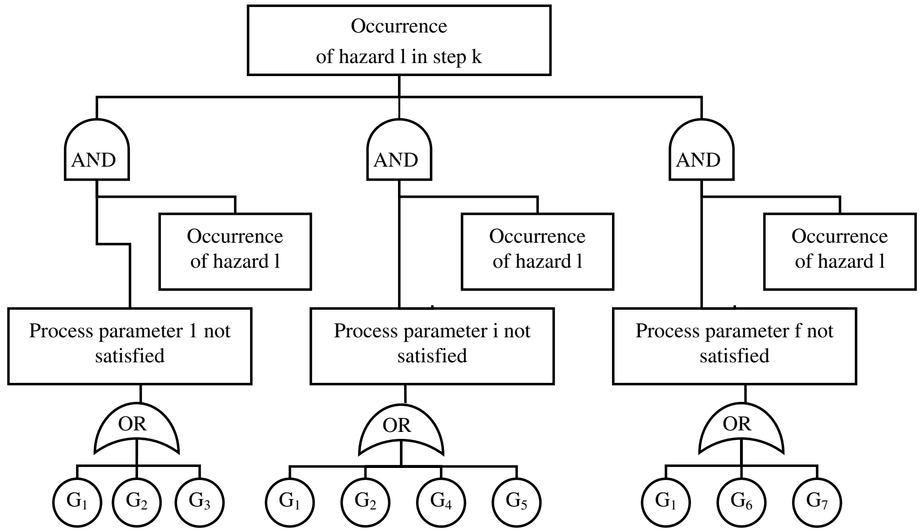

Fig. 2. Example of a fault tree.

ability of the basic events in the tree. *Occurrence* estimates the probability of the failure occurring, while *Detectability* considers how easy it is to detect the failure immediately.

These linguistic variables comprise an attribute and a judgement, and they are translated into fuzzy triangular numbers, which are a useful means for handling information about imprecise and vague problems.

Experts can choose one of three attributes: "certainly, probably and maybe (S, P, M)" to indicate how sure they are of their judgement; and five judgements that define the parameter's intensity: "low, fairly low, medium, fairly high, high (L, FL, M, FH, H)". The judgement defines the value of $b \in [0;1]$, while the attribute defines the width of the base $\overline{ac} \in [0,\ 1;0,\ 3]$. The triangular fuzzy numbers so created are isosceles Fig. 3.

For each parameter in a basic event there are several fuzzy numbers (one for each expert), so an average fuzzy number is created for each parameter by a simple arithmetic mean of the values a_i, b_i, c_i, where i stands for the expert in question.

Once an FTN has been obtained for each parameter of a basic event j (O_j, D_j), these parameters are multiplied $(Gj = Oj \cdot Dj)$ and the result is then defuzzified to obtain a crisp number g_i (Brubaker, 1993), that facilitates the subsequent calculation.

Applying the direct numerical approach to the fault trees (FT_{kl}), using g_i instead of failure probability, gives us the "criticality number" (C_{kl}) of a step k regarding a particular hazard l:

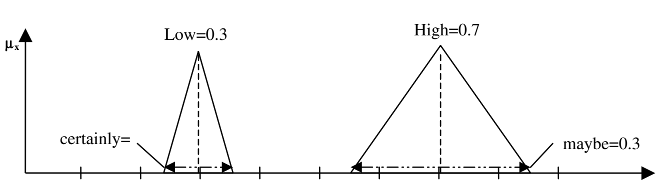

Fig. 3. Fuzzy triangular number (FTN).

$$C_{kl} = 1 - \prod_{i \in FT_{kl}} (1 - g_i) \tag{1}$$

This criticality number represents the propensity of step k to generate hazard l.

Then the experts are asked to judge the severity of the hazard l in the event reaching the final consumer. This judgement is converted directly into a crisp number $S_l \in [0;1]$ for easier implementation.

This enables us to obtain a "risk number" R_{kl} of step k regarding the hazard l simply by multiplying C_{kl} and S_l:

$$R_{kl} = C_{kl} \cdot S_l \tag{2}$$

Once we have an R_{kl} for each step and for each potential hazard that might be generated in the step, we can represent the results in a diagram, which has the R_{kl} on the Y axis and the process steps on the X axis.

By creating two conditions – a lower bound (LB) and an upper bound (UB), which are specified by the experts as the smallest risk above which a CCP is considered necessary and the highest risk beyond which a CCP is definitely essential – some very simple rules are created to pinpoint which hazards are relevant and which steps in the process are CCPs. These rules compare the value of R_{kl} against the LB and UB:

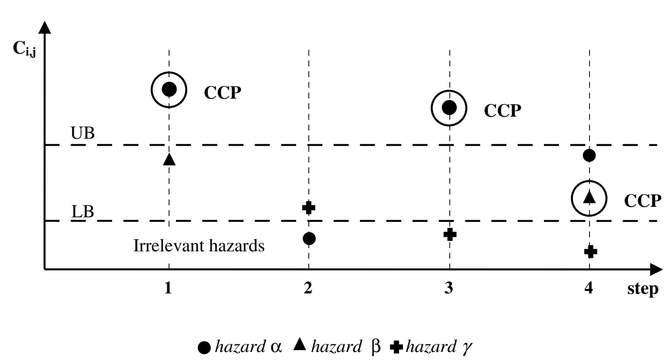

Fig. 4. Detecting relevant hazards and CCPs.

- if all R_{ki} referring to the hazard i are below LB for each step $k|\exists R_{ki}$ then i does not need a CCP;

Table 1
Example of standardized occurrence judgment

Failure occurrence	Quantification
Low (L)	Frequency of failure > 3 years
Fairly low (FL)	1 < frequency of failure < 3 years
Medium (M)	7 months < frequency of failure < 1 years
Fairly high (FH)	4 < frequency of failure < 7 months
High (H)	4 < frequency of failure

- if all R_{ki} referring to the hazard i are between LB and UB for each step $k|\exists R_{ki}$ then i has just one CCP in the last step $k|\exists R_{ki}$;

Table 2
Example of standardized attributes

Attribute	Explanation
Certainly (S)	The expert knows exactly how dependable his answer is
Probably (P)	The expert has some doubts about his answer
Maybe (M)	The expert has considerable doubts about his answer

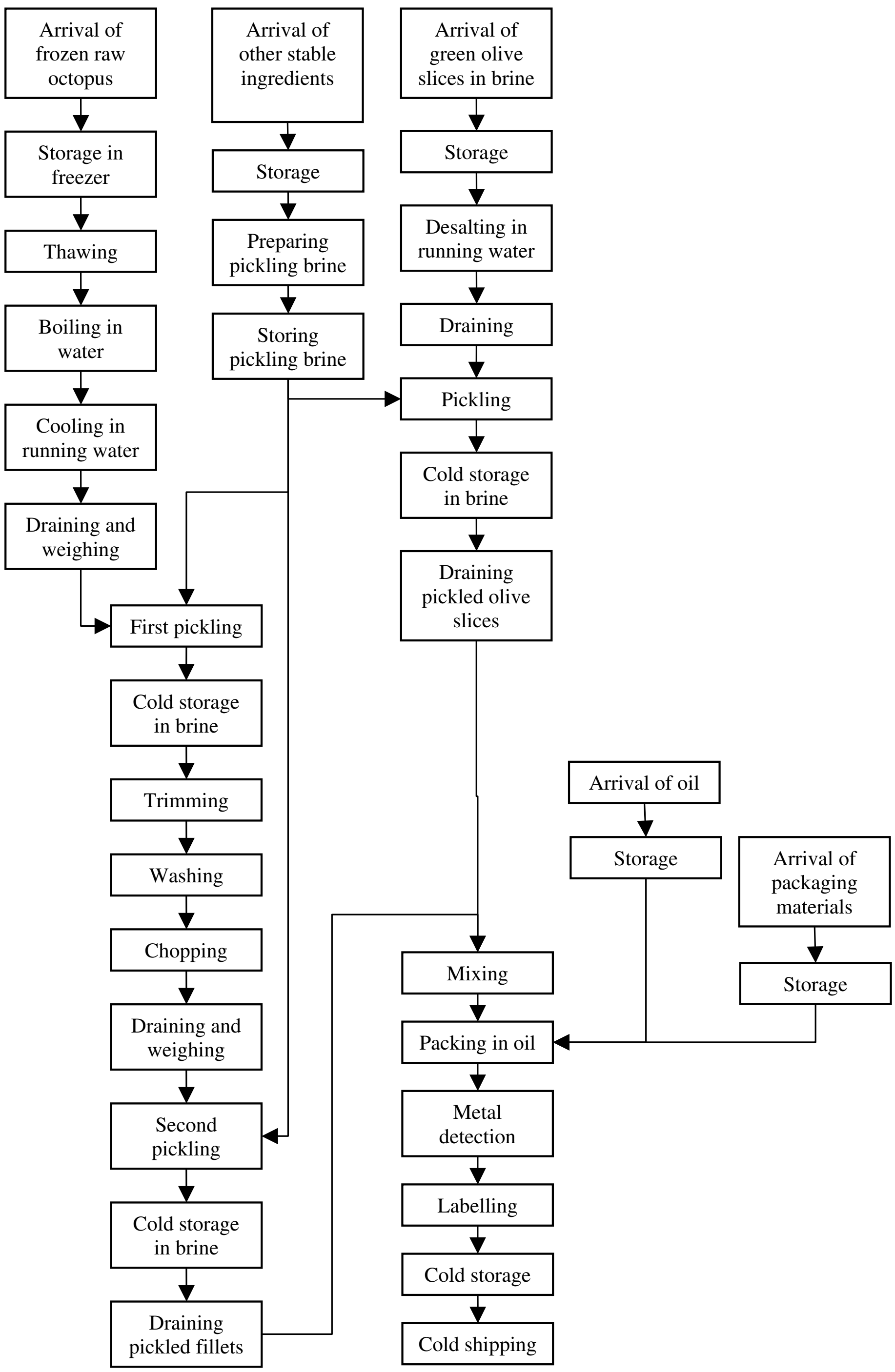

Fig. 5. Flow chart for octopus salad production.

- if only one R_{ki} referring to the hazard i is above UB between steps $k|\exists R_{ki}$ then i has just one CCP in that step k;
- if more than one R_{ki} referring to the hazard i is above UB between steps $k|\exists R_{ki}$ then i has a CCP in each of the steps where $Rki >$ UB.

Fig. 4 illustrates the relevant hazard and CCP identification process.

In this paper, the UB and LB are defined by experts because they answered questions and know what meaning they gave to their answers. In a software application, the UB and LB should be chosen by the software designer and the experts' answers should be standardized using Tables 1 and 2, such as the one given below.

4. Case study

The above-described alternative approach to implementing an HACCP system was applied to an Italian seafood company that has been producing seafood products since 1861. The company supplies a wide variety of fish and shellfish, such as seafood salads, or mackerel and anchovy fillets. The different strategy in implementing the first and second principles of HACCP was applied to an octopus salad product. This is a ready-to-eat food for the general consumer, obtained by marinating chopped octopus and olives, then packaging it with oil in a plastic tray. The process flow chart for octopus salad is shown in Fig. 5.

A panel of experts (i.e., academics, production managers, product safety and quality managers), comprising a number of people large enough to reduce the bias due to individual opinions, was created to apply the proposed

Table 4
Critical control points identified for octopus salad

Critical control point (CCP)	Significant hazards
Arrival of frozen gutted fish receiving	Environmental chemical contaminants and pesticides
Arrival of packaging materials	Migration of chemical constituents
Boiling in water	Bacterial pathogen survival
Cooling and rinsing in running water	Bacterial pathogen growth and toxin formation
First pickling and cold storage	Bacterial pathogen growth and toxin formation in end product
Trimming, washing, chopping, draining and weighing	Bacterial pathogen growth and toxin formation
Second pickling and cold storage	Bacterial pathogen growth and toxin formation in end product
Pickling of olive slices and cold storage in brine	Bacterial pathogen growth and toxin formation in end product
Metal detection	Metal inclusions
End product storage	Pathogen growth and toxin formation
End product refrigerated shipment	Pathogen growth and toxin formation

Table 3
Excerpt from hazard-analysis worksheet for octopus salad

Ingredient/Processing step	Identify potential hazards introduced, controlled or enhanced at this step	Justify your decision	What measures can be applied to prevent the significant hazard?
Arrival of frozen gutted octopus	Contamination by bacterial pathogen from harvest area	Frozen seafood can be a natural source of pathogens	A subsequent cooking step based on the assumption of a high bacterial load
	Pathogen growth in transit	Potential thermal abuse could raise pathogen levels	As above
	Parasites	A potential parasite hazard exists in octopus	A subsequent cooking step that will kill the parasites
	Environmental chemical contaminants and pesticides	Raw seafood can be a natural source of environmental chemical contaminants	Check all incoming product to ensure that supplier certifies that raw fish was harvested from waters officially classified as safe
	Metal inclusions	Damaged gutting tools	Metal detection on packaged product
Boiling in water	Bacterial pathogen survival	Without proper processing time and temperature, bacterial pathogens may survive	Adequate cooking time and temperature
	Parasite survival	Parasites have a lower thermal resistance than bacterial pathogens	
	Water contaminants	Unlikely to occur. Drinking water is used	
Second pickling and storage in cold brine	Bacterial pathogen growth and toxin formation in end product	Higher end product pH	pH < 4.5 in the loin muscle of the largest octopus chops before draining and packaging is allowed
		Thermal abuse	Cooler air temperature
Metal detection	Metal inclusions	Detector may not function properly	Hourly checks to ensure detector is on and daily tests on its sensitivity
End product cold storage	Bacterial pathogen growth and toxin formation	Thermal abuse	Monitor air temperature

HACCP implementation procedure, using the Delphi method, standardized occurrence judgment and standardized attributes reported in Tables 1 and 2 respectively. This is a structured process investigating a complex or ill-defined issue by means of a panel of experts (Linstone & Turoff, 1975) and it is particularly suitable in the case of complex, interdisciplinary problems often involving a number of new concepts (Meredith, Raturi, Amoako-Gyampah, & Kaplan, 1989). The HACCP work group developed hazard-analysis worksheets, identifying the potential food contamination at each step of the production process, an excerpt of which is shown in Table 3.

Thus, after applying the above-described method and defining the UB and LB, the potential critical control points identified are as shown in Table 4.

5. Conclusion

The proposed method is a different strategy for successfully implementing the first two principles of HACCP.

Nowadays, the brainstorming session that completes the hazard identification process is an "a priori" analysis and its conclusions depend heavily on HACCP teamwork experience, knowledge and sensitivity – and CCPs are subsequently only determined for hazards emerging as relevant from said analysis.

The method proposed here is an "a posteriori" analysis in that it establishes the relevant hazards and the CCP only after conducting a rational and careful analysis of the production process, that leads to an understanding of the propensity of a given step to generate each particular hazard.

This method may not seem to simplify the development of HACCP principles 1 and 2, but its strength lies in that it can be upgraded in a software system, wherein relational databases correlate hazards with ingredients, process steps and parameters, procedures and so on, thus enabling the automatic creation of fault trees.

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