

Confusion determination of critical control point (CCP) via HACCP decision trees

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Abstract

Hazard analysis and CCP determination are the backbones of HACCP development and implementation. The rest of HACCP principles depend on these two principles. A decision tree is used to assist in determining the CCP. There are two types of decision trees used in the HACCP system that is decision trees for raw material/package material and process step. Various methods of the decision tree used in HACCP systems not only have advantages, but it can also contribute to the confusion in its application by practitioners. Although the decision tree is just a tool to help determine the CCP, its use is a significant impact on the HACCP team, consultants and decision-making authority in determining the CCP and sensitive raw materials in a structured manner.

Keywords

Food hygiene

Food safety

GMP

HACCP

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Introduction

After completion of hazard analysis, HACCP team shall be responsible for determining critical control points (CCP). CCP determination involves a thorough examination of the raw materials and process steps that are listed in the process flow diagram. HACCP team has to identify potential hazard in raw materials and process steps and establish specific control measure for the identified hazard. The problem is that what material or process to be identified as a sensitive raw material and CCP. Much debate among members of the HACCP team (Schmidt and Newslow, 2013) may also apply to consultants and the authority regarding this issue.

It is important to understand that HACCP is a system that revolves around food safety, not food. Therefore, quality system, in particular, CCP is related to food safety issues, not related to the issue of food quality. According to Schmidt and Newslow (2013), CCP can be distinguished by the CP as defined as follows: "Control Point (CP) is any step at which biological, chemical and physical factors can be controlled. Critical control point (CCP) is any step at which factors can be controlled when this control is essential to prevent food safety hazard, eliminate a food safety hazard, or reduce a food hazard to an

acceptable level."

CCP is the backbone of the HACCP plan in which all other HACCP principles are based on it. Correct CCP determination is an issue in HACCP, due to all affords in the system are devoted to these measures (Damikouka *et al.*, 2007). Thus, the CCP must be realistic, which means the number of CCP is not too much to an amount that does not make sense, as an example mixing of the dry product has a 600 CCP (Wallace and Williams, 2001). Number of CCP has affected the food safety system and essential to ensure effective HACCP system for daily practice. For example, two CCPs in the production of dried smoked meat (Asefa *et al.*, 2011), six CCPs for kenkey production of traditional foods national food Ghana (Amoa-Amua *et al.*, 2007) and six CCPs for vacuum packed sauced porks in food companies in China (Wang *et al.*, 2010).

The effective implementation of HACCP failures has been reported in the various foods industrial sectors. The main problem is poor training and lack of training in this area (Mensah and Julien, 2011; Macheke *et al.*, 2013). Weakness in both cases would directly affect the effectiveness of the implementation of HACCP (Karaman *et al.*, 2011). Misunderstanding of HACCP team, consultants and authority the purposes of the pre-requisite program, no ability to

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determine significant risk properly, and eventually establish a very complex HACCP plan with a lot of CCP (Mortimore, 2001).

It is important to the HACCP team, authority, and consultant to determine the relationship between the sensitive raw material, CCP, and CP to achieve food safety. The confusion in this matter will lead to the development of weak food safety systems, lost its credibility and ineffective HACCP implementation especially in resource management (Wallace *et al.*, 2014). HACCP system does not aim at the CCP to be determined or established, but give priority to critical process that requires control measures to ensure the safety of food produced (Schmidt and Newslow, 2013). In fact, a little CCP will give a more pronounced effect because it allows the production of unsafe products (Mortimore, 2001).

Significant hazards that have been identified can be determined whether CCP or sensitive material by using decision tree (NACMCF, 1997; Codex, 2003; MS 1480: 2007). The decision tree was having a plurality of series of questions used to provide explanation or understanding but has the same objective, which is leading to a correct decision making on the determination of sensitive materials and CCP. Application of the decision tree requires HACCP team, authorities and consultants to think more deeply using knowledge built as a result of work experience, training, and scientific data necessary to determine it (Sampers *et al.*, 2012). The skills required for CCP determination are product knowledge, production process, food safety hazards and measures needed to eliminate, reduce and control identified hazards to an acceptable level (Mortimore and Wallace, 1998).

According to Mortimore (2001) between the problems or errors that often occur in the process of determining the CCP is too much 'hazard' and 'CCP'. This results in a complex HACCP system is developed and one of the reasons why the HACCP failures in the company. This problem is related to several issues: (a) errors in determining the scope of implementation and confusion during the hazard analysis and quality aspects of food safety; (b) lack of expertise or skills in determining the significant hazard that underlies the determination of the CCP also present; (c) misconceptions about the role of PRP in the implementation of the HACCP system; (d) increase unnecessary CCP by guidance from consultants, clients and authorities.

Methodology

Based on the review of journal articles as well as

reports from Department of Standard Malaysia, Food Safety and Quality Division (Ministry of Health) and Standards and Industrial Research Institute of Malaysia (SIRIM); the major challenges faced by SMEs in implement HACCP were the determination of critical control point. It is also investigated on how these challenges influence the capability of SMEs towards food safety scheme certification. Important issues such as SMEs capabilities to fulfill minimum standard requirements and sustainability HACCP practice are identified to be problems that could arise (Hasnan *et al.*, 2014). These issues were analysed in connection with SME's difficulties to design an effective HACCP Plan. The analysis was based on a comprehensive review of Malaysian authoritative reports, standard requirements and data of journal articles, scholarly books, and magazines, newspapers as well as information obtained.

Decision trees

Decision trees have been used as an aid to the selection of critical control points as part of the development of hazard analysis critical control point (HACCP) systems (Codex, 2009). A decision tree developed specifically for the purpose to determine whether: identified hazards were a threat to a product; identified hazards were a food safety risk; source of the hazard; and whether there are control measures available for prevention, eliminate or reduce the hazard to an acceptable level (Horchner and Pointon, 2011). In this study, there were 4 decision trees consist of Codex (1997), Codex (2009), FAO (1997) and MS 1480: 2007 have been used for comparison. The major scope of decision trees was covered evaluation of significant hazard and control measure, the process specifically designed, contamination, and elimination of hazard. Through the study, there was no decision tree for raw material and packaging material established by Codex guidelines, but it was available in MS 1480: 2007.

Results and Discussion

This section is divided into three parts. The first part presents the advantage of a decision tree in CCP determination for the HACCP Plan development. The second section is the comparison of decision tree formats for process steps in determining CCP. The third section is regarding format of a decision tree for the raw material/packaging material.

Decision tree

The determination of significant hazards in raw materials and process steps as sensitive raw materials

and CCP can be done based on the knowledge and experience of the HACCP team members to make use of decision tree. A decision tree is used as guidance in the determination of sensitive material or CCP. The decision tree provides a logic reasoning approach when determining CCP (MS 1480: 2007). Decision trees are applied to brainstorming session among HACCP team members by following the structured questions (Wallace *et al.*, 2012). The situation is more beneficial regarding cooperation between members of the HACCP team for the HACCP development.

Comparison of decision tree for process step

Various versions have been issued for decision tree (NACMCF, 1997; FAO, 1997; Codex, 1997; Codex, 2003; Codex, 2009), and there are some different words, but most of them put the CCP in the same place. Comparison of the Codex decision tree (1997), FAO (1997), Codex (2009) and MS 1480: 2007 is shown in Figure 1, Figure 2, Figure 3 and Figure 4.

There was not much difference decision tree of Codex (1997) (Figure 1) and Codex (2009) (Figure 2) regarding the number of questions. Each of them respectively consists of 5 and 4 questions. An additional question in Figure 1 as compared with Figure 2: Is there a hazard in the process? This issue to guide the HACCP team about the hazard that there might be a step in the process under review. Then followed by a second question related to control measures to significant hazards identified. Here, the need to process control measures must be related to food safety issues. Questions 1 and 2 of the decision tree (Codex 1997) have summarised together in question 1 decision tree (Codex 2009). The word 'process' was used in the first question in decision tree (Codex 1997) and no longer used in questions 3. It means question 3 is referring to the process step in question 1 and not a control measure in question 2. Questions 3, 4 and 5 in the Codex (1997) decision tree are the same as the Codex (2009) decision tree.

Comparison decision tree FAO (1997) with decision tree Codex (2009), there are similarities between the numbers of questions to determine CCP. Question 1 in decision tree FAO (1997) does not use the word 'control measure' instead of using 'preventive measure'. The use of the different word could lead to a difference meaning and action. The preventive measure is the steps or action taken to ensure that the potential hazard does not happen. However, it does not indicate mitigation measures where the hazard can be prevented, controlled and reduced to an acceptable level. Some control actions allow anything harmful to happen, but it is

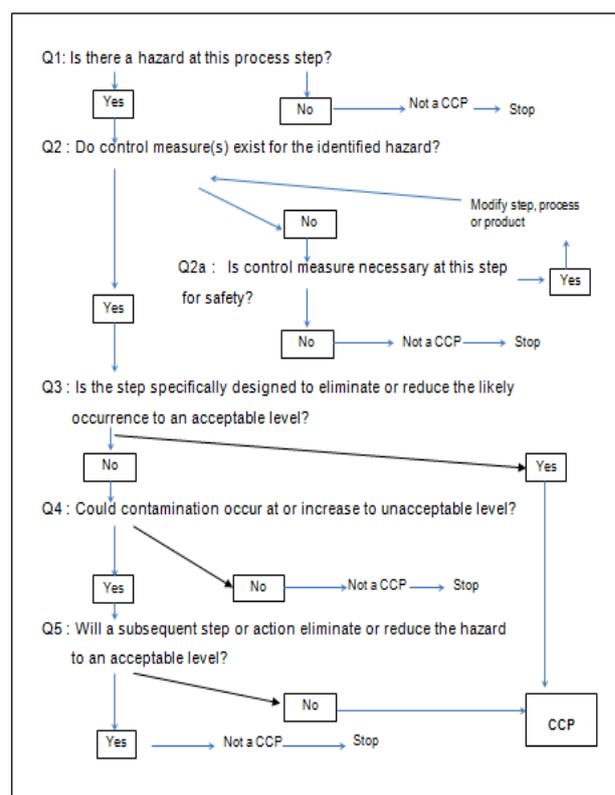


Figure 1. Decision tree (Codex, 1997)

in a controlled manner without exceeding the limit. 'Zero risk' can't be achieved in the production of food, approach through the decision tree is allowed risk owners to define the level of acceptability of the presence of contaminants in food, such as maximum residue level (MRL) for pesticides in food stage, or stage level of acceptance or tolerance to risk (Havelaar *et al.*, 2010).

Question 2 in decision tree FAO (1997) did not use the word 'process specifically designed' but 'step eliminate or reduce the likelihood of occurrence of this hazard'. If this question is not entirely understood, it could cause misinterpretation that steps process as a control measures and leads to a shortcut for the CCP determination.

The decision tree used in the MS 1480: 2007 for the process step is similar with Codex (2009) accept the first question, where the word 'significant hazard' and 'hazards identified' respectively used in decision tree MS 1480: 2007 and Codex (2009). The correct word used is a significant hazard due to CCP determination is a step after completion of hazard identification and hazard analysis that aimed to determine significant hazard (Mortimore and Wallace, 2013). The use of the words in decision tree questions did not have a significant impact when fully understood by the trained and experienced HACCP team.

CCP determination is assisted through the application of a decision tree that describes the

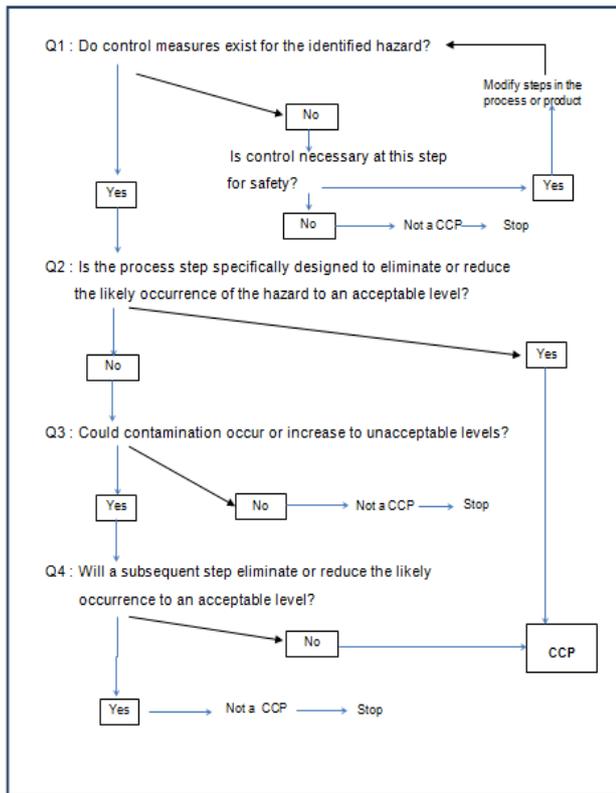


Figure 2. Decision tree (Codex, 2009)

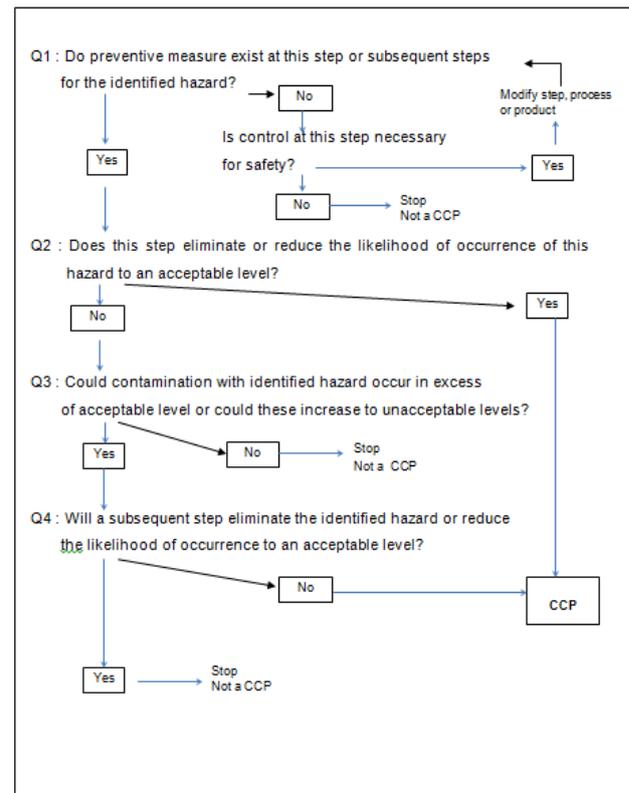


Figure 3. Decision tree (FAO, 1997)

approach results in a more logical (Codex, 2003). Application of the decision tree must be reasonable concerning the operation of the production, slaughter, and processing, storage, and distribution. A decision tree is used as a guide when determining CCP. The decision tree may not apply to all situations. Another approach may be used. Training in its use is needed (Codex, 2009).

Significant hazard and control measure

If a significant hazard has been identified by a process step where control is necessary for product safety and no control measures established, then modifications to the product and the process must be done, or at a first step, to provide control measures (Codex, 2003). The necessary amendments should involve step process, the process itself, its products or the provision of new procedures that can control food safety hazards (Mortimore and Wallace, 2013). For example, if the HACCP team to worry about the hazard of metal fragments in the processing but there are no control measures in the next process be able to remove it, then efforts should be made to modify by installing a system that can remove the metal fragments such as a magnetic trap or metal detector in the next process step (Wallace *et al.*, 2011).

Concerning a significant hazard in raw material or process step the hazards were caused by the three types of hazards whether biological, chemical and

physical associated with raw material/packaging material and process steps in the production line. The HACCP team must have an understanding, knowledge and experience of biological, physical and chemical hazards that associated with their products (Wallace *et al.*, 2012). Failure to determine the actual hazard in material or process step could cause miss hazard identification and miss hazard analysis that will result in product possibly contains hazard and unsafe to eat (Panisello and Quantick 2001; Wallace *et al.*, 2014).

Process specifically designed

Question 2 of the decision tree: Is the process specifically designed to eliminate and reduce the likely occurrence of the significant hazard to an acceptable level? This question is often causes difficulties to the HACCP team. It provides a shortcut to the HACCP team to determine the CCP when the answer to this question is 'Yes.' The question is asking for the process step and not a control measure. Process step that is specifically designed means that the process itself created specifically with the aim to eliminate or reduce the hazard to an acceptable level. The absence of this process will result in the production of unsafe products. For example, in the production of pasteurized dairy products, where the pasteurization process at a temperature of 72°C for 15 seconds is a process that is designed to control the vegetative

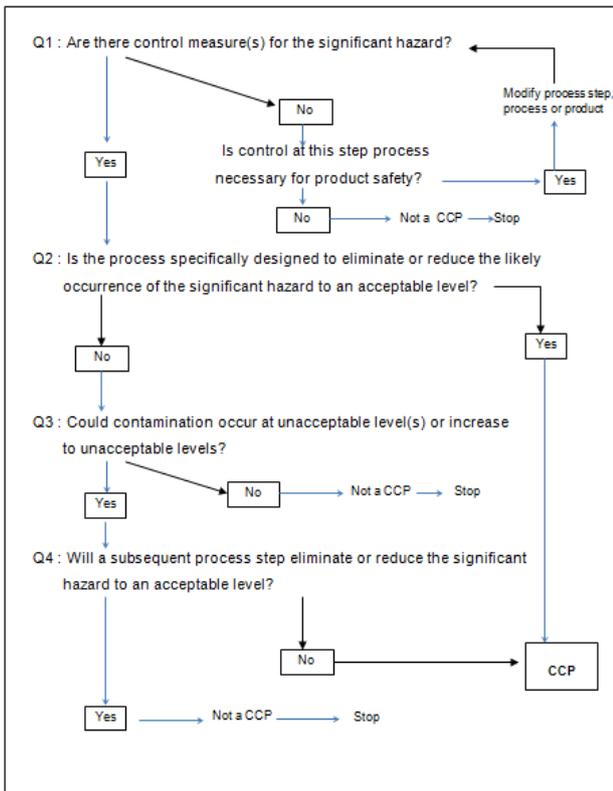


Figure 4. Decision tree (MS 1480: 2007)

pathogens, while storage at room temperature is not a process specifically designed to control hazards such as insect infestations (Mortimore and Wallace, 1998).

Much confusion among the HACCP team for considering the cooking process in general as a process specifically designed to eliminate and reduce hazards to acceptable levels. Whenever the cooking process is not a process specifically designed to control the hazards, then HACCP team must answer ‘No’ rather than ‘Yes.’ Not all the cooking process is ‘CCP’ where half of the cooking process with high temperatures is to change the physical structure of the product compared to the safety of foods such as bread baking process, but at the same time the high temperature causes the elimination of vegetative pathogens (Wallace *et al.*, 2011). The baking process is a process step to make a product without that processed bread is not possible to be produced. The situation is even more confusing because some step of the process itself is a control measure.

If the HACCP team confused by referring step process as a control measure, then, as it is known where control measures are indeed the measures established to control significant hazards. Thus, whenever a control measure is questioned, then it will give the answer “Yes,” the results will lead to more than the actual CCPs (Wallace *et al.*, 2011). Even though it is good, but then the HACCP system becomes more complex and difficult to manage. Therefore, if there

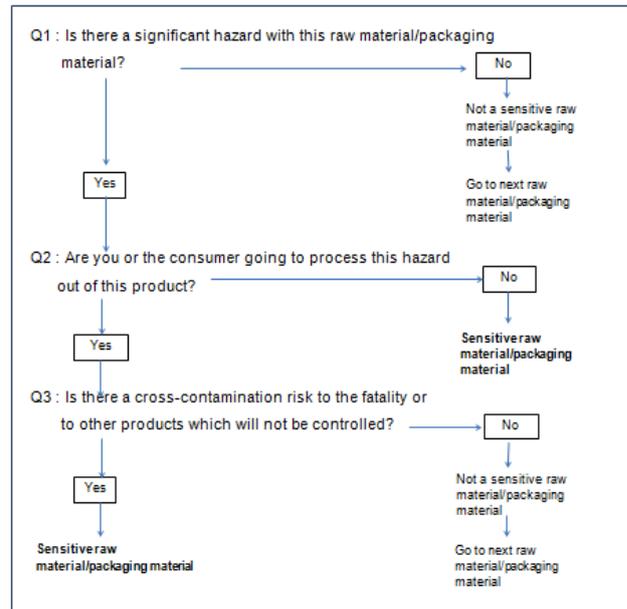


Figure 5. Decision tree for raw material/ packaging material (MS 1480 : 2007)

are doubts in HACCP team to answer ‘Yes,’ then, they should use other alternative routes to give an answer ‘No’ and turn to the 3rd question. For example, if the cold storage rooms with hazards identified are the growth of pathogens, is not a process that is designed to control hazards, but one crucial step process to ensure that perishable ingredients are always in good shape for the production process and subsequent delivery.

Contamination

For Questions 3: Could contamination occur at unacceptable levels or increase to unacceptable levels? For this question, the HACCP team or consultants who are responsible for assisting company forgot to think several issues that could lead to the answer to the question above. Among the issues needs to be considered are: (a) the situation surrounding the process likely to include the hazard; (b) the possibility of cross-contamination by food handlers; (c) the possibility of cross-contamination by raw materials or products; (d) the conditions of temperature and time can increase the hazard; (e) product builds up in dead-leg spaces and may increase the hazard; (f) any other factors or conditions that can cause contamination to increase to unacceptable levels.

Contaminated raw material/product will result in cross-contamination when in contact with other surfaces such as equipment and hardware, the hands of food handlers, packaging materials, working table or conveyor and other raw materials (Loken, 1995). Cross-contamination on food contact surfaces and other raw materials/product can be solved through

washing hands, isolation area to process raw materials and cooked food, separation of the storage of raw materials and finished products, storage of raw materials undercooked food, wash equipment after use and using different equipment according to the raw materials (Codex, 2012; Holah *et al.*, 2012). Cross-contamination of food products is high due to contamination of food contact surfaces (Yousif *et al.*, 2013). Also, studies conducted by Aarnisalo *et al.* (2006) have shown packing machine, conveyor, cutter, and the cooling machine was the equipment that presents much cross-contamination problems in processing and aseptic packaging.

All raw materials potentially containing threats will cause cross-contamination and control measures should be established to solve the issues. Compliance with hygiene regulations is necessary to avoid cross-contamination problems (Tajkarimi *et al.*, 2013). If raw materials such as meat or poultry which contains biological hazard when stored together with vegetables that are used in the manufacture of salad will cause cross-contamination.

The finished good products are not allowed to be stored along with the raw materials to avoid cross-contamination and need to be stored separately. Research in the kitchen of hospital found the floor surface in the area of store storage and processing area; swab test showed the content of aerobic bacteria, yeast, and mold, coliform, *E. coli* and *S. aureus* is high especially in the summer (Yousif *et al.*, 2013). If any raw materials are stored along with the finished goods, the raw material should be stored in the bottom of the good finished product and make sure the temperature is outside danger zone, 5-60°C (Jianu and Chis, 2012). Closing the food prepared with suitable container will also prevent cross-contamination.

Environmental factors are among the factors that could cause a significant impact on microbial contamination and is closely related to the construction of process flow diagram. Process flow diagram should reflect processes such as transferring, cooling and process steps that are performed at room temperature. These situations may create change for the growth of pathogenic microbe with small numbers and thus multiply to produce toxins and becomes the hazard (Van Donk and Gaalman, 2004). For example, in processing of beans in Brazil, the HACCP team has to consider the storage of beans as a CCP due to uncontrollable temperature and relative humidity (Garoyeb *et al.*, 2009) which exceeded the limits set by Codex with the temperature between 0-10°C and humidity below 70% (CAC, 2004). Temperature and high humidity in the storage area without any control

will encourage the growth of fungus and thus increase the production of aflatoxin in nuts. If the answer to question 3 is 'Yes', it means there is contamination that could occur or increase to an unacceptable level, and then go to question 4. If the answer is 'No', repeat from the beginning of decision trees with other significant hazards.

Hazard elimination

Question 4: Will a subsequent process step eliminate or reduce the significant hazard to an acceptable level? If this question should not be thoroughly examined by the team HACCP, it could cause a significant hazard to the process being studied as a CCP if the answer is 'No'. This question refers to the processes of the production that have similar functions to eliminate and reduce hazards to acceptable levels. For example, the installation of the metal detector and magnetic trap to control the iron pieces in rice flour processing. Here, there might be two CCPs, one from the magnetic trap and another is from the metal detector. Any piece of iron that was failed to be captured by a magnetic trap will be detected by the metal detector. So, again the absence of controls on the significant hazard of metal fragments after the metal detector causes the metal detection process as the last process step to control the food safety. Therefore, the metal detection process is a CCP and magnetic trap as a control measure to reduce the burden on the CCP process (Mortimore and Wallace, 2013).

In other instances, the production of dried smoked meat with significant hazards identified are pathogenic yeast and fungal toxigenic metabolites (Asefa *et al.*, 2009), the brining process using NaNO₃ at cold temperatures (4°C) is not a CCP as a significant hazard of pathogenic yeast can be controlled by the sequence of other processes such as smoked and drying process (Martin *et al.*, 2003). Brine reduces water activity in meat and inhibits microbial growth, as a result, increase the durability and safety of the product (Blesa *et al.*, 2001). The smoking process at a temperature of 20-30°C speed up the drying surface of the meat and inhibits the growth of microbes as well as the CCP to pathogenic yeast (Asefa *et al.*, 2011).

Understanding the questions no.4 in the decision tree will help to minimize the number of CCPs that can be managed effectively (Wallace *et al.*, 2011). Also, it is allowed the company to provide control measures at an early stage on significant hazards in the production process to reduce the burden on the CCP process. The absence of control measures at an early stage can cause a significant hazard to the CCP

process too high and likely miss control of significant hazards (Mortimore and Wallace, 1998).

Decision tree for the raw material/ packaging material

Based on to MS 1480: 2007, there are two types of decision trees which respectively used to determine sensitive raw material/packaging material and to determine the CCP to process step. By referring to the Codex guidelines, there is no example of a decision tree that is included in the guidelines for the determination of the sensitive raw material/packaging material, while an example of a decision tree for the determination of the CCP only. The absence of a decision tree to determine sensitive raw material/ packaging material in Codex guidelines leads the industry to use a decision tree for process step to determine the significant hazard in raw material/packaging and so on, will provide the status of either CCP or CP. Whereas, raw materials and packaging materials should not be specified as a CCP or CP, otherwise sensitive or not sensitive material (MS 1480: 2007).

This confusion is observed in the implementation of HACCP vacuum packed sauced porks where the main raw and the support materials are should not be evaluated through a decision tree for process step but accurately assessed through a decision tree for the raw material/packaging material (Wang et al., 2010). In this case, biological hazard identified in main raw materials (pork and poultry) is caused by pathogenic microbes and parasites; meanwhile, the chemical hazard is antibiotic residues. So, those materials upon assessing through decision tree for raw material/packaging material should be a sensitive raw material, not a CCP. The decision tree of MS 1480: 2007 for raw material and packaging material is shown in Figure 5.

Conclusion

A decision tree is very useful tools for the HACCP team, consultants and authorities in determining CCP to the process steps and sensitive raw material/packaging material in raw material/packaging material. However, errors and misunderstandings in its application could cause significant impact to the HACCP plan, especially the number of CCP and sensitive raw material/packaging material. In certain conditions, the increasing number of CCPs or sensitive raw materials is considered good due to the control is in place even though the HACCP plan is too complex. However, the worst part is that a decision tree could lead to the miss identification

of CCP or sensitive raw material/ packaging material that make product unsafe for consumption.

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