Simple users’ guide to the hazard analysis critical control point concept for the control of food microbiological safety

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A simple guide to the application of the hazard analysis critical control point (HACCP) system for microbiological hazards is described which clearly outlines the rules to be followed for the identification and management of critical control points. The use of this guide will assist those persons or companies considering applying HACCP to understand precisely what the HACCP system is and how it should be used, as well as assisting those already applying HACCP analysis to standardize and formalize their approach.

Keywords: hazard analysis critical control point; microbiological safety

The hazard analysis critical control point (HACCP) concept is a systematic approach to the identification and assessment of microbiological hazards and risks associated with the manufacture, distribution and use of a particular foodstuff. The concept was first presented in 1971 (APHA, 1972), initially for microbiological hazards, and has been applied extensively in the food service and food manufacturing sectors (Bauman, 1974; 1990; Munce, 1984; Peterson and Gunnerson, 1974; Bryan et al., 1981; Warne et al., 1985; Snyder, 1986; Bryan, 1988). The initial development and application of the technique began in North America, but the concept has now become increasingly accepted by the UK foods industry and by reputable international bodies of scientists eminent in food microbiology as the most effective approach to the control of foodborne disease. Despite this, progress in applying the concept throughout the food industry in the UK and Europe has been relatively slow, due in part to the absence of a simple user's guide to the application of the technique. It is worth noting that HACCP analysis is specifically mentioned in the draft enforcement Codes of Practice being progressed under the UK Food Safety Act 1990 and this could stimulate increasing European interest.

This paper outlines a simple user's guide to the application of the HACCP concept. The paper is not intended to be a definitive guide, but rather a simple introduction to its basic application. For a full history of the development of the HACCP concept, a more detailed discussion of its mechanics and illustrations of its application, the references cited herein should be consulted.

METHODOLOGY

What is the HACCP concept?

The accepted definition of the HACCP concept is: 'a systematic approach to the identification and assessment of the microbiological hazards and risks associated with the manufacture, distribution and use of a particular foodstuff and the definition of means for their control' (ICMSF, 1988).

The HACCP analysis consists of six steps (ICMSF, 1988):

1. Identification of hazards and assessment of the severity of those hazards and their risks associated with the growing, harvesting, processing or manufacture, distribution, preparation and/or use of a raw material or final product.
2. Determination of critical control points (CCPs) at which hazards can be controlled. A CCP may be a
The hazard analysis study team and its terms of reference

A HACCP study will require the acquisition and evaluation of technical data and, as a minimum, the study should be carried out by a microbiologist or other appropriate specialist who is an expert in the particular operation. However, it is much more preferable to establish a hazard analysis study team consisting of a process manager or supervisor responsible for the process in question, an engineer, a quality assurance manager and the microbiologist. The use of such a multidisciplinary study team will greatly improve the decisions made by the group.

The terms of reference for the study must be defined clearly at the outset and the detail must be confirmed by the study team. Each study should be carried out with particular micro-organisms or groups of organisms considered as the potential hazards to each product or group of products. For example, typical terms of reference for three different studies may be:

1. listeria (infectious pathogen) as a potential hazard in soft cheese;
2. Clostridium botulinum (an anaerobic toxin-forming spore former) as a potential hazard in vacuum-packed chill-stored smoked trout; and
3. Staphylococcus aureus enterotoxin (an aerobic toxin former) in dry pasta.

It is preferable to select specific hazards (e.g. salmonella or staphylococcal enterotoxin) for each study as this will allow the definition of specific controls. Each potential microbiological hazard must be chosen after taking into account the use of the product by the consumer, (e.g. in the three examples given, normal consumer use would not destroy the microbial hazard if it were present in the final product. The study team must have a clear view on the types and levels of hazard (e.g. salmonella, C. botulinum, S. aureus) that are regarded as dangerous to the consumer.

Analysis

The first step is to audit the entire process under study to produce a flow diagram of the process that can be used as the basis for the study.

Audits must be carried out by closely following actual processing operations. Effective auditing techniques which structure data collection have already been described (Mayes and Kilsby, 1989), but whatever auditing technique is used, the flow diagram arising from the audit data should contain as a minimum, details of all raw materials used, all processing and packaging stages and a complete time-temperature history throughout the process and distribution, together with data on pH/Aw conditions and other parameters affecting growth, survival, death, or possible contamination. Additional data such as the hygienic design characteristics of equipment and hold-up volumes should also be collected. Data must also be collected on the instructions for the use of the product by consumers. Once such a flow diagram is available it may be used by the study team to identify where hazards can be introduced into the product and the associated CCPs that will minimize the risk or prevent the hazard from occurring.

This is best carried out as a team activity. The nominated study team leader should proceed through the entire process, using the audit data as a guide, and ask a series of questions at each stage to determine: (1) if the hazard under study (e.g. salmonella) can be introduced into the product either via raw materials or processing or can be allowed to grow to dangerous levels; (2) if the formulation or composition of the raw materials or product is essential to the safety of the product and (3) if the processes are specifically rendering the raw materials, intermediate product, or final product safe by removing, inhibiting, or preventing contamination and/or growth of the hazard under discussion to dangerous levels.

A consideration of the hazards should take into account realistic potential process deviations e.g. higher or lower product times and temperatures, pH and Aw values, and the amount and distribution of any preservative. Consideration should also be given to the
For each raw material used:

Q1. Could the raw material realistically contain the hazard under study i.e. salmonella at levels dangerous to the consumer?

YES \[\rightarrow\] REPEAT FOR REMAINING RAW MATERIALS

NO

For each process stage:

Q3. Is the formulation composition or structure of the product essential for preventing increase of the hazard under study (e.g. salmonella) to levels dangerous to the consumer?

YES \[\rightarrow\] REPEAT FOR REMAINING PROCESS STAGES

REPEAT Q1 FOR REMAINING PROCESS STAGES

Q4. Could this process stage realistically allow contamination with the hazard under study to dangerous levels, or allow it to increase to a dangerous level?

YES \[\rightarrow\] REPEAT Q1 FOR REMAINING PROCESS STAGES

REPEAT Q4 FOR REMAINING PROCESS STAGES

NO

This process stage must be regarded as a critical control point for this hazard

User's guide to HACCP concept: T. Mayes

For each raw material used:

Q1. Could the raw material realistically contain the hazard under study i.e. salmonella at levels dangerous to the consumer?

YES \[\rightarrow\] REPEAT FOR REMAINING RAW MATERIALS

NO

Raw material microbiological quality must be regarded as critical control point for this hazard

Figure 1 Critical control point decision tree: raw materials

For each process stage:

Q3. Is the formulation composition or structure of the intermediate product or final product essential for preventing increase of the hazard under study (e.g. salmonella) to levels dangerous to the consumer?

YES \[\rightarrow\] REPEAT FOR REMAINING PROCESS STAGES

REPEAT Q1 FOR REMAINING PROCESS STAGES

Q4. Could this process stage realistically allow contamination with the hazard under study to dangerous levels, or allow it to increase to a dangerous level?

YES \[\rightarrow\] REPEAT Q1 FOR REMAINING PROCESS STAGES

REPEAT Q4 FOR REMAINING PROCESS STAGES

NO

This process stage must be regarded as a critical control point for this hazard

Figure 2 Critical control point decision tree: process, location, practice or procedure

possibility of cross-contamination to and from ingredients, the product, people, process equipment and the processing environment.

The simple decision trees in Figures 1 and 2 can be used to help the identification of CCPs. These decision trees are discussed in the following section.

Raw materials

To determine if any of the raw materials used in the final product are CCPs, the study team should answer Question 1 (and if necessary Question 2) for each raw material used.

Question 1. Could the raw material realistically contain the hazard under study at levels dangerous to the consumer?

The study team should use whatever data is available to them, e.g. epidemiological information, previous supplier performance, published information, to judge the answer to this question. If the team is confident that the answer is ‘no’, then the raw material under question will not be regarded as a CCP, and the study team should ask the question of the remaining raw materials.

If the study team are unsure of the answer, they should assume the ‘yes’ response and move to Question 2.

Question 2. Will processing, including correct consumer use, guarantee the removal of the hazard or reduction to a level regarded as safe?

The study team should assume that the hazard is present in the raw material and should proceed sequentially through the process using the audit data as a guide and determine if any process steps (including consumer use), will remove or reduce the hazard to a safe level. If the answer to this question is ‘yes’, then the microbiological quality of this particular raw material is not critical and the study team should ask Question 1 of the remaining raw materials. If the answer is ‘no’, the microbiological quality of the raw material must be regarded as critical.

The use of the ‘correct consumer use’ phrase in the question means that the product is being judged safe at the point of consumption; if a judgement is to be made about product safety at the point of manufacture, the above phrase should be omitted from the question.

Process stages

To determine if a process stage, location, practice or procedure used is a CCP the study team should answer Questions 3, 4 and either Question 5 or 6 for each process stage.

Question 3. Is the formulation, composition or structure of the product essential for preventing an increase of the hazard under study to levels dangerous to the consumer?

The study team should use the appropriate technical data (e.g. pH, A, concentration and type of preservatives, water droplet size) to judge whether the formulation, composition or product structure is essential for preventing an increase of the hazard to levels dangerous to the consumer. This judgement should be made at each process stage identified during the audit.

Question 4. Could this process stage realistically allow contamination with the hazard under study to dangerous levels, or allow it to increase to a dangerous level?

The study team should use the audit data, together with visual observations made during the audit, to judge whether the formulation, composition or product structure is essential for preventing an increase of the hazard to levels dangerous to the consumer. This judgement should be made at each process stage identified during the audit.

Question 4. Could this process stage realistically allow contamination with the hazard under study to dangerous levels, or allow it to increase to a dangerous level?

The study team should use the audit data, together with visual observations made during the audit, to judge the answer to this question for each process stage. The study team should consider whether the immediate processing environment (i.e. people, equipment, walls, floors, drains, raw materials) may contain the hazard under study and thereby contaminate the product. The study team must also be aware that it is...
possible that no single process stage will allow an increase of the hazard to dangerous levels, but over a number of process stages (i.e. integrated time and temperature), the amount of increase may reach dangerous levels. In this instance the study team may regard the entire group of process stages allowing the increase as a CCP, or, alternatively, the final process stage allowing an increase to dangerous levels may be regarded as critical. The study team must therefore consider not only the specific process stage under discussion, but also the accumulated effect of subsequent process stages when answering this question. The team should include consideration of the following: (1) is the process stage carried out in an environment likely to contain the hazard; (2) is product packaging essential for the prevention of contamination at this stage; (3) is cross-contamination from another product or raw material possible; (4) is cross-contamination from personnel possible; (5) are there any void spaces in the equipment that will allow the product to stagnate and allow increase of the hazard; (6) are the bulk product time-temperature conditions such that the hazard will increase in the product? Technical data on product formulation will be necessary to answer points 5 and 6.

If the answer to Question 4 is 'yes' for any process stage, or group of process stages, the study team should immediately consider Question 5 for that same process stage(s).

**Question 5.** Will subsequent processing, including correct consumer use, guarantee removal of the hazard or reduction to a level regarded as safe?

If the answer to Question 5 is also 'yes' the process stage(s) under discussion from Question 4 is not critical, and the study team should ask Question 4 of the remaining process stages. However, if the answer to Question 5 is 'no' then the process stage(s) under discussion is a CCP. In this situation the study team must clearly define precisely what is critical i.e. is it the actual process, its location, or a practice or procedure associated with the process stage(s).

If the answer to Question 4 is 'no', then the study team should immediately consider Question 6 for that same process stage.

**Question 6.** Is this process stage specifically intended to remove, inhibit, or prevent contamination and/or increase of this hazard to dangerous levels?

The study team should use the audit data to judge the answer to this question for each process stage. This question will identify those processing stages that are specifically intended to impart microbiological safety to the product, e.g. pasteurisation, retorting, cooking, chilling, freezing, canning and aseptic packing etc.

If, after answering 'no' to Question 4, the team also answer 'no' to Question 6, then the process stage is not critical and the study team should ask Question 4 of the remaining process stages. If, however, the answer to Question 6 is 'yes', then that process stage is critical to the safety of the product.

The study team should base their discussion on the flow diagram and should include a consideration of equipment design, the manner in which the process is managed and situations which could realistically occur that are not covered by the flow diagram. A significant amount of technical data may be necessary to make decisions on the given questions, an indication of the range of data is given in Table 1.

### Table 1 Technical data required for a HACCP study.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Technical data required for a HACCP study. This table is a list of the type of technical data required for a HACCP study. Not all the data will be required for all studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Epidemiological data on microbial pathogens</strong></td>
<td>Incidence of foodborne illness, Surveillance programmes</td>
</tr>
<tr>
<td><strong>Raw material, intermediate and final product data</strong></td>
<td>Formulation, pH, Presence of preservatives, Packaging materials and conditions, Product structure, Processing conditions, Storage and distribution conditions, Shelf life, Consumer use instructions, pack labelling, Consumer target groups</td>
</tr>
<tr>
<td><strong>Processing data</strong></td>
<td>Number and sequence of all processing stages including storage, Range of product time-temperature conditions at each process stage, Rework handling operations, High-flow risk separation systems in use, Flow conditions (for liquids), Presence of void spaces in processing equipment, Efficacy of cleaning and disinfection, Possibilities for cross-contamination</td>
</tr>
<tr>
<td><strong>Microbiological data</strong></td>
<td>Likely presence of microbiological hazards in raw materials (see also epidemiological data), Growth rates of microbial hazards in food products, Death rates of microbial hazards under a range of processing conditions</td>
</tr>
</tbody>
</table>

### Results of the analysis

After completing these questions, the study team should have identified the CCPs applicable to the combination of hazard, process and product under study. For each CCP identified, the study team must also identify specific criteria (i.e. limits and tolerances) that indicate whether a CCP is under control and also specific procedures to monitor that each CCP operates under control.

CCPs may be raw materials, or a location, practice, procedure or process stage, but the key point is that CCPs must be specific. For example: the absence of salmonella in a raw material; the hygiene standard in a production assembly room; separation of raw and cooked facilities; chlorination of can cooling water; and pasteurization of product. Each CCP must have a specific control procedure. Control procedures, limits, tolerances and monitoring systems must be established for each CCP. Table 2 indicates how, in the examples given, the following could apply.

In the examples discussed, the CCP identifies what must be controlled, the 'control procedure' identifies how that CCP will be controlled, the 'limit' is the target or standard aimed at for each CCP, with the 'tolerance' identifying the degree of latitude (if any) at each CCP. The 'monitoring system' describes the methods by which management are able to ensure that all the above are operating within specification, thereby ensuring that each CCP operates in control. Monitoring must be carried out at specified intervals, if necessary in accordance with a statistically based sampling plan. Statistical treatment of some data may be necessary to ensure that the process is in control and to rapidly detect an out of control situation. Full records must be
Table 2 Examples of CCP management

<table>
<thead>
<tr>
<th>CCP</th>
<th>Control procedure</th>
<th>Limit</th>
<th>Tolerance</th>
<th>Monitoring system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence of salmonella in raw material</td>
<td>Supplier assurance</td>
<td>Absent in 25 g</td>
<td>No tolerance</td>
<td>Plant records and inspection, microbiological intake testing</td>
</tr>
<tr>
<td>Hygiene standard</td>
<td>Specification of cleaning and sanitation system; design of equipment and facilities</td>
<td>&lt; $10^7$ TVC cm$^{-2}$</td>
<td>Mean $&lt;10^7$ cm$^{-2}$ Max $10^7$ cm$^{-2}$</td>
<td>Visual and microbiological examination of plant</td>
</tr>
<tr>
<td>Separation of raw and cooked facilities</td>
<td>Physical separation by design and controlled access</td>
<td>Complete segregation</td>
<td>No tolerance</td>
<td>Visual</td>
</tr>
<tr>
<td>Chorination of cooling water</td>
<td>Automatic dosing</td>
<td>5 ppm</td>
<td>3–5 ppm</td>
<td>Continuous chlorine monitor; regular sampling of water for chlorine levels</td>
</tr>
<tr>
<td>Pasteurization of milk</td>
<td>Correct design, installation and operation of pasteurizer</td>
<td>71.5°C for 15 s</td>
<td>71.5–73°C for 15 s</td>
<td>Continuous record of product time-temperature; records of plant sensor calibration, diversion and operation</td>
</tr>
</tbody>
</table>

TVC = total viable count of bacteria

kept of all decisions reached during the study, and in particular of all CCP management decisions.

Also essential for the correct implementation and operation of HACCP, but outside the scope of this paper, are the introduction of systems (including identification of responsibilities) to ensure that the proper corrective action is taken when a CCP operates out of control, verification that the HACCP system is working correctly, and the full incorporation of the HACCP data into the company’s quality assurance system.

**DISCUSSION**

There is an increasing body of well informed opinion that recognizes the value of HACCP as the most effective means for controlling foodborne disease (World Health Organization, 1988; 1990; National Academy of Sciences USA, 1985; Joint US Department of Agriculture/Health Education and Welfare National Advisory Committee on Microbiological Criteria for Foods, 1990).

This paper has outlined a simple users guide to the use of HACCP, indicating in simple terms exactly how to carry out a study and how to manage the results generated. It is strongly recommended that people considering using the HACCP concept should initially keep such studies simple and direct and hopefully the users guide will provide valuable assistance in this respect.

When properly completed and implemented, a HACCP study will identify those factors that directly affect the microbiological safety and quality of the product under consideration. This will allow the food producer to concentrate his technical resource into those critical areas, identifying specific control procedures, limits, tolerances and monitoring systems, and thereby utilizing a much more cost-effective control system than is normally achieved by traditional inspection and microbiological testing regimes. In summary, technical resources are specifically targeted at those aspects of production that critically affect the safety and quality of the product.

HACCP is not a solution to all food safety problems. If the data generated from the HACCP study is not implemented and updated, the original study will have been a waste of time. Unless management are committed to implementing the results of the HACCP study there is no point in starting. A HACCP study will not in itself prevent all microbiological problems occurring – ‘absolute safety is absolutely unattainable’ (Hall, 1981). However, the results of a HACCP study will indicate to management how best to control hazards. In short, the results of a HACCP study will provide management with the correct information for the task; it is then up to the management to use that information correctly.

**REFERENCES**

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