

CITY OF MILWAUKEE HEALTH DEPARTMENT

HACCP PLAN GUIDANCE

Items to submit for approval of Haccp plan:

1. Variance application (if necessary)
2. Product Description
3. Recipes if using restricted ingredients
4. Flow Chart
5. Hazard Analysis
6. Haccp Plan
7. Supporting documents (if referenced in plan)
8. Statement /Description of employee training
9. Validation section

HACCP PRINCIPLES

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles:

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

There are twelve tasks required to develop a HACCP plan and these are designed to ensure that the seven principles are applied correctly. Principle 1, which is to conduct a hazard analysis, requires that the first five tasks have all been addressed in a logical and honest manner so that all real hazards associated with the commodity have been identified. The twelve tasks are discussed briefly below.

Task 1 - Establish a HACCP team

To fully understand the commodity system and be able to identify all likely hazards and CCPs, it is important that the HACCP team is made up of people from a wide range of disciplines. The team should include:

- A team leader to convene the group and to direct the work of the team ensuring that the concept is properly applied. This person must be familiar with the technique, be a good listener and allow all participants to contribute.
- A specialist with a detailed knowledge of the commodity system is required. This specialist will have a major role in the production of the commodity flow diagrams.
- People, such as packaging specialists, raw material buyers, distribution staff or production staff, farmers, brokers, who are involved with the process, and have working knowledge of it, may be brought into the team temporarily in order to provide relevant expertise.

If any changes are made to composition or operational procedures, it will be necessary to re-assess the HACCP plan in the light of the changes.

The first activity of the HACCP team is to identify the scope of the study. For example, will the whole commodity system be covered or only selected components? This will make the task more manageable and specialists can be added to the team as and when they are required.

Task 2 - Describe the product

To start a hazard analysis, a full description of the product, should be prepared using a form such as that shown below. This should include information relevant to safety, e.g. mycotoxin regulation/target level, composition, physical/chemical properties of the raw materials and the final product, the amount of water available for microbial growth (a_w), the amount of acid or alkali in the product (pH). Also information regarding how the product is to be packaged and stored should also be considered together with facts regarding its' shelf life and recommended storage temperatures. Where appropriate; labeling information and an example of the label should be included. This information will help the HACCP team to identify 'real' hazards associated with the process.

Name of product
Full description of product including structure/variety, processing parameters, additive concentrations, storage instructions, pH/ A_w /moisture levels, <i>and any mycotoxin target levels</i> .
Conditions of storage and distribution
Shelf Life
Packaging
Instructions on the label
Recommendation for further processing required before consumption
Intended use , e.g. will the end product be cooked before consumption?

Task 3 - Identify the product's intended use

How the product is intended to be used is an important consideration. Information on whether the product will be consumed directly, or be cooked, or be further processed, will all have a bearing on the hazard analysis, see task 6). The nature of the target group for the product may also be relevant, particularly if it includes susceptible groups such as infants, the elderly, and the malnourished. This information can be recorded on the same form as the product description, see above.

Task 4 - Draw up the commodity flow diagram

The first function of the team is to draw up a detailed commodity flow diagram (CFD) of the commodity system, or that part of it which is relevant.

Task 5 - On site confirmation of flow diagram

Upon completion of the CFD, members of the team should visit the commodity system to compare the information present on the CFD with what actually happens in practice. This is known as "walking the line", a step by step practice to check that all information regarding materials, practices, controls etc. have been taken into consideration by the team during the preparation of the CFD. The site for which the HACCP plan is being designed should be visited as many times as possible to ensure that all relevant information has been collected.

Task 6 - Identify and analyze hazard(s) - (Principle 1)

Effective hazard identification and hazard analysis are the keys to a successful HACCP Plan. All real or potential hazards that may occur in each ingredient and at each stage of the commodity system should be considered. Food safety hazards for HACCP programs have been classified into three types of hazards:

- Biological: typically foodborne bacterial pathogens such as *Salmonella*, *Listeria* and *E. coli*, also viruses, algae, parasites and fungi.
- Chemical: There are three principle types of chemical toxins found in foods: naturally occurring chemicals, e.g. cyanides in some root crops, and allergenic compounds in peanuts; toxins produced by micro-organisms, e.g. mycotoxins, and algal toxins; and chemicals added to the commodity by man to control an identified problem, e.g. fungicides or insecticides.
- Physical: contaminants such as broken glass, metal fragments, insects or stones.

The probability that a hazard will occur is called a risk. After hazard identification, a hazard analysis must be conducted to understand the relative health risk to man posed by the hazard. It is a way of organizing and analyzing the available scientific information on the nature and size of the health risk associated with the hazard. The risk may have to be assessed subjectively and simply classified as to whether or not it is likely to occur. Only those hazards considered by the HACCP team to be likely to occur are taken forward to Stage 7, Principle 2.

Once a food safety hazard has been identified, then appropriate control measures should be considered. These are any action or activity that can be used to control the identified hazard, such that it is prevented, eliminated, or reduced to an acceptable level. The control measure may also include training of personnel for a particular operation, covered by GAP, GMP, and GHP.

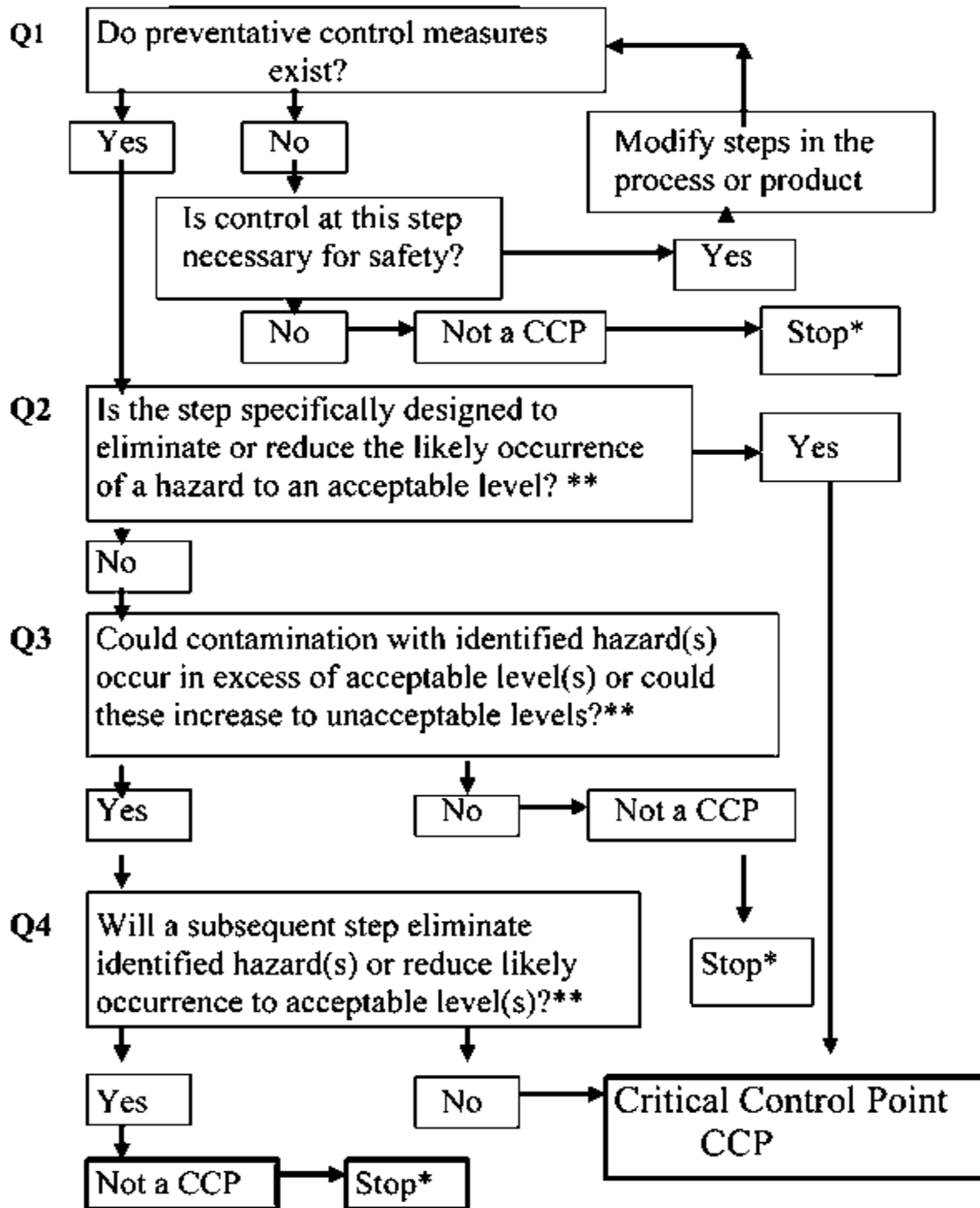
Step	Potential Hazard(s)	Justification	Hazard to be addressed in plan?	Control Measure(s)
5. Cooking	Enteric pathogens: e.g., <i>Salmonella</i> , verotoxigenic- <i>E. coli</i>	enteric pathogens have been associated with outbreaks of foodborne illness from undercooked ground beef	Y	Cooking

Task 7 - Determine the critical control points (ccps) - (Principle 2).

Each step in the commodity flow diagram, within the scope of the HACCP study, should be taken in turn and the relevance of each identified hazard should be considered. It is also important to remember the stated scope of the HACCP analysis at this stage. The team must determine whether the hazard can occur at this step, and if so whether control measures exist. If the hazard can be controlled adequately, and is not best controlled at another step, and is essential for food safety, then this step is a CCP for the specified hazard. A decision tree (see below) can be used to determine CCPs. However, the HACCP team's judgment, expertise and knowledge of the process are the major factors in establishing CCPs.

If a step is identified where a food safety hazard exists, but no adequate control measures can be put in place either at this step or subsequently, then the product is unsafe for human consumption. Production should cease until control measures are available and a CCP can be introduced.

CCP DECISION TREE



Task 8 - Establish critical limits for each ccp - (Principle 3)

Critical limits must be specified and validated for each CCP. Criteria often used include measurements of temperature, time, moisture level, pH, water activity, and sensory parameters such as visual appearance. In the case of mycotoxins for example, they may include the moisture content or the temperature of the commodity. All critical limits, and the associated permissible tolerances, must be documented in the HACCP Plan Worksheet, and included as specifications in operating procedures and work instructions.

Process Step	CCP	Critical Limits
5. Cooking	YES	Oven temperature: ___ ° F Time; rate of heating and cooling (belt speed in ft/min): ___ ft/min Patty thickness: ___ in. Patty composition: e.g. all beef Oven humidity: ___ % RH

Task 9 - Establish a monitoring procedure - (Principle 4)

Monitoring is the mechanism for confirming that critical limits at each CCP are being met. The method chosen for monitoring must be sensitive and produce a rapid result so that trained operatives are able to detect any loss of control of the step. This is imperative so that corrective action can be taken as quickly as possible so that loss of product will be avoided or minimized.

Monitoring can be carried out by observation or by measurement, on samples taken in accordance with a statistically based sampling plan. Monitoring by visual observation is basic but gives rapid results, and can therefore be acted upon quickly. The most common measurements taken are time, temperature and moisture content.

Task 10 - Establish corrective action - (Principle 5)

If monitoring indicates that critical limits are not being met, thus demonstrating that the process is out of control, corrective action must be taken immediately. The corrective action should take into account the worst case scenario, but must also be based on the assessment of hazards, risk and severity, and on the final use of the product. Operatives responsible for monitoring CCPs should be familiar with and have received comprehensive training in how to effect a corrective action.

Corrective actions must ensure that the CCP has been brought back under control. They must also include appropriate disposition of any affected commodity or product. Whenever possible an alarm system should be introduced which will activate when monitoring indicates that the critical limit is being approached. Corrective action can then be applied to pre-empt a deviation and prevent the need for any product disposition.

Task 11 - Verify the HACCP plan - (Principle 6)

Once the HACCP plan has been drawn up, and all of the CCPs have been validated, then the complete plan must be verified. Once the HACCP plan is in routine operation, it must be verified and reviewed at regular intervals (at any change in process, process laws and at least yearly). This should be a task of the person charged with the responsibility for that particular component of the commodity system. The appropriateness of CCPs and control measures can thus be determined, and the extent and effectiveness of monitoring can be verified. Microbiological and/or alternative chemical tests can be used to confirm that the plan is in control and the product is meeting customer specifications. A formal internal auditing plan of the system will also demonstrate an ongoing commitment to keep the HACCP plan up to date, as well as representing an essential verification activity.

Ways in which the system can be verified include:

- collecting samples for analysis by a method different from the monitoring procedure
- asking questions of staff, especially CCP monitors
- observing operations at CCPs
- formal audit by independent person

Task 12 - Keep record - (Principle 7)

Record keeping is an essential part of the HACCP process. It demonstrates that the correct procedures have been followed from the start to the end of the process, offering product traceability. It provides a record of compliance with the critical limits set, and can be used to identify problem areas. Furthermore, the documentation can be used by a company as evidence of 'Due Diligence Defense' as required, for instance, by the Food Safety Act 1990 (HMSO), in the UK.

Records shall be kept for a minimum of 90 days. Records that should be kept include: all processes and procedures linked to CCP monitoring, deviations, and corrective actions.

Documents should also include those that recorded the original HACCP study, e.g. hazard identification and selection of critical limits, but the bulk of the documentation will be records concerned with the monitoring of CCPs and corrective actions taken. Record keeping can be carried out in a number of ways, ranging from simple check-lists, to records and control charts. Manual and computer records are equally acceptable, but a documentation method should be designed that is appropriate for the size and nature of the enterprise.

The following is an example of a HACCP plan summary table:

CCP	Hazards	Critical limit(s)	Monitoring	Corrective Actions	Verification	Records

IMPLEMENTATION AND MAINTENANCE OF THE HACCP PLAN

The successful implementation of a HACCP plan is facilitated by commitment from top management. The next step is to establish a plan that describes the individuals responsible for developing, implementing and maintaining the HACCP system. Initially, the HACCP coordinator and team are selected and trained as necessary. The team is then responsible for developing the initial plan and coordinating its implementation. Product teams can be appointed to develop HACCP plans for specific products. An important aspect in developing these teams is to assure that they have appropriate training. The workers who will be responsible for monitoring need to be adequately trained. Upon completion of the HACCP plan, operator procedures, forms and procedures for monitoring and corrective action are developed. Often it is a good idea to develop a timeline for the activities involved in the initial implementation of the HACCP plan. Implementation of the HACCP system involves the continual application of the monitoring, record-keeping, corrective action procedures and other activities as described in the HACCP plan.

Maintaining an effective HACCP system depends largely on regularly scheduled verification activities. The HACCP plan should be updated and revised as needed. An important aspect of maintaining the HACCP system is to assure that all individuals involved are properly trained so they understand their role and can effectively fulfill their responsibilities

RESOURCES

1. University of Wisconsin- Madison, Center for Meat Process Validation:
<http://meathaccp.wisc.edu/>
2. New York City's Reduced Oxygen Packaging Haccp Plan Requirements and Guidelines for Developing a Plan:
<http://www.nyc.gov/html/doh/downloads/pdf/rii/rii-red-oxygen-packaging.pdf>
3. City of Minneapolis Haccp page- includes templates:
<http://www.minneapolismn.gov/health/inspections/HACCP>

