Design of CCP Monitoring Programs

QUICK SUMMARY

The Critical Control Point (CCP) retains a special and important place in the monitoring and control of food safety. It is the output of an assessment relating to a specific food process and ensures significant hazards requiring management are effectively monitored and controlled when a deviation is detected.

Proper design of CCP monitoring programs is an essential element of an effective food safety management system. This whitepaper covers the main considerations and elements of a well-designed CCP monitoring program.
1 INTRODUCTION

One of the few things we can be certain of in our world is uncertainty. Philosophers have been preoccupied by this phenomenon for centuries and the seemingly relentless drive of nature to introduce change and variation into even the most stable of systems. This is not necessarily a bad thing. Many believe that uncertainty or variation is the key driver behind all developments and improvements in nature. Whether this is true or not, one thing we know for sure is that variation in a manufacturing process if not controlled will lead to product failures, waste and overall poor quality. In food manufacturing it can also lead to food safety issues. The eminent statistician, W. Edwards Deming, dedicated much of his career to studying the nature of variation in production processes and came to many conclusions including: “If you can’t describe what you are doing as a process, you don’t know what you’re doing”. This tells us a lot about the nature of food safety management. HACCP is the tool we use to describe ‘what we are doing’. Once we know this we can then get on with the business of monitoring and checking and the Critical Control Point (CCP) is the highest expression of this tool.

Describing and Monitoring are two sides of the same coin. One without the other is meaningless. As Deming states, once we can describe what we are doing we can then measure and monitor our performance. The data from monitoring can be fed back into our understanding to improve it and our feedback loop is complete. The scope of this whitepaper does not cover the Describing stage which is the subject of HACCP planning in general. Instead we will focus on the Monitoring aspect of food safety and specifically the CCP. Proper design of CCP monitoring programs is an essential ingredient in any food safety management system capable of producing safe food products. Since variation is an inevitable part of any process we must assume it will happen and when it does our monitoring program will detect it especially when critical limits are exceeded. Only then can we take the required corrective action that protects the consumer and the business. In many ways CCP’s are the last line of defence and demand we put sufficient time and resources into their proper design, maintenance, review and improvement.

2 DEFINITION OF CCP MONITORING

Before we examine the detail of an effective CCP monitoring program it is important to clearly define what we mean when we speak about CCP’s and Monitoring. Here are some widely used definitions:

**Critical Control Point (CCP):** Step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

This standard definition of a CCP refers normally to a specific stage or step in the process. As we know all food manufacturing processes are made of a sequence of steps, activities and stages which ultimately lead to the production of the final food product ready for distribution to the consumer. Depending on the process there will likely be one or more specific steps in the process which if not maintained under control may lead to the consumer becoming ill or being impacted adversely. It is also possible that certain food processes do not have a CCP in the strict context of Codex and global food standards. However, the best practice described in this whitepaper remains valid for general PRP’s, operational PRP’s and quality control points (QCP).
**Monitoring** - The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

In this definition, we view monitoring as an activity conducted by the company focused on measuring and collecting data relating to processing parameters. This information allows us to decide whether the CCP is under control and therefore the process is producing safe food – this is why monitoring is such an important activity in your food safety system. It is also important to point out that the above definition mentions parameters and not the specific hazard of concern. It is often the case that direct measurement of the hazard, e.g. pathogens, is not possible or practical. Monitoring will need to rely on measuring a secondary parameter such as temperature to make your decisions on product safety in real time.

3 WHY IS MONITORING NEEDED?

As already mentioned, variation is an inherent part of any process. Once we have defined and validated the specific parameters in our process that are required to produce safe food we must, using the principles of HACCP, check that we are achieving control and more importantly know in a timely fashion when we are a not. This is the main objective of monitoring in the context of food safety.

We also use monitoring to track these process parameters to enable the identification of trends toward a critical limit that may trigger process adjustments. This is where the principles of Statistical Process Control (SPC) come into play.

Compliance is another key driver for implementing monitoring programs for CCP’s. In many jurisdictions HACCP is a legal requirement and with this comes the obligation to establish programs which monitor the safety of food. Under the GFSI, HACCP as defined by Codex is cited as a fundamental requirement for certification. The certification process itself requires the auditing of the HACCP system and the specific monitoring programs in place. Commercially, customers and large retailers will require a robust system of monitoring programs to be installed in the operation as a prerequisite for approval as a customer.

4 DETERMINATION OF CCP’S

The CCP as a control method has its origins in HACCP. It is differentiated from other control measures such as PRP’s in that it relates to a specific hazard at a specific process step that is validated as being essential to food safety. Other control methods usually focus on general and less significant hazards. Hazard Analysis Critical Control Point (HACCP) is a tool used to assess potential hazards in a food process following which control and monitoring programs can be established to ensure the on-going production of safe products. It is a systematic and scientific tool which uses robust analysis and risk assessment to develop a system of safety focused on the specific process under study. When conducting a HACCP study a number of principles are applied as follows:
Table 1: Principles of the HACCP System

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
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<tbody>
<tr>
<td>Principle 1</td>
<td>Conduct a hazard analysis – to identify the specific hazards requiring control including the character and risk associated with each hazard.</td>
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<tr>
<td>Principle 2</td>
<td>Determine the Critical Control Points (CCPs) – these are the specific steps in your process which need to be tightly controlled and where deviation can lead to customers being impacted.</td>
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<tr>
<td>Principle 3</td>
<td>Establish critical limit(s). These are the parameter limits which if exceeded will lead to the production of unsafe food products and where you must take appropriate corrective action.</td>
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<tr>
<td>Principle 4</td>
<td>Establish a system to monitor control of the CCP.</td>
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<tr>
<td>Principle 5</td>
<td>Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.</td>
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<tr>
<td>Principle 6</td>
<td>Establish procedures for verification to confirm that the HACCP system is working effectively.</td>
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<tr>
<td>Principle 7</td>
<td>Establish documentation concerning all procedures and records appropriate to these principles and their application.</td>
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</table>

The above principles or similar principles are defined by various global organizations and standards for food safety including CODEX. You will see that the majority of these principles relate to the monitoring of CCP’s and what is expected. The first principle of interest is Principle 2 – Determine the Critical Control Points. It is important to get this right. Monitoring can be an expensive businesses and when we are required to dedicate resources we want to focus on the most critical aspects of our process. This is where CCP determination is used.

Once a hazard has been identified as significant the next step is to determine whether it is a CCP. The normal method of doing this is to use a structured Decision Tree which asks a series of questions about the hazard and the process step under consideration and depending on the answers, drives the user to a decision as to whether the step is a CCP or not a CCP. The following is a typical decision tree employed to determine CCP’s.

While the above decision tree is widely used in the food industry and can assist in the identification of the most critical steps in your process it can at times lead to incorrect CCP’s or too many CCP’s. In this regard it should be used as a useful tool and not replace the best judgement, knowledge and experience of your HACCP team. Once you have identified the relevant CCP’s in your operation you are now ready to start designing the elements of your CCP monitoring programs.
A critical limit is that point of the parameter where the product moves from being safe to being unsafe. It is a qualitative change in the conditions of the process or product which declares that the product is potentially harmful to human health or depending on the scope of your HACCP system, illegal for distribution to the market. Critical limits are the purest expression of your food safety management system. They define clearly when food safety control has been lost and actions need to be taken. In other words, the product you are producing contains a hazard(s) at levels which exceed those considered safe.

The following graph is a representation of where critical limits fit in a normal food process. Here a particular parameter is monitored as a CCP. As measurements are taken they are plotted to show a trend of the data. Critical limits have been determined and are indicated by the horizontal red lines both above and below the target. Once the process deviates beyond these limits the product is deemed to be unsafe.

According to the principles of HACCP a critical limit should be determined for each CCP. These critical limits should be established to ensure the identified acceptable level of the food hazard in the end product is not exceeded. Some parameters which are commonly used as critical limits include temperature, time, pH, moisture, Aw, salt concentration and acidity. By definition this means that critical limits must be measurable. If you cannot assign a measure to the monitoring program for the CCP then you need to reconsider whether it is a CCP or if it can be controlled as a CCP. In such cases you may need to redesign the process step or seek alternative methods of determining the safety of the product. Where a critical limit is based on subjective data (such as visual inspection of product, process, handling, etc.) it is important that the CCP is supported by instructions, visual standards, specifications or education and training.

A key item of data relating to critical limits is the expected amount of the hazard in the final product. This may not always be known or easily identified. This is where you need to draw upon a va-
riety of sources, research and available data to support you in the setting of critical limits. The following are the main sources of data used to establish critical limits:

Where possible it is best practice to establish the critical limit in the context of preventative control. This means using an additional layer of control in the form of Targets and Warning limits. Targets are used to set the mean point of the process and where you want the process to be centred while warning limits can be used to alert you to a drift in the process prior to non-conforming or unsafe product being produced. In the example below we can see the setting of upper and lower specification limits (CCP’s), upper and lower warning limits and a target for a cooking process. This provides the company with two layers of control for the CCP and in addition allows the company to specify the action to be taken when both warning and critical limits are exceeded.

![Figure 3: Setting of Critical Limits for Cooking Process](image)

6 METHODS OF MONITORING

Monitoring is the measurement or observation at the CCP to confirm the process is operating within the critical limit. It is the key to your HACCP system and in many ways your entire food safety management program. It can be argued that regardless of how robust your PRP’s and general management systems are, if the CCP monitoring is weak then your entire food safety control is also weak.

The nature and character of the method of monitoring will depend on the critical limit relating to the CCP. The monitoring procedure must be capable of detecting loss of control at the CCP (where the CCP has exceeded the critical limits) in a timely fashion sufficient to protect the consumer from possible exposure to the hazard. There are two basic types of monitoring procedures:

| Legislation | National and international regulations and legislation will often specify the legal limits for certain processes and products. For example, processing temperatures for cooked meat products, maximum levels of microorganisms and chemical contaminants. |
| Industry Guides | There are a number of industry guides and codes of practice which set up operational and product specifications which can be used as critical limits. These are usually published by large research centres. |
| Expert Advice | This can be received from consultants, microbiologists, toxicologists and chemical and inspection devices suppliers. |
| Experimental Data | This is used to support the setting of critical limits particularly for micro specifications and may come from planned experiments, challenge studies and micro testing of materials and final products. |
**On-line Systems:** On-line systems measure the critical parameter during the process. They can be continuous where the parameter is continuously recorded, e.g. temperature, or discontinuous where readings are taken automatically at specified intervals during the process. On line systems are the ideal set up for CCP monitoring but can be expensive and not always practical.

**Off-line Systems:** Off-line systems tend to be manual in nature and involve taking samples for testing and measurement of critical factors. This approach is normally discontinuous and based on an assumption that the sample(s) are representative of the process.

In the ideal world, all CCP’s would be on-line and continuous and be capable of taking automatic actions where deviations are detected. An example of this would be an in-line pasteurization system where the product is passed through a plate heat exchanger and continuously measured for temperature. Where the temperature falls below the minimum pasteurization temperature the product is automatically diverted back to the incoming product tank and personnel alerted to the deviation. This above scenario is not always possible and the majority of CCP’s are maintained using a system of inspection and testing.

The frequency of testing and inspection will vary greatly depending on the risk of the product, the nature of the hazard and the local controls. In all cases, the frequency of inspection must be consistent with preventing unsafe product reaching the consumer in the event of a deviation outside critical limits. For example, there is little point in checking a CCP every 2 days if product from day one is shipped to the customer and can be potentially consumed. There should always be sufficient scope to withdraw product before it enters the distribution chain. Where the test result cannot be obtained for a significant period of time a positive release system should be considered.

In some cases CCP monitoring may not relate directly to a process parameter at a specific step, e.g. cooking temperature. The critical limit may involve an event or task that occurs at a defined interval. For example, in the treatment of water for bottling the CCP may be microfiltration to remove pathogens such as cryptosporidium. Over time the effectiveness of the micro filter may diminish and therefore need to be replaced prior to the product becoming contaminated. In this case monitoring the total time and usage of each filter and their replacement is the monitoring method.

When it comes to determining what will be monitored it will usually be a characteristic of the product or process which allows you to confirm compliance with the related critical limit. Some general examples include measurement of temperature in a cooking processes required to achieve a lethal kill of specific pathogens; measurement of the pH of an acidifying ingredient when critical for the production of an acidified food or measurement of line speed when critical to adequate cooking or chilling in continuous line processes. In some companies you may also find the monitoring procedure includes the checking of certificates of analysis of incoming raw material. These may accompany the delivery and indicate the absence of specific hazards in the material. It is debatable whether these are in fact CCP monitoring methods; however, each business should decide what CCP monitoring programs best suit their needs and understanding of local risks.

It has already been mentioned that monitoring methods must allow for timely results. Lengthy testing procedures which provide results days after the event are of little value. For example, microbiological testing is seldom effective for monitoring CCPs. Physical and chemical measurements are preferred monitoring methods because when testing they produce rapid results. Examples of physical and chemical monitoring programs typically found in the food industry include:

**Time and temperature:** This is a common combination of control parameters used to address microbiological hazards. Specifically they are used to cause a specific reduction in the number of
pathogenic bacteria in food products like meats, fish and dairy. Unit processes that fall under this CCP include pasteurization and sterilization. They are often followed by a rapid cooling step designed to maintain product attributes and prevent the germination of spore forming pathogens.

Water Activity (aw): Pathogen growth can be controlled by limiting water activity (aw). This is the amount of water available in the food matrix for microbial growth. Drying products have a water activity below 0.85 which is effective for limiting pathogen growth. In this case, samples may be collected during the drying process and tested for water activity. The process is completed when aw falls below 0.85.

Acidity (pH): Pathogen growth can be controlled by limiting the pH of the product to a level that does not allow growth. For instance, the growth of Clostridium botulinum, which leads to botulism, is controlled in acidified products by adding acid to lower the pH to 4.6 or below. In this case, the pH of an acidifying agent may be monitored before it is added to a batch.

The monitoring program will determine the selection of the monitoring equipment. Equipment used for monitoring CCPs can vary and there can be a number of options for measuring the same parameter. Examples of monitoring equipment include:

- thermometers
- clocks
- scales
- pH meters
- water activity meters
- chemical analytical equipment.

In all cases the equipment used for monitoring must be accurate to ensure control of the hazard. The variability of the monitoring equipment should be considered when setting the critical limit. For example, if a minimum internal temperature of 145°F is necessary to kill pathogens in a product and the thermometer has an accuracy of ± 2°F, then the critical limit should be set no lower than 147°F. Periodic calibration or standardization is necessary to ensure accuracy. The HACCP plan is normally used to define the requirements of the monitoring program.

7 MONITORING FREQUENCY

Monitoring can be continuous or non-continuous. Where possible, continuous monitoring should be used. Continuous monitoring is possible for many types of physical and chemical parameters. Examples of continuous monitoring include:

- Time and temperature of a batch pasteurization process which is continuously monitored and recorded on a temperature-recording chart.
- In line metal detectors and scanners.

A monitoring instrument that produces a continuous record of the measured value will not control the hazard on its own. The record needs to be observed periodically and action taken when needed. The length of time between checks will directly affect the amount of rework or product loss when a critical-limit deviation is found. In all cases, the checks must be performed in time to ensure that irregular product is isolated before shipment. It is possible to set up the system to alert
the user immediately when a deviation occurs. This will reduce the amount of suspect product produced but can often require more capital investment in the control system.

When it is not possible to monitor a CCP on a continuous basis, it is necessary for the monitoring interval to be short to detect possible deviations from critical limits or operating limits. The frequency of non-continuous monitoring should be partially determined from historical knowledge of the product and process.

8 THE CCP MONITOR

The CCP monitor for each program should be clearly defined. They can come from any layer within the organization such as:

- Line personnel
- Equipment operators
- Supervisors
- Maintenance personnel
- Quality-assurance personnel

In all cases they should be trained and records of this training maintained. This should include a clear signature and date from the trained CCP monitor. The company should seek where possible to base the monitoring as close to the step as possible, e.g. the line machine operator. This ensures that those who are operating the equipment on a daily basis are the owners of the control rather than moving it up the organizational structure away from the point of control. Those responsible for monitoring a CCP should:

- Be trained in the CCP monitoring techniques
- Fully understand the importance of CCP monitoring
- Have ready access to the monitoring activity
- Accurately report each monitoring activity
- Immediately report critical-limit infractions so that immediate corrective actions (Principal 5) can be taken.

The monitor’s duties should require that all unusual occurrences and deviations from critical limits be reported immediately to make sure adjustments and corrective actions are made in a timely manner. All records and documents associated with CCP monitoring must be signed or initialled by the person doing the monitoring. The monitoring procedures should also be available to the monitor.

9 MONITORING RECORDS AND DOCUMENTATION

Each monitoring program should have in place a record for all results and a clearly documented procedure for conducting the monitoring activity, including deviations and corrective actions. In regard to records of monitoring results you have a number of options:
Manual

This method involves using manual paper records to indicate the test to be conducted, frequency and critical limits. CCP monitors will use the record to capture results and record specific events regarding deviations. This method is quick and inexpensive to set up and requires less training than other methods. Paper systems can be error prone and difficult to manage. They can be open to abuse and lead to invalid data being recorded without the knowledge of senior management. They also make data analysis time consuming.

Semi-Manual

This involves using various standard software packages like MS Excel. Basic spread sheets and workbooks capture the data results entered by the user. Again these can be inexpensive and quick to set up. They also support rapid data analysis.

They are limited in terms of design to allow for recording and relational analysis of data. In addition they may also allow for changing of results and poor validation.

Automatic Electronic Data Record

These systems are usually found on on-line monitoring and continuous systems such as metal detectors, check weigters, scanners and in-line probes. They are excellent at automating the data collection and analysis process and can be set up to provide automatic alerts when deviations are detected. They can facilitate correction of the process before out of limit conditions are reached.

Electronic Records

This involves using bespoke software applications which capture data from manual data entry or automatically from in-line systems. They can be set up to ensure only valid data is recorded and alert the user to out of limit conditions and specific corrective actions to be taken by the user. Automatic logs of all data entry by user and subsequent changes are often features of these software solutions. They can also allow for automatic report generation reducing the time required to analyse data and drive improvement.

Table 2: CCP Monitoring Program Record Keeping

Figure 4: Monitoring Record
In some jurisdictions such as the USA and EU where electronic records are used they must comply with specific legal codes to ensure the efficacy of the data collected is maintained and inspectors will accept these records as auditable. For example, in the USA effective August 1997, the Electronic Records; Electronic Signature final rule (21 CFR Part 11) sets forth the requirements for the creation, modification, maintenance, archival, retrieval, and transmittal of electronic records and also the use of electronic signatures when complying with the Food and Drug Administration (FDA) regulation. Among other technical controls this requires users to:

- Re-enter their password for each record signing
- Each time a record is modified the previous version of the record must be maintained in an archive
- Every 90 days the user will be required to change their password

Procedures for CCP Programs should be sufficiently detailed to ensure the CCP Monitor can perform their duties correctly and in a repeatable fashion. The procedure should be drafted and approved by a competent manager who has been trained in the principles of HACCP.

The HACCP Plan is the highest level document in your system. It is used to define the requirements of each CCP monitoring program and is a valuable working document which should be controlled and available to each CCP monitor. The following is an example of a HACCP Plan.

Figure 5: HACCP Plan
10 CORRECTIVE ACTION AND DEVIATION MANAGEMENT

It is a core principle of HACCP that corrective actions are taken when the monitoring results show a deviation from the Critical Limit. Corrective actions should be defined clearly by a competent manager who has been trained in the principles of HACCP. Corrective actions must prevent hazards reaching the consumer. In this regard corrective actions shall be documented in procedures which are available to CCP monitors and leave no room for interpretation. Records of corrective actions shall be maintained. Defining clear corrective actions is the key. The following is an example of how to define corrective actions:

- Stop production
- Place all products since the last control check on Hold
- Inform QA Supervisor
- Test all products on hold and release if negative
- Destroy product if a positive result is obtained
- Investigate cause of deviation and correct

Figure 6: Example of Deviation Action notified to CCP Monitor following
Product Benefits

- Easily record and manage all elements of your food safety system including HACCP and CCP monitoring, PRP’s, management systems and documents
- Eliminate paper using the 30 integrated modules that come as standard
- Access and work with your system from any location at anytime
- Stay up to date and fully compliant with software that updates automatically in line with changes to global food standards
- Improve compliance and audit outcomes through the action driven features of the software
- Accelerate compliance with all of the international food safety standards including the BRC, SQF, IFS & FSSC 22000.
- Spend less time managing your food safety system and more on value adding activities

Product Features

- Dashboards & KPI’s
- 100’s of reports as standard
- Notifications
- Multi-site management & oversight
- Real-time legal and alert updates to dashboard
- Roles & security
- Actions management
- Safe and secure web based solution
- No internal IT support or data back-up required
- Unlimited Users
- 24/7 world class customer support
- Covers in complete detail the requirements of the SQF, BRC, IFS, FSSC 22000, retailer standards and legislation
- FDA 21 CFR Part 11 –Technical Compliance
- Automatic audit log
- One click data export