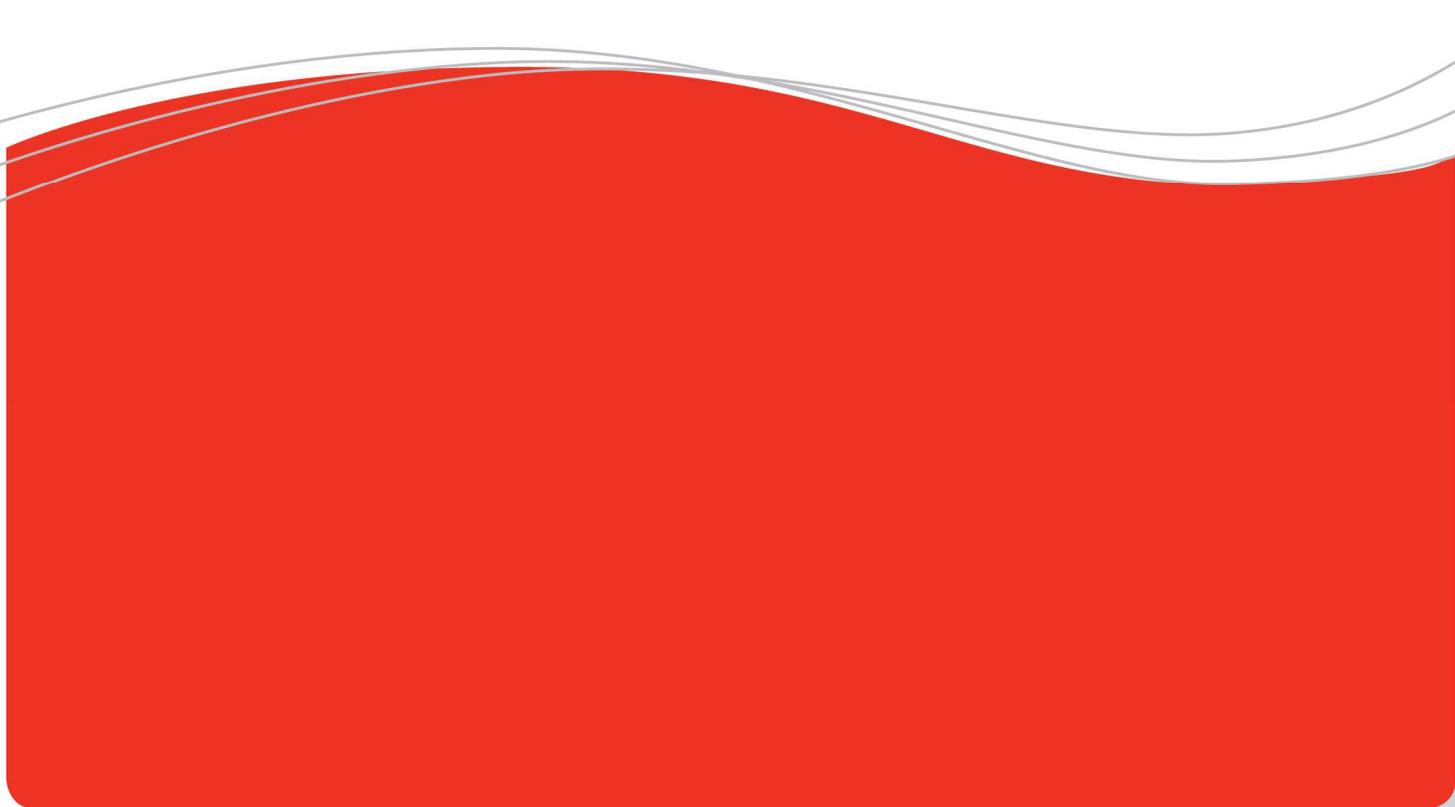




FMEA and HACCP: A comparison



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Introduction

FMEA and Control planning is being used more and more in industry. In the food industry companies use HACCP (Hazard Analysis and Critical Control Points). This methodology is used to guarantee the safety of the food produced. HACCP is used to identify and eliminate microbiological, chemical and physical hazards in a food production process. Hazards that if left uncontrolled could result in illness or even death. At a first pass it looks similar to the FMEA/Control Plan combination so what are the similarities and what are the differences.

For simplicity we will use FMEA to mean the FMEA and its associated Control Plan.

Origins

Most readers will know that FMEA originated in the Aviation/Nuclear/Military industries. It was adopted by NASA for the space program and migrated to automotive, semiconductors and industry more broadly. Surprisingly HACCP had its origins with NASA as well. NASA was keen to ensure that any food consumed by astronauts would not make them ill, even a simple illness could have serious consequences on a space mission. To their surprise there was no formal system in place that answered this question. So in the 1960s NASA worked with the Pillsbury Company to establish a system. Pillsbury used HACCP to guarantee food safety for NASA and actually adopted the program for the whole company. A general guideline has been developed. The current version of the Recommended International Code of Practice-General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application was adopted by the Codex Alimentarius Commission in 1997. The HACCP Guidelines were revised in 2003. The Code has been sent to all Member Nations and Associate Members of FAO and WHO as an advisory text, and it is for individual governments to decide what use they wish to make of the Guidelines.



Developing the FMEA and HACCP

FMEA is a very strict process where the steps and documents are specified in detail. There are minor differences between different countries or industries. For example the AIAG registration used in automotive industry in the USA is different from the VDA registration used in Germany. In HACCP there are international guide lines but every country can define their detailed approach and documentation.

Table 1 shows the sequence of tasks implementing the two systems

FMEA	HACCP
1 Assemble FMEA team	1 Assemble HACCP team
2 Create design FMEA	2 Describe product
	3 Identify intended use
3 Construct process flow	4 Construct flow diagram
	5 On-site confirmation of flow diagram
4 Create FMEA	6 List all potential Hazards
Establish potential risks	Conduct a Hazard analysis
Establish severity, occurrence and detection	Consider control measures
Establish critical characteristics	
Establish the root cause	
Establish controls	
Establish corrective actions	
	7 Determine CCP's
5 Create Control plan	8 Establish critical limits for each CCP
Establish critical limits	
Establish what to measure, where, how often	
Establish corrective actions	
	9 Establish a monitoring system for each CCP
	10 Establish corrective actions
	11 Establish verification procedure
	12 Establish documentation and record keeping

Table 1: Implementation tasks for FMEA and HACCP

In common

As FMEA and HACCP are used as risk analysis techniques and both were heavily utilized by NASA it should come as no surprise that there are some similarities. The implementation tasks of FMEA are very similar to tasks 1 to 10 of the HACCP implementation.



The process flow

The effectiveness of both depends on an accurate as is process flow. This is the real process flow used on the production line with the real rework loops and hold points that were never included in the process owner's original flow.

Their role in the quality system

The FMEA and HACCP should be active, living documents. They should be reviewed regularly and updated with lessons learned and ideas from best practice.

In order to be effective both processes require staff at all levels to be trained in their use.

Differences

FMEA, HACCP and relation to total quality system

FMEA can be used from product concept through to product manufacture. We develop System, Design and Process FMEA's to minimize the risk of defects or non-conformance. HACCP is focused on the safety risk factors of the food manufacturing process. Before starting with HACCP prerequisite programs should be in place. For example building layout, waste management, Good Hygienic Practice, pest control etc. all need to be considered but are not part of the HACCP. Potential Hazards which are not part of HACCP should still be controlled. This is for example a requirement in ISO 22000. These control points are called Operational Prerequisite Program (OPRP) points. For example metal detection is a CCP point, use of the correct production code is a OPRP point and inspection of a bottle is neither a CCP nor a OPRP point because it is not a potential Hazard.

Customer requirements versus safety analysis

A useful FMEA will consider any risk at all the steps in the real "as is" process flow related to customer satisfaction. Safety analysis is part of this process. HACCP only concerns itself with "Critical Control Points". At any particular point in the process HACCP is only applied if a Hazard is "reasonably likely to occur" and the consequences are "relatively serious". Applying these criterion means that not every process step or quality characteristic is bound to occur in the HACCP.



Estimates of risk

When performing an FMEA we use the Risk Priority Number (RPN) to establish the level of risk. This is a multiple of Severity (of the product defect for the customer) X Occurrence (of the root cause) X Detection (of the root cause). HACCP uses different criterion. The Hazard must be “reasonably likely to occur” and the consequences must be “relatively serious”. This requires some judgment and experience on behalf of the manufacturer.

Possible problems with the product and limits

HACCP defines three ways in which a food product can be affected. These are the introduction of biological, chemical or physical hazard. The limits for these are established for example by legislation, best practice or expert knowledge. The FMEA will consider the consequences of any variation of the product on the customer’s experience. Specification limits for all relevant characteristics are established and during process studies statistical limits will be used.

Verification and record keeping

Steps 11 and 12 are part of the HACCP. They are also applied in industries applying FMEA but not specifically as part of the FMEA. Verification can be done by applying audits or by sampling. Results can be stored in a quality system for example a SPC system.

Documentation

Documentation is a key part of FMEA and HACCP. You need to be able to say what you will do and demonstrate that you have performed this way. HACCP uses separate forms where that information is more integrated in FMEA.

Conclusions

HACCP is very similar to the sections of FMEA that are concerned with customer safety and requirements set by legislation. The FMEA goes further in examining in detail every aspect of customer requirements. HACCP drives excellence in every aspect of food safety. FMEA drives excellence in every aspect of customer satisfaction. With modern software HACCP and prerequisite programs like GHP and ISO22000 can be integrated in a FMEA implementation. If required the system could allow the HACCP to be extracted separately for audit purposes. A system that would allow the HACCP and FMEA to be developed in parallel would allow a food manufacturer to aim for the highest standards in food safety, GHP and customer satisfaction.