

HACCP: GOVERNMENT CONTROL OR INDUSTRY DUE DILIGENCE SELF CONTROL?

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Introduction

Somehow, HACCP, which was started in 1968 as a food operation program for the food industry to control natural hazards in food from land farms and water farms, has turned into a government-driven and -mandated program of record keeping by operators to convince the government that they had control of all critical control points when the regulators were not watching.

This is absolutely NOT the intent of HACCP as originally described in the Procedures of the 1971 National Conference on Food Protection, NASA, or the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) document, "Hazard analysis and critical control point principles and application guidelines." The government is never mentioned as the entity responsible for food safety. The operator producing the food is responsible. The fact that there is government inspection is a sign of failure of some of the industry to adequately control hazards, according to government regulations. HACCP is a science-based, industry process system for operators to use for risk management. HACCP requires operators to analyze processes in food operations; identify the biological, chemical, and physical hazards that management determines to be significant; and then, show due diligence in the development of controls to reduce the hazards to a tolerable risk level and frequency of occurrence.

HACCP does not guarantee zero defective products. No system can do that, because there is always the chance for human error. There is no zero risk in consuming food. Millions of meals containing raw ingredients are consumed each day by people, and cooks are not perfect in controlling pathogenic substances. With HACCP, however, it is not the government that decides on risk. It is the operator and the operator's insurance agent who will have to pay liability claims in case of illness or death. The government can certainly set goals of reducing deaths from pathogens such as *Listeria monocytogenes* by commercially processed food in the U.S. However, it is up to the individual food producer to decide on the risk that he/she is willing to take in terms of government penalty for producing product, once in a while, that the government happens to sample and find positive for *L. monocytogenes*.

The HACCP Team and Risk Reduction

One of the biggest oversights by our government-driven HACCP program is that it puts government and the inspectors in charge of a company's quality assurance program. This is totally wrong. The HACCP literature discusses how the HACCP team sets up a program, does flow charts, identifies significant hazards, selects and validates controls, decides on process monitoring procedures and then, specifies corrective action and verification. The government thinks that it must monitor the processes' records and verify the records, because operators do not care. Nothing is further from the truth. It is the responsibility of management and the HACCP team to monitor the controls and corrective actions through review of the records and continually reduce risk.

Continuous Process Improvement

Omitted in government HACCP is continuous improvement of processes. The risk of an employee error and a defective food being produced must be continually reduced. This effort is led by the HACCP team. The procedures for doing this are well described in the books on Total Quality Management, Quality Assurance, Quality Circles, etc. The goal of the team, along with new process development, is to improve the stability of each process. The stability of the process is described in statistics as the process capability index. The greater the value of the process capability index, the more stable the process is, and the more likely the process is to produce product without defects. The simple equation for this is as follows (Kane, 1989).

$$\text{Cp (process capability index)} = \frac{\text{upper specification limit} - \text{lower specification limit}}{6\sigma}$$

If the value of the index is greater than 1, the process is considered stable, because more than 6 standard deviations of product is being produced within the upper and lower specification limits. If it is less, the process variability needs to be reduced.

Doing Continuous Improvement

The starting point for this HACCP team continuous process improvement is to select the process variables to be measured – variables that truly measure and predict the components in the product that relate to customer's safety and quality expectations of the customer. Some variables might include:

- No *Salmonella*, *L. monocytogenes*, and *E. coli* in 25 grams.
- Less than 100 *Bacillus cereus* and *Clostridium perfringens* spores per gram.
- pH below 4.0.
- Aflatoxin less than 10 micrograms per gram.

These customer-desired safety outcomes are then related to process variables such as:

- Supplier conformance with purchasing specifications.
- Cook temperature and time.
- Cooling temperature and time.
- Acid added.
- Less than 1 environmental sample in 9 positive for *Listeria* spp.

In order to visualize the performance of a process, the process variables are plotted using the traditional QC chart (Figure 1).

Some of the simple out-of-control signals for a control chart that the HACCP team can use include:

- A run of 8 or more consecutive points on one side of the center line.
- A run of 6 or more consecutive points up or down is considered unusual.
- If there is 1 or more points above the UCL (upper control limit) or LCL (lower control limit).

The HACCP team, with all of its expertise, looks for cause-effect relationships for out-of-control conditions and, if appropriate, changes processes to make them more stable and improve the process capability index.

Figure 1. QC Control Chart

		VARIABLES CONTROL CHART (\bar{X} & R)																		PART NO.		CHART NO.				
		PART NAME (PRODUCT)						OPERATION (PROCESS)						SPECIFICATION LIMITS												
OPERATOR		MACHINE				GAGE				UNIT OF MEASURE				ZERO EQUALS												
DATE																										
TIME																										
SAMPLE MEASUREMENTS	1																									
	2																									
	3																									
	4																									
	5																									
SUM																										
AVERAGE, \bar{X}																										
RANGE, R																										
NOTES																										
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
AVERAGES																										
RANGES																										

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Summary

HACCP should not be a thought of as government-mandated program. The government simply sets process performance standards such as 10^{-6} reduction of pathogens on fingertips; 10^{-5} reduction of *Salmonella* in hamburger; and Food Safety Objectives (FSOs) of 100 or fewer *L. monocytogenes* per gram of ready-to-eat food at consumption. It is up to operators, using HACCP as their scientific method for risk management, to continually improve the stability of process through employee training and process improvement to reduce variability. HACCP is a very systematic process analysis tool for the manufacturer to meet consumer safety and quality goals and government process safety standards. It is a very good way to show due diligence in case a defective product injures a consumer. Most important is that the HACCP records are really not for the government, but are, first and foremost, for the HACCP team to use in improving the stability of processes. Therefore, there is less chance of producing a defective product. Without HACCP records and statistical process analysis of the records, the operator is "flying blind" and has no idea whether tomorrow's product will probably meet standards or be defective. With HACCP team continuous improvement, tomorrow's process performance becomes highly predictable.

References:

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