INTRODUCTION

In risk management of foodborne disease, there are two components.

1. Proper diagnosis of the technical causes of foodborne disease and specification of simple, doable controls by the worker on the line.
2. Specification of a management system that enables / empowers the worker on the line to do the control 100% of the time. In effective retail HACCP, there should be 100% "inspection" by employees. If they are taught to check each item and not sell it if they would not eat it themselves.

One contributing factor to the foodborne disease problem is an overemphasis on the seven HACCP principles that were specified in 1992 by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). Below is a list of these principles. They are incomplete, because they do not include management and continuous risk reduction. Remember, HACCP, as currently defined, is for slaughter and food processing. Bryan and I are the only ones who have scientifically applied HACCP to the retail level, and I am the only one who has generalized and validated HACCP controls for recipes.

NACMCF HACCP

NACMCF HACCP consists of a pre-step followed by doing the seven Principles.

Pre-HACCP

- Assemble the HACCP team.
- Describe the food and the method of its distribution
- Identify the intended use and consumer of the food.
- Develop a flow diagram that describes the process.
- Verify the flow diagram. (COMMENT: In the retail food industry, there are hundreds of food flows in a unit.)

Principle 1. Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur. Describe the preventive measures.

- Step
- Identified hazard
- Is it or is it not a hazard that is a significant risk that must be controlled?

Principle 2. Identify the critical control points in the process where a significant risk / hazard can be prevented, eliminated, or reduced to an appropriate level of protection (ALOP).

Principle 3. Establish critical limits for preventive measures associated with each identified critical control point (CCP) and control of a significant risk.
**Principle 4.** Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control or determine if the process is out of control, beyond a critical limit. (COMMENT: The government has not specified the correct thermometers, pH meters, etc. to use to monitor and has not said how the sample will be taken or where a sample will be measured.)

**Principle 5.** Establish corrective action to be taken when monitoring indicates that there is a deviation from the established critical limit. (COMMENT: There is virtually no government guidance based on science.)

**Principle 6.** Establish effective record-keeping procedures that document the monitoring of the HACCP process to provide evidence that it was in control.

- Observation of what process control / critical limit?
- Was it by direct observation or record review?
- Who did it?
- Corrective action(s) / persons responsible
- Verification

NOTE: This actually includes **Principle 7.** Establish procedures for verification that the HACCP system is working correctly.

**REAL CAUSES OF FOODBORNE DISEASE**

What are the real causes of foodborne diseases in retail food operations? These causes are based on epidemiological data from outbreaks. The following list is based on Weingold et al. (1994), and provides a commonsense list of factors that contribute to foodborne illness in New York State. However, their list is really only a subset of what Bryan (1988) reported. Since Bryan included an analysis of outbreaks throughout the U.S., his factors have also been included. In both cases, these authors have chosen to list the causes in order of frequency. HACCP says that the goal is zero foodborne disease. Therefore, I have listed the causes in order of the flow of food through the retail food facility.

I start at purchasing, which includes a probable incoming contamination level, and I consider each step until we get to the point of consumption (i.e., from "farm to fork") (Snyder, 1994). The following is my rearrangement of the factors from Weingold et al. and Bryan into the flow analysis of a retail / home food operation. All of the following factors have contributed to / caused foodborne illness. One must be sure that they cannot do so in the system, under analysis.

**Cause (Referenced to Actual Cases)**
1. **Purchasing, receiving, and food storage factors**
   a. Contaminated ingredients
   b. Unapproved source / obtaining food from unsafe sources
   c. Natural toxicant / mistaken for edible variety
   d. Contaminated water
   e. Toxic container
   f. Growth during seed germination
   g. Poor dry storage
2. **Pre-prep and preparation factors**
   a. Toxic containers / pipelines
b. Cross-contamination

c. Hand contact with implicated food / colonized person handling implicated food

d. Unclean equipment / improper cleaning of equipment and utensils

e. Inadequate thawing

f. Inadequate cooking / canning / heat processing

g. Inadequate acidification

h. Slow, inadequate drying

i. Improper fermentation

j. Incorporating contaminated, raw food into foods that receive no further cooking

3. Transport and serving factors

a. Preparation several hours before serving

b. Inadequate hot holding

c. Added poisons, chemicals; intentional additives, incidental additives

d. Consumption of raw or lightly cooked food of animal origin

e. Post-processing contamination

4. Leftover factors

a. Improper cooling

b. Anaerobic packaging

c. Lapse of 12 or more hours between preparing and eating / use of leftovers

d. Inadequate reheating

e. Flies on food

Three major causes that are missing from both Weingold et al. and Bryan are nutrition, allergy-causing compounds, and hard foreign objects, which I include in my HACCPs.

A HACCP-BASED TOTAL QUALITY MANAGEMENT FOODBORNE DISEASE PREVENTION PROGRAM

The seven principles of HACCP provide reasonable guides for identifying scientific causes and control, but they do not include the management component that is necessary to make HACCP happen. What is preventive HACCP, then? In my view, it is a company program that protects the company from the liability of contaminated food, employees, and the environment such as city water (i.e., the sources of the hazards). The government is not supposed to, and does not, have any responsibility for protecting operators who make mistakes that cause foodborne illness or death. Operators must show due diligence and defend themselves to lawyers, defenders, and juries. Therefore, the hazard control system that we need to discuss is not one that pleases regulatory officials, but is one that provides a defense in case of an employee error that causes a foodborne illness or death.

The following is my abbreviated list that I use when I audit a unit to validate that it has an effective, HACCP-based, due diligence program that would provide adequate defense in case of a lawsuit.

1. Validate the management QA program.

a. Is management using operating data from monitoring of processes and employee behavior to continuously improve all processes?

b. Can the CEO "walk the operation" and identify all hazards and technical and behavioral controls?
c. Are all employees trained according to validated, safe operating procedures before given food-handling tasks to perform? (Remember, FDA does not validate its controls that it includes in the retail code.)

d. Is training from written, validated, correct, HACCP-based policies, procedures, and standards in order to be uniform, reproducible, and capable of being improved?

e. A written test is not adequate. Are employees tested for mastery of HACCP tasks and then coached by supervisors until critical behaviors are a habit?

2. Validate that the food system description is up to date. Each time there is any change, the new procedures must be validated as safe by someone with adequate HACCP competencies.
   a. Are the environment, facilities, and equipment correctly described? What does the establishment plan to add? Is management making adequate provisions?
   b. Is each menu item correctly described, and how it is made?
   c. Are all styles of service described, to include take-out, home delivery, catering, etc.?

3. Validate that GMPs are up to date:
   a. Are procedures for cleaning, sanitizing, and maintenance of environment, facilities, and equipment up to date?
   b. Is employee personal hygiene up to date?
   c. Are all emergency situations considered?

4. Validate full HACCP control over all ingredients; their source; and microbiological, chemical, and hard foreign object hazards.

5. Validate that recipes are safe.
   a. Ingredients and amounts.
   b. Procedures to make food safe.
   c. Customer handling of food.
   d. Leftovers.

6. Validate operations. Check operating data. Check for opportunities to improve, based on:
   a. Daily operating reports.
   b. Customer feedback.
   c. Employee team feedback.
   d. Self-audits.
   e. Outside audits.

7. Validate the improvement program/change.
   a. Does the unit have a list of opportunities?
   b. Are these opportunities prioritized?
   c. Is the unit doing R&D to determine exactly what to change? Does it validate that the new procedure is better than the old?
   d. Does management schedule change, fund, and allow time?

IMPLEMENTING HACCP-BASED TQM
Just how long does it take to do a HACCP? If I am with an owner who knows all of his or her recipes, I can set up a basic recipe HACCP in four hours, because most controls are common from unit to unit. The more important question is, "When does the HACCP become effective?" It could be as little as four additional hours, if there is an employee meeting and all employees do what they are told. This never seems to happen. So far, people want to write HACCPs, but then, they file them away and ignore them, and say they have a HACCP. They may have a HACCP
program, but they are not doing HACCP. The retail food industry educates--it does not train employees to build habits. I have listed the employee behaviors (see http://www.hi-tm.com/Documents/0091t&c.html) that must occur 100% of the time in order for a manager to say honestly that there is a low risk of a foodborne illness when someone eats at his or her establishment. The probability of correct employee task performance is the correct measure.

One final factor is keeping the written HACCP program up to date in a unit. This is the difficult part. First and foremost, the manager must list the job of each employee so that each employee can be taught to do the critical tasks. Currently, only the chain restaurants have this level of organization and training. They do not follow through, however, and the government does not hold them accountable for precontrol using HACCP.

So, let's get started using HACCP. Let's recognize, though, all of the parts to the control of the contamination of food, people, and environment:

1. Correct government information
2. Government personnel who are well trained in HACCP process analysis
3. An industry that is held accountable for using the information.

Today, none of this is being done. HITM, through the IFT, intends to provide HACCP leadership through industry self-control.

REFERENCES

My home page (www.hi-tm.com) provides more information.
If you cannot find the answer on my web site, send another question.

O. Peter Snyder, Jr., Ph.D.
Hospitality Institute of Technology and Management
670 Transfer Road, Suite 21A
St. Paul, MN 55114
TEL: 651 646 7077 FAX: 651 646 5984
e-mail: osnyder@hi-tm.com
web site: http://www.hi-tm.com