

Food Safety Systems: Good Manufacturing Practices (GMPs), Sanitation Standard Operating Procedures (SSOPs), and Hazard Analysis-Critical Control Points (HACCP)

What is safe food?

Clearly, *safe* food is food we can eat without getting sick. This definition, though straightforward, is subject to many personal qualifications. Objectively, an individual may belong to one of the “at-risk” categories: very young; very old; pregnant woman; or a person with impaired immunity due to chemotherapy, HIV infection, or immunosuppression after a transplant. Food-associated illness can also be subjective — e.g., the reaction of someone who just found half a worm in an apple they were eating.

Let's look briefly at the illnesses we are trying to prevent. The most common are infections (e.g., salmonellosis, viral gastroenteritis) and intoxications (e.g., botulism). *Infections* are caused by agents that are viable (infectious) in the food when it is ingested and colonize the body before causing disease. *Intoxications* are caused by preformed poisonous substances (some of microbial origin) present in food when it is eaten. There are also *allergies*, caused by an abnormal immune reaction by a few people's bodies to otherwise wholesome food, and *intolerances*, caused by inability to metabolize specific food components that other people can digest without difficulty. Finally, there are a few foodborne diseases called “*idiopathic illnesses*,” whose mechanisms are not understood.

A fundamental challenge to the food system is that safety is impossible to prove. Whether it is a raw food material, a specific consumer product, or a particular lot of a final food product, no amount of inspection and testing can guarantee absolute safety to the consumer — especially if the consumer abuses or contaminates the food in some way. However, many activist groups are demanding exactly this — that food be handled, inspected, and tested in such a way as to spare the consumer any consequences of his or her own folly. HACCP is, in many cases, an answer to this dilemma, if it is applied in a valid way. This course undertakes to show how HACCP should be used and, incidentally, how it should not.

As will be discussed further later, hazards associated with foods may be microbiological, physical, or chemical in nature. Because of very different perceptions and recording systems, it is impossible to compare the frequencies and severities of these; the present course will focus primarily on microbiological hazards.

How does safe food “happen”?

Through much of the prehistory and history of humanity, food safety was less of a consideration for most people than just having something to eat. Still, useful *traditions* had evolved as to which foods to eat and how to harvest, preserve, and prepare them. Every product of human ingenuity in the food field (e.g., agriculture, drying-dehydration, mechanical harvesting, canning, refrigeration, freezing of food, etc.) led to departures from these traditions — and enabled the

earth to support many more people than formerly. We may sometimes decry these forms of progress, but we cannot abandon them without condemning huge portions of the world's current population to starvation.

Unlike other predators, humans now kill the youngest and healthiest animals to eat. This was not always true: in traditional village cultures, a family's moribund cow was slaughtered and the carcass shared with the neighbors. [Tevye in *Fiddler on the Roof*: "When a poor man eats a chicken, one of them was sick!"] When producers of surplus food began to offer it for sale or barter, the consumer's eyes and nose, and the seller's reputation, were the only guarantees of safety.

Government activity

Late in the 19th century, society had evolved in the direction of greater urbanization, while science had demonstrated that many illnesses, foodborne and other, were caused by microorganisms. The increasingly urban, literate society was alarmed by narratives such as Upton Sinclair's *The Jungle*, which described highly unsavory conditions in slaughterhouses of the time. Public outcry led to the passage of food safety laws in the U.S.; it appears that similar events were occurring in other developed countries at about the same time. Because the connection of microbes to foodborne disease was still being made, emphasis was on inspection of slaughter facilities and on the prevention of economic fraud ("adulteration"), such as adding water to milk or sawdust to sausage batter.

"Traditional" approaches to food quality and safety started with inspection. Someone looked at the food, and perhaps touched, smelled, even tasted it, to see whether it was "all right." Many foods are now graded for quality on these bases, but it is hard to detect real health hazards organoleptically. Unfortunately, both the food industry and (to some extent) government use *quality* as a code word for *safety* in certain instances, speaking of "quality assurance" when referring to safety programs.

As the connection between foodborne disease and microorganisms became increasingly clear, more and more sampling and microbiological testing were done. Specifications of various sorts were instituted; these were usually based on the presence or actions of indicator organisms, rather than pathogens, because pathogens are typically present only at low levels and because testing for each of a number of potential pathogens would be very expensive. In general, the choice of bacterial indicators was predicated on a perceived connection between these organisms, *fecal* contamination, and foodborne disease.

Nowadays, consumer activists are increasingly demanding that food actually be sampled and tested for pathogens. This usually (not always) entails *destructive* testing — the food that is tested is destroyed in the process and is therefore not available to be eaten. Even when test results are available rapidly, most tests are performed in laboratories, rather than at the point of food sampling, so there are delays. Also, negative results should not be reassuring unless a large portion of each food lot is consumed in testing. Since most tests are negative in modern day

food systems, the destruction of food becomes highly significant.

U.S. food safety agencies

The principal federal food safety agencies are the U.S. Food and Drug Administration (FDA, in the Department of Health and Human Services) and the Food Safety and Inspection Service (FSIS, in the U.S. Department of Agriculture). The FDA is a creature of the Pure Food and Drug Act (1906, much amended), and the USDA's inspection function (most notably the Food Safety and Inspection Service) is based on the Meat (1906) and Poultry (1957) Inspection acts (also much amended). The USDA includes a number of other divisions, notably the Animal and Plant Health Inspection Service (APHIS), which is the lead group in dealing with the bovine spongiform encephalopathy (BSE; "mad cow") emergency.

FDA operation is based on drop-in inspections. The inspectors are allowed to enter the plant only during normal operating hours, must not take photographs, and have had access only to thermal processing records (as opposed to other records of plant operation). Inspections take place infrequently because FDA is chronically understaffed. GMPs (discussed below) were intended to give the plants a formula for approved operation, so that inspectors had less corrective action to take when they did arrive in a processing facility. Although FDA also has jurisdiction over foods in storage and distribution (if they are in interstate commerce), this aspect of the operation has received less emphasis. FDA has agreements with many states to supplement their inspection activities. FDA was given jurisdiction over seafoods fairly recently and has mandated HACCP in the seafood industry as a regulatory tool. Fruit juices are also now in the HACCP system under FDA inspection, and HACCP is being phased in (voluntarily) as part of the Pasteurized Milk Ordinance.

USDA's FSIS operates by continuous in-plant inspection. In slaughter operations, inspectors are expected to see each animal ante- and post-mortem and to make specific examinations for certain abnormalities. With the advent of regulatory HACCP, as we will see on another occasion, there are considerable hints that "hands-on" inspection of every carcass by FSIS personnel may be coming to an end. Expert committees commissioned to recommend updated inspection methods have proposed that a HACCP plan be substituted, without specifying what this would entail. The inspectors' union has filed suit to prevent this; also, the congressional acts that established "conventional" meat and poultry inspection remain in effect. Consumer activists have favored HACCP over what they describe as "poke and sniff" inspection, but it appears that they do not want individual inspection of carcasses to cease — they just want more microbiological testing of meat and poultry. They are also distrustful of the enhanced role of industry in the HACCP approach. This is the opposite of how HACCP was supposed to work in the space program, but it seems to be a major part of the USDA Pathogen Reduction Program ("Mega-Reg") that will be discussed later.

The Mega-Reg was issued in 1996. It required that all meat and poultry slaughter and processing establishments have a Sanitation Standard Operating Procedure (SSOP) in place by January 1997, large (≥ 500 employees) plants have a HACCP plan in place by January 1998, and

small (10–499 employees) and smallest (<10 employees) plants have HACCP plans in place by January 1999 and 2000, respectively. In addition to some traditional HACCP measures, the Mega-Reg prescribed sampling a portion of carcasses by swabbing, with limiting levels of “generic” *E. coli* and limiting frequencies of *Salmonella* detection prescribed. In addition, *E. coli* O157:H7 was declared an “illegal adulterant” in raw ground beef.

Meanwhile, states that conduct their own inspections for intrastate meat and poultry may or may not adopt HACCP (California has not, but only *custom* slaughter is inspected by state personnel). Some states have sued to be permitted to ship state-inspected meat and poultry interstate, and perhaps internationally. This seems to violate the federal Meat and Poultry Inspection acts, but FSIS plans to get all of the states doing their inspections exactly like FSIS, whereby the question of who did the inspection will be moot. It is not clear that this strategy will succeed, given the U.S. Congress’ history of defending states’ rights. A court decision against Ohio during 2000 was based on the premise that USDA-FSIS could not possibly know whether the state was doing an equivalent inspection job unless there were FSIS inspectors continually present, even though the Meat and Poultry Inspection acts (federal) require the states to do an equivalent job at all times. Similar challenges to FDA jurisdiction seem not yet to be occurring — FDA has been “partnering” with comparable state agencies (e.g., the California Department of Health Services), to avoid duplicating inspections where the state has already gone.

On another front, a great many international trade agreements have been concluded in recent years. It is largely the USDA position that countries not following USDA’s new inspection procedures rather closely will not be allowed to sell their meat and poultry to the U.S. This presents considerable problems, in that the U.S. has been a net exporter of food, and other countries are not visibly impressed with our regulations. For example, many countries are very familiar with HACCP and have been using it for years; but because it has not become a regulatory tool, their versions of HACCP are much more like what was designed for the space program than like FSIS’s. Regulation in Europe seems to depend more on inspection than the U.S., at substantially greater cost. In many situations, operations that are required in the U.S. are prohibited in some other countries, and vice versa. Many efforts to reconcile these differences are in progress, but the U.S. shows very limited commitment to these. At the same time, many European regulations seem rather to be designed to protect their system of agriculture than the consumer’s health. Trade in meat has been greatly complicated by use of hormones and other growth enhancers in North America and the advent of bovine spongiform encephalopathy (BSE; “mad cow disease”). Also, all food imports to the US now require advance notice to FDA (even for products that are in USDA jurisdiction), and all foreign food companies that plan to export to the US must be registered with FDA, ostensibly as defenses against bioterrorism.

Since the event of September 11, 2001, a great deal of emphasis has been placed on preventing food bioterrorism. The Department of Homeland Security, through the Federal Bureau of Investigation, is attempting to organize the US food safety agencies at all levels and the food industry to prevent product tampering that might lead to foodborne disease. A great many interagency agreements are being put into place and even tested against mock terrorism events. This is very much a work in progress, and Congress has a great deal to say about how the system

evolves. Some of this evolving system will be described in the lecture on Operational Risk Management later in the quarter.

Preview of Risk Analysis

A fairly new discipline that has broad possible applications (not restricted to food) is *Risk Analysis*. More time will be devoted to this topic later in the course, but it will be mentioned here as a guide to understanding trends in food safety organization. Risk analysis comprises three complementary processes: risk assessment, risk communication, and risk management. Today, we will only look briefly at the first and third of these.

Risk assessment is a means of determining which of potential hazards associated with a food is worthy of control measures. Risk assessment weights potential hazards from a long list, on the bases of estimated probability of occurrence and severity of outcome. In cases like the risk of contracting variant Creutzfeldt-Jakob disease by eating portions of cattle with bovine spongiform encephalopathy (BSE; “mad cow disease”), concern over severity seems completely to overwhelm the extremely low probability of occurrence.

Risk management is whatever is done to mitigate the risk. The systems to be discussed here (GMPs, SSOPs, and HACCP) are all approaches to risk management. They are not mutually exclusive. GMPs and SSOPs can be used alone or together in certain situations, but HACCP typically works best if both GMPs and SSOPs are in place, so these are often called “prerequisites” to HACCP.

“Prerequisites” or adjuncts to HACCP

The success of HACCP often depends on proper application of Sanitary Standard Operating Procedures (SSOPs) and of Good Manufacturing Practices (GMPs — sometimes called Current Good Manufacturing Practices, CGMPs).

In pre-harvest situations and many post-harvest situations that do not entail processing of food, what are called HACCP-based programs are most nearly SSOPs and “Good **Agricultural** Practices” (GAPs).

GMPs are generally specified by government as part of the regulatory process. HACCP plans and SSOPs have traditionally been food industry initiatives — to the extent that they have become mandated regulatory instruments, they have taken on a considerably different shape than when they were the creatures of the industry. GAPs are also to be specified by government; due to lack of a science base for most proposed GAPs, they are treated as advisory for the time being.

“Quality” as a code word for *safety* of food: Food producers, processors, and vendors have consistently avoided use of the word *safety* for fear of appearing to have a problem. Therefore, although HACCP is supposed to be about safety rather than quality, the industry has usually chosen to use the word *quality*, rather than safety, when designing and implementing HACCP-

related programs. This has been a successful attempt to confuse the public — it will surely cause the industry problems in the long run.

What are GMPs?

Good Manufacturing Practices are “prescriptive” (i.e., “Thou shalt!” rather than “Thou shalt not!”) regulations first introduced by the FDA in the 1970s. Previously, federal food regulations basically told what must not be done (“proscriptive”).

Originally, it was envisioned that a GMP would be designed and implemented for each food under FDA jurisdiction, but eventually the focus fell on canning vs everything else.

“Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers” regulations became effective in January of 1973. In 1979, additional GMP regulations covering acidified foods and thermally processed pet foods were issued. These appear in 21 CFR and have the force of law.

GMPs cover every aspect of food processing, from the building and grounds of a food processing establishment to the actual receipt, storage, processing, and shipping of foods. As the word “manufacturing” indicates, the concept is primarily applied to processing, rather than to other aspects of the food system.

In other applications, there are proposed “Good Agricultural Practices” for pre-harvest food safety and the FDA Food Code for distribution and retailing of food, including food service. GAPs are voluntary at present, whereas the Food Code, like the Pasteurized Milk Ordinance (PMO), is to be adopted and enforced by the states. States may adopt any, all, or none of the Food Code, but the PMO is required in its entirety if a state wishes to sell its milk and milk products in interstate commerce.

What’s HACCP?

Hazard Analysis: Determining what microbiological, physical, or chemical risks are associated with a food that threaten harm to the consumer. **It’s about safety.**

Critical Control Point: A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. **It’s (largely) about processing.**

What’s “different” about HACCP?

- The focus is on control of the process, rather than of the end product.
- A process may (but need not) have more than one CCP — if there is no legitimate CCP, it’s not HACCP.

- HACCP ordinarily entails a good deal of documentation, especially to show that values were maintained within Critical Limits at the CCP.
- Critical Limits for a CCP are ideally established for variables that can be continuously or frequently monitored, yielding instant or prompt results. Sending samples to a laboratory for later analysis and reporting is discouraged.

History of HACCP

HACCP grew out of a collaboration between NASA, the Pillsbury Company (in particular, the late [2001] Dr. Howard Bauman), and the US Army Natick Laboratories. The objective was to provide a zero-defect food supply for the astronauts. Testing the end product was recognized as ineffective for this purpose. Derived from a quality assurance system called “Failure Mode Analysis,” the system focused on “Critical Control Points” in processing that, properly monitored, could assure a safe end product.

The CCP concept was introduced publicly at a National Conference on Food Protection in Denver in 1971; the report of the conference barely mentions Hazard Analysis. The merging of Hazard Analysis and risk assessment came later. Although cost was no object at that time in the space program, it soon became clear to the food industry that the HACCP system was a cheaper approach to food safety at the same time that it offered better results. Food processors in the U.S. and Europe were applying HACCP from within during the 1980s.

In 1985, a subcommittee of the National Academy of Sciences’ Committee on Food Protection suggested that HACCP be required by regulation. Specific occasions on which HACCP (and SSOPs) has been made mandatory by FDA and USDA since 1996 will be discussed in the contexts in which they occur in the course.

More recently, Codex Alimentarius, a subsidiary of the Food and Agricultural Organization and the World Health Organization (UN), has undertaken international HACCP standards. The World Health Organization is also promoting the HACCP approach to treatment of drinking water.

Some potential readings:

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