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Items to be Included in a Food Safety Handbook for Artisan Cheese Makers

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by

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ABSTRACT

Items to be Included in a Handbook of Food Safety for Artisan Cheese Makers

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Current written resources for artisan cheese makers include topics concerning cheese history, cheese recipes, budget planning, culture selection, processing parameters, and only limited discussion of food safety associated with cheese manufacturing. Most often food safety discussions center on HACCP, which typically are not included in artisan cheese operation planning. Recent changes in the regulatory landscape, including the Food Safety Modernization Act, make this information timely and needed. This research is designed to identify and collect a majority of topical ideas that should be included in a Food Safety Handbook for Artisan Cheese Makers. Where possible, expansion of the ideas has been included. It is felt that this information, once collected could be put in a handbook for artisan cheese makers that would provide a day-to-day reference manual for making safe, high quality Artisan cheese.

To Carole Irish

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David A. Irish

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> A cheese may disappoint. It may be dull, it may be naïve, it may be over sophisticated. Yet it remains cheese, milk's leap toward immortality. - Clifton Fadiman –

When an individual or company determines to begin manufacturing cheese there are several key elements to the operation that must be remembered. These elements make up a system of control that allows the company (or individual) to manufacture a product of high quality, while maximizing its profits and minimizing cost and waste. While there is a considerable amount of discussion that could take place as to exactly what the key elements are, there is one that stands out as paramount in the discussion, **food safety**. No matter what else you do, at the end of the day, food safety matters.

In terms of cheese manufacturing, food safety must be thought of as the over-arching principle that governs what, how, and why, we do what we do. Someone getting sick because of bacterial contamination, injured due to foreign material, or having an allergic reaction caused by improper processing or incorrect labeling, is to be strictly and specifically avoided.

The collection of milk from animals and the production, distribution and sale of cheese come together as a complex system. At the moment of milking, the milk is as good as it ever will be and anything we do to the milk can affect it in so many ways.

People view eating food as a very safe activity as we have come to expect our food to be safe. The topic of food safety often catches National attention when there is a food borne illness outbreak, contamination issue or allergen labeling issue. Everyone involved in cheese processing

needs to understand the impact these kinds of events can have on the day-to-day perception of cheese. All companies must consider the economic impacts food safety has on their business.

When we think of **food safety** we must remember that *all foods can be hazardous to some one*. For example, hot dogs could be a choking hazard if given to an infant, chocolate that is labeled "Does not contain nuts," when it really has nuts could be hazardous to someone that is allergic to nuts. Eating is a potentially risky activity. The average US consumer eats 4.7 lbs. of food every day (USDA, 2011). In a year that is equal to 1700 pounds. In a lifetime of 60 years that is over 100,000 pounds of food. In that same, 60 year lifetime cheese will make up nearly 1800 pounds of that total. A safe wholesome food literally means, an item of food, that when consumed by the average individual, results in no ill health effect and satisfies the need for taste and energy. The words, "average individual" mean the common person who is not in the extreme ends of health. Not too old, not too young, not immune compromised, or suffering from something that makes them more susceptible to disease.

Food safety includes contamination from chemicals, foreign material, and bacteria. Food safety is a deeply complex subject. To some degree or another, every company or individual that produces and sells food, take some sort of measures to ensure food safety. The level to which a company acts in regard to food safety depends on their vision. How do they see the safety of cheese (food in general) impacting their lives and the lives of their customers'?

Like it or not we live in the age of food safety. Many of the issues that are publicized in the media are serious, while others are sensationalized. Certainly in the current economy the idea of spending additional money and time on food safety is an idea of serious consideration. As an artisan cheese maker you must ask yourself where food safety stands on your priority list.

In other words, you need to give food safety serious consideration. This book was written to help you do just that.

There are three goals that have been built into this handbook. First, to educate the small to medium processors on the dangers of what they currently do not know or do not completely understand. Second, to give a wide view perspective of food safety and the impact food safety issues can have on the overall reputation of the cheese industry. And lastly, to assist the reader in determining where his/her operation fits into this picture and what measures are in need of immediate implementation.

Food Safety, as it pertains to cheese is specific, in that certain State laws allow for the making of cheese from raw milk under certain storage conditions. Whether or not a company chooses to make cheese from raw or pasteurized milk is strictly up to the processor and is governed by state law. Whether or not you make your cheese from raw or pasteurized milk is a serious question, which you alone must answer.

In an attempt to make this handbook easier to understand the following analogy will be used.

> When someone purchases a new car and proceeds to read the owners manual they will discover that the manual says that the oil should ***always be checked before starting the engine***. Now that seems like a lot of work to go through before starting your car, but racecar drivers do this every time. Imagine the impact if the engine in a racecar were totally ruined as a result of starting the car without oil in the engine. It wouldn't just be financial. It would impact their income, reputation, image *in* the industry, and the image *of* the industry.

> Prevention of pathogens contamination in the foods you make is like oil in the engine. Verifying that you have oil in the engine doesn't guarantee that nothing else will go wrong, but it is the first level of defense before you start the car.
>
> If you heard about a race team that forgot to check the oil and ruined an engine what would you think of that race team? Would your opinion change depending on their experience, financial status, or size of their operation? No! Any team that would make that mistake would be looked at with suspicion. Consumers have the same view of people who make cheese. **No one who makes cheese would forget to ensure that food safety protocols are in place for every aspect of their operation.** When your cheese is associated with a Food Safety issue the results won't just be financial. It will impact your income, your reputation, your image *in* the industry, and the image *of* your industry. And people won't judge you based on your size or income.

From this analogy, you will be able to determine where you are in relation to food safety activities. It is expected that you determine your specific level of commitment to food safety and that commitment will carry you as you move along. How you react to, work to avoid and learn to understand food safety will go along way in determining the level of action you take to ensure that you make and sell a safe food product.

As you consider your role in food safety keep in mind that we sometimes judge others harder than we do ourselves. People often say "I am only human, give me a break", or, "nobody's perfect". That is the excuse we use for ourselves, but do we extend that same view to others? If the teller at the bank counts back our change incorrectly, or our favorite athlete missed

a catch, or our waitress messes up our order do we say, “ah, that’s ok, you’re only human”? No we don’t. We expect people who are getting paid for doing something to do it right. That is how you will need to look at yourself, as a cheese maker, or cheese making company, people (consumers) expect you to do it right, every time.

How Safe is the Food Supply?

> "The poets have been mysteriously silent on the subject of cheese." - G.K. Chesterton –

It can be estimated that 99.99 percent of all the food in the U.S. is safe. That calculation is based on knowing that there are approximately 320 million people in the United States who are eating at least three meals and 2 snacks a day. And there are about 46 million injuries, illnesses or deaths due to contamination or unsafe things in food. So when you do the math, that comes out to somewhere around 99.99%.

This percentage seems to be fantastic. And it would be if it were a score on a test, a basketball shooting percentage, or any numbers of other things. What does it mean that our food supply is 99.99% safe? It means that in every 10,000 servings of food one person will either get injured, ill or die. Because we are talking about people we would like to push that number out to 99.9999%, which is one in every 1,000,000 servings.

Consider that it takes 625 pounds of cheese to equal about 10,000 servings of cheese and therefore a one in 10,000 chance of failure would be 99.99%. Expanding that to another decimal place it would take 6,250 pounds of cheese or a one in a 100,000 chance, or, 62,500 pounds of cheese for a one in a million chance. Now that is a number we can live with, pun intended.

There are several methods of evaluating the effectiveness of food safety controls, which include, observational audits, microbiological sampling, environmental sampling, and finished product sampling. As this information is for the benefit of artisan cheese makers it is necessary to use data and examples of what is currently happening in the artisan cheese industry. As a way

to demonstrate the importance of these evaluating methods, let us look at a study of Vermont Artisan cheese making.

Artisan cheese makers in state of Vermont were asked if they were willing to participate in a study that checked the safety and quality by inspection, bacteriological studies, and observations while cheese was being made. Of those that were contacted fifteen Artisan cheese makers agreed to participate in the study of their operations.

The investigators looked at the general plant conditions, the cheese making operation, and the environmental conditions of the plant. Some of the observations that were made during the study include: there was no checking of sanitizer concentrations done at the facilities, footwear was not properly cared for, there were items entering the cheese vats that should not have been, which include: pH meters, glassware, cups, human hands, and arms. The inspectors found rusty shelves and equipment even in new plants, cracks and openings in the walls and floors, rooms that were used for multiple purposes which could result in cross contamination, inadequate tools and chemicals for cleaning, and standing water on the floor.

When the investigators were present at the time of cheese making they noticed a general lack of technical expertise. Some of those items included: weighing out of starter culture, checking physical and chemical properties of the cheese, lack of record keeping such as make sheets, temperature checks, acidity, and lot numbers of ingredients.

The investigators also took microbiological samples from raw milk, finished product, and the environment. Raw milk samples were tested for *Staphylococcus aureus (S. aureus)*, *Escherichia coli* (*E. coli*) O157:H7, *Listeria* species (sp.), and *Salmonella* sp. In the raw milk there was one isolation of a raw milk sample that contained *E. coli* O157:H7, *S. aureus* was isolated multiple times in the raw milk, *Listeria* sp. and *Salmonella* sp. were not detected.

Microbial sampling of the product included tests for *S. aureus*, *E. coli* O157:H7, *Listeria* sp., *Salmonella* sp., standard aerobic plate count, and coliform count. Of the products that were tested there was one isolated from cheese made from raw milk which had *E. coli* O157:H7, *S. aureus* was not detected, *Listeria* sp. and *Salmonella* sp. were not detected, a standard aerobic plate count of 640 colony forming units/ml (cfu/ml), and a coliform count of 9 cfu/ml were the average.

Microbial sampling from the environment were tested for *Listeria* sp. and it was found in or on boots and footwear, standing water on the floor, in drains, on milk cans, crates, and pallets.

As this information shows the cheese industry (specifically Artisan) has some work to do in order to make as safe a food product as possible. The implications of having pathogenic bacteria in the environment are serious as they can be incorporated into the product relatively easily.

CHEESE
What is it Really?

Basic Process of Making Cheese

For the purposes of this handbook only natural cheese varieties will be discussed. Natural cheeses are those cheeses that are made from only milk and the additives necessary to make cheese. The source of milk is important to the type of cheese that is being made but not so important as to the basic cheese making steps. Cheese can be acidified with acid or bacteria, it can be set by the acid or by enzymes and can be colored or not. The basic principles of making cheese are the same for all varieties of natural cheese. The object is to concentrate the solids portion (fat, protein, vitamins, etc.) of the milk by removal of water (whey). (See Figure I-A, Cheese Making Process).

Several years ago there was a TV ad for cheese, which stated that men used to believe that the moon was made of cheese. We went there and found out it wasn't so we haven't gone back. The ad ends with the words, "Ahh, the power of cheese!" Truly there is power in this remarkable food. Cheese is an incredibly functional food that can be used as a stand-alone food item or more commonly as an ingredient; cheese has always played a role in the world's food supply.

Cheese is so intertwined with life itself that it is written about, sung about and even used as an image of insult, by Shakespeare in his play; *The Merry Wives of Windsor*.

Cheese has been an integral part of life on earth for thousands of years. Job, from the Old Testament says to the Lord, "hast, thou not poured me out as milk, and curdled me like cheese?" (Bible). That is an interesting image Job used considering that he said it in regard to his lamentation. Maybe only a cheese maker could truly understand the implication Job makes in this statement. The process of turning milk into cheese is irreversible. It is a physical change that involves the addition of acid, heat, cutting, and pressure.

Cheese Making Process

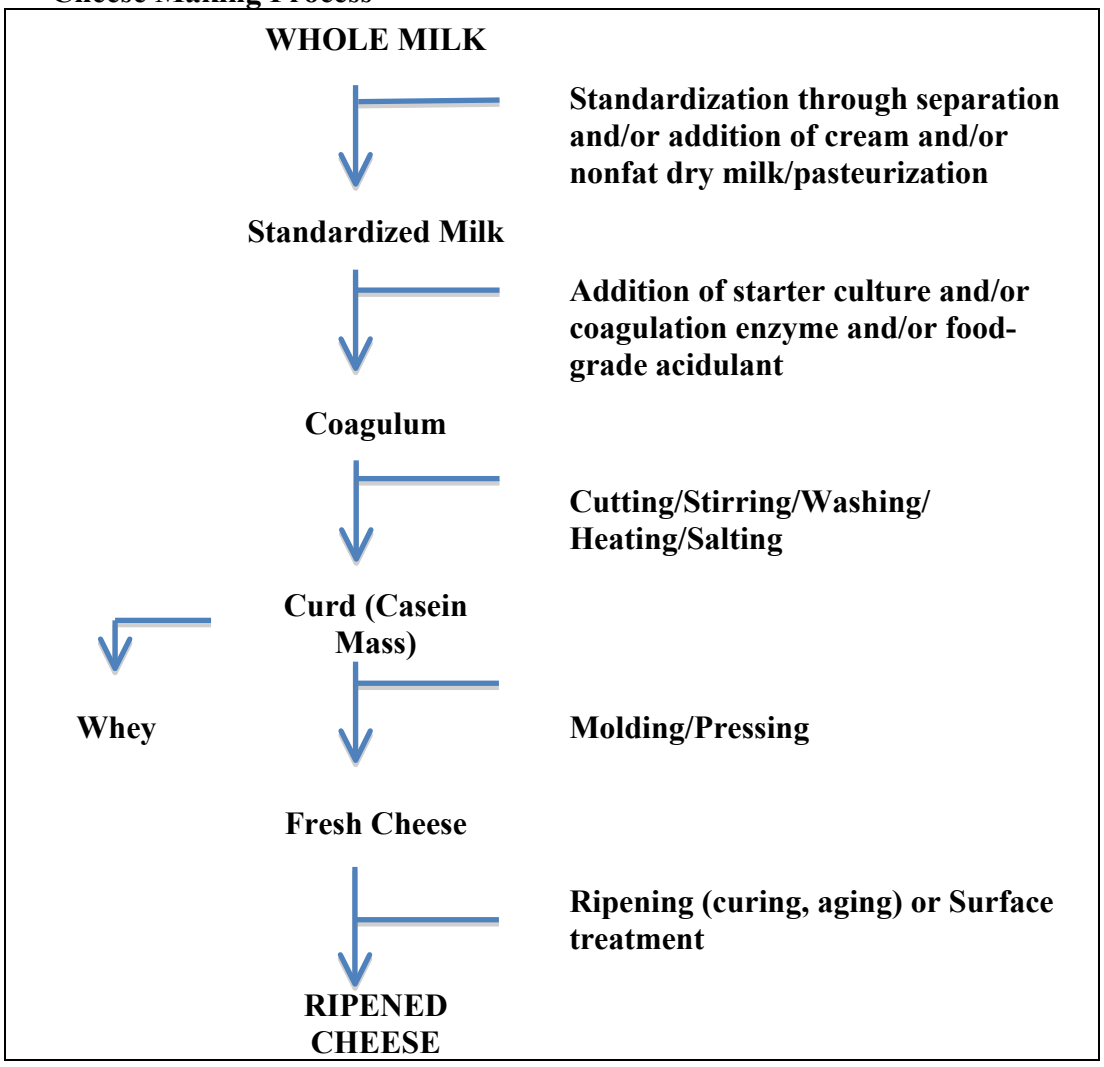

Figure 1. Generalized basic cheese making process

Cheeses as we know them today are common and most people don't give much thought as to how they are made. The basic steps involved in cheese making have not changed much over the centuries. Cheese in its simplest definition is concentrated milk. The process of making cheese allows the solids, and some of the liquid in milk, to be stored for later consumption. Most likely discovered by the accidental association of milk and enzymes its production dates back thousands of years and through many cultures.

The dictionary defines cheese as "a food made from the pressed curds of milk" (Dictionary, 2011). With that as a definition it is no wonder that there are thousands of cheese varieties currently, and many more yet to be discovered. Dr. Jeff Broadbent, Professor of Microbiology at Utah State University, and resident cheese expert, has this to say about cheese.

> "The dictionary definition of cheese falls well short of the marvelous food that so many of us enjoy. Cheese, to me, is virtually unique among foods because it is biologically alive and deliberately consumed in that state. Even day-old cheese contains tens of millions of live bacteria, and numbers stay high for months and even years as the cheese matures. Fortunately, these microbes are not fearful, disease-causing cells. They are industrial workhorses; steadily churning away inside the cheese matrix as they convert the bland curd into delicious mature cheese. This remarkably complex and dynamic process is scripted by the type and composition of the milk used in cheese making, the microbes and enzymes that become trapped in the curd, and the specific manufacturing and ripening regimens that are employed. Along the way, the microbes and enzymes break down the basic elements of milk, the carbohydrate, citrate, proteins, and lipids, in a manner that ultimately change a highly perishable food, milk, into a more stable and high-value distinctive cheese. Amazing."

As this statement indicates, cheese is a remarkably complex system wherein the dynamic processes continue long after the cheese is made. These ongoing metabolic processes are the result of the different components of the cheese breaking down over time. The type of

milk used and the processing steps employed during processing, along with storage conditions serve as a determining factor in the ripening (aging) of cheese. Of course not all cheeses are aged but the same idea applies to fresh cheese varieties that are ready for sale immediately after production.

Reg Scott in his book, *Cheesemaking Practice*, says, "A perusal of the literature concerning cheese reveals almost 2000 names applied to cheese, and periodically more names appear as new varieties are made" (Scott, 1998).

Altering the basic make procedure of a cheese recipe will result in a different cheese. For example, Cheddar, Monterey Jack, and Parmesan style cheese can all be made from the same formula. The difference in the finished products would be the result of modification of specific steps in the make procedure. Color would be added to the Cheddar and not to the Monterey or Parmesan. Cooking of the curd would be done at slightly different temperatures. After draining the whey, the Monterey curd would be washed to remove the lactose and to increase the moisture of the final cheese. Cheddar and Parmesan would not include a wash step. After draining the whey on the cheddar and Parmesan, the curd would be dry stirred for a time to remove additional moisture. In this case, the Parmesan would be dry stirred for 3 times longer than the cheddar. Aging, in the case of the cheddar and Parmesan style, would be accomplished at warmer temperatures (Monterey jack is not aged) and the lower moisture of the Parmesan would result in a different flavor and color of the cheese.

Code of Federal Regulations

In the United States, the Code of Federal Regulations (CFR) has specific requirements for final characteristics of cheese. These are referred to as Standards of Identity. When a cheese product has a Standard of Identity the products must conform to the standard in all respects. These specifications govern the production, distribution, labeling, and sale of cheeses in the United States. The Code of Federal Regulations is the promulgated law from the Food and Drug Administration (FDA) and the standards for cheese are found in the Code of Federal Regulations Title 21, section 133. This can be accessed on the Internet through the FDA web site. The following table (Table 1) shows the Federal Standards for Select Varieties of Cheese.

Standards of Identity are specified by definition by the following:

- The ingredients used (including the kind and quality of optional ingredients, such as color).
- The composition (the maximum moisture content and the minimum percentage of fat in the cheese solids or in the total mass of the cheese).
- The requirements concerning pasteurization of the milk or an alternate minimum ripening period.
- Production procedures.
- Any special requirements peculiar to a variety or class of cheese.

For cheeses not governed by a standard of identity, FDA has established standards for classes of cheese designated by consistency. (See Table 2.) Cheeses that do not meet a specific standard of identity cannot be sold as that variety and must be sold as a different, specialty cheese or not sold at all.

Table 1. Federal Standards for Select Varieties of Cheese

Select Varieties of Cheese			
Cheese	**Maximum Moisture (%)**	**Minimum Milkfat in Solids (%)**	**Minimum Milkfat in Cheese (%)**
Soft, unripeded			
Cottage	80	-----	4
Cream	55	-----	33
Neufchatel	65	-----	20-33
Soft, Ripened			
Brie	-----*	50	27.7 +1.8
Camembert	-----*	50	24.3 +0.6
Semi-soft, ripened			
Blue	46	50	27
Brick	44	50	28
Gorgonzola	42	50	29
Monterrey Jack	44	50	28
Muenster	46	50	27
Firm/hard, ripened			
Cheddar	39	50	30.5
Colby	40	50	30
Edam	45	40	22
Gouda	45	46	25.3
Gruyere	39	45	27.5
Swiss	41	43	25.4
Very hard/Grating, ripened			
Asiago (aged)	32	42	28.6
Parmesan	32	32	21.8
Romano	34	38	25.1
Pasta filata			
Mozzarella (semi-soft)			
whole milk	52-60	45	18
low-moisture, part skim	45-52	30-45	14
Provolone (hard)	45	45	24.8

**No specific federal standard other than class standard for soft ripened cheese requiring a minimum of 50% milk fat in the cheese solids. (See Table 2.)*
Source 21 CFR 133, 2011

Table 2. Federal Standards for Classes of Natural Cheese Designated by Consistency.

Designated by Consistency		
Consistency	**Maximum Moisture (%)**	**Minimum Milkfat in Cheese (%)**
Hard-grating	34	32
Hard	39	50
Semi-soft	50 (more than 39%)	50
Semi-soft, part skim	50	45 (less than 50%)
Soft	Not specified	50

Source 21 CFR 133, 2011.

So then, what is cheese? It is an amazing food that takes on the unique characteristics of the animal that supplied the milk, the people who made the cheese and the place in which it was produced.

HISTORY OF CHEESE

The merits of cheese depends on the places and the beasts…

-Bartolomeo Platina, 1475 A.D.

Accidentally Discovered

Cheese, from a grocery store today, has only existed for about 100 years. Cheese as a food, is nearly as old as civilization. Cheese making began shortly after the domestication of animals that can be milked (sheep, goats, cows, yaks, water buffalo, camels, etc.) In the early days of cheese making the process was a normal result of milk going bad. Cheese was most likely discovered accidentally by the combination of milk, lactic acid producing bacteria and the enzymes that coagulate milk. The first cheeses would have been salty and quite sour with little consistency from day-to-day and even less from month to month. Lacking ability to properly control temperature, milk quality, animal feed, and environmental conditions the early cheese maker would take what he could get. In addition to variations in taste and consistency early cheeses would have been susceptible to bacterial contamination and spoilage. Contamination from bacteria certainly caused many food borne illnesses and even death.

Early cheese making was an art where a certain individual understood what to do and only a few people could make good cheese. Without understanding of the precise mechanisms of change the cheese maker had to "feel" their way through the make process, and adjust accordingly. Some cheese makers today, suggest that early cheese making was ten percent science and ninety percent art, whereas today it is ninety percent science and ten percent art. The art of cheese making is having enough understanding of the process that you can apply the science.

Evolved Based on Location

Evidence suggests (History, 2011) that the science of cheese making took a great leap forward due in part to the record keeping of the European monks that made cheese for the monasteries. Their care and attention to detail resulted in advances in the understanding of why specific things happened during cheese making. Knowing the cause and effects of the process allowed the monks control over some aspects of the process. These controls provided more consistency from month-to-month and possibly day-to-day. Around the turn of the Twentieth Century advances in technology made cheese making a more fully controlled process with product consistency, from vat-to-vat, being a key outcome.

Of cheese, Harvey Day said, "People who know nothing about cheeses reel away from Camembert, Roquefort, and Stilton because the plebian proboscis is not equipped to differentiate the sordid from the sublime." Truly the range of flavors offered by the nearly limitless varieties of cheese results in varied reactions to the taste of a cheese, be it liked or hated.

As the following quotes suggest, cheese can take on the role of both revered and rebuked.

"Cheese has always been a food that both sophisticated and simple humans love."
- M.F.K. Fisher

"Many's a long night I've dreamed of cheese - - toasted, mostly."
- Robert Louis Stevenson

"Cheese is the biscuit of drunkards."
- Grimod de La Reyniere

"How can you be expected to govern a country that has 246 kinds of cheese?"
- Charles de Gaulle

As these quotes indicate there are strong views concerning cheese. Some contend that it is strictly a lower class food while others say that it is the food of the wealthy.

A worldview of cheese reveals that not all world populations embrace cheese the way Europe, the Middle East, and the Americas do. The knowledge and acceptance of cheese followed the spread of European culture and until modern times was nearly unheard of in Oriental cultures and in most places outside Europe (History, 2011). Up until the 19th century, all cheese production was by the traditional method, single batches of cheese made on the farm or in the home, for local distribution only.

Modern Cheese

Factory style cheese was first introduced in Switzerland in 1815 (History, 2011). Jesse Williams is credited as the founder of industrial cheese manufacturing when in 1851 he began using milk from local farms to produce assembly line style manufacturing in Rome, New York (Rome, 2011), (History, 2011). Commercial cheese production was limited until after World War II, when the United States and Europe began producing more commercial cheese than traditional cheese, which has continued ever since (History, 2011). The late 20th Century saw processed cheese varieties being consumed more than traditional cheese varieties.

Back to Artisan Cheese

Today, the pendulum has started swinging back toward artisan style cheese making. Over the last 15-20 years hundreds of traditional style cheese operations have opened throughout the United States. People who produce traditional style cheeses are called Artisan (any traditional style cheese making) or Farmstead (milking and cheese making on the same land).

Consumers are willing to pay additional cost for cheese that is made by an individual rather than a large manufacturing facility. It is important to remember that artisan cheese makers

represent a very small amount of the total volume of cheese produced in the United States. Regardless of the limited amount of artisan cheese being produced, the sheer number of people making artisan cheese has caught the attention of regulatory officials.

The increased interest in artisan cheese making has creating its own set of struggles for both artisanal cheese maker and the consumer. The cheese makers want the old style feel to their cheese: all natural, full flavor, simple packaging. And the consumer wants the guarantee of high quality, consistent taste, function, and the benefits of food safety. Done properly, the desires of the producer and the consumer can be satisfied. The key is to focus on food safety at every step of the cheese manufacturing process.

REGULATORY REQUIREMENTS

History of Food Regulation in the United States

After becoming a country in 1776, the people of the United States were mostly governed by state laws. Each state enacted laws that allow the citizen of that state, rights and powers that were controlled on a state level. Very few laws were enacted on a federal level and this is particularly true for laws related to the regulation of food. This was due in part to the way the government was organized (state based regulation), and to the way food processing was carried out.

Early to Mid 1800s

In the late seventeen and early eighteen hundreds nearly all food manufactures made products that were intended to be sold locally. Lack of refrigeration, transportation, and storage facilities made it nearly impossible to ship perishable products over long distances. Additionally, the country was agricultural based where most people grew food for their own use or purchased it locally. As advances in production, distribution and storage became more common place food began crossing state lines and beyond. As distribution of foods expanded so did the number of questionable food manufacturers. Fraud, poisoning, and "fake" food and medicines became more common and the government sought ways to stop this type of activity. Without laws to govern the sale and distribution of food, manufactures did as they dared. In 1862, Abraham Lincoln signed into law the creation of the United States Department of Agriculture (USDA). At that time The Bureau of Chemistry was part of the USDA.

Mid to Late 1800s

In 1883, Dr. Harvey Wiley became the chief chemist of the Bureau of Chemistry. He is considered the leader of the "Pure Food Crusade". Major advancements in the understanding of food additives were achieved under his leadership due in part to the formation of "The Poison Squad". This group of chemists and able-bodied volunteers studied the effects of questionable food additives by the volunteers consuming the various substances while the scientist observed the effects.

Early 1900s

Dr. Wiley's passion for and work in this field lead to the signing of the first Federal Law governing the manufacture, sale, and distribution of foods and drugs which was enacted by congress in 1906 and was called the Pure Food and Drug Act. The main points to the Pure Food and Drug Act were to prohibit the interstate (across state lines) commerce in misbranded and adulterated foods, drinks and drugs. The mission of the law was to control poisoning and fraud. The Pure Food and Drug Act of 1906 remained in effect until 1938.

In 1933, the Food and Drug Administration (FDA) recommended that the act be modified because several loopholes existed in the law. The loopholes had to do with the identity and quality standards of food and the place in which food was manufactured. The original Pure Food & Drug Act did not specify the expectations of the building in which product might be produced only the cleanliness of the product. When the new law passed in 1938 it was called the Federal Food, Drug and Cosmetic Act (FDCA). One key elements of the FDCA was the establishment of identity and quality standards for food and attempted to fill the loopholes in the 1906 law. The wording of the portion of the 1938 law that specifically address the loopholes are:

- Section 402(a)(3) of the act specifies that "food has been manufactured under such conditions that it is *unfit* for human consumption."

- Section 402(a)(4) Considers that food *may be* adulterated if it is prepared, packaged, or held under insanitary conditions whereby if *may have* become contaminated with filth or rendered injurious to health.

These elements of the 1938 FDCA significantly changed the face of food processing. Instead of the regulatory agencies looking at the finished product quality alone, they were now allowed to look at the specific product quality and identity standards. In addition, plant operating, cleanliness and location could be considered in the over all evaluation of the plant. The impact of these changes to the food laws was dramatic. Not only were companies expected to produce high quality, legal product; they were to conduct the operations of the plant according to established quality principles and ensure that the "may be" clause left no room for questioning the product integrity. The move from only finished product examination to both product and processing facility opened the door to different interpretation of the law. A plant producing high quality product, but less than substantial facilities could be under FDA action because of the potential of contamination rather than the result of contamination. The impact of these changes has been positive.

Late 1900s

The next change in the FDCA came in the 1960s when the FDA decided to clarify the FDCA through good manufacturing practice (GMP) regulations. It took a few years to hammer out and establish GMP and they were proposed in 1968 and finalized in 1969. Shortly after the implementation of good manufacturing practices the FDA considered moving to industry-specific GMP expectations. This idea was short-lived and in the late 1970s the FDA decided to revise the general GMP guidelines rather than adopting industry specific GMPs. Again, this

revision took some time and it wasn't until 1986 that the FDA published revised food Good manufacturing practices.

Things remained unchanged until 2002 when the FDA formed a Food GMP modernization-working group. This group was to up-date GMPs to meet the ever-changing landscape of food manufacturing in the United States. Much discussion and investigation was conducted and several groups felt that industry-specific regulations of good manufacturing practices were still a preferred way to go. In 2004 the FDA announced that the efforts to modernize the standards were continuing but no large-scale changes were made during the first decade of the 21st century. It wasn't until 2011 that changes to the law were finalized which culminated with the signing of the Food Safety Modernization Act in 2011.

Present and Future

In January of 2011 President Obama signed into law the Food Safety Modernization Act (FSMA), which is the most expansive changes to US food laws since 1938. The FSMA gave expanded power to food law enforcement authorities, enacted new food import requirements, provided major new program activities for the FDA and increased inspection authority.

The FSMA covers all foods produced for human consumption except meat poultry and some egg products, which are governed by the USDA. New powers to recall tainted foods, increase inspections, demand accountability from food companies and oversee farming operations. Additionally this law grants greater authority to initiate recalls, rather than wait for court actions or voluntary recall by the company. The FSMA requires most food producers to develop hazard prevention plans and environmental monitoring programs, and gives FDA access to those records when requested. The legislation calls for FDA to increase inspections of foreign

food facilities and the riskiest domestic facilities, which would be inspected within 5 years of enactment and every 3 years thereafter.

GOOD MANUFACTURING PRACTICES

Introduction

In April 2012 my wife was cooking breakfast for the family and poured the remainder of a box of Cream of Wheat cereal into a measuring cup. She than prepared the water and the salt, got the water boiling and as she was starting to pour the cereal into the boiling water she noticed something in the measuring cup and when she pulled it out it was a piece of wood. The wood was obviously from a pallet. It was about an inch and a quarter long, by 3/8 inch wide and about 1/8 inch thick. Upon closer examination we found that that piece of wood had got stabbed in to the end of the carton and went through the carton and into the cereal.

So how does a piece of wood get from where the pallet is on the floor, up high enough that it is in the proper position to have its point go into the box and then into the product? Believe it or not, these things happen often. So what does it mean when we say principles of making safe wholesome cheese? What that really means is that everybody who works in the food facility has a responsibility towards quality and safety of the food. Here used, the word responsible is best thought of as “able to respond” rather than responsible for. In other words, your organization must give everyone working in the food manufacturing process the power to act in the best interest of the customer. We have to be very diligent and make sure that what we do doesn’t take anything away from the product that were making.

Current Good Manufacturing Practices

One of the primary drivers of how we conduct ourselves in the food industry is the U.S. Code of Federal Regulations (CFR). Part of the CFR is dedicated specifically to Good Manufacturing Practices (GMP). GMP's are the basis of what we trust all food manufacturers are doing. Just as we assume others are looking out for our safety, our customers will be expecting that we do the same. With that in mind we are ready to discuss, in some detail, the expectations of the GMP's.

Personnel. You and the people who are going to assist you in making cheese will be in essence the management of the plant. As a manager of a food manufacturing facility it is important that you understand your role. One of the primary responsibilities of management is to ensure the safety of the personnel who work for you and the people who eat your products. To that end this section covers the expectations of the people who are, or will become food handlers in your operation.

We are exposed to disease multiple times a day. Touching objects, tending children, working, playing and living life puts us in direct contact with diseases. As food manufacturers we must do all we can to prevent the intentional or accidental contamination of our food from people and the diseases they might carry. The following guidelines will direct you in maintaining appropriate controls in your facility.

- Watch for signs of illness, sickness or possible exposure in the people who work at your facility.
- Illness, sickness or other issues can be detected by examination, appearance or observation.

- Any person who is observed to have an illness, open wound, boil, sore, infected lesion, or other abnormal microbial contamination should NOT be in direct contact with food, food contact surfaces, or food-packaging material.
- It is necessary to exclude these individuals from the operation until their conditions are corrected.
- Instruct your personnel of the importance of this measure and train them to report such conditions to you immediately.

Cleanliness of the individual and the storage of personal belongings also need to be considered. It is necessary that personal items be stored outside of the production/processing area. Storage lockers or other acceptable means of excluding such items from the product area are to be use and monitored by management. Keep the following ideas in mind.

- Outer garments of personnel should be suitable for the operation.
- Maintenance of personal hygiene and adequate personal cleanliness.
- Hand washing – before beginning work, after breaks and lunches, after any absence from the workstation and any time hands may have become contaminated.
- Removal of all unsecured jewelry.
- Maintaining gloves – gloves should be of impermeable material, clean and intact. Gloves should be replaced often and as needed.
- Hairnets, beard covers, caps or other restraints.
- The use of gum, food, drinks; tobacco (smoking or chewing) is not permitted in the work area.
- Take necessary precautions to ensure that perfume, cosmetics, medicines, and any other items associated with personnel are kept out of the product.

Training in these practices are the responsibility of management and should be taught to all employees on a regular basis. Management should be completely versed in, and understand the importance of these measures and are responsible to see that they are carried out by all persons in the plant.

***Building and Grounds*.** The place in which you intend to make your cheese will have a significant impact on the safety of the cheese you make. There are specific expectations for the walls, floors, ceiling, drains, toilet facilities, storage areas and office space. These expectations are based on sound quality principles that have been tried and tested over the years. These guidelines apply to all grounds (buildings, storage facilities and trucks) associated with the plant and shall be maintained in a condition that will protect the food from contamination. The following guidelines apply.

- Proper storage of equipment that is being used or maybe used in the future.
- Removal of litter and waste on a regular basis, which includes the keeping of waste receptacles clean and stored in a way that protects from contamination of the product by waste.
- Cutting of weeds, grass, shrubs and trees to eliminate areas where breeding or harborage of pests may occur.
- Adequate draining of water from all areas that may contribute to contamination by seepage, foot-borne filth, or provide a breeding place for pests.
- Operating an adequate waste treatment and disposal system (i.e. whey or other by products) so that it is not a source of contamination.
- Adjacent property/grounds that are not under the operator control shall be monitored and appropriate action taken to ensure that no contamination issues arise.

The building and grounds should be of sufficient size and suitable construction and designed to facilitate maintenance and sanitary operations for food manufacturing purposes. Use the following guidelines in order to ensure protection against contamination.

- Provide sufficient space for equipment operation and storage.
- Provide sufficient separation of various plant operations by use of location, time, partition, airflow or enclosed systems.
- Constructed in a manner that the floors, walls and ceilings may be kept clean and in good repair.
- Condensate from fixtures, ducts and pipes does not contaminate the food.
- Provide adequate space between equipment so that employees can perform their duties.
- Adequate lighting in hand-washing, dressing, locker room, toilet rooms and processing areas.
- Light bulbs should be safety type (coated or shielded) to ensure that breakage will not result in contamination of the product, product contact surfaces or packaging material.
- Adequate ventilation and operation of fans so that they minimize the potential for contamination.
- Doors, windows, openings must provide adequate self-closure and screening or other protection against pests.

These items may seem “over-the-top” but they are necessary to ensure that the construction, operation, and day-to-day activities are in harmony with sound food safety protection.

Sanitary Operations

General Maintenance – the building, fixtures and other physical facilities of the plant shall be maintained in a sanitary condition sufficient to prevent adulteration of food, food contact surfaces and materials.

Chemicals including grease, oil, fuel, processing chemicals and cleaning compounds and sanitizing agents should all be used in accordance with label directions. Additionally, cleaning compounds and sanitizing agents used in cleaning of utensils and equipment shall be conducted in a manner that protects against contamination/adulteration. Only chemicals that are expressly used for the following can be stored in a food processing plant.

- Required to maintain clean and sanitary conditions
- Necessary for use in laboratory testing
- Those necessary for plant and equipment maintenance and operation
- Those necessary for use in the plants operation

Cleaning chemicals are specifically allowed for the use of cleaning. Once clean the equipment and plant are to be allowed to drain freely of all cleaning & sanitizing chemicals such that they will not contaminate the food. Storage and handling of cleaning & sanitizing chemicals should also be conducted so as to minimize the potential of accidental or intentional introduction into the food. Use the following guidelines to ensure that cleaning and sanitizing chemicals do not contaminate food, food contact surfaces or packaging material.

- In their concentrated form, cleaning and sanitizing chemicals are toxic, corrosive and may cause harm to individuals.
- Their storage, dispensing and use should be monitored and controlled.

Pest control is another area of general maintenance that needs to be address on a continual basis. According to the regulations, no pest shall be allowed in any area of the food plant. Guard or guide dogs are the only exception. The use of insecticides or rodenticides is permitted only under precautions and restrictions. Only a licensed applicator can dispense pest control chemicals. The use of bait stations on the outside of the building must be done according to regulation and in compliance with GMPs. Flytraps, electrocution traps and mousetraps can only be used in the plant under proper regulatory guidelines. Screens on doors, windows and other openings must be completely sealed and may not lead directly into processing areas. It is best to have outside contractors with insurance coverage handle pest control duties in a food processing facility.

Sanitation of Food-contact surfaces must be accomplished according to all stated GMPs. All food contact surfaces, including utensils and food contact surfaces of equipment shall be cleaned as frequently as necessary to protect against contamination of food. Dry areas of the plant must kept dry and in a sanitary condition at all times. Wet processing areas are to be cleaned and sanitized as necessary to provide sanitary conditions at all times. Non-food contact surfaces should be cleaned as frequently as necessary to protect against contamination of food. Single serve articles (paper cups, towels, plastic utensils, etc.) should be stored, handled, dispensed, used and disposed of in a manner that protects against contamination. Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that “it” will routinely render the equipment or utensil properly cleaned and sanitized. Portable equipment that is used in a food processing facility should be handled and stored such that it protects food contact surfaces from contamination.

Sanitary facilities such as water, sewer and toilet rooms shall be properly equipped and accommodate necessary use. Water supply that is sufficient for the operation shall be derived from adequate source(s) and must be safe and of adequate sanitary quality. Running water shall be provided in all areas where necessary for cleaning of equipment or utensils and for use in employee sanitary facilities.

- Plumbing shall be of adequate size and design, and properly installed and maintained to carry sufficient quantities of water to required locations throughout the plant
- Properly convey sewage and liquid disposable waste from the plant
- Avoid constituting a source of contamination or unsanitary condition
- Provide adequate floor drainage in all areas of the plant
- Provide that there is NOT backflow from or cross connections between discharge waste water or sewage, and potable water supplies

Sewage disposal shall be made into an adequate sewage system or disposed of through other adequate means. Toilet Facilities shall be provided for all plant employees, which will be adequate and readily accessible. This may be accomplished by:

- Maintaining the facilities in a sanitary condition
- Keeping the facilities in good repair at all times
- Providing self-closing doors
- Providing doors that do not open into processing areas. Use of double doors or positive air-flow systems is acceptable

Hand-washing Facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. This may be accomplished by:

- Hand-washing & sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and sanitize their hands
- Effective hand-washing and sanitizing preparations
- Sanitary towel service
- Foot or motion sensing, water activation devices to protect against recontamination of clean & sanitized hands
- Readily understandable signs directing employees to wash and sanitize their hands before starting work, when hands have or may have become contaminated, after using toilet facilities or as directed by procedure or policy
- Refuse receptacles that are constructed and maintained in a sanitary manner
- Rubbish and offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, pest attractant, harborage or breeding area, and to protect against contamination

Equipment & Utensils – All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. Equipment should be installed and maintained as to facilitate cleaning of the equipment and all adjacent spaces. All food –contact surfaces shall be corrosive-resistant, non-toxic, able to withstand environmental conditions of use, & protect food from be contaminated by any source. Seams on food-contacts surfaces shall be smoothly bonded and maintained to minimize accumulation of food particles. Non-food contact equipment shall be constructed to be cleanable

and properly maintained. Holding, conveying and manufacturing systems shall be designed and constructed and be maintained in an appropriate sanitary condition.

Each freezer or cold storage compartment used for storage of food capable of supporting growth of microorganisms shall be fitted with a indicating thermometer, temperature-measuring device. Instruments & controls used for measuring, regulating, or recording conditions that control or prevent the growth of undesirable microorganisms (pH, Temperature, Acidity) shall be accurate, maintained and in adequate number for their use.

Compressed air or other gases mechanically introduced into the food or used to clean food-contact surfaces or equipment shall be treated in such a way as to not contaminate food.

Processes and Controls – All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food SHALL:

- Be conducted in accordance with adequate sanitation principles.
- Employ appropriate quality control operations to ensure food is suitable for human consumption.
- Sanitation for the plant under the supervision of one or more competent individuals
- Precautions taken to ensure that production procedures do not contribute to contamination from any source.
- Chemical, microbial, or extraneous material testing employed where necessary.
- Rework material must be safe and handled appropriately.

Raw Materials & Other Ingredients – Incoming raw materials, and other ingredients are to be inspected and segregated then stored as appropriate to prevent contamination or deterioration. Raw materials shall be washed or cleaned as necessary. Water used for washing and cleaning shall be safe and of sanitary quality. Wash and rinse water may be reused if it does not increase

the level of contamination in the food. Containers & carriers of raw materials should be inspected to ensure they did not contribute to the contamination or deterioration of the food. Raw Materials and other ingredients shall either NOT contain microorganisms that produce food poisoning or shall be pasteurized or otherwise treated during manufacturing. Raw materials or other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current FDA regulations prior to being added to any food. Raw materials, other ingredients or rework susceptible to contamination with pests, microorganisms or extraneous material shall comply with FDA regulation. Raw materials, other ingredients or rework shall be held in appropriate containers, which protect against contamination. All rework shall be identified as such. Frozen raw material and other ingredients shall be kept frozen. Thawing of frozen material shall be accomplished without risk of becoming adulterated. Raw materials or other ingredients that are received or stored in bulk form shall be held in a manner that protects against contamination.

Manufacturing Operations – Equipment, utensils and finished food containers shall be cleaned and sanitized as necessary. Equipment shall be dismantled for cleaning. All food manufacturing, including packaging and storage shall be conducted so that microbial contamination is controlled. Monitoring of physical factors (time, temp. pH, humidity, pressure, flow rate) is a primary means to achieve control. Foods that support the rapid growth of microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated. Compliance to this requirement can be accomplished by:

- Maintaining refrigerated foods at or below 45 F, (7.2 C).
- Maintaining frozen foods in a frozen state.

- Maintaining hot foods at or above 140 F, (60 C).
- Heat treating, acid or acidified foods that are to be held at room temperature.

Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling water activity, which prevents or controls microorganisms, shall be adequate, and particular to the food. Work-in-process shall be handled in a manner that protects against contamination.

Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. Equipment, containers, and utensils used to convey, hold or store raw materials, work-in-process, rework, or food shall be constructed, handled and maintained in a manner that protects against contamination. The use of a suitable method of protecting against extraneous materials in the food shall be employed. Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination.

Compliance methods include:

- Use of HACCP.
- Sanitation Program.
- Using safe and suitable containers and packaging materials.
- Providing physical protection against contamination (airborne).
- Using sanitary handling procedures.

Dry or dehydrated foods that depend on aw to protect against undesirable microorganisms shall be processed at a safe moisture level. This can be controlled by:

- Monitoring the water activity of food
- Controlling the soluble solids-water ratio in finished food.

- Protecting finished food from moisture pick-up, by use of a moisture barrier or by other means

Foods that rely on pH to control the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance methods include:

- Monitoring the pH of raw materials, food in process, and finished food.
- Controlling the amount of acid or acidified food added to low-acid food.

When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality and shall be used only if it has been manufactured in accordance with current good manufacturing practices. Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

Warehousing and Distribution **–** Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of food and the container.

Raw Material Quality

Everything starts with high quality raw materials. There is an old saying, "garbage in, garbage out!" That is certainly true for dairy products. Keep in mind that everything you do to the milk after it leaves the animal will be your responsibility to control. If you are the one milking the animals there are additional responsibilities. Processors of milk products should know their supplier by visiting the farm to make sure that your supplier is keeping your best interest in mind.

Protection of raw materials involves the proper inspection, storage and use. All incoming raw materials should be inspected at the time of receipt to ensure that they are…

1. The correct item
2. Properly contained, labeled and no observable damage
3. Matches quantity and quality of items ordered
4. Can be used for intended purpose
5. Rotated so that the first materials in are the first to be used.

Fluid products such as milk, cream, rennet, calcium chloride or other processing aids should be refrigerated. Refrigeration aids in shelf life of liquids. Temperature should be between, 38-44 degree-F. Other items such as powders, solids or semi-solid substances may also be kept at refrigeration temperatures. Always read and follow the manufacturers recommended storage methods and temperature range.

Keep powders and dry ingredients dry. Moisture can create clumping, or complete solidification thus rendering the powdered products unusable. Dry products rely on the low moisture to keep bacteria from growing. Added moisture to dry ingredients could allow bacteria the opportunity to grow. Keep them cool and stored so that cross-contamination doesn't occur

from other ingredients or to other ingredients. Broken or damaged bags, boxes or containers should be quickly repaired, replaced or discarded.

As a measure of food safety, access to raw materials should be limited to those individuals necessary to carry out proper processing. Be aware of tampering, movements of items that are out of the ordinary or activities in the storage areas that are unexpected or questionable.

Sanitary Design

In order to talk about sanitary design we first need to understand the differences between a food contact surface and a nonfood contact surface. A food contact surface by definition are those surfaces that contact human food and those surfaces from which drainage onto the food or on to surfaces that contact the food ordinarily occurs during the normal course of operation. This includes utensils and food contact surfaces of equipment. Nonfood contact surfaces are everything else.

A restaurant is a good example of the difference between food contact surfaces and non-food contact surfaces. As you picture a restaurant you can image all the things that the food comes in contact with; plates, silver ware, cooking pots, serving spoons, cups, pitchers, etc. You can also picture those things that you never want the food to come in contact with; table, floor, walls, equipment, the waiter's hands, dust, insects, trash, etc. You get the idea. Food contact surfaces are strictly those items that are okay touching the food while everything else is non-food contact. Think for a moment about the difference between wooden kitchen utensils of the old world versus modern kitchen utensils. The wood cracks, chips and absorbs material from the environment. This makes it difficult, if not impossible to clean. Smooth, intact surfaces on modern kitchen utensils make them easy to clean, and they don't absorb material. Cracks and crevices in the wood hold food, oils and other materials where as modern dishes and utensils resist this kind of contamination. Sanitary design is the idea that everything having to do with the construction, equipment, and processing of food products is done in a way that makes it easy to clean and resistant to contamination. There are three primary areas of sanitary design, which include, Construction of the facility, design of the equipment and flow of product through the processing facility.

Principles of Sanitary Design – Construction

- Walls, and ceilings of sound material
- Floor that as sloped properly for drainage
- Drains large enough to remove all water
- Toilet facilities properly constructed
- Windows not allowed to open to the outside environment
- Self closing doors
- Office and storage areas are isolated from processing

Principles of Sanitary Design – Equipment

- Microbiologically cleanable
- Made of compatible materials
- Accessible for inspection, maintenance, cleaning/sanitation
- No liquid collection points
- Hollow areas hermetically sealed
- No niches
- Sanitary operational performance
- Hygienic design of maintenance enclosures
- Hygienically compatible with other systems
- Valid cleaning and sanitation protocols

Principles of Sanitary Design – Processing

- Distinct hygienic zones established in the facility
- Personnel and material flows controlled to reduce hazards
- Water accumulation controlled inside facility

- Room air flow and room air quality controlled
- Site elements facilitate sanitary conditions
- Building envelope facilitates sanitary conditions
- Interior spatial design promotes sanitation
- Building components and construction facilitate sanitation
- Utility systems designed to prevent contamination
- Sanitation integrated into facility design

The other part of construction design is how the plant is laid out. Product should flow from one end to the other and a physical separation is needed between production, packaging, and maintenance areas. Air handling systems need to have filtered air so that they don't draw contaminated air in from the outside but push air to the outside. During construction the equipment placement is important there needs to be ample space around the equipment which would allow facilitation of safety, performing work, cleaning, inspecting, doing maintenance, and to expand your operation when you add new equipment. There should be 36 inches directly around any piece of equipment and 60 inches minimum between two pieces of equipment. This is important for employees' morale, effectiveness and attitudes. The employer has the same benefit of those three and government agencies such as OSHA, the FDA, the USDA, and the Department of Health are interested in plant lay out as well.

Lighting and ventilation are important and there must be adequate lighting in all rooms as well as in all areas of the room. It needs to be well ventilated to preclude odors and condensation from forming. Walls and ceilings need to be cleanable, non-porous, and have limited number of penetrations and any penetration must be caulked closed. The floors and the drains should not

have any cracks or gaps and they should be anti-slip to prevent anyone from falling. They should be in good repair and have proper drainage with trapped drains.

Sanitary design, Construction. Toilet facilities must comply with local ordinances. They can have no direct opening into a processing area. They should have self-closing doors, cleaned, well lighted and ventilated. Doors and windows throughout the plant should meet the following expectations: all outer openings effectively protective against entry of flies and rodents. Outer doors are self-closing. Screens open outward to ensure that any fly that might be trapped on the screen would move out when the door is opened rather than letting them in when the door is opened. Waste containers need to be of adequate size, emptied on a daily or regular basis, and use proper liners. Top disposable garbage containers need to have a self-closing lid or maybe even a foot-activated lid.

Other construction expectations include super structures such as: I beams, support columns, trusses, wall supports, angle iron, and T beams etc. Any of those that are metal need to be completely welded, there can be no openings where product can be trapped, no exposed threads, no pooling of water, no ledges that can become a shelf for debris or tools or other items that someone might set on them. The seams between joints need to be sealed. When angle iron is used for super structure it should be placed so there is no ledge on which for the product, water or dust can remain. If channel iron is used it has to be placed so that it is on an angle where the channel is down rather than up. I beams should be set so they read like an I from the end rather than like an H so that there is no harborage. T beams should be with the T on the top not on the bottom. Any open or hollow tubing needs to be completely sealed with welds. Once a penetration is made it should be resealed so that it does not get any harborage inside and

contaminations coming out. Channel iron is especially important to watch and needs to have covers put on it so that it does not contribute to the contamination of the food product.

Any material used in the manufacturing equipment or utensils needs to be 316 stainless or higher grade, it needs to have a smooth finish, it needs to be cleanable, which means it has to have adequate access so there is no harborage or recess areas in the design of the equipment. Complete drainage so that there is no free standing water and the proper use of standoffs. A standoff is used to hold wires, hosing, tubing and pipes away from the flat surface so that it can be cleaned behind it and everything would be free draining. Corners need to have the proper radii so that there is no chance that you have a square corner that would harbor product. For metal-to-metal joints, there should be no flat surfaced joints, no exposed threads, and full welding with no stich welding.

Hygienic Zones

As we talk about items that need to be done in a food plant to make food safe it is sometimes good to use analogies that make sense to everyone. When we talk about the different zones that we establish within our plant such as a raw area, a pasteurized area, a finished product area those things are easily thought of as boundaries or barriers. If we establish a barrier between rooms such as a wall, a partition, maybe a boundary or partition between a vat and the outside of the vat such as a lid or those kinds of things. Those barriers or boundaries stop us from going were we should not go. Barriers or boundaries can be established as either procedural of physical. A procedural boundary is an activity, a policy, or something that everyone is trained to do that protects the food by not allowing us to cross a boundary when the procedure is followed. To put that in perspective it's similar to a procedure or policy that says you should not text while driving. Texting while driving has been shown to increase the risk of an accident so not texting while driving is a boundary that prevents this from happening. Similarly we establish policies and procedures within a plant that control the activities of people, which keep food safe. A physical barrier is a wall, a floor, a ceiling, a lid, a roped off section, whatever it is that physical stops people from doing certain activities. In the automobile example this would be the wearing of a seat belt. A seat belt is a physical boundary that stops you from moving forward quickly when a car is in an accident thus, resulting in less damage to the driver or passengers in the car. When we establish physical boundaries in our plant we set up a way that people and people's activities do not interfere with the quality of the product.

In cooperation with boundaries are zones that we establish in the plant. There are four zones in any food processing facility: zone one, zone two, zone three, and zone four. Zone one is anything that the product touches or any surface that can be drawn, dripped, drained, or fall into

the product. So anything and everything that the product touches in its clean state and anything that would fall into or on the product or on the surface that the product touches would be considered zone one. Zone two is anything close to but outside of zone one. Let's say we have cheese in a vat the inside of the vat is zone one, the outside of the vat is zone two. The inside of the lid for a vat is zone one, the outside of the lid is zone two. Anything that contains product but also has an external surface to it would be considered zone two on the outside. Zone three is the super-structure; the legs, the stand, the support structure of the equipment, and generally it is thought of as being three feet and up. It's the walls and the ceilings and the clamping, the beams that hold the building up. It's the stuff that is external to the equipment or external in the building. Zone four is the floor, anything that can crawl, run, walk, slide, drip; anything that associated with the floor would be zone four.

FOOD DEFENSE

After September 11, 2001 there was a consolidation of many of the Federal Government programs and agencies, particularly those involved in safety. The newly created Department of Homeland Security (DHS) along with the Department of Health and Human Services was responsible for keeping the people of the United States safe from all threats. One effect this consolidation had was that the safety of large quantities of food was looked at as a possible target by terrorist. Food Defense protocols became law in 2003 as the Food and Drug Administration (FDA) handed down rules and regulation regarding food defense. Food Defense was based on the idea that persons involved in the manufacture, storage and distribution of food could be used as a means of terrorist activity. Food defense is used to minimize the possibility of this happening in food, drugs, and other facilities were large numbers of people could be effected. There are four main security measures employed in food defense, namely, outside, inside, personnel, and incident response. All measures associated with food defense are aimed at ensuring that facilities, grounds and systems are protected from intentional contamination, the key word being intentional.

Outside Security Measures are associated with the physical security, shipping/receiving security and mail handling security. Concerning physical security it is expected that the plant boundaries will be clearly defined and secured to prevent unauthorized entry. All entrances, such as windows, doors and access points are secured. The perimeter of the plant and property is inspected periodically for suspicious activity. Outside lighting needs to be present to deter unauthorized activity. Any outside storage buildings need to be secure and monitored as necessary to prevent unauthorized access or activity. Shipping and receiving areas are to be

secured and inspected periodically for any unauthorized activity. Incoming shipments are inspected for tampering and incoming and outgoing vehicles are inspected for suspicious activity. Loading and unloading activities are scheduled and monitored. Loading docks are locked or secured to prevent unauthorized access. Incoming and outgoing shipments are to be secured with locks or seals to prevent tampering. Mail is to be handled (sorted/opened) away from any food ingredient or packaging material. Personnel handling the mail are to be aware of proper handling of suspicious mail and U.S. Postal Service guidelines.

Inside Security Measures include those activities that take place in the plant and involve the observation and monitoring of ingredients and activities. In general terms, all personnel involved in the manufacturing of food products must be aware of their surroundings and report any suspicious activity to appropriate personnel. Measures to ensure compliance include the installation of barriers that restrict access, emergency lighting to ensure safety of personnel during emergencies, and an emergency alert system that is in place, tested and reviewed with emergency contact information. Unexpected changes in inventory should also be reported. Specific guidelines are in place for animal harvesting facilities. Storage of ingredients is a critical area of food defense. Access to storage areas are to be restricted to needed personnel only. Stock should be rotated, first in – first out. Labels and packaging materials are controlled to prevent theft and misuse. Periodic examination of storage areas and the materials stored there is conducted to ensure compliance. Ingredients and water/ice supplies must be protected from intentional contamination by securing storage areas, restricting access, periodic inspection, and working with ingredient suppliers to ensure proper measures at their site. Chemicals, hazardous materials and cleaning and sanitizing chemicals are to be secured in a locked storage area. Keep up to date inventories of chemicals, along with investigation of missing or suspicious activity.

Personnel Security Measures include those steps of identification of employees, contractors and visitors. Rules governing the movement, activities and access by personnel are clearly defined and understood by all personnel. Those individuals that are not employed at the facility are to be escorted at all times, identified in some way as visitors and are trained to understand these expectations. All persons visiting the plant should sign a log showing the date, time and reason for their visit. All employees shall be trained to understand food defense measures, which include their own duties, suspicious activities and unusual observations.

Incident Response Security Measures include those activities associated with the detection or suspicion of adulterated or potentially harmful products or activities. These activities include but are not limited to; customer complaint information, reporting unusual activities correctly, responding to phone, verbal or electronic threats, and the reporting of security breaches. Plant personnel's contact information is on file and up to date. Product that is to be withdrawn from the market or recalled must be done according to written plans and in compliance to good manufacturing practices. Only necessary key personnel with proper training will be allowed to carry out recall/withdrawal procedures.

In summary, food defense is designed as a proactive approach to food safety concerning the intentional contamination of food. It covers all areas of the food processing facility, warehouse, distribution and packaging and is based on heightened awareness after September 11, 2001.

SANITATION

What is sanitation? The word sanitation comes from the word sanitary and is a condition relating to public health and hygiene. All floors, walls, ceilings, ledges, cracks, gaps, product, raw materials, packaging materials, air handling systems and people should not contribute to contamination of product. All of these come together as a fairly complex area of food safety we call sanitation. Sanitation involves every aspect of the food processing facility. It is not just the cleaning of equipment, but also the placement of equipment, the organization of the facility and the way in which people, product and processes work together.

Master Sanitation Cleaning Schedule

One of the main principles to sanitation is, knowing what to clean and when to clean it. This is sometimes called a master cleaning schedule or a master sanitation-cleaning schedule, it provides a system that is organized and standardized; yet it is adaptable to various operations and circumstances. It maintains consistency in cleaning frequency and the results and it covers all area of the plant including: production, processing, packaging, offices, break rooms, warehouses, and the grounds outside. The master sanitation-cleaning schedule addresses the following questions. What needs to be cleaned? How often should it be cleaned? Who, by position is responsible for cleaning it? What training is needed to perform the cleaning? What cleaning supplies are needed? How will cleaning be verified? And by whom? How will cleaning and verification be documented? There are three different kinds of cleaning that we do in the dairy plant, specifically in the cheese operation. We do daily cleaning, which are those tasks that are primarily designed to maintain operational cleanliness that is the floors, the garbage, the walkways, the footpaths, all of the items we clean every day. Then there is periodic cleaning

which includes those tasks which are not performed on a daily basis but rather on a as needed basis or a scheduled period such as, tanks, silos, holding equipment, packaging equipment, vats, bathrooms, pasteurizers, anything that we do on a normal routine. The third is maintenance cleaning which involves those tasks which are associated with the cleaning of physical facilities and services like electrical panels, grease, oil, lubrications, tools, the maintenance shop, the forklifts, or hand trucks, or any other thing we might use.

Color Coding Systems

Important in the master sanitation cleaning schedule is the inclusion of a system of color-coding so that you know what brushes, buckets, cleaning utensils can be used on a given piece of equipment. Normally you use white for pasteurized surfaces and equipment, red for raw product surfaces and equipment, yellow for environmental cleaning such as walls floors those kinds of things, black would be drains and or toilets.

Sanitation Standard Operating Procedure

Another key element to any sanitation for a plant is the development and use of a Standard Operating Procedure (SOP.) A SOP is a list of items that need to be done every time to ensure that sanitation is done correctly. If you include the simple list to ensure that this is done it makes it easier for someone who typically doesn't do this job to do it. The first step to making a SOP is to plan for results. Any standard operating procedure should relate to some kind of goal, you want to make sure that you are reaching that goal in executing this standard operating procedure. Secondly, you would make a draft of the SOP, write down what you need to do, how you do it, and where can you find supplies. This draft does not need to be perfect. Third, you review the SOP and make sure everybody who is involved would understand the process if given the SOP. Next you would test the procedure making sure that what you've written down actually

works and that you can execute those standard operating procedures based on the procedure itself. And then you would post it, make it available to people who might be doing that task. And the last step, (seven) is monitoring the outcome of the procedure. Because people, processes, management and equipment change these documents are always being updated. You can't write one and then leave it. As those changes come to pass you'll have to modify the procedure. So make sure your standard operating procedures remain up to date. There are two questions that must be answered in order for a standard operating procedure to be fully correct 1) does everybody who is using that standard operating procedure getting the same results?, and 2) if the answer to #1 is no then what's missing? So people need to make sure that the system works and if it doesn't work than why doesn't it work?

Proper cleaning of dairy processing equipment

In discussing the proper cleaning of dairy processing equipment we must always start with safety. Safety, as it relates to cleaning and sanitation chemicals can be summarized into two headings, Personal Protective Equipment (PPE) and Proper procedures including label instructions. The chemicals that are manufactured specifically for the removal of food residue from equipment are hazardous. Just as they will dissolve food residue these chemicals will attack and dissolve skin. Protect yourself with proper personal protective equipment. This is especially important when it comes to the eyes. Gloves, aprons, boots and eye protection are standard equipment during cleaning and especially during transport and additions of concentrated chemicals. Use concentration of chemical cleaners and sanitizers is usually less than 3 percent. However, the concentrated product can be as high as 50 percent. This means that in the concentrated form they are as hazardous as they ever will be. Adding the chemical to water is a best practice that helps to reduce risk. The blending of cleaning chemicals is never

advised unless there is a specific written document instructing you to do so. When preparing cleaning and sanitation solutions it is best to follow the manufacturers label instructions. Some people believe that using higher concentrations of chemicals is better for clean. This is not the case and in fact it is more dangerous and can be corrosive to materials and even damage equipment. Always read and follow label instructions for making up cleaning and sanitation chemicals.

Aspects of cleaning. There are three primary reasons or aspects of clean that need to be considered when we clean dairy processing equipment. These are that we have obligations to our trade, moral obligations to our customers and legal obligations to the governing powers. Our competitive markets demand that we make and sell only high quality products. The adverse effects of poor quality and poor standards must be kept in mind at all times. We are constantly under scrutiny from our customers. Just as we expect doctors, police or fire fighters to give their best to the jobs they have to do our customers expect that we are doing the same. We would never be happy with a doctor who said, "Oh, I was just having a bad day". Like wise our customers fully, and rightfully expect that we have their best interest in mind at all times. US laws and regulations attempt to protect the consumer in respect to health and quality. Failure to meet legal obligations on both a local and National level can result in severe action. The key to regulatory compliance is to focus on prevention rather than reaction.

Cleaning Objectives. Cleaning and sanitizing can be thought of in terms of the level of cleanliness that is obtained. Things can be physically clean, Chemically clean, Bacteriologically clean, or sterile. The level to which you clean your equipment is the same no matter what level of cleanliness you intend to reach. Physical cleanliness is the removal of all visible dirt, soil, product, etc. Chemical cleanliness is the removal of not only all visible dirt, but also

microscopic residues, which can only be detected by taste or smell but are not visible to the naked eye. Bacteriological cleanliness is obtained when bacterial contamination is reduced to a certain level. Sterile cleanliness is the removal, or destruction of all microorganisms and is difficult to obtain. Cleaning with detergent should obtain physical cleanliness as well as chemical cleanliness. It almost never results in a bacterialogically clean state. Bacteriological cleanliness can only be accomplished through the application of an approved sanitize, which results in a 5-log reduction of the bacteria.

Cleaning Chemistry. The chemistry of cleaning could be a book in and of itself. For our purposes we will discuss different types of dirt/soils, and cleaning terms such as surface tension, soap, surfactant, chelating agents and built caustics. Dirt is any unwanted substance that is on our equipment. It can be dirt, soil, product residue, grease, oil, stains, or films. These substances can come from the product, the environment, people, lubricants, chemicals or many other sources. For the most part these substances can be placed in two different groups, organic and inorganic. Organic compounds are those substances that contain carbon such as oils, grease, fat, sugar, and protein. In organic substances are minerals, mineral salts, milk stone, rust, and hard water. It takes different chemicals to clean these different substances. The following table (Table 3) shows the different substances and what chemicals clean them and the relationship to pH.

Table 3. Soil, Soil Type, Cleaning Chemical and Use pH.

Dirt/Soil	**Organic/Inorganic**	**Cleaning Chemical**	**Use pH**
Fats and Oils	Organic	Caustic/Alkaline	9-10
Protein	Organic	Caustic/Alkaline	9-10
Sugar	Organic	Caustic/Alkaline	7-9
Minerals (rust, scale, hard water, milk stone)	Inorganic	Acid	3-4

The following cleaning terms need to be understood by all persons associated with cleaning chemistry.

Surface Tension – The attraction of water molecules to one another that is displayed when water beads up on a surface.
Soap – Any basic cleaning agent produced by the saponification of fats and oils with an alkali.
Surfactant – A blended word that comes from surface-active agent. These molecules contain both water loving (hydrophilic) and water hating (hydrophobic) properties. They are absorbed at the liquid-liquid interface and make cleaning solutions "wetter". Surfactants are some times called wetting agents.
Built Caustic – Specifically formulated cleaner designed with specific chemicals for specific cleaning applications.

The main goal of cleaning is removal of soil and prevention of soils re-depositing on the surface. Surface tension is important in cleaning chemistry because of its effect on flushing away dirt. Water molecules like to be next to each other. This is known as surface tension. People wax their cars because they want the water to bead up, rather then spread over the surface of the car. Waxes, fats, oils and other molecules cause this to happen because the water would rather be associated with itself than with the fat or oil. This surface tension makes it very difficult to rinse away dirt. The dirt and the water must be in contact with each other in order to wash the dirt away with the water. Water is made "wetter" (less surface tension) by addition of a surface-active agent, called a surfactant. Surfactants join the dirt to the water by having both

hydrophilic and hydrophobic properties. The hydrophobic ends of the molecules bind with the dirt and the hydrophilic ends join with the water so the dirt can be rinsed off and not redeposit on the surface. The blending of fat molecules and alkali is a process called saponification, a long version of the word soap. Soaps work because they have the properties described above, the binding of dirt and the washing away with water. A built caustic is a cleaning solution that has specific properties (surfactants) that make cleaning a specific type of equipment easier. This would be the case in cleaning chemicals designed to clean High Temperature Short Time (HTST) pasteurizers. Because of the heat involved, the product characteristics and length of time operating the pasteurizer it needs a specific cleaner for properly cleaning.

Cleaning Procedures

Sanitation Overview. Cleaning and sanitation of dairy equipment plays a primary role for ensuring high quality, safe food for our customers. Sanitation also plays a key role in the overall effectiveness of our HACCP, Food Safety and Food Defense Programs. Sanitation includes all aspects of cleaning that are carried out during the course of normal start-up, production, and shut down procedures. Each step in the cleaning and sanitizing process must be completed correctly in relationship to the equipment that is being cleaned. Every cleaning cycle should consist of at least six specific steps in order to be effective. These six steps are to be completed in sequential order and according to the parameters given in the specific procedure.

Product Recovery. Residual product in the lines, tanks and equipment should be removed as soon as possible after production ends. Collection of this product, where applicable, can be saved in order to avoid loss of profit. Where use of the product residue is not applicable, it should still be collected so that additional waste in the sewer system can be avoided. Removal of product residue is essential to proper cleaning as excess product residue can dirty cleaning

solutions beyond workable levels. Product residue can be scraped, flushed, or collected in any way that is necessary to avoid leaving too much on the equipment.

Pre-rinse. Once product recovery has been completed, a complete pre-rinse of all equipment surfaces should be conducted. The pre-rinse is designed to remove nearly all-remaining soil from the surface. Because most pre-rinse activities are accomplished by hand, the water used during pre-rinse should be less than 120 F to protect the safety of sanitation workers.

Detergent Cleaning. Cleaning with a detergent should remove all residual soil from the equipment. Cleaning chemicals are to be used according to manufacturers instructions, NO EXCEPTIONS. Cleaning can be accomplished by, either, mechanical or manual means. Both are effective and should be selected based on the type of equipment; time allowed to clean and the availability of CIP systems. Regardless of what method is used the cleaning solution should come in contact with every portion of the surface being cleaned.

Post Cleaning Rinse. Post cleaning rinse is necessary to remove all soil and detergent from the surface. Detergents hold soil particles in suspension so that they can be flushed away. This takes place during the post cleaning rinse. The water for the post cleaning rinse should be high quality with minimal hardness, no off-odors and no off colors. Rinsing should continue until all soil and detergent has been removed. In systems with large volumes of water a pH measurement may be necessary to determine the point at which all detergent residue has been washed off. Be sure to know the pH of the rinse water prior to beginning the rinse so that comparison can be made to the water coming off of the equipment during rinsing.

Inspection. Once the equipment has be cleaned and rinsed an inspection can be conducted. Inspections must be thorough; with the intent of finding any remaining soil. The

inspection should be conducted visually and tactilely. Care must be taken not to cut or injure the hands during inspection. The use of additional light may be helpful during inspection. Look for places that are hard to get clean. Look up, down and sideways remembering that soils can be splashed or sprayer in all directions. Areas of the equipment that are not clean must be cleaned and inspected again. Once it is determined that the equipment is clean and properly rinsed the next step and be conducted.

Sanitizing. Previously cleaned surfaces can be treated to obtain a 5-log reduction in the bacteria levels. This is accomplished by application of chemical, or physical sanitizers. Chemical sanitizers are acids, iodine, quaternary ammonium compounds or other suitable chemicals. Physical sanitizers are steam and hot water. Regardless of the method used, the treatment must be used on clean surfaces and be approved as a food plant sanitizer.

Controlling Cleaning Variables

In addition to the steps of cleaning there are four variables to cleaning that, when controlled will drastically assist in the overall effectiveness of sanitation. These four elements are:

Temperature

Action

Concentration and

Time

Temperature is a vital variable in the cleaning cycle. Temperatures that are too low will result in less effective cleaning and the need for additional time, action and concentration. Temperatures that are too high can cause a safety risk, damage equipment and "burn-on" proteins that are more difficult to remove later. Pre and Post rinse water should be between 115-

120˚F. This temperature range will encourage the liquefaction of butter fat and not allow proteins to be "burned-on" the surface. Additionally this temperature is safe for manual application. In CIP systems the temperature of the cleaning solution should be 145-160˚F, depending on the type of soil that is to be cleaned. For those systems that are heating food products the temperature will need to be higher, while cold system can be cleaned at temperatures less than 145˚F. Manual cleaning water should never be more than 125 F as scalding can occur when water at this temperature comes in contact with the skin.

Action refers to the mechanical action needed to remove soils from the surface. Mechanical action can be supplied by a person using a brush or by the turbulent flow of liquids under pressure. Regardless of the method used to create mechanical action the action must be enough to correctly perform the task. In CIP systems, ensuring that the flow during cleaning is 1.5 times the flow during production creates the necessary mechanical action. COP tanks (tanks with circulating pumps) should be filled only to a point that good mechanical action can take place. Over-filling prevents proper mechanical action. Hand scrubbing with brushes, pads or scrappers is sufficient in most cases to remove soils from the surface. Careful inspection of the surface as cleaning is being done should be an on-going process to ensure that all soil deposits are removed.

Concentration of the cleaning chemicals is vital to proper cleaning of food processing equipment. There is really only one prime rule as to cleaning concentration, use what the manufacture recommends. Testing of cleaning chemicals should be done to ensure that proper concentrations are being used. Adding additional chemicals will not necessarily clean better, however it will make the cleaning solution more dangerous to use and more corrosive to equipment, gaskets and soft metals. Residual product residue, hard water and over-use of

cleaning chemicals will lessen the effectiveness of cleaning solutions. Changing, or re-charging of cleaning solutions is necessary as these solutions be come solid.

Time is a relative term. Cleaning times are specific to each piece of equipment and change according to the method of cleaning. 20-minutes per cleaning cycle is a good rule-of-thumb for all CIP applications. HTST, separators and other specific processing equipment will require longer cleaning cycles. Generally, 10-Minutes for foam applications and "as needed" for manual cleaning applications. NEVER lower cleaning cycle times without firm, sound reasoning, and properly changed cleaning procedures which have been developed in cooperation with manufacture recommendations.

Additional Cleaning Ideas. In addition to the cleaning step and the elements of cleaning mentioned above there are a few other items of note that need to be discussed. It is known that a 16-degree increase in temperature of cleaning solutions, doubles the cleaning efficiency. This is the reason that CIP systems are targeted for 145-160 F. An additional reason for that temperature range is that butterfat melts at 90 F, turns to liquid at 112 F, adding 32 more degrees quadruples the cleaning efficiency which results in a temperature of 145 F. Other items of note are;

- Never leave foam or cleaning solutions to dry on any surface
- Never mix cleaning chemicals in any form unless specifically instructed to do so by a sanitation standard operating procedure
- Change cleaning solutions often (important in manual cleaning)

Be sure that the sanitizer you are using is compatible with the application. This includes the type of equipment/process, the gasket material and other substances associated with the process.

CONTROLLING CROSS CONTAMINATION

Contamination Types

There are three main types of cross contamination: chemical, biological, and physical. Each of these contaminations has specific guidelines that assist in keep food protected from contamination. Chemical cross contamination is associated with pesticides, lubricants, epoxies, sealants, paints, food additives, processing aides, cleaners, and sanitizers. Biological contamination is associated with bacteria, yeasts, molds, and viruses. Because these things do not typically travel on their own we control them by controlling their movement through good manufacturing practices, segregation of raw and cooked foods, foot traffic, fork lift and car traffic, visitors (contractors, inspectors, and other people), air, and water. Physical cross contamination comes from metal, glass, wood splinters, insects, egg shells, fruit pits, hair, gum, jewelry, and other things that can come from personal items that are brought into the operation. Allergens can also be a form of chemical or physical cross contamination. None of the contaminants that we have discussed have legs or any other means to travel; they rely on our mistakes and our laziness to get around. Imagine if you were having an operation and just before going to sleep you heard a crash of something being dropped and the doctor says “pick those up we will need them later.” That would be disturbing. You would fall off to sleep wondering what kind of contamination you might get. People who eat our cheese likewise, expect that we are doing the right things.

Controlling Bacterial Contamination

Hand Washing – Your hands go everywhere that you do. Hands are used for everything and they are never product contact, hands are the enemy. If gloves are being used remember that the gloves are designed to protect the product from your hands. Gloves, unlike hands can be put on clean then sanitized and removed when dirty. Gloves get dirty just like your hands and must be replaced when contaminated by the environment. Your mother always said wash your hands before you eat, after you go the bathroom, and before doing other important things and she was correct. So it is the last thing you do before starting work, it is the first thing you do after using the restroom or when your hands are contaminated. If you didn't just wash your hands then your hands are not clean.

There are several steps to making sure that we wash our hands properly.

1. Use running water that you can turn on without use of your hand. Wet your hands with as warm of water as possible.
2. Use detergent.
3. Scrub your hands, between your fingers, around your fingernails and cuticles, on the back of your hand, up around the wrist, around the thumbs, and up the arm as far as possible. It is a good idea to also roll up any sleeves so they get out of the way when you are washing your hands.
4. Rinse your hands completely.
5. Dry your hands with a disposable towel making sure that your hands are completely dry.
6. Throw your used towel in a trash receptacle. It is a good idea to use the acronym TACT to remember how to wash your hands.

- T stands for **time**; count to twenty while you are washing your hands or sing happy birthday to yourself this will ensure that you spend enough time cleaning your hands.
- A is for **action** really scrub your hands, nails, between the fingers, on the backs of the hands.
- Use soap **concentration** of a high quality nature so that it provides a good cleaning effect.
- **Temperature**, as hot as water as you can stand.

Always go longer than the person next to you that will ensure that you wash your hands more.

Controlling Microorganisms

Microorganisms are living organisms so small that they often can only be seen using a microscope. Pathogenic bacteria and yeasts and molds are included with microorganisms. Bacteria contamination of food can result in public health significant issues. Unlike a physical hazard (metal, glass), which would harm the individual eating it, bacteria could be spread throughout the food and could be shipped to multiple states affecting a significant number of people. Some basics about microorganisms are that they need the same things we do: food, water, shelter, and warmth. When bacteria get settled in they reproduce rapidly, this is called harborage. During processing we use several methods to control mold and bacterial growth, time and temperature, moisture, sanitation, pH, restriction of travel, oxygen, and acid. We can remember these things by thinking of the acronym FATTOM. FATTOM is the enemy, certain **foods** have bacteria in them already, **acid** can affect the growth of bacteria, **temperature**, **time**, **oxygen**, and **moisture**. FATTOM.

When we talked about something being contaminated that means we had bacteria, germs, filth, or unsanitary conditions. Anything that is not clean is considered contaminated. Cells of

bacteria come in different forms; vegetative cells are cells capable of growth they are alive, functioning, and have various levels of health. Spore forming bacteria are cells that are capable of surviving harsh environmental conditions by encasing themselves in a protective shell. Germination is to begin to grow after a period of dormancy. Aerobic bacteria require or grow in the presence of free oxygen. Anaerobic bacteria require or grow in the absence of free oxygen. The cycle of a bacteria life has four primary stages. During the **lag phase**, the bacteria are becoming acclimated to a certain environment and are recovering. The **log phase,** which is rapid growth there is little to no death phase taking place and growth is exponential (two becoming four, becoming eight, becoming sixteen) and so on. The **stationary phase**, the third phase, is where growth and death are relatively equal. The use of food is maximized and the bacteria stay at the same numbers because of growth and death being equal. The fourth phase is the **death phase**, food can be in short supply, environmental conditions, like acid or other changes can take place causing a faster death rate than a growth rate resulting in a net change of negative bacteria populations. There are several major bacteria that are associated with food pathogenic issues.

Bacteria of Concern

Clostridium botulinum (*C. botulinum*) is a bacterium that produces a toxin that causes botulism. It causes blurred vision, dry mouth, difficulty swallowing, and paralysis of the respiratory muscles. It has a high fatality rate, it is anaerobic, spore forming bacterium, which means that it grows without the presence of free oxygen and is able to survive harsh environments by forming spores. It is found in soil, marine sediment, animal intestinal tracts, vegetables and grains, and all in anaerobic conditions. The control of these bacteria is based on proper heating especially in canned foods.

Clostridium perfringens (*C. perfringens*) causes food poisoning, nausea, diarrhea usually mild, and doesn't last too long. It's an anaerobic, spore forming bacteria. It is found in soil, intestinal tracts of healthy people, and animals including pigs, cattle, poultry, and fish. Control of this organism is based on heating and cooling of food quickly and staying out of the temperature danger zone between 40°F and 140°F.

Escherichia coli (*E. coli*) is a bacterium that causes gastroenteritis, which includes fever and diarrhea. Sometimes results in death usually from dehydration. It is not a spore former it is easily killed and is found in the intestinal tract of people and animals always associated with fecal matter. Control is obtained through proper good manufacturing practices.

Listeria monocytogenes (*L. monocytogenes*) is a bacterium that causes listeriosis it includes fever, intense headache, nausea, vomiting, delirium, and sometimes a coma. It has a 30% fatality rate. It is not a spore former, it is found throughout the environment and can survive dry and cold conditions. Control is obtained through proper good manufacturing practices and processing temperature controls.

Salmonella species are bacteria that cause salmonellosis in humans, which results in sudden headache, abdominal pain, diarrhea, nausea, vomiting, and fever. Death can follow through dehydration. Salmonella is not a spore former, it is found in animal and human gastrointestinal tracts and in chickens. Control is correct processing for heating, acid development, and doing sanitation, and good manufacturing practices.

Staphylococcus aureus (*S. aureus*) is the final bacteria, this bacteria causes staphylococcal food poisoning by the generation of a toxin. This would include abdominal pain, diarrhea, nausea and vomiting. It is not a spore former; staph produces a toxin that are heat stable. Once the bacterium has grown in food even if it is re-heated the toxins can remain viable

and cause intoxication in human beings. About 50% of people carry staph as normal bacteria on their skin, in their nose, and in other parts of the body. Control of these bacteria is found by good manufacturing practices, covering sores, boils, or other cuts on the skin. No sneezing or coughing in the production area.

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APPENDICES

Appendix A – A selection of terms from this appendix will be used to make a shortened glossary of technical terms that are appropriate for inclusion in the food safety handbook for artisan cheese makers.

Appendix B – A document pulled from the FDA web site covering the basics of HACCP principles, which could be included in the food safety handbook for artisan cheese makers.

Appendix C – A proposed outline that is more appropriately organized for a food safety handbook for artisan cheese makers than the information currently in this thesis.

APPENDIX A

TECHNICAL TERMS IN CHEESE MAKING AND QUALITY

Acid – A descriptive term for cheese with a pleasant tang and sourish flavor due to a concentration of acid. By contrast, a cheese with a sharp or biting, sour taste indicates an excessive concentration of acid, which is a defect.

Acid Food or Acidified Food - Food that has an equilibrium pH of 4.6 or below

Acid Curd – The custard-like state that milk is brought to when a high level of acidity is created. The acidity is produced by the activity of starter culture bacteria, and it precipitates the milk protein into a solid curd.

Acidity – The amount of acidity (sourness) in the milk. Acidity is an important element in cheesemaking and it is produced by cheese starter culture bacteria.

Acrid – A term used to characterize cheese that is sharp, bitter or irritating in taste or smell.

Adequate - that which is needed to accomplish the intended purpose in keeping with good public health practices

Adulteration – is to render poorer in quality by adding another substance, typically an inferior one.

Aftertaste – The last flavor sensation perceived after tasting a cheese. Pronounced aftertastes usually detract from the pleasure of a cheese.

Aged – Generally, a cheese that has been cured longer than six months. Aged cheeses are characterized as having more pronounced and fuller, sometimes sharper flavors than medium-aged or current-aged cheese.

American – A descriptive term used to identify the group of American-type cheeses, which includes Cheddar, Colby, granular or stirred-cured and washed or soaked-cure cheeses. Monterey Jack is also included in this group.

Amino Acids – Amino acids are the building blocks of proteins. Typically, proteins are made from a mix of 20 different amino acids. The amino acids in the protein give each protein its unique properties. Some amino acids are: Arganine, histidine, glycine, lysine, trytophan, phenylalinine. All amino acids contain nitrogen; some amino acids (methionine and cysteine) also contain sulfur.

Ammoniated or Ammoniacal – A term describing cheese that either smells or tastes of ammonia as a result of being overripe or mishandled, i.e., Brie, Camembert and Chevres. A hint of ammonia is not objectionable, but heavy ammoniation is.

Annatto – A natural vegetable extract, which is used to color cheese.

Appearance – A term referring to all visual assessments of cheese from its wrapping, rind, color and texture to how it looks when handled, broken or cut.

Aroma – A general tem for the odor or scent of cheese. Cheese may lack aroma or display aromas, which range from faint to pronounced, depending upon the cheese variety. Aroma is closely allied to flavor, although cheese with a distinct odor may exhibit a mild flavor while cheese lacking odor may present a strong flavor. Aromas may also specify particular tastes or scents, such as fruity, earthy, oily, and nutty. The cheese rind may have a different odor than its interior. The aroma of any cheese is most distinctive when the cheese is first cut into.
Aromatic – A descriptive term for cheeses with distinct, pronounced aromas.

Assertive – A term indicating the presence of a pronounced taste or aroma.

Astringent – A term descriptive of a harsh taste with a pucker, almost medicinal quality.

Baby – A smaller quantity of cheese, which has been formed into a mini-wheel or cylinder-like shape.

Bacteria – Microscopic unicellular organisms found almost everywhere. Lactic acid-producing bacteria are helpful and necessary for the making of quality hard cheeses.

Bacteria Linens – A red bacteria, which is encouraged to grow on the surfaces of cheeses, like Brick or Limburger to produce a sharp flavor.

Bacterial-Ripened Cheese – A cheese upon whose surface bacterial growth is encouraged to develop in order to produce a distinct flavor. Brick and Limburger are examples of bacterial-ripened cheeses.

Barny or Barnyardy – A descriptive term referring to strong farm-related aromas. Sometimes also called cowy. This characterization does not always indicate a negative quality.

Barrel – A style of Cheddar cheese specifically produced for the manufacture of Pasteurized Process cheese.

Basic Ingredient – A term usually referring to the milk source from which a cheese is made, such as cow's milk, ewe's milk, or goat's milk. Rennet, cultures or enzymes and salt are also considered basic ingredients of cheese.

Bitter – An unpleasant, biting flavor usually an after-taste. A bitter after taste is sometimes associated with variations in manufacturing and curing or aging procedures. It is more prevalent

in cured cheeses having higher moisture contents. Bitterness is often confused with astringency. True bitterness is a sensation that is typified by the aftertaste of grapefruit peel.

Bleu – The French word for blue that is used in reference to the Blue-veined cheese varieties.

Block – The most common style of cheese produced for wholesale distribution. Descriptive of the size and shape of cheese before it is cut for distribution and sale. It is recognized as one of the major styles of natural cheese and is aged in 20, 40, 60, or 640 pound blocks.

Bloomy Rind – A descriptive term for an edible cheese rind (crust) that is covered with a harmless, flavor-producing growth of white penicillium mold. Spraying the cheese surface with spores of Penicillium candidum mold before curing forms the bloomy rind. Occasionally, brown, pink or red specks are interspersed through the white mold as it ages or cures. Bloomy-rind cheeses, such as Brie, Camembert and some Chevres, are classified as soft ripened.

Blue-Veined – A characteristic of cheese varieties that develop blue or green streaks of harmless flavor-producing mold throughout the interior. Generally, veining gives cheese an assertive and piquant flavor.

Body – The physical attributes of cheese when touched, handled, cut or eaten. The body may feel rubbery, firm, elastic, soft, resilient, yielding, supple, oily, etc. When rolled between the fingers or cut, it may appear waxy or crumbly. It's "mouthfeel" may be grainy or creamy. A cheese also may be felt to determine its condition or ripeness.

Brine – A salt-and-water solution in which some cheese varieties are washed or dipped during the cheesemaking process. Certain cheeses, such as Feta, are packed or stored in brine.

Brining – A step in the manufacture of some cheese varieties where the while cheese is floated briefly in a brine solution. Brining is common in the production of Mozzarella, Provolone, Swiss, Parmesan and Romano cheeses.

Broken Down – This term refers to a change in the texture of cheese. For example, cheese may change from a firm, smooth or coarse, curdy or rubbery texture to a waxy (similar to cold butter), mealy or pasty texture.

Brushed – During the curing process, washed-rind cheese varieties are "brushed" with liquids such as brine, beer, wine or brandy to maintain a moist rind and impart distinctive, earthy flavors. Parmesan and other hard cheeses may be brushed or rubbed with a vegetable oil.

Bulk Cheese – Cheese in its original manufactured form such as a 40-pound block of Cheddar.

Butterfat – The fat portion (cream) in milk. Butterfat can vary from 2.5 to 5.5 percent of the total weight of milk.

Buttermilk – The sour liquid which remains after churning butter from cultured cream. The liquid remaining after churning sweet cream is sweet cream buttermilk.

Buttery – A descriptive term for cheese with a high fat content, such as the double and triple creams or cheese with a sweet flavor and creamy texture reminiscent of butter.

Casein – The principal protein in milk. During the cheesemaking process, casein solidifies, curdles or coagulates into cheese through the action of rennet.

Catch Weights – The variable weights of individual pieces of cheese. For example, a 5-pound loaf of Muenster may be slightly over or under 5 pounds.

Chalky (Color) – A desirable attribute referring to the true white color or smooth, fine-grained texture of older Chevres and young Brie. However, a chalky appearance on the surface is undesirable in many cheese varieties, such as Cheddar.

Cheddar-Type – A term used to classify cheeses that share characteristics exemplified by Cheddar which may include the process of manufacture, consistency, texture, odor or flavor. Colby is a Cheddar-type cheese.

Cheddaring – The process used in making cheddar whereby piles of small curds that have been separated from the whey are knit together and cut into slabs. The slabs are then repeatedly turned over and stacked to help drain additional whey and aid in the development of the proper acidity (pH) and body of the cheese. These slabs are then cut or milled into curds and placed in the cheese molds and pressed.

Cheese Board – A board measuring 6 inches square and 1 inch think of maple or birch, often used to aid in the draining of soft cheeses such as Camembert. Larger cheese boards are often used to hold aging cheeses.

Cheesecloth – A coarse to finely woven cotton cloth used to drain curds, line cheese molds, and perform a host of other cheesemaking functions.

Cheese Color – A coloring added to the milk prior to renneting which will impart various shades of yellow to the cheese. Most coloring is derivative of the annatto tree.

Cheese Mat – A wood reed cheese mat often used to aid in the drainage of soft cheeses such as Coulommiers or Camembert.

Cheese Salt – A coarse flake salt. Salt that has not been iodized is the most desirable type to use in cheesemaking.

Cheese Starter Culture – A bacterial culture added to milk as the first step in making many cheeses. The bacteria produce an acid during their life cycle in the milk. There are two categories of starter culture; mesophilic and thermophilic.

Cheese Wax – A pliable wax with a low melting point which produces and airtight seal which will not crack. Many hard cheeses are waxed.

Chemical – A descriptive term for a cheese aroma or flavor taint which usually indicates improper manufacture or contamination with foreign materials.

Chevres – The plural form of the French word for goat which was originally used to classify all cheese varieties made form French goat's milk, but now commonly refers to all goat cheeses.

Chymosin – The active enzyme in rennet. Rennets can be obtained from calf stomach or produced by fermentation. Some rennets are made by fermentations using yeast or bacteria that have had the DNA for chymosin added, these are called recombinant rennets.

Clean – (1) A descriptive term for cheese that is free of unpleasant aromas, off flavors and uncharacteristic textures. (2) A lack of lingering aftertaste when eating cheese, i.e., a clean finish.

Clean Break – The condition of the curd when it is ready for cutting. A finger or thermometer inserted into the curd at a 45˚angle will separate the curd firmly and cleanly if the curd has reached that condition.

Close – A descriptive term for cheese with a smooth, tight texture, such as Cheddar. A close texture contains few, if any, mechanical holes. A cheese with small holes, like Colby, is characterized as open.

Coagulatin (Curdling) – A step in cheese manufacture when milk's protein, casein, is clotted by the action of rennet or acids.

Code Date – A date stamped on a package of cheese that is used to determine the age and quality state of the product. It may be a pull date, pack date, or sell-by date.

Cold Pack (Club Cheese) – A blend made from different bathes of cheeses of the same variety, or two or more varieties of maid and sharp natural cheese which have been ground (comminuted). Cold Pack is not heat treated or cooked at the time of packaging like processed cheese.

Color – The color of the rind and the interior of any cheese is an indication of its variety, condition and quality. In all cases, the color should be characteristic of the cheese type. Cheese colors naturally range from snow-white to deep yellow. Orange cheeses, such as Cheddar, are colored with annatto – a tasteless, odorless natural vegetable dye – during manufacturing.

Colostrum – The first milk a cow gives after claving. Very high in protein, Colostrum is used in Spain for the production of Armada, a strong semi-firm cheese.

Comminuted – Breaking down or grinding cheese into small particles through a mechanical cutting action. Cheese that has been comminuted is used in the manufacture of Cold Pack cheese.

Consistency – The degree of hardness or softness of cheese. Classifications of cheese by consistency include: soft, semi-soft, semi-firm, firm and hard.

Cooked – (1) Nearly all milk is heated or warmed to some degree during cheesemaking; however, the term cooked is reserved for those varieties whose curd is heated in order to regulate moisture content and degree of hardness. Parmesan curds, for example, are cooked at a higher temperature than Cheddar curds. (2) As a tasting term, cooked refers to a flavor aroma associated with the use of over-pasteurized milk.

Cooking – A step in cheesemaking during which the cut curd is warmed to expel more whey.

Coulommiers Mold – A two-piece stainless steel mold consisting of two hoops, one resting inside the other. The mold is used for making Coulommiers cheese.

Cowy – See Barny.

Critical Control Point – a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or filth in the final food or decomposition of the final food.

Creams, Single, Double or Triple – A classification of cheese derived from the butterfat content on a dry matter basis. Single Creams contain at least 50% butterfat in the cheese solids (dry matter); Double Creams contain at least 60% butterfat; and Triple Creams contain at least 70% butterfat. See Milk fat Content and Milk fat in the Dry Matter (FDM).

Creamy – A descriptive term for cheese texture or taste. Creamy texture is soft, spreadable and, in some cases, runny. Creamy flavors are characterized as rich and are associated with cream-enriched cheeses, such as double or triple creams. Creamy may also refer to color.

Crumbly – A descriptive term for cheese that is easily broken into chunks or falls apart when cut, such as Blue cheese. An excessively crumbly texture indicates dryness. Cheese that has been frozen may become crumbly or grainy.

Culture – See Starter.

Curd – The solid custard-like state of milk achieved by the addition of rennet. The curd contains most of the milk protein and fat.

Curdling – See Coagulation.

Curing – The method, conditions and treatment from manufacturing to market, such as temperature, humidity and sanitation, that assist in giving the final cheese product the distinction of its variety. Sometimes used synonymously with aging and ripening. See Aging and Ripening.

Current (Young) – Generally semi-firm, firm, or hard cheese varieties that have been cured two weeks to 30 days. Such cheeses usually have mild flavors.

Cutting the Curd – A step in cheesemaking in which the curd is cut into equal-sized pieces.

Dairy Thermometer – A thermometer which ranges from 0℉ to 212℉, and can be used to measure the temperature of milk during cheesemaking.

Daisy – A cheese style, traditionally a 22-pound wheel of Cheddar, which has been coated with wax and cheesecloth.

Defect – Any less than ideal quality factor in a cheese. Sometimes a factor found in cheese due to improper manufacture, handling or contamination. Defects can refer to packaging, finish, surface, texture or taste.

DNA – DNA, or deoxynucleic acid, is the molecule that makes up our genes. DNA provides the template for making protein.

Double Cream – The French term for cheese containing from 60 to 74 percent butterfat in the cheese solids (dry matter). The average cheese has a 40 to 50 percent fat content.

Draining – A step in cheesemaking in which the whey is separated form the curd by pouring the pot of curds and whey into a cheesecloth-lined colander.

Drip Tray – A tray which is placed under a mold during the pressing of a cheese. The drip tray allows the whey to drain into a sink or container.

Dry Matter – All the components of cheese (solids) excluding moisture (water). Dry matter includes proteins, milkfat, milk sugars, and minerals.

Dutch-Type – A classification of cheese varieties that share similar characteristics, such as in methods of manufacture, consistency, texture, smell or taste, with cheeses produced in the Netherlands. Edam and Gouda are considered Dutch-type cheeses. Tilsit may appear under this classification, although it is not produced predominantly in Holland.

Earthly – A descriptive term for cheese varieties with rustic, hearty flavors and aromas. Cheese flavor compounds in this category share a common occurrence with those actually present in freshly-plowed earth or forest litter. Goat, sheep and monastery-type cheese may be characterized as earthly and exhibit assertive flavor and aroma.

Emmentaler –The Swiss word for Swiss cheese.

Emulsifier –A substance or mixture that is used in the production of processed cheese to create its smooth body and texture. It is composed of salts of common food acids.

Enzyme –Enzymes are proteins that speed up chemical reactions. Some enzymes are : Lipases (or esterases) – break proteins into peptides, peptidases – break peptides into smaller peptides, amino peptidases – break peptides into amino acids.

Eye – A void or hole within cheese that is caused by the formation of trapped gas, as a result of fermentation, during the curing process. The presence of eyes is typical of cheeses in the Swiss group and can range from pin sized to pea size or larger.

Family (Group) – A term for cheese varieties that share similar characteristics.

Fat Content – The amount of butterfat/fat in any cheese. Fat content is determined by analyzing the fat in the dry matter of cheese. The fat is expressed as a percentage of the entire dry matter. See Dry Matter.

Fatty Acids – Fatty acids are one of the building blocks for making fats and oils. The types of fatty acids that make up a fat determine its physical and chemical properties. Some fatty acids are oleic acids, linoleic acid, stearic acids, lauric acid.

Feed – A descriptive term for cheese that exhibits and odor or taste that is directly related to the particular feed consumed by a cow or other animal before milking. The aroma or flavor may be unpleasant if the feed was turnips or intriguing if the feed was apples or mountain clover.

Ferme (Fermier) – The French term for farm-produced cheeses.

Fermented – An aroma reminiscent of yeast or alcoholic fermentations.

Filled – A descriptive term for cheese from which all butterfat has been removed and in its place a vegetable oil has been used as a substitute. Filled cheese also is referred to as imitation.

Finish – (1) The process of finishing, refining, or curing cheese to desired ripeness. Soft-ripened cheeses are sprayed on the surface with a harmless white mold (Penicillium Candidum) whose growth helps ripen the cheese. Depending upon cheese variety, other finishing methods include washing the rinds of cheese and the daily turning of cheeses. Temperature and humidity are tightly controlled during the finishing process. (2) The way a cheese is packaged, such as a hard natural rind, a bandage of cheese cloth and wax or vacuum packaging may be referred to as its finish. (3) The aftertaste of cheese may be described as having a clean finish, bitter finish, sour finish, earthy finish, and so forth.

Firm – A classification of cheese varieties which exhibit a relatively in elastic and unyielding texture. Cheddar and Swiss are examples of firm cheeses.

Fishy – A descriptive term referring to the unpleasant flavor of overripe, high moisture cheese varieties. Often is associated with ammoniacal flavors.

Flaky – A descriptive term for cheese that breaks into flakes when cut. A flaky quality is typical of Parmesan, Romano, Asiago and Cheddar when aged over 10-12 months.

Flat – (1) A descriptive term for tasteless cheese which normally yields a distinct flavor. Cheese with reduced levels of sodium and salt is often referred to as flat. (2) A style of Cheddar weighing from 35-37 pounds which has been coated with wax and cheese cloth.
Flavor – A general term for the taste a cheese presents as it is eaten. Flavor is detected in the mouth and also by the nose. Flavors, in order of ascending aggressiveness, are described as faint (fleeting), mild (light or bland), pronounced (distinct) or strong (intense). Flavors may also be described by the tastes they resemble such as nutty, salty, buttery, fruity and peppery. Flavor is categorized by aftertastes as well as by initial taste.

Food - anything that is intended for consumption by humans or animals and includes raw materials and ingredients.

Food-contact surfaces – are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operation. Food contact surfaces include utensils and food-contact surfaces of equipment.

Fondu – The French word for process cheese. This term should not be confused with "Fondue", a Swiss dish often made with cheese. See Pasteurized Process Cheese

Force Ripening – A method of speeding the ripening of a cheese by the application of a warmer environment than normal to naturally ripen the cheese. The cheese may be force ripened at room temperature or in a cooler set at a higher than normal temperature. Ripening may also be accelerated by modifying the enzymes. These cheeses are used primarily in processed cheese and as a food ingredient.

Foreign Flavor – See Chemical.

Formaggio – The Italian word for cheese.

Fresh – A term typically used to classify cheese varieties that have not been cured, such as Mascarpone, Cottage Cheese, Cream Cheese or Ricotta. Cheeses that have been cured for very short periods, such as Feta, may also be classified as fresh.

Fresh Mozzarella – A soft Mozzarella, with a very high moisture content, that is meant to be eaten soon after it is produced. In Italy, balls (Bocconcini) of fresh Mozzarella are stored in water and usually consumed the same day they are made. Due to high moisture content, fresh Mozzarella has a very short shelf life.

Fromage – The French word for cheese.

Fruity – A descriptive term for the sweet, fragrant aroma or flavor which is characteristic of certain semi-soft cheeses, such as pouy De Montagne or American Muenster and some hard mountain cheese varieties. Baby Swiss and some Cheddars also present a fruity quality.

Gamey – A descriptive term for cheeses with strong flavors and penetrating aromas.

Gassy – A descriptive term for cheeses in packaging which becomes bloated. This may be air as a result of an increase in holding temperature or altitude, or it may indicate microbial production of carbon dioxide.

Goat – A classification of cheese made from goat's milk.

Goaty – Distinctive flavor of cheeses made from goat's milk.

Grainy – (1) A descriptive term for gritty texture which is desirable in certain hard-grating cheeses, though not to the point of mealiness. Parmesan and Romano exhibit a granular or grainy texture. (2) A flavor term that may be used to describe grainlike (wheat) flavors that occur as the result of ripening.

Grana – The Italian term for hard-grating cheese. Parmesan, Romano, Asiago, Parmigiano-Reggiano, Grana Padano and Sapsago are among the grana-type cheese varieties.

Grassy – A descriptive term for cheese with a weedy taste that is related to the type of feed a cow has consumed, such as silage, bitterweed, leeks or onions, prior to milking. See Feed.

Green – Cheese that is immature or young. In this context, green does not refer to Sapsago which sometimes is called "Green cheese" because of its color.

Gummy – A descriptive term for the overly plastic, sticky texture of some soft cheese varieties, especially processed types. Gummy also refers to overripe rinds that have become sticky.

Hard – a classification of cheese based upon texture. Parmesan is a hard cheese.

Hard-Grating – A descriptive term for cheeses, such as Parmesan, Romano, and Asiago that are well-aged, easily grated and primarily used in cooking. See Grana.

Hole – Similar to "eyes" characteristic of Swiss cheese but smaller. Cheese varieties such as Havarti or Pyreenes exhibit small pin holes which create a lacy texture and appearance.

Homogenization – A mechanical breaking up of the fat globules in milk so that the cream will no longer rise in the milk.

Imitation Pasteurized Process Cheese Spread – A cheese that possesses all the properties of pasteurized process cheese spread except the butterfat content is significantly lower than federal standards allow for labeling as a cheese spread.

Intense – A descriptive term for cheese with strong concentrated aromas and flavors.

Interior – The cheese inside a rind or crust, which is certain cheeses is also referred to as paste (Brie).

Kaas – The Dutch word for cheese.

Kase – The German word for cheese.

Lactic – (1) A general description applied to cheese exhibiting a clean, wholesome, milky and slightly acidic flavor or aroma. (2) The type of organism included in starter cultures for cheesemaking.

Lactic Acid – Acid created in milk during cheesemaking. Cheese starter culture bacteria consume the milk sugar (lactose) and produce lactic acid as a byproduct.

Lactose – The sugar naturally present in milk. Lactose can constitute up to 5 percent of the total weight of milk.

Lait Cru – The French term for raw or unpasteurized milk.

Laiterie or Laitier – The French words for dairy farmer or dairyman which appear on French cheeses made in a creamery or factory. See Ferme.

Lipase – (1) And enzyme found in raw milk and also produced by microorganisms that splits fat molecules into fatty acids which cause flavor. (2) Lipase flavor is a term also used to describe rancidity, especially where these flavors are desired in cheeses. See Rancid.

Lipolysis – Lipolysis is the breakdown of fat into its constituent fatty acids.

Lot – the food produced during a period of time indicated by a specific code.

Marc – The white brandy or eau de vie made form grape pomace. Marc may be used as a solution of curing washed-rind cheese.

Mammoth – A style of cheese, usually Cheddar, weighing between 75 to 12,000 pounds.

Matieres Grasses – The French term for dry matter.

Mechanical holes – Small, irregular openings in the body of cheese that are cause by manufacturing method and not by gas fermentation. Colby, Brick, Muenster and Monterey jack are varieties with natural, mechanical openings. See Open.

Medium-Aged (Mellow) – Generally, semi-firm, firm or hard cheeses that have been cured for three to six months. Medium aged cheeses are usually mellow and smooth-textured. Frequently used in regard to Cheddars.

Mesophilic Cheese Starter Culture – A blend of lactic acid-producing bacteria, which is used to produce cheese when the cooking temperature is 102℉ or lower.

Microorganisms – yeast, molds, bacteria, and viruses and include, but are not limited to species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mild (Young) – A descriptive term for light, unpronounced flavors. Mild also refers to young, briefly-aged
Cheddars.

Milkfat Content – The fat content of cheese expressed as a percentage of the total cheese weight. Milkfat content depends upon the richness of milk used in cheesemaking and how much moisture is lost during ripening.

Milkfat in the Dry Matter (FDM) – The fat content of cheese expressed as a percentage of the total solids of cheese. Most cheeses are in the rage of 45-55 percent milkfat in the dry matter because the dry matter stays constant in a unit of cheese while moisture content in that cheese may vary.

Moisture Content – See Fat Content.

Mold – (1) A condition created by the growth of various fungi during ripening that also contributes to the individual character of cheese. Surface molds ripen from the rind inward. Internal molds, such as those used for Blue cheese, ripen throughout the cheese. A moldy character can be clean and attractive or unpleasantly musty or ammoniated. (2) Mold also refers to the fungus itself. (3) A hoop or container that cheese is shaped in.

Mouthfeel – See Texture.

Monastery-Type – A term used to classify cheese that originated and are still produced in the monasteries of France, such as Port du Salut. Monastery-type also refers to other cheese varieties with similar attributes and may also include a variety of washed rind cheeses.

Mottled – A defect in cheese appearance that is characterized by an irregular, splotchy color on the rind or interior.

Mushroomy – A descriptive term for ripened cheese, such as Brie, with and aroma and flavor that is similar to the clean, pleasant fragrance of mushrooms. The flavor is produced by the surface mold which is actually related to the commercial mushrooms. A mushroom aroma may also be detected in other soft or semi-soft varieties.

Milling – A step in cheese making during which the curd is broken into smaller pieces before being placed in a cheese press.
Molding – A step in cheesemaking during which the curd is placed in a cheese mold. The cheese mold will help produce the final shape of the cheese and aids in drainage.

Mold-Ripened Cheese – A cheese upon whose surface (and/or interior) a mold is encouraged to grow. Two types of mold are most common in cheesemaking. They are blue mold for the blue cheeses and white mold for Camembert and related cheese.

Natural – (1) A general classification for cheese that is made directly from milk. Whether the milk is pasteurized or unpasteurized has no bearing on the designation as "natural". (2) Refers to the cheesemaking process whereby cheese is made directly from milk by coagulation or curdling the milk, stirring and heating the curd, draining the whey and collecting or pressing the curd.

Natural Rind – A rind that develops naturally on the cheese exterior through drying while ripening without the aid of ripening agents or washing. Most semi-firm or hard cheeses have natural rinds that may be thin like that of bandaged Cheddar or thick like that of Parmesan, Pecorino Romano and wheel Swiss, Emmentaler.

Nutty – A descriptive term for cheese with a nut-like flavor as is characteristic of Swiss-types. Cheddars may exhibit a flavor reminiscent of walnuts; fresh Goat cheese and Gruyere are said to resemble the taste of hazelnuts. The flavor compounds that cause these sensations are actually found in nuts.

Off – A term referring to undesirable flavor or odor taints that are too faint or ill-defined to be more precisely characterized.

Oily – A descriptive term that may refer to texture, aroma and flavor. Cheese held out of refrigeration for extended periods may also appear oily.

Open – A term applied to cheese varieties containing small, mechanical holes that develop as a result of the manufacturing process. The holes may be small or large, densely patterned or randomly scattered and irregular in shape. The blue mold that grows in Blue cheese forms around the openings in through punctures made with steel pins into the cheese. (See Mechanical Holes) Pin holes are not to be confused with the open eyes in Swiss-type cheeses which are caused by fermentation. See Close.

Ost – The Scandinavian word for cheese.

Overripe – A term descriptive of cheese that has passes its ideal state of ripeness.

Pack Date – A code date put on cheese to indicate the date the cheese was packed and shipped by the manufacturer.

Paraffin – A wax coating applied to the rinds of some cheese varieties for both protection during export and extended lifespans. Paraffin may be clear, black, yellow or red.

Part-Skim – A term used to denote the manufacture of a cheese, such as Mozzarella, with partly skimmed milk. This yields a lower-fat cheese that may have desirable properties compared to the full-fat cheeses. See Skimmed Milk.

Pasta Filata –Translated literally from Italian, "to spin paste or threads". Pasta Filata refers to a type of cheese where curds are heated and then stretched or kneaded before being molded into a desired shape. The resulting cheese has great elasticity and stretches when cooked or melted. Cheeses in this family include Mozzarella, Provolone, and String.

Paste – A descriptive term for the interior texture of soft-ripened cheeses, such as Brie, that exhibit a semi-soft to runny consistency.

Pasteurization – The process of heating milk to a specific temperature for a specific period of time in order to destroy any disease-producing bacteria and check the activity of fermentative bacteria. See Pasteurized.

Pasteurized – A term that describes milk that has been heat-treated to destroy bacteria. Most factory-produced cheeses are made from pasteurized milk to ensure greater control over quality and more uniform consistency. Processed cheeses also may be pasteurized to check further ripening.

Pasteurized Process Cheese – A blend of fresh and aged natural cheese that have been shredded, mixed and heated (cooked) with an addition of an emulsifier salt, after which no further ripening occurs.

Pasteurized Process Cheese Food – A variation of Pasteurized Process cheese, which contains less fat and has higher moisture content. It differs from process cheese in that either nonfat dry milk or whey solids and water have been added, thus reducing the percentage of actual cheese in the finished product.

Pasteurized Process Cheese Spread – A variation of Pasteurized Process cheese which contains a higher moisture content and lower milkfat content than process cheese food. A stabilizer is added to prevent separation of ingredients.

Pate – The French word for paste.

Penicillium – Principal genus of fungi used to develop molds on certain cheese varieties during ripening. Penicillium candidum is used to develop many soft-ripened cheese such as Brie; Penicillium glaucum or roqueforti are used for Gorgonzola and Roquefort cheeses, respectively

Penicillium Candidum – A white mold, which is encouraged to grow on the surface of a number of soft mold-ripened cheeses including Camembert.

Penicillium Roqueforti – A blue mold, which is encouraged to grow on the surface and in the interior of a variety of blue cheese.

Peppery – A descriptive term for cheese with a sharp, pepper flavor nuance. Aged Cheddar and aged Goat cheese may be described as peppery.

Peptide – When amino acids join together they form a peptide. A dipeptide contains two amino acids, a tripeptide contains three amino acids. Peptides can be big or small. A protein is a polypeptide that contains many (usually a hundred or more) amino acids.

Persille – The French translation for "parsleyed" which refers to delicately veined Blue varieties, such as Roquefort, Blue and Stilton, where the mold resembles sprigs of parsley.

Pest – refers to any objectionable animals or insect including, but not limited to, birds, rodents, flies, and larvae.

Plant – the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

Pickled Cheese – A term, which may be used to classify cheeses that are stored and packed in a brine solution. Feta is a pickled cheese.

Piquant – A descriptive term for cheese with an appealing sharpness or exhilarating accent of flavor or aroma. Aged Asiago, aged Provolone and Blue cheese are sometimes described by this term.

Plastic Curd – A classification of cheeses whose curd is heated and then kneaded to form various shapes. The Italian term for these cheese varieties is pasta filata. Mozzarella, Provolone and String cheese are plastic-curd type cheeses and may be described as stringlike. See Pasta Filata.

Pressed Cheese – A descriptive term for cheese whose curd has been placed in a mold and literally pressed to form the intended shape of the finished cheese. Fresh, uncured cheese varieties such as Cream or Feta and cured cheeses such as Brick, Cheddar, Parmesan and Romano are examples of pressed cheese.

Pressing – A step in cheesemaking during which the curds are placed in a cheesecloth-lined mold and placed under pressure to remove more whey.

Print – A rectangular style of cheese that has been cut from a 40-pound block. Prints are normally 10-pound loaves.

Process Cheese – See Pasteurized Process cheese.

Processed – A classification of cheese.

Pronounced – A descriptive term for cheese that exhibits a distinct aroma or flavor which is stronger than mild but not as powerful as intense. See Intense.

Proper Break – A term used during the making of Swiss cheese. To make certain the curds are properly cooked, a handful is wadded into a ball. If the ball can be easily broken back into the individual curd particles, this is called a proper break.

Proteolysis – Proteolysis occurs when proteins are broken into smaller peptides and amino acids. Enzymes are often involved in proteolysis, such enzymes are called proteases or proteinases.

Pull Date – A code date stamped on cheese to indicate when the product should be removed from stock as being too old.

Pungent – A descriptive term for cheese with an especially poignant aroma or sharp, penetrating flavor. Limburger cheese aroma is classes as a pungent aroma.

Queijo – The Portuguese word for cheese.

Queso – The Spanish word for cheese.

Quality Control Operation_- a planned and systematic procedure for taking all actions necessary to prevent the food from being adulterated within the means of the act.

Rancid – A term that relates to flavors caused by the release of free fatty acids form butterfat. Lipase enzymes cause the release of fatty acids. Some cheeses are not supposed to have flavors caused by fatty acids in high concentrations, such as Cheddar, while other, such as Romano, gain much of their flavor form the "rancidity" of fatty acids. In many diary flavors excessive rancidity is considered a notable defect. See Lipase.

Raw Milk – Milk that has not undergone pasteurization.

Red Bacteria – A special bacterial growth (Bacteria linens) which is encouraged to grow on cheese such as brick and Limburger.

Redressing – The changing of cheesecloth on a draining or pressed cheese. This helps keep the cheesecloth form sticking to the cheese.

Rennet – An extract from the membranes of claves' stomachs which contains rennin, an enzyme that aids in coagulation milk or separation curds form whey. Rennet-like enzymes, also used commercially, are produced by selected fungi and bacteria.

Rennet (Animal) – Rennet is derived from the fourth stomach of a milk-fed calf. It contains the enzymes rennin which has the ability to coagulate milk. Animal rennet is available in tablet or liquid form.

Renneting – A step in cheesemaking in which rennet is added to milk in order to bring about coagulation.

Rework – clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Rind – The outer surface of cheese. A rind varies in texture, thickness and color. Cheeses may be rindless, display natural rinds or possess rinds that are produced by harmless mold. See Natural Rind and Bloomy Rind.

Rindless – Cheese without a rind. Some rindless varieties, such as Brick and Colby, are ripened (cured) in plastic film or another protective coating to prevent rind formation. Other cheeses, such as Feta, are rindless because they simply are not allowed to ripen.

Ripe – A descriptive term for cheese that has arrived at peak flavor through aging. The optimum period of aging varies widely among cheese varieties.

Ripening – The chemical and physical alteration of cheese curing the curing process. See Curing and Aging.

Robust – A descriptive term for cheese with a very strong aroma and full, flavor.

Rubbery – a term characterizing the resilient feel and texture of a cheese. Generally, a term for cheese that is overly chewy or excessively elastic in texture.

Runny – A descriptive term for cheeses that have returned to a partially liquid state as a result of insufficient drainage of whey or exposure to excessive heat. Soft-ripened cheese varieties often become runny at the peak or ripeness or if place in warm temperatures for long periods.

Rustic – A descriptive term for cheese with a hearty or earthy flavor and an assertive aroma. Country or mountain cheeses are sometimes referred to as rustic.

Safe-Moisture Level – is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

Salting – A step in the cheesemaking process requiring the addition of salt. Depending upon the cheese variety, salt can be added while the cheese is in cured form or rubbed on the cheese after it is pressed. Salt is used to help preserve cheese as well as to enhance its flavor. Cheese also may be soaked in a salt solution which is a process termed brining.

Salty – Most cheese possess some degree of saltiness. Pronounced saltiness is characteristic of specific varieties, however excessive saltiness is a defect. Cheeses lacking in salt are described as dull or flat.

Sanitize – to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Satiny – A descriptive term referring to the texture and “mouthfeel” of soft, spreadable cheese

varieties. A satiny texture is characteristic of perfectly ripe Brie. Also sometimes referred to as a smooth, silky texture. See Silky and Velvety.

Sell-By Date – A code date put on cheese to indicate the date by which the manufacturer recommends that the cheese be sold at retail to the consumer.

Semi-Firm – A classification of cheese based upon texture. Edam and Gouda are examples of semi-firm cheese varieties.

Sharp – A descriptive flavor term referring to the fully developed flavor of aged cheese such as Cheddar, Provolone and some Blue varieties. The flavor is actually sharp and biting, but not excessively acid or sour.

Sheep – A classification of cheese made from ewe's milk.

Sheepy – Characteristic flavor of some cheeses made from ewe's milk.

Silky – See Satiny and Velvety.

Skimmed Milk – The milk which remains after all or part of the cream containing the fat has been removed.

Smoked Cheese – Cheese that has been smoked in a process similar to smoking meat. Methods for the smoking cheese include addition of liquid smoke to the brine or smoking over identified woodchips. Smoked Cheddar, Swiss and Provolone yield a unique flavor.

Soapy – Descriptive of a taste caused by long-chain fatty acids sometimes present in cheese which is caused by excessive milkfat breakdown.

Soft cheese – A cheese, which is not pressed, contains high moisture content, and is aged for a comparatively short period of time.

Soft-Ripened – A classification of cheese based upon texture. Brie and Camembert are examples of soft-ripened cheese varieties.

Solids – See Dry Matter.

Sour Milk – Milk that has been made acidic by fermentation. The predominant acid formed is lactic acid. See Starter and Lactic.

Sour – A descriptive term for cheese with an excessive acid content. However, a mild, tangy, sour flavor can be attractive in young cheeses. Tartness is the same as sourness in flavors.

Sour-Milk Cheese – Cheese that has been curdled (coagulated) by natural souring or by the addition of lactic acid bacteria. Sour-milk cheese does not use rennet for coagulation. Cottage cheese is an example of this type of cheese.

Specialty Cheese – A subjective term used to classify cheeses which is of exceptional quality, notably unique or produced in limited quantities. Cheeses that are combinations of different cheese types also may be referred to as specialty. For example, Blue/Brie is a soft-ripened cheese with a blue vein mold throughout.

Spiced – A term sometimes used to classify all cheese varieties containing spices, herbs or flavorings. For example, Caraway Gouda is a spiced cheese.

Spicy – A descriptive term for cheese varieties with a peppery, herby character.

Springy – A descriptive term for cheese with a resilient texture that "springs back" when gently pressed. Ripe or nearly ripe, soft-ripened varieties should be springy.

Stabilizer – An additive used to retard deterioration. A stabilizer may be natural, such as salt, or artificial.

Starter – A culture that normally consists of varying percentages of lactic acid, bacteria or mold spores, enzymes or other microorganisms and natural chemical which is used to speed and control the process of curdling milk during cheesemaking.

Starter culture – Bacteria added to milk used for cheesemaking and yogurt. The starter cultures produce acid, which causes the milk to ferment.

Sticky – See Gummy.

Stringlike – See Plastic Curd.

Strong – A descriptive term for cheese with a pronounced or penetration flavor and aroma.

Style – A classification of cheese based upon its shape, size and packaging.

Supple – A term describing the body of certain cheese when handled. Supple cheese varieties, such as Fontina, are somewhat elastic, consistent and yielding.

Surface-Ripened – A term referring to cheese that ripens form the exterior when a harmless mold, yeast or bacteria is applied to the surface. Bloomy-rind and washed-rind cheeses are surfaced-ripened; also referred to as soft-ripened.

Swiss-Type – A term used to classify cheeses that share the common characteristic of eyes (holes) in their interior. Eyes develop during the curing process when gas, formed though fermentation is trapped and expands thus forming holds. The size of eyes can range from as small as a pea in Baby Swiss to the larger holes typical of Aged Swiss. The original Switzerland Swiss is known as Emmentaler.

Tangy – (1) A descriptive term that refers to a pleasing acidity or tartness which is a very distinct and somewhat penetrating flavor common to Chevres, certain Blues and less assertive Bel Paese. (2) In broad terms tangy indicates a lingering, usually acidic flavor. (3) A reference to the specific flavor of individual varieties, as in a Cheddar tang.

Tart – See Sour.

Taste – See Flavor.

Texture – A general term for the "fabric" or "feel" of cheese when touched, tasted, or cut. Characteristics of cheese texture may be smooth, grainy, open or closed, creamy, flaky, dense, crumbly and so forth, depending upon the specific variety.

Thermophilic Cheese Starter Culture – A bacterial starter culture, which is used for the making of cheeses which have a high cooking temperature. Recipes for Italian cheeses and Swiss cheese call for a thermophilic culture.

Tomme – Sometimes spelled Tome, this French word for cheese is native to the Haute Savoie section of France. The word precedes the names of certain cheeses such as Tomme de Savoie or Tomme de Beaumont. The Tommes have much in common with the washed-rind cheese produced in the monasteries of France.

Topnote – A fleeting, very light aroma or flavor usually detectable when a cheese is first cut or tasted.

Top-Stirring – The stirring of the top ¼ inch of non-homogenized milk during cheesemaking in order to keep the cream from rising immediately after rennet has been added to the milk.

Triple Cream – The French term for cheese, which contains more that 75 percent butterfat in the cheese solids. See Creams and Fat Content.

Triglycerides – Triglycerides is the technical name for what are usually called fats and oils. A triglyceride is made when three fatty acids are chemically bound to a glycerol molecule.

Turophile – A lover of cheese. Taken from the Greek word turos (cheese) and the root phil (love).

Type – A term used to classify or categorize cheeses that share common characteristics, such as degree of firmness, texture, flavor and manufacturing procedure, with a widely known and established cheese variety.

US RDA – The abbreviation for United States Recommended Daily Allowance, which refers to the nutritional contributions which foods, such as cheese, make to the diet.

Uncooked Cheese – See Cooked Cheese.

Variety – The generic name of a cheese by which it is most commonly identified such as Cheddar, Colby, Blue, etc.

Velvety – A descriptive term for cheese exhibiting an ultrasmooth texture. See Satiny and Silky.

Washed-Rind – A cheese rind that has been washed periodically with brine, whey, beer, cider, wine, brandy or oil during ripening. The rind is kept moist to encourage the growth of orange-red bacteria. The bacteria may be scraped off, dried or left to further rind development. Washed-rind and bloomy-rind cheeses compose what is termed the soft-ripening (surfaced ripened) classification. Limburger is a washed-rind cheese.

Water Activity – (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Waxy – A term describing the wax-like appearance of a cheese body, or its texture when tasted or cut. See Texture.

Weeping – A descriptive term referring to Swiss-type cheese whose eyes glisten with bits of moisture. This is caused by the release of moisture by proteins as they are broken down during ripening. Weeping often indicates that a cheese has achieved peak ripeness and will exhibit full flavor.

Whey – (1) The thin, watery part of milk that separates from the coagulated curds during the first step of the cheesemaking process. It still contains most of the milk sugar or lactose found in milk. (2) A classification of cheeses made predominantly from the whey obtained during the manufacture of other cheese like Gjetost. Ricotta can be made from whey.

Whey Taint – A term used to describe off-flavors in cheeses, particularly Cheddar, which resemble soured or fermented whey. The sometimes are also known as unclean or utensil-like flavors which refers to their similarity to unwashed cheesemaking equipment that is allowed to remain at room temperature.

White Mold – A white mold (Penicillium candidum), which is encouraged to grow on a number of soft cheeses in order to develop a pungent flavor. Camembert is perhaps the most famous of these cheeses.

Whole Milk – Milk that is neither skimmed nor enriched with extra cream.

Wisconsin State Brand/Wisconsin Grade A – These grades appear on American cheeses which meet the state's highest quality. Each grade meets the same high standards and they are interchangeable.

Wrapping – The exterior material used to enclose or cover cheese for protection and storage. Examples of wrapping material include leaves, plastic, cloth, paraffin and foil

Young – See Current and Green.

APPENDIX B

Food and Drug Administration HACCP Guidelines

Hazard Analysis Critical Control Point

Hazard Analysis Critical Control Point (HACCP) is a food safety system. The HACCP system is based on prevention rather than reaction, and has been shown to be very successful at preventing contamination of food during manufacturing. Originally developed during the early days of the United States space program HACCP has gained popularity and government support throughout the food industry. The implications of someone becoming sick while in space was a driving force behind the development of a concise food safety system. Together the National Aeronautical Space Administration (NASA) and the food industry (specifically Pillsbury) developed the HACCP system, which verifies all aspects of the food manufacturing process to ensure that the food will be safe for consumption. Prior to the HACCP system, foods processors relied on inspection and correction, which resulted in gaps in the food safety aspects of the manufacturing process.

The HACCP system is based on the concept of prevention by careful analysis of the entire food manufacturing process. HACCP does not function as a zero risk program. That is to say that rather than complete elimination of a hazard the program also allows for reduction, or minimization of some risks. Additionally, HACCP functions as a management tool that works at all levels of the operation to ensure control rather than reaction. Although HACCP was initially started to prevent “space food” from causing food born illness the entire food chain system can be addressed using the principles of HACCP. For example, HACCP plans are applicable to

basic agriculture, such as (farming and ranching), retail operations (grocery stores), food service (restaurants, deli's, etc), and transportation and distribution. Some aspects of food processing are required by regulatory agencies to have HACCP plans, which include meats, dairy, juice and seafood.

Before discussing the HACCP system in detail it is necessary to understand a broader view of HACCP. In order for a HACCP system to function it needs to be understood that the system is made up of several key components, which include the HACCP Program, Prerequisite programs and the HACCP plan. The following table (Table 4) briefly identifies the interrelated nature of the three components of the HACCP system of food safety.

The HACCP program is the commitment to food safety that a company makes. It is the way in which people think about food safety, and public health. It is the vision the people from all aspects of the food manufacturing operation. This must be in place and unquestionable in order for the HACCP system to be successful. Prerequisite programs are also necessary to ensure that the HACCP system can succeed. Prerequisite programs make it possible to control the process.

The HACCP system is based on science, it is straightforward and logical and the controls are found in planning, controlling and documentation.

The HACCP system consists of five preliminary steps and seven principles:

Five Preliminary Steps

1. Assemble the HACCP team
2. Describe the Food and its distribution
3. Identify intended use and consumers of the food
4. Develop a Process Flow Diagram (PFD)
5. Verify the Process Flow Diagram

Table 4. Interrelated Nature of HACCP System Components

Component Name	**Main Topics**	**Comments**
HACCP Program	1. Food Safety mind set 2. Management commitment 3. Buy-in at all levels	From the top down, all levels of the operation need to understand and agree that food safety matters. Cooperation and assistance should be expected and provided at all levels.
Prerequisite Programs	1. Good Manufacturing Practices 2. Sanitation 3. Cross Contamination Prevention 4. Hand Washing 5. Proper Documentation 6. Maintenance Operations & Safety 7. Recall, Traceability & Hold/Release 8. Allergen controls 9. Food Defense programs 10. Education & Training	All prerequisite programs should be in place prior to establishing a HACCP plan. These programs form the basis of solid manufacturing practices so that together with a HACCP plan food safety will be achieved.
HACCP Plan	1. Preliminary Steps 2. Seven Principles of HACCP 3. Documentation, Forms, Verification, Monitoring activities 4. Validation of the HACCP plan	These are the written, tangible element of Plan.

Developing a HACCP team is critical to the success of the HACCP program

Seven Principles to HACCP

1. Conduct a Hazard Analysis (HA)
2. Determine the Critical Control Points (CCP)
3. Establish Critical Limits (CL)
4. Establish Monitoring Procedures
5. Establish Corrective Action (CA)
6. Establish Record-Keeping and Documentation Procedures
7. Establish verification procedures

These seven principles need to be well understood prior to developing a HACCP plan. Each of these principles will be discussed in detail later in this document.

In order to understand the principles of HACCP it is necessary to know why HACCP is more effective in preventing food safety issues. As stated earlier, prior to HACCP, the only safety system was inspection and correction. Inspection and correction is a detailed look at the plant operation that is designed to identify gaps, deficiencies or mistakes in the process. Inspection and correction is a snap shot of the process at a specific point in time. Because inspections are conducted on an infrequent basis the items that are discovered must be happening at a high rate in order to be detected. Finding a deficiency and correcting it does little to ensure that the problem does not reoccur. Inspections identify issues after they have occurred so product that was produced prior to finding the issues remains in question. On the other hand, HACCP corrects problems as they happen because the process is continually monitored and corrections are completed immediately. Monitoring and corrective action are two of the seven principles of HACCP. Acting in this way helps to lessen the amount of product that is out of specification. Inspections generally only discover food safety violations that are gross or have a high occurrence rate. Low levels problems that happen on a low frequency are not detected.

This results in the potential of producing product that will not meet the expectations of the customer.

In contrast, HACCP systems detect small variations in the process and continually keep the system in correct operational parameters. Additionally, HACCP food safety systems operate on continuous real-time control where the process has been evaluated, critical limits established, monitoring methods in place and corrective action is documented and easy to implement.

Food and Drug Administration HACCP Document

The following information (pages 97-135) is taken from the FDA web site on HACCP and examples of HACCP plans and documentation.

EXECUTIVE SUMMARY

The National Advisory Committee on Microbiological Criteria for Foods (Committee) reconvened a Hazard Analysis and Critical Control Point (HACCP) Working Group in 1995. The primary goal was to review the Committee's November 1992 HACCP document, comparing it to current HACCP guidance prepared by the Codex Committee on Food Hygiene. Based upon its review, the Committee made the HACCP principles more concise; revised and added definitions; included sections on prerequisite programs, education and training, and implementation and maintenance of the HACCP plan; revised and provided a more detailed explanation of the application of HACCP principles; and provided an additional decision tree for identifying critical control points (CCPs).

The Committee again endorses HACCP as an effective and rational means of assuring food safety from harvest to consumption. Preventing problems from occurring is the paramount goal underlying any HACCP system. Seven basic principles are employed in the development of HACCP plans that meet the stated goal. These principles include hazard analysis, CCP identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping and documentation. Under such systems, if a deviation occurs indicating that control has been lost, the deviation is detected and appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous products do not reach the consumer.

In the application of HACCP, the use of microbiological testing is seldom an effective means of monitoring CCPs because of the time required to obtain results. In most instances, monitoring of CCPs can best be accomplished through the use of physical and chemical tests, and through

visual observations. Microbiological criteria do, however, play a role in verifying that the overall HACCP system is working.

The Committee believes that the HACCP principles should be standardized to provide uniformity in training and applying the HACCP system by industry and government. In accordance with the National Academy of Sciences recommendation, the HACCP system must be developed by each food establishment and tailored to its individual product, processing and distribution conditions.

In keeping with the Committee's charge to provide recommendations to its sponsoring agencies regarding microbiological food safety issues, this document focuses on this area. The Committee recognizes that in order to assure food safety, properly designed HACCP systems must also consider chemical and physical hazards in addition to other biological hazards.

For a successful HACCP program to be properly implemented, management must be committed to a HACCP approach. A commitment by management will indicate an awareness of the benefits and costs of HACCP and include education and training of employees. Benefits, in addition to enhanced assurance of food safety, are better use of resources and timely response to problems.

The Committee designed this document to guide the food industry and advise its sponsoring agencies in the implementation of HACCP systems.

DEFINITIONS

CCP Decision Tree:

A sequence of questions to assist in determining whether a control point is a CCP.

Control:

(a) To manage the conditions of an operation to maintain compliance with established criteria.

(b) The state where correct procedures are being followed and criteria are being met.

Control Measure:

Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Control Point:

Any step at which biological, chemical, or physical factors can be controlled.

Corrective Action:

Procedures followed when a deviation occurs.

Criterion:

A requirement on which a judgement or decision can be based.

Critical Control Point:

A 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.

Critical Limit:

A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Deviation:

Failure to meet a critical limit.

HACCP:

A systematic approach to the identification, evaluation, and control of food safety hazards.

HACCP Plan:

The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP System:

The result of the implementation of the HACCP Plan.

HACCP Team:

The group of people who are responsible for developing, implementing and maintaining the HACCP system.

Hazard:

A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis:

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Monitor:

To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Prerequisite Programs:

Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Severity:

The seriousness of the effect(s) of a hazard.

Step:

A point, procedure, operation or stage in the food system from primary production to final consumption.

Validation:

That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification:

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

HACCP PRINCIPLES

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the critical control points (CCPs).

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

GUIDELINES FOR APPLICATION OF HACCP PRINCIPLES

Introduction

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement

and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Prerequisite programs such as current Good Manufacturing Practices (cGMPs) are an essential foundation for the development and implementation of successful HACCP plans. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the food industry around the world.

The following guidelines will facilitate the development and implementation of effective HACCP plans. While the specific application of HACCP to manufacturing facilities is emphasized here, these guidelines should be applied as appropriate to each segment of the food industry under consideration.

Prerequisite Programs

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Examples of common prerequisite programs are listed in Appendix A. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of cGMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide

the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Many of the conditions and practices are specified in federal, state and local regulations and guidelines (e.g., cGMPs and Food Code). The Codex Alimentarius General Principles of Food Hygiene describe the basic conditions and practices expected for foods intended for international trade. In addition to the requirements specified in regulations, industry often adopts policies and procedures that are specific to their operations. Many of these are proprietary. While prerequisite programs may impact upon the safety of a food, they also are concerned with ensuring that foods are wholesome and suitable for consumption (Appendix A). HACCP plans are narrower in scope, being limited to ensuring food is safe to consume.

The existence and effectiveness of prerequisite programs should be assessed during the design and implementation of each HACCP plan. All prerequisite programs should be documented and regularly audited. Prerequisite programs are established and managed separately from the HACCP plan. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP plan. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of a HACCP plan, the HACCP team may decide that the routine maintenance and calibration of an oven should be included in the plan as an activity of verification. This would further ensure that all the food in the oven is cooked to the minimum internal temperature that is necessary for food safety.

Education and Training

The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information the control of foodborne hazards related to all stages of the food chain. It is important to recognize

that employees must first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP.

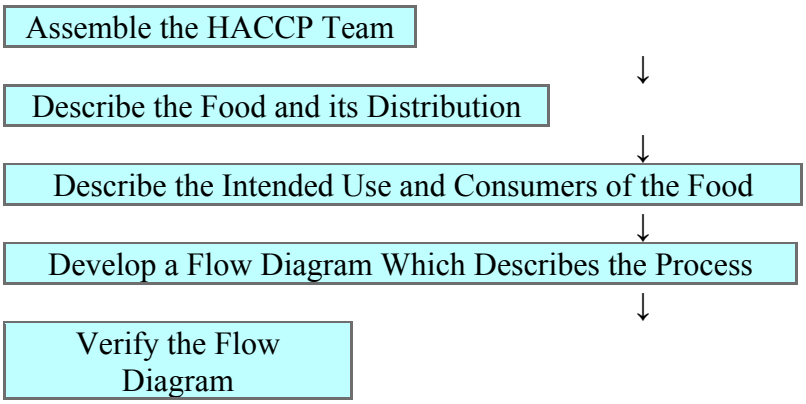
Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP plan.

Developing a HACCP Plan

The format of HACCP plans will vary. In many cases the plans will be product and process specific. However, some plans may use a unit operations approach. Generic HACCP plans can serve as useful guides in the development of process and product HACCP plans; however, it is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan.

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process. The five preliminary tasks are given in Figure 1.

Figure 1. Preliminary Tasks in the Development of the HACCP Plan



Assemble the HACCP Team

The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan. The team should be multi disciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation. In addition, this fosters a sense of ownership among those who must implement the plan. The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process. However, a plan which is developed totally by outside sources may be erroneous, incomplete, and lacking in support at the local level.

Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP plan. Such individuals should have the knowledge and experience to correctly: (a) conduct a hazard analysis; (b) identify potential hazards; (c) identify hazards which must be controlled; (d) recommend controls, critical limits, and procedures for monitoring and verification; (e) recommend appropriate corrective actions when a deviation occurs; (f) recommend research related to the HACCP plan if important information is not known; and (g) validate the HACCP plan.

Describe the food and its distribution

The HACCP team first describes the food. This consists of a general description of the food, ingredients, and processing methods. The method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient

temperature.

Describe the intended use and consumers of the food

Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immunocompromised individuals, the elderly, etc.).

Develop a flow diagram which describes the process

The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the establishment. The flow diagram need not be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive (see Appendix B). Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.

Verify the flow diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

After these five preliminary tasks have been completed, the seven principles of HACCP are applied.

Conduct a hazard analysis (Principle 1)

After addressing the preliminary tasks discussed above, the HACCP team conducts a hazard analysis and identifies appropriate control measures. The purpose of the hazard analysis is to develop a list of hazards which are of such significance that they are reasonably likely to cause

injury or illness if not effectively controlled. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns. A hazard is defined as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the word hazard as used in this document is limited to safety.

A thorough hazard analysis is the key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis and identification of associated control measures accomplish three objectives: Those hazards and associated control measures are identified. The analysis may identify needed modifications to a process or product so that product safety is further assured or improved. The analysis provides a basis for determining CCPs in Principle 2.

The process of conducting a hazard analysis involves two stages. The first, hazard identification, can be regarded as a brain storming session. During this stage, the HACCP team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. Based on this review, the team develops a list of potential biological, chemical or physical hazards which may be introduced, increased, or controlled at each step in the production process. Appendix C lists examples of questions that may be helpful to consider when identifying potential hazards. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation.

A knowledge of any adverse health-related events historically associated with the product will be of value in this exercise.

After the list of potential hazards is assembled, stage two, the hazard evaluation, is conducted. In stage two of the hazard analysis, the HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of sequelae, and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. In addition, consideration should be given to the effects of short term as well as long term exposure to the potential hazard. Such considerations do not include common dietary choices which lie outside of HACCP. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled. The team must consider the influence of likely procedures for food preparation and storage and whether the intended consumers are susceptible to a potential hazard. However, there may be differences of opinion, even among experts, as to the likely occurrence and severity of a hazard. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan.

Hazards identified in one operation or facility may not be significant in another operation

producing the same or a similar product. For example, due to differences in equipment and/or an effective maintenance program, the probability of metal contamination may be significant in one facility but not in another. A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during future reviews and updates of the hazard analysis and the HACCP plan.

Appendix D gives three examples of using a logic sequence in conducting a hazard analysis. While these examples relate to biological hazards, chemical and physical hazards are equally important to consider. Appendix D is for illustration purposes to further explain the stages of hazard analysis for identifying hazards. Hazard identification and evaluation as outlined in Appendix D may eventually be assisted by biological risk assessments as they become available. While the process and output of a risk assessment (NACMCF, 1997)(1) is significantly different from a hazard analysis, the identification of hazards of concern and the hazard evaluation may be facilitated by information from risk assessments. Thus, as risk assessments addressing specific hazards or control factors become available, the HACCP team should take these into consideration.

Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure (e.g. pasteurization of milk).

For example, if a HACCP team were to conduct a hazard analysis for the production of frozen cooked beef patties (Appendices B and D), enteric pathogens (e.g., *Salmonella* and verotoxin-

producing *Escherichia coli*) in the raw meat would be identified as hazards. Cooking is a control measure which can be used to eliminate these hazards. The following is an excerpt from a hazard analysis summary table for this product.

Step	**Potential Hazard(s)**	**Justification**	**Hazard to be addressed in plan? Y/N**	**Control Measure(s)**
5. Cooking	Enteric pathogens: e.g., *Salmonella*, verotoxigenic-*E. coli*	enteric pathogens have been associated with outbreaks of foodborne illness from undercooked ground beef	Y	Cooking

The hazard analysis summary could be presented in several different ways. One format is a table such as the one given above. Another could be a narrative summary of the HACCP team's hazard analysis considerations and a summary table listing only the hazards and associated control measures.

Determine critical control points (CCPs) (Principle 2)

A critical control point is defined as a 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. The potential hazards that are reasonably likely to cause illness or injury in the absence of their control must be addressed in determining CCPs.

Complete and accurate identification of CCPs is fundamental to controlling food safety hazards. The information developed during the hazard analysis is essential for the HACCP team in identifying which steps in the process are CCPs. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree (Examples of decision trees are given in Appendices E and F). Although application of the CCP decision tree can be useful in determining if a

particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. A CCP decision tree is not a substitute for expert knowledge.

Critical control points are located at any step where hazards can be either prevented, eliminated, or reduced to acceptable levels. Examples of CCPs may include: thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of a food to a pH necessary to prevent toxin formation could also be CCPs. Different facilities preparing similar food items can differ in the hazards identified and the steps which are CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, processes employed, etc.

Establish critical limits (Principle 3)

A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical limits should not be confused with operational limits which are established for reasons other than food safety.

Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limits may be based upon factors such as: temperature, time, physical dimensions, humidity, moisture level, water activity (aw), pH, titratable acidity, salt

concentration, available chlorine, viscosity, preservatives, or sensory information such as aroma and visual appearance. Critical limits must be scientifically based. For each CCP, there is at least one criterion for food safety that is to be met. An example of a criterion is a specific lethality of a cooking process such as a 5D reduction in *Salmonella*. The critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and experts.

An example is the cooking of beef patties (Appendix B). The process should be designed to ensure the production of a safe product. The hazard analysis for cooked meat patties identified enteric pathogens (e.g., verotoxigenic *E. coli* such as *E. coli* O157:H7, and salmonellae) as significant biological hazards. Furthermore, cooking is the step in the process at which control can be applied to reduce the enteric pathogens to an acceptable level. To ensure that an acceptable level is consistently achieved, accurate information is needed on the probable number of the pathogens in the raw patties, their heat resistance, the factors that influence the heating of the patties, and the area of the patty which heats the slowest. Collectively, this information forms the scientific basis for the critical limits that are established. Some of the factors that may affect the thermal destruction of enteric pathogens are listed in the following table. In this example, the HACCP team concluded that a thermal process equivalent to 155° F for 16 seconds would be necessary to assure the safety of this product. To ensure that this time and temperature are attained, the HACCP team for one facility determined that it would be necessary to establish critical limits for the oven temperature and humidity, belt speed (time in oven), patty thickness and composition (e.g., all beef, beef and other ingredients). Control of these factors enables the facility to produce a wide variety of cooked patties, all of which will be processed to a minimum internal temperature of 155° F for 16 seconds. In another facility, the HACCP team may

conclude that the best approach is to use the internal patty temperature of 155° F and hold for 16 seconds as critical limits. In this second facility the internal temperature and hold time of the patties are monitored at a frequency to ensure that the critical limits are constantly met as they exit the oven. The example given below applies to the first facility.

Process Step	CCP	Critical Limits
5. Cooking	YES	Oven temperature:___° F Time; rate of heating and cooling (belt speed in ft/min): ____ft/min Patty thickness: ____in. Patty composition: e.g. all beef Oven humidity: ____% RH

Establish monitoring procedures (Principle 4)

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Monitoring serves three main purposes. First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is loss of control and a deviation occurs at a CCP, i.e., exceeding or not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken. Third, it provides written documentation for use in verification.

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical limit deviation, monitoring procedures must be effective. Ideally, monitoring should be continuous, which is possible with many types of physical and chemical methods. For example, the temperature and time for the scheduled thermal process of low-acid canned foods is recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on

the chart, the product from the retort is retained and the disposition determined as in Principle 5. Likewise, pH measurement may be performed continually in fluids or by testing each batch before processing. There are many ways to monitor critical limits on a continuous or batch basis and record the data on charts. Continuous monitoring is always preferred when feasible. Monitoring equipment must be carefully calibrated for accuracy.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs are often associated with production (e.g., line supervisors, selected line workers and maintenance personnel) and, as required, quality control personnel. Those individuals must be trained in the monitoring technique for which they are responsible, fully understand the purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the results of monitoring. In addition, employees should be trained in procedures to follow when there is a trend towards loss of control so that adjustments can be made in a timely manner to assure that the process remains under control. The person responsible for monitoring must also immediately report a process or product that does not meet critical limits.

All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring.

When it is not possible to monitor a CCP on a continuous basis, it is necessary to establish a monitoring frequency and procedure that will be reliable enough to indicate that the CCP is under control. Statistically designed data collection or sampling systems lend themselves to this purpose.

Most monitoring procedures need to be rapid because they relate to on-line, "real-time"

processes and there will not be time for lengthy analytical testing. Examples of monitoring activities include: visual observations and measurement of temperature, time, pH, and moisture level.

Microbiological tests are seldom effective for monitoring due to their time-consuming nature and problems with assuring detection of contaminants. Physical and chemical measurements are often preferred because they are rapid and usually more effective for assuring control of microbiological hazards. For example, the safety of pasteurized milk is based upon measurements of time and temperature of heating rather than testing the heated milk to assure the absence of surviving pathogens.

With certain foods, processes, ingredients, or imports, there may be no alternative to microbiological testing. However, it is important to recognize that a sampling protocol that is adequate to reliably detect low levels of pathogens is seldom possible because of the large number of samples needed. This sampling limitation could result in a false sense of security by those who use an inadequate sampling protocol. In addition, there are technical limitations in many laboratory procedures for detecting and quantitating pathogens and/or their toxins.

Establish corrective actions (Principle 5)

The HACCP system for food safety management is designed to identify health hazards and to establish strategies to prevent, eliminate, or reduce their occurrence. However, ideal circumstances do not always prevail and deviations from established processes may occur. An important purpose of corrective actions is to prevent foods which may be hazardous from reaching consumers. Where there is a deviation from established critical limits, corrective actions are necessary. Therefore, corrective actions should include the following elements: (a) determine and correct the cause of non-compliance; (b) determine the disposition of non-compliant product

and (c) record the corrective actions that have been taken. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken. Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Establish verification procedures (Principle 6)

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The NAS (1985) (2) pointed out that the major infusion of science in a HACCP system centers on proper identification of the hazards, critical control points, critical limits, and instituting proper verification procedures. These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system. An example of a verification schedule is given in Figure 2.

One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end-product testing, since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records.

Another important aspect of verification is the initial validation of the HACCP plan to determine

that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Information needed to validate the HACCP plan often include (1) expert advice and scientific studies and (2) in-plant observations, measurements, and evaluations. For example, validation of the cooking process for beef patties should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty.

Subsequent validations are performed and documented by a HACCP team or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized.

In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the HACCP plan is resulting in the control of the hazards. If the results of the comprehensive verification identifies deficiencies, the HACCP team modifies the HACCP plan as necessary.

Verification activities are carried out by individuals within a company, third party experts, and regulatory agencies. It is important that individuals doing verification have appropriate technical expertise to perform this function. The role of regulatory and industry in HACCP was further

described by the NACMCF (1994) (3).

Examples of verification activities are included as Appendix G.

Figure 2. Example of a Company Established HACCP Verification Schedule

Activity	Frequency	Responsibility	Reviewer
Verification Activities Scheduling	Yearly or Upon HACCP System Change	HACCP Coordinator	Plant Manager
Initial Validation of HACCP Plan	Prior to and During Initial Implementation of Plan	Independent Expert(s)(a)	HACCP Team
Subsequent validation of HACCP Plan	When Critical Limits Changed, Significant Changes in Process, Equipment Changed, After System Failure, etc.	Independent Expert(s)(a)	HACCP Team
Verification of CCP Monitoring as Described in the Plan (e.g., monitoring of patty cooking temperature)	According to HACCP Plan (e.g., once per shift)	According to HACCP Plan (e.g., Line Supervisor)	According to HACCP Plan (e.g., Quality Control)
Review of Monitoring, Corrective Action Records to Show Compliance with the Plan	Monthly	Quality Assurance	HACCP Team
Comprehensive HACCP System Verification	Yearly	Independent Expert(s)(a)	Plant Manager
(a) Done by others than the team writing and implementing the plan. May require additional technical expertise as well as laboratory and plant test studies.			

Establish record-keeping and documentation procedures (Principle 7)
Generally, the records maintained for the HACCP System should include the following:

A summary of the hazard analysis, including the rationale for determining hazards and control measures.

The HACCP Plan Listing of the HACCP team and assigned responsibilities. Description of the food, its distribution, intended use, and consumer. Verified flow diagram. HACCP Plan Summary Table that includes information for: Steps in the process that are CCPs The hazard(s) of concern. Critical limits Monitoring* Corrective actions* Verification procedures and schedule* Record-keeping procedures* * A brief

summary of position responsible for performing the activity and the procedures and frequency should be provided The following is an example of a HACCP plan summary table:

CCP	Hazards	Critical limit(s)	Monitoring	Corrective Actions	Verification	Records

Support documentation such as validation records.

Records that are generated during the operation of the plan.

Examples of HACCP records are given in Appendix H.

IMPLEMENTATION AND MAINTENANCE OF THE HACCP PLAN

The successful implementation of a HACCP plan is facilitated by commitment from top management. The next step is to establish a plan that describes the individuals responsible for developing, implementing and maintaining the HACCP system. Initially, the HACCP coordinator and team are selected and trained as necessary. The team is then responsible for developing the initial plan and coordinating its implementation. Product teams can be appointed to develop HACCP plans for specific products. An important aspect in developing these teams is to assure that they have appropriate training. The workers who will be responsible for monitoring need to be adequately trained. Upon completion of the HACCP plan, operator procedures, forms and procedures for monitoring and corrective action are developed. Often it is a good idea to develop a timeline for the activities involved in the initial implementation of the HACCP plan.

Implementation of the HACCP system involves the continual application of the monitoring, record-keeping, corrective action procedures and other activities as described in the HACCP plan.

Maintaining an effective HACCP system depends largely on regularly scheduled verification activities. The HACCP plan should be updated and revised as needed. An important aspect of maintaining the HACCP system is to assure that all individuals involved are properly trained so they understand their role and can effectively fulfill their responsibilities.

(1) National Advisory Committee on Microbiological Criteria for Foods. 1997. The principles of risk assessment for illness caused by foodborne biological agents. Adopted April 4, 1997.

(2) An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. 1985. National Academy of Sciences, National Academy Press, Washington, DC.

(3) National Advisory Committee on Microbiological Criteria for Foods. 1994. The role of regulatory agencies and industry in HACCP. Int. J. Food Microbiol. 21:187-195.

APPENDIX A

Examples of Common Prerequisite Programs

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of cGMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Common prerequisite programs may

include, but are not limited to:

Facilities.

The establishment should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials.

Supplier Control.

Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.

Specifications.

There should be written specifications for all ingredients, products, and packaging materials.

Production Equipment.

All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.

Cleaning and Sanitation.

All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.

Personal Hygiene.

All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.

Training.

All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

Chemical Control.

Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.

Receiving, Storage and Shipping.

All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness.

Traceability and Recall.

All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

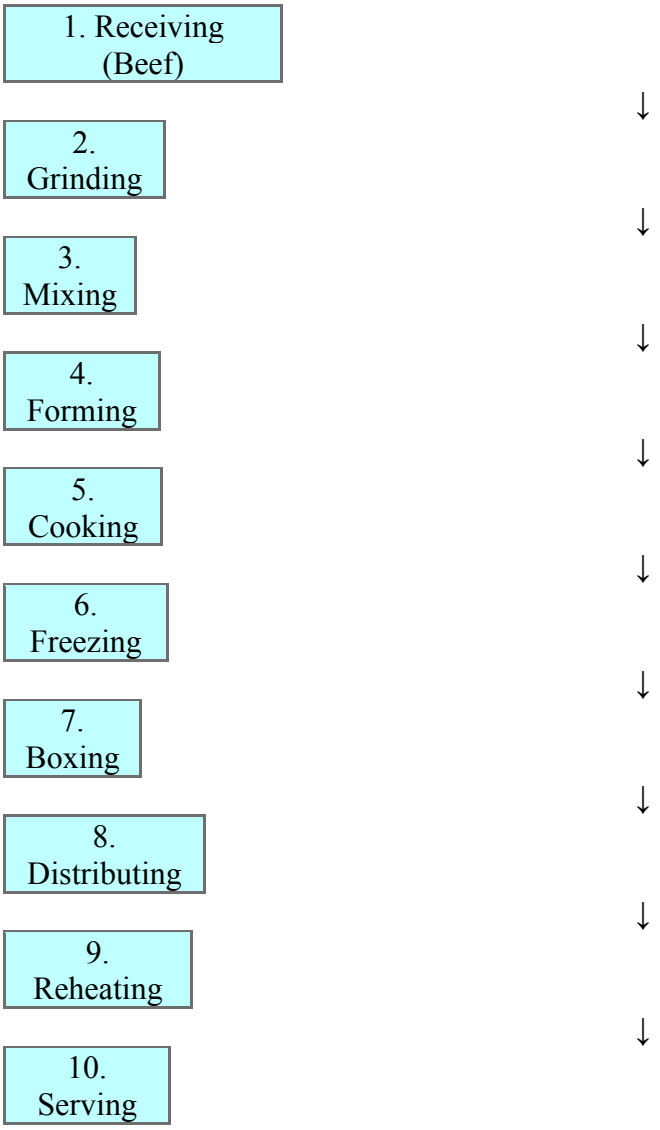
Pest Control.

Effective pest control programs should be in place.

Other examples of prerequisite programs might include quality assurance procedures; standard operating procedures for sanitation, processes, product formulations and recipes; glass control; procedures for receiving, storage and shipping; labeling; and employee food and ingredient handling practices.

APPENDIX B

Example of a Flow Diagram for the Production of Frozen Cooked Beef Patties



APPENDIX C

Examples of Questions to be Considered When Conducting a Hazard Analysis

The hazard analysis consists of asking a series of questions, which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

Ingredients

Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?

Are potable water, ice and steam used in formulating or in handling the food?

What are the sources (e.g., geographical region, specific supplier)

Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.

What hazards may result if the food composition is not controlled?

Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?

Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?

Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

Procedures used for processing

Does the process include a controllable processing step that destroys pathogens?

If so, which pathogens? Consider both vegetative cells and spores.

If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?

Microbial content of the food

What is the normal microbial content of the food?

Does the microbial population change during the normal time the food is stored prior to consumption?

Does the subsequent change in microbial population alter the safety of the food?

Do the answers to the above questions indicate a high likelihood of certain biological hazards?

Facility design

Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?

Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

Is the traffic pattern for people and moving equipment a significant source of contamination?

Equipment design and use

Will the equipment provide the time-temperature control that is necessary for safe food?

Is the equipment properly sized for the volume of food that will be processed?

Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

Is the equipment reliable or is it prone to frequent breakdowns?

Is the equipment designed so that it can be easily cleaned and sanitized?

Is there a chance for product contamination with hazardous substances; e.g., glass?

What product safety devices are used to enhance consumer safety?

- metal detectors
- magnets
- sifters
- filters
- screens
- thermometers
- bone removal devices
- dud detectors

To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?

Are allergen protocols needed in using equipment for different products?

Packaging

Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

Is the package clearly labeled "Keep Refrigerated" if this is required for safety?

Does the package include instructions for the safe handling and preparation of the

food by the end user?

Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?

Are tamper-evident packaging features used?

Is each package and case legibly and accurately coded?

Does each package contain the proper label?

Are potential allergens in the ingredients included in the list of ingredients on the label?

Sanitation

Can sanitation have an impact upon the safety of the food that is being processed?

Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?

Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

Employee health, hygiene and education

Can employee health or personal hygiene practices impact upon the safety of the food being processed?

Do the employees understand the process and the factors they must control to assure the preparation of safe foods?

Will the employees inform management of a problem which could impact upon safety of food?

Conditions of storage between packaging and the end user

What is the likelihood that the food will be improperly stored at the wrong

temperature?

Would an error in improper storage lead to a microbiologically unsafe food?

Intended use

Will the consumer heat the food?

Will there likely be leftovers?

Intended consumer

Is the food intended for the general public?

Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?

Is the food to be used for institutional feeding or the home?

APPENDIX D

Examples of How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards*				
Hazard Analysis Stage		Frozen cooked beef patties produced in a manufacturing plant	Product containing eggs prepared for foodservice	Commercial frozen pre-cooked, boned chicken for further processing
Stage 1 *Determine potential* Hazard *hazards associated* Identification *with product*		Enteric pathogens (i.e., E. coli O157:H7 and Salmonella)	Salmonella in finished product.	Staphylococcus aureus in finished product.
Stage 2 Hazard Evaluation	*Assess severity of health consequences if potential hazard is not properly controlled*.	Epidemiological evidence indicates that these pathogens cause severe health effects including death among children and elderly. Undercooked beef patties have been linked to disease from these pathogens.	Salmonellosis is a food borne infection causing a moderate to severe illness that can be caused by ingestion of only a few cells of Salmonella.	Certain strains of S. aureus produce an enterotoxin, which can cause a moderate foodborne illness.
	Determine likelihood of occurrence of potential hazard if not properly controlled.	E. coli O157:H7 is of very low probability and salmonellae is of moderate probability in raw meat.	Product is made with liquid eggs which have been associated with past outbreaks of salmonellosis. Recent problems with Salmonella serotype Enteritidis in eggs cause increased concern. Probability of Salmonella in raw eggs cannot be ruled out. If not effectively controlled, some consumers are likely to be exposed to Salmonella from this food.	Product may be contaminated with S. aureus due to human handling during boning of cooked chicken. Enterotoxin capable of causing illness will only occur as S. aureus multiplies to about 1,000,000/g. Operating procedures during boning and subsequent freezing prevent growth of S. aureus, thus the potential for enterotoxin formation is very low.
	Using information above, determine if this potential hazard is to be addressed in the HACCP plan.	The HACCP team decides that enteric pathogens are hazards for this product. **Hazards must be addressed in the plan.**	HACCP team determines that if the potential hazard is not properly controlled, consumption of product is likely to result in an unacceptable health risk. **Hazard must be addressed in the plan.**	The HACCP team determines that the potential for enterotoxin formation is very low. However, it is still desirable to keep the initial number of S. aureus organisms low. Employee practices that minimize contamination, rapid carbon dioxide freezing and handling instructions have been adequate to control this potential hazard. **Potential hazard does not need to be addressed in plan.**
* For illustrative purposes only. The potential hazards identified may not be the only hazards associated with the products listed. The responses may be different for different establishments.				

APPENDIX E

Example I of a CCP Decision Tree

Important considerations when using the decision tree:

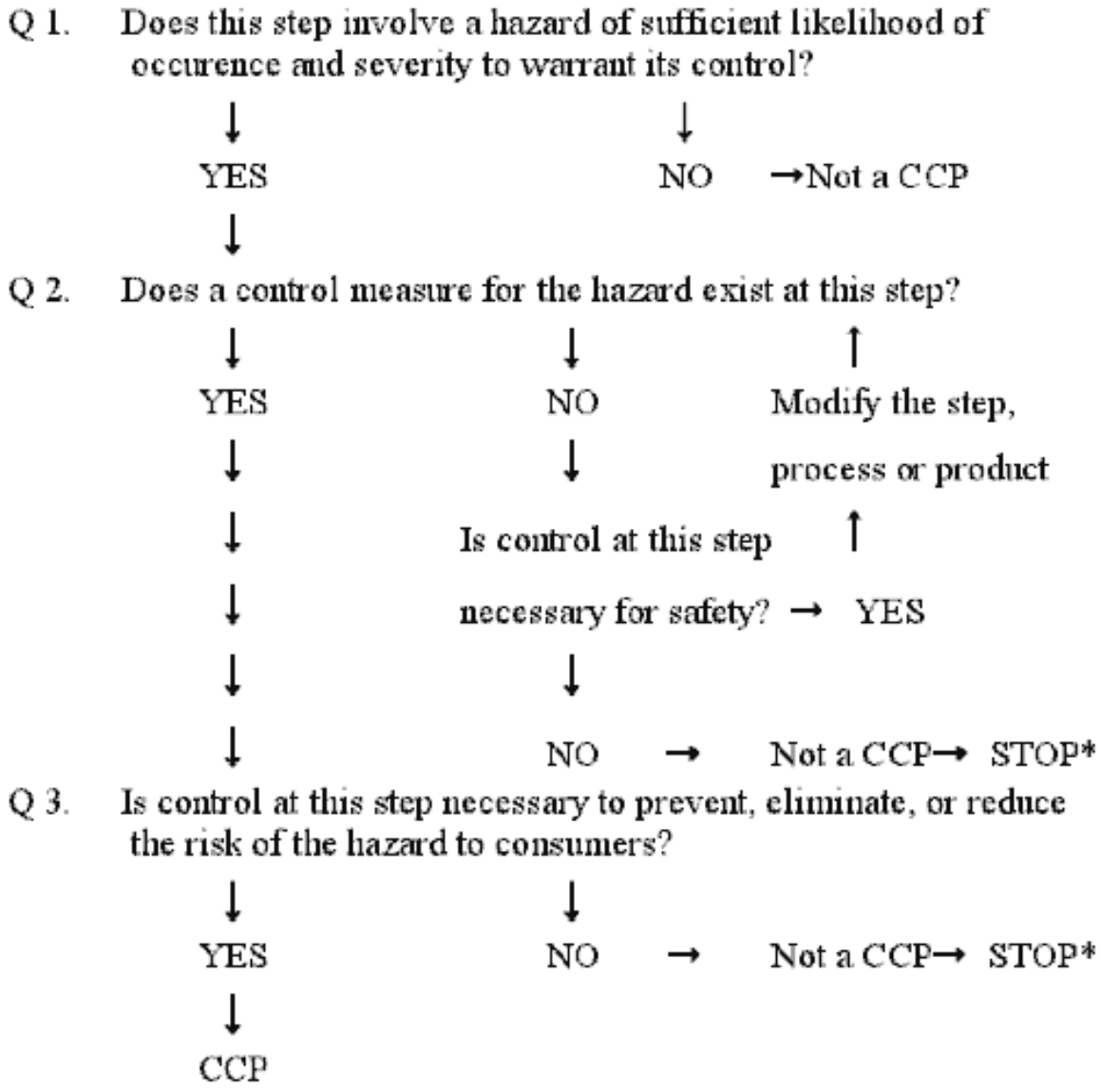
The decision tree is used after the hazard analysis.

The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan has been identified.

A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.

More than one step in a process may be involved in controlling a hazard.

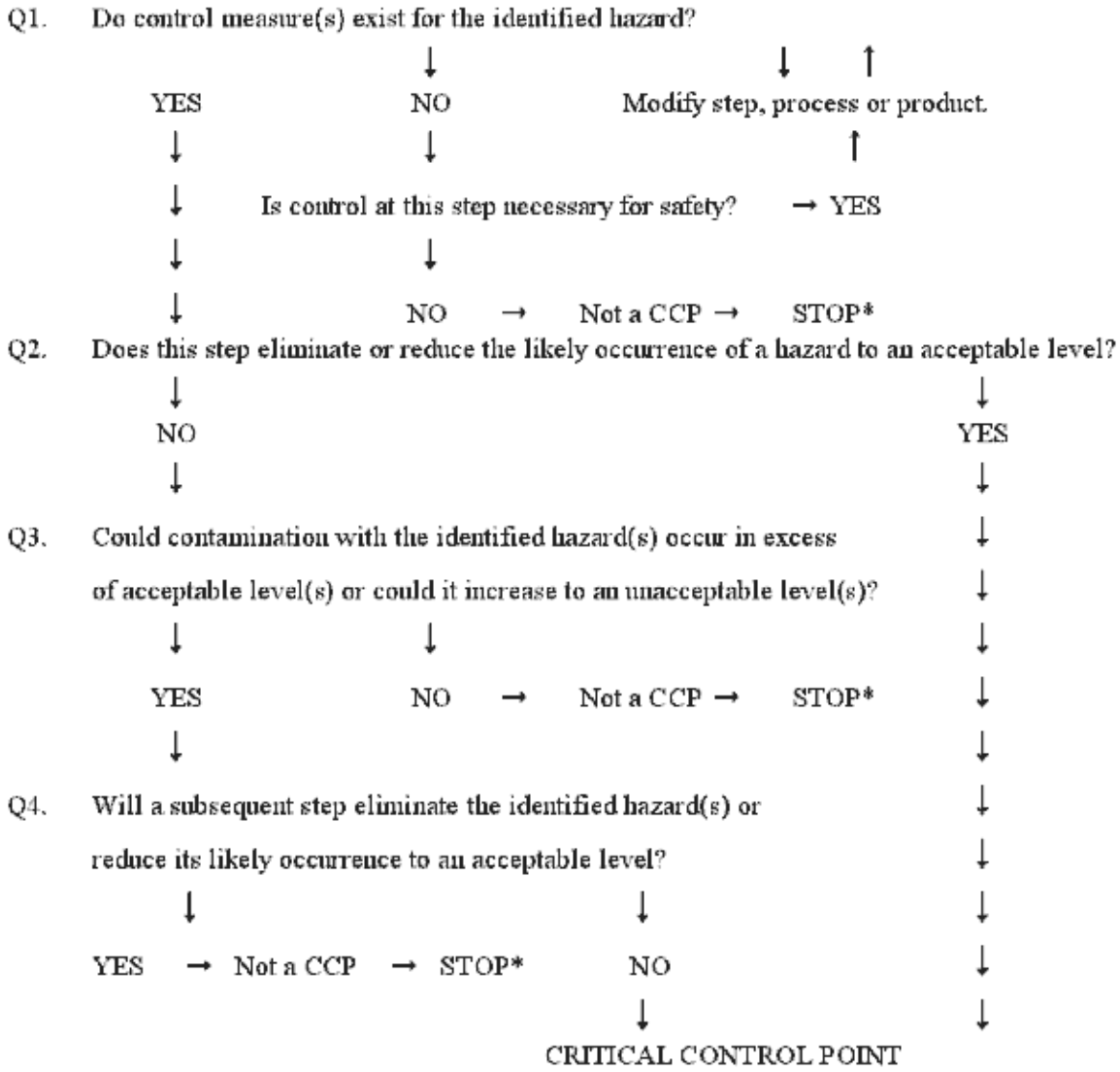
More than one hazard may be controlled by a specific control measure.



* Proceed to next step in the process.

APPENDIX F

Example II of a CCP Decision Tree



*Proceed to next step in the described process

APPENDIX G

Examples of Verification Activities

Verification procedures may include:

- Establishment of appropriate verification schedules.
- Review of the HACCP plan for completeness.
- Confirmation of the accuracy of the flow diagram.
- Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
- Review of CCP monitoring records.
- Review of records for deviations and corrective actions.
- Validation of critical limits to confirm that they are adequate to control significant hazards.
- Validation of HACCP plan, including on-site review.
- Review of modifications of the HACCP plan.
- Sampling and testing to verify CCPs.

Verification should be conducted:

- Routinely, or on an unannounced basis, to assure CCPs are under control.
- When there are emerging concerns about the safety of the product.
- When foods have been implicated as a vehicle of foodborne disease.
- To confirm that changes have been implemented correctly after a HACCP plan has been modified.
- To assess whether a HACCP plan should be modified due to a change in the process, equipment, ingredients, etc.

Verification reports may include information on the presence and adequacy of.

The HACCP plan and the person(s) responsible for administering and updating the HACCP plan.

The records associated with CCP monitoring.

Direct recording of monitoring data of the CCP while in operation.

Certification that monitoring equipment is properly calibrated and in working order.

Corrective actions for deviations.

Sampling and testing methods used to verify that CCPs are under control.

Modifications to the HACCP plan.

Training and knowledge of individuals responsible for monitoring CCPs.

Validation activities.

APPENDIX H

Examples of HACCP Records

Ingredients for which critical limits have been established.

Supplier certification records documenting compliance of an ingredient with a critical limit.

Processor audit records verifying supplier compliance.

Storage records (e.g., time, temperature) for when ingredient storage is a CCP.

Processing, storage and distribution records

Information that establishes the efficacy of a CCP to maintain product safety.

Data establishing the safe shelf life of the product; if age of product can affect safety.

Records indicating compliance with critical limits when packaging materials, labeling or sealing specifications are necessary for food safety.

Monitoring records.

Verification records.

Deviation and corrective action records.

Employee training records that are pertinent to CCPs and the HACCP plan.

Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert.

APPENDIX C

PROPOSED OUTLINE FOR FOOD SAFETY HANDBOOK FOR ARTISINAL CHEESE MAKERS

1. Introduction
2. Section I Cheese and its History
    a. Chapter 1 – Cheese, What is it really?
        i. Basic process of making cheese
        ii. Code of Federal Regulations
        iii. Classes of Cheese
        iv. Specialty Cheese
    b. Chapter 2 – History of Cheese
        i. Accidentally discovered
        ii. Evolved based on location
        iii. Modern Cheeses
        iv. Back to artisan cheese
3. Section II – Regulatory Requirements
    a. Chapter 3 – History of Food Regulation in the US
        i. Early to mid-1800s
        ii. Mid to Late-1800s
        iii. Early 1900s
        iv. 1906 – 1938
        v. 1938 – Present
    b. Chapter 4 – Good Manufacturing Practices
        i. History of GMPs
        ii. GMPs
        iii. GMP Information and Training
        iv. Cross Contamination & Hand Washing
        v. Documentation
            1. Traceability and Recall
            2. Production Documentation
            3. Questionable Product Handling
        vi. Maintenance for Food Safety
    c. Chapter 5 – Food Safety Modernization Act of 2011
        i. New Powers
        ii. Greater Authority
        iii. Increased Access
        iv. Time-stamped Inspections
        v.
4. Section III – Physical Contamination of Cheese
    a. Chapter 6 – Physical

i. Metal
ii. Glass
iii. Plastic
iv. Wood
v. Debris

b. Chapter 7 – Chemical
i. Cleaning Supplies
ii. Non-Labeled Ingredients
iii. Greases & Oils
iv. Allergen Controls

c. Chapter 8 – Bacterial
i. Microbial Basics
1. Control Methods
a. Time and Temperature
b. Moisture
c. Sanitation
d. pH
e. Restriction of Travel
2. Specific Pathogens
a. Clostridium botulinum
b. Clostridium perfringens
c. Escherichia coli (E. coli)
d. Listeria monocytogenes
e. Salmonella spp.
3. Staphylococcus aureus

5. Section IV – Food Safety Control Measures
a. Chapter 9 – Pathogen Control Program
i. Separate Raw from Ready To Eat
ii. Follow all GMPs
iii. Controlled Floor Conditions
iv. Sanitary Design of Building & Equipment
v. Effective Sanitation Procedures and Controls
vi. Environmental Monitoring

b. Chapter 10 – Sanitation
i. The Big Picture of Sanitation
ii. Master Sanitation Cleaning Schedules
iii. Color Coding Systems
iv. Sanitation Standard Operating Procedures (SSOP)
v. Cleaning of Dairy Processing Equipment
1. Aspects of Cleaning
2. Cleaning Objectives
3. Cleaning Chemistry
4. Cleaning Procedures
5. Sanitizing Procedures
6. Modes of Chemical Application
7. Summary

c. Chapter 11 – A Food Safety/Quality Principles Approach
6. Section V – Principles of Sanitary Design
    a. Chapter 12 – Sanitary Design in the Facility
        i. Building/facility
            1. Hygienic Zones
            2. Personnel & Material Flow Controlled
            3. Standing Water Controlled
            4. Air Movement & Air Quality
            5. Site Elements
            6. Interior Spatial Design
            7. Building Components & Construction
            8. Utility Systems
            9. Sanitation Integrated
        ii. Food Defense Security Measures
            1. Outside
            2. Inside
            3. Personnel
            4. Incident Response
    b. Chapter 13 – Sanitary Design in the Equipment
        i. Thinking Outside the Pipe
            1. Microbiologically Cleanable
            2. Compatible Materials
            3. Accessible for Inspection, Cleaning & Maintenance
            4. No Liquid Collection
            5. Hollow areas Avoided or Sealed
            6. No Niches
            7. Sanitary Operational Performance (Running Clean)
            8. Hygienic Design of Enclosures
            9. Hygienic Compatibility with Other Systems
            10. Validated Cleaning & Sanitation Protocols
7. Section VI – Concluding Chapters
    a. Chapter 14 – Food Safety In Perspective
        i. Graph of deaths by reason
    b. Chapter 15 – Case Study
        i. Kenny's Farmhouse Cheese

Appendix

Glossary of Terms

Hazard Analysis Critical Control Points