Creating a Food Safety Plan

HACCP Principles

So our learning objectives are to discuss the regulatory requirements of a written food safety plan in B.C.; we'll discuss the benefits associated with implementing a HACCP plan, and apply the principles of HACCP to a food process. And then we hope to have an opportunity to discuss some of the challenges that environmental health officers might observe when inspecting food plants that have food safety plans.

Codex is the published document that we refer to and codex has seven principles of HACCP that many of you are probably familiar with. In the BC food premise regulations we only are responsible for implementing the first five principles that you see there, which are:

- Identifying hazards
- Establishing critical control points
- Establishing critical limits
- Establishing our monitoring procedures and
- Establishing corrective actions

Although the regulations don't require us to implement verification procedures and record-keeping, we will discuss them today so that you understand the complete seven principles.

So why do we implement a food safety plan? Our number one reason of course is to meet regulatory requirements. And by virtue of that, it does help us to produce safe food. Most companies, when they implement a HACCP plan, observe improved operations, improved quality, reduction of rework, production efficiencies, and hopefully less likelihood of a recall. And when a consumer recognizes that you are using HACCP principles, it improves your reputation, and overall we can ensure customer satisfaction.

So what is HACCP? And I always like to point out that the acronym is HACCP and it’s Hazard Analysis *and* Critical Control Point, so that you keep in mind that it's a two-part program, where first we are identifying all hazards in our process and then determining how we're going to control the hazards: whether we can prevent them from occurring, or do we need to operate at that process step operating it as a critical control point? HACCP is a very systematic process. We follow through those seven principles, we complete the forms, so it's a systematic way to prevent food safety hazards from occurring in your production process.

There’re two elements to our HACCP program. So we have our HACCP` documentation, which is process-related. And we're looking at the hazards associated with the process steps. And then we have our HACCP prerequisite programs. You may have heard the term “good manufacturing practice,” “preventive controls,” or “prerequisite programs.” They're really fundamentally the same. It's just the methods that we use to prevent hazards from occurring. And we'll take a look at those.

The current regulations do not require food companies to prepare complete prerequisite programs, but as they move up in their HACCP implementation activities, they will likely develop more detailed prerequisite programs. But we'll just take a brief look at what's involved in the prerequisite programs. So there's up to 11 prerequisite programs depending on how you categorize them.

But their overall goal is to ensure that you have a clean working environment and they emphasize good manufacturing practices, which are the behaviors that we have learned over time to prevent food safety hazards. Good manufacturing practices, a term we use a lot—a simple example of a good manufacturing practices, is things like in production facilities, we've learned to cove walls so that it's not a right angle between the floor and the wall, so that it's easier to clean. Or we teach people personal hygiene-type activities. And all of these things will help us to prevent hazards.

So there's 11 prerequisite programs that are generally listed, and we'll go through them in a minute but I'd first like to give you a little history of how prerequisite programs have come about. So we'll look at that list of 11 prerequisite programs in a moment.

I put up this slide to show you that good manufacturing practices and the development of prerequisite programs, it's really nothing new. This is an old quality control textbook from 1966. And this Kramer and Twigg book is still used. There's been further editions, but there's a statement here of the responsibilities of the quality control department. If you look at the list, you can see how many of those things like inspection of raw products, sanitation procedures, shipping and storage controls—these have just been morphed into the structure of the prerequisite programs that we use today.

I also like to point out some of the reasons why these have come about by showing you this book, *The Jungle*, that was written by Upton Sinclair in 1906. He was a journalist. And he got a job in a packing plant in Chicago, which was the hub of meat packing in the early 1900s. And he wrote this book, *The Jungle*, and it was a stomach-turning expose of unsanitary conditions and deceitful practices. It really was meant to be the story of the immigrant class and how poorly they were treated when they came to North America and were working in these food processing plants. But when the book was published, there was such a public outcry of the things he talked about that were going on in the food plant, that the United States passed their Pure Food and Drug Act, which is the beginning of the Food and Drug Act that we know today.

So just a couple of examples to get us going on good manufacturing practices and preventive controls. Here's an example from the book:

> "These rats were nuisances and the package would put poisoned bread out for them. They would die. And then rats, bread and meat would go into the hopper together."

So of course, today we have pest control programs and usually an outside pest control company will come in and deal with our pest issues on a routine basis.

> "There was no place for the men to wash their hands before they ate their dinner. So they made a practice of washing them in the water that was to be ladled into the sausage."

So of course, today we have a regulation indicating that we need to have a sufficient number of appropriately stocked hand wash stations for people to use.

> "Under the rigid system of economy which the packers enforced, there were some jobs that it only paid to do once in a long time. And among these was the cleaning of the waste barrels. Every spring they did it and in the barrels would be dirt and rust and old nails and stale water. And cartload after cartload of it would be taken up and dumped into the hoppers with fresh meat and sent out to the public's breakfast."

So of course, today we have scheduled preventive maintenance programs and sanitation tasks that we do.

And then finally, just as an interesting one with respect to adulteration, of course something that we shouldn't do in the food industry, some of the products:

> "...They would make into smoked sausage, but as the smoking took time and was expensive they would call upon their chemistry department and preserve it with borax and color with gelatin to make it brown."

So it's a good book. If you ever have the opportunity to read it, it's kind of a real eye-opener of the situation in meat packing plants at the turn of the previous century.

HACCP Prerequisite Programs

Although they're not a requirement of the written food safety plan, companies will have some level of implementation. So we'll just take a moment to take a brief look at what's involved in each prerequisite program. And remember by establishing these, we are developing practices that are implemented throughout the entire facility to prevent food safety hazards. The first one is premises. And when you're thinking of premises, think of an empty building and its location and suitability for being a facility where you process food. So we're evaluating our floors, walls, ceilings, the lighting, the HVAC system, and interior and exterior surroundings of the building, and determining that it is a suitable place to make food.

The next program, transportation and storage is where we evaluate our incoming materials and then how they're handled throughout the facility. So we'll be taking a look at storage of incoming materials, storage of work in progress and then how we handle our finished products through distribution. Also, within that program is where we monitor the temperatures of our freezers and coolers. So you can see that it's to ensure that our input materials and finished products are handled properly. Part of that is having a purchasing and supplier program. And when you start buying your inputs, you will approve some suppliers and buy your ingredients only from approved suppliers. And part of that program would be to get documentation such as specification sheets from your suppliers about the input you're purchasing.

Our input program, or our raw material program also has a large component of allergen control. So we need to be aware of what allergens we're bringing into our facility, whether the ingredient itself is an allergen, or ensuring that we look at the specification sheets of our incoming materials to see if any of the ingredients of our ingredients have allergens. So you need to look at component ingredients of the ingredients you purchase as well. So those three; transportation, purchasing and allergy control ensure that we're buying appropriate ingredients for our process. And then our next prerequisite program, "equipment and maintenance" is ensuring that we have a preventive maintenance program and that we buy equipment that is suitable for use in a food processing plant.

Number six is personal hygiene and training. And of course it's a very important program to ensure that our employees are well-trained with respect to hygiene practices, and also their technical roles in the facility as well. So if they are the person that is monitoring the CCP, they need some specific HACCP training and an understanding of their responsibilities at the critical control point. The premise regulations also require that companies have a written sanitation plan, and all of that would be covered

in the cleaning and sanitation prerequisite program. Pest control is generally considered a part of sanitation and the written sanitation plan also records your activities with pest control.

I'm going to skip past recall for a moment and then, operational controls is a program where we're taking a look at allergen risk cross-contamination, foreign materials, as well as some of the labelling aspects of our food product. And it's predominantly controlling allergens. A newer program that the companies are implementing now is food defense. And that's just ensuring things like tamper, evident, packaging or procedures you have in place at your facility to ensure it's a secure place; like visitor policy, signing in, this type of thing at a food plant. Now you'll notice, I didn't mention recall as a prerequisite program because we'll see that prerequisite programs are used in your hazard controls. At a particular process step, you're going to identify a hazard and then try to determine which prerequisite program is used to control that hazard.

So let's say for example, we have a process step where we might be concerned about personal hygiene. So we'll have an example, like pathogen contamination due to improper employee hygiene practices. And we've identified that hazard, and we're going to control it by having a well-developed personal hygiene and training program. And that's how we use prerequisite programs. So as you identify hazards, you're going to determine which prerequisite program is used to control the hazard. And that's why I've pulled recall out. Recall is not a program that you are going to use to control a hazard. It's a prerequisite program that you have in your back pocket, hoping that you never use it, but you need to be prepared and know what to do in the event of a recall, so that if that event happens you pull out your recall plan, everybody knows their tasks, and you can deal with the problem product in a quick and safe manner.

Product Description

So how do we do a HACCP based food safety plan? As I said, it's very systematic. So we're going to complete a couple of documents to get us going and the “getting ready” section there, we're going to complete a product description form. We're going to list our incoming materials. And then we're going to develop a process flow diagram that states our steps from receiving through all the manufacturing steps, through to distribution. So that “start getting ready” part. And then once we have those documents prepared we can begin our hazard analysis and the implementation of the five principles that we will use here. So let's start by getting ready and looking at the product description.

The product description form that has been developed by the Ministry of Health is a useful form of 14 questions that you will answer to get an understanding of the hazards associated with your product. We're going to use the example of cookies, and you may be aware that there's many example or generic plans up on the Ministry of Health website that you can invite your processing plants to use, or take a look at them yourselves, to get an idea of how to complete these documents. They're a very good resource. Today we're going to use the cookie example and just go through the 14 question and see how they're answered.

In this company, we're making just two types of cookies. We're going to keep it quite simple today. So you just indicate the product name and any other information about them. So here they're just including the weight of the package, 500 grams. What's important to know, particularly for the initiation of your hazard analysis is the next couple of questions that are quite related to food safety. We want to know what type of product our product is. So is it raw, ready to eat, ready to cook, or is it going to be used as an ingredient and further processing? So these cookies are a baked product and are considered, ready

to eat. Now, if a product is raw or we're anticipating that consumers are going to cook it, that is going to affect our hazard analysis as we will see later.

The next question, where we list some of the important food safety characteristics is an application of FAT TOM. And here the cookie products really don't have any food safety characteristics such as low pH. They do probably have a low water activity, but there's no addition of preservative or the normal food safety hurdles that we usually discuss. So these cookies are a pretty safe product. We do however have to concern ourselves with the allergens. And so the chocolate chip cookie is bringing in both wheat, egg, milk, and soy allergens, and the almond cookie also has some almond allergen that we need to be aware of.

The next question is also important with respect to the quality attributes and food safety. And we just list whether or not our product has any ingredients that have a regulatory limit such as preservatives or food additives. So you would just state how much is used and be aware that you are using a regulated ingredient.

Then to help us with our next document, which is the process flow diagram, we make a list of the steps from receiving through to shipping and distribution. We'll talk about it again as we get into the third form but try to keep your processing steps simple: receive, store, ship, because there will be other documents, the standard operating procedures, where you'll be writing the details of what is going on at each one of those steps. We'll see these laid out in the process flow diagram in a subsequent slide.

In our product description we also need to describe how we package the product and again, thinking food safety, you would indicate if it's vacuum pack, modified atmosphere mapping, packaging, or perhaps high-pressure processing. But in this case, the cookies are simply packed in a plastic film and then in a cardboard box. And it's good to be complete here because it will help you as you list all your incoming materials, if you state the packaging of the product itself, as well as the shipping cartons that will be used to distribute it to your customers. Then we need to record how we store our products and what kind of instructions might be on the label. So keep refrigerated, keep frozen, refrigerate after opening, any type of information like that, that is going to be told to the consumer.

In this case, the cookies are shipped at room temperature and that they need to be shipped in a clean truck. And our procedures would be where we inspect that truck.

The shelf-life is also included on the product description, and the shelf-life is something that we need to experiment with or determine for our products. Here with the cookies, we've said three months at room temperature. If your shelf-life is something that is refrigerated or a frozen temperature, in this field you want to include the temperature. So it's four degrees Celsius or minus 18 degrees Celsius. Whatever's pertinent for your product. With shelf-life testing, as I've mentioned, it is something that you need to determine for your product. And so I encourage companies to keep a library sample and establish it over time and get some real numbers.

We do have a tendency sometimes to just say, “I think it'll last six months or nine months.” We really do need to develop this experimentally.-The format that we show here is the one that's in the labeling regulations. So it's year-year, month-month, day-day, and the month-month is two letters, like J-A,-F-E, M-R, because we're a bilingual country. And that best-before date is considered bilingual if you do it that way. And then finally, an important part of the product description is understanding who's going to eat your product. And if there is a risk to a sensitive population. So we think of the elderly, the

immunocompromised and infants as a sensitive population. And if we were selling to that population specifically, we would indicate it here on the product description form.

For the cookies, we are just selling to the general population, but I'll just give you an example from my own experience of selling to a specific population. I worked at a spray drying plant in the United States for two years, and it was a dairy operation. And we spray-dried many types of milk products, whey protein powders, skim milk powder, and whey powder, but as well we spray-dried baby formula. And so, because that was a product that was being specifically sold to a population, we had certain procedures before spray-drying infant formula. So we had a large cleanup before, we did some swabbing and we had some different testing procedures for the product that was going to be sold to children. So be aware of who's going to be eating your product. And if it is a specific population, that's a sensitive population, then we need to indicate that on the product description form.

We also have to consider how the consumer might mishandle our product. And this is particularly important. If you have cooking instructions or “keep refrigerated,” we need to consider that and address it during our hazard analysis. In this situation, the cookies—we're not relying on consumers to cook this product, but we do indicate that they may get quality defects such as staling if they're past the best-before date. As well as understanding who is going to be eating your product, you need to know where it will be sold. Our cookies here are, they're going to be sold to food service, retail, distributor, or wholesale, but our product on some occasions might be an ingredient for someone else. So you might be stating here, it's going to be sold to another processor who will be using it as an ingredient, and that may affect your hazard analysis and how you control things in your plant.

In Canada, of course, we have mandatory information that must be on a food product label, and it's listed here. We require the product name, the net weight, list of ingredients and allergen statement, or a precautionary allergen statement If there is allergen cross-contamination risk in our facility. We have nutrition facts table and of course handling instructions best-before date. And we must have a company address so that a purchaser can get in contact with you if there is a problem. And then our shipping containers require less information, but still product name, best-before date, list of ingredients so that it's on the outside of the shipping container.

Incoming Materials and Process Flow

So we'll move on to the next form, which is where we list all incoming materials in the facility. And the food safety plan from the ministry has five categories that we complete here. So first we want to a list of all our ingredients that we're bringing into the facility, we're going to list any food contact processing aids. In this case, we have a baking spray that they're using on the pans. Then we'll make a distinction between food contact and non-food contact. So we first have our food contact packaging, materials, the film that is going to be used for the cookies.

And then there's a list of non-food contact packaging materials. And we want to list everything here from the shipping containers, the labels that are used, the shrink wrap that goes around the pallet, the wooden pallets themselves, because all of these things need to have the hazard analysis done to them. Also on the incoming materials in our food safety plan, we will list the chemicals that we use in the facility. And here we have the soap, the hand sanitizer and then the cleaning degreaser and sanitizer, and any lubricants or things that you will use on your equipment, that you would also list them here. These chemicals will be listed again in our sanitation plan and with further information about them, like

our use rate and how they're used and applied. But in this first incoming material table we'll just list them in that section.

So we've now completed our product background form. So we know something about our product. We have a list of all incoming materials that are coming into the facility, and now we can begin our process flow diagram. So as I mentioned before, keep it simple, use verbs and just simply state the step. So we start with receiving, and then we showed that we have three storage areas. We have room temperature storage, cooler refrigerator storage, and packaging material storage. In this case, it says packaging material storage is in a separate location. That's fine. I just want to point out, in my experience, often the room temperature storage for dry ingredients is the same room as the packaging material storage. The reason we're making this a distinction is because in our process flow diagrams we want to show where each one of those packaging or ingredients is brought into the process.

So we make that distinction in our first storage step of showing that although they could be the same room, its different storage procedures, so freezer storage, room temperature, cooler, and packaging area. Then we get into the steps, so keep it simple. We're going to weigh ingredients, mix them. And then all of these subsequent steps are with respect to forming and getting the cookies onto the sheet ready for baking, and then cooling them after baking, transfer, bagging, weighing, we have a metal detection step that we will see becomes our critical control point. Then our final packaging storage and shipping to our customers. So, what we will do then is after completing these, we want to take a look at the hazards at each one of those process steps, and I'll start with this suggestion now, and we'll do it again, but as you're looking at the process steps, try to think of what could go wrong at each step, and the way I walk through it is I think of each prerequisite program and I go, like let's just say for receiving: "What could go wrong with sanitation at this step? What could go wrong with personnel training at this step? What could be wrong in our receiving program?"

And I think that will help you identify hazards and ensure that you've done a complete hazard analysis at each process step.

Hazard Identification

So now we'll get into how to complete the HACCP table and explore the seven principles of HACCP. As I mentioned, the BC Food Premise Regulations only require a food processing facility to complete the first five principles, which is identifying the hazards, establishing the critical control points, establishing the critical limits, developing our monitoring procedures at each critical control point, and establishing corrective actions in the event that our monitoring indicates that our critical limit wasn't met. But we will discuss verification and record keeping, even though they're not mandatory at this time in the program.

So our first step is to identify all hazards, and I think most people in the room here are familiar that there are three hazard types that we look at, biological, chemical, and physical, and they're defined as a material or agent that when present in a food can make the food unsafe and cause illness, injury, or death. We'll also be concerned with the risk of cross-contamination in our facility as we do our hazard analysis, so here's the definition of cross-contamination, and it's the “...physical movement or transfer of hazards from one person, object, food or place to another.” And we'll be concerned about that with biological and chemical hazards predominantly.

So here are some examples of the hazard types. So our biological hazards, bacteria, yeast, viruses, parasites and toxins. Our chemical hazards... Let me just go back to biological for a moment. When we are discussing our biological hazards, we are concerning ourselves with biological hazards that might come in with our raw materials, as well as activities in our plant, so cross-contamination of biological contamination due to improper cleaning activities, so we want to take a look for hazards in both our raw materials, as well as our process steps.

When you look at the list of chemical hazards, you can see that some of those could be associated with our incoming ingredients, such as the pesticides, the antibiotics or agricultural products, fertilizers, those types of things that might be coming in with our raw materials. We could have cross-contamination, chemical cross-contamination due to our cleaning chemicals that we use, and a number of the ones listed there such as colours and preservatives, nutritional additives, those are ingredient-related and perhaps due to overuse of a preservative or a nutritional additive, like a vitamin or a mineral.

And then allergens are generally included in the chemical hazards, because we're generally allergic to the protein component, and also here you see toxins, and the toxins that are the by-product of microbiological growth, like the *Staphylococcus aureus*, the toxin is considered a chemical hazard. You do see people keep the toxin in the biological hazard, but it's more commonly considered a chemical hazard.

Then we need to consider the physical hazards that might be a problem in our facility, and again we can see that some come in with our raw materials, and some are due to activities in the facility. So our raw ingredients might bring in some bone fragments in meat ingredients, stones or rocks from incoming ingredients from during the primary production at harvesting, and then glass, if we're a glass-filling operation, we need to be concerned about glass breakage. And then there's some hazards associated with our people, such as hair or jewelry or things like that, so of course we deal with that in our personal hygiene program. And then physical hazards associated with good housekeeping, so dirt and dust, pests, so we want to control that. And then finally, packaging materials, so that as we are opening our ingredients and using them, we want to ensure that we don't get little bits of packaging into the product that we're making. With our understanding of the types of hazards, biological, chemical, and physical, we can start thinking of the hazards that might occur at each process step.

Hazard Identification Part A

The first principle of HACCP then is to identify hazards, and as food processors or environmental health officers, we do have an understanding of some foods that we do consider to be potentially hazardous foods, and that is... That's something that we would've identified in our product description form, but here we see some examples of potentially hazardous foods that are commonly known. So raw meats, pastries filled with meat, cheese, or cream, cooked rice—the cooling step of course is very important to that—other products there such as tofu, very neutral pH. Fresh garlic in oil, again, we're concerned there with botulism. Fresh eggs, gravy, good source for—microorganisms can grow easily in there. And then dry soup mix, once the water is added, it's a good environment for microbial growth. So that list has come from the BCCDC, and there's a reference there if you want to look at it again.

We also have identified some practices in food operations that are potentially hazardous, and as you see, we can look back again at FAT TOM, and many of these are related to time and temperature abuse,

so such as improper cooling, advance preparation, giving the food an opportunity for microbial growth, inadequate reheating, improper hot holding, poor handling of leftovers, and inadequate cooking. Those practices are time and temperature-related and can lead to abuse. We also have things such as an infected person could be a source of cross-contamination, and then how we handle an unsafe source, or use of leftovers.

With respect to food processing, I'd like to think of use of leftovers and just give the example of a practice that sometimes occurs in food processing, which is how we handle rework. And unfortunately, rework has a bit of a negative connotation in the food industry, but there are times when it makes sense to rework or try to reprocess a product rather than waste it or throw it out or dispose of it. And a simple example of a suitable rework loop is in the ice cream manufacturing world, we make ice cream mix out of cream, 36% butterfat and milk that's at 4% butterfat, and we're trying to... We make a mix that has a finished product fat of 10%.

Now, sometimes when you're making ice cream mix, you might have a blending issue and the mix might not have the correct fat, and rather than throw it out, we'll just rework that mix into the next batch, and the process is actually called correcting the mix, and we just get the ingredients balanced. And it makes sense to correct the mix, there's nothing wrong with it, but that connotation of rework is kind of a negative, but you can see it's a suitable activity here.

Another example of rework, and a little bit more significant hazard, is in the hot dog industry. So hot dogs is a batter that gets put into casings, and then the casings are cooked, maybe smoked, and then the casing is removed. Sometimes when you remove the casing, the tip of the hot dog might be damaged or misshapen, and so they don't want to put that in the package, and so they're going to rework those hot dogs into the next batch. You can actually cut cooked hot dogs up into very small pieces and rework them in the batter into the next batch.

But this is an example of where we need to consider allergen cross-contamination, because some hot dogs may use a soy protein as a stabilizer in their product, and some hot dogs may use a caseinate, which is a milk protein, in their product, and so when we are reworking hot dogs, we need to ensure that we rework like-products into like-products to prevent that allergen cross-contamination risk. And when we get to the process flow diagram, you'll also see that if rework is a part of the process, then you need to indicate that on your process flow diagram, and so the hazards associated with using rework would be included in your hazard analysis.

Hazard Identification Part B

So, still on principle number one, lots of work to do in the “identify hazards” steps, so we're going to identify hazards associated with our ingredients, hazards associated with our processing steps, as well as hazards that we are...that we identify that are cross-contamination risks in our facility. In some of the higher-level HACCP implementation activities, such as the Global Food Safety Initiative, or even a CFIA HACCP program, one of the basic product information—or the getting ready forms that we also use—is the plant schematic, where we will map the flow of people and materials through the facility, and that helps us highlight cross-contamination risks. However, in the food safety plan for the Food Premise Regulations, we're not required to draw that plant schematic, but it is a useful document to help you identify hazards.

So the first thing we're going to do is look at all our ingredients and think about what biological, chemical, and physical hazards might be associated with the ingredient. And I just want to point out that you're not thinking about the receiving step of the ingredients, you're thinking about the ingredient. Does that ingredient have any hazards that I'm bringing into the facility? Is it a raw ingredient? Does it have an allergen associated with it? Is there a preservative in it that I need to consider? So we want to have an awareness of the ingredients that we are bringing into our facility.

After we've done that hazard analysis, we'll take a look at each processing step from receiving through to distribution, and identify the hazards that would...that could occur at each step, and then develop how we're going to prevent them from occurring. And then finally, we would take a look at our plant schematic or the flow in the facility and identify any cross-contamination risks. And our goal here is to identify the hazards, and then determine how we're going to control these hazards or reduce the risk of the hazard to an acceptable level.

There's many sources of information to help you with your hazard analysis activity. There are the example documents that have been developed by the Ministry of Health, and there's about 15 of those, and so they're a good starting point. There's lots of generic model examples available on the internet, and in particular, you can use the Reference Database for Hazard Identification that has been prepared by the Canadian Food Inspection Agency.

You'll also get information from your suppliers. As I mentioned, you're going to have an approved supplier program, and will request a specification sheet for each ingredient that you use. You might also get an allergen checklist from each supplier, so that they'll indicate what allergens are associated with the product, or what allergen cross-contamination risks are associated with the ingredients due to what else is being made in their facility. So there's some useful sources of information to help you with your hazard analysis.

The CFIA database is a pretty good document. It's slightly cumbersome as a searchable database, but it is worthwhile looking at, and this slide here shows its homepage, and on the left-hand side here, there's a listing so you can go into ingredients and incoming materials, and they have a pretty good list of ingredients and hazards associated with them. And then processing steps, receiving, cooking, *et cetera*, they have some example hazards that you might want to consider when doing your own hazard analysis. So the link is there, and you can try it to look at specific hazards.

So, as I mentioned, there's a lot of work to be done between principle one and principle two, so we've identified hazards and we are going to see if they can be controlled, first with a prerequisite program, or is this process step something that we're going to consider as a critical control point, or there may be other operational controls, and in general, what we're talking about here is how we're going to deal with allergens. Allergens are something that are very challenging to operate as a critical control point, but they are a significant hazard, so we give them some special attention.

I do want to point out that there can be more than one control measure for each hazard, and often I find when you take a HACCP course and you're doing some hazard descriptions at a process step, we don't think thoroughly about all the hazards that could occur because we're just trying to give some examples, but I'll give you an example of how there can be more than one control measure at each hazard, for example, in our storage areas.

So we have a cooler, and we're holding it at four degrees because we want to ensure that all our ingredients are held at four degrees, so our hazard that we might identify would be pathogen growth

due to time and temperature abuse. So there's three control measures that are going to be used there, we're going to have... Within our transportation and storage program, we are going to ensure that the cooler is at four degrees C. In our equipment maintenance program, we're going to ensure that our equipment maintenance is done and that our cooler is always operating properly. And then as well, there's an aspect of personnel training, where we train our people that somebody has the responsibility of checking the cooler a couple of times a day and recording it on the appropriate record sheet. So as you're doing your hazard identification, you may see that more than one prerequisite program will be involved in controlling the hazard or will be used as a control measure.

Hazard Controls

So here are some examples of controls, and so we've looked at biological hazards, so bacteria, yeast, molds, *et cetera*, and again we can apply FAT TOM and look at things like time and temperature abuse, so our possible controls would include freezing, cooling, our cooking step, and...cooking and cooling and freezing and holding cold. Our sanitation program could be a possible control for preventing pathogen growth. Other FAT TOM factors such as low water activity or low pH or adjusting water activity using sugar and salt would be possible controls of biological hazards, and then use of preservatives also for controlling biological hazards. We use our supplier program to ensure that we're buying ingredients from a suitable person and that we're not bringing in products that don't meet our specifications in microbial criteria.

For our chemical hazards, again, we have controls such as proper storage so that there's not a risk of contamination from other ingredients; I think this is important with allergens, we'll usually have a specified storage area for allergen-containing ingredients, so there's no cross-contamination risk. Our recipe or formula will control our use of preservatives and other food additives, so that falls into also ensuring that we weigh ingredients properly, follow regulatory guidelines for use of preservatives and other additives. Allergen control is considered here in our chemical hazards, and we deal with that with ensuring our employees are trained properly for dealing with allergens, we label our food products properly to identify any allergen risks, and then our supplier program will also be used to make us aware of any chemical hazards that we might be bringing into our facility, and any buying criteria that we want to include.

Physical hazards: as I mentioned, they can come from incoming materials, come from our employees, and also our operations within the facility, and there's a number of techniques that we use to control these hazards, such as metal detectors, filters, screens, trying to filter out some of these potential physical hazards. And also our personal hygiene program, where we specify employee behavior, so not wearing jewelry, no earrings, wearing hairnets so there's no risk of hair getting into products, and ensuring people are trained properly to follow those rules.

Hazards and Critical Control Points

So, now that we have an understanding of the types of hazards and how we're going to control them and use our prerequisite programs as preventive measures, let's take a look at how we describe hazards at each process step. And so I generally recommend just... You're going to take your processing steps, keep them in order, so you're going to start with receiving and walk through all the processing steps through to distribution. I try to encourage people to use a two-part statement when you identify your

hazards, and so here at the “Refrigerated storage of ingredients,” we've identified “Potential chemical contamination,” and why is it happening? “Due to improper storage of allergen and non-allergen products.”

And I find if you use that two-step process, it leads you into selecting your prerequisite program more easily. So “potential chemical contamination due to improper storage,” we're going to deal with that by our allergen control program, and in the right-hand column of the hazard analysis form, we detail how we're going to do that, we're going to “Store allergen and non-allergen products separately.”

For “Mixing, sheeting, and cutting,” here we're concerned about improper employee practices, we've identified the hazard of “potential pathogen contamination due to improper personnel practices” in handling, and we deal with that by training our employees, and we monitor their behavior in the facility to ensure that they're washing their hands and wearing hairnets, *et cetera*.

As we move on to baking, a more significant hazard, we have pathogen survival due to improper temperature distribution and time applications, and the risk of growth of, or survival of the listed pathogens there, and how we're going to control that is baking.

Now, this is going to lead into being a critical control point, and I'm going to show you how we use the decision tree, because people have had challenges in the past determining whether a hazard can be controlled by a prerequisite program, or it needs to be controlled as a critical control point.

A critical control point has been defined as a step in the process or a point in your process where controls are essential to preventing hazards or reducing them to an acceptable level. HACCP has been around for 50 years now, and when we started out, we simply described a CCP as a step in the process where loss of control would result in a food safety hazard, but now as we are doing more risk analysis at each one of these hazards, we may find steps in the process where it's not possible to prevent or eliminate the hazard entirely, but we can reduce it to an acceptable level, so over time, our definition of a critical control point has moved to a more quantitative assessment of...and how we're going to control it.

So, we need to identify these critical control points and how we're going to deal with it at this step in the process, because there may not be a step further on in the process where we can control the hazard, so we must eliminate it, prevent it, or reduce it to an acceptable level at that particular process step.

CCP Decision Tree

So, back in 1993 with the Codex document that was published, they included this CCP decision tree which was developed to help people make this decision, and we'll go through this decision tree and look at the questions that are included here. So, remember that we're trying... We've identified all hazards in the process steps, and now we are taking a look at how we're going to control them, so ideally we would like to control hazards with a prerequisite program. We'd like to have as few CCPs as possible in our process, by ensuring we have well-developed prerequisite programs, and so you're going to ask yourself the question after you've described the hazard, "Can I control this hazard with a prerequisite program?" And if you determine that there is not a control measure that will control the hazard, you're going to move on to question two.

Let's take a look at baking again, okay? So here in baking, we say, "Pathogen survival due to improper time and temperature application in the oven." So yes, we are going to... At this baking step, we're going to have identified that we do need to have equipment maintenance to ensure that the ovens are working properly. We're going to calibrate our ovens, perhaps on an annual basis, have someone come in and do some maintenance. We are going to train our employees how to use the oven and how to bake the cookies that we're making.

But to actually ensure that the cookies that are cooked to our 85 degrees for two minutes CCP that we'll see in a moment, we need to actually measure the temperature, and I hope that demonstrates to you the difference between controlling with a prerequisite program, and then determining that it really needs to be a critical control point where we're going to apply the principles of HACCP.

So we've identified the hazards, and now we're determining that this baking step is going to be a critical control point.

So we'll move on to question number two, "Can you control the hazard with a control measure?" Yes, we can. We can measure the temperature of the cookie in the oven at some point. So we're going to say "Yes," and continue on with the decision tree. The third question of the decision tree, "Is the hazard at an acceptable level now, or could it increase?" So if we remember, our hazard concern is pathogen survival, so if we haven't baked the cookie properly, then there is the risk that the hazard could get worse, so we're going to answer "Yes" to that question.

The question four, "Will this process step eliminate or reduce the hazard to an acceptable level?" That's why we're baking, we want to achieve the right time and temperature treatment, and so the answer to that question is yes. So at this point in time, we have decided that the product... The step is a CCP, and we'll carry on with the other principles of HACCP. There is another question there, "Will a later step in your production eliminate or reduce the hazard?" And I'll give you an example of where that question might come into play. Remember, we want to have as few critical control points as possible, so if you have determined that there is a step later on in the process that will control the hazard, you might want to just operate that second process step as the CCP.

An example of that would be a company that operates with two metal detectors, and you might have a metal detector for screening ingredients as they're coming into the facility, and then a second metal detector when you are at the packaging step and going into the finished product storage area. And so if you asked yourself the questions for metal detection, "Can you control the hazard with a control measure?" Yes, I'm going to run the product through the metal detector. "Is the hazard at an acceptable level now, or could it increase?" If you don't run the product through the metal detector, you won't have identified that there is a metal hazard, and so it is at an unacceptable level. "Will this process step eliminate or reduce the hazard to an acceptable level?" Yes, that's why we're running the product through the metal...the raw materials through the metal detector.

But when we get to that final question, "Will a later step in your production eliminate or reduce the hazard?" You're going to say, "Oh yeah, there is a second metal detector, so the hazard's going to be controlled then." So you could control it as a CCP at that second process step, but it's my observation that in industry, people have just found it easier to consider them both critical control points and develop the monitoring procedures at that point.

Now, back here between question one and two, if you ask yourself the... Oops. If you ask yourself the question, "Is the identified hazard controlled by a prerequisite program?" And you haven't identified a

prerequisite program that control the hazard, you move on to question two, "Can you control the hazard with a control measure?" There may not be a control measure, and so you're going to have to re-evaluate, because you now have an uncontrolled hazard, and it's suggested here that you might modify the process step, your production process, or your product. So you may discover that you're going to have to add a cook step, or you're going to have to change your formulation somehow to reduce water activity, or change your packaging method, but at that point you have an uncontrolled hazard, and you need to modify your process.

And so as you do your hazard identification, remember we're identifying all hazards, and we want to ensure that at the end of this operation, we have dealt with all hazards, so they're going to either be controlled with a prerequisite program, controlled with a critical control point, or we may identify some uncontrolled hazards that we need to do something to fix that situation, but we are going to address every hazard that we have identified.

So here in our cookie example then, we've identified the biological hazard, pathogen survival due to improper temperature distribution and time-temperature applications, and so we're evaluating our baking step and we've identified it as CCP 1B. So as you go through your hazard analysis, you're just going to be going through it sequentially. Do each step, identify the hazards, record the control measure, and then move on to the next process step. So it follows then that the first CCP that you identify would be number one in your process flow, and you include the symbol, whether it's a biological, chemical, or physical hazard, and then the next hazard, next CCP that you identify would be number two—and then include the hazard type in with the symbol.

Differences Between CCPs and Prerequisite Controls

This is out of a book that is by one of my favorite HACCP auditors John Surak, who's a retired professor from South Carolina, and he wrote this book called *The Certified HACCP Auditor,* and I feel this paragraph sums up the understanding of how prerequisite programs are used in a facility versus how critical control points are used.

Remember, this is a two-step process where we're going to identify all hazards, and in this step between “identify all hazards” and “establishing our critical control points,” there's a lot of work where we're trying to determine how we are going to control these hazards. And so as Surak states here, in the bold there,

> "The difference between CCPs and prerequisite programs is that prerequisite programs ensure that food products are wholesome and do not contain objectionable contaminants, whereas CCPs are established solely for the purpose of controlling significant life or health-threatening food hazards."

So our CCPs are going to be very process-related, associated with the product, whereas the prerequisite programs that we develop are dealing with the operation of the entire facility. So further on in the paragraph we see, "CCPs address food safety only, while prerequisite programs overlap into product quality, and may involve other types of control, such as quality, or control points in operational steps." And as we are developing our prerequisite programs and...I think it makes logical sense if you are ensuring that your receiving practices are done properly, yes, that's going to control food safety, but it's also going to contribute to the overall success of your food processing.

And so finally, "CCPs are specific to individual products and production lines, whereas prerequisites such as sanitizing and employee hand-washing typically are implemented across an entire facility." And the example there of the glass, broken glass from overhead light fixtures can be a significant food hazard, but glass control is a prerequisite program, because we want to ensure that our facility operates correctly. So, re-reading this paragraph after we go through the principles and understand how a CCP is determined will probably be beneficial.

Critical Limits

Once we've identified our critical control points, we need to establish critical limits. Because if you don't have a critical limit, some boundary at your CCP, it's worthless.

I've pointed out here that it needs to be measurable. Again, we can apply FAT TOM and think of time and temperature relationships, water activity, pH, and use of preservatives, et cetera.

A critical limit is a boundary or a standard that must be met to ensure that a health hazard does not occur at the CCP. It really is a limit that separates safe from unsafe. I stated here it separates safe from potentially unsafe products. Of course it can be a challenge to establish your critical limit.

Sometimes we have the advantage of a regulatory requirement, such as in the dairy industry we have regulated time and temperature for pasteurization. With respect to use of preservatives, there's regulations in the food and drug regulations for use rates. Or we may have an industry standard that is commonly used. Such as in the meat industry, they have acceptable bone fragment size of incoming materials. It may be established for you, or you may have to do some work to develop your own critical limit and validate that it will control the hazard that you have identified. That will be establishing critical limits.

But if you think of it as something measurable, I think it makes logical sense. When you compare it to something like a prerequisite program where we say that employees must wash their hands before starting work, that's a bit of a challenge to measure. Although I was out at a blueberry farm one time and I asked the fellow, how do you ensure that people have washed their hands? He looked at me and he said, "Is the sink wet?" I thought, "That's a pretty good way to determine." Or is there any soap used? Or are there paper towels in the garbage can?

We can monitor our prerequisite programs as well. But we really use this term measurable when we're talking about critical limits and ensuring that we have some boundary that will help us establish if the food product is unsafe.

Here are some examples of critical limits. Baking 85 degrees Celsius for one minute, and that's the CCP we've identified for our cookies. Pasteurization, the legal pasteurization of 72 degrees Celsius for 15 seconds. Then our metal detector, with a metal detector, we have these test wands that have specific metal fragment sizes. In this case, we have 2.5 millimeters ferrous, 2.5 millimeters non-ferrous and 3.30 millimeter stainless steel. Those test wands are put on the food product and passed through the metal detector to ensure our metal detector is working and would segregate any products that have a metal fragment in them.

You need to establish your critical limit for your CCP. For the cookie then just to carry on with the principles, our CCP number one, baking, we have established a critical limit of an internal temperature of the product must be at least 85 degrees Celsius for a minimum of one minute.

Monitoring and Corrective Actions

Just a reminder, our critical limits are the boundaries that we establish to ensure that the CCP is under control, and to make that decision as to whether or not the product is safe or unsafe. Then the remaining principles such as, monitoring, verifying, and corrective actions are procedures we do to ensure that our CCP is under control. The first one we'll look at is monitoring.

Monitoring is a planned sequence of observations that you do every time. It's observations or measurements used to assess whether a critical limit is being met. At this step, we just want to establish, Who's doing the monitoring? What are they doing? How do they do the task? Where do they record it? Then of course, what do they do if they determined that the critical limit has not been met and the product would then be considered unsafe?

We're doing it at the process step. It's genuinely the operators. As you write your monitoring procedures, you want to say what the operator at the process step is doing. Also, I really want to emphasize that you need to state the frequency. It's every day, every batch, every four hours, something to ensure a frequency that you've established so that the product will be safe.

A reminder answered the question who, what, when, where, why, so your procedures will include what you're going to check. In the cookie case, its temperature, you want to be very specific of how they're going to do it. Here, we're going to suggest we do it the top tray of the oven. Ensure people use the thermometer properly. Then record it on the daily baking record.

As we've seen previously, there may be some prerequisite programs that are also involved at the process step. Equipment maintenance is part of the baking operation. We've also listed here equipment calibration procedures. You may be using a thermometer that needs to be calibrated, a pH meter, something that needs some attention.

For the cookie, our specific instructions are that the operator would measure the product's internal temperature from different areas of the oven and be specific, top, middle, and bottom, during each baking session. We show them how to insert the thermometer and then wait until the thermometer is steady and take the reading and then record it on the daily baking record. As part of this, your personnel training program, you would have a record that this particular employee, the operator at this process step has been trained how to do the CCP monitoring.

In the event that we have not achieved our critical limit, then we need to have a prepared corrective action so that the unsafe food product doesn't get out into commerce.

Our corrective actions, their specific goal is to control the hazard. We also will want to investigate what went wrong and try to prevent it from happening again. Our corrective action procedures usually include who we're going to tell when there is a problem. Then what we're going to do with the affected product. Our goal then is to correct the problem during processing rather than discovering at the end of the process.

Keep in mind, HACCP is a preventive way of ensuring food safety and its overall goal is to reduce our reliance on finished product testing and try to evaluate or prevent these situations from occurring. Monitoring our CCP is the appropriate way to do that and having prepared corrective actions in the event that we don't meet our critical limit.

For the cookie example, our goal is to have our critical limit of 85 degrees Celsius for one minute. Our suggested corrective action, if we haven't achieved that is to continue cooking until 85 degrees is reached, and then you may establish a criteria that if after a certain period of time you can't achieve the critical limit, you might discard the product. But we would like to be able to correct the situation before throwing everything out.

In the cookie example, our corrective actions we've indicated are: when critical limits are not met, we're going to try to bake the product for a longer period of time to ensure that it achieves 85 degrees for one minute. Or if we can't do that and we'll destroy the product. We're then going to investigate the cause of the nonconformance and take necessary actions to prevent it from happening again. Is there a problem with the oven? Do we need maintenance? Or is it just not being used properly? But investigate and prevent that occurrence from happening again. Then HACCP emphasis on record keeping, we're going to record our nonconformances or corrective actions on the daily baking record, including the date, time, and then we always sign our production records.

Verification and Record Keeping

Those principles, identifying hazards, establishing critical control points, establishing the critical limits, establishing monitoring procedures, and establishing corrective actions. Those are the minimum requirements of the Ministry of Health food safety plan. There are two other principles in HACCP, in the Codex principle of HACCP. They're good to know and good to implement. We'll go through them here, even though they're not a regulatory requirement at this time.

Verification, its ultimate goal is to ensure that our monitoring procedures are being done properly and our corrective actions are being followed, if they're required. They also ensure that our overall HACCP plan is working and that the critical limit that we've established is suitable for the product. There may be new information that comes to us and we need to re-evaluate our hazard and this we would do in our verification activities. Verification are procedures, tests, sampling, and other evaluation tools to see if a control measure at a CCP is working effectively, and that it controls a hazard appropriately. As I mentioned, you're going to ensure monitoring the corrective actions are followed, by doing verification activities you will see that your employee training is effective and that your overall food safety plan is effective, and the critical limit you've established controls the hazard.

One of the major activities of verification is a record review. We've seen in monitoring, the person might be doing it every four hours, every day, every batch. In verification, it's usually less frequent and somebody else will be doing it because they're observing that the person doing the monitoring task is doing it properly. Record review at the end of the week, or the end of the day, is a common verification activity. Myself to ensure that employee training is effective, I've set up verification activity schedules every two weeks, I'll go out and watch a person do their task. Watch the receiver do their task. I'll watch the operator do their monitoring task at a CCP. When I've worked in a plant where we ran a metal detector, the monitoring procedure was done every 15 minutes by the operator, and at least twice a day, somebody from the quality control department would come down and do the same monitoring

task as them, just to ensure that it's working properly. We're basically ensuring that the monitoring is being done properly and identifying any other hazards that should be dealt with.

Again, you're going to ask yourselves the question, "Who's doing it? What are they doing? How do they do it? Where do they record it?" This will ensure that the record keeping is appropriate.

For here for the verification procedures of the cookie, a different person is doing it at the end of the production day, a supervisor is going to review the daily baking record to ensure that it's been completed properly once per week, ensure the temperature checks follow the written monitoring procedures. You go to the step with a copy of the standard operating procedure and follow it and making sure it's up to date. Then if during your record review, you discover that there was a missed monitoring activity or there was a non-conformance, then you're going to investigate the cause of the non-conformance and prevent it from occurring again. Then of course HACCP has its record keeping. Your verification activities in this case, they're going to record them on the daily baking record, but you might have some other documents that you're going to complete as well.

But your record keeping is a key part of the HACCP plan. It demonstrates how well your food safety plan is working, and you can ensure your products are safe. Also keep in mind that this record keeping can become a legal document if there is ever a product that is unsafe, or you have a problem with, or a recall, you're going to be going back and looking at these records to find out what has happened. It's very important that your people are trained appropriately to complete the records properly and signing them and the date and understanding that falsification of records could be a significant issue. Reinforce no falsification of records.

In the example here of the cookie, we just have a daily baking record. As an example then, we see the monitoring of the step. They're doing it every hour or so, every couple hours, and different batch numbers. They record the temperature top, middle and bottom. You can see at one o'clock, one of the racks was only at 82 degrees Celsius. So their corrective actions came into play. For batch number two, the internal temperature of the cookie was not right. It wasn't 85 degrees Celsius. So the cookies were just returned to the oven and baked again until the internal temperature reached 85 degrees C. But they did note the nonconformance and indicated how they dealt with it.

That brings us to the end of the seven principles. At this point, your food safety plan then includes your product description table, where we learn something about the product by answering those 14 questions. They give us an understanding of our ingredients, our process steps, and our packaging and distribution activities. We're going to have a list of all incoming materials, ingredients, packaging materials, and cleaning chemicals that we use in the facility, and then our HACCP table. The complete hazard analysis is good to include, but at the regulatory level, well we're really just looking at the CCP table. But I do encourage people to do a complete hazard analysis and then continue the development of their complete prerequisite programs. This completed food safety plan, those three tables would be submitted to the EHO.

That brings us to the end of the food safety plan section. Just a reminder there of section 23 of the food premise regulations that food processing operators must establish principles one through five, hazard identification, establishing CCPs and their critical limit, and developing the monitoring procedures and corrective actions to ensure that those critical limits are met and safe products are produced. Then just to remind you that it is a good practice to also include the verification procedures and develop your record keeping activities. There's the benefit of doing a food safety plan, and certainly one of the things

that—it does give you peace of mind and comfort that your customers will be satisfied with your products when you know that all of your hazards are identified and under control, whether it be with a prerequisite program or that you establish them as a CCP.

Conclusion

Over the weekend, I was reading an article on the challenges of HACCP implementation and it listed some of the things that people are having difficulty with and some of it is making the distinction between: is it a CCP or is it controlled by prerequisite program? The challenges of validating at their CCP.

But one thing that does tend to be included in these types of lists is the challenge of record keeping. And I think as long as we continue to ask people to do it and reinforce the value of doing it and then verifying that it has been done, that all of these practices will be implemented.