**Introduction to HACCP**

Please note: This transcript was taken directly from the VoiceThread presentation and is therefore written in a narration or speaking style.

**Slide 1: Introduction to Hazard Analysis and Critical Control Point Systems**

The next lesson will be the introduction to hazard analysis and critical control point systems, also known as HACCP.

**Slide 2: Need for Food Safety**

HACCP was developed in response to food safety concerns. If you look at the Centers for Disease Control prevention, the CDC, they have published a paper in 2010 that discusses the estimation of foodborne illnesses in the United States. From this information they’ve garnered about 48 million cases of foodborne illness requiring 128,000 hospitalizations and approximately 3000 deaths.

**Slide 3: Need for Food Safety**

In the first lesson we discussed a little bit about food businesses and who they are regulated by. In the case of the USDA-Food Safety Inspection Service, they regulate meat and poultry slaughter and further processing including ready-to-eat meats. They also oversee egg inspection, primarily breaking plants and further processed eggs.

FDA, the Food and Drug Administration, takes care of and regulates all foods moving it through interstate commerce excluding meat, poultry, and eggs. However they do deal with eggs on the farm as well as hard-cooked eggs.

Then we also have the state and local agencies that deal with food service, retail, as well as institutional food safety. Typically this is done in cooperation with the FDA. For example: in Pennsylvania, the Pennsylvania Department of Agriculture is responsible for food service retail, sampling, and inspections as well as some other establishments including dairy, fruit and vegetable, and other entities.

**Slide 4: HACCP Concept**

HACCP basically is a management system focused mainly on prevention of hazards to ensure the production of safe food products. As I said, it's prevention rather than reaction. So what we intend to do is use a systematic approach to determine what the hazards are and then how one goes about controlling them.

The good thing about HACCP is that it has demonstrated its efficacy in a number of food commodities. We will talk a little bit about that later on. But it's also applicable to all phases of food production so you can use it on the farm, you can use it during food processing, you can use it during distribution and storage, as
well as elements in food service retail, and even opportunities to use HACCP with consumers. We call that consumer control points.

**Slide 5: HACCP Concept**
As we just said, it's a systematic approach and what it does is employs a science and technology to plan control and document the safe production, handling, and preparation of foods. It's based upon 7 principles. We will talk about those in a little more detail. Basically, HACCP covers 3 types of food safety hazards. Though we talked earlier about radioactive hazards, we are not going to discuss that in the context of HACCP. But it does cover unintentional contamination associated with biological, chemical, and physical hazards. These include bacterial pathogens, pesticides, allergens, glass, metal, wood, and plastic.

**Slide 6: HACCP Concept**
So why should one adopt HACCP? Well, we know that right now if there is an outbreak or recall, the ultimate responsibility is on the business or establishment producing that food. So you bear, or the industry bears, the ultimate responsibility for producing safe foods. There's also increasing regulatory pressure on food establishments to put preventative systems in place. While we've had some HACCP plans operating for seafood and juice and meat and poultry, it's only been recently as part of the Food Safety Modernization Act that we are going to see implementation of HACCP-like principles across other sectors of the food supply. Also it's important that we have a systematic approach to looking at hazards in our food supply because we can't test, microbiologically or with other methods, for everything to ensure safety. So we have to have risk-based prevention programs in place and that's what HACCP strives to accomplish.

**Slide 7: Origins of HACCP**
If you look at the origins of HACCP, It actually started in the 1950s with Pillsbury. It was also helped and developed through Natick Labs up in Massachusetts and ultimately employed by NASA as a way to ensure safe foods for spaceflight. You can only imagine what a foodborne illness in space would be like. In the 1970s, canned foods had undergone basic changes with regard to food safety, which employed a lot of HACCP principals that we will be talking about. And in the 1980s there was a push to use HACCP in more progressive companies. It was discussed, but not widely adopted until the 1990s.

**Slide 8: Origins of HACCP**
In 1985, the National Academy of Sciences sent out a document that endorsed the concept of HACCP. It was in 1988 at the National Advisory Committee on the Microbiological Criteria for Foods, also known as NACMCF was formed. And they actually helped sort of round out the current concepts that we see with HACCP. In 1989 they issued a report describing the 7 principles. And in 1992 and 1997 some revisions were made based on additional information and experience that they've had as HACCP was being implemented under different food sectors.
Slide 9: Origins of HACCP
In 1995, FDA issued the seafood HACCP regulation that mandated that all seafood facilities process their products for human consumption using HACCP, and was implemented in 1997.

Slide 10: Origins of HACCP
In 1996 the FSIS, the Food Safety Inspection Service, developed the Pathogen Reduction Act also known as the “mega reg”. They took what we knew about HACCP and adapted it to meat and poultry establishments. They changed the regulation from the inspector looking at every single type of carcass that went by to relying more on a science-based inspection. And that's what the impetus was before plants had to do this. There were changes in the roles of inspectors, instead of looking at every single carcass they had to evaluate paperwork to make sure that the HACCP plan was operating as the plant intended. And what it ultimately does as part of this whole process was put the responsibility of the production of safe foods on the processing plants. While the inspectors are there every day in a meat and poultry plant, the reality is that the meat and poultry plant says “this is how we’re going to control this hazard, this is our critical control point, this is how we’re going to monitor that critical control point and make sure that we don’t have hazards getting into the food supply.”

Slide 11: USDA HACCP Regulation: Meat & Poultry
The rule that came out in 1996 focuses on prevention and reduction of microbial pathogens on raw products that can cause illness as well as in ready-to-eat products. In addition to some of those requirements for HACCP, it also clarifies that the industry is accountable for producing safe food. But, the government is ultimately responsible for setting the food safety standards and for maintaining rigorous inspections and a strong enforcement program. So while the plant writes the plan, and implements it, the government is there to make sure that it's operating, that the records are being kept, that it's working as the plant intended.

Slide 12: USDA HACCP Regulation: Meat & Poultry
My experiences are mostly with meat and poultry so I apologize if we have some more information on meat and poultry but it sort of revolutionized and sort of brought HACCP back into the forefront. In 1996 to 2000 was when everybody was implementing HACCP in the meat industry. And what they did was they sort of segwayed in. They allowed plants to come in gradually. Large plant started first with HACCP and then the smaller and medium plants came in a bit later. And then the very small plants, which are your local butcher shops, came into HACCP in 2000.

And what they required in addition to writing the plan, and implementing it was also looking at generic E. coli testing. The rationale was that every animal has E. coli in his intestinal tract and if you have levels of E. coli on carcasses, that's indicative of fecal contamination from the intestinal tract. So what plants have to
do is test for generic E. coli and this test is for nonpathogenic E. coli; on carcasses as well as in raw and fresh meat, as an indicator of fecal contamination. In addition, USDA also came in and started doing Salmonella testing. Any meat or poultry facility that produces a meat product has to meet salmonella standards. This means that you can't have so many positives for salmonella in a given sampling set. If you do, you're in violation, you have to go back, reassess your plan, look at interventions that you can do and then implement those in the process.

**Slide 13: Current Status of HACCP**
Currently in the United States, HACCP is employed in meat poultry, seafood and juice. The new Food Safety Modernization Act that was signed into effect in 2010 and starting in 2011 will require comprehensive prevention-based controls across the food supply using HACCP principals and other food products other than those that are not currently under HACCP. This would include dairy, fruit and vegetable, and other processed food commodities.

From an international standpoint, the Codex Alimentarius Committee on Food Hygiene provides international standards that are used overseas. And again, if you're going to do any type of global distribution of your food product, you may have to meet some of those requirements as well. In 2006, the European Union mandated that all food operators adopt procedures based on HACCP. So basically that means that anything that's being imported in the United States is under HACCP. Anything that we export to the EU must be under HACCP as well. There has been adoption by other countries including Canada, Australia, and Japan and HACCP is pretty much known worldwide.

**Slide 14: Current Status of HACCP**
If we look at the current status of HACCP in a couple of other areas we do know that there's been widespread adoption of HACCP by other companies that don't require HACCP. Typically it's voluntary. There are also some cases that establishments or industry will require their suppliers or co-packers to implement HACCP as a prerequisite for doing business. So basically if I'm working in the food industry and my ingredients are not produced under HACCP, I can request that you operate under HACCP and if you're not, I can find another supplier for that particular ingredient.

There is also movement of HACCP into producer, retail, and food service operations. They are little different in the concepts of HACCP but the same principles do apply in this case. There's also a number of types of standards that are available through ISO 22,000, global food safety initiative, and safe quality foods also has specific requirements for auditing and a lot of these require HACCP as a component of their standards.
So something to think about: if you want to become a global player with your food company then you really need to think about how you're going to do this and you may need to meet requirements that are established by these entities. The beauty of this is that it gives you some kind of framework with which to work with and sometimes suppliers will, if they see an SQF certification they know exactly what that means and therefore they're more likely to do business with you because you've met the standards for the SQF for example. In this particular PowerPoint I have provided a couple of links to websites if you want to learn more about ISO 22,000, SQL, and the food safety initiative.

Slide 15: Status of HACCP
As I mentioned, there are a couple of different viewpoints when it comes to HACCP. There's a scientific HACCP: looking at your hazard analysis, the risk assessment that goes along with that. Then there is a regulatory HACCP: the FDA and USDA will come in and see what you're doing. Does it meet the regulatory guidelines? Does it follow all of the regulations set forward by HACCP in the Code of Federal Regulations, the CFR? And then as I just mentioned is the business component of HACCP. If you don't have HACCP in your plant, chances are you could be dropped as a supplier for your customers. It's just the way of doing business in this day and age.

Slide 16: Prerequisites for HACCP
So when we start off with a HACCP program there's a couple things we need to do first. Remember, HACCP has a strong foundation associated with what we call prerequisite programs. And this sets the stage for HACCP to provide ongoing support. So some of these prerequisite programs might include sanitation standard operating procedures. And this is basically a very detailed, written out sanitation program for equipment, for sanitizers, for employee training; all of this is documented and kept as part of a prerequisite program for your HACCP plan.

Good manufacturing practices, also known as GMP's, allergen, glass, or ingredient control programs also can be considered prerequisite programs. Any type of preventative maintenance for equipment that might have issues with metal shavings coming off, you want to have preventative maintenance. If your refrigeration system needs to have refrigerant and air flow maintained, that's considered preventative maintenance because that refrigeration becomes an integral part of your HACCP plan especially if it's a critical control point. In addition you might also have employee training. How many times a year are they undergoing food safety training? Do they understand the importance of personal hygiene? = those kind of things can be considered prerequisite programs. And there's a foundation with which the HACCP program is built.

Once you have all this in place, you obviously have to have a HACCP team that's going to develop the HACCP plan. That team will then develop a flow diagram of the development in the process. So the process from receiving to manufacturing
to weighing, boxing, wrapping, and storage and distribution can all be part of that. In addition you also need information on your list of ingredients with name of suppliers as part of your HACCP plan. The HACCP team can work on that because you might have a team that is composed of a number of individuals including folks from marketing, buying (your buyers involved in that), as well as plant managers, quality assurance/quality control personnel, anybody, even maintenance too. These individuals will sit down then look at the process of the product, look at the suppliers and ingredients in the flow diagram, look at the distribution, the shelf life of the product, any other kind of description you might have for that.

These are all done for prerequisites for HACCP. If you haven't taken a HACCP course, they do offer face-to-face courses through Penn State. I teach HACCP to the meat and poultry industry. My colleague Dr. Luke LaBorde also teaches it for FDA regulated companies. And also the Grocery Manufacturers Association or GMA also has an online HACCP course that you can take if you want to learn more information about this.

**Slide 17: HACCP Principles**
There are 7 HACCP principles and they are listed here. What we will do is go through each one of these so that we have an understanding of HACCP.

1. Complete a hazard analysis
2. Determine the Critical Control Points (CCPs) required to control the identified hazards
3. Establish the Critical Limits (CL) that must be met at each identified CCP
4. Establish procedures to monitor the CCP(s).
5. Establish corrective actions to be taken when there is a deviation identified by monitoring a given CCP
6. Establish procedures for verification
7. Establish effective record keeping systems

**Slide 18: Principle 1: Hazard Analysis**
The 1st principle is establishing a hazard analysis. And we do this as a way to look at all the hazards that are going to be introduced to the process. And what you do is you look at how many of these can be controlled by other measures later on in the process and whether or not they present a significant risk to consumers. And this is important. The USDA requires a thorough hazard analysis to be included in the HACCP plan. FDA does not require an extensive amount of information on the hazard analysis with the HACCP plan. Either way, this is a very critical point in the HACCP planning process: to determine the types of hazards that are going to be introduced and whether or not they can be controlled later on with other interventions or other processes that can control this.
So the 3 types of hazards are biological, physical, and chemical. Biological would include your vegetative pathogens as well as spore formers such as Clostridium botulinum. There are also physical elements such as metal, wood, plastic, and glass. As well as chemical hazards such as allergens, pesticides, antibiotics, or even sanitizers.

**Slide 19: Principle 2: Critical Control Points**
Principle 2 is establishing critical control points. And this is our “CCP”s-when you hear that, that's what it means. Basically in this particular step, after you've done your hazard analysis, you are going to identify and evaluate control measures for the hazards that you've identified in the hazard analysis that can be used to prevent, eliminate, or reduce the food safety hazards to acceptable levels. Some of these critical control points are very basic concepts such as cooking, cooling, refrigeration, high-pressure processing, irradiation and metal detection.

**Slide 20: Principle 3: Critical Limits**
Once you have your critical control points identified, then you have to identify a critical limit. This step focuses on establishing criteria for setting critical limits and operating limits for control measures that you've identified at those critical control points. The step also focuses on establishing parameters to identify or signify when the CCP is in or out of control. Some of examples of critical control limits might be the internal temperature of the cooked product (168°F) the temperature of a refrigerated product (38°F), some type of chilling parameters with stabilization with the USDA-how fast that product gets down to 40° in the specified time frames and whether or not you're using a metal detector. Those are some examples of critical limits.

**Slide 21: Principle 4: Monitoring of CL’s**
The 4th principle is the monitoring of those critical limits. So after you've established a critical limits for the critical control points you have to focus on monitoring. And what you do then is establish procedures to monitor the critical control points to determine and document whether the critical limits are being met. It basically comes down to the “who, what, when, where, and how monitoring” will be done for that particular contract critical control point. So an example of a critical limit would be quality insurance personnel measure the internal temperature of the ground beef patty, near the center the product, with a calibrated meat thermometer. This is an example of monitoring a critical limit.

**Slide 22: Principle 5: Corrective Action**
Principle 5 is corrective action. What happens here is when you have a deviation or something that occurs when you're doing and measuring a critical limit, you have to have some kind of action to bring the critical limit or the critical control point back under control. You must address types of corrective actions, the options, and the procedures for taking corrective actions. And this includes record-keeping and regulatory requirements as well.
So if you have a product that didn't meet proper cooking temperature, you can actually put it back in and cook it until it reaches 160°F but you must document it in a record on a form and then what happened to the product. So you put it back into the cooker, allowed it to cook to certain temperature and then record that information. Another example is adding a denaturant or a green dye to the product and sending it to rendering. Or if the product is unacceptable for whatever reason, didn't meet the temperature of the cooling parameters and is a question about the safety of that and you wanted get rid of it, you can send it to rendering with the green dye, divert the contaminated product away from the plant. Get rid of it. In the case that you have a positive for a pathogen in ground beef you can divert that product into a cook plant where heat treatment will kill any of the microorganisms that might be in there or you might have to retrain employees in some cases. These are all examples of corrective actions.

**Slide 23: Principle 6: Verification**

The 6th principle is verification. This step focuses on establishing activities that determine the validity of the HACCP plan and verifies that the system is operating according to the plan. In a lot of cases, this might include something like microbial testing of the product. If you're cooking a product and you want to vary to verify that the cooking step is doing what it's supposed to, you may have that product tested for pathogens, or other indicator organisms to determine that the product is being cooked adequately.

In other cases you might use wand sensitivity for metal detectors, you might also want to conduct challenge studies to support your process, making sure that you are meeting the cooking temperature and that the pathogens are being reduced but this tends to be an expensive approach. You could also use microbial modeling, you might do something like pre-shipment review which is verification of all the documents that are employed before the product goes out the door, you can also have the verification for the long term which could be yearly re-assessment activities such as third-party audits, internal audits, food safety assessments by the regulatory agencies. These are examples of verification activities.

**Slide 24: Principle 7: Record Keeping**

And last but not least principle 7 is record keeping. I like to say that with recordkeeping: if you didn't write it down it didn't happen. This step is excruciatingly important in the HACCP plan. This step focuses on establishing recordkeeping procedures to ensure that there's evidence, to trace the production history of the product and verify that it was produced in accordance with the HACCP plan.

These records include the hazard analysis that we talked about in the very beginning, any type of papers that you might have, any type of regulatory
documents, any type of data from experiments or studies, any type of bio microbiological test results, calibration logs, anything that proves that you have an audit. These are all important parts of the HACCP planet should be kept with the HACCP plan.

**Slide 25: Role of HACCP and Foodborne Illness**

It's interesting to note that when HACCP was implemented, especially if we look at the meat and poultry industry will probably see this more so in the next couple of years as we implement HACCP another food processing establishments, that regulations, especially in 1997, we've seen a decline in the rate of foodborne infections in humans. And this is coincided with the prevalence of pathogens isolated from meat and poultry products. And it's actually to levels that were before HACCP was implemented.

Again, the FDA has introduced programs to prevent foodborne illnesses including good agricultural practices (GAPs), also regulations requiring the refrigeration and safety labeling of shell eggs, implementation of HACCP in the seafood and juice industries, food safety education of food handlers including those at retail establishments, and increased regulation of imported food and industry efforts including new intervention technologies. So combined, it has been hypothesized that implementation of HACCP and use of HACCP has resulted in a decrease in overall foodborne illness in the human population.

**Slide 26: References and Additional Reading**

For this particular section I have highlighted a number of different references and additional reading to support some of the items that have been discussed here in this lecture. The next 2 slides provide this information and also provide you with some information on HACCP. As I indicated in the talk, if you are interested you can undergo an introduction early HACCP course and receive certification by the International HACCP Alliance out of Texas A&M University. I strongly recommend that if you not HACCP serve certified you might want to do so. I haven't done justice with the whole HACCP course in the segment but you'll understand as we go through this process that HACCP is an important part of setting up a food defense plan and having it in place also makes the development of the food defense plan that much easier.

CDC Estimates of Foodborne Illness in the United States 2011 -
http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_E_2011ESTIMATES.pdf

Centers for Disease Control and Prevention -
http://www.cdc.gov/foodborneburden/

University of Florida EDIS: HACCP: An Overview - http://edis.ifas.ufl.edu/fs122
NC State University: HACCP History and Conceptual Overview -
http://www.ce.ncsu.edu/risk/pdf/hulebak.pdf

University of Nebraska: Overview of HACCP Principles -
http://foodsafety.unl.edu/haccp/start/gettingstarted.html

Seafood Network Information Center: Seafood HACCP Alliance -
http://seafood.ucdavis.edu/haccpalliance.html

Slide 27: References and Additional Reading
No Audio.

FDA: Juice HACCP -
http://www.fda.gov/food/foodsafety/hazardanlysiscriticalcontrolpointshaccp/juicehaccp/default.htm

Federal Register: Department of Agriculture Food Safety and Inspection Service -

FDA: The New FDA Food Safetly Moderization Act (FSMA) -
http://www.fda.gov/Food/FoodSafety/FSMA/default.htm


SQF Institute - http://www.sqfi.com/

Slide 28: Discussion
At this point, I'd like to engage the students in a discussion and I would like you all to add comments on the next couple of slides either by clicking on an icon to record if you have a microphone or to include something in text. So if you would take the opportunity and remember that your participation in these discussion questions is important, it does count towards your participation in the class and I strongly recommend that you take the time to answer the next couple of questions.

The first one is: “why is HACCP important in the food industry?”

Slide 29: Discussion
The next question is “how does HACCP compare to previous inspection approaches?”

Slide 30: Discussion
“What role do interventions play in HACCP programs for the food industry?”
Slide 31: Discussion
“What role, if any, does microbiological testing play in HACCP?”

Slide 32: Discussion
“In your opinion, how should HACCP be applied from farm to table?”

Slide 33: Discussion
And lastly, "what is the role of HACCP in regard to food defense?”