Welcome to Lecture 18 – Food Safety Regulation, Who Regulates What? In this lecture we will talk about who regulated which foods using which types of legislation. This is an overview of the food industry regulation.

The objectives for this lecture are as follows. I will Describe the local, state, and regional authorities involved in food safety in the United States. Explain the roles of the predominate food safety agencies in the US including the FDA, USDA, EPA. List the foods regulated by each agency and the divisions responsible for their regulation. Determine steps of regulation from farm to fork.

I would like to add a lecture note here. Regional, local, and state guidelines for food safety are not uniform. Federal guidelines are uniform, every state must have guidelines that are at least as stringent as federal law. Once they have done that, they are free to make additional guidelines. We are going to see a couple examples of that. Guidelines and agencies may vary from state to state. In Florida for example, we may have Hillsborough Country regulating something while in another state, that same item would be regulated by their State department. Certain agencies which regulate specialized groups such as disabled groups, tribal groups, etc., may not be covered in this lecture in the interest of time.

Here we are thinking about what happens in Florida, or in Tampa with state and local regulations. Food establishments may be subject to local, regional, and state food safety codes. These codes must be at least as stringent as federal requirements. There is a Florida Statute which lists the requirements for food establishments in Florida. Please don’t memorize this statute, I give it here for anyone who wants more information. Please note that these regulations can be changed. Some of what you see in this lecture may vary over time.
In most states you must have a permit to operate. Operating a food establishment requires this permit. It is issued by a local regulatory agency. How do you get one? You apply, an inspection does an inspection, and you pay a registration fee. These permits are not transferable between establishments or from one owner to another. If you own three franchises, you cannot use one permit for those 3 restaurants. In addition, if someone buys out your facility, they need a new permit. Any significant changes to an establishment requires issuing a new permit. Say for example, Shell’s Seafood suddenly decided to sell Mexican food. They would have to have a new permit. Food producers are also required to register with the federal government. This is mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

One of the reasons we require a permit to operate is to prevent people from selling foods they are not permitted to sell. For example, this producer was licensed to sell maple syrup but not cider. Even though he was warned that cider products were unsafe, he sold them anyway in a local farmer’s market. This resulted in an *E. coli* O157:H7 outbreak and he was sentenced to jail time and fines. I think it is important to note that he was actually prosecuted under Michigan’s food law. This is unique as a number of states can use their own prosecution or it can go to the federal level.

Recall that big list of food establishments from the beginning of the course. That list is broken down into different agencies when we begin talking about licensing and inspection. In the state of Florida, the following food establishments are licensed and inspected by the local health department. Hillsborough County Health Department. They will inspect schools, adult daycares, assisted living, detention facilities including juvenile, jail, and prison, civic and fraternal organizations, bars and lounges many of which serve food, and theaters.
Continuing this topic, the Department of Business and Professional Regulation licenses and does the inspections for restaurants, hotels, and food trucks. Two points here, first of all this data is public. If you want to look up your favorite restaurant, look up the Department of Business and Professional Regulation website and your restaurant will be there. You can look at their last inspection. The second item is that food trucks must be permitted. Many people think this is not fair because they are small business owners but do you think the food should be safe? [note added: the concern is the cost related to inspection/licensing]. Next we come to the Department of Agriculture and Consumer Services and they regulate groceries and convenience stores. We will talk a little more about them later. The next time you go to your grocery, check out the scales (in produce or at the checkout) it will have a little sticker on it saying it is certified by the Department of Agriculture and Consumer Services. This is because produce items are charged by weight. DACS confirms that those scales are within the specs they are supposed to be operating in. Daycares are regulated by the Department of Children and Families. Hospitals and nursing homes will fall under the Agency for Healthcare Administration. As you can see, the regulation guidelines can get rather complicated.

If you looked up your favorite restaurants, you might have noticed that not all restaurants are inspected at the same frequency. The reason is because a risk-based approach is used. The more risky the foods prepared, the more likely inspection is to occur. The frequency of inspections is dependent upon the following. The quantity of the meals served. The type of food served and we particularly pay attention to potentially hazardous foods. The amount of food preparation. The population served and critical violations observed. For example, if a restaurant had a critical violation in the past, that might trigger an extra inspection. If you look at the example from the Florida Department of Health you will see that a school that prepares its own food may have as many as 4 inspections per year. However, a detention facility that receives catered meals may only get inspected once a year. By the way, there are places on the agency’s websites to make complaints. If you are concerned about foods at a restaurant, you can go in and request an inspection.
Inspections are generally done in three different stages. In the first phase, and inspector comes in for a pre-inspection conference and review of previous inspection. They will discuss what they are looking for any what they saw in the past. Then they do the inspection itself in phase 2. And finally in phase 3 they talk about the results of the inspection. Any violations they found will be disclosed immediately. Some states use a letter grade system for inspections. As seen on right, these must be posted in New York City. If an establishment has an A, it is likely a great place to go and eat (safety speaking). Needless to say, there are 3rd parties involved who provide consulting services to help your establishment earn an A grade.

The inspection could involve many items but most inspections will focus on the following items. Obviously the most important is the food and the supplies. They are interested in personal hygiene and employee health. Temperatures are critical, temperature abuse issues, holding temps, etc. They will also look at cleaning and sanitizing procedures, equipment and utensils, water supply and waste disposal, and pest control. These are really the main issues of concern.

What do they do if they find a critical violation? If a critical violation such as temperature abuse or cross contamination is discovered during and inspection, corrective action must be taken immediately. If action is not taken immediately, the inspector has the power to go ahead and shut down the restaurant. This happened recently in 3 Pasco County restaurants. Violations generally lead to a temporary closing. Once the problems have been addressed, most restaurants can reopen. Occasionally the problem can be addressed right on site such as foods stored at incorrect temperature. However, if the temperature is wrong because the refrigerator is broken, they may be shut down until it is fixed.
I pulled an inspection report from a restaurant for you so you would know what they look like. This is from Tijuana Flats which as you probably know is right off campus here. I wanted you to note that Tijuana Flats had quite a few high priority violations. Note that many of these were repeat violation which means they probably had to fix them right away before serving food again. This is 2014 and I haven’t checked for an update but they probably got inspected again pretty quickly after all of these violations. Again there are found at the Department of Business and Professional Regulations webpage if you want to check for an update. Note the classification of high priority, these are violations that could contribute directly to a foodborne illness or injury. Do you agree that these could cause serious injury or illness? Cheese, milk, creamer, or other dairy held at greater than 41 degrees Fahrenheit. So, in the temperature danger zone. Next one down, lettuce, temperature danger zone. Next, tomatoes, temperature danger zone. So we have obvious issues here that could have resulted in an foodborne illnesses.

In Florida, agricultural products are inspected by FDACS the Florida Department of Agricultural and Consumer Services. Since the previous slides have focused on restaurants, I wanted to remind you that production of foods is also regulated in the fields. FDACS must use criteria at least as stringent as those used by FDA and USDA for agricultural products. FDA and USDA have overall authority and basically can inspect whatever they like.

That is a lot of agencies and you might be wondering what that had to do with YOUR food. So I put an example here of a tomato which might not be complete but it has some of the key steps. If you begin with a tomato produced in Florida that is regulated by the Florida Department of Agriculture and Consumer Services (FDACS). You might ship this tomato to a ConAgra plant and the shipping is regulated by the Department of Transportation. Once it arrives at ConAgra, it is processed and packaged and that plant is regulated by the FDA. At this point you are going to ship it again, once again regulated by DOT. We are shipping to Moe’s which is a restaurant and therefore regulated by the Florida Department of Business and Professional Regulation. However, what if this Moe’s is located in the USF Food Court? That is located at a school and schools are regulated by Hillsborough County Health Department. So before you ever ate the Moe’s burrito, it went through an awful lot of regulations. If someone tells you your food is not regulated, they are being disingenuous.
That brings us to our big 3 federal regulatory agencies. Recall we have already talked in this lecture about local and state. The primary federal agencies that protect our food supply, and I am sure you already knew this as you have gone through most of this class already, are the FDA, the USDA, and the EPA.

The FDA regulates most foods. It is estimated that 80-90% of all foods, domestic and imported are regulated by the FDA. This does not include meat, poultry, some eggs and some fish. These are regulated by the USDA. However, there is a caveat here, what happens if the meat, poultry, or eggs end up in processed foods? The processed foods would be regulated by the FDA. Processing foods complicates the regulations. The FDA does regulate some animals and birds not regulated by the USDA, often referred to as wild game. This is an odd rule as many people think wild game is or should be regulated by the USDA. This could change in the future. Specifically, the agency regulates facilities that manufacture, package, process, or hold foods for consumption in the United States. Moreover, the agency provides guidance to the more than 3,000 state, local, and tribal agencies which regulate retail food establishment.

Again if someone tells you that the FDA does nothing to protect our food supply, they are being very disingenuous. Please pay attention to this really long list that is continued on the next slide. One of the most important things the FDA does is issue recalls. They also investigate outbreaks. They respond to food emergencies. They regulate foods and dietary supplements. Dietary supplements is an area that is getting very hot right now because some deaths have been associated with supplement use. The FDA is really starting to crack down on these. The FDA provides the public with information regarding the safe handling of foods. The FDA also provides the public with information regarding the signs and symptoms of foodborne illness. They take an active role in food defense and food safety and also do research in food safety. They provide guidance to industries on safe food production. They ensure compliance and enforcement of food law. Now remember, they don’t write the laws, they ensure compliance and enforcement. They also participate in international and interagency food safety coordination.
To be more specific about the FDA’s role with respect to food safety; they sets standards with respect to composition, quality, labeling, and safety of food and food additives. They perform routine inspections of food processing plants, food storage, and imported foods to ensure that safety standards are maintained. They are responsible for the toxicological safety of food packaging materials. This is something you may not have thought about but recall when we talked about how certain medals can leach into foods. The FDA would be involved in prohibiting the use of those medals. And they ensure that foods are not adulterated/misbranded.

I know we have already talked about adulteration and misbranded foods but I put them here again in case you were still unsure of the difference between the two. Adulteration = refers to food that contains filth, is decomposed or otherwise unfit, is produced in unsanitary conditions, or contains poisons or other harmful substances damaging to health. Misbranded = refers to food that is falsely or misleadingly packaged or labeled. Adulteration is often done on purpose while misbranding is usually a mistake.

The FDA is probably best known for their food recalls. The FDA can request a food recall if the agency has determined that a potential hazard exists in a particular food product which would justify regulatory action. Most food recalls are voluntary. However, recently FSMA has allowed greater authority for mandatory food recalls. The FDA has begun to use mandatory recall rule. Most recalls are due to mislabeling.

There are 3 classes of food recalls, class I is the most serious. These are foods that may cause serious adverse health consequences. The current (now past) recall for Blue Bell Ice Cream which contains Listeria is a Class I recall. Class II are foods that would result in a temporary or reversible health problem. Class III are foods that are not likely to cause danger to health. You might be wondering what is a Class III recall, this might include a recall done because someone found a mouse baked into the side of their bread. It is not likely that would cause a health problem but it is obviously a sanitation problem.
The FDA enforces a number of federal laws including the Federal Food, Drug, and Cosmetic Act and its amendments which we have already talked about. The FDA also enforces the Food Modernization and Safety Act which we will cover in lecture 19. And the FDA enforces food facility registration, domestic and foreign facilities that manufacture, package, process, or hold foods for consumption in the US must register with the FDA. In other words, you have to be known to the FDA to import your foods into the US.

The FDA provides guidance to people who want to produce food. I mentioned before the FDA Food Code. It is a model for retail establishments with recommendations for promoting food safety and sanitation. If you wanted to start an establishment and produce a certain type of food you could get the FDA Food Code and read about the best practices for producing that type of food. There is also what is known as CGMP or current good manufacturing processes which is on the next slide. And of course there is HACCP which we just covered.

The CGMP or current good manufacturing processes are FDA guidelines for the description of the methods, equipment, facilities, and controls for producing processed foods and dietary supplements. In other words, FDA guidelines on which equipment is the safest, what your facility should look like for safety, controls you should consider, these sorts of things. Following CGMP guidelines ensures quality. This is also a good way to ensure labeling and packing requirements are followed because those guidelines are in there.

And if you don’t use CGMP and HACCP, you will get a warning from the FDA. I wanted you to note that this letter was sent by the Florida District FDA to a Florida distributor. So it is not just suggested that you use CGMP and HACCP, they are cracking down on anyone who is not doing this.

Our next big food agency on the federal level is the USDA or the United States Department of Agriculture. The USDA’s mission is to ensure that the nation’s supply of meat, poultry, and eggs is safe, wholesome, properly labeled, and packaged. This includes both domestic and imported products. You can see on the right some of their inspection stickers.
And again we have a whole laundry list of things the USDA is responsible for. They are responsible for fair marketing of agricultural products. This includes the National Organic Program. You may not have been aware of this but the USDA regulates the Organic program. They are responsible for quite a lot of agricultural research. They are responsible for protecting US agricultural resources from pests and diseases. They do this through plant and animal disease surveillance and they have agricultural checkpoints. You may have seen these. If you drive major highways you may come across a USDA Agricultural Checkpoint. They are responsible for regulating GMOs but this really means in the field. It is unclear who would be responsible for regulating labeling of GMOs as many of those foods would be processed and would fall under FDA regulation. So again the labeling GMO issue is complicated. As far as developing, research, growing in the fields, that is USDA’s part. They are responsible for managing wildlife damage. Growing of crops must have minimal effect on the environment. They administer the animal welfare act and they do this with the Humane Society. You might be surprised to learn that they also administer SNAP sometimes called Welfare, it is the nutrition assistance program for children and low-income persons. The food safety and inspection service (or FSIS) for meat, poultry, and eggs, is also part of the USDA.

Although USDA is involved in a lot of important research, we really want to be sure to cover the hands on things that they do. Let’s talk about FSIS the Food Safety and Inspection Service. You can see an inspector in the picture checking dates on foods. The FSIS is the agency that ensures that the Nation’s supply of meat, poultry, some fish and some egg products is safe, wholesome, correctly labeled, and correctly packaged. Under federal law the FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry and egg processing plants.
The USDA/FSIS enforces federal laws. These include the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act. And that is only parts of that last act, we will talk about why in the last part of this lecture when we talk about “weird” foods. And they also enforce the Agricultural Marketing Act. Unfortunately, there were some meat inspectors that were killed in the year 2000. They had gone to a facility were a guy was using unsafe procedures to produce sausage. He was told to quit producing the foods but he went ahead and started up production again. They went back for another inspection and this person cornered and shot and killed some of the inspectors.

What are inspectors looking for? They inspect all meat and poultry animals to look for the following. They look for any signs of disease. No diseased animal is allowed to enter the food supply at any time. You may have seen some terrible pictures or videos of this happening. Some are false but some are egregious flaunting of the law. They are also looking for contamination and facilities that are dirty and they are looking for abnormal conditions. No animal may be slaughtered and dressed unless an inspector has examined it. Inspectors are present at all times during slaughter, the plant may not operate without an inspector present. In other words, slaughter houses have to have an inspector present at all times if they are operating. However, processing plants only have to have an inspector visit once a day. They can come more than that, but the requirement is just once a day.

You may be surprised to know that no foreign producer can ship meat or poultry into the United States until the FSIS determines whether they are providing a level of safety equivalent to that of the United States. Meat and poultry are 100% visually inspected before exportation. We do know which countries and facilities are allowed to export foods to the US. We do have people in those facilities. Sometimes those person are 3rd party providers which we have certified and we are hoping they are following the procedures as they are supposed to be followed. Please note the picture on the right. There is some legislation going around about country of origin labeling. This is a very hot topic right now. The food industry is against country of origin labeling. They would prefer you didn’t know that some of your foods are from mixed countries. For example, you may have a processing plant in the United States that processes meat from Canada, the US, and Mexico. Any particular lot that comes out, they don’t really know which of the 3 countries the meat came from. This law would require them to stamp their foods with all 3 countries like you see here. There is some concern that the consumer would say what
I wanted to be sure to cover the Agricultural Marketing Service because one of the labels you may see on meat is the grading system. The FSIS/AMS does inspections for wholesomeness. This refers to an official examination of food to determine if it is wholesome and free from adulteration. This inspection is performed by FSIS. They also do grading which refers to the process of evaluating foods relative to specific, defined standards in order to assess its quality. Again this is quality and not safety which is why we haven’t really talked too much about this in our course. It is performed by the marketing services and they are allowed to do this under the Agricultural Marketing Act of 1946.

Which brings us to the EPA or Environmental Protection Agency. You will not be surprised to see that there is a great big list of things they do as well. They are responsible for ensuring that the chemicals used on food crops do not endanger public health. Most importantly, they register new pesticides. They determine the allowed residue levels of those chemicals. They review pesticides of concern. They review and evaluate all health data on pesticides. This is important, it says ALL health data. Decisions are not made on single papers, peer-reviewed or not. It is rather the entire body of the research on that pesticide which is used to decide if it is safe for use. They review data on pesticide effects on the environment and especially on non-target species. They analyze the costs and benefits of pesticide use. They coordinate with federal and state agencies. The laws enforced by the EPA include the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act (FD&C).

In addition to other major environmental initiatives, the EPA is mainly responsible for regulating drinking water. Ice and water should be treated like any food group as we have discussed a number of times in this course. The FDA regulated bottled water. That brings us to one of those tricky things with foods. If water is in a bottle, it is regulated by the FDA, if it comes out of a tap, it is regulated by the EPA.
Some foods may fit unusual categories of regulation. I just told you about water and we will cover it here. Seafood is one of those as well and so are eggs. We are only discussing a few of these in the interest of time. Milk has some unusual regulations but we are not going to cover them here.

Let’s start with municipal water supplies. What you can see here are some aerial views of Tampa’s Water Treatment Plant. The water treatment plant gets water from the Hillsborough river. The water come in from the river can be fairly polluted. Once processed, it is quite clean. That is regulated by the EPA. Municipal water, often know as tap water, is regulated by the EPA. The EPA regulates under the Safe Drinking Water Act. This allows testing for 90 potential contaminants and is actually more stringent than the FD&C. Because the FDA regulates bottle water under just FD&C and the EPA regulates under multiple laws, tap water is more highly regulated than bottled water.

The FDA regulates bottle water under FD&C and it is regulated as a food. Bottled water is subjected to laboratory testing, just like municipal water. They might do microbiological, physical, chemical, and even radiological testing. I can tell you that Tampa Water Department does all of the above for your tap water. Like foods, bottled water is subject to good manufacturing processing guidelines. Bottled water is second only to soda for sales in the United States. If the bottle says “drinking water” it probably came from a municipal water source. For example, if you have Dasani or Aquafina, look on the bottle and see if it says where the water came from. For example, the Coca-Cola plant may take water out of the Atlanta municipal water supply and put it through additional processing to make Dasani. They are pretty proud of their website and you can look at their website to see how it is done. This water is highly regulated! At first it was regulate by the EPA as Atlanta tap water, then by the FDA as bottled water. Please note that “Spring water” such as Zephyrills is not a municipal water source so it is only regulated by FDA.

Which brings us to seafood. The FDA operates a mandatory safety program for all fish and fishery products. However, there is extra regulation here as Federal/State/County agencies participate in the Interstate Shellfish Shipper’s List. Any company that wants to ship shellfish state to state has to be on this list and approved to do so. In addition, the Federal/State agencies administer the National Shellfish Sanitation Program which provides guidelines for the safe production of shellfish.
Here is another level of interesting regulation that goes on with seafood (please note instructor misspoke and said shellfish). The National Marine Fisheries Service is part of the US Department of Commerce National Oceanic and Atmospheric Association or NOAA. You might be surprised to know that NOAA is involved in some of your food inspection. [Note added: remember that data showing mercury in Atlantic seafood, it was from NOAA]. They perform voluntary seafood inspections and grading. This isn’t required but most people want to do this to be competitive. It is a fee-for-service and it focuses on marketing and quality attributes. In other words, this is not a safety thing. The authority is granted under the Agricultural Marketing Act.

This brings us to the really strange regulation of eggs by the FDA and the USDA. Some people believe this regulation is a bit backwards of how it should be. The FDA regulates eggs and egg laying facilities. Note that there are new requirements to reduce the presence of Salmonella Enteritidis in egg-laying facilities and the FDA is heavily involved in this. In other words, if your egg is still in the shell, the FDA regulates it. However, once your egg leaves the shell, the USDA is in charge. They are in charge of any egg products under FSIS. So if you see on the grocery shell products like Eggology or these Organic Egg Whites, the USDA regulates these.

I want to add a note here about the CDC because sometimes people get confused about what the CDC does. The CDC is responsible for monitoring, identifying, and investigating foodborne diseases. They do this through things like FoodNet, PulseNet and others we have already talked about. The CDC works with other federal, state, and local agencies, as well as universities and industry to develop foodborne disease control methods. CDC also evaluates the efficacy of control methods. And this is where people tend to get confused so: PLEASE NOTE: The CDC is not a food regulatory agency, this slide is included to remind that they have an important role in food safety they are not involved in food regulation.
A great big thank you to the folks who made this slide because you can look in one place at who regulates what. FDA regulates food (but not meat), dietary supplements, bottled water, seafood, wild game, and eggs in the shell. The USDA grades raw fruit and vegetables, regulates meat and poultry, regulates processed eggs and grades eggs, and certifies organic products. NOAA grades fish. EPA regulates drinking water and pesticides. There are a few agencies here we didn’t talk about such as Customs and Border Protection which does front-line enforcement and referral. The Department of Justice which is involved in law enforcement. The FTC is involved in advertising and the Alcohol and Tobacco Tax and Trade Bureau regulates alcohol. We didn’t cover alcohol in this course as it really isn’t a food but you are probably quite aware that alcohol has its own restrictions and regulations.

I added this slide just be sure you were clear on a couple of the concepts in this lecture. Reminder: food products are commonly regulated by multiple agencies. Example: frozen dinners containing meat. The meat is regulated by the USDA. However, once the food is processed and packaged, it is regulated by the FDA. Example: GMOs. The USDA regulates GMO crops. However, once processed and packaged, they are regulated by the FDA. Can you see why this complicates the issue of GMO labeling?

To sum up this lecture, the FDA is responsible for ensuring that all domestic and imported food products (except most meats and poultry) are safe, nutritious, and accurately labeled. The USDA (FSIS) regulates most meat, poultry, and some egg and some fish products. The EPA regulates pesticides and municipal water supplies.