As promised, we have made our way to the Food Safety Modernization Act or FSMA. This lecture can be a bit dry like the HACCP one but it is also the most important food safety legislation to appear in the last 70 years. I show you a picture of “MyPlate” just as a reminder that some of the FSMA is aimed at nutrition.

The Objectives of this lecture are as follows; describe the FDA’s role in the new Food Safety Modernization Act. Identify the mandates of the new legislation and new authorities given to the FDA. The FDA has identified five big areas assigned to them in the FSMA. These are prevention, inspection and compliance, response, imports, and enhanced partnerships. We will be talking about each of these.

FSMA was signed into law in January of 2011. It is the first food safety act which aims to prevent food contamination. In the past, most guidelines were written to address outbreaks after they occurred. However, FSMA uses a science-based approach to prevent outbreaks from occurring. Not all parts were implemented in 2011, some are very slow to get started. We will not worry too much about which are already in play.

Background on FSMA. The act enables the FDA to better protect public health by strengthening the food safety system. It changes the focus to risk-based food safety standards. In other words, which microorganisms, physical hazards, and chemical hazards pose a demonstrated risk to which food groups. For example, if we are going to work with chicken, we want to think about Salmonella, we don’t want to worry about Vibrio.

Again the FDA has identified 4 mandates as the powers given to them under FSMA. We will talk about the importance of each.
Let’s begin with the mandate known as prevention. FDA for the first time will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. Prevention will include: controls for food facilities, produce standards and prevention of intentional contamination. Remember that I told you that bioterrorism/agroterrorism would be addressed by FSMA and here it is. The FSMA was passed but as you can see in the figure, not all of the states supported the legislation. The reason I included this figure is that in the future this could change. Some or all of this act could be repealed.

The prevention mandate starts with food facilities. The following are the mandatory preventative controls required for food facilities. They must evaluate hazards that could affect food safety. The must identify controls to prevent hazards. The must monitor controls and they must keep records. The must have an action plan to correct problems. The FDA will require food facilities to implement a written preventative control plan that addresses each of these issues. Do this sound like HACCP to you?

This is a reminder that HACCP is a prevention-based program. The new FSMA prevention guidelines require must of the same procedures as HACCP but use a science-based, risk-based analysis to better guide food safety initiatives. The two systems work very well together.

One of the most important things to come out of this legislation which falls under the prevention mandate is produce standards. The recent high profile outbreaks involving produce (includes fruits and vegetables) highlights the need for mandatory produce safety standards. The FDA is required to use a science-based standard for safe production and harvesting of produce. These standards must consider the following items. The must consider naturally occurring hazards, intentional contamination, the soil that is used, hygiene, packaging, and animal proximity to field and water supplies. On the right hand side I show you an article demonstrating transmission of E. coli O157:H7 from contaminated manure and irrigation water to lettuce. The FDA is still taking comments on the produce standards so they are not yet complete (as of Summer 2015).
The prevention mandate includes prevention of intentional contamination. FDA must issue regulations to protect against the intentional alteration of foods. FDA must establish science-based mitigation strategies to prepare and protect the food supply at specific vulnerable points. I put a picture of *Aspergillus flavus* here to remind you that aflatoxin is one of the most deadly natural toxins and the introduction of *Aspergillus flavus* could be dangerous.

Moving on to the second major mandate: Inspection and Compliance. Food safety standards will only work if producers and processors comply, FDA is given the following tools to ensure compliance: They can do mandatory inspections, they have records access and they have testing by accredited laboratories.

It is a bit complicated how they did this mandated inspection frequency. Mandatory inspection frequency is based on risk. High risk domestic facilities must be inspected within 5 years of FSMA enactment and no less than every 3 years thereafter. At least 600 foreign facilities must be inspected in the first year and double those inspections for the next 5 years, which you can see here. The idea is that we don’t want facilities to go long periods of time without being inspected.

The FSMA gives the FDA more access to records. They will have access to any records they want really. This includes industry food safety plans and the records firms will be required to keep documenting. So HACCP required recordkeeping but were those records available to FDA? I ask this question as much of the records were on paper. This moves much of that recordkeeping to computers and gives FDA more reliable and faster access.

Under that second mandate, Inspection and Compliance, the FDA allows testing by accredited laboratories. You can see a picture of a food laboratory here on the right. The FDA must first establish a program for laboratory accreditation to ensure US food testing labs meet high-quality standards. This is important, the lab must be accredited to do this type of testing. Then certain foods can be tested in these accredited labs. This is one of the hardest things to put into play because the laboratories are expensive. The tests themselves are expensive and you need to pay the employees and buy equipment. Many states are ramping up this testing but it will be slow going.
This brings us to the 3rd FDA mandate: Response. The FDA must be able to respond when preventative controls fail. This is the part that gives FDA mandatory recall authority. They also have expanded administrative detention, which we will describe in the next slides, suspension of registration, enhanced product tracing abilities, which are some pretty neat systems we will talk about. And additional recordkeeping requirements for high risk foods.

The office of Inspector General includes an armed law enforcement branch of the US government. If someone wants to refuse a mandatory recall order, they could find themselves in some very big trouble.

First let’s talk about mandatory recall and this something that I think a lot of us in food safety are very happy to see. The FDA should have the power to pull any product off the shelf that is dangerous. The FDA may now issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to do so by the FDA. In the past, the FDA could only do this for baby food. So if they couldn’t do a mandatory recall they would ask the company to do a voluntary recall. If the voluntary recall request was ignored, the FDA would resort to using the media. They would go on the news and say these foods are dangerous, don’t eat them. That was much more damaging to the company than a recall would have been. In most cases that would work but in some cases it would not. Now the FDA can recall whatever they want. I want you to remember that pet foods are made by big companies and they can be recalled by the FDA.

I mentioned that the Response part of this included expanded administrative detention. That is a fancy way of saying we can hold this as long as we want to. The FDA uses what is called “administrative detention” to prevent suspected unsafe food from being moved. Say for example they get a tip that an import is coming to the US that was already rejected by Brazil. An inspector in Brazil may report that they rejected foods as unsafe so the company has decided to attempt to sell the foods in the US. The FDA can say hold it. Until we have a chance to inspect that food, none of it can enter the country. This mandate allows the FDA flexibility in detaining products that are potentially in violation of the law. It also gives them an “out” for certain things. For example, you will recall the FDA implicated tomatoes in an outbreak that was actually caused by Serrano peppers. This law allows the FDA to detain those foods without proven cause. This does not mean the companies who lost money (the tomato companies) cannot sue to get their money back but it does get the FDA off the hook. [note added: the government actual would cover the costs, not the FDA].
Another the tool the FDA has now as part of the Response mandate is Suspension of Registration. The 2002 Public Health Security and Bioterrorism Preparedness and Response Act required registration of food facilities. You cannot produce any foods in the United States or for import into the United States without being registered. The new FDA mandate allows the FDA to suspend that registration. For example, if a company refused mandatory recall, the FDA could suspend their registration prohibiting them from making ANY foods. If the FDA determines that the food produced many result in serious consequences or deaths, they may pull a producer’s registration. You remember when I showed you the FDA warning letters and some stated that the company had been warning the past? The FDA can say, we sent you too many warning letters, they were ignored, so we are going to suspend your registration. A facility that is under suspension is prohibited from distributing food.

Under the Response mandate is also Enhanced Product Tracing Abilities. The FDA is directed to establish a system for tracking both domestic and imported foods. You may be wondering why this is such an issue but consider our current recall of cumin contaminated with peanuts. These products are not labeled “contains peanuts” so dozen of recalls resulted. One company was importing this contaminated cumin which then went on to dozens of other companies. For months and months new recalls were issued as many companies discovered they were affected by this product. So the idea is to create a system where the FDA can rapidly identify the recipients of foods to prevent or control outbreaks. We would be able to identify everyone who got that cumin in hours rather than months.

Another thing identified by FSMA is shortcomings related to high risk foods. So the idea is that the type of records we have for cereal do not need to be as complete as those kept for something like chicken. Recordkeeping is already required for inspection and compliance and for HACCP, this is additional recordkeeping. This mandate is for facilities that manufacture, process, pack, or hold high-risk foods. Some of these were falling through the cracks and the amount of recordkeeping needed wasn’t getting done.
Which brings us to our new mandate which is Imports. The new mandates are the most far reaching requirements to ensure food safety of imported goods. This is because we have identified a number of food safety hazards that are potentially linked to imported foods. The FDA mandate will provide for importer accountability which we will talk about next. Third party certification, certification for high-risk foods. Voluntary qualified importer program which again we will talk about next and the authority to deny entry for any foods. A large number of fruits are imported and so is seafood.

One of the new parts of the Imports mandate is importer accountability. This requires that the importer is responsible for verifying that their foreign suppliers have adequate preventative controls to ensure that the food they produce is safe. In other words, the importer has to ensure the food they import is safely produced. In the past there has been food that was not safe imported into the countries and there were outbreaks that occurred and the person who imported was totally off the hook because they didn’t produce it. That is going to change. If you are going to import foods into the US, you are responsible for ensuring the people you import from are producing safe food.

The Import mandate also allows for Third Party Certification. It creates a program through which qualified third parties can certify that foreign food facilities comply with US food safety standards. To get an idea of what this might look like, there may be a third party certifier that is present in China. They are trained by the FDA, they then get certified as a third party certifier by the FDA. Now tons of businesses in China who want to export to the US can use this service directly in China to certify that their foods are safe. This will facilitate entry of imports and will allow multiple importers to use the same certifier for their foods. Some companies and lawyers have quickly responded to this and they provide services to food facilities.

Here are high risk foods again. I purposely used the same pictures so you would note this is another new guideline for high risk foods. This one falls under Imports. Requires that high-risk imported foods are accompanied by a credible third party certificate or other assurance of compliance as a condition of entry into the US. To put that in plain text: this allows the FDA to enforce US standards for high-risk foods on foreign producers. Your food has to be as safe as food produced in the US or you cannot import it.
The Import mandate also allows for the creation of the voluntary qualified importer program. The FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Only certified facilities may participate. The point of this is that it allows quick import from known safe importers. For example, if we always import products such as Cadbury into the US, they don’t have to go through a whole new process just to import from a new facility, or a different product from the same facility. This allows brands we know are safe to be imported quickly.

The Import mandate also allows us the authority to deny entry. The FDA may refuse entry into the US of food from a foreign facility if the FDA is denied access to that facility. Remember that the FDA can inspect whatever they want if you are planning on importing food into the US then the FDA can come to your country and they can look at your facility. If you deny them access, they are going to deny entry of your foods. They can also do this if the FDA is denied access to the country in which the facility is located. You will see that we have certain countries we allow to import into the US certain foods, and other countries we do not. For example, we may import beef from country A but not country B. Note that certain products are prohibited from certain countries due to various reasons including political and biological. This is sometimes used to play political games. For example, a shipment of corn containing GMOs was denied by China. So we countered by not accepting a shipment of goods from China in the US. Border control agents will ask visitors if they are carrying any food products. You technically cannot bring foods into the US without the benefit of inspection.

The next mandate is Enhanced Partnerships. The FSMA recognizes that all food agencies must work together. So there are things that USDA does that the FDA does not need to be doing. Same for the EPA. There has been some talk about creating a single food safety agency. Similar to how many agencies now fall under Homeland Security. Many of us are not really sure this is the best idea. The idea of this mandate is to build state and local capacity, to build foreign capacity, and to rely on inspections done by other agencies. So in other words, the FDA does not need to do an inspection if the USDA already did it.
The FSMA Enhanced partnerships allows for the following. The FDA must assist state and local agencies to enhance food safety and defense. Provides FDA with a new multi-year grant mechanism to facilitate investment in State capacity to more efficiently achieve national food safety goals. I talked to you about building laboratories and that they are expensive? These grants will help with those expenses.

We also want to enhance foreign capacity building. The FDA must provide assistance to expand the capacity of foreign governments and their industries. Why because these are the governments who are importing products into the United States. We want to be sure the food that is coming in is safe. In addition, we are exporting to those countries and we want to ensure for them that our products are safe. This provides training to foreign governments and food producers on US food safety requirements. You will not be surprised to learn that we work very closely with the Canadian Food Inspection Agency. As you can imagine, many of the countries present in the US are also present in Canada and some of them are owned in Canada as we have a very close relationship with them.

This Enhanced Partnerships mandate allows for reliance on inspections by other agencies. The FDA is authorized to rely on inspections from agencies such as the USDA for meat. There is no reason to send a second inspector when the USDA is already trained in doing this. USDA inspections would thus be perfectly acceptable. Interagency agreements are in place for inspection of seafood facilities as well, both domestic and foreign.

I wanted to remind you that even though the laws were passed in 2011, implementation can be sort of slow. Again, you may read this years from now and realize one of these laws has been repelled or changed. In April of 2011 officials of the USDA proposed holding meat and poultry products until results of safety testing came back indicating that the products are safe for release to consumers. The FSIS also intended to hold imported meat and poultry to await testing. At last check, this hasn’t been implemented. The testing takes so long that foods would be lost. While it would be great to have this testing, it might not be practical.
The summary for this lecture is as follows. The Food Safety Modernization Act (FSMA) is the most far-reaching food legislation ever adopted. The new authorities and mandates required of the FDA are aimed at preventing foodborne outbreaks using science and risk-based factors. The FDA was required to enforce most of these mandates by the year 2012 (please note instructor misspoke here and said 2011). The FDA did not meet all of these mandates by 2012 and implementation is still ongoing.

Just a note here that I used the FDA’s website to create this lecture. The legislation is so new that it really hasn't appeared in any food safety textbooks, yet.