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FDA'S New Food Safety Regulations, Part Two

Understanding "Foreign Supplier Verification Program" and "Accreditation of Third-Party Auditors"

Webinar

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Understanding "Foreign Supplier Verification Program" and "Accreditation of Third-Party Auditors"

Dec. 16, 2015

Speaker: Kathleen A. Hardee, Co-Chair Food & Ag Group, Polsinelli.

Operator: Hello, and welcome to "FDA'S New Food Safety Regulations, Part Two: Understanding "Foreign Supplier Verification Program" and "Accreditation of Third-Party Auditors." This webinar is being presented by FDAnews.

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I would now like to introduce our speaker.

Kathleen A. Hardee has more than 25 years of legal experience representing clients in the food industry, products liability, business disputes, transportation matters, and in toxic and mass tort litigation. Polsinelli's Food & Drug Group is an industry based, cross-disciplinary group which brings together dozens of attorneys with experience in every area of the law. Hardee's strategy when working with clients is to identify and attain their business goals while minimizing risk, including reducing litigation exposure. She has tried cases in both state and federal courts across the country. She is also a trained mediator. Her client base includes food industry manufacturers, producers and distributors, businesses in commercial disputes, product manufacturers who have been or could be sued for injuries relating to those products, officers and directors, businesses looking to proactively work to minimize their liability risks, and transportation carriers and brokers.

I'll now turn over the floor to Ms. Hardee.

Hardee: Good afternoon. This is Kathy Hardee again, and we're going to try and pick up where we left off this afternoon. This morning we talked about the two primary core principles under FSMA, the preventative control rules for human food and the preventative control rules for animal food. This

Hardee (cont.): afternoon we're going to be talking about two additional core rules, or two more pillars issued by the FDA under FSMA, and that is the Foreign Supplier Verification Program and the Third Party Accreditation Rules. Because both of these rules pertain primarily to food or ingredients that are imported from foreign countries into the United States, it makes sense to discuss these two rules together.

My understanding is that everybody on the webinar this afternoon was also on this morning when we discussed the rules and history behind the creation of FSMA and the reasons why it was created and why it was developed. I'm not going to go back through that, but I do want to draw your attention back to some of the guiding principles under FSMA.

The primary reason behind FSMA to keep in mind was that it was designed for the purpose of creating a coordinated systems of laws to protect the integrity of the food supply. That coordination necessarily includes foods that are coming from foreign countries, whether it's just a food ingredient or whether it's a food product. To create a fully coordinated system, we have to include not just what's happening in this country, but on more of a global front.

Again, the seven pillars of FSMA are these final rules. We talked about one and two this morning. We're talking about four and five this afternoon. Four and five, Foreign Supplier Verification Program and third party accredited rules, were submitted to the federal register on October 31st of 2015. So these also are final rules that we have to look at, also applied to both human food and animal food. And there really is no difference in the requirements for each of these rules. The differences always come in because, again, the word flexibility is woven into every rule. The specific requirements for each of these programs is always said to be left to be flexible enough to conform with the requirements, A, of a particular food; and B, of a particular food facility.

The two rules work together to implement the safety standards for both human and animal food which may be imported into this country from foreign suppliers. The overall purpose of this with the rest of the world is to ensure that any human or animal food or their ingredients, when they're imported into the U.S., have to be produced under the same safety standards of food which is produced here. In other words, if a food is produced here to comport with the preventative controls for human foods, if a human food is imported from another country, it has to be assured that the food from that foreign country meets all the preventative control rules that we apply to human food that's manufactured here.

The difficulty with that is that it's all happening overseas. When we go to extend beyond the borders, how do we manage and confirm that the same rules are being followed? How do we audit that? How do we verify that? At an initial baseline level, the rule says that the food from a foreign country can't be adulterated nor misbranded with respect to food allergy labeling.

But it's broader than that. Essentially, they want every standard that is imposed upon foods manufactured here to be applied to foods that are manufactured elsewhere. And it's not just completed foods, it's also ingredients that come from a foreign country.

Unlike the original or even the supplemental draft of these rules, the final rule for preventative control for both domestic and foreign foods has evolved so that a lot of the theories and ideas you heard about this morning are going to carry over into these rules. One of the things that you might look for is the supply chain requirements and the requirements of the preventative control rules, to see how those two concepts are applied to foreign foods or foreign ingredients when they come into this country.

Just like foods that are produced here, foreign foods have to go through preventative controls. The preventative controls have to be managed, including monitoring activities, corrective activities and verification. Sometimes they're called something different and you can rely on different people to do it.

Hardee (cont.): But in essence, foreign food has to jump through all of the same hoops that a food that's manufactured here does. It has to go through hazard analysis. It has to have preventative controls. And all those controls have to be managed in the same way.

The question first is, who is responsible for ensuring the safety of imported foods? Therefore, who has to have a foreign safety verification program? A foreign safety verification program is something that's different than preventative control. It accomplishes the same things, but in different ways. So at a baseline level, the person responsible for having an FSVP to ensure the safety of imported foods is an importer, and the importer is defined as the U.S. owner or consignee of a food product offered for import into the United States.

You're going to see, as we go through this rule, there are more exceptions to every definition and every requirement in this rule than there are rules themselves. So we're going to try to get a high-level picture of the rule. If you think you fall within one of the exceptions, I suggest that you look at that later. But let's just get a big picture up of what generally is going to be required.

Most people who are reporters are the U.S. owner or the consignee of the food being imported into this country. If there's no U.S. owner or consignee at the time the food comes into the country, the importer is the U.S. agent or the representative of a foreign owner or consignee of the food at the time that it's imported, and you have to have a signed statement or consent. There are some exceptions for certain types of importers, and there are exceptions for certain types of food. And there are certain levels of exceptions.

The limited exceptions are that importers who don't have to conduct hazard analysis and who can verify their foreign suppliers by obtaining assurances of their foreign suppliers compliance are only subject to limited standards. The importers who import dietary supplements are subject to only limited SVP requirements. Very small importers, if you meet that definition, only have to have limited SVP requirements. Importers from certain small countries or certain small importers, if you're a qualified facility—and that, again, is a term of art, as is products from farms which are not covered farms, which is also a defined event. And then shell egg producers are only subject to limited FSVP requirements.

There then is importers which are exempt from bigger portions of SVP. Importers are exempted in large part from FSVP if they import certain types of foods from a foreign supplier who is in a country that the FDA has officially recognized as being comparable to or equivalent to the safety standards that are in place in the United States.

When the draft of these rules first came out, the FDA was suggesting certain countries. Maybe people who were in compliance with the European standards would be recognized as being substantially similar to the safety requirements here, and therefore, you wouldn't have to do an SVP if you were importing a food from that country. They threw out a couple of example countries that they were considering.

In this final rule, they backtracked, and they've said that the FDA has currently not recognized any foreign country as being approved to have safety standards that are equivalent. So that means that right now, there's nobody who can rely on this limitation. They are working on a definition. They've got a program started where they're going to work to identify who these countries are going to be and they'll form a list. At this point it doesn't exist.

If you think that you have a country that you're exporting from which imposes safety standards that are as high as the United States, I would not say that you're exempt from the large portions of the SVP. But you are allowed to consider their high standards as part of your verification requirements under the SVP.

Hardee (cont.): When this is put in place, this is going to make the process a lot easier. But at this point, the system for identifying who these countries are and the approval from the FDA hasn't been given yet.

Continuing to focus again on importers, this is a little bit more about the countries that the FDA is looking at for equivalent to that of the United States. And the system that they're working on is the system recognition initiative. Like I said, it's not in place yet. They're working on it, and life will be made much easier for people importing finished products or component parts at that time.

There are then certain importers that are exempted all together from SVP requirements. That only happens if you're a facility who has locations in both the United States and overseas. In that case, you're essentially importing from a facility that's your own facility, and so both you and your sister company are both subject to the human and animal preventative food control. If you have a company in a country who is subject to the preventative controls, you don't have to also have an SVP for products coming from that country. The preventative controls that you're exercising take the place of an SVP.

So that kind of starts off with your broad definition of which importers have to meet SVP requirements, and whittles down a large part of them into who is left for having to complete SVPs. There's a little more whittling to do, though. SVP has some exemptions for certain types of food.

There's no SVP requirements for juice, fish and fishery products subject to HAACP. If foods are for research or evaluation rather than consumption, they're not subject to SVP requirements. Alcoholic beverages and certain ingredients for use in alcoholic beverages fall under different regulations and they're not subject to SVP. Food that is coming into this country to only be processed and then exported elsewhere for consumption is not subject to SVP. Low-acid canned foods are exempt. And then finally, food that is subject to the regulation of the USDA does not fall within SVP.

I know you're sitting here thinking, is there anybody that actually has to comply with SVP? And unfortunately, yeah, there are some. After you figure out whether you are an employer who is subject to SVP requirements, the question then becomes, who is your foreign supplier? Because the assurances that you have to get under an SVP program have to come from or have to be about your foreign supplier. The foreign supplier may or may not be your customer, and may or may not even be a company that you have contact with.

Generally the foreign supplier is the establishment that manufactures, processes or produces the food, who raises the animals, who harvests the food that's exported to the United States, without further manufacturing or process by another establishment. If the food is manufactured or established by another establishment and you then purchase from that establishment, for your purposes, the foreign supplier is the establishment that's doing the manufacturing and processing. So normally, you only have to go back one step in the food chain.

The exceptions, though, are that if the intermediary between you and that manufacturer is somebody who is not doing anything other than packing the food, holding the food, relabeling food, if their activities are de minimis and they're considered an intermediary. And they're not the foreign supplier, so you have to be checking on what the foreign supplier is doing.

You can, in part, rely upon what that intermediary tells you, as long as that intermediary is doing verification activities and provides you with documentation of that. But if the intermediary is a de minimis handler of the food, the foreign supplier that you have to be worried about is one step back from that. There are also intermediaries who are harvesting produce, but not the growers of produce. And if they're the harvesters that don't really do anything other than pack and hold the produce, again, they're an intermediary and they're not a foreign supplier that you need to be concerned about.

Hardee (cont.): So if you've worked your way through all of these exceptions and determined that you are an importer and you do have a foreign supplier, a foreign supplier verification program looks, in large part, like a preventative control program, with some exceptions. You have to conduct a hazard analysis. You have to evaluate the food risk and compare the food risk to that foreign supplier's performance with respect to safety. You have to then conduct supplier verification activities, and you have to exercise corrective actions.

Which all sounds good, but you may be trying to do all of this halfway around the world. And that's what makes this program so difficult. The idea of only letting food into this country which meets the safety standards of the food that's manufactured in this country makes total sense. The problem is that in implementing it, it becomes hugely impractical. Most companies don't have the manpower to go across the world to confirm that. The FDA certainly doesn't have the money to be running all over the world to confirm that.

So that's where the second part of today's discussion comes up, which is in the third party accredited auditors program. The third party accreditors are people who have received the training so that they can fulfill a lot of these obligations for you. The concern is that as we impose more and more safety standards, and as we enforce those safety standards at customs as these foods start to come in, there's going to be all kinds of hang-ups. Somebody is not going to have the right documentation. People aren't going to be able to substantiate all of the particulars of these new rules. And given the shelf life of most food, we're going to have a real problem in importing food.

So there's two actual programs that are going to help get this through, and a third actually that's been laid out without a lot of specifics so far. The first one is the Foreign Supplier Verification Program to show that you've gone through all of your safety checks. Two is the Third Party Accreditation Rule, where you can retain someone to perform some or all of your safety checks for you. And then there's also a program that we're going to discuss a little bit later which is called Voluntary Qualified Importer Program, and under that program there are going to be foreign suppliers who can volunteer to perform certain kinds of verifications and safety checks which will get them on a list to show that they are regularly meeting safety requirements, and as proposed, their foods are going to go through import much more quickly than everybody else's.

So first, as with preventative controls, the foreign supplier verification hazard analysis tries to determine whether there's any biological, chemical, physical agent that's associated or has the potential to be associated with a food or the facility in which it's manufactured and processed, and reasonably likely to cause illness or injury. And whether that hazard is known or reasonably foreseeable to cause a potential injury significant enough that a knowledge person establish more controls or measures to minimize or prevent the standard.

You're going to see under this SVP that there's a split analysis in a lot of cases, and in some cases they allow you to focus on the facility. Is this a good facility, and do they generally create good products? And they're going to allow you to look at the food product. So you may have an SVP that covers a particular facility. You may have an SVP that covers a particular product out of that facility. But they allow you to perform your verification duties with respect to subsets as opposed to having to verify a whole foreign supplier when all you're concerned about is the particular chocolate, for example, that may come from that foreign supplier. You don't have to go through all these activities with respect to everything that that foreign supplier manufactures.

Then again, with respect to foreign supplier verification programs, we've got this concept of a qualified individual. The whole process, again, has to be overseen and implemented by a qualified individual, but a qualified individual under the Foreign Supplier Verification Program is not the same as a qualified

Hardee (cont.): individual under the Preventative Control Program. One is someone who is qualified with respect to the preventative control rules, and one is someone who is qualified with respect to the Foreign Supplier Verification Program. It very well may be the same person. A bottom line is that they not only have to have the scientific background, but they have to understand the differences in the rules between the two. Again, there's a standardized curriculum that people are working on that isn't ready yet. You can also use a third party to do these.

The other thing that's thrown in here, and again, it relates to relationships with foreign countries, is that once the FDA begins approving foreign countries to have similar safety programs, if there are foreign governments who have performed SVP criteria on particular companies, you can rely upon those approved government programs and government entities. Again, those haven't been identified yet.

The other person who can perform some or all of your qualified programs is a third party auditor. And the third party auditors are going to be talked about in a minute.

When you do a food risk analysis for an SVP, and when you evaluate your supplier performance, you've got to look at, first, the hazards. The hazards are something that you may or may not have seen when you performed your hazard analysis within your own facility in this country. But you have to extend your hazard analysis to determine, given where this is coming from, given the supplier this is coming from, are there hazards that may be discovered in the food product before it gets to you over which you have no control? And if you can identify those hazards based upon what you know about the food and what you know about the foreign supplier, then you need to put something in place to help protect those hazards.

This is where we get into the same concept as the supply chain programs that are under the preventative controls rules we talked about this morning. A supply chain program looks at hazards that occur upstream before the food ever gets to you. In this case, a foreign supplier verification program looks at the hazards that occur upstream when the upstream is outside of this country.

So you look identify the analysis, and then you start evaluating the supplier's performance. Is that supplier doing something significantly minimized or prevents a hazard? Is that supplier's processes and practices relating to safety to food good? In trying to evaluate this, you can look at their reports, any complaints about them. What is their record with respect to safety? You compare what they're doing to applicable FDA regulations, and any other factors that you think are reasonable in determining how they're handling risks. Especially risks similar to what you're looking at and what their history has been as far as being able to control those risks.

So the foreign supplier verification activities occur after you identify what the risks are, and the foreign supplier verification activities, again, are left to be particularly broad and open-ended. Again, they throw in the word flexible. The flexibility is said to be there because they want you to be able to create verification programs that allow you to verify what your hazards are with respect to particular foods, with respect to particular facilities, with respect to particular countries. The problem with allowing so much flexibility is it doesn't give you really any hard and good examples of what they want you to do.

Just like with preventative control rules, the supplier verification activities have to include written activities. You have to write down what you intend to do. You have to write down that you did it. You have to write down what the results are. Activities almost always need to include annual onsite visits, and these onsite audits are required any time there's an identified risk that could result in serious adverse health consequences or death. I think it's a good idea, based upon the harms identified, that unless they're very, very minimal, onsite visits are always a good idea. And using a trained third party accreditation auditor is something that can be the person that you want to use for your annual onsite audit.

Hardee (cont.): For verification, you can do sampling and testing. You can review safety records. You can rely on an auditor or other third party, so long as you always look at the documented results of their verification activities. You can't turn total verification over to anybody else and never look at the results and think that you're insulated. Even if you hire somebody who you believe is an expert to do this kind of verification, you have to always look at their results.

So once you do the verification, just like, again, the preventative control rules, you have to build in corrective actions. You have to include in your foreign verification supplier program what corrective actions you anticipate having to take, although there's always going to be something that comes up that's not something that you anticipated.

At a minimum, you have to take a corrective action if a foreign supplier doesn't utilize the processes and procedures that are equivalent to the same level of public health protection as what's being provided in the United States. You have to take corrective action if the foreign supplier has produced any kind of food that's adulterated or misbranded with respect to allergen labeling. Those are the two minimum times you have to take corrective action.

Corrective action depends on the circumstances, and it could be anything, including the discontinuance of that foreign supplier until the causes have been addressed. But again, just like with every one of the rules, corrective actions have to be documented. You have to document what occurred. You have to document what you considered with respect to corrective action. You have to document what you chose to do, why you chose to do that, and why you rejected something else. So again, documentation of everything in this program is important.

The SVP program can be performed by one of three people. If you've got the manpower and you've got the ability, you as the importer can perform your entire SVP program. If you've got a qualified individual and you have the ability to go over and to verify and audit and correct and manage your foreign supplier, you have the absolute right to do it yourself, as long as you're using a qualified individual to do that. The SVP responsibilities can be performed by a foreign government or agency once that foreign government or agency has been approved by the FDA as having the same level of public health and safety protection for their food program. Again, that's not in place.

As a third option, the foreign supplier verification responsibilities can be performed by third party auditors. This falls under the third party accreditation rule. And you can rely upon these third parties if you select someone who is trained, someone who is certified, and someone who produces the documentation of their investigation. And again, even if you turn it over to the third party, you, as the importer, still have the obligation of reviewing that documentation, reviewing those results, and confirming that it's being done right.

The other rule that we've been referring to all morning is accredited third party certification. And accredited third party certification is a voluntary program for the accreditation of third party certification bodies and auditors. Someone who has gone through this program and received the certification, they can conduct good safety audits under preventative controls doing it domestically here in this country. They can perform verification activities for foreign suppliers under an SVP. And they can confirm compliance with good manufacturing processes.

The other two things that they can do are issue certifications of foreign facilities and foreign foods. That's under a different program that I'll talk about in just a minute. But what I want to caution you about is that we talked this morning that the requirements under a food safety program, under the preventative rules for human food and for animal food, is not the same as a HAACP program. I've had several calls from people who are operating as food safety consultants, and upon further talking with them, when I ask about

Hardee (cont.): the accreditation being offered by the FDA and the approved curriculum that's required under the food safety program, they don't know what I'm talking about.

So a lot of people who are still out there as food safety consultants are HAACP trained, and not to take away from that, but they also have not necessarily learned the additional requirements and the differences in the requirements for being able to certify, implement and verify a food safety plan under FSMA. So an accredited third party certification, someone who is certified under this will be able to do all of those things, and will be able to make sure you're complying with all of the laws. If someone contacts you as a food safety consultant and says that they can do that, if they're not a third party accredited certified institution or individual, then they're not the person that you can rely on to meet your legal obligations.

As I said, the third party accredited entities, besides helping you with your preventative control, helping you with your foreign supplier verification programs, can also issue certifications for facilities and certifications for foreign bodies. This is a program, Voluntary Qualified Importer Program, VQIP, which is going to be a great program. I'm not sure how long it's going to take to get in place, but there will be a program where foreign suppliers who ship here on a regular basis, whether they're shipping finished product goods or whether they're shipping ingredients that are going to go into another good, they can volunteer to become accredited under VQIP.

Once they're certified, either their facility as a whole is certified or whether a particular food within their facility is certified, then when they get to customs, they go through first. There's not going to be the hold-up at customs because they have all their paperwork and they met all of the foreign verification supplier program requirements. All of the concerns that people are worried are going to result in delays at customs should be bypassed once this program gets in place. It's the third party accreditation individuals who can issue the certification to get these foreign suppliers into this program. And whether it's the entire facility or whether it's particular food products, if you can work with a foreign supplier who is a part of one of these programs, you're going to have a lot easier time at customs.

The accreditation of third parties can be certain foreign facilities, particular foreign foods. And as with everything else, I don't know how long it's going to take for this program to really get up and running. There are a lot of things here in FSMA and a lot of really good ideas. But every report that FDA turns in about everything they've done—they send a regular report to Congress—in every single report it says, but we need more money to be able to do this. I don't know that that's being responded to, at least in an effective way.

One of the ways that they're trying to make this happen is that there are partnerships that are being forged between state and federal teams with respect to inspections. There's partnerships that are being forged between certain countries. And I think that the third party accreditation is the way to make sure that there are people who are trained who can come in and do some of these jobs that the FDA just neither has the manpower nor the money to be able to do. So without the money, some of these programs will allow for some of these good ideas to happen, but just like it took a long time to create the system, it's going to take a while for some of this to actually occur.

Under this program, if a third party accredited auditor comes in and wants to help a foreign supplier become certified, then to get a certification for a voluntary qualified importer you have to be audited. There's two kinds of audits that a person can go through. You can do a consultative audit or you can do a regulatory audit. You can't be certified under VQIP until you pass a regulatory audit.

So one of the things that they're offering is consultative audits in preparation to do a regulatory audit. You can have one of these third party accredited auditors come in and do an audit of your company. It's only for internal purposes. It's not going to be turned over to the FDA. It tells you where your problems

Hardee (cont.): are and how to fix them so that when they come back through to do the regulatory audit, you're in a better position to be qualified. The only exception to that is that if in a consultative audit a third party auditor finds that there is a problem that could cause a serious risk to public health, they do have to report that to the FDA. But if you're simply trying to make sure you have all of your ducks in a row to get your certification, you can have a consultative audit done prior to the regulatory audit.

Once a regulatory audit is done, the results of that audit are reported to the FDA, and assuming all goes well, then either the facility or a particular product in the facility becomes certified as a VQIP. And I wouldn't say gets a free pass, but gets an expedited pass through customs when it gets there.

When we look at the compliance dates for both foreign supplier verification programs and for third party accreditation rules, generally importers have to comply with the requirements within 18 months after publication. The rule was published on November 27, 2015, so most of you are looking at 18 months from that date. If a foreign supplier, your supplier from overseas, is directly subject to FSMA and they have to do preventative controls, compliance with the Foreign Safety Verification Program must occur six months after the supplier is required to meet those rules.

As we talked about this morning, the supplier has to be able to get its own preventative control rules in place before its customers start demanding reassurance that it's in compliance. If the importer itself is a U.S. manufacturer, the preventative control rules contained in the date for complying with the preventative control rules and for complying with the supply chain program include verification of foreign suppliers, so you don't have to go through an SVP.

That's about all I have on these two rules pertaining to importing. I know that there are more exceptions and nuances to these two rules than just about any of the rules that have been published so far. But I think that you can see generally the same concepts that we talked about this morning with the preventative control rules try and carry forward here. The difficulty is you're dealing with foreign countries. You're dealing with a distance where it's hard for you to monitor what they're doing. It's even harder for the FDA to be able to monitor what they're doing. And so it's a lot more difficult. And with the various exceptions and nuances, it's also a little more difficult to read.

If anybody has any questions, I'd be glad to answer them now. Or if you think of any questions later, I'd be glad to answer them at any time.

Operator: Thank you. Ladies and gentlemen, now is your opportunity to have your questions answered by our presenter. Please remember this portion of the conference is also being recorded, and please limit yourself to one question at a time. To ask a question, please press *1 on your telephone keypad. I will announce you by the city from which you are calling. Your name and company will remain anonymous. You may hear a few seconds of silence as we bring you onto the line. You will then be live, and will be able to ask your question. Again, please press *1 on your telephone keypad to ask a question. You may also submit questions by email to questions@fdanews.com or use the Q&A panel within Webex.

Our first question will come from Kyle Asay from FDAnews. You may go ahead, Kyle.

Asay: Thank you. With everything you're talking about, with the problems of inadequate funding and so forth, it sounds to me as though the infrastructure to actually do the inspections and enforce these regulations, do you think it's actually going to be in place by the time that the deadlines for compliance are reached?

Hardee: I don't think that it is. I mean, I think you're absolutely right. I don't think that they are going to have the infrastructure. There's been some talk that initial inspections following the compliance deadlines

Hardee (cont.): are going to be more advisory than they are going to be punitive. I wouldn't count on that, but I think that there's going to be a period of a lot of advising.

Now if you run into the situation where you have to actually be forced into a position of recalling an adulterated food, I don't think they're going to cut you any break because they weren't able to audit you. But a lot of this is going to involve a ramp up of teaching. It's going to involve a ramp up of enforcement. And it's going to involve time just to create some of the conceptual ideas that I think are really good, but it's just going to take time to put them together.

So I think for a period of time you're not going to see really harsh results from inspections. But I think you have to do your best to try and comply because, A, you're required to by the compliance dates; but B, if there is a serious problem, the fact that you weren't trying to comply is going to result in them coming down even harder on you.

Asay: I'm not seeing any other questions coming in yet. So I was going to also ask, with the foreign supplier stuff, obviously there's all those exemptions in terms of different food categories, and then there's the whole idea that if the other country has a similarly robust program, there's a potential for exemptions there. I'm wondering about the flipside. Obviously this won't be codified, but you may know as an industry insider. Are there any particular countries or particular foods that are areas of special concern, that have been problematic historically?

Hardee: I think probably everyone would agree that foods from China are usually viewed with more caution. I think also one of the things that's not talked about a lot is that one of the reasons that prompted us, besides all of our own self-interests, to upgrade our food supply laws was that there were other countries who were bypassing us. Companies who develop food and who have to export into other countries have to comply with a lot more regulatory requirements than if they kept their food here.

So I don't think it's going to take all that much time for the FDA to at least be able to come up with the preliminary list of countries that they trust and whose food safety laws and whose inspection abilities are such that you should be able to rely upon them, at least for certain things. So I think this is a great benefit, but there are certain countries that I think it's going to be a long time, if ever, before they appear on that list.

Operator: [Operator gives instructions to ask a question.]

I'm showing no further questions in the queue. Do you have any closing comments before we wrap up?

Hardee: I don't. I know this afternoon's session was a lot of information with a lot of exceptions to every rule. But if anyone should have any questions at any time, just let me know. As these rules have now been passed, the FDA has promised guidance documents that should help to explain this out a little more. There are programs that are continuing to be developed that will help not only the identification of countries you can rely on, but also the curriculum for qualified people and how to put together a verified food safety plan. Those are all guidances that the FDA plans upon issuing, plus training and other resources.

So there's a lot more to come. Right now, we're simply talking from the language of the rules themselves and what the FDA has said publicly about what they intend those to mean. So this is going to be continually changing, and things that we may not have anticipated will continue to develop. But I think you can get an overall picture from what we've talked about today, and also get a picture of, this is a big plan. This is a cohesive plan. And on its face it works really well. There are just some parts of it that are going to take a while to get into place.

Operator: Thank you very much. On behalf of FDAnews I would like to thank our speaker and you.

Just as a reminder, if you'd like a recording of this session, you can order the CD and transcript package from FDAnews by visiting our website or contacting customer service.

This now concludes today's webinar. To end this call, simply hang up your phone and close your browser. Thank you.