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Jamerson: Hi, my name is Cal Jamerson. I am the Produce Safety Extension Associate with Kansas State University Research and Extension. Today, I'm going to be talking about the Produce Safety Rule coverage and exemptions with Don Stoeckel, the Midwest Regional Extension Associate for the Produce Safety Alliance at Cornell. How're you doing, Don?

Stoeckel: I'm doing well thanks, Cal.

Jamerson: So, the goal of our webinar today is to get into the examples and importance of definitions in the Rule and how packinghouses are affected by this. So, Don if you would, could you first explain the concept of exempt, excluded, and covered in the Produce Safety Rule?

Stoeckel: So the Produce Safety Rule has those three different, we'll call them buckets, and the first bucket is you're excluded – it just means that the Produce Safety Rule does not apply to you at all. The second bucket is exempt – if you're exempt, even though you don't have to follow most of the Produce Safety Rule, you still have to do some things in the Produce Safety Rule. In general, those things you have to do involved demonstrating that you're exempt from the Produce Safety Rule. They have some documentation requirements to show that they are exempt and not required to follow some parts of the Produce Safety Rule. And then if you're covered, you're covered. The Produce Safety Rule applies. Everything that you do that is relevant to Produce Safety Rule, you have to follow the Rule's requirements.

Jamerson: Okay, so let's start with excluded then. What falls into the first bucket of excluded?

Stoeckel: Generally speaking, that's the de minimis exclusion. So, if you're a farm – and de minimis just means the minimum threshold – if you're farming, you're selling less than about \$25,000 in produce, you're excluded. I do want to point out to you though, just to make sure that we're clear, that that \$25,000 is all produce, and it is inflation-adjusted – so what is the number this year, I'm just looking at my sheet here – the number this year is \$28,075.

Jamerson: Okay, so to be excluded – that first thing is, it's just sales of produce. You're under the, right now you said for 2020 inflation amounts \$28,075 – you are excluded from the Rule.

Stoeckel: If your three year average produce sales have been less than \$28,075 – you're excluded from the Produce Safety Rule.

Jamerson: Okay, what else is excluded from the Produce Safety Rule?

Stoeckel: Well, let me think. That's the only reason a farm would be excluded, but there are certain produce items that are excluded. The most famous one would be the ones that are rarely consumed raw. There's a list of 34 things that FDA has written into the Produce Safety Rule that says they're rarely consumed raw – that includes things like eggplant, pumpkins, winter squash – what else is relevant in that list, I know you know this list as well as I do, Cal, what else is relevant – sweetcorn, potatoes, a lot of beans, dry beans – not green beans but dry beans.

Jamerson: I know typically at the training, I usually tell people: “If you could pluck it from the field and eat it raw,” while that's not always the case because some people tell me, “Oh no I'll that stuff raw that's on the rarely consumed list.” So it's not perfect, but it's an easy way to think about it.

Stoeckel: Some people eat sweet corn and potatoes raw, but it's still on the rarely consumed raw list. So I guess the important thing is to make sure you know that list, because even if it doesn't match how you handle your produce, what's important is whether the inspector can look at that list and say, “These things are rarely consumed raw.” Those items of produce are excluded from the Rules, so if your farm only grows sweet corn, even though you sell more than \$25,000 worth of sweet corn – you're not covered for anything because all the produce you sell is excluded from the Produce Safety Rule if all you sell is sweet corn.

Jamerson: So, rarely consumed raw still falls under the definition of produce for that first criteria of sales dollars.

Stoeckel: Bingo. Oh, there is one more thing that's excluded, Cal, and that's food that's produced for personal or on-farm consumption.

Jamerson: Okay, let's get into exemptions then. Explain in greater detail how you can get a qualified exemption and how it works.

Stoeckel: Well, I gotta say the qualified exemption is probably the majority of questions I answer at Produce Safety Alliance. Right, generally speaking these are smaller farms that are selling less than \$500,000 a year of total food – that's not just produce – total food. That includes your jams, that includes milk, that includes hay, includes animal food, not just human food. But if you're selling less than \$500,000 in total food, the inflation adjustment amount of that is \$561,494 – three year running average and the majority of that food is sold to something called a qualified end user – then you're qualified exempt. The requirement that you're stuck with, with a qualified exemption, is just that you have to demonstrate that you're qualified exempt, so you have to have records of who did you sell to and how much did you sell and you have to do the annual review of those records to demonstrate you're still eligible for qualified exemption. And then one other requirement for those farms is that they must put on a placard, a sign, or the packaging if packaging is required, the full business address of the farm, and I think that's probably because it makes it easier to do trace-back if there were ever a problem so that the consumer, the buyer, knows what farm they got that produce from.

[05:35]

Jamerson: Okay, so food is different than produce in that it's all things basically eaten by a man and animal.

Stoeckel: Correct.

Jamerson: And then you mentioned a qualified end user. Could you explain what that is?

Stoeckel: The easy one is a qualified end user is the consumer. Doesn't matter where the consumer is, if you're selling it directly to the person who is going to eat it, or the animal that's going to eat it, then that is a qualified end user. The other part of the definition of a qualified end user is if you're selling the food to a restaurant or it's a retail food establishment that's located within the same state, within 275 miles, or the same tribal reservation, then those are also considered qualified end users. Retail food establishment includes grocery stores, it includes your farm stand.

Jamerson: So, if I'm selling it directly, myself, to Walmart or Hy-Vee or Price Chopper, or any of the grocery stores, you're telling me because the store is not consuming the food, but that in that scenario, that's still a qualified end user?

Stoeckel: The easiest way to explain it is one receipt or two receipts. The reason I bring this up is because, you mentioned it like the big stores, if you sell to the distribution center and then the distribution sells it to the grocery store, that's two receipts – that's not a qualified end user because you're not selling it directly to the retail food establishment. If you sell it directly to – and let's make it simple, Stan's Corner grocery store – if you sell directly to Stan's Corner grocery store and Stan sells it directly to the customers, that's just one receipt in between you and the customer. That's a qualified end user. But, if you sell it to the Hy-Vee/Walmart/Kroger warehouse that then resells it to their grocery stores, that's two receipts. And my current understanding is that that is not a qualified end user sale.

Jamerson: So, in essence it boils down to if you use a middleman in any way, shape, or form, like a distribution center, a broker, and they then turn around and sell the produce, even if it's still the same Walmart down the street that you were going to sell to, it is not counted the same when we look at qualified exemptions.

Stoeckel: Right. Couple of things that might be relevant to the farms that you work with. Something like an Amish auction house, if you sell through the auction house. Because the auction never took possession of the produce – that's considered a one receipt. As long as you're selling it to the consumer or the retail establishment. And then the other one, when it gets a little stickier because it depends on how they operate is a co-op. If the co-op buys from the farm and then aggregates it and sells it to a buyer – that is a two receipt situation, and that particular co-op scenario would not be a qualified end user. But other co-op scenarios might be qualified end user. I hope that makes a little bit of sense.

Jamerson: It does. So, in essence, it depends how the food hub's operating: is it a broker role or just you're still doing direct-sell yourself as a grower.

Stoeckel: Yeah exactly. And I think the simplest way to think about it is that one receipt, two receipt idea.

Jamerson: Then, so that's the one form of exemption is these qualified exemptions. And the one thing you talked about with that sign, placard, label – that's the modified requirements for labeling outlined in the Produce Safety Rule.

Stoeckel: Yeah that's right.

Jamerson: And that specifies at that point of sale, is where this information needs to be. So, basically do you want to talk a little about, you know, that if a sticker or label is required versus if it's not, and how that affects the modified labeling?

Stoeckel: Well, I don't know Cal. I think the nut of the whole thing is the consumer needs to know where the produce was grown. There are rules that the farms who are selling probably know better than I do about when there is a requirement for a label and when there's not requirement for a label on the food that you have packaged for individual sale. When a label is required the business address needs to be on the label. If there's no label required, then it can be on the sign of your farm stand, it can be on the invoice, as long as the consumer knows where that produce was grown. Now, do you want to talk about the sticky situation of what if a farm is buying and reselling the produce?

[10:04]

Jamerson: Oh, I do, but first, when you talked about that label, so then knowing, a key takeaway there is that even if a label is not required, in your situation, you would still have to post somewhere at the point of sale or making consumers aware of that farm business name and address where the produce was from.

Stoeckel: Right. Who did they buy it from?

Jamerson: Now, let's get into, what I call rabbit holes, of the farmer buying and then either repackaging or supplementing his sales with it. How does that work? How does that fall into all this?

Stoeckel: Well there, I guess there are two important things to say about that. One is that if you're helping out a neighbor and reselling their produce, those sales count as part of your sales and if those sales put you over the \$25,000 marker, then that means you are not excluded anymore.

Jamerson: So what if, I don't take possession of any of that money. So, whatever I sell his stuff for is put in a separate money bag and I deliver it straight to him at home. Would that still be the case in this scenario if it never goes into my bank account and then I reimburse him?

Stoeckel: That's a very good question Cal. That would make sense in the one receipt, two receipt paradigm, the way we were talking about it before, it makes sense to me that as long as there's not a receipt between you, that you didn't buy it from your neighbor to resell, that makes sense to me. You and I can talk all day long. What matters is what the inspector cares about and if it's important to a farmer, to their day-to-day decisions, and staying on the right side of the rule – they should reach out to the Department of Agriculture or Produce Safety Network to make sure that your understanding is actually within the requirements of the rule. We can help, but we're not going to have all the answers.

Jamerson: And then Kansas specifically, if you ever get questions, don't hesitate to reach out to us at Extension, 'cause we're here to help you navigate and understand this and anytime we don't know the answer we will find the information that you need for your farm.

Stoeckel: We got down to rabbit hole about who is selling what produce.

Jamerson: Oh but I like the rabbit hole, it shows the complexity and the moving parts.

Stoeckel: I mean, let's make it a little simpler. Let's say you've got a farm stand and you know that your customers are always looking for, we'll say tomatoes, it's a tomato time of year, and you ran out of tomatoes but you know your neighbor's got some tomatoes. So, you go buy some from your neighbors and you just throw that onto your farm stand – now those sales do count as your sales, without a doubt. So, that falls into your sales of produce and your sales of food. The question is: do you have to put on your farm stand “this is grown at my farm and my neighbors farm”? And according to the draft guidance that FDA has recently put out, you would have to disclose both farms. I don't think you have to label every tomato as to where it was grown. My understanding is that the modified labeling requirements state that the farm where the produce was grown needs to be displayed at the point of sale.

Jamerson: Okay, so if I'm buying to supplement, in that scenario, could I keep them separate if I chose to differentiate, you know – this is my farm, Bob's farm, and then over here in this other pallet is Mike's farm?

Stoeckel: Right. Especially if you've got different varieties of tomatoes and you just want to say, "These heirlooms were growing at my farm, and these slicers were grown at Bob's farm."

Jamerson: So, in the first hypothetical, we're getting into some farm examples, I am a grower selling \$23,000 a year in produce through my CSA. How am I impacted by all this?

Stoeckel: Well, if you're only selling \$23,000 that's less than that \$28,000 rolling average of produce, so you would be excluded from the rule. I would just make sure that you are confident that that \$23,000 includes all the produce that you're selling. It's gonna include the potatoes, the sweetcorn, the winter squash, all those rarely consumed raw pieces of produce.

Jamerson: So, in the next hypothetical: I'm growing \$40,000 a year in pumpkin sales, \$2000 a year in raspberries, and I actually use a broker who sells it all to varying grocery stores. Now, how am I impacted?

Stoeckel: Well that's an interesting one. Even though pumpkins are rarely consumed raw, they're still produce. So, those sales count as produce sales which puts you over the exclusions limit of \$28,000. Some of the produce that you're selling is covered – those raspberries would have to be grown under the constraints of the Produce Safety Rule depending on who your buyers are. If your buyer was, if you were selling the pumpkins locally at your farm stand, well you would be exempt under the qualified exemption because you were selling to qualified end users. But since you're selling through a distributor, that's not a qualified end user, then that's going to put you into coverage status, even though you're only growing \$2000 worth of covered produce.

Jamerson: So, that would mean I have to follow every aspect of the Produce Safety Rule with my \$2000 in raspberry sales?

[15:33]

Stoeckel: That's right.

Jamerson: A lot of times we do the trainings, I'll hear different growers say, "Oh I'm just gonna change what I grow, how I grow," and to me it's, you know, especially on the extension side, we can help you become compliant with the rule. It seems daunting and it seems like a lot, and it is, but there's a couple of core areas that really are not that complicated to be compliant with. So, I always tell growers, first work with extension and the people who are here to help you before you change how you farm based on the Produce Safety Rule. You want to encourage ag-growers, especially in the state of Kansas, I'm sure that's the case with every single state.

Stoeckel: Well, I'll add onto that. I mean, how many times have you heard somebody say, "It ain't rocket science, keep the poop off produce." I mean, the minimum requirements are keep poop off produce and then keep some records to demonstrate what you do. And when a farm starts thinking about getting out of fresh raspberry sales and taking the hit to sell 'em into processed, and that financial hit, that's a big deal. It may not be that hard to meet the requirements of the rule.

Jamerson: So, that is the qualified exemption. So, how does commercial processing fall into play with the Produce Safety Rule?

Stoeckel: Oh yeah, so I guess I just opened that can worms didn't I by saying you could tell your fresh raspberries into a processing step, into canary, or whatever. So there's an exemption for produce that's intended for commercial processing. Just keep in mind that commercial processing isn't

any processing – it's processing with a kill-step. We're talking about canning, we're talking about acidified foods, we're talking about like juices going into a HACCP process. If you are selling your produce into a commercial processing with the kill-step, you're eligible for an exemption, the part of the rule that still applies is some documentation. It's only fair that you disclose to the buyer that that produce was not grown under the conditions of Produce Safety Rule, and then eventually the buyer will have to send you back an assurance that says that they do not plan to sell it as fresh produce, that they plan to either commercially process it themselves or sell it into a commercially processing step. So, there's a two way exchange from the farm standpoint, there's specific language in the Produce Safety Rule that you can put on your invoice that says "this produce was not grown under the conditions of Produce Safety Rule."

Jamerson: Okay, so in a hypothetical then: I'm running a dunk tank with, you know, 125 to 150 parts per million of chlorine and I'm using a single pass wash system with an injector and I'm running 25 PPM of chlorine sanitizer through that as well. Is that commercial processing?

Stoeckel: No. First thing is, processing is not an activity under Produce Safety Rule, so you would be a mixed farm, mixed type facility. The point you're trying to get to is that it has to be a kill-step. When we say a kill-step we're not talking about 90% kill, we're talking about like 5 logs, 99.999% kill. There's hardly any chance that any pathogens are going to survive that commercial processing. Some of the exam, I listed some of the examples that thermally processed, the canning, the acidified foods, the HACCP systems, but things like distilling, fermentation into beer or wine, refining your food into oils – those are also considered processing steps with kill-steps.

Jamerson: Okay, and then you actually had a perfect segue into the next area, talking about farms, facilities packinghouses. I know this can be a little complex, we'll try to break it down step by step. So, farms and facilities are treated differently under the Produce Safety Rule under FSMA. So, if you have a packinghouse, it could be a farm or it could be a facility. Why does that matter?

Stoeckel: It matters because FSMA has, the Food Safety Modernization Act has, what is it, 7 or 8 rules. A couple of them are relevant to farms – 7 of them? Thank you. The Produce Safety Rule applies to farms. Facilities have to follow the Preventive Controls Rule for Human Foods. So it does make a difference whether you're a farm or a facility because you are subject to a different set of rules if you're a facility.

[20:12]

Jamerson: So, going into the definitions a little. What makes, you know, the farm packinghouse, whether it's you know, what defines it as either being a farm or a food facility?

Stoeckel: So, let's start with the easy part of it. The easy part of it is what do you do in that packinghouse. Because your packinghouse can be a facility whether or not it's on a farm if it's doing anything that's considered manufacturing/processing. And there's a useful FDA factsheet, if you're not sure which ones are manufacturing/processing activities. Generally speaking, you're talking about the second cut, you're talking about thermal processing, even freezing – it is considered a manufacturing/processing activity. Those things automatically put you into the category of a facility. All you're doing is packing or holding produce at your packinghouse, then you might be either a farm or a facility. The first thing that you have to pay attention to is where is the packinghouse – if it's on a primary production farm, if that packinghouse is right next to the fields – well, it's part of the farm, it's doing farm activities, it's part of the farm. What gets tricky is when the farm, when the packinghouse's off-farm. So, do you want to talk more about that?

Jamerson: Oh, I do. But, to go into a little more detail on that first part. So, typically on a packhouse, you know, your activities are going to be grading, sorting, washing, packing, labeling, and holding. If I'm just doing those things – am I a food facility in that scenario or am I a packinghouse?

Stoeckel: If those are the only things you're doing and none of those things fall under manufacturing/processing, and you're located where the food is grown on the farm, then you're a farm, not a facility.

Jamerson: So if I've got my field, and I've got my packhouse, and I'm just doing those standard activities, you know, I just fall under the Produce Safety Rule, and my packinghouse will fall under all the different criteria within the Produce Safety Rule.

Stoeckel: Right.

Jamerson: And then you mentioned the packinghouse would have to be on that primary production farm.

Stoeckel: Right oh.

Jamerson: So, let's talk about off-farm packinghouses and how they are impacted by the Produce Safety Rule.

Stoeckel: Okay, a packinghouse that's only doing those activities that you named earlier, the things that are associated with the farm, if it's off-farm, it can still be considered a farm, it's considered a secondary activities farm because the packing is a secondary activity of the farm. It can be considered a secondary activities farm if more than half the produce that runs through the packinghouse comes from the majority owner of the packinghouse. So that would be a secondary activities farm.

Jamerson: Okay, so we'll use the example of Mike's farm. He has a standalone packhouse called Packing Produce LLC. As long as Mike's farm owns the packinghouse and is doing more than half produce from the produce he's growing on Mike's farm, you can opt to be a farm.

Stoeckel: That's right.

Jamerson: Same example then. You have Mike's farm and then his Packing Produce LLC. If he is packing other grower's produce on top of his, how would that impact classification of his packinghouse?

Stoeckel: To a point, it wouldn't make a difference. But, if Produce Packers LLC is actually the point of the business and 90% of the produce that goes through that packinghouse is coming from all the adjacent farms, and only 10% of it is actually coming from Mike's farm, then the majority of the produce that's coming through is not from the majority owner and it would no longer fall under the definition of a secondary activities farm. So, then it would be a facility.

Jamerson: Okay. And a key thing for everyone with facilities is you are required to register that facility with FDA.

Stoeckel: That's right. It's the Biosecurity Act – it came after 911 – that requires food processing facilities to register with the FDA. The farm and facility definitions get really convoluted and they're so mixed up with each other. And honestly, a lot of people who own a packinghouse have made comments that it's not reasonable for a risk-based system to treat one operation that's operating exactly the same as another operation under different rules because of who owns it and where it's

located. The risks to the produce are the same either way. So, FDA listened to those comments. To their credit, they put out an enforcement discretion a couple of years ago that said for a packinghouse that other than – not for activities, but just because of ownership structure or where it's located – then they still have to treat the produce right, but there are two things: Under Produce Safety Rule, you've got all the post-harvest sanitation and handling activities and under the Preventive Controls Rule for Human Foods you've got the current good manufacturing practices. Those are about the same thing. So, the FDA said is that you can choose between Produce Safety Rule or CGMPs. And you're currently under enforcement discretion from the Preventive Control Rule.

[25:44]

Jamerson: So, if I have a farmer-to-packhouse, regardless of if it's on my primary farm or I have it off-site, and I'm doing other people's produce at that packhouse, like if it's processing multiple different produce, still doing those same activities that don't classify as manufacturing/processing, I can opt to follow the Produce Safety Rule criteria with my off-site packhouse.

Stoeckel: Right. If you are running an off-site packinghouse and you're trying to decide whether to use the Produce Safety Rule or CGMPs, enforcement discretion means you can do either one. You don't have to follow Preventive Controls Rule. If the question you're asking yourself is, "Do I have to register as a facility?" then you have to pay close attention to the current definition of a secondary production farm. If you don't fit within the current definition of a secondary production farm, which includes the ownership structure and who grew the produce that you're working through your packinghouse, you're a facility, you have to register as a facility. Even if you're under this enforcement discretion.

Jamerson: The reason that matters is, you know, when you register as a facility with FDA, when the enforcement discretion, one way or the other, you know, becomes the way it is or it goes away, then you would have to follow the CGMPs and the Preventive Controls Rule.

Stoeckel: Right, that's an excellent point.

Jamerson: And then the big, to me, from the grower side, the big takeaway is, they are very similar – the Produce Safety Rule and CGMPs. As a grower, for me, a big takeaway is, it becomes important, the registration aspect, because when the enforcement discretion, if it goes away, if you have to register with FDA, you now fall under Preventive Controls Rule, which would mean you need a PCQI trained person, you have to do a hazard analysis identify control [inaudible]. Which is very similar, to those who have experience with HACCP, they're like cousins, right, but it does change, in that you know, the Produce Safety Rule does not require a written food safety plan.

Stoeckel: That's right.

Jamerson: Preventive Controls, it's a completely different ball game in that regard.

Stoeckel: I am nodding my head, which nobody who's listening can see. I think you did a great job of summarizing that, Cal.

Jamerson: And with that we are out of time. I want to thank Don Stoeckel with Produce Safety Alliance for taking time for this deep-dive into the Produce Safety Rule coverage and exemptions. If you



have questions, reach out to your University Extension and Department of Agriculture. Thanks for listening.

[28:21]

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*Transcribed by Melanie Arthur, National Farmers Union Intern*