

**Shayla:** Hello and welcome to the FSIS webinar on the PHIS Adulterated Product Monitoring Module. I'm Shayla Bailey and I will be the FSIS moderator for this event. We have presentations and a live demo lined up for you today, but I wanted to go over a couple of logistics first.

We plan to [00:00:19 inaudible] questions at various points during the webinar. To ask questions, you can either submit them via the chat panel in the WebEx screen, at any point during the presentation. Or you will be able to ask verbal questions once we reached that point in the presentation. If at any time you need technical assistance, please send a chat to our event producer, Michelle, and she will help you out.

Now, I'd like to introduce Dr. Phil Bronstein, the FSIS Assistant Administrator for the Office of Field Operations, to get us started with our formal agenda. Dr. Bronstein.

**Dr. Bronstein:** All right. Thanks, Shayla. Hello everyone. As Shayla said, my name is Phil Bronstein. I'm the Assistant Administrator of our Office of Field Operations, and I really wanted to welcome everyone to our webinar today, which is going to highlight our newest modules to our Public Health Information System or PHIS, and it's called the Adulterated Products Monitoring Module, or APM for short.

But really excited about this module because it brings just about every major agency function under one umbrella. As we come in a little shy of our 10-year anniversary of PHIS implementation, and just about nine years from introducing and making available features in PHIS for industry use. APM within the PHIS will now allow us to combine the different data streams for products of concern into one robust system, and allow us to directly connect with your establishment's profile, any verification data that we have in your establishment, and the information from potentially adulterated product in commerce, which will allow us to have a more streamlined data driven holistic analysis, that will allow us to meet our regulatory obligations in a much more efficient and timely manner.

APM is being implemented in two phases. The first phase is already been implemented back in October, and that was mostly for the headquarter staff, district offices, and field operation, as well as our office of investigations, enforcement, and audit, Compliance Investigation Division. By allowing all those staffs to create and manage industry reports for adulterations, which we call high risk, inside PHIS.

The next phase and the final phase is for the implementation of APM will be on March 1<sup>st</sup>. What this means is that we are going add on additional features for our in-plant personnel and industry to put data directly into the

APM. That means that we are using from our side that we're... that the remaining paper-based process of what's in the agency, will be moving to a fully electronic version within PHIS. In-plant personnel will begin entering establishment data reported on adulterated misbranded products into PHIS, and for industry with this module, you will have the option, and I want to stress this, an option to use the electronic reporting tool in PHIS. It's not mandatory, but it is providing you with another option to self-report if you choose to use it. If it's your preference to continue with the current processes that you're doing, by providing that information to your IPP or calling the district office, you can continue to choose those processes. PHIS has been designed with an electronic version of the form 8180.1, which is the notice of receipt of adulterated or misbranded product, and designed to meet all of our regulatory requirements that are outlined in 9CFR part 418, as well as the ability to validate compliance of all other statutory and regulatory requirements for adulterated and misbranded product. We know from our 10 years of experience with PHIS, the system and your data within that system are secure. We have a robust role-based procedures that really make sure that the information, all the information in PHIS is only being viewed by the people that need to look at that information.

There had been many questions on data exposure from others seeking information through the Federal Freedom of Information Act, and as a reminder, all of the data that the agency creates, collects, and maintains is subject to FOIA regardless of the format, whether that's paper, electronic, or anything else. Establishments can request pre-released notification, if they believe a FOIA response contains their proprietary data. I would encourage you to reach out directly to our FOIA office, if you had any additional questions or concerns about any of your documents or the APM module, and the information that's going to be contained within that module. Their email address is fsis.foia@usda.gov. Now, I want to go ahead and hand this meeting off to Rochelle [00:05:19 inaudible] from our Recon Management and Technical Analysis Division at headquarters in [00:05:24 inaudible] She will be going through a PowerPoint presentation and a live demo of the APM module. Then we'll take your questions and proceed with a brief walkthrough of our PHIS environment, where industry can test this new module, and finally, we'll briefly touch on a few points about [00:05:42 inaudible] level two procedures. Rochelle?

**Rochelle:**

Thank you very much, Dr. Bronstein, and thank you everyone on the line for joining us today. I will be discussing an overview of the APM industry report of adulteration case type and connecting a demonstration at how to enter and submit a case into the system. As Dr. Bronstein already iterated, the Adulterated Product Monitoring System is a new module in PHIS that will capture events of adulteration or misbranding when product is shipped or received by a federal establishment.

Again, regulatory requirements for notification of adulteration or misbranded product are unchanged. However, the logistics of reporting the notification have been updated and are incorporated into the APM module. Industry personnel will have the option to submit an industry report of adulteration or IRA in PHIS APM, to provide notification to the local FSIS district office, in accordance to with title 9CFR418.2. Reporting is so required within 24 hours of determining that they have received or have shipped adulterated or misbranded products that has entered commerce. The receiving establishment still also have the option to notify inspection program personnel when they received adulterated or misbranded product. IPP will complete a report in APM as a digital mechanism for the FSIS form 8140-1. Receiving or shipping establishments also still have the option to notify the district office directly, such as via phone or email, and the district office will complete an IRA in APM. In order to provide notification through an IRA, the establishment must submit a report in the system, in order to satisfy the regulatory requirement of notification as per 9CFR418.2. Cases that are left in draft status would not satisfy the regulatory requirement. The system will keep draft cases for two days before they are automatically deleted. However, this does not extend the 24-hour notification requirement for the regulation.

An industry user with level two [00:08:04 inaudible] access associated with the federal establishment can submit an industry report of adulteration in PHIS APM. The information entered in the IRA will be reviewed and evaluated by the district office overseeing the notifying establishment. The district office may follow up with the establishment as needed during the agency's assessment. This slide describes the visibility of IRA cases submitted to the system. When cases are in draft status prior to submission, only the user who created the draft can view and submit it. Once the case is submitted to the system, the industry user who created the case can see a read-only view. Industry users, after notifying the establishment, can also see a read-only view of cases that other personnel in their establishment submitted. FSIS district office personnel and IPP, who oversee the notifying establishment and any associated non-notifying establishment can see the case. Industry users at the non-notifying establishment, for example, the shipping establishment when the case is submitted by a receiving establishment cannot view the case. Industry users at the notifying establishment can see a read-only view of cases that are created by the district office, when the district is notified directly, such as by phone or email, and creates a case in APM. However, industry users cannot view attachments uploaded by agency users.

This slide shows a screenshot of how to access APM from your PHIS profile. I'm now going to start a live demonstration, to walk you through how to

create and submit an IRA in APM. But before I go into the demo, I'd like to pause here and find out if there are any questions at this time.

**Shayla:** Thanks, Rochelle. I don't have any questions via chat. I'll turn it over to Michelle, to let us know if there are any folks who want to ask a verbal question at this time.

**Michelle:** All right, ladies and gentlemen, if you would like to ask a question via phone, please press #2 on your telephone keypad to enter the question queue. You are also welcome to submit written questions in your chat box. To submit the question in your chat box, and select all panelists from the dropdown menu in the chat panel, and send. Once again, to ask a question via phone, please press #2.

All right. I do not see any questions in queue at this time.

**Rochelle:** Thank you, Michelle, and thank you, Shayla. In that case, we will proceed with the demo. The content that should be displaying on your screen is the PHIS homepage, for a plant management role. To access APM on PHIS, log in to PHIS and select the APM dropdown from the left side navigation menu. Select inquiries to navigate to your APM homepage.

The system will load to my APM homepage on the recently viewed report tab. I also have two other tabs on my inquiries homepage. Draft reports will show reports that I have started but have not submitted, and pending reports and official reports that will show submitted reports I have access to.

From your APM homepage, to create a new case, click create report at the top of the page, and select create report from the IRA menu. There is an important message here at the middle of the screen, the newly created report shall be submitted to the agency within two days, draft reports older than two days will automatically be deleted by the system.

**[00:12:37 inaudible]** create report will open to the IRA case creation wizard. There are three tabs, notify your information, establishment information, and summary. On the notify your information tab, please note that this notifying establishment role, either shipping or receiving cannot be revised once the draft is created. The system will default to its receiving establishment. If you are a representative from the shipping establishment, you'll need to select the shipping establishment radio button.

The next tab for establishment information will correspond to the selected notifying establishment role. If the user select shipping establishment, the following tab will ask for shipping establishment information and vice-versa

for a receiving establishment. The notifier first and last name will auto populate based on your log in information. We also have the option to enter additional information as pretext in the notifier information field. A phone number is required to proceed to the next page by selecting x.

On the establishment tab, options in the grid will be limited to establishments in your PHIS profile. Clicking select in the last column of the grid will select your establishment and proceed to the summary page. The summary page in the case creation where there displays the information entered or selected on the notifier in establishment tab. We can click previous to make any edit, or click finish to create our draft IRA case.

The webpage will refresh to display the IRA case in draft status, and the case header will show a draft case number. The notifier information page will display and will include the information entered during the case creation wizard. All information on this page is fully editable except for the first and last name. You can click on the links in the light green navigation bar in the header to navigate through other pages in the IRA case, establishments, product, attachments, and summary.

The establishments tab will display the information for the notifying establishment that I entered in the case creation wizard.

The user can now enter information for any other involved establishments in the appropriate section when applicable. For example, if the notifying establishment is a shipping establishment and ships to another establishment, I can click 'Select' under the receiving establishment section. You can search for an establishment by entering the district, establishment number, or establishment name criteria and click 'Find'. Clicking 'Select' in the last column of the search results grid will add it to the establishment tab in the appropriate section. Changes can be made to the establishment information by selecting 'Change' or 'Remove' in the appropriate section. The information for the establishment under the notifying role can only be changed and cannot be removed. At this point, if the user needs to change the notifying role from shipping to receiving or vice versa, you would need to delete the case and start a new job. Before we proceed to the next section, I'd like to pause here and see if we have any questions so far on case creation or these first two tasks.

**Shayla:** We do have a question in the chat. Stephanie Benson asks, "Can non-notifying establishments see or not see submitted reports?"

**Rochelle:** Non-notifying establishments cannot see submitted reports. In this example, the notifying establishment is the shipping establishment, Establishment J. Establishment J will see a read-only view once the case is submitted.

Establishment B as the non-notifying establishment will not be able to view the case.

**Shayla:** We do have another question from Ashley Peterson via chat that asks, "Can corporate users create notifications or is it limited to plant management only?"

**Rochelle:** PHIS user roles with plant management or corporate access can create an IRA case. I believe that Carol will go into that in depth later in the presentation as well.

**Shayla:** As a follow-up I believe to the non-notifying establishment question, we have Kim Rice asking, "So we can't see if it happened at our facility?"

**Rochelle:** That is correct. If the establishment does not create the case, you will not be able to view the case; however, any follow-up from the district office would provide the information needed, in order to conduct any activities that need to be performed during follow-up.

**Shayla:** Our next question via chat asks, "If I'm the receiving establishment doing the notification, can multiple shipping establishments be listed?"

**Rochelle:** Only one establishment can be listed as a shipping establishment; however, there is an option to add additional establishments with comments for those establishment roles. The ability to enter that establishment information is the same as when we were entering the receiving establishment, in this example, same searchability. The only difference is that you can select a role and enter comment that will display in the case. If there are potentially more than one shipping establishments, you would want to enter one in the shipping establishment information, and add any additionally involved establishments in the 'Add Additional Establishment' section.

**Shayla:** Thank you, Rochelle. Then another question that came in asks, it's from Zack Cameron, and he asks, "Can corporate users see all IRAs submitted from their establishment?"

**Rochelle:** Yes. Anyone with PHIS access from the establishment that has an appropriate role and access for APM, will be able to see cases submitted by their establishment.

**Shayla:** Jeremy Caldwell asks, "The only notification of a case against my establishment will then come from the district office. Is that correct?"

**Rochelle:** I may be misunderstanding the question, but I believe he is asking if he is identified as the non-notifying establishment; and that would be correct. Very similar to how information is transcribed currently with 418.2

notification, if the shipping establishment in this example notified the district office, the district office would then notify any other associated district office, or if the receiving establishment is in the same district office, notify the receiving establishment for any follow-up activity. That does not mean that the shipping establishment in this example would not notify the receiving establishment or vice versa directly.

**Shayla:** Then he also asks, "Once a case is closed, will there be a history of cases against my establishment that they can view?"

**Rochelle:** Once a case is closed, it does stay in the system. It will be marked as a closed case, but that information will still be available in APM.

**Shayla:** Then Tina Brendan asks, "What happens if the shipping establishment and the receiving establishment both submit an IRA for the same incident?"

**Rochelle:** If there are duplicate cases in the system for the same event, the district offices will evaluate which case was submitted first and one will likely be removed from the system; however, of course, the data in the cases will be evaluated to determine if there are any discrepancies, anything that the agency needs to follow up on.

**Shayla:** It looks like that's all the questions we have in chat right now. Michelle, do we want to take some verbal ones right now please?

**Michelle:** All right. Ladies and gentlemen if you would like to ask a question via phone, please press #2 on your telephone keypad to enter the verbal question queue. Once again, #2 will enter you into the queue. We do have a question on the phone. Caller, your line is unmuted. You may ask your question.

**Kim:** Yes. This is Kim Rice. I just want to ask another clarifying question. If the issue originated in my facility, and the receiving facility created the record and it was closed, it remains in the system, but I still can't see it even once it's closed.

**Rochelle:** That's correct. The non-notifying establishment does not have the ability to view the case, even when the case is closed.

**Kim:** Does it show up somewhere else in my record for that facility?

**Rochelle:** No. It will be logged in the system, so your establishment will be logged as the shipping establishment for the case, but again, you would not be able to view the case.

**Kim:** Thank you.

**Shayla:** All right, we are moving to the next question in the queue. Caller, your line is unmuted. You may ask your question.

**Male Speaker:** I think she asked the exact question that I was just about to ask about. It was kind of my written question as well, that if I had a case against my establishment and it's closed, everything, there's no way for me to go back and see a history or a trend of cases issued against my company from establishments. It doesn't sound like there is. Sounds like I can only view cases that I levy against other establishments.

**Rochelle:** That is correct. Again, viewability for submitted cases is limited to the establishment who submitted the case to the system.

**Michelle:** All right. There are currently no additional questions in the queue.

**Shayla:** We did have a couple more come in via chat, so I'll circle back to those before we continue on with the presentation. We had one person ask, let's see, "If the shipping establishment determines that the adulterated product does not come from their plant, how is that reflected in the system?"

**Rochelle:** Once a case is submitted to the system, there is a process that the agency will conduct during their evaluation and document the results of the outcome in the case. We have an analysis section of the case available to agency users, where such information can be documented before the case is closed.

**Shayla:** Great. "If the shipping and receiving establishments both start the notification and only the first will be kept, does that mean or do you recommend that if they're told by the receiver that they notified the district, should they hold off on treating the notification themselves?"

**Rochelle:** Again, the establishment does have the option to create an IRA, notify the district office directly at any time; however, if there is more than one case in the system for the same event of shipment of adulterated or misbranded product, the agency will evaluate those on a case-by-case basis, to determine if any information needs to be removed from the system.

**Shayla:** Thank you. Then, we did have kind of a comment come in that... just a point of clarification that establishments will always be notified, right, if they were recorded as the shipping establishment by the district office. The process doesn't really change, this is just an addition to PHIS, right?

**Rochelle:** That is absolutely correct. The process does not change, the only difference here is a digital mechanism to provide your information, as opposed to maybe an email summary and attachment [00:26:04 inaudible]

**Shayla:** Those notifications will still occur for folks who are kind of nervous about not being able to see the records that are submitted in some cases, right?

**Rochelle:** Yes, that is correct. The district office will continue to conduct notifications and follow-ups.

**Shayla:** Another question we have is... and it's kind of a comment and a question, "In many cases, both the shipping and receiving establishments must both notify under 418.2, but only one, whichever company is selected arbitrarily by the district as the official case, so if the other duplicate is deleted, then one of the parties will not be able access the case, but one will, right? That's what they're asking.

**Rochelle:** If a case is removed from the system, that is correct; however, again, the agency will need to evaluate that information on a case-by-case basis. Not necessarily that a case would be deleted in every situation.

**Shayla:** Then another question that we just got in was, "Will this information be included in our quarterly reports from FSIS?"

**Rochelle:** I will defer to Dr. Bronstein on that question.

**Dr. Bronstein:** Yes, sure. No, at this time we don't have any intention on putting that into the quarterly reports.

**Shayla:** Thank you. That is all the questions we have right now, so I think we'll go ahead and keep the agenda and the demo moving, and we'll certainly have opportunity for more questions along the way.

**Rochelle:** Thank you very much, Shayla. I'm going to proceed to the product page. This page includes sections for adulteration or misbranding information, product information, product disposition, and optional carrier information. The adulteration or misbranding section is used to enter information including the date the issue was identified, the issue type, and issue description, including how the issue was discovered and how the scope was determined, and a likely root cause or a description of how the issue occurred. To enter the issue type, I'm going to select the blue view issues link. This link will open an issues hierarchy. Selections in the first column will generate corresponding sections in the second column and so forth. Some selections will open up to four columns and some only two. Some selections throughout the hierarchy are check marks, and some options will display as check fields such as 'Other' or 'Mislabeling'.

The first two columns are required to be completed to submit a case in the system, however, we would encourage you to provide as much information as possible in this section when submitting the case for FSIS review.

Selecting 'Validate Issue' at the bottom of the page will perform a system check, to ensure no required fields are missing. I get a validation for closure path validation message. I'm going to select 'Save Issues' and then click 'Cancel' to return back to the product page. I'm going to enter a date that the adulteration or misbranding was identified. This is not necessarily the date the product was received or shipped, or necessarily the date that I'm reporting to the agency. This the date when my establishment determined that I ship or receive adulterated or misbranded products. Point to enter free text in the issue description and likely [00:30:06 inaudible]. The Product Information section on the left-hand side of the screen is used to document the date shipped or received and products information. Selecting the establishment same as notifying establishment checkmark will enter the information for the establishment notifying the agency of the issue. This would generally be used when products are labeled with information for the establishment who's creating the case. Otherwise, it would be manual entry of the establishment number and producer name on the product. The HACCP selections are dependent on selections in the previous field and can only be entered in order. In other words, you can't select a finished product category without first selecting a HACCP category. If I select raw non-intact, my following selections will be only raw non-intact and so forth. Selecting non-intact beef will open my species to beef, and all of my product groups will be non-intact beef. Comments can be entered in free text by selecting the add comment link. The product quantity and disposition section on the right-hand side of the screen is used to document the amount of products implicated in commerce and under control. The amount under control auto populates based on the difference between the amounts implicated and in commerce.

If the amounts documented in the quantity of products need to be estimates at the time of submission, please include a comment on this page to indicate as such. If products under control is located offsite, you can select product location offsite, and enter any details for the product location establishment number, or free text the product location details. There's also the ability to add carrier information at the bottom of the screen by opening the carrier's section and clicking Add a carrier. Carrier information is not required to submit the case for review. Clicking Save at the bottom of each page is good practice, to make sure that the system saves your data, and it does not timeout. The attachment page provides the opportunity to upload documents by selecting the upload an attachment link. Select your file and document type. Include a short description of the document and select upload. Your file will display in the grid and the document type and description are editable. The document can also be removed after upload if needed. My summary page displays the information I entered in the case. If any revisions are needed prior to submission to FSIS review, navigate back to the appropriate page, update the information, and save the case. I'd like

to pause here for any additional questions before we go into step three case submission.

**Shayla:** I don't see any questions in the chat right now. We'll go have and check on the verbal queue. Michelle?

**Michelle:** Once again, ladies and gentlemen, if you have a question you would like to ask via phone, please press #2 on your telephone keypad to enter the question queue. Once again, pressing #2 will enter you into the question queue. All right, and I currently do not see any questions in queue.

**Shayla:** We did have one come into the chat that asks if edits can be made after the user submits the information to the DO.

**Rochelle:** Thank you for that, Shayla. In that case, I'll move forward into the submission discussion. When I'm ready to submit the case, I'm going to click Submit for review at the bottom of my page or submit at the top of my page. This system will perform a validation to make sure that no missing... or required information is missing. In this case, I receive an error message because I have the product location offsite checkmark selected and no additional details. I'm going to remove that selection, save the case, and submit for review. Once the case is submitted, again, all pages will be in read-only mode. The industry user will no longer be able to make changes to the information previously entered. However, we do still have the option to add additional attachments. Again, the draft must be successfully submitted to the system within two days or the draft will be deleted. The establishment is not required to perform any additional notification to the district office once the case is submitted in PHISAPM. This is an example of the product page in read-only mode after case submission. If the case is created by the district office because you notified them directly and did not self-report in APM, your read-only view will look very similar. The only difference is you will not see the attachments tab. Please also be advised that this system will timeout after 30 minutes of inactivity and will display errors when attempting to enter information after that time. There are certain fields in the case that are required to submit the case to the system. Those fields include the date, the adulteration or misbranding was identified, at least one issue. If the issue cannot specifically be identified at the time of submission, we would recommend selecting other and entering details to describe the problem, the date the product was shipped or received, the product name, establishment number and producer name on the product, HACCP information, and the amounts of product implicated in commerce and under control. That concludes the demo portion of today's webinar. Are there any additional questions at this time?

**Shayla:** We do have a couple that have come in via the chat. The first one asks, if a receiving establishment reports to the district office via PHIS, and the shipping establishment reports by email, will the district office put the info into the PHIS system?

**Rochelle:** Yes, the notification will be entered into PHIS as an IRA by the district office.

**Shayla:** Then the next question asks, if the establishment does not or cannot complete the notification via PHIS, but does so via email with the information then the input, I think that's kind of the same thing, right, will be input into the module for historical purposes?

**Rochelle:** Yes, if the district office is notified directly, the district office will create the IRA with the information provided by the establishment.

**Shayla:** Great. That's all the questions I have via chat. Do we have any in the verbal queue?

**Michelle:** I do not currently see any questions in the queue. But once again, ladies and gentlemen, if you would like to ask a question via phone, please press #2 on your telephone keypad to enter the question queue. All right, I do not see any. There is one question that just popped in. Caller, your line is unmuted. You may ask your question. Caller, please go ahead. Your line is unmuted. You may ask your question.

**Male Speaker:** Yes, I was wondering, do you still submit if you have to, if you're doing a corrective action or whatever, do you still submit that to your IIC, or does it go into this system somewhere?

**Rochelle:** You can submit your corrective actions directly to your point of contact, either your IIC or the district office.

**Male Speaker:** Okay. Thank you.

**Michelle:** All right. I do see another question in queue. Caller, your line is unmuted. You may ask your question.

**Male Speaker:** Hello, thank you. Does this fully take place or replace the form 8140, or do we still have to fill that out and send it into the district office?

**Rochelle:** For the 8140-1 form, IPP have the ability to create a digital case in the system as a mechanism to complete that form. If you as the receiving establishment are notifying IPP that you received adulterated or misbranded product, you would notify IPP directly and IPP can create the equivalent case in the system to an 8140-1 form. Again, the establishment does still have the option to directly notify IPP as the receiving establishment, to notify the

district office as the shipping or receiving establishment, or to self-report the issue as an IRA and APM.

**Male Speaker:** Okay, so if we did use this system here, then we're not obligated to submit a separate 8140 then?

**Rochelle:** That is correct. Only one method of notification would be required.

**Male Speaker:** All right, thank you very much.

**Michelle:** All right. I do not see any additional questions in queue. But once again, ladies and gentlemen, #2 will enter you into the question queue.

**Shayla:** We do have [00:40:59 crosstalk] oh, sorry.

**Rochelle:** Sorry, Shayla. I'd like to go back to the question for corrective action. If you are the notifying establishment providing corrective action, you do have the ability after the case is submitted to upload additional attachments to the case. If you are the non-notifying establishment and do not have access to upload attachments to the case, you would want to provide that information directly to your point of contact, the district office.

**Shayla:** I think that's a great clarification. We do have a few questions that have come in via chat. One person submitted that, as an example, if a bone chip is found by a consumer in one package of ground beef, how would quantity of implicated products be determined?

**Rochelle:** The implementation of the APM doesn't change the establishment's method of evaluation. The only difference is it's providing that information to the district office through the APM. If the quantity of products you are providing is an estimate, or is even less than a pound, and you can certainly enter that information into the case, any comments on the quantity of product can be entered on the product page as well.

**Shayla:** All right, another question. Let's see. Can an establishment meet that 24-hour notification requirement verbally, and then later report the incident electronically?

**Rochelle:** If the establishment is notifying the district office in accordance with 418.2 within the 24 hours, and the district office can create the IRA in the system.

**Shayla:** Then, if an establishment sends a submission to the district office, can IPP view or edit the submission?

**Rochelle:** IPP does have the ability to view a case that was submitted by an establishment and their assignment.

**Shayla:** Can you print the report? Is there an option for doing that?

**Rochelle:** At this time, no, there is no option to extract the information out of the system in a document report.

**Shayla:** All right, and continuing with our chat questions, if a receiving facility implicates my facility as shipping, I determine as a shipping establishment that the FM did not originate from my facility. Will my establishment be removed from the final record?

**Rochelle:** Not necessarily. The establishment information needs to be included in the case. However, the analysis that is conducted and documented by the district office would include information that the, in the case of this question, foreign materials did not originate from the initially identified establishment.

**Shayla:** Continuing with those, so if they DO, the district office issues an IRA, and an establishment finds errors, can corrections to that IRA be made?

**Rochelle:** Yes, absolutely. If there's information entered in a district created IRA that is not accurate, communication should occur between the establishment and the district office in order to update the information, to ensure the information in the system is accurate.

**Shayla:** Then a question about verbal notification. If the district office is verbally notified and they create the notification, will that establishment be able to see it in PHIS?

**Rochelle:** Yes. When the district office creates the IRA when they are directly notified by the establishment, the notifying establishment does have the ability to view a read-only view of the case. The only difference is that there will not be an attachment tab viewable. Agency attachments are not able to be viewed by industry. If the industry wants to be able to view the entire read-only case after submission including attachments, the industry would need to create the case and attach any documents on it themselves.

**Shayla:** I think that clarifies that, that view piece which we had a few additional questions that have come in about that. It's really about who submits it, correct?

**Rochelle:** That is correct. The notifying establishment does have read-only view once the case is submitted. A non-notifying establishment does not have read-only view of the case even after it is submitted or closed. A notifying establishment does also have read-only view of the case, if the case is created by the district office in the system, however, the attachment tab will

not be available for viewing by the notifying establishment, when the case is created by an industry user. I'm sorry, an agency user.

**Shayla:** Thank you. Then our last question, so we can go ahead and move on with the rest of this presentation. We do have a question that asks, when the system plans to go live?

**Rochelle:** The system will be available to industry users starting March 1<sup>st</sup>.

**Shayla:** Great. Thank you. That's all the questions we have in chat.

**Rochelle:** Thank you very much, Shayla and Michelle. At this time, I am going to hand the all over to Ms. Carol Spencer, Program Manager for the Office of Field Operations.

**Carol:** Thank you, Rochelle. Good morning. I am Carol Spencer, Program Manager for PHIS. Thank you for joining the call. I'm ready to advance. Okay, sorry.

My presentation is going to primarily focus on a few flight changes for getting your new, or updating your current EOF level two credentials, direct you to our industry test environment. All of our systems, the industry test environment and PHIS reduction or the live environment require all users to have EOF level two authentication in our system's role-base, as part of our security layers.

Previously, we directed that you go to the Department of Agriculture's website to begin the enrollment process for EOF level two, there have been some changes there, so we have two options available for you, and that is to go to our PHIS live environment. This is the website you see on the screen now. When you log in to that environment, if you don't have the correct credentials, you will automatically be taken to the screen, where you began the enrollment wizard. When completing the wizard, it is important that you use your personal information and not your company information. The only company information we ask that you use during completing the wizard is your email, so PHIS can start mapping you to your establishment. This is the screen you will see if you don't have the correct credentials, and you can start creating your account by clicking that top button that says create account, or the bottom that says create account. The screen is a redirect from our PHIS website for the sole purpose of obtaining your EOF level two. Once your information is verified and you are issued your EOF level two credentials, the next screen you should see is in PHIS, where you would select from the left menu, APM, to navigate to Adulterated Product Monitoring module.

The website on this page is for the industry test environment, and the second option you have to log in and obtain your credentials. The same process and the same enrollment wizard is available here. I would recommend if you are attempting to use PHIS for the first time, you use this website to obtain your credentials, and start to become familiar with PHIS and the APM module. This environment has been refreshed and ready to use today, with the data from our production environment. In the case of APM, if there has been a report of adulteration started, Dr. Bronstein mentioned earlier that we have started putting in information during our phase one, you'll be to see it here, as well as other menu items in screens that are available to you based on your role. The big difference between the two environment is that whenever you enter the test environment will not trigger any regulatory action, and the APM menu items will not be available to you in production, as Rochelle mentioned, until March 1<sup>st</sup>. If you have any issues with your EOF level two or PHIS environment, here's our email box that some of you may be familiar with. Please send us an email, and we'll certainly reach out and help you navigate what is needed.

I mentioned there earlier, the PHIS is role-based, and we've had a couple of questions about that. Corporate access. You will have access to the establishments under you once you're invited by that establishment. This information has not changed, and it's in our detailed and our user guide, and posted on our website. We also have the quick reference guides on how to set up your roles. The end of February, right before we start March 1<sup>st</sup>, we'll update those guides to PHIS. Inside PHIS, there's a help button, some of you may be familiar with, that has our user guide, and they'll be placed there as well. I think I'm ready to go to the live screen. We wanted to just show you industry test environment, in case you're not familiar with it. This is what you'll log in to. It has a 800 number, if you need help, as well as our email, if you need assistance there. Here, a person has logged in as plant management, that's the role. Again, you see the menu items available. If you logged in as a corporate user, you would see different menu-- similar, but more expanded menu items on the left. I would take any questions about enrollment in our environment.

**Shayla:** All right. Thank you, Carol. No questions at this time via chat. I'll go ahead and let Michelle let folks know about the question queue.

**Michelle:** Once again, ladies and gentlemen, if you would like to ask a question via phone, please press #2 on your telephone keypad to enter the question queue. Once again, pressing #2 will enter you into the question queue. I do see we have one question in queue. Caller, your line is unmuted. You may ask your question.

**Female Speaker:** The question I had was for what we were going over the last time. I just didn't get in in time. Can I still ask now?

**Shayla:** That's okay, you can go ahead and ask. Of course, of course. Go right ahead.

**Female Speaker:** Typically, the receiving establishment is going to be the one that notifies because we both have the 24-hour requirement. If the receiving establishment notifies the district office, and they put it into PHIS, and then we turn around and either email or put it in PHIS. I guess my question is, hypothetically, is it always going to be the receiving establishment's record that stays in PHIS? Do you have any thought on that?

**Rochelle:** Hi, this is Rochelle. No, certainly not necessarily. Again, the regulatory requirements are unchanged. If the shipping establishment is notified by the receiving establishment of the issue and submits an IRA case to the system, that will be reviewed by their district office. If the shipping establishment is notified by their district office that the receiving establishment submitted a report and they were identified as shipping establishment, then the shipping establishment would not need to create a report, because they were made aware of the situation by FSIS. The regulatory requirements don't change. Again, the only difference is you'll have the ability to log in to PHIS APM to submit your information, as opposed to submitting it to the district office either by phone or email.

**Female Speaker:** Thank you.

**Michelle:** All right. I think we do have another question in queue. Caller, your line is unmuted. You may ask your question.

**Male Speaker:** Yes, I'm just following up a little clarification. No matter who submits first, if the shipping company submits and that's the record that stays into it. Now, my understanding that the receiving company can never see that information because they won't be able to access the document?

**Rochelle:** Right. Again, only the notifying establishment for the case that's created in the system can view the case once it's submitted. If the shipping establishment creates the case in IRA, they can see the read-only view after submission. If the receiving establishment creates the case in IRA, they can see read-only view. They will still be able to see the cases in the system for issues that they notify the agency on. If the receiving establishment submits the case to the system, the receiving establishment or district office notifies the shipping establishment, and the shipping establishment does not need to create a case in IRA, that shipping establishment would not have access to viewing the case created by the receiving establishment.

- Male Speaker:** We better keep pretty good records because if we pull up in PHIS, it could only show half of the reports. Just the ones we did, although they are not just all the ones we were involved in.
- Rochelle:** Right.
- Male Speaker:** Correct?
- Rochelle:** It will only show case... yes, it will only show cases that your establishment had submitted that you have access to.
- Dr. Bronstein:** Correct. This is Phil Bronstein. I just want to reiterate that that this isn't the only means of communication that FSIS will have between the two establishments. Nothing has changed in that process. If you are the receiving establishment or you're the producing establishment, the district office and the in-plant personnel will continue to have the same conversations and the same processes that we have before. This is merely a way for if you are directly going to put this in there, appreciate that there might be some proprietary information, whether you're the receiving or the producing establishment and what we're trying to do there is make sure that that information is not passed around to anyone who doesn't need to see it. It doesn't mean that you can't talk to the district office, the in-plant personnel, or whoever, to understand what's going on with the processes. This isn't the only way which we are going to be communicating [00:59:16 inaudible] events.
- Michelle:** All right. I do not see any additional questions in the verbal queue. Once again, ladies and gentlemen, pressing #2 will enter you into the verbal question queue.
- Shayla:** We do have a few questions that came in via chat. One asked for the email address for assistance on account issues. You can see that right on the screen that we're viewing right now. It is phistechnicalqa@fsis.usda.gov. I will send that in the chat as well. Then, we also have a question about EOF access for folks, and this audience member is asking if you have EOF access for later submissions cannot be updated or upgraded to level two, or do you have to create a whole new account to get level two EOF access?
- Carol:** Hi, this is Carol Spencer. Yes, you can update it to level two via the same room. I just went through, logging into PHIS, you have to have level two, so it will automatically take you to a wizard to do your upgrade.
- Shayla:** All right. Another question we have come in, asks, if the industry has some suggestions on potential changes or improvements to APM, will they be considered by FSIS?

**Carol:** Hi, this is Carol again. Yes, they would. We'd like for you to please send those suggestions to our technical Q&A box.

**Shayla:** I'll provide that address to all the attendees today. I'm just going to add that to the chat. Again, it's phistechnicalqa@fsis.usda.gov, for those who are on the phone only, and the rest of you is coming to you via chat.

**Carol:** Thank you.

**Michelle:** We do have a question on the phone. Caller, your line is unmuted. You may ask your question.

**Male Speaker:** Thank you. For the team and myself, I'm having problems getting the notifications of our micro testing results, the monthly ones from LIMS-Direct, I emailed them a few times, and just recently, yesterday again. Is any of this going to be interactive or do we just continue to follow up with LIMS-Direct help on that?

**Dr. Bronstein:** This is Phil Bronstein. LIMS-Direct is a separate system. It's not connected to PHIS. But if you're getting your information through there, you will have to continue to contact them. But if you can just email me at philip.bronstein@usda.gov, I'll make sure and just let me know what results you're looking for, what your establishment result, I'll pass it on the folks that run LIMS-Direct.

**Male Speaker:** All right. Thank you very much.

**Dr. Bronstein:** You're welcome.

**Michelle:** All right. I do not see any additional questions in queue. But once again, ladies and gentlemen, #2 will enter you into the question queue.

**Shayla:** We also see no more questions via chat. If you want to go ahead and continue, I think that would be great.

**Michelle:** There are no additional questions on the phone.

**Carol:** That ends my presentation.

**Dr. Bronstein:** All right. Well, thanks a lot everyone for calling in, asking your questions. As we did state, if you do have and look into this process, if you do have any suggestions, or anything that you would like to see potential changes or improvements to APM, or anything else with PHIS, please make sure you communicate with us. We really do appreciate the time. We hope you found the live demonstration of the process to be helpful. I do want to say, I've talked to several people about adulterated product modules over the last

few months, and I did want to put out one feature that we didn't really highlight, but we did talk about a little bit, and that is the document upload feature. If you do have... putting the base information into PHIS, but if you have additional information about trace back or about any of the other information that would identify the scope in any of the group cost analysis that you have done, in any situation, you can upload documents to be associated with that any time. We don't at any way, shape, or form want you to do less when following up on any product that may have been shipped into commerce that shouldn't have. We do want to acknowledge that all of that information is very valuable and for yourself, and for the agency. Feel free to include as much as you want to by uploading documents that are associated with any of the records in the IRA. With that, I want to just thank everybody for calling in. You have a great rest of the day.

**Michelle:**

That concludes our conference. Thank you for using Event Services. You may now disconnect.