

**Public Health Information System (PHIS)**  
**Industry Meeting – Q&A**  
**May 11, 2011**

The summary below is based on questions and answers regarding the Public Health Information System (PHIS) discussed at a May 11, 2011, meeting with industry representatives hosted by the Food Safety and Inspection Service (FSIS) at Department of Agriculture (USDA) headquarters in Washington, D.C.

*1. Could you please show screen shots of plant profile information and new NR forms?*

There are no regulatory changes for the domestic industry for PHIS. The NR form is essentially the same as always; it does look somewhat different from the old form as it appeared in the Performance Based Inspection System (PBIS). However, there are some changes to note. First, the number of the NR form is a random, system generated number. It contains 14 alpha numeric characters, but does not have any information like establishment number or date associated with it. It is followed by a / 1 (or 2, 3, 4...) used to designate the number of paper forms that are presented to establishments with the same NR. The change is that we record each non-compliance with regulations, and count the number of non-compliance with regulations, not the number of NR forms.

Tasks can take multiple days to complete, and might have multiple regulatory non-compliances resulting from them. We continue to instruct inspectors to notify the establishment orally and in writing of any non-compliance found in a timely manner. So, if they do a task that takes three days to complete, and day 1 they note a non-compliance, the inspector would notify the plant in writing. That form would have the slash 1 (/ 1) after the NR number. If on day 3 of the task, they note another NC with another regulation, they would notify the establishment and that one would have the same 14 character number and /2. When the task is completed, a full NR will be printed with all NCs listed on it per regulation. It is still only one NR form. We can think of it loosely like the continuation sheets in PBIS.

The big change is that the system will be tracking and counting each regulation that is verified, and each one that is found non-compliant. That is the basis for the counting, not the number of procedures done and NR forms. Each time an inspector does any task, they are to check off which regulations that they have verified. Then check off any that they find non-compliant. The number of regulations verified becomes the denominator, and the number of regulations found non-compliant is the numerator for reporting purposes.

We are making some minor changes on the form for clarity. Once that is done, we will be posting an example on the Website with some graphic explanation of what goes into each block where it is not self-explanatory.

- 2. Can you share an updated time-line for roll-out of the following programs?*
- a. Domestic inspection—additional circuits*

- b. Import*
- c. Export*

FSIS is still finalizing its budget allocations for the current fiscal year and thus will have more definitive dates for the next PHIS implementation available by the time of its next meeting with industry in June 2011.

*3. We understand that FSA questions can be answered only with a “yes” or “no.” How does FSIS intend to handle those questions for which industry has not historically provided answers (i.e. pre-harvest and food defense)?*

Food Safety Assessment (FSA) tools have not changed in PHIS. There are yes/no questions and a text box to support the yes/no response. The only question FSIS asks about food defense is, “Does the plant have a food defense program?”

*4. We understand that when establishment personnel are afforded access to PHIS, they will only be allowed one primary and one back-up (total of 2 users) per establishment. What is the purpose for this restriction? Does FSIS understand that this will be enormously problematic if/when lab result reporting is incorporated into this system?*

“One primary and one back-up” refers to the plant PHIS Administrator’s role rather than the user role. A plant may have as many backup PHIS Administrators as it wishes. However, access to multiple plants by the same user is not allowed at the present time.

*5. What is the purpose of inspection copying all of our prerequisite programs into PHIS verbatim?*

Inspection program personnel are not instructed to copy prerequisite programs verbatim into PHIS, nor does PHIS provide the means to enter prerequisite programs verbatim. Personnel are to enter basic data related to establishments’ hazard analysis and HACCP plans and prerequisite programs as well as other supporting documentation as discussed in FSIS PHIS Directive 5300.1, “Managing the Establishment Profile in the Public Health Inspection System (PHIS).” Instructions (with examples) for entry of establishment profile information are provided in “How-To Instructions: Establishment Profile” in the PHIS User Guide (section 3.2.1), which is accessible on FSIS’ PHIS website at [http://www.fsis.usda.gov/PDF/PHIS\\_UserGuide\\_Domestic\\_Pages19-67.pdf](http://www.fsis.usda.gov/PDF/PHIS_UserGuide_Domestic_Pages19-67.pdf).

*6. We are hearing that the system times out after a period of inactivity and that typing in a text box is not considered “actively” working in PHIS. Does FSIS realize that many industry prerequisite programs are many pages in length? Is there a plan to optimize the system such that the inspector isn’t timed out while trying to input information?*

FSIS is aware of this issue and is working to resolve it. A time-out feature is also built into eAuthentication (eAuth) for security reasons. FSIS recommends that users help address this issue by saving their work often.

*7. We understand that the HAV procedure is conducted based on our programs as copied into PHIS. Why wouldn't this procedure be based on the actual HACCP programs in effect at the establishment? Surely FSIS realizes the impossibility of ensuring that the HACCP plan information, as recorded in PHIS, is current at all times.*

No one has yet conducted a Hazard Analysis Verification (HAV) in PHIS. HAV is based on plant profile information and should not be confused with Food Safety Assessment methodology, which includes a review of all processes and procedures. The plant profile in PHIS needs to be kept up to date. Inspectors should view the plant profile at least once every 30 days to make sure it is current. HAV in PHIS is expected to begin around January 2012, when users will be trained and comfortable with PHIS.

*8. Thinking of the establishment specific information being collected/maintained by PHIS, how can FSIS ensure confidentiality? What will prevent a relief or patrol inspector from sharing/disclosing information from one establishment to the next? We are hearing that there is no mechanism (aside from "fear of consequences") in place to ensure that this does not happen. If my entire HACCP plan and prerequisite programs are housed in PHIS, I do not want that information shared with my competitors!*

FSIS is very sensitive to this concern. FSIS employees take an oath that includes acknowledgement for meeting standards of conduct as a representative of the Federal Government and FSIS is confident that employees are aware of their scope of responsibility. In addition, all PHIS reports contain a confidentiality header and footer stating that the document is confidential. Anyone with any issues in this regard should call the USDA Office of Inspector General Hotline.

*9. We are hearing that inspectors are having issues with connectivity. We are also hearing that there are large periods of time when the system is unavailable. Is that due to the number of users currently trying to access the system? If so, how does FSIS plan to bring the other 2/3 of all circuits on-line? Will this apparent band width problem prevent industry from gaining access to this system?*

FSIS has the same connectivity access challenges that any national or private entity deals with in ensuring high speed reliable service. FSIS meets these challenges by employing several options for connectivity including DSL, Cable, EVDO cards and UTN lines to meet specified standards of performance based upon what connectivity options are available in a local area. Band width is not a problem as PHIS has load-balanced servers (many servers), and when the volume of user activity is high, PHIS switches from server to server as more users join.

*10. It does not appear at this time that FSIS will be able to provide us any type of report out of PHIS. The QA manager has asked the IIC if they will be able to provide any reports to let us know where we are at and how we are doing and she has talked all the way up to the District and is saying that no one knows how to get us the information. We need some clarification on this since we do not have access to the system. Are their resolutions on providing feedback like was received on PBIS tasks?*

At the current time, FSIS does not have reports available for plants to access. Although FSIS has generated reports for inspectors, some inspectors might not see very much of a report if they try to generate one because there are not enough data in the system at this time. More data will be available with which to complete reports in June or July, so that would be the best time for reports to be provided. The NR history spans both the PBIS and PHIS systems, and the inspector should be able to provide this information to plants. If a report is run and there are insufficient data to complete the report, the screen will say, "No data returned." Also, some reports could contain blanks if the establishment data are incomplete. Some task codes have changed in PHIS, and therefore some reports could show incorrect data. FSIS is addressing these issues and is continuing to test the system to ensure that the data are correct. FSIS will provide an update on Industry Reporting features at the next meeting with industry in June 2011.

*11. Directive 5300.1 mentions FSIS entering construction information into the PHIS system. What types of construction will be recorded?*

This mostly is concerned with plants that are producing ready-to-eat products and these plants' *Listeria monocytogenes* procedures. Examples of construction that might occur in a plant include the movement of equipment or the building of walls.

*12. PHIS collects inspector notes, will FSIS provide a printed copy to management teams?*

No copies of inspection notes will be provided. The notes are intended to help inspectors maintain information that assists them in providing an agenda for weekly meetings with plant management. With regard to the issue of whether Memorandums of Interview (MOI) can be changed, the answer is that an inspector cannot change an MOI, but he or she can submit a modified MOI.

*13. Is one of the reasons FSIS has reduced their effort in the Weekly Slaughter Report is due to the transition of PHIS (please see the attached report). In the second paragraph of this reports it mentions FSIS has installed a new computer system and apparently are unable to keep up with the data. This data is very valuable to us as we try to provide the industry accurate estimates of export volumes compared to US production.*

FSIS is working with the National Agricultural Statistical Service (NASS) to get the livestock slaughter statistics posted by the Agricultural Marketing Service (AMS) as soon as possible. When available, the report will be posted to AMS' website at <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateG&navID=MarketNewsAndTransportationData&leftNav=MarketNewsAndTransportationData&page=LSMarketNewsPageOther>.

*14. Can you provide some insight into the plans for the walk through of the PHIS system in June/July? Audience and goals?*

The walkthrough of the PHIS system has been tentatively scheduled for July 14, 2011, at a location to be determined. The goal of the presentation will be to familiarize industry representatives with PHIS' basic features and capabilities.

*15. We had requested the latest version of W3 NRs be posted as a stand-alone list... As we understand it, the DO is getting the information to make decisions regarding levels of inspection for establishments based on their compliance and W3 NR rate. What means does the establishment have to access to this information and know where do they stand? Is FSIS comparing them at this point for purposes of FSAs and additional HAVs? If so, can the information be shared with the establishments at a minimum by the FLS during their visit?*

FSIS will complete a stand-alone W3NR list as soon as possible and will make it available in PHIS. In PBIS, HAV was not a task, and PBIS did not use W3NR rates to schedule inspection procedures. PHIS is not presently using W3NR rates to schedule inspection procedures but will use W3NR rates for this purpose after deployment of the PHIS HAV function in January 2012. FSIS is also holding off on using the W3NR date to access FSAs. The Agency wishes to use W3NRs for FSAs and will provide an accurate date for deployment of this function at the meeting with industry representatives to be held in July. The plants that are still using PBIS are continuing to use the data provided by the system.

*16. They must develop a process for a 'corporate' person to have access to multiple plants.*

FSIS is aware of the issue request and will continue to explore options for this process.

*17. The local FSIS should still provide the PHIS equivalent of the "Establishment HACCP Summary" of tasks performed, etc.*

HAV data will be accessible in PHIS.

*18. An industry training session/webinar should be offered for companies to understand what training has been given to inspectors.*

Please see response to Question 14.