

## **Public Health Information System (PHIS) Industry Briefing on Domestic Inspection**

**March 9, 2011  
2 p.m.–3 p.m.**

1. When is the specific implementation date of the PHIS system?

**RESPONSE: The components will be implemented in sequential stages, starting with the domestic component. Implementation of the domestic component will take place in various locations over several weeks, starting on April 11, 2011.**

2. Will all four modules be implemented at the same time?

**RESPONSE: Due to logistical considerations, it will be necessary to implement the domestic component in four phases—for one quarter of all circuits in each phase—tentatively scheduled to begin on April 11, 2011. The import component will be implemented for all users simultaneously in the summer of 2011. The export component, which will involve approximately 120 countries to which the United States exports products, will be implemented after deployment of the domestic component is completed.**

**The fourth component, predictive analytics, will be operational in conjunction with the other components. The portions of predictive analytics that relate to each component will be operational as each component becomes operational. The predictive analytics component will be under continual refinement as data are analyzed and utilized according to the *FSIS Strategic Data Analysis Plan for Domestic Inspection* published in September 2010.**

3. Please provide information on the security to the system so that export users' computer systems are not at jeopardy to unlawful intrusions from outside computer users.

**RESPONSE: Connecting to PHIS does not increase or decrease the security of export users' computer equipment. FSIS will not require any software to be installed on their computers, and all access to PHIS will be through a secure mechanism, much like access to online banking sites.**

**PHIS will give establishments and import/export brokers an important role in that security. PHIS will ensure that each user's access to data is appropriately defined by that person's role in doing business through PHIS. PHIS will provide access to data that are appropriate only for that specific establishment or broker.**

**FSIS is using USDA's eAuthentication (eAuth) system and an invitation key as the primary method for managing security for each individual who uses PHIS. The invitation key, which will be mailed to each establishment, will be specific to a person—such as the establishment's General Manager or Vice President—whom the company has designated for access to the system.**

4. We still want to know about security (i.e. what happens when employees with access leave the company). We also want to better understand the corporate versus plant roles/views. We understand that there will be a corporate role, but we have very little information about what exactly that means.

**RESPONSE: PHIS does not have a corporate role available. Each plant will be given an invitation key that will grant plant administrative access to the first individual designated as PHIS plant administrator. FSIS recommends that a minimum of one additional individual also be assigned this role. Each individual with plant administrative access will be able to remove access for any individual, including another PHIS plant administrator. This allows for the removal of access for individuals who have left a company.**

5. PHIS system administrator uses the invitational key and will have the authority to assign and remove permissions of other individuals. What should be done if the PHIS system administrator is removed from the administrator position (relocates, terminated, etc.)? How is that "change of command" to be facilitated to ensure data security?

**RESPONSE: FSIS recommends a minimum of one additional individual be assigned this role. Each individual with plant administrative access will be able to remove access for any individual, including another PHIS plant administrator.**

6. All users have to have an eAuth username and password. Once this is attained, does the PHIS system administrator have to assign the person to his/her plant and grant permissions, or is this done automatically. Can an individual that has attained the eAuth be a user at multiple facilities? An example of this would be employees of the corporate office that have responsibility for multiple plants. Is there any limit on the amount of plant personnel who are eAuthenticated per site?

**RESPONSE: Each individual at a plant, not including the initial PHIS plant administrator who used the invitation key, will need to use our User Enrollment process. As individuals use this process, their requests for access will be routed to the PHIS plant administrator(s) for the plant for which they have requested access.**

**PHIS, as designed, does not allow for an industry user to access multiple plants. This is the case for both the Domestic and Export functionality at this time.**

7. Explain, in detail, the process for e-Authentication.

**RESPONSE:**

**1. *Authorize a PHIS plant administrator.*** FSIS strongly encourages owners and operators to carefully consider designating at least 2 people as PHIS plant administrators. They would have the authority to manage access for other individuals designated to use PHIS on the company's behalf.

**2. *Request eAuth accounts.*** For those individuals to be designated to use PHIS on the establishment's behalf, are asked to submit requests for USDA Level 2 eAuthentication (eAuth) accounts sooner rather than later. Each employee must complete the submission themselves. To create a Level 2 eAuthentication account, the first step is for users to sign up via <https://eauth.sc.egov.usda.gov/eAuth/selfRegistration/selfRegLevel2Step1.jsp>. Within a few minutes, you will receive a confirmation e-mail message with instructions on how to proceed.

**3. *Get your identity verified.*** Users are required to have a Local Registration Authority (LRA) verify their identity in person. Users must do this before they can receive a password for their eAuth account. Once users have completed the first step and responded to the confirmation email, the second step is to make an appointment with a Local Registration Authority (LRA) at a USDA Service Center. Use the USDA Service Center Locator at <http://offices.sc.egov.usda.gov/locator/app?type=lra> to find an agent in your area using the map provided.

**4. *Keep eAuth accounts secure.*** Each owner/operator, and any other person with an eAuth account, is responsible for keeping his or her own log-in information secure. It is important that you maintain your eAuth password in a secure location and that you not share it with others; it is unique to you as an individual.

8. Can the USDA help us better understand the day-to-day changes for industry and inspection program personnel? How does PHIS change the daily interaction with IPP?

**RESPONSE:** Changes will be minimal, if any. PHIS will not change industry's daily interactions with FSIS' inspection program personnel. See response to Question 9.

9. If there is not much change to the inspection system when PHIS is implemented, then why is there so much conversation about the USDA's "new system?"

**RESPONSE:** What is "new" about PHIS is not additional or revised requirements or regulations but rather greater efficiency and enhanced ability to detect food safety problems quickly and prevent breakdowns.

**PHIS provides a single access point for reference materials such as policy documents, certificates, regulations, and memoranda of agreement, thereby allowing inspection personnel to avoid time-consuming searches for paper documents and rather to spend more time on important inspection activities. In addition, records of tasks completed, results obtained, and compliances verified as well as supervisory alerts, information on establishments' food safety "track records," and prompts for follow-up procedures can also be accessed.**

**The system will allow FSIS to coordinate effectively internally, with our stakeholders and other agencies, improving investigations and contaminant tracing. As the system is further developed, it will facilitate sharing of data among inspection personnel, their managers and headquarters on a daily basis, giving FSIS decision makers a better picture of what is happening across the country, as it is happening.**

10. What access will the IPP have to other establishment information? Will it be for only the plant they work for or universal access to all plant data? How does this relate to IPP that have multiple assignments?

**RESPONSE: With PHIS, IPP will have access to the same types of establishment information as they have right now in the Performance-Based Inspection System (PBIS).**

11. There has been little discussion about Hazard Analysis Verification (HAV). How does this review compare to FSA's from scope and time to complete? Will HAV impact regulatory action? If yes, please provide examples.

**RESPONSE: PHIS does not create any new requirements for industry. The HAV does not take the place of Food Safety Assessments (FSAs), which will continue to be performed by Enforcement Investigations and Analysis Officers (EIAOs) and be an in-depth review and analysis of an establishment's entire food safety system. Findings of noncompliance with regulations will be recorded and require corrective action by establishments. The HAV procedure directs the Consumer Safety Inspectors (CSIs) to review the hazard analysis for all HACCP process categories. The HAV will serve as a screening process to identify issues of concern in the design of establishments' food safety systems.**

12. Are NRs required to be completed using the PHIS system?

**RESPONSE: When findings of inspection verification tasks indicate noncompliance with regulatory requirements, inspection program personnel will record the regulatory noncompliance in PHIS and will provide the establishment with a noncompliance report (NR) that documents the finding. Establishments are not required to respond to**

NRs either in writing on paper, or electronically through PHIS, but are encouraged to do so.

13. What is the impact to the plant if they do not use PHIS?

**RESPONSE:** If a plant does not have computer access and an Internet connection, it will not be required to use PHIS. It will still receive a paper copy of each noncompliance record and will be able to provide a written response on the paper copy. Appeals regarding noncompliance records will still be accepted in paper copy format.

Off-line inspection personnel at such plants will still use PHIS to enter their results and findings from verification procedures.

14. Will the establishments be able to review the algorithm that will be used to assess their plants?

**RESPONSE:** Detailed information about the decision criteria used to schedule for cause Food Safety Assessments (FSAs) and increased HAV tasks are described in the “Data-Driven Inspection for Processing and Slaughter Establishments - Public Health Decision Criteria” which was posted on the Agency’s website in September 2010 and is available at [http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010\\_Strategic\\_Data\\_Analysis\\_Plan.pdf](http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Strategic_Data_Analysis_Plan.pdf).

15. Other than WR3 NRs, what are other alerts that PHIS will be tracking? Where can this list be found?

**RESPONSE:** There is a misunderstanding about what an alert is. An alert as an electronic message (email and/or dashboard message) that notifies a user that important information is available somewhere in the system. This information is already available in the system; the alerts just help ensure that things don’t fall through the cracks. Alerts are not “tracked” and do not trigger other events. Typical alerts are represented in the documents referenced in the previous question. Alerts will not go to establishments. Alerts are only provided to FSIS staff to help them with their inspection duties. *(See attached slide for preliminary list of alerts)*

16. Has FSIS addressed the findings and recommendations made by NAS in its two reports related to the Public Health Risk-Based Inspection System? And if so how were they addressed?

**RESPONSE:** FSIS has adopted the recommendations made by NAS. The “FSIS Strategic Data Analysis Plan for Domestic Inspection” and the “Data-Driven Inspection

**for Processing and Slaughter Establishments - Public Health Decision Criteria” reports describe FSIS’ current approach to data driven inspection. These reports specifically reference NAS recommendations addressed by our approach. These reports were formally submitted by the FSIS Administrator to the NAS committee. We also provided a briefing to NAS in April 2010, describing the improvements made to PHIS in response to NAS.**

17. What the Rolling NR Rate is and how it compares to the other plants in its grouping/District would be valuable.

**RESPONSE: FSIS intends to provide W3NR rates on its Website by operation type. We are not calculating separate rates by district. These rates will be updated periodically. See response to Question 16.**

18. Will users be able to determine from PHIS what the plant/establishment public health NR average is? How often will this be recalculated? Is information available to compare to “peer” establishments?

**RESPONSE: Yes, an establishment will be able to determine their total NR and public health related NR rates. We intend for this to be recalculated monthly. The “peer” rates will be posted as described in the answer to the previous question. This data will be included in a report.**

19. FSIS has identified three reports that will be available for industry (Inspection Profile, Regulations Verified and Sampling Results Report). Can we have more detail on what is included in the Regulations Verified report?

**RESPONSE: The Regulations Verified report will be a summary of inspection tasks performed and the regulations verified through those inspection tasks. The final format of this report is undergoing Agency clearance.**

20. Who will be able to provide an establishment management team with the current industry average for public health NRs? How often will this information be available?

**RESPONSE: Please see responses to Questions 17 and 18.**

21. Can reports and other metrics be communicated to the plants via eAuth?

**RESPONSE: General information such as national W3NR rates will be posted on the Agency’s Website and will not require eAuth. Establishment specific information such**

**as the three reports listed in Question 19 will be available through PHIS and will require eAuth.**

22. Please describe the extent of authority of a company administrator.

a. Once a company has registered with eAuthentication, does the company administrator have authority to assign other employees to work in the system?

**RESPONSE: It should be noted that PHIS does not have a corporate role available. PHIS is based on a plant administrator role. The designated PHIS plant administrator will have the authority to assign and remove permissions of other individuals granted authority to conduct business with FSIS through PHIS.**

b. Can a company administrator have the ability to restrict the use of certain functions (i.e., address book, product list, plant approvals, etc.) to a limited number of employees?

**RESPONSE: Yes, the PHIS plant administrator will be able to assign functions to employees as appropriate according to the roles played by the employees in the organization.**

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