

# Small Plant NEWS

Vol. 3, No. 5

## Inside

NOIEs, Part 1: Understanding the Rules of Practice .....	2
Food Safety Resources .....	3
Commonly Asked Questions & Answers ...	3

## Small Plant NEWS

**Editor:** Keith Payne

**Production:** Joan Lindenberger,  
Sally Fernandez

**Design:** Gordon Wilson

**Contact:** *Small Plant News*, USDA/FSIS,  
Aerospace Building, 3rd Floor, Room 405,  
14th and Independence Ave., SW,  
Washington, DC 20250. (800) 336-3747  
E-mail: [SmallPlantNews@fsis.usda.gov](mailto:SmallPlantNews@fsis.usda.gov)

The U.S. Department of Agriculture prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at (202) 720-2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Ave., SW, Washington, DC 20250-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.

## Developing Food Defense Plans: Shifting Greater Awareness Into Action

By Keith Payne

People are ill, injured, or even dying. Your company name and product are involved. A recall is initiated. Your production lines are halted. Jobs are lost.

Unfortunately, these things can happen. If someone or some group intentionally attacks your plant, employees, or products, it can be too late to remedy a situation that could undo all the years, possibly generations, of hard work you've put into your business.

One way to mitigate the risk of an intentional attack and its aftershock is to develop a food defense plan. This type of plan helps you identify the steps you can take to minimize the risk that food products in your plant will be intentionally contaminated or tampered with, and it helps to increase your level of preparedness.

"Food safety, which addresses predictable and unintentional risks, is best addressed through the Hazard Analysis and Critical Control Point (HACCP) plan," said Kim Green, director of the Food Defense Assessment Staff for the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) Office of Data Integration and Food Protection.

"On the other hand, food defense addresses intentional attacks on the safety or quality of food. It's not well suited to HACCP, which is why a plant's HACCP plan should not be used as a substitute for a food defense plan,"

added Green.

Some of the information you use to create a plan may possibly exist in your HACCP plan, Sanitation Standard Operating Procedures, and other documents, such as emergency response procedures. Make sure to consult these documents for information.

"When creating a plan, you need to realize why having a written food defense plan matters," said Green. "First and foremost, having one will help you maintain a safe working environment for your employees, provide a quality product to your customers, and protect your company's bottom line."

"Also, simply writing it down will improve the process of creating a plan," said Cathy Crawford, an associate with the HACCP Consulting Group, L.L.C. "It doesn't have to be complicated. In addition to minimizing your liability, a plan is important because, more often, insurance companies and third-party auditors expect to see a written plan."

Another reason for having a written plan is simply to look at your operation from a risk perspective and identify the risk factors that apply to you. Are you making large batches of food or foods with short shelf lives? Are the products you're making uniformly mixed? Do your products reach certain higher risk populations? How easy is it for others to

Continued on Page 4 ...

# NOIEs, Part 1: Understanding the Rules of Practice

By Jane Johnson

Perhaps at some point in the past, you've received a Notice of Intended Enforcement (NOIE). Regardless of receiving one or not, it is helpful to understand NOIEs and your responsibilities and rights as a business owner or operator.

As the first of a series of three articles featuring NOIEs, we'll begin by reviewing the Rules of Practice as they pertain to the NOIE.

For starters, FSIS issues an NOIE to a plant for a noncompliance that does not pose an imminent threat to public health. However, this noncompliance may warrant a withholding or suspension action if not corrected. So, if this happens, what role do the Rules of Practice serve?

The Rules of Practice, which are found in Title 9 of the *Code of Federal Regulations* (CFR), Section 500, are FSIS' enforcement regulations that guarantee you, the plant, receive due process rights under the law. Simply stated, they provide a procedure that helps to ensure that FSIS enforces regulations in a fair and consistent manner.

There are three types of enforcement actions defined in Section 500: regulatory control action, withholding action, and suspension.

## Regulatory Control Action

A regulatory control action is the type of enforcement most commonly used by in-plant FSIS inspectors. They use regulatory control actions to identify regulatory noncompliance and prevent the movement of product or the use of equipment or a facility until the noncompliance is corrected.

FSIS inspectors don't have to notify you in advance; however, they must notify you immediately once the action is taken. You may receive this notification from the inspector orally or in writing as a noncompliance record (NR).

The CFR also gives you the right to appeal regulatory control actions regardless of whether the notification was given orally or as an NR. The regulatory control action (and NR) can be appealed through the Office of Field Operations chain-of-command, beginning with either the inspector who made the finding that resulted in the action or with the immediate supervisor. No level in the chain-of-command may be skipped. You simply have to go in order.

## Withholding Actions

A withholding action is when FSIS withholds the mark of inspection from an establishment. This type of action may be applied to a product produced by a particular process or to all products in the plant. This is considered a more severe type of enforcement than a regulatory control action because it can affect a larger part of your plant or process.

Because withholding actions may result in a greater disruption of your ability to produce than a regulatory control

action, they're only taken after careful evaluation of the facts. The decision to take an immediate withholding action can be made by whomever is in charge for FSIS at the establishment—such as the inspector-in-charge, his or her designee, or the frontline supervisor—or the District Office.

You also have the right to appeal withholding actions. The appeal begins with the person who took the action—or with the next level of FSIS supervision—and may continue through the Office of Field Operations chain-of-command.

## Suspension Actions

Suspension is holding back the assignment of inspectors to a plant, and it can have a severe impact for several reasons. First, a suspension usually lasts longer than a withholding action. Second, as you already know, federally inspected establishments cannot legally apply the marks of inspection to product without an assigned inspector, so this action may stop all production. Of course, a suspension may also only be applied to a specific production process, stopping operations only in that area.

Like withholding actions, suspensions are only taken after careful evaluation of the facts. The decision to suspend inspection is made at the District Office or at a higher level of authority.

Again, you do have the right to appeal a suspension. The appeal process begins with the person who took the action, probably a deputy district manager or district manager, or his or her immediate supervisor, and may then move through the Office of Field Operations' chain-of-command.

It's important to remember that withholding and suspension actions may be taken with, or without prior, notification. The NOIE is the prior notification given to the plant, in writing, stating that a withholding or suspension action will be taken unless the circumstances leading to the NOIE are corrected. For example, FSIS inspectors may take a withholding or suspension action without prior notification (i.e., without issuing an NOIE) because the establishment is handling or slaughtering animals inhumanely. However, prior notification (issuance of an NOIE) will be given prior to a withholding or suspension action if the Sanitation Standard Operating Procedures have not been properly implemented or maintained as in the regulations.

In the second part of this series, we'll take a look at additional situations and whether they require prior notification or not.

For more information on the Rules of Practice or NOIEs, call the Small Plant Help Desk at 1-877-FSISHelp (877-374-7435), email [Info.Source@fsis.usda.gov](mailto:Info.Source@fsis.usda.gov) or visit FSIS' Web site at [www.fsis.usda.gov](http://www.fsis.usda.gov).

# Food Safety Resources

By Sally Fernandez

Are you looking for practical examples of compliance with the Humane Methods of Slaughter Act? Check out the Humane Interactive Knowledge Exchange Scenarios (HIKES) on the FSIS Web site at [www.fsis.usda.gov/FSIS\\_Employees/HIKE\\_Scenarios/index.asp](http://www.fsis.usda.gov/FSIS_Employees/HIKE_Scenarios/index.asp).

You'll find different scenarios, written to keep FSIS personnel current on regulatory requirements, directives, and notices. These will be useful to plant management as well. This valuable learning and reference tool covers topics ranging from cattle in chutes and drive alleys to double stunning.

The HIKES are designed with the written scenario showing on the left side of the screen with inspection procedure and links to pertinent regulations on the right side of the screen. After the scenario is described, there's a discussion section and then a conclusion. Additionally,

if you have a HIKE-related question, you can email it to [HIKE@fsis.usda.gov](mailto:HIKE@fsis.usda.gov).



## Commonly Asked Question & Answer

**Q.** *When inspectors (Federal or State) collect scheduled residue samples, should they recommend that the plant hold the sampled carcasses?*

**A.** Yes, according to FSIS Directive 10,800.1, "Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program." FSIS recommends that plants hold these scheduled sample carcasses until the Agency reports the results to prevent a recall if the laboratory detects a residue at a violative level. Also, when product is held by the plant, Federal or State inspectors should document the decision by recording it in action block

22, "Product Held," on FSIS Form 10,210-3, Requested Sample Program.

**Q.** *Are records generated as part of a plant's prerequisite program required to be reviewed when the establishment performs pre-shipment review?*

**A.** No. A plant is not required to review prerequisite program records during pre-shipment review. However, the records generated under the prerequisite program would need to be maintained as part of the plant's decisionmaking documents (see Title 9 of the Code of Federal Regulations, Section 417.5(a)(1)).

... Continued from Page 1

gain access to your premises?

Examining risks such as these can increase awareness and change attitudes. “It’s basically a culture change,” said Crawford. “And bringing this change among your employees about food defense is much like the culture change we as a society have accepted with tightened security at airports.”

Think about attacks on the food supply that have already happened, such as these true life cases:

- Oranges injected with Mercury – Israel, 1978;
- Restaurant salad bars laced with *Salmonella* – The Dalles, OR, 1984;
- Fast food with rat poison – China, 2002; and
- Ground beef with nicotine – Michigan, 2003.

Regardless of the motives, or whether terrorists, activists, competitors, or disgruntled employees are the attackers, these attacks can happen, and in your facility. The effects are devastating—potential loss of life, serious health injuries, financial losses, or complete ruin of your livelihood.

“The more we share these stories, the more awareness we’ll bring to the issue,” said Crawford.

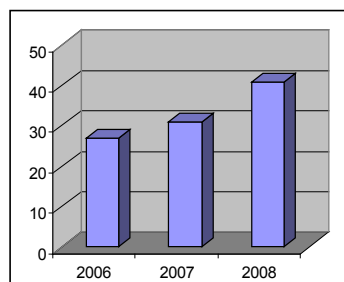
“There is definitely greater awareness about this issue within the small plant community,” said Dr. Joe Harris, president and chief executive officer of the Southwest Meat Association. “However, what matters most is translating this greater awareness into action.”

Recent FSIS survey results indicate there is more action being taken by the industry. For instance, 41 percent of *all* plants in 2008 indicated they have a functional food defense plan, representing a 14-percent increase from 2006. The percentage of small plants with food defense plans went up from 44 percent in 2007 to 58 percent in 2008.

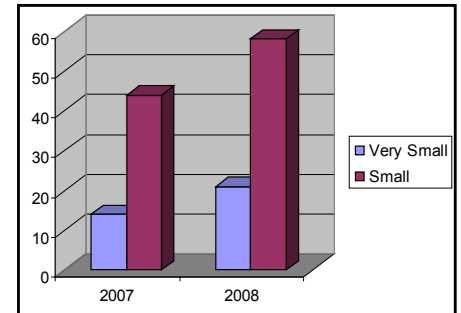
“That’s great progress, and it’s very encouraging to see these results,” said Karlease Kelly, assistant administrator of FSIS’ Office of Outreach, Employee Education, and Training.

The percentage of very small plants with food defense plans also increased—from 14 percent in 2007 to 21 percent in 2008. “So, there is also good progress with the smallest plants too, but clearly we want to see more improvement,” added Kelly.

**Percentage of Plants with a Food Defense Plan**



**Percentage of Small and Very Small Plants with a Food Defense Plan**



“Those who haven’t adopted the food defense concept and developed his or her own plans really need to do so,” commented Harris. “FSIS has developed some great tools to help plants develop his or her own food defense plans. And, if they don’t do this, it may be forced upon them under different, more stressful circumstances.”

To put a written food defense plan into action, there are three distinct phases that you will go through, which include:

- 1) Conducting a self-assessment,
- 2) Developing a food defense plan, and
- 3) Implementing your food defense plan.

These steps provide an opportunity to identify areas where security measures could be enhanced. Once implemented, your plan can assist you with employee training and response and recovery actions. Key areas include:

- Inside and outside security;
- Slaughter and processing security;
- Storage security;
- Shipping and receiving security;
- Water and ice security; and
- Mail-handling security.

The overall plan should strengthen these areas to protect your facility and products from intentional contamination. FSIS has developed guidance on developing a food defense plan that can be found on its Web site at [www.fsis.usda.gov/Food\\_Defense\\_&\\_Emergency\\_Response/Guidance\\_Materials/index.asp](http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Guidance_Materials/index.asp).

Whether you use FSIS’ food defense plan guidance or some other source, the recommendations in this booklet will still provide you with useful information on what elements to consider and address. For questions or clarification about these guidelines, call FSIS’ Policy Development Division at (800) 233-3933.

It’s important to remember that there is no “one-size-fits-all” approach to creating a food defense plan. It can be long or short, whichever is appropriate for your operation. What matters most is to develop a plan and make it a living document for the protection of your customers and your business.